Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)

Title	:	DREAMM-1: A Phase I Open-label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity and Clinical Activity of the Antibody Drug Conjugate GSK2857916 in Subjects with Relapsed/Refractory Multiple Myeloma and Other Advanced Hematologic Malignancies Expressing BCMA
Compound Number	:	GSK2857916
Effective Date	:	18-NOV-2019

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the End of Study Clinical Study Report for Protocol GSK Document Number 2012N155299_05.
- This RAP is intended to describe the safety, clinical activity and pharmacokinetic analyses required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

RAP Author(s):

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1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to update the list of displays to be included in the End of Study Clinical Study Report for Protocol:

Revision Chronology:		
2012N155299_00	2013-DEC-26	Original
2012N155299_01	2014-MAR-01	Amendment No. 1. Country specific Amendment for the United Kingdom to address required changes per MHRA. Updated Exclusion Criteria to exclude subjects with current corneal disease or history of corneal disease. Updated QTc withdrawal criterion to modify QTc withdrawal for QTc >500msec and to include > 60 msec increase from baseline. Updated Data Management Section 12 to include details on dissemination of data and communication plan.
2012N155299_02	2014-MAR-20	Amendment No. 2. Global Amendment to address required changes per the FDA. Updated Inclusion Criteria with minimum weight requirement. Updated Blood Volumes. Revised Time and Events Tables. Corrected typographical errors.
2012N155299_03	2014-MAY-05	Amendment No. 3. Country specific Amendment for Canada to address required changes per Health Canada. Updated preparation instructions of GSK2857916.
2012N155299_04	2016-MAY-05	Amendment No. 4. Global Amendment to include patient reported outcome instruments in the Part 2 multiple myeloma cohort and refine the lymphoma histologies eligible in Part 2 BCMA-expressing lymphoma cohort. Additionally, the requirement for 60% of tumor cells staining positive for BCMA expression was removed. The total number of subjects that may be enrolled is presented by a range of 80 to 95 to provide an updated estimate based on the number of subjects who enrolled at the time of the amendment. Additional modifications include: changing the time-point specific blood specimens are collected for baseline/pre-treatment immunogenicity and biomarker measurements, and the visit window for certain assessments.
2012N155299_05	2017-NOV-02	Global amendment to include additional follow up of multiple myeloma subjects for ocular exams (for those whose corneal signs or symptoms have not resolved), additional patient reported outcome instruments, addition of time-to-event endpoints as exploratory objectives. Subjects who have completed treatment or the 3 month follow up visit (end of study) prior to amendment 5 will be reconsented for further follow up and survival status. Other administrative changes are also included

1.1. RAP Amendments

Revision chronology: updated the list of displays (Appendix 12 of RAP Amendment 1 for primary analysis) for multiple myeloma and lymphoma subjects to be included in the End of Study Clinical Study Report for Protocol. For multiple myeloma subjects, only displays with information that may significantly change after primary analysis are included. For lymphoma subjects, given the small number of subjects, the majority of the displays will be listings.

2. SUMMARY OF KEY PROTOCOL INFORMATION

There are no changes to the planned analyses, analysis method and data handling convention as described in RAP amendment 1. The only update is the list of displays for end of study analysis.

3. REFERENCES

GlaxoSmithKline Document, Reporting and Analysis Plan Amendment 1 for study ID BMA117159: Phase I Open-label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity and Clinical Activity of the Antibody Drug Conjugate GSK2857916 in Subjects with Relapsed/Refractory Multiple Myeloma and Other Advanced Hematologic Malignancies Expressing BCMA. Effective date as 06-NOV-2018.

4. APPENDICIES

4.1. Appendix 12: List of Data Displays

4.1.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.0010 to 1.xxxx	11.0010 to 11.xxxx
Efficacy	2.0010 to 2.xxxx	12.0010 to 12.xxxx
Safety	3.0010 to 3.xxxx	13.0010 to 13.xxxx
Pharmacokinetic	4.0010 to 4.xxxx	14.0010 to 14.xxxx
Population Pharmacokinetic (PopPK)	5.0010 to 5.xxxx	15.0010 to 15.xxxx
Pharmacodynamic and / or Biomarker	6.0010 to 6.xxxx	16.0010 to 16.xxxx
Pharmacokinetic / Pharmacodynamic	7.0010 to 7.xxxx	17.0010 to 17.xxxx
Section	**Listings**	
ICH Listings	1.0010 to 1.xxxx	
Other Listings	30.0010 to 30.xxxx	

4.1.2. Deliverables

Delivery [Priority] [1]	Description
DS [X]	During Study
DE [X]	Dose Escalation
IA SAC [X]	Interim Analysis Statistical Analysis Complete
SAC [X]	Final Statistical Analysis Complete

NOTES:

1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort.

4.1.3. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.0010	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	EOS SAC
1.0011	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	EOS SAC
1.0013	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
1.0020	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Only deliver if data change after primary analysis SAC	EOS SAC
1.0021	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	EOS SAC
1.0023	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
1.0053	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
Protocol Deviation					
1.0043	All Treated	DV1	Summary of Important Protocol Deviations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
Demographic and Baseline Characteristics					
1.0073	All Treated	DM1	Summary of Demographic Characteristics (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0291	Enrolled	DM11	Summary of Age Ranges (NHL)	Include columns "No Treatment", "Part 2 NHL", "Total"	EOS SAC
1.0083	All Treated	DM5	Summary of Race and Racial Combinations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
1.0193	All Treated	MH1	Summary of Past Medical Conditions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
1.0203	All Treated	MH1	Summary of Current Medical Conditions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
1.0213	All Treated	CM8	Summary of Concomitant Medications (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	EOS SAC
Exposure and Treatment Compliance					
1.0243	All Treated	OEX5	Summary of Exposure to GSK2857916 (Part 2 NHL)	Report for population: 3.4 NHL, (Summarize: Total) Do not need "Dose Intensity " section. Use 4, <4, >4 cycles	EOS SAC
Duration of Follow-up					
1.0310	All Treated	FAC2	Summary of Duration of Follow-up (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include all optional columns.	EOS SAC
1.0311	All Treated	FAC2	Summary of Duration of Follow-up (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include all optional columns.	EOS SAC
1.0313	All Treated	FAC2	Summary of Duration of Follow-up (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Include all optional columns.	EOS SAC

4.1.4. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.0030	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	EOS SAC
3.0031	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	EOS SAC
3.0033	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC
3.0793	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC
3.0060	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	EOS SAC
3.0061	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	EOS SAC
3.0063	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC
3.0693	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	EOS SAC
3.0713	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	EOS SAC
3.0700	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total).	EOS SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0701	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	EOS SAC
3.0703	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total).	EOS SAC
3.0131	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	EOS SAC
3.0133	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC
3.0141	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	EOS SAC
3.0143	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC
3.0273	All Treated	LB1	Summary of Chemistry Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	EOS SAC
3.0283	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	EOS SAC
3.0293	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values,	EOS SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	
3.0303	All Treated	LB1	Summary of Hematology Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	EOS SAC
3.0313	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	EOS SAC
3.0323	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	EOS SAC
ECG					
3.0223	All Treated	VS1	Summary of Change from Baseline in Vital Signs (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Add Cycle, Visit. Include baseline values.	EOS SAC
3.0373	All Treated	EG1	Summary of ECG Findings (Part 2 NHL)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	EOS SAC
3.0393	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (Part 2	Report for: Part 2 NHL,	EOS SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			NHL)	(Summarize: Total). Include only 'worst-case post-baseline'	
3.0403	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Include only 'worst-case post-baseline'	EOS SAC
Death					
3.0570	All Treated	DTH1a	Summary of Deaths (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	EOS SAC
3.0571	All Treated	DTH1a	Summary of Deaths (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	EOS SAC
3.0573	All Treated	DTH1a	Summary of Deaths (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC
Anti-Drug Antibody					
3.0843	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC
3.0853	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	EOS SAC

4.1.5. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Concentration					
4.0013	PK	PK01	Summary of Plasma GSK2857916 (ADC) PK Concentration-Time Data (Part 2 NHL)		EOS SAC
4.0023	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) PK Concentration-Time Data (Part 2 NHL)		EOS SAC
4.0043	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data (Part 2 NHL)		EOS SAC

4.1.6. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Concentration					
14.0013	PK	PK16	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC
14.0023	PK	PK16	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC
14.0043	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC
14.0053	PK	PK17	Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC
14.0063	PK	PK17	Mean Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part NHL)		EOS SAC
14.0083	PK	PK17	Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC
14.0093	PK	PK18	Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC
14.0103	PK	PK18	Median Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC
14.0123	PK	PK18	Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		EOS SAC

4.1.7. Pharmacokinetic / Pharmacodynamic (and / or Biomarker) Figures

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
16.0014	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (ADC) (All Treated)	disease type color-coded	EOS SAC
16.0024	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Total Antibody) (All Treated)	disease type color-coded	EOS SAC
16.0044	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for cys-mcMMAF (All Treated)	disease type color-coded	EOS SAC

4.1.8. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.0010	All Treated	ES2	Listing of Reasons for Study Withdrawal (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0011	All Treated	ES2	Listing of Reasons for Study Withdrawal (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0021	All Treated	CP_RA1p	Listing of Planned and Actual Treatments (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0030	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation (All	Report for sub-population: All	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Treated MM)	Treated MM.	
1.0031	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Protocol Deviations					
1.0040	All Treated	DV2	Listing of Important Protocol Deviations (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0041	All Treated	DV2	Listing of Important Protocol Deviations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0050	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0051	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Populations Analysed					
1.0061	All Treated	SA3a	Listing of Subjects Excluded from Any Population (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Demographic and Baseline Characteristics					
1.0071	All Treated	DM2	Listing of Demographic Characteristics (Part 2 NHL)	Report for sub-population: Part 2 NHL. Add BMI (kg/m2).	EOS SAC
1.0081	All Treated	DM9	Listing of Race (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Prior and Concomitant Medications					
1.0620	All Treated	OCM1A	Listing of Concomitant Medications (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0621	All Treated	OCM1A	Listing of Concomitant Medications (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Exposure and Treatment Compliance					
1.0090	All Treated	OEX8A	Listing of Exposure Data (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0091	All Treated	OEX8A	Listing of Exposure Data (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0100	All Treated	ODMOD10A	Listing of Dose Reductions (All Treated MM)	Report for sub-population: All Treated MM. Include Planned Time.	EOS SAC
1.0101	All Treated	ODMOD10A	Listing of Dose Reductions (Part 2 NHL)	Report for sub-population: All Treated MM. Include Planned Time.	EOS SAC
1.0110	All Treated	ODMOD12A	Listing of Dose Delays (All Treated MM)	Report for sub-population: All Treated MM. Include Planned Time. IDSL standard does not report demographic info. PPD to check with PPD PPD regarding planned time and cycle day. If it is too much programming work to change now, we can keep it as it is.	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0111	All Treated	ODMOD12A	Listing of Dose Delays (Part 2 NHL)	Report for sub-population: All Treated MM. Include Planned Time. IDSL standard does not report demographic info. PPD to check with PPD PPD regarding planned time and cycle day. If it is too much programming work to change now, we can keep it as it is.	EOS SAC
1.0120	All Treated	ODMOD15A	Listing of Dose Escalations (All Treated MM)	Report for sub-population: All Treated MM. Include Age(y)/Sex/Race, Cycle, Visit. For C2MD, list the dose escalations where a dose escalation is indicated in the data – from the site.	EOS SAC
1.0121	All Treated	ODMOD15A	Listing of Dose Escalations (Part 2 NHL)	Report for sub-population: All Treated MM. Include Age(y)/Sex/Race, Cycle, Visit. For C2MD, list the dose escalations where a dose escalation is indicated in the data – from the site.	EOS SAC
1.0490	All Treated	ODMOD14A	Listing of Incomplete Infusions (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0491	All Treated	ODMOD14A	Listing of Incomplete Infusions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0500	All Treated	ODMOD17A	Listing of Infusion Interruptions (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0501	All Treated	ODMOD17A	Listing of Infusion Interruptions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Adverse Events					
1.0140	All Treated	OAE04	Listing of All Adverse Events (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0141	All Treated	OAE04	Listing of All Adverse Events (Part 2 NHL)	Report for population subgroup: Part 2 NHL. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0150	All Treated	OAE03	Listing of Subject Numbers for Individual Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0151	All Treated	OAE03	Listing of Subject Numbers for Individual Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0160	All Treated	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0161	All Treated	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
1.0180	All Treated	OAE04	Listing of Fatal Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	EOS SAC
1.0181	All Treated	OAE04	Listing of Fatal Serious Adverse Events (Part 2 NHL)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	EOS SAC
1.0190	All Treated	OAE04	Listing of Non-Fatal Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	EOS SAC
1.0191	All Treated	OAE04	Listing of Non-Fatal Serious Adverse Events (Part 2 NHL)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	EOS SAC
1.0460	All Treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0461	All Treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0470	All Treated	OAE04	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0471	All Treated	OAE04	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0200	All Treated	OAE04	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0201	All Treated	OAE04	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0240	All Treated	OAE04	Listing of Adverse Events Leading to Dose Reduction (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0241	All Treated	OAE04	Listing of Adverse Events Leading to Dose Reduction (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0250	All Treated	OAE04	Listing of Adverse Events Leading to Dose Interruptions or Delays (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0251	All Treated	OAE04	Listing of Adverse Events Leading to Dose Interruptions or Delays (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0510	All Treated	OAE04	Listing of Adverse Events Leading to Incomplete Infusions (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				listings.	
1.0511	All Treated	OAE04	Listing of Adverse Events Leading to Incomplete Infusions (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0520	All Treated	OAE04	Listing of Adverse Events Leading to Infusion Interruptions (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0521	All Treated	OAE04	Listing of Adverse Events Leading to Infusion Interruptions (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	EOS SAC
1.0270	All Treated	OAE04	Listing of Corneal Events (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0271	All Treated	OAE04	Listing of Corneal Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0530	All Treated	OAE04	Listing of Thrombocytopenia (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0531	All Treated	OAE04	Listing of Thrombocytopenia (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0540	All Treated	OAE04	Listing of Hematologic Toxicity (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0541	All Treated	OAE04	Listing of Hematologic Toxicity (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0550	All Treated	OAE04	Listing of Neutropenia (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0551	All Treated	OAE04	Listing of Neutropenia (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0260	All Treated	OAE04	Listing of Infusion Related Reactions (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0261	All Treated	OAE04	Listing of Infusion Related Reactions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Hepatobiliary (Liver)					
1.0410	All Treated	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0411	All Treated	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0420	All Treated	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0421	All Treated	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
All Laboratory					
1.0330	All Treated	OLB7	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0331	All Treated	OLB7	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0320	All Treated	OLB13	Listing of Laboratory Data with Character Results (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0321	All Treated	OLB13	Listing of Laboratory Data with Character Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0350	All Treated	UR2A	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
1.0351	All Treated	UR2A	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
ECOG Performance Status					
1.0430	All Treated	PS5A	Listing of ECOG Performance Status (All Treated MM)	Report for sub-population: Part 2 NHL.	EOS SAC
1.0431	All Treated	PS5A	Listing of ECOG Performance Status (Part 2 NHL)	Report for sub-population: All Treated MM.	EOS SAC
Response					
1.0560	All Treated	RE5	Listing of Investigator-Assessed Responses (All Treated MM)	Report for sub-population: All Treated MM. List investigator reported response by visit.	EOS SAC
1.0561	All Treated	RE5	Listing of Investigator-Assessed Responses (Part 2 NHL)	Report for sub-population: Part 2 NHL. List investigator reported	EOS SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				response by visit.	
Death					
1.0390	All Treated	DTH3	Listing of Deaths (All Treated MM)	Report for sub-population: All Treated MM. include the time from last dose in the listing and Number of Cycles/Last Dose (optional columns in DTH3).	EOS SAC
1.0391	All Treated	DTH3	Listing of Deaths (Part 2 NHL)	Report for sub-population: Part 2 NHL. include the time from last dose in the listing and Number of Cycles/Last Dose (optional columns in DTH3).	EOS SAC
PK					
1.0631	PK	PK07	Listing of Plasma GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (NHL)		EOS SAC
1.0641	PK	PK07	Listing of Plasma GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (NHL)		EOS SAC
1.0661	PK	PK07	Listing of Plasma cys-mcMMAF Pharmacokinetic Concentration-Time Data (NHL)		EOS SAC

4.1.9. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Medical Conditions					
30.0011	All Treated	MH2	Listing of Past Cancer-Related and Non-Cancer Related Medical Conditions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0021	All Treated	MH2	Listing of Current Cancer-Related and Non-Cancer Related Medical Conditions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Concomitant Medications					
30.0310	All Treated	OCM1A	Listing of Prophylactic Medication for Infusion-Related Reactions (All Treated MM)	Report for sub-population: All Treated MM. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	EOS SAC
30.0311	All Treated	OCM1A	Listing of Prophylactic Medication for Infusion-Related Reactions (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	EOS SAC
30.0320	All Treated	OCM1A	Listing of Eye Medications (All Treated MM)	Report for sub-population: All Treated MM. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	EOS SAC
30.0321	All Treated	OCM1A	Listing of Eye Medications (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please replace the 2nd column as 'Drug Class/Drug	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Name' and the last column as 'Reason for Medication'	
Blood and Blood Supportive Care Products					
30.0380	All Treated	BP4	Listing of Blood Products (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0381	All Treated	BP4	Listing of Blood Products (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0390	All Treated	BP5	Listing of Blood Supportive Care Products (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0391	All Treated	BP5	Listing of Blood Supportive Care Products (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Substance Use					
30.0370	All Treated	SU2	Listing of Substance Use (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0371	All Treated	SU2	Listing of Substance Use (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Anti-Cancer Therapy, Radiotherapy and Surgical Procedures					
30.0041	All Treated	AC6	Listing of Prior Anti-Cancer Therapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0050	All Treated	AC7	Listing of Anti-Cancer Radiotherapy (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0051	All Treated	AC7	Listing of Anti-Cancer Radiotherapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0060	All Treated	OSP3	Listing of Prior/On Treatment Cancer and Non-Cancer	Report for sub-population: All	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Related Surgical Procedures (All Treated MM)	Treated MM.	
30.0061	All Treated	OSP3	Listing of Prior/On Treatment Cancer and Non-Cancer Related Surgical Procedures (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0400	All Treated	FAC3	Listing of Follow-Up Anti-Cancer Therapy (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0401	All Treated	FAC3	Listing of Follow-Up Anti-Cancer Therapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Disease Characteristics					
30.0081	All Treated	DC4	Listing of Disease Characteristics at Screening (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0361	All Treated	DC3	Listing of Disease Characteristics at Initial Diagnosis (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Exposure					
30.0130	All Treated	OEX9	Summary Listing of Overall Exposure and Dose Modifications (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0131	All Treated	OEX9	Summary Listing of Overall Exposure and Dose Modifications (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Adverse Events					
30.0540	All Treated	OAE4	Listing of Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0541	All Treated	OAE4	Listing of Serious Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0550	All Treated	OAE04	Listing of Drug-Related Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0551	All Treated	OAE04	Listing of Drug-Related Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0560	All Treated	OAE4	Listing of Drug-Related Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0561	All Treated	OAE4	Listing of Drug-Related Serious Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0450	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Corneal Events		EOS SAC
30.0460	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Thrombocytopenia		EOS SAC
30.0470	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Neutrupenia		EOS SAC
30.0480	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Hematologic Toxicity		EOS SAC
30.0490	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Infusion related reactions		EOS SAC
Deaths					
30.0570	All Treated	DTH5	Listing of Subject Numbers for Specific Causes of Deaths (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0571	All Treated	DTH5	Listing of Subject Numbers for Specific Causes of Deaths (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Laboratory					
30.0530	All Treated	OLB7	Listing of Grade 3 and Grade 4 Laboratory Data (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0531	All Treated	OLB7	Listing of Grade 3 and Grade 4 Laboratory Data (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0580	All Treated	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0581	All Treated	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0160	All Treated	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0161	All Treated	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Constitutional Symptoms and Organ Examinations					
30.0510	All Treated	OCS3	Listing of Constitutional Symptoms (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0520	All Treated	OOE2	Listing of Organ Examinations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Left Ventricular Ejection Fraction					
30.0500	All Treated	OLVEF2A	Listing of Left Ventricular Ejection Fraction Results (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0501	All Treated	OLVEF2A	Listing of Left Ventricular Ejection Fraction Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
ECG					
30.0140	All Treated	OECG5A	Listing of Fridericia's QTc Values of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0141	All Treated	OECG5A	Listing of Fridericia's QTc Values of Potential Clinical	Report for sub-population: Part 2	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Importance (Part 2 NHL)	NHL.	
Vital Signs					
30.0440	All Treated	OVT7A	Listing of Vital Sign Values of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0441	All Treated	OVT7A	Listing of Vital Sign Values of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
Ocular Exam					
30.0260	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0261	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC
30.0330	All Treated	SAFE_L2	Listing of Abnormal Conjunctival Exam Results (All Treated MM)	Report for sub-population: All Treated MM. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	EOS SAC
30.0331	All Treated	SAFE_L2	Listing of Abnormal Conjunctival Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	
30.0340	All Treated	SAFE_L2	Listing of Abnormal Slit Lamp Anterior Chamber and Slit Lamp Lens Exam Results (All Treated MM)	Report for sub-population: All Treated MM. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	EOS SAC
30.0341	All Treated	SAFE_L2	Listing of Abnormal Slit Lamp Anterior Chamber and Slit Lamp Lens Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	EOS SAC
30.0350	All Treated	SAFE_L2	Listing of Indirect Fundoscopic Exam and Intraocular Pressure Results (All Treated MM)	Report for sub-population: All Treated MM. Include: Centre ID/ Subj., Age(y)/ Sex/ Race,	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	
30.0351	All Treated	SAFE_L2	Listing of Indirect Fundoscopic Exam and Intraocular Pressure Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	EOS SAC
30.0810	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results for Subjects with Ocular Exam Results in Follow-up (All Treated MM)		EOS SAC
30.0811	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results for Subjects with Ocular Exam Results in Follow-up (Part 2 NHL)		EOS SAC
Health Outcomes					
30.0590	All Treated	VS4	Listing of Symptom Impact and HRQoL Item Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List scores for Bone Pain Worst, Bone Pain Average, Fatigue	EOS SAC
30.0591	All Treated	VS4	Listing of Symptom Impact and HRQoL Item Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List scores for Bone Pain Worst, Bone Pain	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Average, Fatigue	
30.0600	All Treated	VS4	Listing of NEI-VFQ-25 Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List overall composite score and 11 sub-scores.	EOS SAC
30.0601	All Treated	VS4	Listing of NEI-VFQ-25 Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List overall composite score and 11 sub-scores.	EOS SAC
30.0610	All Treated	VS4	Listing of OSDI Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List total score and 3 sub-scores.	EOS SAC
30.0611	All Treated	VS4	Listing of OSDI Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List total score and 3 sub-scores.	EOS SAC
Anti-Drug Antibody					
30.0620	All Treated	SAFE_L3	Listing of Anti-GSK2857916 antibody results (All Treated MM)	Report for sub-population: All Treated MM.	EOS SAC
30.0621	All Treated	SAFE_L3	Listing of Anti-GSK2857916 antibody results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	EOS SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PKPD					
30.0691	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	EOS SAC
30.0701	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	EOS SAC
30.0721	PKPD		Listing of Fridericia's QTc Change from Baseline and cys-mcMMAF Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	EOS SAC

Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)

Title	:	DREAMM-1: A Phase I Open-label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity and Clinical Activity of the Antibody Drug Conjugate GSK2857916 in Subjects with Relapsed/Refractory Multiple Myeloma and Other Advanced Hematologic Malignancies Expressing BCMA
Compound Number	:	GSK2857916
Effective Date	:	06-NOV-2018

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol GSK Document Number 2012N155299_05.
- This RAP is intended to describe the safety, clinical activity and pharmacokinetic analyses required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

RAP Author(s):

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TABLE OF CONTENTS

PAGE

1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Study Report for Protocol:

Revision Chronology:		
2012N155299_00	2013-DEC-26	Original
2012N155299_01	2014-MAR-01	Amendment No. 1. Country specific Amendment for the United Kingdom to address required changes per MHRA. Updated Exclusion Criteria to exclude subjects with current corneal disease or history of corneal disease. Updated QTc withdrawal criterion to modify QTc withdrawal for QTc >500msec and to include > 60 msec increase from baseline. Updated Data Management Section 12 to include details on dissemination of data and communication plan.
2012N155299_02	2014-MAR-20	Amendment No. 2. Global Amendment to address required changes per the FDA. Updated Inclusion Criteria with minimum weight requirement. Updated Blood Volumes. Revised Time and Events Tables. Corrected typographical errors.
2012N155299_03	2014-MAY-05	Amendment No. 3. Country specific Amendment for Canada to address required changes per Health Canada. Updated preparation instructions of GSK2857916.
2012N155299_04	2016-MAY-05	Amendment No. 4. Global Amendment to include patient reported outcome instruments in the Part 2 multiple myeloma cohort and refine the lymphoma histologies eligible in Part 2 BCMA-expressing lymphoma cohort. Additionally, the requirement for 60% of tumor cells staining positive for BCMA expression was removed. The total number of subjects that may be enrolled is presented by a range of 80 to 95 to provide an updated estimate based on the number of subjects who enrolled at the time of the amendment. Additional modifications include: changing the time-point specific blood specimens are collected for baseline/pre-treatment immunogenicity and biomarker measurements, and the visit window for certain assessments.
2012N155299_05	2017-NOV-02	Global amendment to include additional follow up of multiple myeloma subjects for ocular exams (for those whose corneal signs or symptoms have not resolved), additional patient reported outcome instruments, addition of time-to-event endpoints as exploratory objectives. Subjects who have completed treatment or the 3 month follow up visit (end of study) prior to amendment 5 will be reconsented for further follow up and survival status. Other administrative changes are also included

1.1. RAP Amendments

Revision chronology:

RAP Section	Amendment Details
Reporting and Analysis Plan_Study#_Final_V1 [26-JUN-2018]	
Reporting and Analysis Plan_Study#_Amendment_Final_V1 [Insert Date]	
Section 2.1 Changes to Protocol-Specified Analysis Plan	• Clarified that EOI concentration is not Cmax for cys-mcMMAF • Clarified definition of urine PK interval parameters • Added analyte ratio determination and summaries
Section 5.2.2. Examination of Subgroups	• Added a subgroup of "Penta-refractory", defined as refractory to: Bortezomib and Carfilzomib and Lenalidomide and Pomalidomide and Daratumumab. Accordingly, the existing forest plot described in Section 7.3.1.4 Subgroup Analysis of ORR (exploratory analysis) will also include this added subgroup.
Section 8.7. Other Safety Analyses (Ocular Exam)	• Added summary of best corrected visual acuity (BCVA) at additional visits (i.e. the last follow-up exam) to existing displays. • Added summary of subjects who experienced corneal clinical signs at additional visits (i.e. end of study treatment visit and last follow-up exam) to existing displays
Section 9.1.2.1. Noncompartmental Analysis	• Clarified that EOI concentration is not Cmax for cys-mcMMAF • Clarified definition of urine PK interval parameters
Section 9.3.1.1. Exploratory assessment of dose proportionality (PK analyses)	• Clarified that dose proportionality assessment is based on Part 1 Cycle 1 data
Section 9.3.1.2. Assessment of Accumulation Ratio (PK analyses)	• Clarified definition of accumulation ratio for consistency with study design • Changed analyses from model approach to descriptive statistics
Section 9.3.1.3. Assessment of Analyte Ratios (PK analyses)	• Clarified definition of analyte ratio for consistency with study design • Changed analyses from model approach to descriptive statistics
Section 16.9.1. Population Pharmacokinetic (PopPK) Dataset Specification	• Updated PopPK dataset specification
Section 16.10.1. Pharmacokinetic / Pharmacodynamic Dataset Specification	• Updated PK/PD dataset specification
Section 16.12.4.Study Population Tables and Section 16.12.13.ICH Listings	• Remove summary tables and listing of screening failure. The data was not collected

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

Changes from the originally planned statistical analysis specified in the protocol are outlined in Table 1.

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
• Time to response (TTR) is defined as the time between the date of first dose and the first documented evidence of response (PR or better). Subjects without confirmed response (PR or better) will be censored at the censoring date for TTP.	• Time to response (TTR) is defined as the time between the date of first dose and the first documented evidence of response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).	• To be consistent with GSK Integrated Data Standards Library (IDSL) standard
• Time to best response (TTBR) analyses was not planned.	• Time to best response (TTBR), defined as the time between the date of first dose and the best response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better), was added as an exploratory endpoint.	• To further evaluate clinical activity of GSK2857916.
• The 'Pharmacokinetic (PK) Population' is defined as those subjects in the "All Treated" population from whom at least one PK sample was obtained, analyzed, and was measurable.	• All subjects in the 'All Treated' population who had at least 1 non-missing PK assessment (Non-quantifiable [NQ] values will be considered as non-missing values).	• To be consistent with the latest GSK (IDSL) standard.
• For cys-mcMMAF, after single dose, Cmax and AUC(0-t) will be derived and after repeat dose Cmax and Ctrough.	• For cys-mcMMAF, after single dose, Cmax and AUC(0-t) will be derived and after repeat dose Ctrough.	• Preliminary analysis of Part 1 data found that cys-mcMMAF Cmax did not occur at or near EOI in most cases; therefore, sparse sampling schedule did not measure cys-mcMMAF Cmax.
• Urinary recovery of unchanged cys-mcMMAF within the 24 h period collection (Ae(0-24)) will be calculated. Fraction of total cys-mcMMAF dose excreted (Fe) in the 24-h interval will be	• Urinary recovery of unchanged cys-mcMMAF within t hours after the start of infusion (Ae(0-t)) will be calculated. Fraction of total cys-mcMMAF dose	• The 24-h urine collection period may start at a time other than the start of infusion; therefore, the urine collection period may not be 24 h from the start of

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
estimated as Ae(0-24)/cys-mcMMAF Dose	excreted within t hours after the start of infusion (Fe(0-t)) will be estimated as Ae(0-t)/cys-mcMMAF dose. Time t is the time from the start of the infusion to the end of the urine collection period (≤24 h)..	infusion, and the pharmacokinetic parameter definitions have been changed to reflect this.
• Not included	• Calculation of analyte ratios as CEOI (total mAb, unbound mAb, or cys-mcMMAF) to CEOI (ADC) or Ctrough (total mAb, unbound mAb, or cys-mcMMAF) to Ctrough (ADC) at each cycle at which they are determined, adjusted for molecular weights	• To assess exposures to each compound relative to ADC at EOI and trough for each cycle
• Descriptive statistics (mean, standard deviation, median, range) will be used to summarize observed laboratory values and change from baseline in observed value at each scheduled visit, as appropriate	• Descriptive statistics (mean, standard deviation, median, range) will be used to summarize change from baseline in observed value at each scheduled visit, as appropriate	• To be consistent with the latest GSK (IDSL) standard.

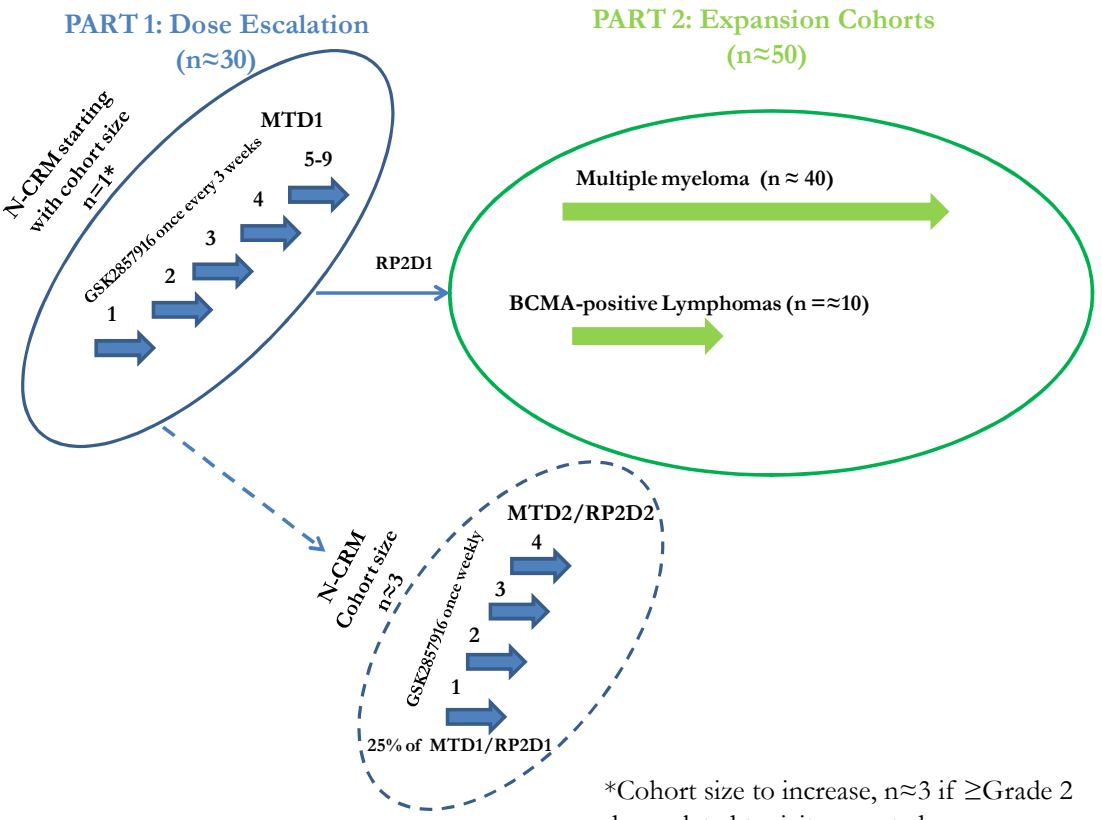
2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To determine safety, tolerability, maximum tolerated dose (MTD), and recommended phase (RP2) dose and schedule of GSK2857916 administered	• Adverse events (AE) and changes in clinical signs and laboratory parameters
Secondary Objectives	**Secondary Endpoints**
• To evaluate the pharmacokinetic (PK) profile of GSK2857916 and the breakdown product cys-mcMMAF after intravenous (IV) single and repeat dose administration in subjects with relapsed/refractory MM and BCMA expressing lymphomas	• GSK2857916 and cys-mcMMAF PK parameters following IV single and repeat dose administration during dose escalation as data permit (e.g., AUCs Cmax, tmax, CL, V_{SS}, t½ [single dose], Cmax and Ctrough [repeat dose]). GSK2857916 population PK parameters in expansion cohorts at the RP2 dose (e.g. clearance (CL), volume of distribution (Vd)), and relevant covariates which may influence exposure (e.g. age, weight, or disease-related covariates e.g. BCMA expression)
• To assess anti-drug antibody (ADA) formation after IV single and repeat dose administration of GSK2857916	• ADA incidence and titers after single and repeat IV dosing of GSK2857916
• To explore the initial anti-tumor activity of GSK2857916 in subjects with relapsed/refractory MM and BCMA expressing lymphomas	• Clinical activity measured as Overall Response Rate (ORR) which is defined as follows: ○ For MM: the percentage of subjects achieving confirmed partial response or better (≥PR) ○ In addition, the percentage of subjects with minimal response (MR) will be assessed for clinical benefit rate (CBR) (Appendix 1 of protocol) • For Lymphomas: the percentage of subjects achieving PR or better (≥PR) (Appendix 2 of protocol)
Exploratory Objectives	**Exploratory Endpoints**
• To evaluate PD markers in MM after treatment with GSK2857916	• sBCMA levels, BCMA receptor occupancy and cell death markers in subjects with MM.
• To explore relationships of GSK2857916 plasma concentrations/exposure with pharmacodynamics (PD), safety and clinical activity	• Relationship between receptor occupancy, tumor cell death markers, sBCMA and GSK2857916 plasma PK parameters; • Relationship between safety/clinical activity (e.g. ORR) and GSK2857916 PK parameters
• To characterize the relationship between clinical response and other biologic tumor characteristics (DNA, protein analysis)	• BCMA expression levels on malignant cells as measured by IHC and/or flow cytometry in tumor tissue, serum sBCMA levels and their relationship to clinical response
• To investigate the relationship between genetic variants in the host and response to study medicine, or susceptibility, severity and progression of disease	• Relationship between host genetic variation and response to study medicine or susceptibility, severity and progression of disease

Objectives	Endpoints
• To explore the effect of GSK2857916 on symptoms (including bone pain, fatigue and visual symptoms) and impacts on HRQoL in subjects with relapsed/refractory MM (Part 2)	• Changes from baseline in bone pain/fatigue and analgesic use as measured by the eDiary • Interviews with subjects to further characterize changes in symptoms (including bone pain/, fatigue and visual symptoms) and impacts on HRQoL
• To explore changes in visual symptoms and function following discontinuation of treatment with GSK2857916	• Changes in visual symptoms and impacts as measured by the OSDI and NEI-VFQ-25 following treatment discontinuation • Follow-up telephone interviews conducted to further understand subjects experience with visual symptoms and changes in symptoms and related impacts following treatment discontinuation
• To explore the initial anti-tumor activity of GSK2857916 in subjects with relapsed/refractory MM in terms of time-to-event (TTE) endpoints (Part 2 MM)	• **Time to progression (TTP)**, defined as: the time from first dose until the earliest date of PD per International Multiple Myeloma Working Group (IMWG), or death due to PD. • **Duration of response (DOR)**, defined as: the time from first documented evidence of PR or better; until the time when disease progression (PD) is documented per IMWG; or death due to PD occurs in subjects who achieve a response, i.e. confirmed PR or better. • **Time to response (TTR)**, defined as: the time between the date of first dose and the first documented evidence of response (PR or better), among subjects who achieve a response, i.e. confirmed PR or better. • **Time to best response (TTBR)**, defined as the time between the date of first dose and first documented evidence of the best response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better). • **Progression-free survival (PFS)**, defined as: the time from first dose until the earliest date of disease progression (PD) per IMWG, or death due to any cause. • **Number of deaths.**

2.3. Study Design

Overview of Study Design and Key Features



Design Features

- **Part 1 Dose Escalation**
  - Population: Subjects with relapsed/refractory MM (originally planned to enrol up to 30 subjects. However, additional subjects were enrolled to explore a new intermediate dose group)
  - Objective: characterize safety, PK, PD, immunogenicity and establish RP2 dose of GSK2857916
  - Two dosing schedules (Schedule 1 and Schedule 2) may be explored:
    - Schedule 1: GSK2587916 once every 3 weeks (21-day cycle) (n=~20)
    - Schedule 2: GSK2587916 once weekly for 3 consecutive weeks, 1-week rest (28-day cycle) (n=~9). Schedule 2 was not actually explored.
  - Serial PK samples will be collected from all subjects in Part 1
- **Part 2 Expansion Cohort(s) (n=~50 subjects)**
  - Population:
    - Subjects with relapsed/refractory MM (up to 40 subjects)
    - Subjects with lymphomas expressing BCMA (up to 10 subjects)
  - Objective: Further evaluate the safety, PK, immunogenicity, and clinical activity of GSK2857916 at the RP2 dose identified in Part 1
  - MM and Lymphoma expansion cohorts will be analyzed separately
  - Sparse PK samples will be collected from all subjects
- Genetics research samples will be collected predose from all subjects

Overview of Study Design and Key Features	
Dosing	• **Part 1 Dose Escalation** Initially, GSK2857916 will be administered (IV) via 60 min infusion once every three weeks (21 days = 1 cycle) on Schedule 1. Once an MTD1 or RP2D has been established on the once every 21-day (Schedule 1), the safety, tolerability, PK, and PD of once-weekly dosing (Schedule 2) of GSK2857916 may be explored as an additional cohort(s). • **Part 2: Dose Expansion Phase** Subjects enrolled in Part 2 dose expansion phase will be administered GSK2857916 at recommended phase 2 dose (RP2D) established based on Part 1 outcomes.
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• This is a non-randomized open-label study.
Interim Analysis	• **Part 1: Dose Escalation Phase** No formal interim analysis is planned for Part 1. Safety, pharmacokinetic and pharmacodynamic marker data will be examined on an ongoing basis to support dose escalation decisions. • **Part 2: Dose Expansion Phase** ○ For MM cohort, one futility analysis based on ORR data was performed after approximately 30 subjects are evaluable (originally 3 futility analyses are planned after approximately 15, 22 and 30 subjects are evaluable). The number of confirmed responses (PR or better) observed will be compared with the stopping rules provided in Section 13.6.2 of the protocol. ○ For the lymphomas expressing BCMA cohort, no interim analyses will be performed, though consideration would be given to closing the cohort should the enrolment be stopped in the MM cohort.

2.4. Statistical Hypotheses / Statistical Analyses

No formal statistical hypotheses will be tested in Part 1. Analysis of the data obtained from Part 1 will only utilize descriptive methods. In Part1, dose escalation/de-escalation decisions will be informed by the Bayesian approach: N-CRM (Neuenschwander-Continuous Reassessment Method) [Neuenschwander, 2008]. Details of the N-CRM model used for this study is described in Section 3.1.1.

The assumption for ORR in part 2 MM cohort is:

The null hypothesis H0: ORR $\leq$ 20%

The alternative hypothesis HA: ORR $\geq$ 40%.

No hypothesis testing is planned for part 2 MM cohort. The methodology utilized is based on the predictive probability of success if enrollment continues to 40 subjects [Lee, 2008]. The predictive probability design is similar to a Green-Dahlberg design in that it allows for early stopping for futility. The differences are that the predictive probability design allows for evaluation of stopping rules as often as after each subject, rather than at only two stages. While the two designs have similar type I and type II error rates, the

probability of early termination is greater with the predictive probability design. In this particular study, one futility analysis based on ORR data was performed after approximately 30 subjects are evaluable (originally 3 futility analyses are planned after approximately 15, 22 and 30 subjects are evaluable).

3. PLANNED ANALYSES

3.1. Interim Analyses

3.1.1. Part 1: Dose Escalation Phase

While no formal interim analysis is planned for Part 1, safety, pharmacokinetic and pharmacodynamic marker data will be examined on an ongoing basis to support dose escalation decisions. Prior to determining the GSK2857916 dose for the next cohort enrolled, exploratory analysis will be conducted to assess the relationship of GSK2857916 dose levels with safety, PK and PD parameters using all data from available cohorts.

Dose escalation/de-escalations decisions will take into account all available data, including but not limited to the safety parameters, PD and PK data of all cohorts assessed. Dose escalation/de-escalation decisions will be informed by the N-CRM (Neuenschwander-Continuous Reassessment Method) [Neuenschwander, 2008]. The N-CRM model used for Schedule 1 is described in detail in Section 3.1.1.1 and Section 3.1.1.2. The method is fully adaptive and makes use of all DLT information available at the time of each dose assignment.

3.1.1.1. Description of the New Continual Reassessment Method

The N-CRM is a type of Bayesian adaptive dose-escalation scheme that estimates the parameters of a statistical model relating dose and toxicity, and is expected to locate the MTD efficiently while minimizing the number of subjects exposed to pharmacologically inactive or unsafe dose levels. The method is fully adaptive and makes use of all the toxicity information available at the time of each dose assignment. N-CRM estimates may be provided at dose escalation meetings as supportive material to the primary 3+3 dose escalation design.

The N-CRM estimates, for each potential dose, the (Bayesian) posterior probabilities that the DLT rate lies in each of four predefined toxicity ranges:

- A dose falls in the **Under-dosing** range if the rate of a DLT at the dose is in the interval [0%, 16%).
- A dose falls in the **Target** toxicity range if the rate of a DLT at the dose is in the interval [16%, 33%).
- A dose falls in the **Excessive** toxicity range if the rate of a DLT at the dose is in the interval [33%, 60%).

- A dose falls in the **Unacceptable** toxicity range if the rate of a DLT at the dose is in the interval [60%, 100%].

Additionally, the following over-dose constraints for the recommended dose will be maintained:

- The posterior probability of the DLT rate lying in the Excessive Toxicity or Unacceptable Toxicity range is 0.25 or less.
- The recommended dose is no more than 2 times that of the previous dose.
- Note that a de-escalation recommendation is possible using this method. At the time of each dose-escalation decision, the dose with the highest posterior probability of lying in the Target Toxicity range (subject to the given constraints) will be the model-recommended dose for the next cohort.

The N-CRM procedure for Schedule 1 will utilize a single subject/cohort run-in phase.

The single subject (small cohort) run-in will be halted when the first ≥ Grade 2 toxicity for which relationship to the investigational agent cannot be ruled out occurs in one subject in Cycle 1 (21 days). At this point, the cohort will be expanded to 3 or more subjects at the same dose level and the escalation will continue to follow the N-CRM procedure as outlined in Table 2

Table 2 Single Subject (Small Cohort) Run-In Procedure for GSK2857916 given on Schedule 1 (once every 21 days)

Dose Level	Number of subjects with ≥G2 toxicity	Dose Escalation/Action
Dose Level 1/Cohort 1	0 out of 1 subject (Sentinel subject)	Predicted starting dose 0.03 mg/kg every 21 days
Dose Level 2/Cohort 2	0 out of 1 subject	Escalate to the next dose level with increase ≤100% of the starting dose
Dose Level 3 and beyond/Cohort 3 and beyond	0 out of 1 subject	Escalate to the next dose level with increase of ≤100% of the dose tested in the previous cohort
	1 out of 1 subject*	Switch to Cohort size of 3 or more subjects

*Increase of doses **up to** 100% of the previous dose may continue until the first ≥ Grade 2 toxicity for which relationship to the investigational agent cannot be ruled out occurs in one subject in Cycle 1 (21 days). At this point the single subject (small cohort) run-in is halted. Continue with N-CRM, with cohort sizes of 3 or more subjects. Increase of doses ≤100% will be considered for subsequent cohorts of 3 or more subjects.

3.1.1.2. Prior Probability Distribution

Elicited prior probabilities of a DLT at each dose were used to determine the prior distribution of the parameters of an explicit logistic dose-toxicity model, namely

$$\ln\left(p_d/(1-p_d)\right) = \alpha + \beta * \ln\left(d/d_m\right),$$

where p_d is the probability of a DLT at dose d, and d_m is a reference dose.

The prior distribution of (α, ln(β)) will be assumed to be bivariate normal with means (standard deviations): E[α]=−1.3281 (1.7153), E[ln(β)]=-0.795 (1), with correlation between α and ln(β) set to ρ=−0.9352 and d_m=0.72 mg/kg.

3.1.1.3. Displays To Be Created For Dose Escalation Review

Review of preliminary data will be performed after completion of each dosing cohort in Part 1. Preliminary safety and study population data may include a demographic summary, adverse event (AE) summary, AE summary by maximum toxicity category, SAE listing, listing of AEs that are reported to be DLT's, and listing of AEs leading to dose modification. Spreadsheets containing relevant study data may also be supplied by the study data manager.

Further, after single subject run-in was halted, after each expanded cohort in dose escalation, the recommended dose from the N-CRM method and updated posterior estimates of the probabilities of being in each dose-toxicity range may be provided. The Fixed and Adaptive Clinical Trial Simulator (FACTS) (Version 2.4 or higher) software from Tessella will be used to make N-CRM calculations.

Prior to determining a dose for the next cohort, exploratory analyses will be conducted to assess the relationship of dose levels with safety, PK, and pharmacodynamic parameters using all data from available cohorts.

The GSK study team, in collaboration with study investigators, will review all relevant data to support:

- whether the current dose had acceptable toxicity, and
- the decision regarding the next dose level based on the totality of the data

3.1.2. Part 2 Expansion Phase

3.1.2.1. Multiple Myeloma Expansion Cohort

During Part 2 (Expansion Cohort), futility analyses of response data will be conducted in order to determine whether the futility criteria for stopping have been met. The study will not be stopped early for efficacy, but is designed to stop early for futility if the predictive probability of success is less than 5%.

For Multiple Myeloma cohort, response data will be reviewed once approximately 30 subjects are evaluable at the RP2D dose and the number of confirmed responses (PR, VGPR, CR, and sCR) will be compared with the stopping rules provided in Table 3 based on predictive probability design of Lee et al. [Lee, 2008].

In addition to considering the recommendations of the futility analyses, final decisions on stopping enrolment in the MM cohort will depend on the totality of the data collected. Should the recommendation to stop for futility be disregarded in favour of a decision to continue the trial based on the totality of the data, the overall type I error rate of the expansion phase will be inflated.

Table 3 Futility Stopping Region for Multiple Myeloma Expansion Cohort

	Number of Overall Responses												
Number of Evaluable Subjects	0	1	2	3	4	5	6	7	8	9	10	11	>11
15	■	■	■										
16	■	■	■										
17	■	■	■										
18	■	■	■	■									
19	■	■	■	■									
20	■	■	■	■									
21	■	■	■	■									
22	■	■	■	■	■								
23	■	■	■	■	■								
24	■	■	■	■	■								
25	■	■	■	■	■	■							
26	■	■	■	■	■	■							
27	■	■	■	■	■	■							
28	■	■	■	■	■	■							
29	■	■	■	■	■	■	■						
30	■	■	■	■	■	■	■						
31	■	■	■	■	■	■	■						
32	■	■	■	■	■	■	■	■					
33	■	■	■	■	■	■	■	■					
34	■	■	■	■	■	■	■	■	■				
35	■	■	■	■	■	■	■	■	■				
36	■	■	■	■	■	■	■	■	■				
37	■	■	■	■	■	■	■	■	■	■			
38	■	■	■	■	■	■	■	■	■	■			
39	■	■	■	■	■	■	■	■	■	■	■		
40	■	■	■	■	■	■	■	■	■	■	■	■	

3.1.2.1.1. Operating Characteristics of the Stopping Rules for Futility

The stopping rule in Table 3 is based on the methodology of Lee et al. [Lee, 2008]. For the MM expansion cohort, starting with 15 subjects and allowing for a maximum sample size of 40, this design will have a type I error rate of 0.075 and 89.8% power. Under the null hypothesis, if the true response rate is 20%, the expected sample size of the design is 23.4 subjects and probability of early termination (PET) is 88.9%. Under the alternative hypothesis, if the true response rate is 40%, the expected sample size of the design is 38.6 subjects and probability of early termination (PET) is 8.5%.

3.1.2.2. Lymphoma Expansion Cohort

No interim analyses will be performed on the BCMA positive lymphomas cohort; though consideration would be given to closing the cohort should the enrolment be stopped in the MM cohort.

3.2. Administrative Interim Analyses

Additional administrative interim analysis may be performed to inform patient safety and efficacy of the drug as needed.

3.3. Final Analyses

The final planned primary analyses will be performed after the completion of the following sequential steps:

1. All participants have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.

A final analysis of the MM population can be done separately, before the NHL cohort completes, and will necessitate separate DBR/DBF activities.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All participants who were screened for eligibility	• Study Population
Enrolled	• All participants who passed screening and entered the study. • Note screening failures (who never passed screening even if rescreened) and subjects screened but never enrolled into the study (Reserve, Not Used) are excluded from the Enrolled population as they did not enter the study.	• Study Population
All Treated	• All eligible subjects who receive at least 1 dose of study treatment. An incorrect treatment schedule or drug administration or an early termination of treatment will not result in exclusion of subjects from this population. • **Sub-populations:** o Part 1: all Part 1 subjects of All Treated population. Note, subjects in Part 1 are exclusively multiple myeloma patients. (2.5 mg/kg will be included in Part 1) o Part 2 MM: all Part 2 MM subjects of All Treated population o All Treated MM: comprise of subjects in Part 1 and Part 2 MM. o Part 2 NHL: all Part 2 lymphoma subjects of All Treated population.	• Study Population • Safety • Efficacy
Evaluable (MM)	• This population is a subset of the 'All Treated' population, who were initially treated at RP2D in the expansion cohort and have at least two post-baseline disease assessments or they have progressed or died or permanently discontinued treatment.	• futility analyses of MM Expansion cohort only
DLT Evaluable	• All subjects fulfilling the 'All Treated' population criteria, and having met the following adequate exposure criteria: o For Schedule 1 (once every 3 weeks dosing) subjects received a complete infusion in cycle 1. o For Schedule 2 (once weekly dosing for 3 consecutive weeks, 1 week rest) subjects receive three infusions, two of which must be complete infusions, in cycle 1. (as increases up to ≤30% are implemented between cohorts, less than 2 complete infusions would result in a total dose closer to the previous dose investigated). (Schedule 2 was not explored in the study) o Any subject in the "All Treated" population who experiences a DLT, as defined in Section 3.3.3 of the protocol will also be included in the DLT evaluable population regardless of exposure.	• Summary of DLT, for Part 1 only

Population	Definition / Criteria	Analyses Evaluated
Pharmacodynamic	• The 'Pharmacodynamic (PD) Population' is defined as those subjects in the "All Treated" population from whom at least one PD sample was obtained, analyzed, and was measurable.	• PD
Pharmacokinetic (PK)	• All subjects in the 'All Treated' population who had at least 1 non-missing PK assessment (Non-quantifiable [NQ] values will be considered as non-missing values).	• PK

Refer to Appendix 12: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarised and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan [08May2017, Version 6.0].

- Data will be reviewed prior to freezing the database to ensure all important deviations are captured and categorised on the protocol deviations dataset.
- This dataset will be the basis for the summaries and listings of protocol deviations.

A separate summary and listing of all inclusion/exclusion criteria deviations will also be provided. This summary will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions				
RandAll NG		Data Displays for Reporting		
Code	Description [1]	Description [2]	Data Display	Order in TLF
A	Active Treatment	GSK2857916 0.03 mg/kg (Part 1 MM)	0.03 mg/kg	1
		GSK2857916 0.06 mg/kg (Part 1 MM)	0.06 mg/kg	2
		GSK2857916 0.12 mg/kg (Part 1 MM)	0.12 mg/kg	3
		GSK2857916 0.24 mg/kg (Part 1 MM)	0.24 mg/kg	4
		GSK2857916 0.48 mg/kg (Part 1 MM)	0.48 mg/kg	5
		GSK2857916 0.96 mg/kg (Part 1 MM)	0.96 mg/kg	6
		GSK2857916 1.92 mg/kg (Part 1 MM)	1.92 mg/kg	7
		GSK2857916 2.50 mg/kg (Part 1 MM)	2.50 mg/kg	8
		GSK2857916 3.40 mg/kg (Part 1 MM)	3.40 mg/kg	9
		GSK2857916 4.60 mg/kg (Part 1 MM)	4.60 mg/kg	10
		GSK2857916 3.40 mg/kg (Part 2 MM)	3.40 MM	11
		GSK2857916 3.40 mg/kg (Part 2 NHL)	3.40 NHL	12

Notes:
[1] This is a single-arm study and only active treatment is planned for the study.
[2] Part 1: dose escalation phase; Part 2: Expansion Cohort; MM: multiple myeloma; NHL: Lymphoma.

5.2. Baseline Definitions

For all endpoints (except as noted in baseline definitions) the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as baseline.

For subjects who did not receive study treatment during the study, baseline will be defined as the latest, non-missing collected value.

For ECG analyses, subject level baseline is defined as the mean of triplicate baseline assessments.

Unless otherwise stated, if baseline data is missing no derivation will be performed and baseline will be set to missing.

5.2.1. Examination of Subgroups

The list of subgroups may be used in descriptive summaries. Additional subgroups of clinical interest may also be considered.

Subgroup	Categories
Age	18 to <65, 65 to <75, >=75
Sex	Male, Female
Ethnic Background	White, Other
ISS Staging at Screening	I, II, III, Other (Unknown or Missing)
Number of prior lines of therapy	<=3,4-5, >5
Type of myeloma	IgG, Non-IgG
Prior Daratumumab Treatment	Yes, No
Refractory to prior anti-cancer therapy	Any Proteasome Inhibitor (PI) Bortezomib Carfilzomib Ixazomib Any Immunomodulator (IMiD) Thalidomide Lenalidomide Pomalidomide Monoclonal Antibodies Daratumumab Daratumumab alone [1] Daratumumab in combination [2] PI+IMiD Daratumumab+PI+IMiD Penta-refractory [3]
Cytogenetics Risk [4]W	High, Other (non-high risk, not done, or missing)
Prior anti-cancer therapy of interest	• With prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors. • Without prior Daratumumab Treatment. • Refractory to Both Immunomodulators and Proteasome Inhibitors.

NOTES:

[1] Defined as prior CTX regimen with Daratumumab as the only drug in the regimen.

[2] Defined as prior CTX regimen with Daratumumab and other drugs in the regimen.

[3] Penta-refractory= refractory to: Bortezomib and Carfilzomib and Lenalidomide and Pomalidomide and Daratumumab.

[4] A subject is considered as high risk if the subject has any of the following cytogenetics: t(4;14), del17p, t(14;16).

5.3. Other Considerations for Data Analyses and Data Handling Conventions

Other considerations for data analyses and data handling conventions are outlined in the appendices:

Section	Component
16.3	Appendix 3: Assessment Windows
16.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
16.5	Appendix 5: Data Display Standards & Handling Conventions
16.6	Appendix 6: Derived and Transformed Data
16.7	Appendix 7: Reporting Standards for Missing Data
16.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the "All Treated" population, unless otherwise specified.

Study population analyses including analyses of subject's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 12: List of Data Displays.

6.2. Disposition of Subjects

A summary of the number of subjects in each of the analysis populations described in Section 4 will be provided (for final analysis, Evaluable population will not be included). In addition, the number of subjects enrolled by center will be summarized by Study Part and Tumor Type using the "Enrolled" population. A separate summary for exclusions from each study population will be displayed (for final analysis, Evaluable population will not be included). A listing of subjects excluded from analysis populations will also be provided.

A summary of subject status and reason for study withdrawal will be provided. This display will show the number and percentage of subjects who withdrew from the study, including primary reasons for study withdrawal. Reasons for study withdrawal will be presented in the order they are displayed in the eCRF.

A summary of study treatment status will be provided. This display will show the number and percentage of subjects who are ongoing or discontinued study treatment and a summary of the primary reasons for discontinuation of study treatment. Reasons for study treatment discontinuation will be presented in the order they are displayed in the eCRF. A listing of study treatment discontinuation will be generated. The listing will include last dose date, and reasons for study treatment discontinuation.

6.3. Demographic and Baseline Characteristics

The demographic characteristics (e.g., age, race, ethnicity, sex, baseline height, and baseline body weight and baseline BMI will be summarized and listed. Age, height, weight and BMI will be summarized using the mean, standard deviation, minimum, median, and maximum. The count and percentage will be computed for sex and ethnicity.

Race and racial combinations will be summarized and listed.

Disease history and characteristics (e.g. time since initial diagnosis in years, stage at initial diagnosis, date of initial diagnosis) at initial diagnosis and screening will be listed. Separate summaries of disease characteristics at initial diagnosis and screening will be provided. Disease characteristics for multiple myeloma subjects at screening, including stage, lines of prior therapy regimens, type of multiple myeloma, myeloma light chain and myeloma immunoglobulin will be summarized and listed.

Medical conditions present at screening will be listed and will be summarized by past and current and by cancer-related and non-cancer related categories.

Genetic characteristics for multiple myeloma subjects at screening will be summarized and listed. Cytogenetic risk for multiple myeloma subjects at screening will be summarized. A subject is considered as having high cytogenetic risk if the subject has any of the following cytogenetics: t(4;14), del17p, t(14;16).

Substance use, including smoking history and alcohol use will be summarized and listed.

Prior anti-cancer therapy will be coded using GSK Drug coding dictionary, then summarized by type of therapy and listed. A listing of prior anti-cancer therapy will show the relationship between ATC Level 1, Ingredient, and verbatim text. A summary of the best response to the most recent prior anti-cancer therapy will be provided. A summary of the number of prior anti-cancer therapy regimens will also be produced.

Prior anti-cancer therapy for multiple myeloma subjects will also be summarized by type of therapy, drug class and subclass. A summary of multiple myeloma subjects refractory to prior anti-cancer therapy by drug class will be provided.

A multiple myeloma subject is defined to be refractory to prior anti-cancer therapy if

[1] the subject's best response to prior anti-cancer therapy is PD or SD, **OR**

[2] the subject's most recent response to prior anti-cancer therapy is PD or SD, **OR**

[3] the subject progress within 60 days of completion of prior anti-cancer therapy.

Summary of subjects with multiple myeloma double refractory to prior Immunomodulator (IMID) and Proteasome Inhibitor (PI) will also be provided. For definition of "double refractory", IMID and PI are not necessary to be in the same regimen.

Anti-cancer radiotherapy will be listed. Prior cancer and non-cancer related surgeries will be summarized. Prior and on treatment cancer and non-cancer related surgeries will be listed.

6.4. Treatment Compliance

Summaries of study treatment exposure and dose modifications (e.g., number of dose reductions, number of dose interruptions) will further characterize compliance. These analyses are described in Section 6.5 'Extent of Exposure'.

6.5. Extent of Exposure

Extent of exposure to GSK2857916 will be summarized.

The number of cycles administered to study treatment will be summarised with mean, median, standard deviation, minimum, and maximum. The number and percentage of subjects who received a given number of cycles (<4, 4, and >4 cycles) will be reported.

Dose intensity (dose delivered per cycle) will be summarized using mean, median, standard deviation, minimum, and maximum by cycle and overall. Dose intensity is the cumulative actual dose divided by the total number of cycles across the entire treatment period. A by subject summary listing of data on exposure to all study treatments will be produced.

Dose reductions will be summarised by number of reductions and reasons for reductions. Dose delays will be summarised by number of delays, reasons for the delays, and delay duration (days). The number and percentage of the delays 1-21, 22-42 and >42 days will be computed. Primary reasons for dose reductions and dose delays will also be summarized by cycle.

Duration of delays is defined as period from the expected start date of dose to actual start date of current dose. Calculation: (actual start date of current dose - expected start date of dose). Expected start date of dose = actual start date of previous dose + 21.

The summaries of dose modifications will be provided only if the data warrant.

All the dose reductions, dose escalations, infusion interruptions, incomplete infusions and dose delays will be listed separately.

A plot showing the number and percentage of subjects treated at different dose levels over time will be provided.

The duration of exposure to study treatment in days (from first day to last day of treatment) will be calculated. A horizontal bar graph of duration of treatment will be produced that displays duration of treatment in days for each subject.

6.6. Concomitant Medications

Concomitant medications will be coded using GSK Drug coding dictionary, summarized, and listed. The summary of concomitant medications will show the number and percentage of subjects taking concomitant medications by Ingredient. Multi-ingredient products will be summarized by their separate ingredients rather than as a combination of ingredients. Anatomical Therapeutic Chemical (ATC) classification Level 1 (Body System) information will be included in the dataset created but will not appear on the listing or summary.

Prophylactic Medication for Infusion-Related Reactions will be summarized by drug class and drug name and listed separately. Eye medications will be listed.

In the summary of concomitant medications, each subject is counted once within each unique ingredient. For example, if a subject takes Amoxycillin on two separate occasions, the subject is counted only once under the ingredient “Amoxycillin”. In the summary of concomitant medications, the ingredients will be summarized by the base only, using CMBASECD and CMBASE. Note: In order to be considered a concomitant medication, the concomitant medication must have been taken at some point during the on-therapy window.

Blood products or blood supportive care products with onset date within the on-therapy window will be included in the summary tables. The frequency and percentage of subjects using blood products and blood supportive care products after the start of study medication will be provided. Supporting listings will also be provided.

6.7. Subsequent Anti-Cancer Therapies

The number and percentage of subjects that received chemotherapy, immunotherapy, hormonal therapy, biologic therapy, radioactive therapy, small molecule targeted therapy, as post study treatment anti-cancer therapy will be summarized. Time from study treatment discontinuation to the first post study treatment anti-cancer therapy will also be included in this summary table.

Follow-up anti-cancer therapy will be coded using GSK Drug coding dictionary, then summarized by ingredient. A listing of the type of follow-up anti-cancer therapy received (chemotherapy, immunotherapy, hormonal therapy, biologic therapy, radioactive therapy, and small molecule targeted therapy for each subject will be provided).

7. EFFICACY ANALYSES

7.1. Primary Efficacy Analyses

No primary efficacy analyses were planned.

7.2. Secondary Efficacy Analyses

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1.1 and Section 7.2.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.2.1. Multiple Myeloma

7.2.1.1. Endpoint / Variables

7.2.1.1.1. Overall Response Rate

Overall Response Rate (ORR), is defined as the percentage of responders (subjects with confirmed stringent complete response (sCR), complete response (CR), very good partial response (VGPR), and partial response (PR) as assessed according to 2011 International Myeloma Working Group (IMWG) criteria (Appendix 1 in the protocol)). Only the assessments from the start of treatment up to the earlier of disease progression or the start of new anti-cancer therapy will be considered. Only new systemic anti-cancer drugs taken are considered as anti-cancer therapy (radiotherapy and surgeries are not considered as systemic anti-cancer therapy for the purpose of this analysis). .

Subjects with only one assessment (therefore not confirmed), or assessments of Not Evaluable or missing response will be treated as non-responders; i.e. they will be included in the denominator when calculating the percentage.

7.2.1.1.2. Response Confirmation Algorithm

The definitions and details to derive unconfirmed and confirmed response are outlined below. For both confirmed and unconfirmed response derivations, only responses assessments from the start of treatment up to the earlier of disease progression or the start of new anti-cancer therapy will be considered. Date associated with response was defined in Section 16.5.5

Definitions:

1. The hierarchy of response classifications from high to low is as following: sCR, CR, VGPR, PR, MR, SD, PD and NE. Response was assessed according to the 2011 Uniform Criteria Consensus recommendations of the International Myeloma Working Group (See Appendix 1 of protocol).

2. Definition of two consecutive assessments: the two consecutive assessments should be taken from two different samples, and NOT based upon the splitting of a single sample.
    a. No minimum time separation between two consecutive assessments is required to confirm response.
    b. If there are two assessments separated by not evaluable (NE) or Missing assessment(s), collapse data by ignoring NE or Missing assessments.
    c. If two consecutive assessments are on different dates, it is assumed that the two assessments are from different samples
    d. If there are multiple assessments on the same date and there is no data to show that they are from different samples, it is assumed these assessments are from the same sample. Then only the response with the lowest magnitude will be selected as the response for that date.

Two-step algorithm for determining the best confirmed response

Step1. Determine the confirmed response sequentially at each time of disease assessment.

A. For confirmed sCR, CR, VGPR, PR, MR, SD, two consecutive assessments are required.
    a. For any two consecutive assessments with different magnitudes, the confirmed response is the response of lower magnitude.
    b. For any two consecutive assessments with the same magnitude, the confirmed response is the response of that magnitude.
    c. Although the response will be confirmed at the time of the second one of the two consecutive assessments, the date of the first one of the two consecutive assessments will be the date of this confirmed response.

Table 4 Summary of the criteria for confirmation of sCR, CR, VGPR, PR, MR, SD

Response at one time-point of two consecutive assessments	Response at the other time-point of two consecutive assessments	Confirmed Response
sCR/CR/VGPR/PR/MR/SD	SD	SD
sCR/CR/VGPR/PR/MR	MR	MR
sCR/CR/VGPR/PR	PR	PR
sCR/CR/VGPR	VGPR	VGPR
sCR/CR	CR	CR
sCR	sCR	sCR

B. For PD, since for this study, no confirmation of PD is required, only one PD assessment is required. Any PD assessment will be confirmed by itself at the time of the PD's assessment.

C. If the subject has only one non-PD /non-NE assessment then the confirmed response is NE at the date of that assessment.

D. If all assessments were NE then the confirmed response is NE at the date for each assessment.

Step 2. Determine the best overall confirmed response in Step 1. If assessments at all visits are missing then the best confirmed response is NE.

Examples:

Example 1.

Step1.

Visit	Response	Confirmed response
1	PR	
2	SD	SD
3	SD	SD

Step 2.

The best overall confirmed response is SD

Example 2.

Step1.

Visit	Response	Confirmed response
1	VGPR	
2	NE	
3	NE	
4	PR	PR

Step 2.

The best overall confirmed response is PR

Example 3.

Step1.

Visit	Response	Confirmed response
1	sCR	
2	sCR	sCR
3	CR	CR
4	PR	PR

Step 2.

The best overall confirmed response is sCR

Example 4.

Step1.

Visit	Response	Confirmed response
1	sCR	
2	CR	CR
3	CR	CR
4	PR	PR

Step 2.

The best overall confirmed response is CR

Example 5.

Step1.

Visit	Response	Confirmed response
1	CR	
2	VGPR	VGPR

Step 2.

The best overall confirmed response is VGPR.

7.2.1.2. Summary Measure

Overall response rate (ORR) and the associated 2-sided 95% exact confidence intervals will be provided by dose level and study part. In addition, Clinical Benefit Rate (CBR), defined as the percentage of subjects with minimal response (≥ MR) will be summarized in the same way as ORR by dose level and study part. Unconfirmed response summaries may be provided for interim analyses. A list of investigator-assessed response at each visit will be listed.

7.2.1.3. Population of Interest

The secondary efficacy analyses will be based on the "All Treated" population, unless otherwise specified. Response data for multiple myeloma will be summarized by Study Part using the All Treated MM population and in subgroup: Prior anti-cancer therapy of interest as defined in Section 5.2.1.

7.2.2. Lymphoma

7.2.2.1. Endpoint / Variables

7.2.2.1.1. Overall Response Rate

For lymphoma patients, clinical activity for lymphomas will be calculated based on ORR defined as the percentage of subjects with confirmed CR or PR, as described in the Revised Response Criteria for Malignant Lymphoma (RRCML, Appendix 2 in the protocol) from the start of treatment until disease progression or the start of new anti-cancer therapy.

A summary of investigator-assessed best response with confirmation will be presented. Subjects with Not Evaluable or missing response will be treated as non-responders; and they will be included in the denominator when calculating the percentage. To be assigned a status of complete response or partial response, all responses must be confirmed by repeat assessments performed no less than four weeks after the criteria for CR or PR were met (RRCML, Appendix 2 in the protocol).

7.2.2.2. Summary Measure

Overall response rate and the associated 2-sided 95% exact confidence intervals will be provided. A list of investigator-assessed response at each visit will be listed.

7.2.2.3. Population of Interest

The secondary efficacy analyses will be based on the "All Treated" population, unless otherwise specified. Response data for lymphoma will be summarized using the Part 2 NHL population.

7.2.3. Strategy for Intercurrent (Post-Randomization) Events

Not applicable to this study.

7.2.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.3. Exploratory Efficacy Analyses

7.3.1. Multiple Myeloma

7.3.1.1. Endpoint / Variables

Time-to-event endpoint - Multiple Myeloma	
Progression-Free Survival (PFS)	defined as the time from first dose until the earliest date of confirmed disease progression (PD) per IMWG (2011), or death due to any cause.
Time to Progression (TTP)	defined as the time from first dose until the earliest date of PD per IMWG (2011), or death due to PD.
Duration of Response (DOR)	defined as the time from first documented evidence of confirmed PR or better until the time when disease progression (PD) is documented per IMWG (2011), or death due to PD among subjects who achieve a response (i.e. confirmed PR or better).
Time to Response (TTR)	defined as the time between the date of first dose and the first documented evidence of confirmed response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).
Time to Best Response (TTBR)	defined as the time between the date of first dose and the best confirmed response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).
Overall survival (OS)	defined as the time from the date of first dose until death from any cause.

In addition, monoclonal protein and serum free light chain lab test values will be plotted. Subgroup analysis for ORR will be performed

7.3.1.2. Summary Measure

7.3.1.2.1. Progression-Free Survival

PFS is defined as the interval of time between the date of first dose and the earlier of the date of first disease progression and the date of death due to any cause. Disease progression will be based on the assessments by the Investigator.

If there is no adequate baseline assessment, the subjects will be censored at their date of first dose. Subjects without any adequate post-baseline tumor assessments will be censored at the date of first dose.

Subjects who progressed or died after an extended period without adequate assessment will be censored at their date of last adequate assessment prior to progression or death even if subsequent information is available regarding progression or death. An adequate assessment is defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR or SD. The date of response at that assessment will be used for censoring. As the assessment schedule may change through the course of the protocol, specific rules for identifying extended loss to follow-up or extended time without an adequate assessment are provided in Section 16.5.4.

For subjects who receive subsequent anti-cancer therapy the following rules will apply:

- If the start date of the anti-cancer therapy is partial (i.e. either missing the day but has the month and year available or missing both day and month), the imputation rules described in Section 16.7.2.1 will be applied. No imputation will be made for completely missing dates.
- If anti-cancer therapy is started without documented disease progression or death OR is started prior to documented disease progression or death, then PFS will be censored at the date of the last adequate assessment that is no later than the date of initiation of anti-cancer therapy (i.e. if an assessment occurs on the same day as the start of new anti-cancer therapy the assessment will be used - as it will be assumed the assessment occurred prior to the administration of new anti-cancer therapy). The date of response at the last adequate assessment will be used as the censoring value.
- If a subject has only a baseline visit or does not have an adequate assessment that is no later than the date of initiation of anti-cancer therapy, PFS will be censored at the date of first dose.
- If a subject has neither progressed nor died nor started new anti-cancer therapy, then PFS will be censored at the date of the last adequate assessment defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR or SD. The date of response will be used as the censoring date.

A summary of the assignments for progression and censoring dates for PFS are specified in Table 5.

Table 5 Assignments for Progression and Censoring Dates for PFS Analysis

Situation	Date of Event (Progression/Death) or Censoring	Outcome Event (Progression/Death) Or Censored
No *(or inadequate)* baseline tumor assessments [1] and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
No post-baseline assessments and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
Progression documented between scheduled visits	Date of assessment of progression [1]	Event
No progression *(or death)*	Date of last 'adequate' assessment of response [2]	Censored
New anticancer treatment started *(prior to documented disease progression or death)* [3].	Date of last 'adequate' assessment of response [2] *(on or prior to starting anti-cancer therapy)*	Censored
Death before first PD assessment (or Death at baseline or prior to any adequate assessments)	Date of death	Event
Death between adequate assessment visits	Date of death	Event
Death or progression after an extended loss-to-follow-up time (two or more missed cycles + 7 day window) [4]	Date of last 'adequate' assessment of response [2] *(prior to missed assessments)*	Censored

1. **In part 1**, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein or b. Urine M-protein or c. Serum FLC assay or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit).
In part 2, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein ≥0.5 g/dL (≥5 g/L) or b. Urine M-protein ≥200 mg/24h or c. Serum FLC assay: Involved FLC level ≥5 mg/dL (≥50 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65) or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit and no later than the first dose date).
2. An adequate assessment is defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR, or SD.
3. If PD or death and New anti-cancer therapy occur on the same day assume the progression or death was documented first (e.g., outcome is progression or death and the date is the date of the assessment of progression or death). If anti-cancer therapy is started prior to any adequate assessments, censoring date should be the date of first dose.
4. Refer to Section 16.5.4 "Extended Loss to Follow-up or Extended Time without an Adequate Assessment".

PFS will be summarized using Kaplan-Meier curves. If there are a sufficient number of progressions or deaths, median PFS, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A figure and listing of PFS time will also be provided. Summary and figure of PFS will be based on

Part 2 MM sub-population and subgroup prior anti-cancer therapy of interest; listing of PFS will be based on All Treated MM population.

7.3.1.2.2. Time to Progression

TTP is defined as the interval of time between the date of first dose and the earlier of the date of first documented evidence of PD, or death due to PD, whichever occurs first.

A summary of the assignments for progression and censoring dates for TTP are specified in Table 6

Table 6 Assignments for Progression and Censoring Dates for TTP Analysis

Situation	Date of Event (Progression/Death) or Censoring	Outcome Event (progression/Death) Or Censored
No *(or inadequate)* baseline tumor assessments [1] and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
No post-baseline assessments and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
Progression documented at or between scheduled visits	Date of assessment of progression [1]	Event
No progression *(or death)*	Date of last 'adequate' assessment of response [2]	Censored
New anticancer treatment started *(prior to documented disease progression or death)* [3].	Date of last 'adequate' assessment of response [2] *(on or prior to starting anti-cancer therapy)*	Censored
Death from causes other than progression	Date of death	Censored
Death or progression after an extended loss-to-follow-up time (two or more missed cycles + 7 day window) [4]	Date of last 'adequate' assessment of response [2] *(prior to missed assessments)*	Censored

[1] **In part 1**, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein or b. Urine M-protein or c. Serum FLC assay or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit).
In part 2, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein ≥0.5 g/dL (≥5 g/L) or b. Urine M-protein ≥200 mg/24h or c. Serum FLC assay: Involved FLC level ≥5 mg/dL (≥50 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65) or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit and no later than the first dose date).
[2] An adequate assessment is defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR, or SD.
[3] If PD and New anti-cancer therapy occur on the same day assume the progression was documented first e.g., outcome is progression and the date is the date of the assessment of progression). If anti-cancer therapy is started prior to any adequate assessments, censoring date should be the date of first dose. Refer to Section 16.5.4 "Extended Loss to Follow-up or Extended Time without an Adequate Assessment".

TTP will be summarized using Kaplan-Meier curves. If there are a sufficient number of progressions or death due to PD, median TTP, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A figure and listing of TTP time will also be provided. Summary and figure of TTP will be based on Part 2 MM population; listing of TTP will be based on All Treated MM population.

7.3.1.2.3. Duration of Response

Duration of Response (DOR) is defined, for subjects with a confirmed response (PR or better) as the time between first documented evidence of confirmed response and disease progression or death due to PD, whichever occurs first.

- Duration of response is derived for patients with a confirmed PR or better only.
- Censoring rules will follow those of the TTP analysis.

DOR will be summarized using Kaplan-Meier curves. If there are a sufficient number of progressions or death due to PD among the responders, median DOR, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A figure and listing of DOR time will also be provided. Summary and figure of DOR will be based on Part 2 MM population and subgroup: prior anti-cancer therapy of interest; listing of DOR will be based on All Treated MM population.

7.3.1.2.4. Time to Response

Time to Response (TTR) is defined as the time from first dose to the first documented evidence of confirmed PR or better, among subjects who achieve a response (i.e., confirmed PR or better).

TTR will be summarized using Kaplan-Meier method. If data permits, median TTR, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A listing of TTR time will also be provided. Summary of TTR will be based on Part 2 MM population; listing of TTR will be based on All Treated MM population.

7.3.1.2.5. Time to Best Response

Time to Response (TTBR) is defined as the time from first dose to the best confirmed response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).

TTBR will be summarized using Kaplan-Meier method. If data permits, median TTBR, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A listing of TTBR time will also be provided. Summary of TTBR will be based on Part 2 MM population; listing of TTBR will be based on All Treated MM population.

7.3.1.2.6. Overall Survival

Overall survival (OS) is defined as the time from the date of first dose until death from any cause. For subjects who do not die, time of death will be censored at the date of last contact.

The protocol is amended to collect long-term survival data (i.e. up to 1 year after last subject completes or discontinues treatment). Subjects who are already completed the study will be contacted to request re-consent.

If all the patients (who were alive at the time of study completion) can be re-consented, OS landmark analysis may be performed at 9 and 12 months using Kaplan-Meier analysis as data permits. A listing of OS will also be provided. The OS landmark analysis will be based on Part 2 MM population; listing of OS will be based on All Treated MM population.

Otherwise, only descriptive analysis (number and % of deaths and lost to follow-up) will be performed.

7.3.1.3. Monoclonal Protein and Serum Free Light Chain

A waterfall plot showing the maximum percent reduction from baseline in Serum M-protein, or Urine M-protein, or difference between two types Serum FLC [Kappa light chain (Kappa LC) and Lambda light chain (Lambda LC)] for each subject will be produced using Part1 and Part 2 MM populations. Only the assessments from the start of treatment up to the start of new anti-cancer therapy will be considered. Only new systemic anti-cancer drugs taken are considered as anti-cancer therapy (radiotherapy and surgeries are not considered as systemic anti-cancer therapy for the purpose of this analysis). The maximum percent reduction will be plotted in the following hierarchical order:

[1] Plot Serum M-protein maximum percent reduction from baseline if data is available;

[2] If [1] is not feasible, plot Urine M-protein maximum percent reduction from baseline if data is available;

[3] If both [1] and [2] are not feasible, plot maximum percent reduction from baseline for difference between two types of Serum FLC if data is available;

Difference between two types Serum FLC

The percent change from baseline for difference between two types of Serum FLC is defined as:

(post-baseline difference-baseline difference) / baseline difference *100%

To calculate the difference, the “involved” and “non-involved” light chains must be determined at first based on the ratio of non-missing values for Serum Kappa LC protein and Serum Lambda LC protein at baseline.

Detailed algorithm is provided as below:

- If the baseline ratio of (Kappa LC/Lambda LC)>1.65, then Kappa LC is defined as involved FLC, and Lambda LC is defined as non-involved FLC. Then
    - Difference between involved and uninvolved = Kappa LC-Lambda LC
- If the baseline ratio of (kappa/lambda)<0.26, then Lambda light chain is defined as involved FLC, and Kappa light chain is defined as non-involved FLC
    - Difference between involved and uninvolved = Lambda LC-Kappa LC
- If the baseline ratio of (Kappa LC/Lambda LC) ≤ 1.65 and ≥ 0.26, then "involved" and "non-involved" FLC can not be determined (ratio is normal), and maximum percent reduction from baseline for difference between two types of Serum FLC won't be available.

In addition, a scatter plot of free soluble BCMA at pre-dose (cycle 1) and maximum percent change from baseline in Serum M-protein, Urine M-protein or difference between two types Serum FLC will be provided following the hierarchical order specified above.

7.3.1.4. Subgroup Analysis of ORR

A forest plot of ORR analysis will be provided for the following subgroups: Age, Sex, Ethnic Background, ISS Staging at Screening, Number of prior lines of therapy, Type of myeloma, Prior Daratumumab Treatment, Refractory to prior anti-cancer therapy, Cytogenetics Risk as defined in Section 5.2.1.

7.3.1.5. Population of Interest

The secondary efficacy analyses will be based on the "All Treated" population, unless otherwise specified (as in Section 4).

7.3.2. Strategy for Intercurrent (Post-Randomization) Events

Not applicable to this study.

7.3.3. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

8. SAFETY ANALYSES

The safety analyses will be based on the "All Treated" population, unless otherwise specified.

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 12: List of Data Displays.

An overview summary of AEs, including counts and percentages of subjects with any AE, AEs related to study treatment, AEs leading to permanent discontinuation of study treatment, AE leading to dose reductions, AEs leading to dose delays OR interruptions, SAEs, SAEs related to study treatment, fatal SAEs, and fatal SAEs related to study treatment will be produced.

A summary of non-serious AEs that occurred in strictly 5% of the subjects or above will be provided (no rounding for the percentage will be used in terms of 5% threshold, e.g., event with 4.9% incidence rate should not be included in this table). The summary will be displayed by SOC and PT.

The relationship between MedDRA SOC, PT, and Verbatim Text will be displayed.

Adverse events (AEs) will be graded according to the CTCAE, Version 4.0. Adverse events will be coded to the preferred term (PT) level using the Medical Dictionary for Regulatory Affairs (MedDRA dictionary).

A summary of number and percentage of subjects with any adverse events by maximum grade will be produced. AEs will be sorted by Preferred term (PT) in descending order of total incidence. The summary will use the following algorithms for counting the subject:

- **Preferred term row**: Subjects experiencing the same AE preferred term several times with different grades will only be counted once with the maximum grade.

- **Any event row**: Each subject with at least one adverse event will be counted only once at the maximum grade no matter how many events they have.

In addition, the frequency and percentage of AEs (all grades) will be summarized and displayed in two ways: 1) in descending order of total incidence by PT only and 2) in descending order of total incidence by System Organ Classes (SOC) and PT and Maximum Grade. In the SOC row, the number of subjects with multiple events under the same system organ class will be counted once.

A separate summary will be provided for study treatment-related AEs. A study treatment-related AE is defined as an AE for which the investigator classifies the relationship to study treatment as "Yes". A worst-case scenario approach will be taken to handle missing relatedness data, i.e. the summary table will include events with the relationship to study

treatment as 'Yes' or missing. The summary table will be displayed in descending order of total incidence by SOC and PT and Maximum Grade.

All AEs will be listed. Additionally, a listing of subject IDs for each individual AE will be produced.

A listing of adverse events recorded as dose-limiting toxicities will be provided. Additionally, a summary of the number of patients experiencing DLT's in each cohort will be provided.

The summary of adverse event by SOC and PT and maximum grade, and AE by PT will also be produced for the following subgroups:

Prior anti-cancer therapy of interest:

- With prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors
- Without prior Daratumumab Treatment
- Refractory to Both Immunomodulators and Proteasome Inhibitors

8.2. Adverse Events of Interest Analyses

There are no pre-defined Adverse Events of Special Interest in the protocol, as it was a first time in human (FTIH) trial. During the course of the study, the analyses of the following adverse events of interest were included upon the safety review team (SRT) requests.

- Corneal events
- Thrombocytopenia
- Neutropenia
- Hematologic Toxicity
- Infusion-related Reactions as collected in the eCRF

For Corneal events, Thrombocytopenia, Neutropenia Hematologic Toxicity, a comprehensive list of MedDRA terms based on clinical review will be used to identify each type of event. Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional adverse events of interest, therefore the list of terms to be used for each event of interest and the specific events of interest will be based on the SRT agreements in place at the time of reporting. The details of the planned displays are provided in Appendix 12: List of Data Displays.

Summaries of the number and percentage of subjects with these events will be provided for each type of events separately by preferred term and maximum grade. The time of

onset and duration of first occurrence of each type of events will be summarized using summary statistics mean, standard deviation, median, minimum value, and maximum. The number and percentage of subjects who have time of onset of first occurrence (1-21, 22-42, 43-63, >63 days) will be reported. The number and percentage of subjects who have duration of first occurrence (1-21, 22-42, >42 days) will be reported.

The summary of event characteristics will also be provided, including number of subjects with any event, number of events, number of subjects with any event that is serious, number of subjects with any event that is related to study treatment, number of occurrences (One, Two, Three or more), maximum grade and the action taken for the event. The percentage will be calculated in two ways, one with number of subjects with event as the denominator and the other with total number of subjects as the denominator. The worst-case approach will be applied at subject level for the maximum grade, i.e. a subject will only be counted once as the worst case from all the events experienced by the subject. For action taken to an event, subject will be counted once under each action, e.g. if a subject has an event leading to both study treatment discontinuation and dose reduction, the subject will be counted once under both actions.

8.3. Deaths and Serious Adverse Events

In the event that a subject has withdrawn consent, no data after the withdrawal of consent date from this subject including death is supposed to appear in the database, which should be part of the data cleaning process. All deaths will be summarised based on the number and percentage of subjects. This summary will classify subjects by time of death relative to the last dose of medication (>30 days or ≤30 days) and primary cause of death (disease under study, SAE related to study treatment, or other). A supportive listing will be generated to provide subject-specific details on subjects who died.

All SAEs will be tabulated based on the number and percentage of subjects who experienced the event. Separate summaries will also be provided for study treatment-related SAEs. The summary tables will be displayed in descending order of total incidence by SOC and PT.

A study treatment-related SAE is defined as an SAE for which the investigator classifies the relationship to study treatment as “Yes”. A worst-case scenario approach will be taken to handle missing data, i.e. the summary table will include events with the relationship to study treatment as ‘Yes’ or missing.

SAEs are included in the listing of all adverse events. Separate supportive listings with subject-level details will be generated for

- Fatal SAEs
- Non-Fatal SAEs.

AEs of maximum grade of 3 or higher will be summarized separately by SOC and PT.

8.4. Adverse Events Leading to Discontinuation of Study Treatment and/or Withdrawal from the Study and Other Significant Adverse Events

The following categories of AEs will be summarized separately in descending order of total incidence by SOC and PT and separate supportive listings will be generated with subject level details for those subjects:

- AEs Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study
- AEs Leading to Discontinuation of Study Treatment
- AEs Leading to Dose Interruptions or Delays
- AEs Leadings to Dose Reductions

8.5. Pregnancies

While pregnancy itself is not considered to be an AE or SAE, any pregnancy complication or elective termination of a pregnancy for medical reasons will be recorded as an AE or SAE as described in the protocol. If subjects and subjects' partner become pregnant while on the study, the information will be included in the narratives and no separate table or listing will be produced.

8.6. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 12: List of Data Displays.

Summary of change from baseline by scheduled visits using mean, median, standard deviation, minimum and maximum will be provided.

Summaries of worst case grade increase from baseline grade will be provided for all the lab tests that are gradable by CTCAE v4.0. These summaries will display the number and percentage of subjects with a maximum post-baseline grade increasing from their baseline grade. Any increase in grade from baseline will be summarized along with any increase to a maximum grade of 3 and any increase to a maximum grade of 4. Missing baseline grade will be assumed as grade 0. For laboratory tests that are graded for both low and high values, summaries will be done separately and labelled by direction, e.g., sodium will be summarized as hyponatremia and hypernatremia.

For lab tests that are not gradable by CTCAE v4.0, summaries of worst case changes from baseline with respect to normal range will be generated. Decreases to low, changes to normal or no changes from baseline, and increases to high will be summarized for the worst case post-baseline. If a subject has a decrease to low and an increase to high during the same time interval, then the subject is counted in both the "Decrease to Low" categories and the "Increase to High" categories.

Separate summary tables for hematology, and chemistry laboratory tests will be produced. Liver function laboratory tests will be included with chemical chemistry.

A supporting listing of laboratory data for subjects with abnormalities of potential clinical concern will be provided. A separate listing of laboratory data with character values will also be provided. For lab test values that can be graded, values of grade 1 or above are defined as values of potential clinical concern. For lab test values that can not be graded, values out of the normal range are defined as values of potential clinical concern.

Detailed derivation of baseline assessment is specified in Section 5.2.

Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of subjects with non-missing value at each particular visit.

8.6.1. Analyses of Liver Function Tests

Summaries of hepatobiliary laboratory events including possible Hy's law cases will be provided in addition to what has been described above.

A plot of maximum total bilirubin versus maximum ALT will be generated. Plots of maximum AST versus maximum LDH and maximum AST versus maximum Creatinine Kinase will be generated.

A Summary of Liver Monitoring/Stopping Event Reporting will be provided. The medical conditions data for subjects with liver stopping events will be listed. The substance use data for subjects with liver stopping events will be listed.

8.7. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs and vital signs will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 12: List of Data Displays.

Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of subjects with non-missing value at each particular visit.

Performance Status

ECOG performance status will be summarized at baseline and each post-baseline scheduled visit. Summaries will use frequency and percentage of subjects at each planned assessment time. A summary of change from baseline by scheduled visits will be performed, as well as the worst case post-baseline and the best case post-baseline changes during the study (improved, no change, deteriorated).

A supporting listing will also be provided.

ECG

A summary of the number and percentage of subjects who had normal and abnormal (clinically significant and not clinically significant) ECG findings will be displayed by scheduled visits as well as for the worst case post-baseline.

The QTc values based on Fridericia formula will be rounded to the integer and the values will be categorized into the following ranges: Grade 0 (<450), Grade 1 (450-480), Grade 2 (481-500), and Grade 3 (≥501). Summaries of grade increase will be provided. These summaries will display the number and percentage of subjects with any grade increase, increase to grade 2 and increase to grade 3 in the worst case post-baseline only.

The changes in QTc values will be categorized into the clinical concern ranges which are specific to changes in QTc: 31-60 and >60 msec. A summary of change in QTc value will display the number and percentage of subjects with a change within each range in the worst case post-baseline only. Subjects with missing baseline values will be excluded from this summary.

A listing of QTc values of potential clinical importance will be provided

The summaries and listing of QTc will use the collected values based on Fridericia formula.

A figure plotting the baseline QTc and the worst-case post-baseline values will be produced. The figure will have reference lines at 480 and 500 msec for both the ordinate and the abscissa axes. There will be diagonal reference lines at equality (i.e. a 45 degree line), at equality plus 30 msec, and at equality plus 60 msec.

LVEF

Absolute change from baseline in LVEF will be summarized in the worst case post-baseline only. Only the post-baseline assessments that used the same method (ECHO or MUGA) as the baseline assessments will be used to derive the change from baseline. The change from baseline will be categorized as follows:

- No change or any increase
- Any decrease
- >0-<10 decrease
- 10-19 decrease
- >=20 decrease
- >=10 decrease and >= LLN
- >=10 decrease and < LLN
- >=20 decrease and >= LLN
- >=20 decrease and < LLN

LVEF results will also be listed with subject level details including absolute change from baseline.

Ocular Exams

For best corrected visual acuity (BCVA), if data is available, summary statistics for the logMAR score at baseline, end of study treatment and last follow-up exam will be displayed separately by eye using mean, median, standard deviation, minimum and maximum. Changes of logMAR score from baseline to end of treatment visit, last follow-up exam and maximum (worst) change from baseline will be summarized based on the following categories: no change/improved vision: a change from baseline <0.12; a possible worsened vision: a change from baseline >=0.12 to <0.3; a definite worsened vision: a change from baseline >=0.3. Subjects with character values of visual acuity exam results will not be included in this summary.

Number and percentage of subjects who experienced corneal clinical signs will be summarized. Among subjects who experienced corneal clinical signs, number and percentage of subjects with/without reported corneal events will be provided. If data is available, the summary will also be provided at end of study treatment visit and last follow-up exam. Visual acuity/ abnormal corneal exam results (eye level) at each visit, and incidence of corneal clinical signs and reported corneal events (subject level) during the study will be listed. The findings considered 'corneal clinical signs' were identified from the pre-defined list of choices in the eCRF.

Listing of abnormal conjunctival exam results, listing of abnormal slit lamp Lens and slit lamp anterior chamber exam results and listing of indirect fundoscopic exam and intra-ocular pressure results will be provided separately.

Constitutional Symptoms (or B-Symptoms)

A summary of the number and percentage of subjects with any constitutional symptom /B-symptom will be displayed by scheduled visits. A summary of improvement, i.e. number of subjects who had no symptoms at each post-baseline scheduled visit and had at least one at baseline, will also be provided.

A supporting listing will be provided.

Organ Examination

The number and percentage of subjects with normal or enlarged organs based on liver and spleen examination by palpation/CT scan will be summarized by scheduled visits.

A supporting listing will also be provided.

9. PHARMACOKINETIC ANALYSES

The pharmacokinetic (PK) analyses will be based on the Pharmacokinetic population, unless otherwise specified.

Pharmacokinetic data from Part 1 of the study will be analyzed using standard non-compartmental methods, and combined data from Part 1 and Part 2 of the study will be analyzed in a population approach using nonlinear mixed effects modeling. Full details are presented in Appendix 12: List of Data Displays.

9.1. Endpoint / Variables

9.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 16.5.3 Reporting Standards for Pharmacokinetic)

9.1.2. Derived Pharmacokinetic Parameters

9.1.2.1. Non-compartmental Analysis

- The pharmacokinetic parameters for Part 1 will be calculated by standard non-compartmental analysis according to current working practices and using Phoenix WinNonlin, version 6.3 or later.
- All calculations of non-compartmental parameters will be based on actual sampling times.
- Pharmacokinetic parameters described in Table 7 will be determined from the Cycle 1 plasma concentration-time data in Part 1 of the study separately for each analyte, as data permit.

Table 7 Derived Pharmacokinetic Parameters

Parameter	Parameter Description
AUC(0-t)	Area under the concentration-time curve from time zero to the time of the last quantifiable concentration (C(t)) will be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
AUC(0-τ)	Area under the concentration-time curve during the dosing interval
AUC(0-∞)	Area under the concentration-time curve extrapolated to infinity will be calculated as: **AUC = AUC(0-t) + C(t) / lambda_z**
%AUCex	The percentage of AUC (0-∞) obtained by extrapolation (%AUCex) will be calculated as: **[AUC(0-inf) – AUC(0-t)] / AUC(0-inf) x 100**
Cmax	Maximum observed concentration, determined directly from the concentration-time data for each cycle. For cys-mcMMAF, Cmax will not be derived when only predose and EOI samples were collected.
tmax	Time to reach Cmax, determined directly from the concentration-time data for each cycle
Cτ,	Trough concentration prior to the next dose for each cycle

Parameter	Parameter Description
Ctrough	
t½	Apparent terminal half-life will be calculated as: **t½ = ln2 / lambda_z**
tlast	Time of last observed quantifiable concentration
CL	Clearance
Vss	Volume of distribution at steady state
λz, lambda_z	Terminal phase rate constant
Ae(0-t)	Urinary recovery of cys-mcMMAF within t hours after start of infusion will be calculated as: **Urine cys-mcMMAF concentration x 24-h urine volume** t = time from start of infusion to end of urine collection period (≤24 h)
Fe(0-t)	Fraction of cys-mcMMAF dose excreted within t hours after start of infusion will be calculated as: **Ae(0-t) / cys-mcMMAF dose**

9.2. Population of Interest

The primary pharmacokinetic analyses will be based on the "Pharmacokinetic" population, unless otherwise specified.

9.3. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK Data Standards and statistical principles. Unless otherwise specified, endpoints / variables defined in Section 9.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

9.3.1. Statistical Methodology Specification

The following pharmacokinetic statistical analyses will only be performed if sufficient data are available.

9.3.1.1. Exploratory assessment of dose proportionality:

The PK-dose relationship initially will be examined graphically by plotting AUC(0-∞), AUC(0-τ), and Cmax as a function of the dose levels administered; AUC(0-t) may be used for cys-mcMMAF. Plots of PK parameters versus dose will be produced, with two plots for each PK parameter. The first will be on a linear scale, and the second will use the logarithmic scale for both axes.

In practice, at least three dose levels are required to assess dose proportionality. Hence, if more than two dose cohorts are required to reach MTD (or recommended dose based on available safety, PK, and response data), dose proportionality of GSK2857916, unbound

antibody, total antibody, and cys-mcMMAF following administration in Cycle 1 will be evaluated, if data permit, using the power model.

Dose Proportionality Analysis
Endpoint(s)
• Log_e-transformed single dose PK parameters listed below for each analyte will be investigated for Cycle 1 Day 1 in Part 1 if data permit. ○ AUC(0-∞) or AUC(0-τ), Cmax, Ctrough for GSK2857916 (ADC), total antibody, unbound antibody ○ AUC(0-t), Cmax, Ctrough for cys-mcMMAF
Model Specification
• Endpoints for each analyte will be separately analyzed using appropriate methods for GSK2857916 doses. • Power Model • Dose proportionality of PK parameters defined above in Endpoints will be assessed following single dose administration of GSK2857916 between 0.03 mg/kg and 4.6 mg/kg, using the power model as described below: $y = \alpha * dose^{\beta}$ where y denotes the PK parameter being analyzed and α depends on subject. • Dose proportionality implies that β=1 and will be assessed by estimating β along with its 90% confidence interval. The exponent, β, in the power model will be estimated by regressing the log_e-transformed PK parameter on log_e-transformed dose. • The power model will be fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. A power model with only subject as a random effect power model will be fitted. The mean slope will be estimated from the power model and the corresponding 90% confidence interval calculated. Model specification (e.g. random statement, variance structure) could be explored for achieving convergence. • If the 90% confidence interval for the slope regressing dose against exposure is contained within the interval (0.8, 1.25), the exposure will be considered to be dose proportional.
Model Checking & Diagnostics
• Refer to Section 9.3.2.
Model Results Presentation
• Power Model • The mean slope and the corresponding 90% confidence interval for each parameter will be produced in tabular format. • Comparative plots of individual PK parameters will be generated by treatment on linear and semi-logarithmic scales. • Supportive SAS output from statistical analysis will be generated.

9.3.1.2. Assessment of Accumulation Ratio:

To assess the extent of accumulation following GSK2857916 repeat dosing, the observed accumulation ratio (Ro) for GSK2857916, total antibody, unbound antibody, and cys-mcMMAF will be determined as ratio of concentration at end of infusion (CEOI) and

Ctrough at steady-state to CEOI and Ctrough after the first dose, respectively, adjusted for any change in GSK2857916 dose.

For the purpose of accumulation ratio analysis, CEOI at each cycle will be used. Preliminary analysis found that cys-mcMMAF Cmax did not occur at or near EOI in most cases; therefore, the cys-mcMMAF accumulation ratio based on CEOI is not based on Cmax.

Accumulation ration will only be derived and analyses will only be performed for subjects who received at least 80% of the planned dose at cycle 1.Ro(CEOI) = CEOI CxD1/CEOI C1D1;
x = 3, 5;

Ro(Ctrough) = Ctrough CxD1/Ctrough C1D1;
x = 4;

Only one accumulation ratio for CEOI and Ctrough will be derived for each subject according to the rules below:

Preliminary pharmacokinetic data indicate that the pharmacokinetics for the third consecutive dose given at the planned interval will be at steady state. Therefore, based on the study design, subjects who meet one of the following criteria will be at steady state

When assessing accumulation ratio based on CEOI:

- Subjects who receive the same dose without delay or change for Cycles 1, 2, and 3 (i.e., with dosing delays of ≤3 days). In this case, Cycle 3 represents steady state. Accumulation ratios are calculated as Cycle 3/Cycle 1.
- Subjects who have a dose reduction or two by Cycle 3, but then dose is maintained at the same level and interval through Cycle 5. Cycle 5 represents steady-state pharmacokinetics, but dose adjustment is needed. Dose adjustment: multiply CEOI values by the ratio (starting dose level/Cycle 3-5 dose level). Accumulation ratio = adjusted Cycle 5/Cycle 1.

When assessing accumulation ratio based on Ctrough:

- Subjects who receive the same dose without delay or change to Cycle 4 (i.e., with dosing delays of ≤3 days). Accumulation ratio = Cycle 4 Ctrough/Cycle 1 Ctrough.
- Subjects who have a dose reduction by Cycle 2, but then dose is maintained at the same level and interval through Cycle 4. Cycle 4 represents steady-state pharmacokinetics, but dose adjustment is needed. Dose adjustment: multiply Ctrough values by the ratio (starting dose level/Cycle 2-4 dose level). Accumulation ratio = adjusted Cycle 4 Ctrough/Cycle 1 Ctrough.

Accumulation ratios of CEOI and Ctrough will be summarised using descriptive statistics by planned initial dose level, graphically presented (where appropriate) and listed.

9.3.1.3. Assessment of Analyte Ratios:

For the purpose of analyte ratio analysis, CEOI at each cycle will be used, and Ctrough is defined as the concentration immediately prior to the next cycle dose. Preliminary analysis found that cys-mcMMAF Cmax did not occur at or near EOI in most cases; therefore, the cys-mcMMAF analyte ratio based on EOI is not based on Cmax.

Analyte Ratios of CEOI and Ctrough are defined as the ratio of CEOI and Ctrough for analytes: unbound antibody, total antibody, and cys-mcMMAF to CEOI and Ctrough for analyte ADC at each cycle:

Ratio of analytes at each cycle versus ADC at Cycle X:

$$\text{Ra (CEOI)} = \frac{\text{CEOI (unbound antibody, total antibody, cys-mcMMAF) Cycle X}}{\text{CEOI (ADC) Cycle X}}$$

X = 1, 2, 3, 5;

$$\text{Ra (Ctrough)} = \frac{\text{Ctrough (unbound antibody, total antibody, cys-mcMMAF) Cycle X}}{\text{Ctrough (ADC) Cycle X}}$$

X = 1, 2, 4;

To fit into the analysis model, the units of the analytes need to be converted from ng/mL or pg/mL to nM as below.

	Original unit	Operation	Converted unit
ADC	ng/mL	/152.1	nM
Total Antibody	ng/mL	/152.1	nM
Unbound Antibody	ng/mL	/152.1	nM
cys-mcMMAF	pg/mL	/1045	nM

Analyte ratios of CEOI and Ctrough for each will be summarised using descriptive statistics by planned initial dose level and cycle, graphically presented (where appropriate) and listed.

9.3.2. Model Checking & Diagnostics

Endpoint(s)	• For Dose Proportionality Analysis (Part 1), Log_e-transformed single dose PK parameters as defined in Section 9.3.1.1, as applicable.
Analysis	• Mixed Effects

Assumptions:

- Model assumptions will be applied, but appropriate adjustments may be made based on the data.
- The Kenward and Roger method for approximating the denominator degrees of freedom and correcting for bias in the estimated variance-covariance of the fixed effects will be used.
- An unstructured covariance structure for the G matrix will be used by specifying 'type=UN' on the RANDOM line.
  - In the event that this model fails to converge, alternative correlation structures may be considered such as VC or CS.
  - Akaike's Information Criteria (AIC) will be used to assist with the selection of covariance structure.
- Distributional assumptions underlying the model used for analysis will be examined by obtaining a normal probability plot of the residuals and a plot of the residuals versus the fitted values (i.e., checking the normality assumption and constant variance assumption of the model respectively) to gain confidence that the model assumptions are reasonable.
- If there are any departures from the distributional assumptions, alternative models will be explored using appropriate transformed data.

10. POPULATION PHARMACOKINETIC (POPPK) ANALYSES

The primary goal of this analysis is to characterize the population pharmacokinetics of GSK2857916 and associated analytes after intravenous of GSK2857916 in participants with multiple myeloma, data permitting. The influence of subject demographics, baseline characteristics including disease activity, and other covariates on the pharmacokinetics of GSK2857916 will be investigated. The individual subject pharmacokinetic parameters will be estimated and documented for the purposes of any subsequent exposure-response (PK/PD) analyses. This analysis will be performed by CPMS and reported separately.

A summary of the planned population pharmacokinetic analyses is outlined below:

- Plasma concentration-time data for GSK2857916 ADC will be subjected to nonlinear mixed effects modelling using the program NONMEM to develop a population pharmacokinetic model. A similar approach may be used on the data from two analytes (ADC and cys-mcMMAF) and three analytes (ADC, total antibody, and cys-mcMMAF) together.
- Individual *post hoc* estimated pharmacokinetic parameters will be summarized descriptively.
- To support this analysis, a population PK dataset will be generated. The details for the dataset specifications are provided in Appendix 9: Population Pharmacokinetic (PopPK) Analyses.

Detailed population PK methodology is presented in Appendix 9: Population Pharmacokinetic (PopPK) Analyses.

11. PHARMACODYNAMIC (AND / OR BIOMARKER) ANALYSES

The pharmacodynamic analyses will be documented in a separate RAP.

12. PHARMACOKINETIC / PHARMACODYNAMIC ANALYSES

12.1. Exposure-Response for Efficacy and Corneal Events

The primary goal of this analysis is to characterize the pharmacokinetic/pharmacodynamic relationships for GSK2857916 administered IV in subjects with multiple myeloma for efficacy and corneal events, data permitting. In these analyses, drug plasma concentration (or pharmacokinetic parameter) data and pharmacodynamic data will be subjected to logistic regression and time-to-event analysis, as appropriate, using suitable software. The influence of subject demographics and baseline characteristics, including disease activity, in this population may be investigated. Detailed PK/PD methodology is provided in Appendix 10: Pharmacokinetic / Pharmacodynamic Analyses. This analysis will be performed by CPMS and reported separately.

12.2. Concentration-QTc Analyses

For each ECG assessment, the individual subject's QTcF change from baseline will be calculated and will be merged with time-matched PK concentration values for the timepoints at which they are available. QTcF change from baseline (y-axis) will be plotted against the PK concentration data (x-axis) separately for each analyte (ADC, unbound mAb, total mAb, and cys-mc-MMAF). If appropriate, linear regression analyses may be performed for each analyte-ΔQTcF plot.

13. HEALTH OUTCOMES ANALYSES

Symptom impact and HRQoL will be assessed using the e-Diary. The Pain (average and worst) and Fatigue (worst) items will be scored as individual items. Baseline will be calculated for each item as the mean of all of the assessments captured in the period prior to Cycle 1 Day 1 (treatment start date) (patients can only start the diary 2 to 4 days prior to Cycle 1 Day 1). There will be no minimum number of data points required to calculate a baseline, if only one day has been completed in this time period then this will be used as Baseline value.

Scores will be created for each pain (bone pain worst, bone pain average) and fatigue item (worst) during the treatment cycle. The mean for each item will be calculated from the available data for assessments on Day 1 through to Day 8 in each cycle (for a score to be calculated, at least 4 of the 8 days must be completed, otherwise data to be set to missing). For the assessment at Day 15 the stand-alone value will be the score for that item for that day. If not completed, then data for Day 15 is set to missing. Change from baseline for all pain and fatigue items will be assessed at each cycle. Change will be calculated for both time points (Day 1-Day 8 average and Day 15).

Visual Functioning Questionnaires (NEI VFQ-25 and OSDI): Data will be collected from end of treatment (EOT) visit as baseline. Additional data will be collected in follow-up visits on a monthly basis for subjects with ongoing corneal events or signs at EOT for 1 year or until resolution, whichever occurs first. These data will not be collected for subjects who already completed the treatment. Due to limited number of on-treatment subjects at the time of protocol amendment, only individual subject data will be listed. Data for both measures will be scored as outlined in the User Manuals.

For the NEI VFQ-25 data will be presented for the overall composite score and the 11 vison-targeted sub-scores: global vision rating, difficulty with near vision activities; difficulty with distance vision activities; limitations in social functioning due to vision; role limitations due to vision; dependency on others due to vision; mental health symptoms due to vision; driving difficulties; limitations with peripheral vision, limitations with color vision; and corneal pain. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Sub-scales with at least one item answered can be used to generate a sub-scale score. Hence scores represent the average for all items in the sub-scale that the respondent answered. Only individual subject data will be listed.

For the OSDI, the total score will be calculated as well as scores for the subscales (ocular symptom, visual related function and environmental triggers). The total OSDI score = ([sum of scores for all questions answered × 100]/[total number of questions answered × 4]). Subscale scores are computed similarly with only the questions from each subscale used to generate its own score. Only individual subject data will be listed.

14. ANTI-DRUG ANTIBODY ANALYSES

For each subject, the results and titers of anti-GSK2857916 binding antibodies, and also ADC and total antibody concentration will be listed for each assessment time point. The frequency and percentage of subjects with positive and negative results will be summarized for each assessment time and overall for each subject by dose cohort. The conclusive results will be based on the total antibody concentration.

15. REFERENCES

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16. APPENDICES

16.1. Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population

This study does not have per protocol population.

16.2. Appendix 2: Schedule of Activities

16.2.1. Protocol Defined Schedule of Events

Please see Section 7.1 of Protocol (Version: GSK Document Number 2012N155299_05). Weekly Dosing Schedule (Dose Escalation) for Multiple Myeloma and Dose Expansion Weekly Dosing Schedule for Multiple Myeloma were not explored in this study.

Weekly dosing schedule was not explored.

16.2.2. Dose Escalation

16.2.2.1. Every 3 Weeks Dosing Schedule for Multiple Myeloma

Time and Events Table for Full Study (Cycle = 21 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X				X	At the start of each cycle	X	
Ocular Exam	X[3]					X[4]	At the start of each cycle[4]	X[4]	
ECOG Performance Status	X					X	At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]		X	X	X[5]	At the start of each cycle[5]	X	
Weight and Height	X	Weight only				Weight only	Weight only - At the start of each cycle	Weight only	
Hematology	X	X[6]		X	X	X	At the start of each cycle	X	
Clinical chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]				X	At the start of each cycle	X	
INR, PTT	X	X[6]		X	X	X	At the start of each cycle		
HBV/HCV tests	X								
CK-MB, Troponin	X[7]			X[7]		X[7]	At the start of each cycle[7]	X[7]	
BNP	X[8]								
UPEP and urine Immunofixation	X					X	At the start of each cycle		
SPEP and serum Immunofixation, Serum M-protein Calculation	X					X	At the start of each cycle		
Kappa, lambda free LC, FLC ratio	X					X	At the start of each cycle		
24 hr urine protein and albumin	X					X	At the start of each cycle		

Time and Events Table for Full Study (Cycle = 21 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
IgG, IgM, IgA	X					X	At the start of each cycle		
CRP, beta2 microglobulin	X					X	At the start of each cycle		
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]		X[11]	X[11]	X[11]	At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	
Extramedullary plasmacytoma imaging	X[13]						At the start of cycles 5[13], 9[13], 13[13]	X[13]	
BM Aspirate (see below for each test required within procedure)**:**									
Disease assessment	X[14]						At the time of Complete Response		
BCMA assessment and PD (flow)	X[15]			X[15]					
FISH testing	X[16]								
BM biopsy for disease assessment and BCMA expression (IHC)	X[17]						At the time of CR (disease assessment only)		
Serum (soluble BCMA)		X[18]	X[18]	X[18]	X[18]	X[18]	Predose at the start of each cycle	X[18]	
Serum (cytokines/chemokines)		X[19]	X			X[19]	At predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)	X					X[20]	At the start of cycles 3[20], 6[20], 9[20], 12[20] and 16[20]	X	
Plasma-cfDNA	X							X	
Peripheral blood (flow for TBNK)	X[15]					X[15]	At the start of each cycle[15]	X[15]	
Serial Pharmacokinetics (blood)		X[21]	X[21]	X[21]	X[21]	X[21]	C3D1 only[21]	X[22]	
Urine PK	X[23]					X[23]	Day 1 of cycles 4[23], 7[23], 10[23], 13[23], 16[23]		
Premedication if needed		X				X	At the start of each cycle		
GSK2857916 administration		X[24]				X[24]	X[24]		
Steroid eye drops		X[25]				X[25]	X[25]		
Adverse Events		Continuous							

Time and Events Table for Full Study (Cycle = 21 days)									
Study Assessments[1]	**Screen**[2]	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Concomitant Medications	X	Continuous							
Survival Status									X[26]
Subsequent Treatment									X[26]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be ± 3 days of scheduled occurrence unless otherwise specified.
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes (±5 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. The Sentinel Subject must be observed for at least 24 hours post EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local lab (troponin I or T) and a central lab (troponin I). CK-MB at the local lab or if not possible by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine;
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. On dosing days, ECG to be performed in triplicate at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 21).** At screening, on interim visits (C1D8 and C1D15) and End of Study obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 5 days before dosing. All ECHOs to be done locally and sent to GSK for central imaging storage.
13. May be performed up to 21 days prior to C1D1 as screening value. Needs to be performed by the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
14. Samples from within 14 days prior to first dose are acceptable.
15. Sample(s) collected for analysis by central lab. The same sample will be used for BCMA (flow) and PD during Screening. On D8 only postdose PD assessment will be performed

16. FISH testing at least for: t(4;14), t(14;16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
17. Archival tissue from up to 60 days prior to study is acceptable
18. A single sample for sBCMA will be collected at C1D8, C1D15 and at the End of Study visit. sBCMA samples will also be collected on C1D1 at predose (within 30 minutes prior to SOI), at EOI (±5 minutes) and on C1D2 24h post SOI. On C2D1 sBCMA will be collected pre-dose (within 30 minutes prior to SOI) and at the EOI (±5 minutes)
19. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction)
20. All ADA samples will be collected prior to each infusion
21. PK samples to be taken (in all subjects) for both GSK2857916 and cys-mcMMAF measurement: C1D1 at pre-dose (within 30 minutes prior to SOI), 0.5 h after the start of the infusion (SOI) (±5 min), at the end of infusion (EOI) just before EOI), 1 h after EOI, 3 h after EOI (±5 min), 8 h after EOI (±15 min), 24h after EOI (±1h) (Day 2); C1D8 1 sample; C1D15 1 sample; C2D1, at pre-dose (within 30 minutes prior to SOI) and at the EOI (just before EOI); C3D1 at pre-dose (within 30 minutes prior to SOI) and at the EOI (just before EOI).
22. Collect 1 PK sample at each subject's final visit.
23. Pre-specified amounts of urine will be collected for PK analysis from the 24 hour urine collection at Screening, C2D1, C4D1, C7D1, C10D1, C13D1, and C16D1. Refer to Section 7.4.2 of the protocol for details.
24. Study drug administration ±3 day window only
25. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
26. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.2.2. Weekly Dosing Schedule (Dose Escalation) for Multiple Myeloma

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X				X	At the start of each cycle	X	
Ocular Exam	X[3]					X[4]	At the start of each cycle[4]	X[4]	
ECOG Performance Status	X					X	At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]		X	X	X[5]	At the start of each cycle[5]	X	
Weight and Height	X	Weight only				Weight only	Weight only - At the start of each cycle	Weight only	
Hematology	X	X[6]		X	X	X	At the start of each cycle	X	
Clinical Chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]				X	At the start of each cycle	X	
INR, PTT	X	X[6]		X	X	X	At the start of each cycle		
HBV/HCV tests	X								
CK-MB , Troponin	X[7]			X[7]		X[7]	At the start of each cycle[7]	X[7]	
BNP	X[8]								
UPEP and urine Immunofixation	X					X	At the start of each cycle		
SPEP and serum Immunofixation and Serum-M protein Calculation	X					X	At the start of each cycle		
Kappa, lambda free LC, FLC ratio	X					X	At the start of each cycle		
24 hr urine protein and albumin	X					X	At the start of each cycle		
IgG, IgM, IgA	X					X	At the start of each cycle		
CRP, beta2 microglobulin	X			X		X	At the start of each cycle		

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]		X[11]	X[11]	X[11]	At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	
Extramedullary Plasmacytoma Imaging	X[13]						At the start of cycles 5[13], 9[13], 13[13]	X[13]	
BM Aspirate (see below for each test required within procedure)**:**									
Disease assessment	X[14]						At the time of Complete Response		
BCMA assessment and PD (flow)	X[15]			X[15, 17]					
FISH testing	X[16]								
BM biopsy for disease assessment	X[18]						At the time of Complete Response (disease assessment only)		
Serum (soluble BCMA)		X[19]	X[19]	X[19]	X[19]	X[19]	Predose at the start of each cycle	X	
Serum (cytokines/chemokines)		X[20]	X	X[20]	X[20]	X[20]	At predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)		X[21]			X[21]	X[21]	At the start of cycles 3[21], 6[21], 9[21], 12[21] and 16[21]	X	
Plasma-cfDNA		X						X	
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[15]		X[15]		X[15]	At the start of each cycle[15]	X[15]	
Serial Pharmacokinetics (blood)		X[22]	X[22]	X[22]	X[22]	X[22]	C3D1 only[22]	X[23]	
Urine PK	X[24]					X[24]	Day 1 of cycles 4[24], 7[24], 10[24], 13[24], 16[24]		
Premedication if needed		X		X	X	X	Each dosing week		
GSK2857916 administration		X[25]		X[25]	X[25]	X[25]	Each dosing week[25]		
Steroid eye drops		X[26]		X[26]	X[26]	X[26]	Each dosing week[26]		
Adverse Events		Continuous							

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Concomitant Medications	X	Continuous							
Survival Status									X[27]
Subsequent Treatment									X[27]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified.
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, dilated fundoscopic examination may be performed within 21 days prior to first dose
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes (±5 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign time points align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hours prior to first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab. CK-MB at the local lab or if not available by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine.
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. On dosing days, ECG to be performed in triplicate at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn** (PK sample should be taken at the exact nominal time; refer to footnote 22). At screening and at End of Study, obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to fi**rst dose;** All ECHOs indicated on dosing days may be performed up to 5 days before dosing**. ECHOs to be done locally and sent to GSK for central imaging storage.**
13. **May be performed up to 21 days prior to** C1D1 as screening value. Needs to be performed by the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
14. Samples from within 14 days prior to first dose are acceptable.
15. Sample(s) collected for analysis by central lab. The same sample collected on Day 1 of cycle 1 prior to dosing will be used for BCMA (flow) and PD u.
16. FISH testing at least for t(4;14), t(14/16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
17. Collect sample prior to dosing.

18. Archival tissue from up to 60 days prior to study is acceptable.
19. A single sample for sBCMA will be collected at C1D8 predose, and at the End of Study visit. sBCMA samples will also be collected on C1D1 at predose (within 30 minutes prior to SOI), at EOI (±5 minutes) and on C1D2 24h post SOI. On C1D15 and C2D1 collect at predose (within 30 minutes prior to SOI) and EOI (±5 minutes)
20. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction
21. All ADA samples will be collected prior to each infusion
22. PK samples to be taken (in all subjects) for both GSK2857916 and cys-mcMMAF measurement: C1D1 at predose (within 30 minutes prior to SOI), 0.5 h after the start of the infusion, at EOI (just before EOI), 1 h after EOI (±5 min), 3 h after EOI (±5 min), 8 h after EOI (± 15 min), and 24h after EOI (±1 h) (Day 2); C1D8 at predose (within 30 minutes prior to SOI), and at EOI (just before EOI); C1D15 at predose (within 30 minutes prior to SOI) and at EOI (just before EOI); C2D1 at predose (within 30 minutes prior to SOI), at EOI (just before EOI); C3D1 at predose (within 30 minutes prior to SOI) and at EOI (just before EOI).
23. Collect 1 PK sample at each subject's final visit.
24. Pre-specified amounts of urine will be collected for PK analysis from the 24 hour urine collection at Screening, C2D1, C4D1, C7D1, C10D1, C13D1, and C16D1. Refer to Section 7.4.2 of the protocol for details.
25. Study drug administration ±1 day window only.
26. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
27. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.

Abbreviations:

ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.3. Dose Expansion

16.2.3.1. Every 3 Weeks Dosing Schedule for Multiple Myeloma

	Time and Events Table for Full Study (Cycle = 21 days)								
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment[34]**	**Monthly Follow up[35]**	
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X	At the start of each cycle	X		
Ocular Exam	X[3]				X[4]	At the start of each cycle[4]	X[4]	X[35]	
ECOG Performance Status	X				X	At the start of each cycle	X		
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X	X	X[5]	At the start of each cycle[5]	X		
Weight and Height	X	Weight only			Weight only	Weight only - At the start of each cycle	Weight only		
Hematology	X	X[6]	X	X	X	At the start of each cycle	X		
Clinical chemistry	X	X[6]	X	X	X	At the start of each cycle	X		
Urine Dipstick	X	X[6]			X	At the start of each cycle	X		
INR, PTT	X	X[6]	X	X	X	At the start of each cycle			
HBV/HCV tests	X								
CK-MB , Troponin	X[7,8]		X[7,8]		X[7,8]	At the start of each cycle[7, 8]	X[7,8]		
BNP	X[9]								
UPEP and urine Immunofixation	X				X	At the start of each cycle			
SPEP and serum immunofixation and Serum M-protein Calculation	X				X	At the start of each cycle			
Kappa, lambda free LC, FLC ratio	X				X	At the start of each cycle			

	Time and Events Table for Full Study (Cycle = 21 days)								
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment[34]**	**Monthly Follow up[35]**	
24 hr urine protein and albumin	X				X	At the start of each cycle			
IgG, IgM, IgA	X				X	At the start of each cycle			
CRP, beta2 microglobulin	X				X	At the start of each cycle			
Pregnancy Test	X[10]					At the start of cycles 5[10], 9[10], 13[10]	X[10]	X[11]	
Chest X-ray	X								
12-lead ECG	X[12]	X[12]	X[12]	X[12]	X[12]	At the start of each cycle[12]	X[12]		
LVEF and valves assessment (ECHO)	X[13]					At the start of cycles 4[13], 9[13]	X[13]		
Extramedullary Plasmacytoma Imaging	X[14]					At the start of cycles 5[14], 9[14], 13[14]	X[14]		
	BM Aspirate (see below for each test required within procedure)**:**								
Disease assessment	X[15]					At the time of Complete Response			
BCMA assessment and PD (flow)	X[16]		X[16, 18]						
FISH testing	X[17]								
BM biopsy for disease assessment	X[19]					At the time of CR (disease assessment only)			
Serum (soluble BCMA)		X[20]			X[20]	Predose at the start of each cycle	X		
Serum (cytokines/chemokines)		X[21]			X[21]	Predose and EOI on D1 of each cycle	X		
Serum (anti-drug-antibodies)		X[22]			X[22]	At the start of cycles 3[22], 6[22], 9[22], 12[22] and 16[22]	X		
Plasma-cfDNA		X					X		
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[23]	X		X[23]	At the start of each cycle[23]	X[23]		
Sparse PK (blood)		X[24]			X[24]	C3D1[24] and C5D1[24] only	X[25]		
Genetics sample		X[26]							

	Time and Events Table for Full Study (Cycle = 21 days)								
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment[34]**	**Monthly Follow up[35]**	
Premedication if needed		X			X	X			
GSK2857916 administration		X[27]			X[27]	X[27]			
Steroid eye drops		X[28]			X[28]	X[28]			
Adverse Events			Continuous						
Concomitant Medications	X		Continuous						
e-Diary	X	X	X	X	X[30]	X[30]	X		
OSDI							X[31]	X[31]	
NEI-VFQ-25							X[31]	X[31]	
Exit Interview							X[32]		
Follow-up Interview								X[33]	
Survival Status								X[29]	
Subsequent Treatment								X[29]	

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing. In the event that a subject has a dose delay due to a non-ocular toxicity and an ocular exam has been performed for that cycle, a repeat ocular exam 3 days prior to dosing may be omitted if the participant did not have corneal signs on the previous exam and does not have any new corneal symptoms.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes, +30 minutes (±15 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for a comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab.
8. CK-MB at the local lab or if not available by a central laboratory.
9. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.

10. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine.
11. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
12. ECGs to be performed in triplicate. On dosing days, ECG to be performed at predose (within 30 minutes prior to SOI) and EOI. At screening, on interim visits (C1D8 and C1D15) and End of Study, obtain a single ECG measurement. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 24)**
13. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 5 days before dosing. ECHOs to be done locally and sent to GSK for central imaging storage.
14. May be performed up to 21 days prior to C1D1 as screening value. Needs to be performed with the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
15. Samples from within 14 days prior to first dose are acceptable.
16. Sample(s) collected for analysis at central lab. The same sample will be used for BCMA (flow) and PD. On D8 only postdose PD assessment will be performed, if applicable (refer to footnote 18).
17. FISH testing at least for: t(4;14), t(14;16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
18. **Additional samples may be collected in some subjects (up to 6) for further exploration of PD.**
19. Archival tissue from up to 60 days prior to study is acceptable.
20. Collect sBCMA at C1D1 predose (within 30 minutes prior to SOI) and at EOI (±5 minutes), C2D1 at predose (within 30 minutes prior to SOI) and at EOI (+- 5 minutes).
21. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction
22. All ADA samples will be collected prior to each infusion
23. Flow cytometry performed central laboratory.
24. PK samples to be taken for both GSK2587916 and cys-mcMMAF measurement on C1D1, C2D1, C3D1, and C5D1 at predose (within 30 minutes prior to SOI) and at EOI (just before EOI).
25. Collect 1 PK sample at each subject's final visit.
26. Informed consent for optional genetics research should be obtained before collecting a sample.
27. Study drug administration ±3 day window only.
28. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
29. All participants should be followed for survival for 1 year from last subject last dose. and whether subsequent treatment for disease was given. Subject does not need to come in for visit. Participants who have completed treatment or the 3 month follow up visit (end of study) prior to amendment 5 will be reconsented for further follow up and survival status.
30. e-Diary to be completed at screening, then Days 1-7, 8, 15 of each treatment cycle. Upon implementation of the e-Diary, these assessments will be required.
31. OSDI and NEI-VFQ-25 to be administered during end of study treatment visit. Additional assessments for subjects who are experiencing corneal symptoms to be completed via telephone on a monthly basis for up to 1 year, or until resolution of symptoms (whichever comes first) during the follow-up period.
32. Exit interview to be performed within 21 days of end of study visit
33. Optional follow-up telephone interview to explore visual symptoms and changes in symptoms and related impacts following treatment discontinuation be performed at least 6 months following the End of Study Treatment visit. This interview would only be for those subjects who experienced corneal symptoms during treatment and consent to participate.
34. End of treatment visit should be performed within 30 days (+7 days) after the last dose or prior to the start of new anti-cancer treatment, whichever is earlier. In cases where more than 30 days (+7 days) have elapsed from the date of the subject's last dose due to dosing delays and a subsequent decision to take the subject off treatment, the end of study treatment visit should be scheduled as soon as possible to allow the final assessments to be performed at the earliest date.

35. Participants with corneal signs or symptoms at the end of study treatment visit should be monitored by ophthalmic exam once a month after the last study dose until deemed clinically stable by an eye care professional complete resolution or for 12 months (whichever comes first). Corneal exams to include BCVA and slit lamp examination (with special focus on cornea). Participants who have completed treatment or the 3 month follow up visit (end of study) will be reconsented for additional ophthalmology follow up.
    Abbreviations:
    ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.3.2. Dose Expansion Weekly Dosing Schedule for Multiple Myeloma

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X		At the start of each cycle	X	
Ocular Exam	X[3]				X[4]		At the start of each cycle[4]	X[4]	
ECOG Performance Status	X				X		At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X[5]	X[5]	X[5]		At the start of each cycle[5]	X	
Weight and Height	X	Weight only			Weight only		Weight only - At the start of each cycle	Weight	
Hematology	X	X[6]	X	X	X		At the start of each cycle	X	
Clinical chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]			X		At the start of each cycle	X	
INR, PTT	X	X[6]	X	X	X		At the start of each cycle		
HBV/HCV tests	X								
CK-MB , Troponin	X[7]		X[7]		X[7]		At the start of each cycle[7]	X[7]	
BNP	X[8]								
UPEP and urine immunofixation	X				X		At the start of each cycle		
SPEP and serum immunofixation and Serum M-protein Calculation	X				X		At the start of each cycle		
Kappa, lambda free LC, FLC ratio	X				X		At the start of each cycle		
24 hr urine protein and albumin	X				X		At the start of each cycle		
IgG, IgM, IgA	X				X		At the start of each cycle		

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
CRP, beta2 microglobulin	X		X		X		At the start of each cycle		
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]	X[11]	X[11]	X[11]		At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	
Extramedullary Plasmacytoma Imaging	X[13]						At the start of cycles 5[13], 9[13], 13[13]	X[13]	
BM Aspirate (see below for each test required within procedure)**:**									
Disease assessment	X[14]						At the time of Complete Response		
BCMA assessment and PD (flow)	X[15]		X[15, 17]						
FISH testing	X[16]								
BM biopsy for disease assessment	X[18]						At the time of Complete Response (disease assessment only)		
Serum (soluble BCMA)		X[19]	X[19]	X[19]	X[19]		Predose at the start of each cycle	X	
Serum (cytokines/chemokines)		X[20]	X[20]	X[20]	X[20]		Predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)		X[21]		X[21]	X[21]		At the start of cycles 3[21], 6[21], 9[21], 12[21] and 16[21]	X	
Plasma-cfDNA		X	X					X	
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[15]	X		X[15]		At the start of each cycle[15]	X[15]	
Sparse PK (blood)		X[22]	X[22]	X[22]	X[22]	X[22]	C3D1[22], C3D15[22], and C5D1[22] only	X[23]	
Genetics sample		X[24]							
Premedication if needed		X	X	X	X	X	Each dosing week		
GSK2857916 administration		X[25]	X[25]	X[25]	X[25]	X[25]	Each dosing week[25]		
Steroid eye drops		X[26]	X[26]	X[26]	X[26]	X[26]	Each dosing week[26]		
Adverse Events		Continuous							

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Concomitant Medications	X	Continuous							
e-Diary	X	X	X	X	X		X[28]	X	
Exit Interview								X[29]	
Survival Status									X[27]
Subsequent Treatment									X[27]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes (±5 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab. CK-MB at the local lab, or if not available by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. ECGs to be performed in triplicate. On dosing days, ECG to be performed at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 22).** At screening and End of Study, obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 7 days before dosing. ECHOs to be done locally and sent to GSK for central imaging storage.
13. May be performed up to 21 days prior to C1D1 as screening value. Needs to be performed with the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
14. Samples from within 14 days prior to first dose are acceptable.
15. Sample(s) collected for analysis at central lab. The same sample collected on Day 1 of cycle1 prior to dosing will be used for BCMA (flow) and PD (refer to footnote 17).

16. FISH testing at least for: t(4;14), t(14;16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
17. Additional samples may be collected from 6 subjects in the MM cohort. Collect sample prior to dosing.
18. Archival tissue from up to 60 days prior to study is acceptable
19. A single sBCMA sample will be collected at C1D1 predose (within 30 minutes prior to SOI) unless otherwise specified. On C1D15 and C2D1 collect samples at predose (within 30 minutes prior to SOI) and at EOI (±5 minutes).
20. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction
21. All ADA samples will be collected prior to each infusion
22. PK samples to be taken for both GSK2857916 and cys-mcMMAF measurement at C1D1 predose (within 30 minutes prior to SOI), EOI (just before EOI), 1 hour post EOI (±5 min), and 3 hours post EOI (±5 min); predose (within 30 minutes prior to SOI) and EOI (just before EOI) on C1D8, C1D15, C2D1, C2D15, C3D1, C3D15, and C5D1
23. Collect 1 PK sample at each subject's final visit
24. Informed consent for optional genetics research should be obtained before collecting a sample.
25. Study drug administration ±1 day window only
26. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
27. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.
28. e-Diary to be completed at screening, then Days 1-7, 8, 15 of each treatment cycle. Upon implementation of the e-Diary, these assessments will be required.
29. 29.Exit interview to be performed within 14 days of end of study visit

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.3.3. Dose Expansion Every 3 Weeks Dosing Schedule for Lymphomas

Study Assessments[1]	Screen[2]	Day 1 C1	Day 8 C1	Day 15 C1	Day 1 C2	D1 of C3-C16	End of Study Treatment[26]	Monthly Follow up[27]	
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X	At the start of each cycle	X		
Ocular Exam	X[3]				X[4]	At the start of each cycle[4]	X[4]	X[27]	
ECOG Performance Status	X				X	At the start of each cycle	X		
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X	X	X[5]	At the start of each cycle[5]	X		
Weight and Height	X	Weight only			Weight only	Weight only - At the start of each cycle	Weight only		
Hematology	X	X[6]	X	X	X	At the start of each cycle	X		
Clinical chemistry	X	X[6]	X	X	X	At the start of each cycle	X		
Urine Dipstick	X	X[6]			X	At the start of each cycle	X		
INR, PTT	X	X[6]	X	X	X	At the start of each cycle			
HBV/HCV tests	X								
CK-MB, Troponin	X[7,8]		X[7,8]		X[7,8]	At the start of each cycle[7]	X[7,8]		
BNP	X[9]								
24 hr urine protein and albumin	X				X	At the start of each cycle			
IgG, IgM, IgA	X				X	At the start of each cycle			
CRP, beta2 microglobulin	X				X	At the start of each cycle			
Pregnancy Test	X[10]					At the start of cycles 5[10], 9[10], 13[10]	X[10]	X[11]	
Chest X-ray	X								
12-lead ECG	X[12]	X[12]	X[12]	X[12]	X[12]	At the start of each cycle[12]	X[12]		
LVEF and valves assessment (ECHO)	X[13]					At the start of cycles 4[13], 9[13]	X[13]		
Serum (soluble BCMA)		X[14]			X[14]				

Study Assessments[1]	**Screen**[2]	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**[26]	**Monthly Follow up**[27]	
Serum (cytokines/chemokines)		X[15]			X[15]	Predose and EOI on D1 of each cycle	X		
Serum (anti-drug-antibodies)		X[16]			X[16]	At the start of cycles 3[16], 6[16], 9[16], 12[16] and 16[16]	X		
Plasma-cfDNA		X					X		
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[17]	X[17]		X[17]	At the start of each cycle[17]	X[17]		
Sparse PK (blood)		X[18]			X[18]	C3D1[18] and C5D1[18]	X[19]		
Genetics sample		X[20]							
CT Scan/PET Scan for disease assessments	X[21]					At the start of cycles 4, 7, 10, 13, and 16			
Premedication if needed		X			X	At the start of each cycle			
GSK2857916 administration		X[22]			X[22]	X[22]			
Steroid eye drops		X[23]			X[23]	At the start of each cycle[23]			
Tumor biopsy for BCMA expression	X[24]								
Adverse Events				Continuous					
Concomitant Medications	X			Continuous					
Survival Status								X[25]	
Subsequent Treatment								X[25]	

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days of scheduled occurrence unless otherwise specified.
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing. In the event that a subject has a dose delay due to a non-ocular toxicity and an ocular exam has been performed for that cycle, a repeat ocular exam 3 days prior to dosing may be omitted if the participant did not have corneal signs on the previous exam and does not have any new corneal symptoms.

5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes, +30 minutes (±15 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to **Table 15 of the protocol** for a comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab.
8. CK-MB at the local lab, or if not available by a central laboratory.
9. BNP to be measured locally at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
10. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine.
11. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
12. On dosing days, triplicate ECGs to be performed at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 18).** At screening, on interim visits (C1D8 and C1D15) and End of Study, obtain a single ECG measurement.
13. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 5 days. ECHOs to be done locally and sent to GSK for central imaging storage.
14. A single sBCMA sample will be collected at C1D1 predose (within 30 minutes prior to SOI). On C2D1 sBCMA will be collected at predose (within 30 minutes prior to SOI) and at EOI (±5 minutes).
15. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction.
16. All ADA samples will be collected prior to each infusion.
17. Sample(s) collected for analysis by central lab.
18. PK samples to be taken for both GSK2587916 and cys-mcMMAF measurement on C1D1 at pre-dose (within 30 minutes prior to SOI), at EOI (just before EOI), 1 h after EOI (±5 min), 3 h after EOI (±5 min); C2D1, C3D1, and C5D1 at pre-dose (within 30 minutes prior to SOI) and at EOI (just before EOI).
19. Collect 1 PK sample at each subject's final visit.
20. Informed consent for optional genetics research should be obtained before collecting a sample.
21. CT/PET or CT scans from within 21 days prior to first dose are acceptable. CT scans are acceptable at all restaging assessments unless CR is suspected, in which case a PET/CT scan will be obtained to confirm CR.
22. Study drug administration ±3 day window only.
23. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drops QID x 4 days starting 1 day prior to treatment.
24. Archived or fresh tissue required for BCMA testing. Refer to Section 5.2.1 of the protocol Inclusion Criterion #4 for eligibility criteria.
25. Record subject's survival status until last subject completes or discontinues treatment and whether subsequent treatment for disease was given. Subject does not need to come in for visit.
26. End of treatment visit should be performed within 30 days (+7 days) after the last dose or prior to the start of new anti-cancer treatment, whichever is earlier. In cases where more than 30 days (+7 days) have elapsed from the date of the subject's last dose due to dosing delays and a subsequent decision to take the subject off treatment, the end of study treatment visit should be scheduled as soon as possible to allow the final assessments to be performed at the earliest date.
27. All participants should be followed for survival for 1 year from last dose. Participants with corneal signs or symptoms at the end of study treatment visit should be monitored by ophthalmic exam every month after the last study dose until deemed clinically stable by an eye care professional or for 12 months (whichever comes first). Corneal exams to include BCVA and slit lamp examination (with special focus on cornea).

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatine kinase; CRP = C-reactive protein; EOI = End of Infusion; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion

16.2.3.4. Dose Expansion Weekly Dosing Schedule for Lymphomas

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X		At the start of each cycle	X	
Ocular Exam	X[3]				X[4]		At the start of each cycle[4]	X[4]	
ECOG Performance Status	X				X		At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X[5]	X[5]	X[5]		At the start of each cycle[5]	X	
Weight and Height	X	Weight only			Weight only		Weight only - At the start of each cycle	Weight	
Hematology	X	X[6]	X	X	X		At the start of each cycle	X	
Clinical chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]			X		At the start of each cycle	X	
INR, PTT	X	X[6]	X	X	X		At the start of each cycle		
HBV/HCV tests	X								
CK-MB , Troponin	X[7]		X[7]		X[7]		At the start of each cycle[7]	X[7]	
BNP	X[8]								
24 hr urine protein and albumin	X				X		At the start of each cycle		
IgG, IgM, IgA	X				X		At the start of every other cycle		
CRP, beta2 microglobulin	X				X		At the start of each cycle		
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]	X[11]	X[11]	X[11]		At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Serum (soluble BCMA)		X[13]	X[13]	X[13]	X[13]			X[13]	
Serum (cytokines/chemokines)		X[14]	X[14]	X[14]	X[14]		Predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)		X[15]		X[15]	X[15]		At the start of cycles 3[15], 6[15], 9[15], 12[15] and 16[15]	X	
Plasma-cfDNA		X						X	
Peripheral blood (flow for TBNK)		X[16]	X[16]		X[16]		At the start of each cycle[16]	X[16]	
Sparse PK (blood)		X[17]	X[17]	X[17]	X[17]	X[17]	C3D1[17], C3D15[17] and C5D1[17] only	X[18]	
Genetics sample		X[19]							
CT/PET Scan for disease assessments	X[20]						At the start of Cycles 3, 5, 7, 9, 11, 13, and 16		
Premedication if needed		X	X	X	X[24]	X	Each dosing week		
GSK2857916 administration		X[21]	X[21]	X[21]	X[21, 24]	X	Each dosing week[21]		
Steroid eye drops		X[22]	X[22]	X[22]	X[22, 24]	X[22]	Each dosing week[22]		
Tumor biopsy for BCMA expression	X[23]								
Adverse Events		Continuous							
Concomitant Medications	X	Continuous							
Survival Status									X[25]
Subsequent Treatment									X[25]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing. In the event that a subject has a dose delay due to a non-ocular toxicity and an ocular exam has been performed for that cycle, a repeat ocular exam 3 days prior to dosing may be omitted if the participant did not have corneal signs on the previous exam and does not have any new corneal symptoms.

5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes after SOI (±5 min), EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI**. On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab. CK-MB at the local lab, or if not available by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. On dosing days, perform triplicate ECGs at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 17).** At screening and End of Study, obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 7 days before dosing. ECHOs to be done locally and sent to GSK for central imaging storage.
13. A single sample for sBCMA will be collected at C1D8 predose, and at the End of Study visit. sBCMA samples will also be collected on C1D1 at predose (within 30 minutes prior to SOI) and EOI (±5 minutes). On C1D15 and C2D1 collect at predose (within 30 minutes prior to SOI) and EOI (±5 minutes)
14. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction.
15. All ADA samples will be collected prior to each infusion.
16. Sample(s) collected for analysis by central lab.
17. PK samples to be taken for both GSK2857916 and cys-mcMMAF measurement at C1D1 predose (within 30 minutes prior to SOI), EOI (just before EOI), 1 hour post EOI (±5 min), and 3 hours post EOI (±5 min); predose (within 30 minutes prior to SOI) and EOI (just before EOI) on C1D8, C1D15, C2D1, C2D15, C3D1, C3D15, and C5D1.
18. Collect 1 PK sample at each subject's final visit.
19. Informed consent for optional genetics research should be obtained before collecting a sample.
20. CT/PET scans from within 21 days prior to first dose are acceptable.
21. Study drug administration ±1 day window only.
22. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drops QID x 4 days starting 1 day prior to treatment.
23. Archived or fresh tissue required for BCMA testing. Refer to Section 5.2.1 of the protocol Inclusion Criterion #4 for eligibility criteria.
24. Also applies to C2D8.
25. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatine kinase; CRP = C-reactive protein; EOI = End of Infusion; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion

16.3. Appendix 3: Assessment Windows

No assessment windows will be applied.

16.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events

16.4.1. Study Phases

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date
On-Treatment	Study Treatment Start Date < Date

Some datasets include the first dosing day as On-Treatment and some exclude the first dosing date as On-Treatment. The first dosing day (Day 1) is considered Pre-Treatment for ECOG, ECG, vital signs, liver events, lab tests, cardiac scan, and other safety domains. The first dosing day (Day 1) is considered to be On-Treatment for adverse events and concomitant medications.

16.4.1.1. Study Time Periods for Concomitant Medications and Blood and Blood Supportive Care Products

Concomitant Medication and Blood and Blood Supportive Care Product start and end dates will be assigned to study time periods in relation to first dose of study treatment as defined below. The start date references time flag variables and end date reference time flag variables will be added to the concomitant medications and blood and blood supportive products datasets, respectively.

- Start **relative to treatment:** Assign to 'BEFORE' if start date is prior to study treatment start date or if subject has not taken any study treatment or (start date is missing and end date is before study treatment start date). Else assign to 'DURING' if the start date falls into the on-therapy period as defined above or if subject is ongoing (not all study treatment discontinuation records completed) or start date is missing. Else assign to 'AFTER' if start date is after the on-therapy period.
- **End relative to** treatment: Assign to 'BEFORE' if end date is prior to study treatment start date or if subject has not taken any study treatment. Else assign to 'DURING' if start date falls into the on-therapy period or if subject is ongoing (not all study treatment discontinuation records completed) or (end date is missing and start relative to treatment not 'AFTER'). Else assign to 'AFTER' if start date is after the on-therapy period or (end date is missing and start relative to treatment='AFTER').

Only on-therapy blood and blood supportive care products that start after the start of study treatment are included in the Blood Products and Blood Supportive Care Product summaries. Therefore, for summary tables, include blood and blood supportive care product records where start relative to treatment in ('DURING') and end relative to treatment in ('DURING','AFTER'). All data will be reported in listings.

Concomitant medication start relative to treatment and end relative to treatment flags are used to select data to include in the Concomitant Medication summaries as follows:

- Summary of Concomitant Medications: This summary will contain medications including those with start date prior to study treatment start date and continue

(missing end date or end date after study treatment start date) on therapy. Note that any medications with start date and end date prior to study treatment start date will be excluded. In addition, any medication that was started during post-therapy will be excluded. Include concomitant medication records where start relative to treatment in ('BEFORE','DURING') and end relative to treatment in ('DURING','AFTER').

- Summary of Concomitant Medications with On-Therapy Onset: This summary will contain medications with start date after study treatment start date. In addition, any medication that was started during post-therapy (see above for definition of post-therapy) will be excluded. Include concomitant medication records where start relative to treatment in ('DURING') and end relative to treatment in ('DURING','AFTER').

16.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	• Study Treatment Start Date ≤ AE Start Date • AE Start Date is missing

NOTES:

- If the study treatment stop date is missing, then the AE will be considered to be On-Treatment.
- Time of study treatment dosing and start/stop time of AEs should be considered, if collected.

16.5. Appendix 5: Data Display Standards & Handling Conventions

16.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: US1SALX00259
HARP Compound	: arprod\gsk2859716\bma117159\
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.1.3 & ADaM IG Version 1.0.	
Generation of RTF Files	
• RTF files will be generated for all tables.	

16.5.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics
• Do not include subject level listings in the main body of the GSK Clinical Study Report. All subject level listings should be located in the modular appendices as ICH or non-ICH listings

Formats
• GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF. The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP's.
Planned and Actual Time

• Reporting for tables, figures and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the subject's listings.

Unscheduled Visits	
• Unscheduled visits will not be included in summary tables and/or figures. For by planned time analysis, unscheduled visits will not be included; For worst-case analysis, unscheduled visits will be included. • All unscheduled visits will be included in listings.	
Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

16.5.3. Reporting Standards for Pharmacokinetic Data

Pharmacokinetic Concentration Data	
PC Windows Non-Linear (WNL) File	PC WNL file (CSV format) for the non-compartmental analysis by Clinical Pharmacology Modelling and Simulation function will be created according to SOP_00000314000 : Non-Compartmental Analysis of Clinical Pharmacokinetic Data. Note: Concentration values will be imputed as per GUI_51487
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to IDSL Statistical Principle 6.06.1. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
NONMEM/Pop PK File	Pop-PK file (CSV format) for the POP-PK analysis by Clinical Pharmacology Modelling and Simulation function will be created according to the data specification detailed in Section 16.9.1 Population Pharmacokinetic (PopPK) Dataset Specification.
NONMEM/PK/PD File	PK/PD file (CSV format) for the PK/PD analysis by Clinical Pharmacology Modelling and Simulation function will be created according to the data specification detailed in Section 16.10.1 Pharmacokinetic/Pharmacodynamic Dataset Specification.
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	The following PK parameters will be derived by the Programmer:
Pharmacokinetic Parameter Data	
Is NQ impacted PK Parameters Rule Being Followed	Yes, refer to [Standards for Handling NQ Impacted PK Parameters].
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards.

16.5.4. Extended Loss to Follow-up or Extended Time without an Adequate Assessment

For subjects, if two or more scheduled disease assessments are missed and are then followed by an assessment of PD or death, PFS will be censored at the last adequate assessment prior to PD or death. When the scheduled disease assessment is every 3 weeks, a window of 49 days (6 weeks + 7 day window) will be used to determine whether there was an extended time without adequate assessment. That is, if the time difference between PD/death and last adequate assessment is more than 49 days, then PFS will be censored at the last adequate assessment prior to PD/death.

16.5.5. Date Associated with Response

Investigator assessment of disease is entered in the eCRF on the VISIT form. The date of the VISIT is captured but the date of the response assessment is not captured separately. The date associated with response will be the visit date for the VISIT on which the investigator assessed disease. A disease assessment may occur at an unscheduled visit. The date of the unscheduled visit would be assigned to any response assessed on that date. In the following section, unless otherwise specified, the disease assessment denotes post-baseline assessment.

16.6. Appendix 6: Derived and Transformed Data

16.6.1. General

Multiple Measurements at One Analysis Time Point
• Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented. • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of Any visit post-baseline row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Study Day

• Calculated as the number of days from First Dose Date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < First Dose Date → Study Day = Ref Date – First Dose Date
  • Ref Data ≥ First Dose Date → Study Day = Ref Date – (First Dose Date) + 1

16.6.2. Study Population

Extent of Exposure
• Number of days of exposure to study drug will be calculated based on the formula: **Duration of Exposure in Days = Treatment Stop Date – (Treatment Start Date) + 1** • Participants who were randomized but did not report a treatment start date will be categorised as having zero days of exposure. • The cumulative dose will be based on the formula: **Cumulative Dose = Sum of Dose at Each Cycle** • Dose intensity per cycle will be based on the formula: **Dose intensity Per Cycle = Cumulative Dose / Total Number of Cycles**

16.6.3. Efficacy

Laboratory Parameters
Serum M-protein, Urine M-protein, Serum FLC

• If a laboratory value which is expected to have a numeric value for summary purposes, has a non-detectable level reported in the database, where the numeric value is missing, but typically a character value starting with '<x' or '>x' (or indicated as less than x or greater than x in the comment field) is present, the number of significant digits in the observed values will be used to determine how much to add or subtract in order to impute the corresponding numeric value.
  ○ Example 1: 2 Significant Digits = '< x ' becomes x – 0.01
  ○ Example 2: 1 Significant Digit = '> x' becomes x + 0.1
  ○ Example 3: 0 Significant Digits = '< x' becomes x – 1

16.6.4. Safety

Adverse Events
AE'S OF Interest
• Corneal events • Thrombocytopenia • Neutropenia • Hematologic Toxicity • Infusion-related Reactions as collected in the eCRF

16.7. Appendix 7: Reporting Standards for Missing Data

16.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion (i.e. as specified in the protocol) was defined as: o For Part 1 (dose-escalation phase), a completed subject is one who has completed at least 1 cycle of study treatment and an End of Study Visit without events causing them to withdraw or discontinue from the study for reasons listed in Section 6.3 of the protocol. o For Part 2 (expansion cohort), a completed subject is one who has received at least one dose of study treatment without events causing them to withdraw or discontinue study treatment for reasons listed in Section 6.3 of the protocol and completed an End of Study Visit. o A participant will be considered to have completed the study if he or she has received at least one dose of the study treatment and, has died before the end of the study, has not been lost to follow-up, or has not withdrawn consent from study participation. • Withdrawn subjects may be replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

16.7.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o These data will be indicated by the use of a blank in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as “Not applicable” and “Not evaluable” are not considered to be missing data and should be displayed as such.
Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.
Responder Analysis	• For endpoints which determine the percentage of responders, subjects with unknown/not evaluable or missing best overall response will be assumed to be non-responders, and will be included in the denominator when calculating the percentages.
Time to Event	• Because study treatment is dependent on the study endpoints (e.g., progression, i.e. not a fixed treatment duration), the length of treatment for each subject will depend on the efficacy and toxicity of the treatment, so the duration of treatment will vary across subjects. Similarly the duration of follow up will also vary. All available time-to-event data will be analyzed using suitable statistical methods; subjects with shorter treatment and follow-up due to the natural history of their disease or medical necessities of the treatment of their disease will not be considered to have missing time-to-event data.

16.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in subject listing displays. • Imputed partial dates will not be used to derive study day, duration (e.g. duration of adverse events), or elapsed time variables. In addition, imputed dates are not used for deriving the last contact date in the overall survival analysis dataset. The imputed AE dates will only to be used in the figures "Profile Plot for Patients with No Corneal Event or Grade 1 Corneal Event" and "Profile Plot for Patients with Grade 2 or Higher Corneal Events". • Imputed dates will not be displayed in listings. However, where necessary, display macros may impute dates as temporary variables for the purpose of sorting data in listings only. In addition, partial dates may be imputed for 'slotting' data to study time periods or for specific analysis purposes as outlined below.

Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing.
	  ○ The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events.
	  ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used.
	• Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.

Concomitant Medications	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention:
	  ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month
	  ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month.
	• The recorded partial date will be displayed in listings.

Anti-Cancer Therapy (Where applicable), Radiotherapy and Surgical Procedures for Time-to-Event Endpoint and Response	• Start dates for follow-up anti-cancer therapy, radiotherapy (where applicable), and surgical procedures (where applicable) will be temporarily imputed in order to define event and censoring rules for progression-free survival, response rate, time to progression, duration of response or time to response (i.e. start date for new anti-cancer therapy). The imputed dates will not be stored on the anti-cancer therapy, radiotherapy, or surgical procedure datasets. • If missing start day, month, and year, then no imputation for completely missing dates • If missing start day and month, then no imputation should be done • If missing start day, then do the following: • If partial date falls in the same month as the last dose of study treatment, then assign to earlier of (date of last dose of study treatment+1, last day of month). • If partial date falls in the same month as the subject's last assessment and the subject's last assessment is PD, then assign to earlier of (date of PD+1, last day of month). • If both rules above apply, then assign to latest of the 2 dates • Otherwise, impute missing day to the first of the month. • If missing end date, then no imputation should be done.

16.8. Appendix 8: Values of Potential Clinical Importance

16.8.1. Laboratory Parameters

Reference ranges for all laboratory parameters collected throughout the study are provided by the laboratory. A laboratory value that is outside the reference range is considered either high abnormal (value above the upper limit of the reference range) or low abnormal (value below the lower limit of the reference range). Note: a high abnormal or low abnormal laboratory value is not necessarily of clinical concern. The laboratory reference ranges will be provided on the listings of laboratory data. Clinical laboratory test results outside of the reference range will be flagged in the listings.

To identify laboratory values of potential clinical importance, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v4.0) will be used to assign grades to the relevant laboratory parameters. NCI-CTCAE v4.0 can be found at http://ctep.cancer.gov/reporting/ctc.html.

For laboratory data which are not listed in the NCI CTCAE v4.0, a summary of values outside the normal range will be provided.

16.8.2. ECG Parameters and vital signs

For ECG and vital signs, the most updated IDSL standard up to the RAP effective date will be followed

16.9. Appendix 9: Population Pharmacokinetic (PopPK) Analyses

16.9.1. Population Pharmacokinetic (PopPK) Dataset Specification

Any deviations between the dataset specification and the final dataset will be documented in the population pharmacokinetic analysis report.

General Description:

1. The type of variables should be either NUM or DATE/TIME unless specified otherwise

2. The dataset is sorted by ID, RTFDD, ANALYTE, ASCENDING EVID unless specified otherwise

3. The data items (columns) in the analysis-ready data file will be in the same order as described in the table below.

4. Exclude observations with DTYPE=IMPUTE

5. Include PKFL=Y (applicable to all datasets)

6. Same rules are applied for all baseline covariates. Baseline rules are as follows:

- Use baseline value as defined by Stats in the lab test datasets and fill it on all rows for each subject;

- If not defined by Stats, set to measurement nearest to, but prior to, time of first dose

- Only in cases where Day 1 measurement is not available, but screening measurement is, the screening values will be used.

- Only in cases where both the Day 1 measurement as well as screening measurement are unavailable, set to -99.

7. 3 significant figures for all values except C, STUDY, SUBJID, ID, CTIME, DATE, ANALN, BQL, MDV, MDV2, OCC, CYCLE, CMT, AGE, GENDER, CANCER, RACE, ETHN, CNC, EXTSMP

8. Only subjects with CANCER=0 will be included in this dataset as the data for the lymphoma patients will not be fully cleaned at the time of the database cut in 4Q2018.

Column Header	Data Item	Codes	Derivation/Comments	Source data set
C	Line number/exclusion identifier	Row Number STM DRM PFD	Set to line/row number unless one or more of the following conditions are met, then set to code: • STM = If a PK sample was taken but the date and/or time of the sample is missing and cannot be derived • DRM= PK samples for which dosing records are missing • PFD=PK samples with CONC reported as NA/NR/NQ/BQL/missing at pre-dose in CYCLE =1	derived
STUDYID	Study ID		Unique identifier for a study	adpc
SITEID	Unique identifier for a study site			adsl
USUBJID	Unique subject identifier			adsl
SUBJID	Subject identifier from source data		SUBJID = SUBJID	adsl
ID	NONMEM subject identifier		Sequential subject identifier across studies after data is sorted by SUBJID. For study BMA117196, the ID will start with PPD For study 205678, the ID will start with PPD	derived
AMT	Amount of GSK2857916 given (in mg)		AMT = ALTDOSE, where PARAMCD=ALTDOSE only on the dosing line. If infusion was stopped early and then restarted, the dosing information will be captured with more than one line. Each line will represent a part of the infusion (for example from start to first interruption and then from restart to end of infusion). AMT will have to be derived separately from restart of infusion until it is stopped. For all other lines use “0”	adex
INFD	Infusion Duration (day)		INFD is the infusion duration and is computed from start and stop time of infusion (in days) (AENDTM-ASTDTM)/60/60/24 This value will only be used on the dosing line. For all other lines use “0” If infusion was stopped early and then restarted, INFD will have to be derived separately from restart of infusion until it is stopped.	adex
INFH	Infusion Duration (h)		INFH is the infusion duration and is computed from start and stop time of infusion (in h) (AENDTM-ASTDTM)/60/60 This value will only be used on the dosing line. For all other lines use “0” If infusion was stopped early and then restarted, INFH will have to be derived separately from restart of infusion until it is stopped.	adex

Column Header	Data Item	Codes	Derivation/Comments	Source data set
RATED	Rate of infusion (mg/day)		RATED = AMT/INFD; This value will only be used on the dosing line. For all other lines use “0” If infusion was stopped early and then restarted, RATED will have to be derived separately from restart of infusion until it is stopped.	derived
RATEH	Rate of infusion (mg/h)		RATEH = AMT/INFH This value will only be used on the dosing line. For all other lines use “0” If infusion was stopped early and then restarted, RATEH will have to be derived separately from restart of infusion until it is stopped.	derived
RTFDD	Relative time from start of first infusion on study (day)		RTFDD=((ADTM-ASTDTM)/60/60/24))	adpc, adex
RTFDH	Relative time from start of first infusion on study (h)		RTFDH=((ADTM-ASTDTM)/60/60))	adpc, adex
RTLDH	Relative time from start of the most recent infusion on study (h) done prior to the PK sample		For pre-dose samples, RTLDH will be calculated considering the most recent infusion done **prior** to the sample. For example, the RTLDH for the pre-dose in Cycle 2 will be computed from the start time of infusion in Cycle 1.	adpc
RTLDD	Relative time from start of the most recent infusion on study (day) done prior to the PK sample		RTLDD= RTLDH/24	derived
NOMTLDD	Planned nominal time relative to start of most recent infusion (day)		NOMTLDH/24	adpc

NOMTLDH	Planned nominal time relative to start of most recent infusion (h)		Derive from PCTPT
			when (PCTPT ='PRE-DOSE), NOMTLDH=0;
			when (PCTPT='DOSE'), NOMTLDH =0;
			when (PCTPT =”30M POST START OF INFUSION (SOI)"), NOMTLDH =0.5;
			when (PCTPT ="END OF INFUSION (EOI)"), NOMTLDH =1;
			when (PCTPT ="1 HOUR POST-EOI"), NOMTLDH =2;
			when (PCTPT ="3 HOURS POST-EOI"), NOMTLDH =4;
			when (PCTPT ="8 HOURS POST-EOI"), NOMTLDH =9;
			when (PCTPT ="24 HOURS POST-EOI"), NOMTLDH =25;
			when (PCTPT ="7 DAYS POST-EOI"), NOMTLDH =168;
			when (PCTPT ="14 DAYS POST-EOI"), NOMTLDH =336;
			when (PCTPT = “PRE-DOSE” and VISIT = CYCLE 2, NOMTLDH = 504;
			when (PCTPT ="END OF STUDY"), NOMTLDH =10000;
				adpc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			otherwise NOMTLDH =.;	
CLOCK	Clock time sample was obtained	Clock time (24 h) '00:00'	TIMEPART (EVENT and DOSING LINE) Format TIME5.	all dataset
DATE	Date of event (MM/DD/YYYY)		DATEPART (EVENT and DOSING LINE) Format DATE9.	all dataset
ANALYTE	Analyte	1= ADC(antibody-drug conjugate) 2= TOTALMAB(total antibody including complex) 3= MMAF(cys-mcMMAF)	This value will be used on all lines except for dosing record line where missing "0" will be used. EXCLUDE MAB PARAMCD in (P1RES, P5RES, P7RES), assign ANALYTE =3, 1, 2 respectively	Derived from adpc
CONC	Plasma concentration (ng/mL) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If AVALC=NA/NR/NQ/BQL/missing, set CONC= "0" Else CONC=AVAL When PARAMCD=P1RES, then CONC=AVAL/1000 [Convert cys-mcMMAF from pg/mL to ng/mL precision (3 significant figures). For example, 0.111 pg/mL= 0.000111 ng/mL]	adpc
DNCONC	Dose-normalized plasma concentration [(ng/mL)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		DNCONC = CONC (ng/mL)/AVAL; where AVAL=adex.PARAMCD=ADOSE (mg/kg) For CONC = "0", set DNCONC = "0"	Derived from adpc, adex
CONCNM	Plasma concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		For ANALYTE = 1, CONCNM = CONC(ng/mL)/152.1 For ANALYTE = 2, CONCNM = CONC(ng/mL)/152.1 For ANALYTE = 3, CONCNM = CONC(ng/mL)/1.045 • MW of ANALYTE =1 is 152.1 kDa • MW of ANALYTE =2 is 152.1 kDa • MW of ANALYTE =3 is 1045 Da For CONC = "0", set CONCNM = "0"	Derived from adpc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
DNCONCNM	Dose-normalized plasma concentration [(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		DNCONCNM = CONCNM (nM)/ AVAL; where AVAL=adex.PARAMCD=ADOSE (mg/kg) For CONCNM = "0", set DNCONCNM = "0"	Derived from adpc
LNCONC	Natural logarithm of the plasma concentration of GSK2857916 (ng/mL) (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		• If CONC = "0" then LNCONC = "0" • Else LNCONC = loge(CONC)	Derived from adpc
LNDNCONC	Natural logarithm of dose-normalized plasma concentration [(ng/mL)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DNCONC = "0" then LNDNCONC = "0" Else LNDNCONC = loge(DNCONC)	Derived from adpc
LNCONCNM	Natural logarithm of plasma concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If CONCNM = "0" then LNCONCNM = "0" Else LNCONCNM = loge(CONCNM)	Derived from adpc
LNDNCONCNM	Natural logarithm of dose-normalized plasma concentration [(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DNCONCNM = "0" then LNDNCONCNM = "0" Else LNDNCONCNM = loge(DNCONCNM)	Derived from adpc
CONC2	Plasma concentration (ng/mL) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		If adpc.AVALC=NA/NR/missing, set CONC2= "0" If AVALC=NQ/BQL, set CONC2 = "LLOQ/2" When PARAMCD=P1RES, then CONC2=AVAL/1000; [Convert cys-mcMMAF from pg/mL to ng/mL precision (3 significant figures). For example, 0.111 pg/mL= 0.000111 ng/mL] LLOQ for ANALYTE=1 is 100 ng/mL (adpc.PCLLOQ for PARAMCD=P5RES) LLOQ for ANALYTE=2 is 200 ng/mL (adpc.PCLLOQ for	Derived from adpc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			PARAMCD=P7RES) LLOQ for ANALYTE=3 is 0.05 ng/mL (adpc.PCLLOQ for PARAMCD=P1RES; as it is in pg/mL, needs to be converted to ng/mL);	
DNCONC2	Dose-normalized plasma concentration[(ng/mL)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		DNCONC2 = CONC2(ng/mL)/ AVAL; where AVAL=adex.PARAMCD=ADOSE (mg/kg) For CONC2 = “0”, set DNCONC2 = “0”	Derived from adpc, adex
CONCNM2	Plasma concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		For ANALYTE = 1, CONCNM2 = CONC2(ng/mL)/152.1 For ANALYTE = 2, CONCNM2 = CONC2(ng/mL)/152.1 For ANALYTE = 3, CONCNM2 = CONC2(ng/mL)/1.045 For CONC2 = “0”, set CONCNM2 = “0”	Derived from adpc
DNCONCNM2	Dose-normalized plasma concentration [(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		DNCONCNM2 = CONCNM2 (nM)/ADOSE (mg/kg) For CONCNM2 = “0”, set DNCONCNM2 = “0”	Derived from adpc
LNCONC2	Natural logarithm of the plasma concentration of GSK2857916 (ng/mL) (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		• If CONC2 = “0” then LNCONC2 = “0” • Else LNCONC2 = loge(CONC2)	Derived from adpc
LNDNCONC2	Natural logarithm of dose-normalized plasma concentration [(ng/mL)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		If DNCONC2 = “0” then LNDNCONC2 = “0” Else LNDNCONC2 = loge(DNCONC2)	Derived from adpc
LNCONCNM2	Natural logarithm of plasma		If CONCNM2 = “0” then LNCONCNM2 = “0”	Derived from

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		Else LNCONCNM2 = loge(CONCNM2)	adpc
LNDNCONCNM2	Natural logarithm of dose-normalized plasma concentration [(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF with imputation for BQL data		If DNCONCNM2 = "0" then LNDNCONCNM2 = "0" Else LNDNCONCNM2 = loge(DNCONCNM2)	Derived from adpc
BQL	Flag for BQL concentration	0 or 1	Set to 1 if adpc.AVALC= NQ/BQL; Else set to 0	adpc
MDV	Missing dependent variable flag.	0 or 1	1 for CONC = "0" and dosing line. 0 otherwise	adpc
MDV2	Missing dependent variable flag 2	0 or 1	1 for CONC2= "0" and dosing line. 0 otherwise	adpc
EVID	Flag indicating whether it is dosing admin info or drug concentration data.	0 or 1	1 on dosing line Set to 0 for all other lines	adex, adpc
CYCLE	Cycle number	>0	1 = Cycle 1, 2 = Cycle 2, 3 = Cycle 3, 4 = Cycle 4, 5 = Cycle 5,… etc EOT=999 Derive from AVISIT Fill CYCLE on all rows Note: Pre-dose belongs to the same cycle as the post dose sample done on the same day.	adpc
OCC	Occasion		If adpc.PCTPT=PRE-DOSE and CYCLE >= 2, then OCC= CYCLE-1, else OCC=CYCLE Fill OCC on all rows Note: This is different from CYCLE variable. OCC considers pre-dose sample to be part of prior cycle.	derived
EXTSMP	Subjects with extensive sampling/data	0= Subjects which do not have	1 will be assigned to subjects which have at least 4 CONC values above BLQ for either ANALYTE=1 or ANALYTE=3 up in OCC=1 0 for remaining subjects	adpc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
		extensive CONC for ADC/MMAF 1= Subjects with extensive CONC for ADC/MMAF	Fill EXTSMP on all rows	
IDOSE	GSK2857916 initial cycle dose (mg/kg)	>0	IDOSE=adex.TRT01A; strip off units	adex
ADOSE	GSK2857916 actual cycle dose (mg/kg)	>0	ADOSE= AVAL; where AVAL=adex. PARAMCD=ADOSE	adex
CMT	Compartment	>0	1 = Dosing line 1= Central Compartment for antibody-drug conjugate when ANALYTE=1 3 = Central Compartment for total antibody (including complex) when ANALYTE=2 5 = Central Compartment for cys-mcMMAF when ANALYTE=3	
RACET	Subject race text	Use CRF/Stats coding	RACET=adrace.ARACE Fill in RACET in all rows for each subject	adrace
RACEN	Subject race numeric		4 - ASIAN - JAPANESE HERITAGE 3 - ASIAN - SOUTH EAST ASIAN HERITAGE 2 - BLACK OR AFRICAN AMERICAN 1 - WHITE - ARABIC/NORTH AFRICAN HERITAGE 0 - WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE	adrace
ETHN	Subject ethnicity	Same coding as CRF/Stats	Fill in ETHN in all rows for each subject - If missing, ETHN = -99	adsl
AGE	Age (years)		• Use value as defined by Stats; • If not defined by Stats, AGE = date of first dose – date of birth • If date of birth is missing, AGE = -99	adsl
SEX	Gender	0 or 1	Male = 1 Female = 0	adsl

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			• If sex is missing, SEX = -99	
BWT	Baseline Weight (kg)		Use Baseline covariate rules. Fill in BWT in all rows for each subject	adsl
WT	Weight (kg)		WT is propagated forward from the most recent measurement for all observations up to the next WT measurement (LOCF). Please capture the values corresponding to the PK time points.	advs
HT	Height (cm)		Height at baseline in cm Fill in HT in all rows for each subject	adsl
BBSA	Baseline Body Surface Area (m^2)		Baseline BSA (m^2) BSA = $0.024265 \cdot HT(cm)^{0.3964} \cdot BWT(kg)^{0.5378}$ Ref: Geometric method for measuring body surface area: a height-weight formula validated in infants, children, and adults. Haycock GB, Schwartz GJ, Wisotsky DH. Use baseline covariate rules	derived
BSA	Body Surface Area (m^2)		BSA (m^2) BSA = $0.024265 \cdot HT(cm)^{0.3964} \cdot WT(kg)^{0.5378}$ BSA is propagated forward from the most recent measurement for all observations up to the next BSA measurement (LOCF). Please capture the values corresponding to the PK time points.	derived
BBMI	Baseline Body Mass Index (kg/m^2)		BBMI = $BWT(kg)/(HT(cm)/100)^2$ Assign BBMI = -99 if negative values would be derived for any of BBMI Use baseline covariate rules	derived
BMI	Body Mass Index (kg/m^2)		BMI = $WT(kg)/(HT(cm)/100)^2$ Assign BMI = -99 if negative values would be derived for any of BMI BMI is propagated forward from the most recent measurement for all observations up to the next BMI measurement (LOCF). Please capture the values corresponding to the PK time points.	derived
CANCER	Cancer type	0 or 1	0=Multiple Myeloma, 1=BCMA positive Lymphomas If TRT01AN = 12, then CANCER=1, else CANCER=0 Fill in CANCER in all rows for each subject	all datasets
BSBCMA	sBCMA level at baseline (ng/mL)		Baseline value is pre-dose on Cycle 1 Day 1. For PARAMCD = SBCMAG, get the values from AVAL column. When AVAL is missing: • and AVALC = ALQ: set to LBULOQ • and AVALC = BLQ: set to LBLLOQ/2	adbiomrk PARAMCD = SBCMAG when ABLFL=Y.

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			• and AVALC = missing: set to -99 Use baseline covariate rules	
SBCMA	sBCMA level (ng/mL)		For PARAMCD = SBCMAG, get the values from AVAL column. SBCMA is propagated forward from the most recent measurement for all observations up to the next sBCMA measurement (LOCF). When AVAL is missing: • and AVALC = ALQ: set to LBULOQ • and AVALC = BLQ: set to LBLLOQ/2 • and AVALC = missing: propagate prior SBCMA value forward until the next measured SBCMA Please capture the values corresponding to the PK time points.	adbiomrk PARAMCD = SBCMA
SBCMAGC	Complex BCMA (ng/mL)		For PARAMCD = SBCMAGC, get the values from AVAL column. SBCMAGC is propagated forward from the most recent measurement for all observations up to the SBCMAGC measurement (LOCF). When AVAL is missing: • and AVALC = ALQ: set to LBULOQ • and AVALC = BLQ: set to LBLLOQ/2 • and AVALC = missing: propagate prior SBCMAGC value forward until the next measured SBCMAGC Please capture the values corresponding to the PK time points.	adbiomrk PARAMCD = SBCMAGC
BCRCL	Baseline Creatinine Clearance (mL/min/1.73 m^2)		eGFR = 175 × $(Scr)^{-1.154}$ × $(Age)^{-0.203}$ × (0.742 if female) × (1.212 if African American) Scr = AVAL; AVAL=adlab.PARAMCD =LB1404 and ABLFL=Y Convert units (µmol/L) to (mg/dL) using the following formula: To convert µmol/L to mg/dL, multiply by 0.0113. Age is expressed in years. Use baseline covariate rules Ref: Protocol	adlb; PARAMCD=LB1404

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			16.4. Appendix 5: Modified Diet in Renal Disease Formula MDRD: eGFR = $175 \times (S_{cr})^{-1.154} \times (Age)^{-0.203} \times (0.742$ if female$) \times (1.212$ if African American) GFR is expressed in mL/min/1.73 m2, SCr is serum creatinine expressed in mg/dL, and age is expressed in years. The link below will auto-calculate the creatinine clearance: http://nephron.org/cgi-bin/MDRD_GFR/cgi	
CRCL	Creatinine Clearance (mL/min/1.73 m^2)		To be computed with same equation as provided for BCRCL CRCL is propagated forward from the most recent measurement for all observations up to the next CRCL measurement (LOCF). Please capture the values corresponding to the PK time points.	adlb
BALT	Baseline ALT (IU/L)		BALT = AVAL; AVAL=adlab. PARAMCD =LB1227 and ABLFL=Y Use baseline covariate rules	adlb
ALT	ALT (IU/L)		ALT = AVAL; AVAL=adlab. PARAMCD =LB1227 and ABLFL=Y ALT is propagated forward from the most recent measurement for all observations up to the next ALT measurement (LOCF). Please capture the values corresponding to the PK time points.	adlb
BAST	Baseline AST (IU/L)		BAST = AVAL; AVAL=adlab. PARAMCD =LB1273 and ABLFL=Y Use baseline covariate rules	adlb
AST	AST (IU/L)		AST = AVAL; AVAL=adlab. PARAMCD =LB1273 and ABLFL=Y AST is propagated forward from the most recent measurement for all observations up to the next AST measurement (LOCF). Please capture the values corresponding to the PK time points.	adlb
BALB	Baseline Albumin (g/L)		BALB = AVAL; AVAL=adlab. PARAMCD =LB1216 and ABLFL=Y Use baseline covariate rules	adlb
ALB	Albumin (g/L)		ALB = AVAL; AVAL=adlab. PARAMCD =LB1216 and ABLFL=Y ALB is propagated forward from the most recent measurement for all observations up to the next ALB measurement (LOCF). Please capture the values corresponding to the PK time points.	adlb
BTBIL	Baseline Total Bilirubin (mg/dL)		TBIL = AVAL; AVAL=adlab. PARAMCD =LB1282 and ABLFL=Y	adlb

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			Use baseline covariate rules	
TBIL	Total Bilirubin (mg/dL)		TBIL = AVAL; AVAL=adlab. PARAMCD =LB1282 and ABLFL=Y TBIL is propagated forward from the most recent measurement for all observations up to the next TBIL measurement (LOCF). Please capture the values corresponding to the PK time points.	adlb
BCRP	Baseline C Reactive Protein (mg/L)		Use baseline covariate rules	adlb
CRP	C Reactive Protein (mg/L)		CRP is propagated forward from the most recent measurement for all observations up to the next CRP measurement (LOCF). Please capture the values corresponding to the PK time points.	
BIGG	Baseline serum IgG (g/L)		BIGG = AVAL; AVAL=adlab. PARAMCD =LB1566 and ABLFL=Y Use baseline covariate rules	adlb
IGG	Serum IgG (g/L)		IGG = AVAL; AVAL=adlab PARAMCD =LB1566 Missing values use -99. IGG is propagated forward from the most recent measurement for all observations up to the next IGG measurement (LOCF). Please capture the values corresponding to the PK time points.	adlb
MAXPRED	Maximum reduction in M-protein or FLC		Obtain AVAL for PARAMCD=MAXPRED. When AVAL is missing, MAXPRED = -999	adrs
RESPRATIO	Transform MAXRED to a ratio to baseline		RESPRATIO = max((100+MAXPRED)/100,0.001) • When MAXRED is missing, MAXPRED = -999 and RESPRATIO= -99 • When MAXPRED is less than -100 e.g. -100.15, RESPRATIO = negative (It is negative but greater than -8.99), then update RESPRATIO = 0.001 • When MAXPRED is equal to -100, RESPRATIO = 0, then update RESPRATIO = 0.001	adrs
COUNTRY	Country code		Fill in COUNTRY in all rows for each subject	adsl
CNC	NONMEM Country code	1 = Canada, 2 = UK	Fill in CNC in all rows for each subject	adsl

<table>
<tr><th>Column Header</th><th>Data Item</th><th>Codes</th><th>Derivation/Comments</th><th>Source data set</th></tr>
<tr><td></td><td></td><td>3 = US</td><td></td><td></td></tr>
<tr><td>IMMU</td><td>Immunogenicity Outcome by Collection Time</td><td>0 = negative

1 = positive</td><td>
<table>
<tr><td rowspan="2"></td><td colspan="2">PARAMCD</td><td rowspan="2">IMMU</td></tr>
<tr><td>PARAMCD = AGBABDS</td><td>PARAMCD = AGBABDC</td></tr>
<tr><td>AVALC</td><td>NEGATIVE</td><td>MISSING</td><td>0</td></tr>
<tr><td>AVALC</td><td>POSITIVE</td><td>POSITIVE</td><td>1</td></tr>
<tr><td>AVALC</td><td>POSITIVE</td><td>NEGATIVE</td><td>0</td></tr>
<tr><td>AVALC</td><td>POSITIVE</td><td>MISSING</td><td>-99</td></tr>
<tr><td>AVALC</td><td>MISSING</td><td>ANY</td><td>-99</td></tr>
</table>
IMMU may not have been assayed at all PK visits. For visits between IMMU visits, imputation rules are as follows:

(1) When there is no change in IMMU between IMMU visits, all PK visits in between will be imputed with</td><td>adis</td></tr>
</table>

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			the same IMMU (2) When IMMU changes from 0 to 1, impute IMMU=1 from the first record after the record known to be IMMU=0 (3) When IMMU changes from 1 to 0, impute IMMU = 1 until the record known to be IMMU=0 Only AVISIT and Day of collection is mentioned for these samples. Exact clock time information is missing. The workaround is to assign PREDOSE CYCLE 1 CTIME to SCREENING immunogenicity samples. For other cycles, as samples were collected at pre-dose, PREDOSE PK time is assigned. For EOT immunogenicity samples, CTIME will be same as PK time point. Use LOCF principle and do not include samples which were collected at non-PK time points except when it is positive. In this dataset, there were no confirmatory positive outcome, so LOCF principle will suffice.	
IMM	Overall Immunogenicity Outcome 0=anti-GSK2857916 negative, 1=anti-	0 = negative	• If IMMU = 1 at any observation for a subject, IMM = 1 • else if all IMMU = -99, IMM = -99	adis

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	GSK2857916 positive (at least one postdose)	1 = positive -99 = missing	Else IMM = 0 Fill in IMM in all rows for each subject	
ORDRESP	Best Confirmed Response	0,1,2,3,4,5, 6	For PARAMCD=BCRSP, assign 0 for PD 1 for SD 2 for MR 3 for PR 4 for VGPR 5 for CR 6 for sCR Fill on all rows	adrs
BECOG	Baseline ECOG status	0 1 2	Fill on all rows	adqs
ECOG	ECOG status	0 1 2	Fill on all rows	
PRIORRX	Prior line of therapy		When addc.PARAMCD= LTXCPSCR, then PRIORRX = AVALC (Extract only the number and not the text) For AVALC = MORE THAN 10 LINES, PRIORRX=11 Fill on all rows	addc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
REFRAC	Refractory status	0 = Double 1 = Other	Fill on all rows	
MMTY	Type of Multiple Myeloma	0 = Secretory 1= Non-secretory	When addc.MMYELOTY=SECRETORY, MMTY=0 When addc.MMYELOTY= NONSECRETORY, MMTY=1 If addc.MMYELOTY is missing, assign MMTY=-99 Fill on all rows.	addc
MMIGTY	Myeloma immunoglobulin	0 = IGA 1 = IGG 2 = IGM 3 = OTHER	When addc.PARAMCD=MYELOIG and AVALC=IGA, then MMIGTY =0 When addc.PARAMCD=MYELOIG and AVALC=IGG, then MMIGTY =1 When addc.PARAMCD=MYELOIG and AVALC=IGM, then MMIGTY =2 For AVALC which is not equal to IGA/ IGG /IGM, then MMIGTY=3 Fill on all rows	addc
BSTAGE	Stage at Screening	0 = I 1 = II 2 = III 3 = UNKNOWN or	When addc.PARAMCD = STAGESCR and AVALC = I, then BSTAGE = 0 When addc.PARAMCD = STAGESCR and AVALC = II, then BSTAGE = 1 When addc.PARAMCD = STAGESCR and AVALC = III, then BSTAGE = 2 When addc.PARAMCD = STAGESCR and AVALC = UNKNOWN or missing , then BSTAGE = 3 Fill on all rows	addc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
		missing		
MMLCTY	Myeloma Light Chain	0 = KAPPA LIGHT CHAIN 1 = LAMBDA LIGHT CHAIN	When addc.PARAMCD = MYELOLC and AVALC = KAPPA LIGHT CHAIN, then MMLCTY = 0 When addc.PARAMCD = MYELOLC and AVALC = LAMBDA LIGHT CHAIN, then MMLCTY = 1 Fill on all rows	addc

16.9.2. Population Pharmacokinetic (PopPK) Methodology

The primary goal of this analysis is to characterize the population pharmacokinetics of GSK2857916 and associated analytes after intravenous administration of GSK2857916 in subjects with multiple myeloma. This analysis will be performed by CPMS and reported separately.

A summary of the planned population pharmacokinetic analyses is outlined below:

- Exploratory data analyses will be performed to understand the content of the analysis dataset with respect to the anticipated models, to search for extreme values and/or potential outliers, to examine the correlation between covariates, and to assess possible trends in the data.
- Drug concentration-time data will be subjected to nonlinear mixed effects modelling using appropriate validated software to develop a population PK model.
- Based on the preliminary analysis, log-transformed drug concentration data for GSK2857916 ADC will be subjected to analysis using a two-compartment IV infusion model parameterized using either clearances and distribution volumes, micro-constants or macro-constants (A, B, ALPHA and BETA), depending on parameters to be estimated. A similar approach may be used on the data from the three analytes (ADC, total antibody, and cys-mcMMAF) together.
- Inter-individual or between-subject variability (IIV or BSV) will be initially modeled using an exponential random effects model. Random effects for clearances and volumes or A and B and BETA will be incorporated, depending on model parameterization used. If the goodness-of-fit plots reveal potential biases in the random effects model, alternative random effects models may be considered.
- An additive error model on a log-transformed data scale reflecting an exponential error residual variability model will initially be used to describe the residual variability. If the goodness-of-fit plots reveal potential biases in the residual variability model, other residual error models will be considered as appropriate.
- Covariate analysis will be performed to explore measurable sources of PK variability. Different approaches may be evaluated for covariate model building including a step-wise process consisting of a forward and a backward selection procedure and/or a full-model approach. Some of the prospectively identified covariates are listed below:
    - Continuous covariates such as age, albumin, measures of body size (e.g., body weight, body surface area, body mass index, lean body mass);
    - Categorical covariates such as gender, race, disease status, immunogenicity status, and geographic region.
- Non-parametric bootstrapping may be performed to test model robustness. The model performance may be evaluated by performing predictive check.
- Individual *post hoc* estimated PK parameters will be summarized descriptively.

- Individual subject PK parameters and exposure measures for Cycle 1 will be estimated and documented for the purposes of any subsequent exposure-response (PK/PD) analyses.

Any analyses not described *a priori* but undertaken based on emerging data will be described in detail in the report.

Data handling considerations are summarized below:

- Drug concentration data which are below the lower limit of quantification, LLQ, (NQ or BLQ) are not reported as a numeric value. Such NQ observations will be either discarded or handled in a special way. When the frequency of NQ is small, the NQ values will be excluded, since discarding NQ values in this case introduces little bias [Beal, 2001]. In situations where there are a large percentage of NQ values, other strategies which may reduce estimation bias will be considered [Beal, 2001; Hing, 2001; Ahn, 2008]. The total number and percentage of NQ values will be calculated and the rationale for the method for handling these NQ values will be documented in the final report. In situations with large number of NQ values, the predictive performance of the model will be assessed to compare the agreement between observed versus predicted proportion of samples below the LLQ.
- Concentrations that are inconsistent pharmacokinetically with the drug concentration-time profile within an individual may be considered as outliers and subsequently excluded from the dataset or analysis. Visual inspection of individual and pooled data and weighted residuals during analysis may be used to identify such outliers. Any such exclusion will be reported and discussed in the analyses summary.
- Missing data will be handled in the following way:
    - Subjects who withdrew from the study and did not provide any PK samples and do not have adequate sampling and/or covariate information will be excluded from the analysis.
    - If dosing and/or sampling times are missing, the relevant concentrations may be excluded from the analysis dataset and summarized in an exclusion listing file. Alternatively, the nominal times of the respective doses and/or samples may be utilized.
    - Imputations of any covariate value will only be performed if the variable is missing for less than 10% of the subjects. For continuous covariates, missing values for an individual subject will be imputed as the gender-specific median value for the study. Any changes to the imputation methods will be justified and documented. If the percentage of missing data is greater than 10%, the variable will only be evaluated in exploratory graphical displays and not in the population analyses. Subjects from race categories with an insufficient number for analysis (typically less than 10% of the subject population) may be re-grouped and/or defined as race “Other.”

16.10. Appendix 10: Pharmacokinetic / Pharmacodynamic Analyses

16.10.1. Pharmacokinetic / Pharmacodynamic Dataset Specification

Dataset specifications for exposure-response analyses of efficacy and of corneal toxicity are provided. Any deviations between the dataset specifications and the final datasets will be documented in the population pharmacokinetic analysis report.

For corneal events:

General Description:

1. The dataset is sorted by SUBJID
2. Three significant figures for all values except those variables which are integers.
3. Only subjects with CANCER=0 will be included in this dataset as the data for the lymphoma patients will not be fully cleaned at the time of the database cut in 4Q2018.

Column Header	Data Item	Codes	Derivation/Comments	Source data set
C	Line number/exclusion identifier	Row Number	Set to line/row number	adae
STUDY	Study ID		1 = BMA117159	adsl
USUBJID	Unique subject identifier			adsl
SUBJID	Subject identifier from source data		SUBJID = SUBJID	adsl
ID	NONMEM subject identifier		Sequential subject identifier across studies after data is sorted by SUBJID. Starting with P	
TOXTYPE	This variable is created to separate out Grade 1 toxicity from Grade 2 and higher.	1,2	2 separate datasets with one line per subject: TOXTYPE = 1 for 1st occurrence of corneal event (CQ01NAM = Corneal Event). If CQ01NAM = missing, add 1 line for that subject.	adae
CORTOX	Presence or Absence of Corneal toxicity	0 or 1	When CQ01NAM ="Corneal Event", then CORTOX=1. When CQ01NAM =missing, then CORTOX=0.	adae
AETOXGRN	Standard Corneal Toxicity Grade	0,1,2,3		adae
WRAETOXGRN	Worst Corneal Toxicity Grade	0,1,2,3	Worst corneal toxicity grade experienced by subject throughout the entire treatment duration	adae
TTECORTOX	Time to corneal toxicity event (day)		• For TOXTYPE = 1 and CORTOX = 1, then TTECORTOX = AESTDY • When TOXTYPE = 1 and CORTOX = 0, then TTECORTOX = LSTCTDT – TRTSDT+ 1 (TRTSDT, LSTCTDT is coming from adsl dataset)	adae, adsl

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			•	
DOAE	Duration of adverse event (days)		This variable is for calculating the duration of adverse event following the 1st occurrence of corneal event in TOXTYPE =1 • When CQ01NAM = Corneal Event and AONGO=N and AENDTF= blank, then DOAE = ADURN; • When CQ01NAM = Corneal Event and AONGO = N and AENDTF= Y/M/D, then DOAE = -99; • When CQ01NAM = Corneal Event and AONGO=Y, then DOAE = (LSTCTDT – ASTDT) + 1; • When CQ01NAM = Corneal Event and AONGO=Y, DOAE = -99 ASTDTF is not missing (has alphabet Y/M/D); • When CQ01NAM = Corneal Event and AONGO=Y, DOAE = -99 if LSTCTDT or ASTDT is missing; • When CQ01NAM = missing, then DOAE = 0;	adae, adsl
DOAECFLCD	DOAE Censoring Flag Code	0 or 1	When AONGO=N, then DOAECFLCD=0 When AONGO=Y, then DOAECFLCD=1	adae
LNDOAE	Log of duration of adverse event		LNDOAE = Log(DOAE); When DOAE=-99, LNDOAE =-99; When DOAE=0, LNDOAE=0	adae
CUMAMTCT	Cumulative dose to TTECORTOX (mg)		When CORTOX=1, • For adex.PARAMCD=ALTDOSE, CUMAMTCT= Cumulative of adex.AVAL till adae.AESTDY • For corneal toxicity that occurred on dosing days, the dose on the corneal toxicity day was not included in the cumulative dose calculation. Here is the code for that: When adae.AESTDY=adex.ASTDY, then CUMAMTCT= Cumulative of adex.AVAL till (adae.AESTDY -1) When CORTOX=0, • CUMAMTCT= AVAL* WEIGHTBL; Get AVAL for adex.PARAMCD=CUMDOSE	adex. adae
TAAUCCT	Time-average AUC till		The area under the plasma ADC concentration–time curve (AUC) per day	popPK output,

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	TTECORTOX (AUC/day)		(AUC/day) will be derived for each patient using the available ADC dosing information, individual patient clearance values from the population pharmacokinetic model, and the time to the occurrence of the corneal toxicity.	adae
CANCER	Cancer type	0 or 1	0=Multiple Myeloma, 1=BCMA positive Lymphomas If TRT01AN = 12, then CANCER=1, else CANCER=0	adsl
AMT	Amount (in mg) of GSK2857916 given in first cycle		AMT = AVAL when PARAMCD=ALTDOSE and AVISIT= CYCLE 1 DAY 1	adex
IDOSE	GSK2857916 initial cycle dose (mg/kg)	>0	IDOSE=adex.TRT01A; strip off units	adex
CMAX	First dose Cmax of ADC – model predicted EOI concentration in Cycle 1 (ng/mL)		Individual model predicted conc. at EOI.	PopPK output
MMAFCMAX	First dose Cmax. of MMAF – model predicted 24 HOURS POST-EOI in Cycle 1 (ng/mL)		Individual model predicted conc. at 24 HOURS POST-EOI in Cycle 1	PopPK output
CTAU	First dose C_{tau} of ADC– model predicted pre-dose concentration Cycle 2		Individual model predicted pre-dose conc.CYCLE 2.	PopPK output
AUC	First dose AUC(0-inf) of ADC (ug.day/mL)		First dose (mg)/Individual Clearance of ADC (L/Day)	popPK output
MMAFAUC	First dose AUC(0-inf) of MMAF (ug.day/mL)		First dose (mg)/Individual Clearance of MMAF (L/Day)	popPK output
TOTCYC	Total number of CYCLES		TOTCYC=AVAL, AVAL for adex.PARAM=Total Number of Cycles	adex
ETHN	Subject ethnicity	Same coding as CRF/Stats	Fill in ETHN in all rows for each subject If missing, ETHN = -99	adsl
AGE	Age (years)		Use value as defined by Stats;	
SEX	GENDER	0 or 1	Male = 1 Female = 0 • If sex is missing, GENDER = -99	
BWT	Baseline Weight (kg)		• Use baseline value as defined by Stats in the lab test datasets; • If not defined by Stats, set to weight measurement nearest to, but prior to, time of first dose	

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			• Only in cases where Day 1 weight is not available, but screening weight is, the screening values will be used.	
BECOG	Baseline ECOG status	0 1 2	Fill on all rows	
ECOG	ECOG status	0 1 2	ECOG is propagated forward from the most recent measurement for all observations up to the next ECOG measurement (LOCF). Please capture the values corresponding to the PK time points.	
PRIORRX	Prior line of therapy		When addc.PARAMCD= LTXCPSCR, then PRIORRX = AVALC (Extract only the number and not the text) For AVALC = MORE THAN 10 LINES, PRIORRX=11 Fill on all rows	addc
REFRAC	Refractory status	0 = Double 1 = Other	Fill on all rows	
MMTY	Type of Multiple Myeloma	0 = Secretory 1= Non-secretory	When addc.MMYELOTY=SECRETORY, MMTY=0 When addc.MMYELOTY= NONSECRETORY, MMTY=1 If addc.MMYELOTY is missing, assign MMTY=-99 Fill on all rows.	addc
MMIGTY	Myeloma immunoglobulin	0 = IGA 1 = IGG 2 = IGM 3 = OTHER	When addc.PARAMCD=MYELOIG and AVALC=IGA, then MMIGTY =0 When addc.PARAMCD=MYELOIG and AVALC=IGG, then MMIGTY =1 When addc.PARAMCD=MYELOIG and AVALC=IGM, then MMIGTY =2 For AVALC which is not equal to IGA/ IGG /IGM, then MMIGTY=3 Fill on all rows	addc
BSTAGE	Stage at Screening	1 = I 2 = II 3 = III 4 =	When addc.PARAMCD = STAGESCR and AVALC = I, then BSTAGE = 1 When addc.PARAMCD = STAGESCR and AVALC = II, then BSTAGE = 2 When addc.PARAMCD = STAGESCR and AVALC = III, then BSTAGE = 3 When addc.PARAMCD = STAGESCR and AVALC = UNKNOWN or missing , then	addc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
		UNKNOWN or missing	BSTAGE = 4 Fill on all rows	

For efficacy

General Description:

1. The dataset is sorted by SUBJID
2. Three significant figures for all values except those variables which are integers.
3. Only subjects with CANCER=0 will be included in this dataset as the data for the lymphoma patients will not be fully cleaned at the time of the database cut in 4Q2018.

Column Header	Data Item	Codes	Derivation/Comments	Source data set
C	Line number/exclusion identifier	Row Number	Set to line/row number	
STUDY	Study ID		1 = BMA117159	adsl
SUBJID	Subject identifier from source data		SUBJID = SUBJID	adsl
ID	NONMEM subject identifier		Sequential subject identifier across studies after data is sorted by SUBJID. Starting with P	derived
PFSCFLCD	PFS Censoring Flag Code	0 or 1	For PARAMCD=PFS_D, CNSR value is assigned to PFSCFLCD 0=Event 1=Censor	adtte
PFSD	PFS (Days)		For PARAMCD=PFS_D, AVAL value is assigned to PFSD When AVAL is missing for PFS_D, then PFSD = -99.	adtte
PFSM	PFS (Months)		For PARAMCD=PFS_M, AVAL value is assigned to PFSM When AVAL is missing for PFS_M, then PFSM = -99.	adtte
PFSY	PFS (Years)		For PARAMCD=PFS_D, (AVAL/365) value is assigned to PFSY When AVAL is missing for PFS_Y, then PFSY = -99.	derived
TTRCFLCD	TTR Censoring Flag Code	0 or 1	For PARAMCD=TTR_D, Assign 1 to TTRCFLCD. For subjects where TTR_D is missing, assign 0 to TTRCFLCD.	adtte
TTRD	TTR (Days)		For PARAMCD=TTR_D, AVAL value is assigned to TTRD. For subjects where TTR_D is missing, assign PFSD to TTRD.	adtte

Column Header	Data Item	Codes	Derivation/Comments	Source data set
TTRM	TTR (Months)		For PARAMCD=TTR_M, AVAL value is assigned to TTRM. For subjects where TTR_M is missing, assign PFSM to TTRM.	adtte
TTRY	TTR (Years)		For PARAMCD=TTR_D, (AVAL/365) value is assigned to TTRY. For subjects where TTR_D is missing, assign PFSY to TTRY.	derived
DORCFLCD	DOR Censoring Flag Code	0 or 1	For PARAMCD=DOR_D, CNSR value is assigned to DORCFLCD 0=Event 1=Censor Assign "." for missing.	adtte
DORD	DOR (Days)		For PARAMCD=DOR_D, AVAL value is assigned to DORD. For subjects where DOR_D is missing, assign "." When TTRCFLCD=0, then DORD = 0	adtte
DORM	DOR (Months)		For PARAMCD=DOR_M, AVAL value is assigned to DORM. For subjects where DOR_M is missing, assign "." When TTRCFLCD=0, then DORM = 0	adtte
DORY	DOR (Years)		For PARAMCD=DOR_D, (AVAL/365) value is assigned to DORY For subjects where DOR_Y is missing, assign "." When TTRCFLCD=0, then DORY = 0	derived
ORDRESP		0,1,2,3,4,5,6	For PARAMCD=BCRSP, assign 0 for PD 1 for SD 2 for MR 3 for PR 4 for VGPR 5 for CR 6 for sCR	adrs
MAXPRED			Obtain AVAL for PARAMCD=MAXPRED. When AVAL is missing, MAXPRED = -999	adrs
RESPRATIO	Transform MAXRED to a ratio to baseline		RESPRATIO = max((100+MAXPRED)/100,0.001) • When MAXRED is missing, MAXRED = -999 and RESPRATIO= -99 • When MAXRED is less than -100 e.g. -100.15, RESPRATIO = negative (It is negative but greater than -8.99), then update RESPRATIO = 0.001 • When MAXRED is equal to -100, RESPRATIO = 0, then update RESPRATIO = 0.001	adrs,derived
RSPTYP	Response Type	1,2,3	1 for Serum M-Protein 2 for Serum FLC	adrs

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			3 for Urine M-Protein	
CUMAMTP	Cumulative dose to progression (mg)		This is needed to derive Time-average AUC till progression. For adtte.PARAMCD=PFS_D, adex.PARAMCD=ALTDOSE, CUMAMTP= Cumulative of adex.AVAL starting from adtte.STARTDT and ending at adtte.ADT For progression that occurred on dosing days, the dose on the progression day was not included in the cumulative dose calculation. Here is the code for that: When adtte.ADT = adex.ASTDT at the last dose for that subject, then CUMAMTCT= Cumulative of adex.AVAL starting from adtte.STARTDT and ending at (adtte.ADT -1)	adex, adtte
TAAUCP	Time-average AUC till progression (AUC/day)		The area under the plasma ADC concentration–time curve (AUC) per day (AUC/day) will be derived for each patient using the available ADC dosing information, individual patient clearance values from the population pharmacokinetic model, and the time to the occurrence of the PFS	popPK output, adtte
CUMAMTR	Cumulative dose to Response (mg)		This is needed to derive Time-average AUC till response. For adtte.PARAMCD=TTR_D, • adex.PARAMCD=ALTDOSE, CUMAMTR= Cumulative of adex.AVAL starting from adtte.STARTDT and ending at adtte.ADT • For response that occurred on dosing days, the dose on the response day was not included in the cumulative dose calculation. Here is the code for that: When adtte.ADT = adex.ASTDT at the last dose for that subject, then CUMAMTCT= Cumulative of adex.AVAL starting from adtte.STARTDT and ending at (adtte.ADT -1) When TTRCFLCD=0 (i.e. subjects who did not respond), then CUMAMTR=TOTAMT	adex, adtte
TAAUCR	Time-average AUC till response (AUC/day)		The area under the plasma ADC concentration–time curve (AUC) per day (AUC/day) will be derived for each patient using the available ADC dosing information, individual patient clearance values from the population pharmacokinetic model, and the time to the occurrence of the response	popPK output, adtte
AMT	Amount (in mg) of GSK2857916 given in first cycle		AMT = AVAL when PARAMCD=ALTDOSE and AVISIT= CYCLE 1 DAY 1	adex
IDOSE	GSK2857916 initial cycle dose (mg/kg)	>0	IDOSE=adex.TRT01A; strip off units	adex
CMAX	First dose Cmax of			PopPK

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	ADC – model predicted EOI concentration in Cycle 1 (ng/mL)		Individual model predicted conc. at EOI.	output
MMAFCMAX	First dose Cmax. of MMAF – model predicted 24 HOURS POST-EOI in Cycle 1 (ng/mL)		Individual model predicted conc. at 24 HOURS POST-EOI in Cycle 1	PopPK output
CTAU	First dose C_{tau} of ADC– model predicted pre-dose concentration Cycle 2		Individual model predicted pre-dose conc.CYCLE 2.	PopPK output
AUC	First dose AUC(0-inf) of ADC (ug.day/mL)		First dose (mg)/Individual Clearance of ADC (L/Day)	popPK output
MMAFAUC	First dose AUC(0-inf) of MMAF (ug.day/mL)		First dose (mg)/Individual Clearance of MMAF (L/Day)	popPK output
TOTCYC	Total number of CYCLES		TOTCYC=AVAL, AVAL for adex.PARAM=Total Number of Cycles	adex
CANCER	Cancer type	0 or 1	0=Multiple Myeloma, 1=BCMA positive Lymphomas If TRT01AN = 12, then CANCER=1, else CANCER=0	adsl
ETHN	Subject ethnicity	Same coding as CRF/Stats	Fill in ETHN in all rows for each subject If missing, ETHN = -99	adsl
AGE	Age (years)		Use value as defined by Stats;	adsl
SEX	GENDER	0 or 1	Male = 1 Female = 0 • If sex is missing, GENDER = -99	adsl
BWT	Baseline Weight (kg)		• Use baseline value as defined by Stats in the lab test datasets; • If not defined by Stats, set to weight measurement nearest to, but prior to, time of first dose • Only in cases where Day 1 weight is not available, but screening weight is, the screening values will be used.	adsl
BECOG	Baseline ECOG status	0 1 2	Fill on all rows	adqs
ECOG	ECOG status	0 1 2	ECOG is propagated forward from the most recent measurement for all observations up to the next ECOG measurement (LOCF). Please capture the values corresponding to the PK time points.	adqs
PRIORRX	Prior line of therapy		When addc.PARAMCD= LTXCPSCR, then	addc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			PRIORRX = AVALC (Extract only the number and not the text) For AVALC = MORE THAN 10 LINES, PRIORRX=11 Fill on all rows	
REFRAC	Refractory status	0 = Double 1 = Other	Fill on all rows	
MMTY	Type of Multiple Myeloma	0 = Secretory 1= Non-secretory	When addc.MMYELOTY=SECRETORY, MMTY=0 When addc.MMYELOTY= NONSECRETORY, MMTY=1 If addc.MMYELOTY is missing, assign MMTY=-99 Fill on all rows.	addc
MMIGTY	Myeloma immunoglobulin	0 = IGA 1 = IGG 2 = IGM 3 = OTHER	When addc.PARAMCD=MYELOIG and AVALC=IGA, then MMIGTY =0 When addc.PARAMCD=MYELOIG and AVALC=IGG, then MMIGTY =1 When addc.PARAMCD=MYELOIG and AVALC=IGM, then MMIGTY =2 For AVALC which is not equal to IGA/ IGG /IGM, then MMIGTY=3 Fill on all rows	addc
BSTAGE	Stage at Screening	1 = I 2 = II 3 = III 4 = UNKNOWN or missing	When addc.PARAMCD = STAGESCR and AVALC = I, then BSTAGE = 1 When addc.PARAMCD = STAGESCR and AVALC = II, then BSTAGE = 2 When addc.PARAMCD = STAGESCR and AVALC = III, then BSTAGE = 3 When addc.PARAMCD = STAGESCR and AVALC = UNKNOWN or missing , then BSTAGE = 4 Fill on all rows	addc

16.10.2. Pharmacokinetic / Pharmacodynamic Methodology

The primary goal of this analysis is to characterize the pharmacokinetic/pharmacodynamic relationships for GSK2857916 administered IV in subjects with multiple myeloma, data permitting. In these analyses, drug plasma concentration (or pharmacokinetic parameter) data and pharmacodynamic data will be subjected to logistic regression and time-to-event analyses, as appropriate, using suitable software. The influence of subject demographics and baseline characteristics, including

disease activity, in this population may be investigated. This analysis will be performed by CPMS and reported separately.

16.10.2.1. Exposure-Response Analyses

16.10.2.1.1. Corneal Events

Presence or absence of corneal events will be described using a conventional logistic regression model for both ≥ Grade 1 and ≥ Grade 2 toxicity. Time to first corneal event will be explored using Kaplan Meier plots categorized by exposure measures. Severity of corneal event will be analyzed using an ordered logistic regression model assuming Grades 0 (no toxicity), 1, 2 and 3, with exposure subdivided into quartiles and quintiles.

16.10.2.1.2. Clinical Response

Presence or absence of clinical response will be described using a conventional logistic regression model. Time to response will be explored using Kaplan Meier plots categorized by exposure measures.

PFS will be explored using Kaplan Meier plots categorized by exposure measures and occurrence of progression may also be described using a conventional logistic regression model.

Duration of response will be explored using Kaplan Meier plots categorized by exposure measures.

Best clinical response will be analyzed using an ordered logistic regression, with response categorized from 0 (progressive disease) to 6 (stringent complete response). Exposure will be treated as a categorical variable subdivided into quartiles and quintiles.

In the ordered logistic regression analyses, the use of categorical measures of exposure in lieu of continuous variables will allow for non-parametric descriptions of response functions.

Best clinical response as assessed by maximum reduction in M-protein or FLC will be analyzed by exposure (continuous and/or categorized by exposure measures).

16.11. Appendix 11: Abbreviations & Trade Marks

16.11.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
Ae(0-t)	Amount of drug excreted in urine from dosing to time t
AIC	Akaike's Information Criteria
A&R	Analysis and Reporting
AUC	Area under the concentration-time curve
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CR	Complete response
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
CBR	Clinical benefit rate
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence interval
CK-MB	Creatine kinase MB-isoenzyme
CL	Clearance
Cmax	Maximum observed plasma drug concentration
CPMS	Clinical Pharmacology Modeling and Simulation
CR	Complete response
CRM	Continual Reassessment Method
Ctrough	Concentration observed prior to the next dose
Cys-mcMMAF	Cysteine-maleimidocaproyl monomethyl auristatin F
DLT	Dose limiting toxicity
DOB	Date of Birth
DOR	Duration of response
DP	Decimal Places
eDiary	Electronic Diary
ECOG	Eastern Cooperative Oncology Group
EOI	End of infusion
eCRF	Electronic Case Record Form
EMA	European Medicines Agency
FACTS	Fixed and adapted clinical trials simulator
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
Fe(0-t)	Fraction of administered dose excreted in urine from dosing to time t
FLC	Free light chain

Abbreviation	Description
FTIH	First time in human
GSK	GlaxoSmithKline
IA	Interim Analysis
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
ITT	Intent-To-Treat
LDH	Lactate dehydrogenase
MMRM	Mixed Model Repeated Measures
MM	Multiple Myeloma
MMAF	Monomethyl auristatin F
MR	Minimal response
MTD	Maximum Tolerated Dose
NCI-CTCAE	National Cancer Institute – Common Terminology Criteria for Adverse Events
N-CRM	A modification of the Continual Reassessment Method (CRM) proposed by Neuenschwander et al.
NEI-VFQ-25	National Eye Institute Visual Functioning Questionnaire - 25
NONMEM	Nonlinear mixed effects modelling
ORR	Overall response rate
OS	Overall survival
OSDI	Ocular Surface Disease Index
PCI	Potential Clinical Importance
PD	Pharmacodynamics
PD	Progressive disease
PDMP	Protocol Deviation Management Plan
PET	Probability of early termination
PFS	Progression-free survival
PK	Pharmacokinetics
PP	Per Protocol
PR	Partial response
PopPK	Population PK
QC	Quality Control
QoL	Quality of life
QTcF	Fridericia's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
REML	Restricted maximum likelihood
Ro	Observed accumulation ratio
RP2	Recommended Phase 2
SAC	Statistical Analysis Complete
SAE	Serious adverse event
sBCMA	Soluble B-cell maturation antigen

Abbreviation	Description
sCR	Stringent complete response
SD	Stable disease
SDSP	Study Data Standardization Plan
SDTM	Study Data Tabulation Model
SOI	Start of infusion
SPEP	Serum protein electrophoresis
SOP	Standard Operation Procedure
t½	Terminal phase half-life
TA	Therapeutic Area
TFL	Tables, Figures & Listings
tlast	Time of last quantifiable concentration
tmax	Time to maximum drug concentration
TTBR	Time to best response
TTP	Time to progression
TTR	Time to response
ULN	Upper limit of normal
UPEP	Urine protein electrophoresis
VGPR	Very good partial response
Vss	Volume of distribution at steady state

16.11.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
NONE

Trademarks not owned by the GlaxoSmithKline Group of Companies
FACTS
NONMEM
SAS
WinNonlin

16.12. Appendix 12: List of Data Displays

16.12.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.0010 to 1.xxxx	11.0010 to 11.xxxx
Efficacy	2.0010 to 2.xxxx	12.0010 to 12.xxxx
Safety	3.0010 to 3.xxxx	13.0010 to 13.xxxx
Pharmacokinetic	4.0010 to 4.xxxx	14.0010 to 14.xxxx
Population Pharmacokinetic (PopPK)	5.0010 to 5.xxxx	15.0010 to 15.xxxx
Pharmacodynamic and / or Biomarker	6.0010 to 6.xxxx	16.0010 to 16.xxxx
Pharmacokinetic / Pharmacodynamic	7.0010 to 7.xxxx	17.0010 to 17.xxxx
Section	**Listings**	
ICH Listings	1.0010 to 1.xxxx	
Other Listings	30.0010 to 30.xxxx	

16.12.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 13: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Population Pharmacokinetic (PopPK)	POPPK_Fn	POPPK_Tn	POPPK_Ln
Pharmacodynamic and / or Biomarker	PD_Fn	PD_Tn	PD_Ln
Pharmacokinetic / Pharmacodynamic	PKPD_Fn	PKPD_Tn	PK/PD_Ln

NOTES:

- Non-Standard displays are indicated in the 'IDSL / Example Shell' or 'Programming Notes' column as '[Non-Standard] + Reference.'

16.12.3. Deliverables

Delivery [Priority] [1]	Description
DS [X]	During Study
DE [X]	Dose Escalation
IA SAC [X]	Interim Analysis Statistical Analysis Complete
SAC [X]	Final Statistical Analysis Complete

NOTES:

1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort.

16.12.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.0010	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0011	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0012	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0013	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0020	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0021	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0022	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0023	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0030	Enrolled	NS1	Summary of Number of Participant by Country and Site ID (MM)	Include columns: No Treatment, Part 1, Part 2 MM, All Treated MM, Total column will be the subjects enrolled to MM cohort. Add a footnote: This summary is based on all subjects enrolled into multiple	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				myeloma cohorts.	
1.0031	Enrolled	NS1	Summary of Number of Participant by Country and Site ID (NHL)	Include columns: No Treatment, Part 2 NHL, Total column will be the subjects enrolled to NHL cohort. Add a footnote: This summary is based on all subjects enrolled into lymphoma cohorts.	SAC
1.0050	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0051	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0052	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0053	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Protocol Deviation					
1.0040	All Treated	DV1	Summary of Important Protocol Deviations (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0041	All Treated	DV1	Summary of Important Protocol Deviations (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0042	All Treated	DV1	Summary of Important Protocol Deviations (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0043	All Treated	DV1	Summary of Important Protocol Deviations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Population Analysed					
1.0060	Enrolled	SP1	Summary of Study Populations (MM)	Report for: Part 1, (Summarize: by ascending dose level, Total). This table is based on subjects enrolled to MM, we do not have screen failure data, hence no screened population. For columns, include No Treatment, No Treatment for Part 1, No Treatment for Part 2 MM, Dose levels in part 1, All Treated in Part 1, All Treated in Part 2, All Treated and Total. Rows: include Enrolled, Part 1, Part 2 MM, All Treated MM, DLT Evaluable, PK, PD	SAC [A]
1.0061	Enrolled	SP1	Summary of Study Populations (NHL)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). This table is	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				based on subjects enrolled to NHL, we do not have screen failure data, hence no screened population. For columns, include No Treatment, All Treated and Total. Rows: include Enrolled, Part 2 NHL, PK, PD	
1.0430	Enrolled	SP2A	Summary of the Exclusions from the Part 1 Population		SAC [A]
1.0431	Enrolled	SP2A	Summary of the Exclusions from the Part 2 MM Population		SAC [A]
1.0432	Enrolled	SP2A	Summary of the Exclusions from the All Treated MM Population		SAC [A]
1.0433	Enrolled	SP2A	Summary of the Exclusions from the Part 2 NHL Population		SAC [A]
1.0434	Enrolled	SP2A	Summary of the Exclusions from the All Treated Population		SAC [A]
1.0435	Enrolled	SP2A	Summary of the Exclusions from the DLT Evaluable Population		SAC [A]
1.0436	Enrolled	SP2A	Summary of the Exclusions from the Pharmacokinetic (PK) Population		SAC [A]
1.0437	Enrolled	SP2A	Summary of the Exclusions from the Pharmacodynamic (PD) Population		SAC [A]
Demographic and Baseline Characteristics					
1.0070	All Treated	DM1	Summary of Demographic Characteristics (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0071	All Treated	DM1	Summary of Demographic Characteristics (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0072	All Treated	DM1	Summary of Demographic Characteristics (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0073	All Treated	DM1	Summary of Demographic Characteristics (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0290	Enrolled	DM11	Summary of Age Ranges (MM)	Include columns "No Treatment", "Part 1", "Part 2 MM", "All Treated MM", "Total"	SAC [A]
1.0291	Enrolled	DM11	Summary of Age Ranges (NHL)	Include columns "No Treatment", "Part 2 NHL", "Total"	SAC
1.0080	All Treated	DM5	Summary of Race and Racial Combinations (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0081	All Treated	DM5	Summary of Race and Racial Combinations (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0082	All Treated	DM5	Summary of Race and Racial Combinations (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0083	All Treated	DM5	Summary of Race and Racial Combinations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0090	All Treated	DM6	Summary of Race and Racial Combination Details (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0091	All Treated	DM6	Summary of Race and Racial Combination Details (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0092	All Treated	DM6	Summary of Race and Racial Combination Details (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0093	All Treated	DM6	Summary of Race and Racial Combination Details (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Prior and Concomitant Medications					
1.0190	All Treated	MH1	Summary of Past Medical Conditions (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0191	All Treated	MH1	Summary of Past Medical Conditions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0192	All Treated	MH1	Summary of Past Medical Conditions (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0193	All Treated	MH1	Summary of Past Medical Conditions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0200	All Treated	MH1	Summary of Current Medical Conditions (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0201	All Treated	MH1	Summary of Current Medical Conditions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0202	All Treated	MH1	Summary of Current Medical Conditions (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0203	All Treated	MH1	Summary of Current Medical Conditions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0210	All Treated	CM8	Summary of Concomitant Medications (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0211	All Treated	CM8	Summary of Concomitant Medications (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0212	All Treated	CM8	Summary of Concomitant Medications (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0213	All Treated	CM8	Summary of Concomitant Medications (Part 2 NHL)	Report for: Part 2 NHL,	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				(Summarize: only for 3.4 NHL).	
1.0380	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more than one category for 'Drug Class' and 'Drug'.	SAC [A]
1.0381	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more than one category for 'Drug Class' and 'Drug'.	SAC [A]
1.0382	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more than one category for 'Drug Class' and 'Drug'.	SAC [A]
1.0383	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				than one category for 'Drug Class' and 'Drug'.	
1.0510	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). If the CRF does not have any coded procedures and collection of surgeries is restricted to prior cancer related surgeries, then a summary is not necessary as the number and percent of subjects with surgeries will be provided in the anticancer therapy display (see Example AC1). Otherwise a simplified version of the summary can be utilized if appropriate (see example OSP2).	SAC [A]
1.0511	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0512	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0513	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Exposure and Treatment Compliance					
1.0240	All Treated	OEX5	Summary of Exposure to GSK2857916 (Part 1)	Report for population: Part 1, (Summarize: by ascending dose level, Total). Do not need "Dose Intensity "	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				section. Use 4, <4, >4 cycles	
1.0241	All Treated	OEX5	Summary of Exposure to GSK2857916 (Part 2 MM)	Report for population: Part 2 MM, (Summarize: only for 3.4 MM). Do not need "Dose Intensity " section. Use 4, <4, >4 cycles	SAC [A]
1.0242	All Treated	OEX5	Summary of Exposure to GSK2857916 (All Treated MM)	Report for population: All Treated MM, (Summarize: Total) Do not need "Dose Intensity " section. Use 4, <4, >4 cycles	SAC [A]
1.0243	All Treated	OEX5	Summary of Exposure to GSK2857916 (Part 2 NHL)	Report for population: 3.4 NHL, (Summarize: Total) Do not need "Dose Intensity " section. Use 4, <4, >4 cycles	SAC
1.0230	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Dose Intensity(mg/kg/cycle)	SAC [A]
1.0231	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Dose Intensity(mg/kg/cycle)	SAC [A]
1.0232	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Dose Intensity(mg/kg/cycle)	SAC [A]
1.0233	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Dose Intensity(mg/kg/cycle)	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0250	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0251	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0252	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0253	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0260	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0261	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0262	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0263	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0270	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0271	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0272	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0273	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0280	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0281	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0282	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0283	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Disease Characteristics					
1.0100	All Treated	DC2	Summary of Disease Characteristics at Screening (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summarize Stage (I, II, III, Unknown, Missing), Lines of therapy completed at screening (1-10 lines, More than 10 lines, Missing), Type of multiple myeloma (Nonsecretory, Secretory, Missing), Myeloma Light chain (Kappa Light Chain, Lambda Light Chain, Missing), Myeloma immunoglobulin (IgA, IgG, Other, Missing)	SAC [A]
1.0101	All Treated	DC2	Summary of Disease Characteristics at Screening (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summarize categories as defined in Table 1,0100.	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0102	All Treated	DC2	Summary of Disease Characteristics at Screening (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summarize categories as defined in Table 1,0100.	SAC [A]
1.0103	All Treated	DC2	Summary of Disease Characteristics at Screening (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0110	All Treated	POP_T1	Summary of Genetic Characteristics at Screening (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0111	All Treated	POP_T1	Summary of Genetic Characteristics at Screening (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0112	All Treated	POP_T1	Summary of Genetic Characteristics at Screening (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0300	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include alll optional columns.	SAC [A]
1.0301	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include all optional columns.	SAC [A]
1.0302	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include all optional columns.	SAC [A]
1.0303	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Include all optional columns.	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0390	All Treated	POP_T2	Summary of Cytogenetics Risk at Screening (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0391	All Treated	POP_T2	Summary of Cytogenetics Risk at Screening (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0392	All Treated	POP_T2	Summary of Cytogenetics Risk at Screening (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
Prior and Follow-up Anti-Cancer Therapy					
1.0120	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0121	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0122	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0123	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0130	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0131	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0132	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0133	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0140	All Treated	POP_T3	Summary of Prior Anti-Cancer Therapy by Drug Class of Agents (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0141	All Treated	POP_T3	Summary of Prior Anti-Cancer Therapy by Drug Class of Agents (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0142	All Treated	POP_T3	Summary of Prior Anti-Cancer Therapy by Drug Class of Agents (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0150	All Treated	POP_T4	Summary of Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0151	All Treated	POP_T4	Summary of Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0152	All Treated	POP_T4	Summary of Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0160	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Therapies should be sorted in highest to lowest incidence. Include radio therapy and surgical procedures.	SAC [A]
1.0161	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Therapies should be sorted in highest to lowest incidence. Include radio therapy and surgical procedures.	SAC [A]
1.0162	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Therapies should be sorted in highest to	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				lowest incidence. Include radio therapy and surgical procedures.	
1.0163	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Therapies should be sorted in highest to lowest incidence. Include radio therapy and surgical procedures.	SAC
1.0170	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Only use last therapy prior to starting study,	SAC [A]
1.0171	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Only use last therapy prior to starting study	SAC [A]
1.0172	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Only use last therapy prior to starting study	SAC [A]
1.0173	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0470	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0471	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0472	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0473	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Duration of Follow-up					
1.0310	All Treated	FAC2	Summary of Duration of Follow-up (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include all optional columns.	SAC [A]
1.0311	All Treated	FAC2	Summary of Duration of Follow-up (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include all optional columns.	SAC [A]
1.0312	All Treated	FAC2	Summary of Duration of Follow-up (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include al optional columns.	SAC [A]
1.0313	All Treated	FAC2	Summary of Duration of Follow-up (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Include all optional columns.	SAC
1.0400	All Treated	FAC2	Summary of Duration of Follow-up for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0401	All Treated	FAC2	Summary of Duration of Follow-up for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0402	All Treated	FAC2	Summary of Duration of Follow-up for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0410	All Treated	FAC2	Summary of Duration of Follow-up for Subjects without Prior	Report for: Part 1, (Summarize: by	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Daratumumab Treatment (Part 1)	ascending dose level, Total).	
1.0411	All Treated	FAC2	Summary of Duration of Follow-up for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0412	All Treated	FAC2	Summary of Duration of Follow-up for Subjects without Prior Daratumumab Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0420	All Treated	FAC2	Summary of Duration of Follow-up for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0421	All Treated	FAC2	Summary of Duration of Follow-up for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0422	All Treated	FAC2	Summary of Duration of Follow-up for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
Blood and Blood Supportive Care Products					
1.0480	All Treated	BP1A	Summary of Blood Products (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0481	All Treated	BP1A	Summary of Blood Products (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0482	All Treated	BP1A	Summary of Blood Products (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0483	All Treated	BP1A	Summary of Blood Products (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0490	All Treated	BP1C	Summary of Blood Supportive Care Products (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0491	All Treated	BP1C	Summary of Blood Supportive Care Products (Part 2 MM)	Report for: Part 2 MM, (Summarize:	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				only for 3.4 MM).	
1.0492	All Treated	BP1C	Summary of Blood Supportive Care Products (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0493	All Treated	BP1C	Summary of Blood Supportive Care Products (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Substance Use					
1.0500	All Treated	SU1	Summary of Substance Use (Part 1)	Report for : Part 1, (Summarize: by ascending dose level, Total). All substance collected in eCRF	SAC [A]
1.0501	All Treated	SU1	Summary of Substance Use (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). All substance collected in eCRF	SAC [A]
1.0502	All Treated	SU1	Summary of Substance Use (All Treated MM)	Report for: All Treated MM, (Summarize: Total). All substance colleced in eCRF	SAC [A]
1.0503	All Treated	SU1	Summary of Substance Use (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). All substance colleced in eCRF	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.5. Study Population Figures

Study Population: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
11.0020	All Treated	POP_F2	Plot of Dose Reduction of GSK2857916 by Cycle (Part 2 MM)	Report for population subgroup: Part 2 MM. Combine 1.9 mg/kg and 1.7 mg/kg dose groups as 1.7 mg/kg. Sort the bar by descending dose levels. Add foot note "Doses 1.9 mg/kg and 1.7 mg/kg are combined and represented by 1.7 mg/kg."	SAC [A]
11.0030	All Treated	OEX12	Plot of Duration of Study Treatment by Response (Part 1)	Report for population subgroup: Part 1. Y axis: dose cohort. Use best confirmed response. Please add the footnote regarding treatment duration consistent with the one in OEX12.	SAC [A]
11.0031	All Treated	OEX12	Plot of Duration of Study Treatment by Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Y axis: dose cohort. Use best confirmed response. Please add the footnote regarding treatment duration consistent with the one in OEX12.	SAC [A]
11.0032	All Treated	OEX12	Plot of Duration of Study Treatment by Response (All Treated MM)	Report for population subgroup: All Treated MM. Y axis: dose cohort. Use best confirmed response. Please add the footnote regarding	SAC [A]

Study Population: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				treatment duration consistent with the one in OEX12.	

NOTES:
A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.6. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
2.0020	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate:	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				(sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table. Footnote: The 95% Confidence Interval is based on Exact method.	
2.0021	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (IMWG 2011) (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	SAC [A]
2.0180	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0181	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (IMWG 2011) (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Clinical Benefit Rate (No p-value) in one table.	
2.0110	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects without Prior Daratumumab Treatment (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	SAC [A]
2.0111	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects without Prior Daratumumab Treatment (IMWG 2011) (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD),	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0040	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	SAC [A]
2.0041	All	RE1a	Summary of Investigator-Assessed Best Response (With	Report for population subgroup:	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
	Treated		Confirmation) for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (IMWG 2011) (Part 2 MM)	Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0060	All Evaluable Subjects MM	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (IMWG 2011) (All Evaluable Subjects MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR).	IA

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0342	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (RRMCL) (Part 2 NHL)	Report for population subgroup: Part 2 NHL. Summarize for 3.4 NHL. Best Response: Complete response (CR), Partial Response (PR). Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (CR+PR).	SAC
Time-to Event Endpoint					
2.0081	All Treated	TTE1a	Summary of Duration of Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.Only summarize for subjects with a confirmed PR or better.	SAC [A]
2.0201	All Treated	TTE1	Summary of Duration of Response for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0161	All Treated	TTE1	Summary of Duration of Response for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				MM. Do not include Hazard Ratio and Log-Rank P-Value.	
2.0171	All Treated	TTE1	Summary of Duration of Response for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0071	All Treated	TTE1	Summary of Progression-Free Survival (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0261	All Treated	TTE1	Summary of Progression-Free Survival for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0131	All Treated	TTE1	Summary of Progression-Free Survival for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0141	All Treated	TTE1	Summary of Progression-Free Survival for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Summary of Progression-Free Survival for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	SAC [A]
2.0091	All Treated	TTE1a	Summary of Time to Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.0101	All Treated	TTE1a	Summary of Time to Progression (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0311	All Treated	TTE1a	Summary of Time to Best Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0321	All Treated	TTE6a	Summary of Kaplan-Meier Estimates of Overall Survival at 9 Months (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Produce if all the patients (who were alive at the time of study completion) can be re-consented.	SAC
2.0331	All Treated	TTE6a	Summary of Kaplan-Meier Estimates of Overall Survival at One Year (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Produced if all the patients (who were alive at the time of study completion) can be re-consented.	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.7. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
M-Protein and FLC					
12.0010	All Treated	RE8b	Percent Change at Maximum Reduction from Baseline in M-Protein (or FLC) Measurement (Part 1)	Report for population subgroup: Part 1. Include text for best confirmed response only. Remove subject ID. Include reference lines for 25%, 0, -25%, -50%, -90%, -100%.. Indicate lab test types by different symbols. Indicate dose groups by different colours of the vertical bars.	SAC [A]
12.0011	All Treated	RE8b	Percent Change at Maximum Reduction from Baseline in M-Protein (or FLC) Measurement (Part 2 MM)	Report for population subgroup: Part 2 MM. Include text for best confirmed response only. Remove subject ID. Include reference lines for 25%, 0, -25%, -50%, -90%, -100%. Indicate lab test types by different shades.	SAC [A]
12.0020	All Treated	EFF_F1	Correlation of Free Soluble BCMA at Pre-Dose (Cycle 1) and Maximum Percentage Change from Baseline in Serum M-Protein, Urine M-Protein or Serum FLC (Part 1)	Report for population subgroup: Part 1. Use best confirmed response. Colored by different dose groups. Use different symbols to indicate Serum M-protein, Urine M-protein, and Serum FLC. Do not include R square and fitted line.	SAC [A]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
12.0021	All Treated	EFF_F1	Correlation of Free Soluble BCMA at Pre-Dose (Cycle 1) and Maximum Percentage Change from Baseline in Serum M-Protein, Urine M-Protein or Serum FLC (Part 2 MM)	Report for population subgroup: Part 2 MM. Use best confirmed response. Do not include R square and fitted line.	SAC [A]
Time-to-Event Endpoint					
12.0041	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves (Part 2 MM)	Report for population subgroup: Part 2 MM. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	SAC [A]
12.0161	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	SAC [A]
12.0081	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	SAC [A]
12.0071	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	SAC [A]
12.0051	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response	Report for population subgroup: Part 2 MM.and only for subjects	SAC [A]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			(Part 2 MM)	with a confirmed PR or better. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	
12.0171	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	SAC [A]
12.0101	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	SAC [A]
12.0111	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. In addition to the number of 'At risk', please also provide the number of event by timepoint for K-M plots.	SAC [A]
Forest Plot					
12.0120	All Treated	EFF_F2	Forest Plot - Overall Response Rate (ORR) (Part 2 MM)		SAC [A]
Profile Plot of Responders					
12.0150	All Treated	EFF_F3	Profile Plot of Responders (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.8. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.0030	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0031	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0032	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0033	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0040	All Treated	AE3	Summary of All Adverse Events by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0041	All Treated	AE3	Summary of All Adverse Events by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0042	All Treated	AE3	Summary of All Adverse Events by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0043	All Treated	AE3	Summary of All Adverse Events by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0910	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0911	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0912	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0913	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0720	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0721	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0722	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0730	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects without Prior Daratumumab Treatment (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0731	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0732	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects without Prior Daratumumab Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0740	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0741	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0742	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0750	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0751	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0752	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects with Prior Daratumumab Treatment and Refractory to Both Immunomodulators and Proteasome Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0760	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects without Prior Daratumumab Treatment (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0761	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0762	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects without Prior Daratumumab Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0770	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0771	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0772	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects Refractory to Both Immunomodulators and Proteasome Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0780	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0781	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0782	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0783	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0790	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0791	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0792	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0793	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0060	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0061	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0062	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0063	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0690	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total).	SAC [A]
3.0691	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
3.0692	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0693	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0710	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0711	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0712	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0713	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0010	All Treated	AE13	Adverse Event Overview (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0011	All Treated	AE13	Adverse Event Overview (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0012	All Treated	AE13	Adverse Event Overview (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0013	All Treated	AE13	Adverse Event Overview (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0100	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0101	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0102	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0103	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0170	DLT Evaluable	DL1	Summary of Dose-Limiting Toxicities during the Determinative Period (Part 1) (Day 1-21)	Report for: Part 1, (Summarize: by ascending dose level, Total). Section 3.3.3 of the protocol: An event will be	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				considered a DLT if its relationship to the investigational agent cannot be ruled out occurs within the DLT reporting period (first 21 days of treatment for schedule 1, and first 28 days for schedule 2)	
Serious and Other Significant Adverse Events					
3.0700	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0701	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0702	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0703	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0080	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0081	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0082	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0083	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0800	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0801	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0802	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0803	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0120	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0121	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0122	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0123	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0130	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0131	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0132	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0133	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0140	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0141	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0142	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0143	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0630	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0631	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0632	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions,	Report for: All Treated MM,	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (All Treated MM)	(Summarize: Total).	
3.0633	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0640	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0641	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0642	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0643	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0650	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0651	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0652	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0653	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0660	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0661	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0662	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0663	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Adverse Events of Interest					
3.0430	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0431	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0432	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total	SAC [A]
3.0433	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0520	All Treated	ESI1	Summary of Characteristics of Corneal Events (Part 1)	Report for: Part 1, (Summarize: by	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				ascending dose level, Total). Summary based on both all subjects and subjects with events.	
3.0521	All Treated	ESI1	Summary of Characteristics of Corneal Events (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0522	All Treated	ESI1	Summary of Characteristics of Corneal Events (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0523	All Treated	ESI1	Summary of Characteristics of Corneal Events (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Summary based on both all subjects and subjects with events.	SAC
3.0180	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0181	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0182	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				resolution: 1-21, 22-42, >42.	
3.0183	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC
3.0150	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0151	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0152	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0153	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0160	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0161	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0162	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0163	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0560	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0561	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and	Report for: Part 2 MM, (Summarize:	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Maximum Grade (Part 2 MM)	only for 3.4 MM)	
3.0562	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0563	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0530	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0531	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0532	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0533	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0190	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				include both 'thrombocytopenia' and 'platelet count decreased'	
3.0191	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should include both 'thrombocytopenia' and 'platelet count decreased'	SAC [A]
3.0192	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should include both 'thrombocytopenia' and 'platelet count decreased'	SAC [A]
3.0193	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should include both 'thrombocytopenia' and 'platelet count decreased'	SAC
3.0580	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0581	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0582	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0583	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0590	All Treated	ESI1	Summary of Characteristics of Neutropenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0591	All Treated	ESI1	Summary of Characteristics of Neutropenia (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0592	All Treated	ESI1	Summary of Characteristics of Neutropenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0593	All Treated	ESI1	Summary of Characteristics of Neutropenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0860	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Neutropenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0861	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of	Report for: Part 2 MM, (Summarize:	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Neutropenia (Part 2 MM)	only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	
3.0862	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Neutropenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0863	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Neutropenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC
3.0550	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0551	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0552	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0553	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: All Treated MM, (Summarize: Total).	SAC
3.0540	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0541	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				on both all subjects and subjects with events.	
3.0542	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0543	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0870	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0871	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0872	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0873	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42,	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				>42.	
3.0110	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0111	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0112	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0113	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0600	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0601	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0602	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0603	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0880	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of	Report for: Part 1, (Summarize: by	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Infusion-Related Reactions (Part 1)	ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	
3.0881	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Infusion-Related Reactions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0882	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Infusion-Related Reactions (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0883	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Infusion-Related Reactions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC
Laboratory: Chemistry					
3.0270	All Treated	LB1	Summary of Chemistry Changes from Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0271	All Treated	LB1	Summary of Chemistry Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0272	All Treated	LB1	Summary of Chemistry Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				baseline values.	
3.0273	All Treated	LB1	Summary of Chemistry Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0280	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0281	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0282	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0283	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0290	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0291	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: by starting dose level and tumor type, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0292	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0293	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC
3.0450	All Treated	OLB11B	Summary of LDH Laboratory Results (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				baseline'. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	
3.0451	All Treated	OLB11B	Summary of LDH Laboratory Results (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0452	All Treated	OLB11B	Summary of LDH Laboratory Results (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0453	All Treated	OLB11B	Summary of LDH Laboratory Results (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0470	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0471	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0472	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0473	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and <	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				5xULN, >=5xULN and < 10xULN, >=10xULN.	
Laboratory: Hematology					
3.0300	All Treated	LB1	Summary of Hematology Changes from Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0301	All Treated	LB1	Summary of Hematology Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0302	All Treated	LB1	Summary of Hematology Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0303	All Treated	LB1	Summary of Hematology Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0310	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0311	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0312	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0313	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Include only 'worst-case post-baseline'	
3.0320	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0321	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: by starting dose level and tumor type, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0322	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0323	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC
Laboratory: Urinalysis					
3.0360	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0361	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0362	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0363	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0680	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0681	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0682	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0683	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
Laboratory: Hepatobiliary (Liver)					
3.0200	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0201	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0202	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0203	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0210	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0211	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0212	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0213	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Coagulation					
3.0330	All Treated	LB1	Summary of Coagulation Changes from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0331	All Treated	LB1	Summary of Coagulation Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0332	All Treated	LB1	Summary of Coagulation Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0333	All Treated	LB1	Summary of Coagulation Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0340	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0341	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include only 'worst-case post-baseline'	SAC [A]
3.0342	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0343	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Include only 'worst-case post-baseline'	SAC
3.0350	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Produce only for lab tests that are	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	
3.0351	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: by starting dose level and tumor type, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	SAC [A]
3.0352	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	SAC [A]
3.0353	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
3.0370	All Treated	EG1	Summary of ECG Findings (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0371	All Treated	EG1	Summary of ECG Findings (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0372	All Treated	EG1	Summary of ECG Findings (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0373	All Treated	EG1	Summary of ECG Findings (Part 2 NHL)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC
3.0390	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0391	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0392	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0393	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Include only 'worst-case post-baseline'	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0400	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0401	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0402	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0403	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Include only 'worst-case post-baseline'	SAC
3.0380	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0381	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0382	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0383	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Vital Signs					
3.0220	All Treated	VS1	Summary of Change from Baseline in Vital Signs (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Add Cycle, Visit. Include baseline values.	SAC [A]
3.0221	All Treated	VS1	Summary of Change from Baseline in Vital Signs (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Add Cycle, Visit. Include baseline values.	SAC [A]
3.0222	All Treated	VS1	Summary of Change from Baseline in Vital Signs (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Add Cycle, Visit. Include baseline values.	SAC [A]
3.0223	All Treated	VS1	Summary of Change from Baseline in Vital Signs (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Add Cycle, Visit. Include baseline values.	SAC
3.0230	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0231	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0232	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0233	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0240	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0241	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0242	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0243	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0250	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0251	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0252	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0253	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0260	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0261	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0262	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0263	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
ECOG Performance Status					
3.0410	All Treated	PS1A	Summary of ECOG Performance Status (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0411	All Treated	PS1A	Summary of ECOG Performance Status (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0412	All Treated	PS1A	Summary of ECOG Performance Status (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0413	All Treated	PS1A	Summary of ECOG Performance Status (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0420	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0421	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0422	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0423	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Left Ventricular Ejection Fraction					
3.0480	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Footnote: LLN: Normal Range Lower Limit.	SAC [A]
3.0481	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Footnote: LLN: Normal Range Lower Limit.	SAC [A]
3.0482	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Footnote: LLN: Normal Range Lower Limit.	SAC [A]
3.0483	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Ocular Exams					
3.0490	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0491	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0492	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0493	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0500	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0501	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0502	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0503	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Death					
3.0570	All Treated	DTH1a	Summary of Deaths (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0571	All Treated	DTH1a	Summary of Deaths (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0572	All Treated	DTH1a	Summary of Deaths (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0573	All Treated	DTH1a	Summary of Deaths (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Constitutional B- Symptoms					
3.0813	All Treated	OCS1	Summary of Constitutional Symptoms over Time (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Organ Examination					
3.0823	All Treated	OOE1	Summary of Organ Examination over Time (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Health Outcome					
3.0830	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0831	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0832	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0833	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Anti-Drug Antibody					
3.0840	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0841	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0842	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0843	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0850	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0851	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0852	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0853	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.9. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory					
13.0130	All Treated	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part 1)	Report for sub-population: Part 1. Pool all subjects together.	SAC [A]
13.0131	All Treated	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
13.0133	All Treated	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
13.0120	All Treated	LIVER9	Scatter Plot of Maximum Bilirubin versus Maximum ALT - eDISH (Part 1)	Report for sub-population: Part 1. Pool all subjects together.	SAC [A]
13.0121	All Treated	LIVER9	Scatter Plot of Maximum Bilirubin versus Maximum ALT - eDISH (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
13.0122	All Treated	LIVER9	Scatter Plot of Maximum Bilirubin versus Maximum ALT - eDISH (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
13.0140	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum LDH - eDISH Plot (Part 1)	Report for sub-population: Part 1. Pool all subjects together. Bold reference lines are not needed. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]
13.0141	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum LDH - eDISH Plot (Part 2 MM)	Report for sub-population: Part 2 MM. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
13.0142	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum LDH - eDISH Plot (Part 2 NHL)	Report for sub-population: Part 2 NHL. Do not include Hy's Quadrant and Temple's Corollary.	SAC
13.0150	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum Creatinine Kinase - eDISH Plot (Part 1)	Report for sub-population: Part 1. Pool all subjects together. Bold reference lines are not needed. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]
13.0151	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum Creatinine Kinase - eDISH Plot (Part 2 MM)	Report for sub-population: Part 2 MM. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]
13.0152	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum Creatinine Kinase - eDISH Plot (Part 2 NHL)	Report for sub-population: Part 2 NHL. Do not include Hy's Quadrant and Temple's Corollary.	SAC
Adverse Events					
13.0160	All Treated	SAFE_F1	Proportions of Subjects with Infusion-related Reactions (Part 1)	Report for sub-population: Part 1. Pool all subjects together.	SAC [A]
13.0161	All Treated	SAFE_F1	Proportions of Subjects with Infusion-related Reactions (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
ECG					
13.0200	All Treated	OECG4	Fridericia's QTc Shifts from Baseline to Worst-case Post Baseline (Part 1)	Report for sub-population: Part 1. Pool all subjects together. If machine read QTcF is missing, use the manual read QTcF and add footnote that Machine and Manual calculate values are	SAC [A]

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				collapsed together.	
13.0201	All Treated	OECG4	Fridericia's QTc Shifts from Baseline to Worst-case Post Baseline (Part 2 MM)	Report for sub-population: Part 2 MM. If machine read QTcF is missing, use the manual read QTcF, and add footnote that Machine and Manual calculate values are collapsed together	SAC [A]
13.0202	All Treated	OECG4	Fridericia's QTc Shifts from Baseline to Worst-case Post Baseline (Part 2 NHL)	Report for sub-population: Part 2 NHL. If machine read QTcF is missing, use the manual read QTcF, and add footnote that Machine and Manual calculate values are collapsed together	SAC
Patient Profile Plot					
13.0190	All Treated	SAFE_F2	Profile Plot for Patients with No Corneal Event or Only Grade 1 Corneal Event (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
13.0191	All Treated	SAFE_F2	Profile Plot for Patients with Grade 2 or Higher Corneal Events (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.10. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Concentration					
4.0010	PK	PK01	Summary of Plasma GSK2857916 (ADC) PK Concentration-Time Data (Part 1)	By dose level	SAC [A]
4.0011	PK	PK01	Summary of Plasma GSK2857916 (ADC) PK Concentration-Time Data (Part 2 MM)		SAC [A]
4.0013	PK	PK01	Summary of Plasma GSK2857916 (ADC) PK Concentration-Time Data (Part 2 NHL)		SAC
4.0020	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) PK Concentration-Time Data (Part 1)	By dose level	SAC [A]
4.0021	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) PK Concentration-Time Data (Part 2 MM)		SAC [A]
4.0023	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) PK Concentration-Time Data (Part 2 NHL)		SAC
4.0030	PK	PK01	Summary of Plasma GSK2857916 (Unbound Antibody) PK Concentration-Time Data (Part 1)	By dose level	SAC [A]
4.0031	PK	PK01	Summary of Plasma GSK2857916 (Unbound Antibody) PK Concentration-Time Data (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
4.0033	PK	PK01	Summary of Plasma GSK2857916 (Unbound Antibody) PK Concentration-Time Data (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
4.0040	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data (Part 1)	By dose level	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0041	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data (Part 2 MM)		SAC [A]
4.0043	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data (Part 2 NHL)		SAC
PK Parameter					
4.0050	PK	PK06	Summary of Derived GSK2857916 (ADC) PK Parameters (Part 1)	By dose level PK06 with both transformed and untransformed values.	SAC [A]
4.0051	PK	PK06	Summary of Derived GSK2857916 (ADC) PK Parameters (Part 2 MM)	PK06 with both transformed and untransformed values.	SAC [A]
4.0053	PK	PK06	Summary of Derived GSK2857916 (ADC) PK Parameters (Part 2 NHL)	PK06 with both transformed and untransformed values.	SAC
4.0060	PK	PK06	Summary of Derived GSK2857916 (Total Antibody) PK Parameters (Part 1)	By dose level PK06 with both transformed and untransformed values.	SAC [A]
4.0061	PK	PK06	Summary of Derived GSK2857916 (Total Antibody) PK Parameters (Part 2 MM)	PK06 with both transformed and untransformed values.	SAC [A]
4.0063	PK	PK06	Summary of Derived GSK2857916 (Total Antibody) PK Parameters (Part 2 NHL)	PK06 with both transformed and untransformed values.	SAC
4.0070	PK	PK06	Summary of Derived GSK2857916 (Unbound Antibody) PK Parameters (Part 1)	By dose level PK06 with both transformed and untransformed values.	SAC [A]
4.0071	PK	PK06	Summary of Derived GSK2857916 (Unbound Antibody) PK Parameters (Part 2 MM)	PK06 with both transformed and untransformed values. If data was not collected, present “No data to	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				report"	
4.0073	PK	PK06	Summary of Derived GSK2857916 (Unbound Antibody) PK Parameters (Part 2 NHL)	PK06 with both transformed and untransformed values. If data was not collected, present "No data to report"	SAC
4.0080	PK	PK06	Summary of Derived cys-mcMMAF PK Parameter (Part 1)	By dose level PK06 with both transformed and untransformed values.	SAC [A]
4.0081	PK	PK06	Summary of Derived cys-mcMMAF PK Parameter (Part 2 MM)	PK06 with both transformed and untransformed values.	SAC [A]
4.0083	PK	PK06	Summary of Derived cys-mcMMAF PK Parameter (Part 2 NHL)	PK06 with both transformed and untransformed values.	SAC
4.0090	PK	PK13	Listing of Derived GSK2857916 (ADC) PK Parameters (Untransformed) (MM)		SAC [A]
4.0091	PK	PK13	Listing of Derived GSK2857916 (ADC) PK Parameters (Untransformed) (NHL)		SAC
4.0100	PK	PK13	Listing of Derived GSK2857916 (Total Antibody) PK Parameters (Untransformed) (MM)		SAC [A]
4.0101	PK	PK13	Listing of Derived GSK2857916 (Total Antibody) PK Parameters (Untransformed) (NHL)		SAC
4.0110	PK	PK13	Listing of Derived GSK2857916 (Unbound Antibody) PK Parameters (Untransformed) (MM)		SAC [A]
4.0111	PK	PK13	Listing of Derived GSK2857916 (Unbound Antibody) PK Parameters (Untransformed) (NHL)		SAC
4.0120	PK	PK13	Listing of Derived cys-mcMMAF PK Parameters		SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			(Untransformed) (MM)		
4.0121	PK	PK13	Listing of Derived cys-mcMMAF PK Parameters (Untransformed) (NHL)		SAC
4.0130	PK	PK03	Summary of cys-mcMMAF Pharmacokinetic Urine Excretin Data (Part 1)		SAC [A]
4.0140	PK	PK11	Listing of cys-mcMMAF Urine Excretion Data (Part 1)	replace Amount Excreted and Excretion Rate with Ae(0-24) and Fe	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Dose Proportionality Analysis					
4.0150	PK	PK_T1	Summary of Results of Dose Proportionality Analysis for GSK2857916 (ADC), GSK2857916 (Total Antibody), GSL2857916 (Unbound Antibody), and cys-mcMMAF PK Parameters Using Power Model (Part 1)	Example: PPD PPD AUC(0-inf), AUC(0-t), AUC(0- τ), Cmax, and Ctrough	SAC [A]
Accumulation Ratio					
4.0160	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) (Part 1)	By dose level, include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC [A]
4.0161	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) (Part 2 MM)	Include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC [A]
4.0163	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) (Part 2 NHL)	Include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC
4.0170	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) (Part 1)	By dose level, include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC [A]
4.0171	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) (Part 2 MM)	Include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC [A]
4.0173	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) (Part 2 NHL)	Include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC
4.0180	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) (Part 1)	By dose level, include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC [A]
4.0181	PK	PK05	Summary of Results of Accumulation Ratio Assessment for	Include Ro(CEOI) and	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			GSK2857916 (Unbound Antibody) (Part 2 MM)	Ro(Ctrough) in one table. 95%CI	
4.0183	PK	PK05	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) (Part 2 NHL)	Include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC
4.0190	PK	PK05	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF (Part 1)	By dose level, include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC [A]
4.0191	PK	PK05	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF (Part 2 MM)	Include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC [A]
4.0193	PK	PK05	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF (Part 2 NHL)	Include Ro(CEOI) and Ro(Ctrough) in one table. 95%CI	SAC
Analyte Ratio					
4.0200	PK	PK05	Summary of Results of Analyte Ratio Assessment for GSK2857916 (Total Antibody) (Part 1)	By dose level and cycle, include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC [A]
4.0201	PK	PK05	Summary of Results of Analyte Ratio Assessment for GSK2857916 (Total Antibody) (Part 2 MM)	Include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC [A]
4.0203	PK	PK05	Summary of Results of Analyte Ratio Assessment for GSK2857916 (Total Antibody) (Part 2 NHL)	Include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC
4.0210	PK	PK05	Summary of Results of Analyte Ratio Assessment for GSK2857916 (Unbound Antibody) (Part 1)	By dose level and cycle, include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC [A]
4.0211	PK	PK05	Summary of Results of Analyte Ratio Assessment for GSK2857916 (Unbound Antibody) (Part 2 MM)	Include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC [A]
4.0213	PK	PK05	Summary of Results of Analyte Ratio Assessment for GSK2857916 (Unbound Antibody) (Part 2 NHL)	Include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0220	PK	PK05	Summary of Results of Analyte Ratio Assessment for cys-mcMMAF (Part 1)	By dose level and cycle, include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC [A]
4.0221	PK	PK05	Summary of Results of Analyte Ratio Assessment for cys-mcMMAF (Part 2 MM)	Include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC [A]
4.0223	PK	PK05	Summary of Results of Analyte Ratio Assessment for cys-mcMMAF (Part 2 NHL)	Include Ra(CEOI) and Ra(Ctrough) in one table. 95%CI	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.11. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Concentration					
14.0010	PK	PK16	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0011	PK	PK16	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0013	PK	PK16	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0020	PK	PK16	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0021	PK	PK16	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0023	PK	PK16	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0030	PK	PK16	Individual Plasma GSK2857916 (Unbound Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0031	PK	PK16	Individual Plasma GSK2857916 (Unbound Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
14.0033	PK	PK16	Individual Plasma GSK2857916 (Unbound Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
14.0040	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.0041	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0043	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0050	PK	PK17	Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0051	PK	PK17	Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0053	PK	PK17	Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0060	PK	PK17	Mean Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0061	PK	PK17	Mean Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0063	PK	PK17	Mean Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part NHL)		SAC
14.0070	PK	PK17	Mean Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0071	PK	PK17	Mean Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
14.0073	PK	PK17	Mean Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
14.0080	PK	PK17	Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.0081	PK	PK17	Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0083	PK	PK17	Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0090	PK	PK18	Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0091	PK	PK18	Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0093	PK	PK18	Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0100	PK	PK18	Median Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0101	PK	PK18	Median Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0103	PK	PK18	Median Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0110	PK	PK18	Median Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0111	PK	PK18	Median Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
14.0113	PK	PK18	Median Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
14.0120	PK	PK18	Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.0121	PK	PK18	Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0123	PK	PK18	Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
Dose Proportionality					
14.0130	PK	LIVER14	Scatter Plot of GSK2857916 (ADC), GSK2857916 (Total Antibody), GSK2857916 (Unbound Antibody), and cys-mcMMAF PK Parameters by Cycle 1 Dose (Part 1)	using log transformed value. for AUC(0-tau), Cmax, PK Parameter value as y-axis and Cycle 1 dose as x-axis; label x-axis with dose value. Use the format of mock up LIVER14, no reference line is needed.	SAC [A]
Accumulation Ratio					
14.0140	PK	PK28	Plot of Individual (+Geometric Mean and 95%CI) of Accumulation Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 1)	Plot accumulation ratios versus dose. Add a reference line at 1 Plot Ro(CEOI)and Ro(Ctrough) on different plots. Only include geometric mean and 95%CI Plot analytes: ADC, total antibody, unbound antibody, and cys-mcMMAF on the same plot.	SAC [A]
14.0141	PK	PK28	Plot of Individual (+Geometric Mean and 95%CI) of Accumulation Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 2 MM)	Add a reference line at 1 Plot Ro(CEOI)and Ro(Ctrough) on different plots. Only include geometric mean and 95%CI Plot analytes: ADC, total antibody,	SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				unbound antibody, and cys-mcMMAF on the same plot.	
14.0142	PK	PK28	Plot of Individual (+Geometric Mean and 95%CI) of Accumulation Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 2 NHL)	Add a reference line at 1 Plot Ro(CEOI)and Ro(Ctrough) on different plots. Only include geometric mean and 95%CI Plot analytes: ADC, total antibody, unbound antibody, and cys-mcMMAF on the same plot.	SAC
Analyte Ratio					
14.0180	PK	PK_F1	Plot of Geometric Mean and 95%CI of Analyte Ratios for GSK2857916 Analytes by cycle (Linear and Semi-Log) (Part 1)	See example in Page 6 of PPD By dose Plot Ra(CEOI) and Ra(Ctrough) on the same plot. Use “Analyte Ratio to ADC” as y-axis label C(x) predose = C(x-1)trough	SAC [A]
14.0181	PK	PK_F1	Plot of Geometric Mean and 95%CI of Analyte Ratios for GSK2857916 Analytes by cycle (Linear and Semi-Log) (Part 2		SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			MM)		
14.0182	PK	PK_F1	Plot of Geometric Mean and 95%CI of Analyte Ratios for GSK2857916 Analytes by cycle (Linear and Semi-Log) (Part 2 NHL)		SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.12. Pharmacokinetic / Pharmacodynamic (and / or Biomarker) Figures

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
16.0010	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (ADC) (MM)		SAC [A]
16.0011	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (ADC) (NHL)		SAC
16.0020	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Total Antibody) (MM)		SAC [A]
16.0021	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Total Antibody) (NHL)		SAC
16.0030	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Unbound Antibody) (MM)		SAC [A]
16.0031	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Unbound Antibody) (NHL)	If data was not collected, present "No data to report"	SAC
16.0040	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for cys-mcMMAF (MM)		SAC [A]
16.0041	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for cys-mcMMAF (NHL)		SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.13. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.0010	All Treated	ES2	Listing of Reasons for Study Withdrawal (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0011	All Treated	ES2	Listing of Reasons for Study Withdrawal (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0020	All Treated	CP_RA1p	Listing of Planned and Actual Treatments (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0021	All Treated	CP_RA1p	Listing of Planned and Actual Treatments (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0030	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0031	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Protocol Deviations					
1.0040	All Treated	DV2	Listing of Important Protocol Deviations (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0041	All Treated	DV2	Listing of Important Protocol Deviations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0050	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0051	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Populations Analysed					
1.0060	All Treated	SA3a	Listing of Subjects Excluded from Any Population (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0061	All Treated	SA3a	Listing of Subjects Excluded from Any Population (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Demographic and Baseline Characteristics					
1.0070	All Treated	DM2	Listing of Demographic Characteristics (All Treated MM)	Report for sub-population: All Treated MM. Add BMI (kg/m2).	SAC [A]
1.0071	All Treated	DM2	Listing of Demographic Characteristics (Part 2 NHL)	Report for sub-population: Part 2 NHL. Add BMI (kg/m2).	SAC
1.0080	All Treated	DM9	Listing of Race (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0081	All Treated	DM9	Listing of Race (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Prior and Concomitant Medications					
1.0620	All Treated	OCM1A	Listing of Concomitant Medications (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0621	All Treated	OCM1A	Listing of Concomitant Medications (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure and Treatment Compliance					
1.0090	All Treated	OEX8A	Listing of Exposure Data (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0091	All Treated	OEX8A	Listing of Exposure Data (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0100	All Treated	ODMOD10A	Listing of Dose Reductions (All Treated MM)	Report for sub-population: All Treated MM. Include Planned Time.	SAC [A]
1.0101	All Treated	ODMOD10A	Listing of Dose Reductions (Part 2 NHL)	Report for sub-population: All Treated MM. Include Planned Time.	SAC
1.0110	All Treated	ODMOD12A	Listing of Dose Delays (All Treated MM)	Report for sub-population: All Treated MM. Include Planned Time. IDSL standard does not report demographic info. PPD to check with PPD PPD regarding planned time and cycle day. If it is too much programming work to change now, we can keep it as it is.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0111	All Treated	ODMOD12A	Listing of Dose Delays (Part 2 NHL)	Report for sub-population: All Treated MM. Include Planned Time. IDSL standard does not report demographic info. PPD to check with PPD PPD regarding planned time and cycle day. If it is too much programming work to change now, we can keep it as it is.	SAC
1.0120	All Treated	ODMOD15A	Listing of Dose Escalations (All Treated MM)	Report for sub-population: All Treated MM. Include Age(y)/Sex/Race, Cycle, Visit. For C2MD, list the dose escalations where a dose escalation is indicated in the data – from the site.	SAC [A]
1.0121	All Treated	ODMOD15A	Listing of Dose Escalations (Part 2 NHL)	Report for sub-population: All Treated MM. Include Age(y)/Sex/Race, Cycle, Visit. For C2MD, list the dose escalations where a dose escalation is indicated in the data – from the site.	SAC
1.0490	All Treated	ODMOD14A	Listing of Incomplete Infusions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0491	All Treated	ODMOD14A	Listing of Incomplete Infusions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0500	All Treated	ODMOD17A	Listing of Infusion Interruptions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0501	All Treated	ODMOD17A	Listing of Infusion Interruptions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Adverse Events					
1.0140	All Treated	OAE04	Listing of All Adverse Events (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0141	All Treated	OAE04	Listing of All Adverse Events (Part 2 NHL)	Report for population subgroup: Part 2 NHL. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0150	All Treated	OAE03	Listing of Subject Numbers for Individual Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0151	All Treated	OAE03	Listing of Subject Numbers for Individual Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0160	All Treated	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0161	All Treated	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
1.0180	All Treated	OAE04	Listing of Fatal Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC [A]
1.0181	All Treated	OAE04	Listing of Fatal Serious Adverse Events (Part 2 NHL)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC
1.0190	All Treated	OAE04	Listing of Non-Fatal Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC [A]
1.0191	All Treated	OAE04	Listing of Non-Fatal Serious Adverse Events (Part 2 NHL)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC
1.0460	All Treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0461	All Treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0470	All Treated	OAE04	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0471	All Treated	OAE04	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0200	All Treated	OAE04	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0201	All Treated	OAE04	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0210	All Treated	OAE04	Listing of Dose-Limiting Adverse Events (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0220	DLT Evaluable	DL3	Listing of Dose-Limiting Toxicities during the Determinative Period (Day 1-21) (Part 1)	Report for population subgroup: Part 1	SAC [A]
1.0240	All Treated	OAE04	Listing of Adverse Events Leading to Dose Reduction (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0241	All Treated	OAE04	Listing of Adverse Events Leading to Dose Reduction (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0250	All Treated	OAE04	Listing of Adverse Events Leading to Dose Interruptions or Delays (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0251	All Treated	OAE04	Listing of Adverse Events Leading to Dose Interruptions or Delays (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0510	All Treated	OAE04	Listing of Adverse Events Leading to Incomplete Infusions (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0511	All Treated	OAE04	Listing of Adverse Events Leading to Incomplete Infusions (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0520	All Treated	OAE04	Listing of Adverse Events Leading to Infusion Interruptions (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0521	All Treated	OAE04	Listing of Adverse Events Leading to Infusion Interruptions (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0270	All Treated	OAE04	Listing of Corneal Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0271	All Treated	OAE04	Listing of Corneal Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0530	All Treated	OAE04	Listing of Thrombocytopenia (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0531	All Treated	OAE04	Listing of Thrombocytopenia (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0540	All Treated	OAE04	Listing of Hematologic Toxicity (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0541	All Treated	OAE04	Listing of Hematologic Toxicity (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0550	All Treated	OAE04	Listing of Neutropenia (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0551	All Treated	OAE04	Listing of Neutropenia (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0260	All Treated	OAE04	Listing of Infusion Related Reactions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0261	All Treated	OAE04	Listing of Infusion Related Reactions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Hepatobiliary (Liver)					
1.0410	All Treated	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0411	All Treated	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0420	All Treated	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0421	All Treated	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
All Laboratory					
1.0330	All Treated	OLB7	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0331	All Treated	OLB7	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0320	All Treated	OLB13	Listing of Laboratory Data with Character Results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0321	All Treated	OLB13	Listing of Laboratory Data with Character Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0350	All Treated	UR2A	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0351	All Treated	UR2A	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
ECOG Performance Status					
1.0430	All Treated	PS5A	Listing of ECOG Performance Status (All Treated MM)	Report for sub-population: Part 2 NHL.	SAC [A]
1.0431	All Treated	PS5A	Listing of ECOG Performance Status (Part 2 NHL)	Report for sub-population: All Treated MM.	SAC
Response					
1.0560	All Treated	RE5	Listing of Investigator-Assessed Responses (All Treated MM)	Report for sub-population: All Treated MM. List investigator reported response by visit.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0561	All Treated	RE5	Listing of Investigator-Assessed Responses (Part 2 NHL)	Report for sub-population: Part 2 NHL.List investigator reported response by visit.	SAC
Time-to-Event Endpoints					
1.0440	All Treated	TTE9	Listing of Progression-Free Survival (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]
1.0570	All Treated	TTE9	Listing of Duration of Response (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0580	All Treated	TTE9	Listing of Overall Survival (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. If all patients can be reconsented.	SAC
1.0590	All Treated	TTE9	Listing of Time to Progression (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]
1.0600	All Treated	TTE9	Listing of Time to Response (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0610	All Treated	TTE9	Listing of Time to Best Response (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]
Death					
1.0390	All Treated	DTH3	Listing of Deaths (All Treated MM)	Report for sub-population: All Treated MM. include the time from last dose in the listing and Number of Cycles/Last Dose (optional columns in DTH3).	SAC [A]
1.0391	All Treated	DTH3	Listing of Deaths (Part 2 NHL)	Report for sub-population: Part 2 NHL. include the time from last dose in the listing and Number of Cycles/Last Dose (optional columns in DTH3).	SAC
PK					
1.0630	PK	PK07	Listing of Plasma GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (MM)		SAC [A]
1.0631	PK	PK07	Listing of Plasma GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (NHL)		SAC
1.0640	PK	PK07	Listing of Plasma GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (MM)		SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0641	PK	PK07	Listing of Plasma GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (NHL)		SAC
1.0650	PK	PK07	Listing of Plasma GSK2857916 (Unbound Antibody) Pharmacokinetic Concentration-Time Data (MM)		SAC [A]
1.0651	PK	PK07	Listing of Plasma GSK2857916 (Unbound Antibody) Pharmacokinetic Concentration-Time Data (NHL)		SAC
1.0660	PK	PK07	Listing of Plasma cys-mcMMAF Pharmacokinetic Concentration-Time Data (MM)		SAC [A]
1.0661	PK	PK07	Listing of Plasma cys-mcMMAF Pharmacokinetic Concentration-Time Data (NHL)		SAC
1.0710	PK	PK15	Listing of GSK2857916 (ADC) CEOI and Ctrough Accumulation Ratio (MM)		SAC [A]
1.0711	PK	PK15	Listing of GSK2857916 (ADC) CEOI and Ctrough Accumulation Ratio (NHL)		SAC
1.0720	PK	PK15	Listing of GSK2857916 (Total Antibody) CEOI and Ctrough Accumulation Ratio (MM)		SAC [A]
1.0721	PK	PK15	Listing of GSK2857916 (Total Antibody) CEOI and Ctrough Accumulation Ratio (NHL)		SAC
1.0730	PK	PK15	Listing of GSK2857916 (Unbound Antibody) CEOI and Ctrough Accumulation Ratio (MM)		SAC [A]
1.0731	PK	PK15	Listing of GSK2857916 (Unbound Antibody) CEOI and Ctrough Accumulation Ratio (NHL)		SAC
1.0740	PK	PK15	Listing of cys-mcMMAF CEOI and Ctrough Accumulation Ratio (MM)		SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0741	PK	PK15	Listing of cys-mcMMAF CEOI and Ctrough Accumulation Ratio (NHL)		SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.14. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Medical Conditions					
30.0010	All Treated	MH2	Listing of Past Cancer-Related and Non-Cancer Related Medical Conditions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0011	All Treated	MH2	Listing of Past Cancer-Related and Non-Cancer Related Medical Conditions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0020	All Treated	MH2	Listing of Current Cancer-Related and Non-Cancer Related Medical Conditions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0021	All Treated	MH2	Listing of Current Cancer-Related and Non-Cancer Related Medical Conditions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Concomitant Medications					
30.0310	All Treated	OCM1A	Listing of Prophylactic Medication for Infusion-Related Reactions (All Treated MM)	Report for sub-population: All Treated MM. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	SAC [A]
30.0311	All Treated	OCM1A	Listing of Prophylactic Medication for Infusion-Related Reactions (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	SAC
30.0320	All Treated	OCM1A	Listing of Eye Medications (All Treated MM)	Report for sub-population: All Treated MM. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				'Reason for Medication'	
30.0321	All Treated	OCM1A	Listing of Eye Medications (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	SAC
Blood and Blood Supportive Care Products					
30.0380	All Treated	BP4	Listing of Blood Products (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0381	All Treated	BP4	Listing of Blood Products (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0390	All Treated	BP5	Listing of Blood Supportive Care Products (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0391	All Treated	BP5	Listing of Blood Supportive Care Products (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Substance Use					
30.0370	All Treated	SU2	Listing of Substance Use (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0371	All Treated	SU2	Listing of Substance Use (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Anti-Cancer Therapy, Radiotherapy and Surgical Procedures					
30.0040	All Treated	AC6	Listing of Prior Anti-Cancer Therapy (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0041	All Treated	AC6	Listing of Prior Anti-Cancer Therapy (Part 2 NHL)	Report for sub-population: Part 2	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				NHL.	
30.0050	All Treated	AC7	Listing of Anti-Cancer Radiotherapy (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0051	All Treated	AC7	Listing of Anti-Cancer Radiotherapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0060	All Treated	OSP3	Listing of Prior/On Treatment Cancer and Non-Cancer Related Surgical Procedures (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0061	All Treated	OSP3	Listing of Prior/On Treatment Cancer and Non-Cancer Related Surgical Procedures (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0400	All Treated	FAC3	Listing of Follow-Up Anti-Cancer Therapy (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0401	All Treated	FAC3	Listing of Follow-Up Anti-Cancer Therapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Disease Characteristics					
30.0080	All Treated	DC4	Listing of Disease Characteristics at Screening (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0081	All Treated	DC4	Listing of Disease Characteristics at Screening (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0360	All Treated	DC3	Listing of Disease Characteristics at Initial Diagnosis (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0361	All Treated	DC3	Listing of Disease Characteristics at Initial Diagnosis (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0290	All Treated	OLB7	Listing of Genetic Characteristics (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0300	All Treated	SAFE_L1	Listing of Disease Characteristics, Prior Treatment, Dose Modification and Response to GSK2857916 (Part 2 MM)	Report for sub-population: Part 2 MM. Provide a line listing by patient with subject identifier, ISS stage at screening, number of prior lines of therapy, refractory to last line of therapy (Y/N), prior use of daratumumab (Y/N), refractory to both IMID and PI (Y/N), Best confirmed response,	SAC [A]
Exposure					
30.0130	All Treated	OEX9	Summary Listing of Overall Exposure and Dose Modifications (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0131	All Treated	OEX9	Summary Listing of Overall Exposure and Dose Modifications (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Adverse Events					
30.0540	All Treated	OAE4	Listing of Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0541	All Treated	OAE4	Listing of Serious Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0550	All Treated	OAE04	Listing of Drug-Related Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0551	All Treated	OAE04	Listing of Drug-Related Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0560	All Treated	OAE4	Listing of Drug-Related Serious Adverse Events (All Treated	Report for sub-population: All	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			MM)	Treated MM.	
30.0561	All Treated	OAE4	Listing of Drug-Related Serious Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0450	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Corneal Events		SAC [A]
30.0460	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Thrombocytopenia		SAC [A]
30.0470	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Neutrupenia		SAC [A]
30.0480	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Hematologic Toxicity		SAC [A]
30.0490	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Infusion related reactions		SAC [A]
Deaths					
30.0570	All Treated	DTH5	Listing of Subject Numbers for Specific Causes of Deaths (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0571	All Treated	DTH5	Listing of Subject Numbers for Specific Causes of Deaths (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Laboratory					
30.0530	All Treated	OLB7	Listing of Grade 3 and Grade 4 Laboratory Data (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0531	All Treated	OLB7	Listing of Grade 3 and Grade 4 Laboratory Data (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0580	All Treated	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria	Report for sub-population: All	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Post-Baseline (All Treated MM)	Treated MM.	
30.0581	All Treated	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0160	All Treated	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0161	All Treated	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Constitutional Symptoms and Organ Examinations					
30.0510	All Treated	OCS3	Listing of Constitutional Symptoms (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0520	All Treated	OOE2	Listing of Organ Examinations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Left Ventricular Ejection Fraction					
30.0500	All Treated	OLVEF2A	Listing of Left Ventricular Ejection Fraction Results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0501	All Treated	OLVEF2A	Listing of Left Ventricular Ejection Fraction Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
ECG					
30.0140	All Treated	OECG5A	Listing of Fridericia's QTc Values of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0141	All Treated	OECG5A	Listing of Fridericia's QTc Values of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Vital Signs					
30.0440	All Treated	OVT7A	Listing of Vital Sign Values of Potential Clinical Importance	Report for sub-population: All	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			(All Treated MM)	Treated MM.	
30.0441	All Treated	OVT7A	Listing of Vital Sign Values of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Ocular Exam					
30.0260	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0261	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0330	All Treated	SAFE_L2	Listing of Abnormal Conjunctival Exam Results (All Treated MM)	Report for sub-population: All Treated MM. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC [A]
30.0331	All Treated	SAFE_L2	Listing of Abnormal Conjunctival Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose,	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Eye, Exam Test, Result	
30.0340	All Treated	SAFE_L2	Listing of Abnormal Slit Lamp Anterior Chamber and Slit Lamp Lens Exam Results (All Treated MM)	Report for sub-population: All Treated MM. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC [A]
30.0341	All Treated	SAFE_L2	Listing of Abnormal Slit Lamp Anterior Chamber and Slit Lamp Lens Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC
30.0350	All Treated	SAFE_L2	Listing of Indirect Fundoscopic Exam and Intraocular Pressure Results (All Treated MM)	Report for sub-population: All Treated MM. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0351	All Treated	SAFE_L2	Listing of Indirect Fundoscopic Exam and Intraocular Pressure Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC
Health Outcomes					
30.0590	All Treated	VS4	Listing of Symptom Impact and HRQoL Item Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List scores for Bone Pain Worst, Bone Pain Average, Fatigue	SAC [A]
30.0591	All Treated	VS4	Listing of Symptom Impact and HRQoL Item Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List scores for Bone Pain Worst, Bone Pain Average, Fatigue	SAC
30.0600	All Treated	VS4	Listing of NEI-VFQ-25 Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List overall composite score and 11 sub-scores.	SAC [A]
30.0601	All Treated	VS4	Listing of NEI-VFQ-25 Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List overall composite score and 11 sub-	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				scores.	
30.0610	All Treated	VS4	Listing of OSDI Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List total score and 3 sub-scores.	SAC [A]
30.0611	All Treated	VS4	Listing of OSDI Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List total score and 3 sub-scores.	SAC
Anti-Drug Antibody					
30.0620	All Treated	SAFE_L3	Listing of Anti-GSK2857916 antibody results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0621	All Treated	SAFE_L3	Listing of Anti-GSK2857916 antibody results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
PK					
30.0630	PK		SAS Output of Results of Dose Proportionality Analysis Using Power Model		SAC [A]
30.0640	PK	PK15	Listing of GSK2857916 (Total Antibody) CEOI and Ctrough Analyte Ratio (MM)		SAC [A]
30.0641	PK	PK15	Listing of GSK2857916 (Total Antibody) CEOI and Ctrough Analyte Ratio (NHL)		SAC
30.0650	PK	PK15	Listing of GSK2857916 (Unbound Antibody) CEOI and Ctrough Analyte Ratio (MM)		SAC [A]
30.0651	PK	PK15	Listing of GSK2857916 (Unbound Antibody) CEOI and		SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Ctrough Analyte Ratio (NHL)		
30.0660	PK	PK15	Listing of cys-mcMMAF CEOI and Ctrough Analyte Ratio (MM)		SAC [A]
30.0661	PK	PK15	Listing of cys-mcMMAF CEOI and Ctrough Analyte Ratio (NHL)		SAC
PKPD					
30.0690	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (MM)	List QTc change from baseline concentration for each visit	SAC [A]
30.0691	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC
30.0700	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (MM)	List QTc change from baseline concentration for each visit	SAC [A]
30.0701	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC
30.0710	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Unbound Antibody) Pharmacokinetic Concentration-Time Data (MM)	List QTc change from baseline concentration for each visit	SAC [A]
30.0711	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Unbound Antibody) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC
30.0720	PKPD		Listing of Fridericia's QTc Change from Baseline and cys-	List QTc change from baseline	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			mcMMAF Pharmacokinetic Concentration-Time Data (MM)	concentration for each visit	
30.0721	PKPD		Listing of Fridericia's QTc Change from Baseline and cys-mcMMAF Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.13. Appendix 13: Example Mock Shells for Data Displays

Example: POP_T1
Protocol: BMA117159 Page 1 of 1
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Genetic Characteristics at Screening for Multiple Myeloma Subjects (Part 1)

Genetics	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
del13	5 (5%)	5 (5%)	10 (5%)
del17p13	5 (5%)	5 (5%)	10 (5%)
t(11:14)	5 (5%)	5 (5%)	10 (5%)
t(4:14)	5 (5%)	5 (5%)	10 (5%)
1q21	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
Missing	5 (5%)	5 (5%)	10 (5%)

PPD

Example: POP_T2
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx

Summary of Cytogenetics Risk at Screening (Part 1)

Genetics	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
High Risk [1]	5 (5%)	5 (5%)	10 (5%)
Other (non-high risk, not done, or missing)	5 (5%)	5 (5%)	10 (5%)

[1] A subject is considered as high risk if the subject has any of the following cytogenetics: t(4;14), del17p, t(14;16).

PPD

Example: POP_T3
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Prior Anti-Cancer Therapy by Drug Class of Agents for Multiple Myeloma Subjects (Part 1)

Drug Class	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
Steroids	5 (5%)	5 (5%)	10 (5%)
Immunomodulator (IMID)	5 (5%)	5 (5%)	10 (5%)
LENALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
POMALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
THALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
Proteasome Inhibitor (PI)	5 (5%)	5 (5%)	10 (5%)
BORTEZOMIB	5 (5%)	5 (5%)	10 (5%)
CARFILZOMIB	5 (5%)	5 (5%)	10 (5%)
IXAZOMIB	5 (5%)	5 (5%)	10 (5%)
Chemotherapy	5 (5%)	5 (5%)	10 (5%)
Stem Cell Transplant	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
HDAC Inhibitor	5 (5%)	5 (5%)	10 (5%)
Monoclonal Antibody	5 (5%)	5 (5%)	10 (5%)
CXCR4	5 (5%)	5 (5%)	10 (5%)
DARATUMUMAB	5 (5%)	5 (5%)	10 (5%)
ELOTUZUMAB	5 (5%)	5 (5%)	10 (5%)
SILTUXIMAB	5 (5%)	5 (5%)	10 (5%)
Engineered T Cell Therapy	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
Not Classified	5 (5%)	5 (5%)	10 (5%)

PPD

Example: POP_T4
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Multiple Myeloma Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (Part 1)

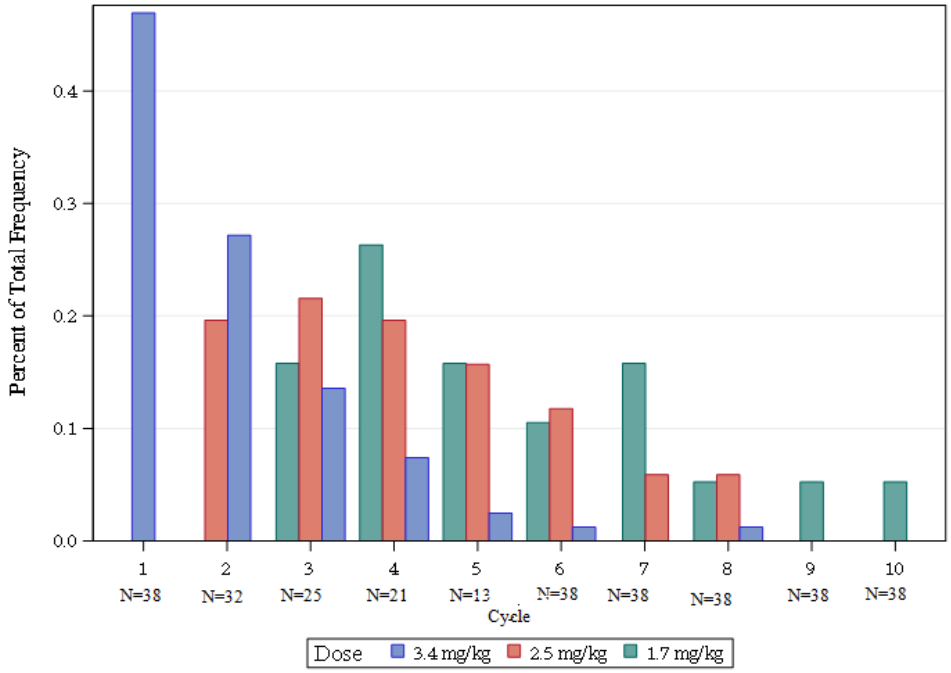
Drug Class	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
Immunomodulator	5 (5%)	5 (5%)	10 (5%)
LENALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
POMALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
THALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
Steroids	5 (5%)	5 (5%)	10 (5%)
Proteasome Inhibitor	5 (5%)	5 (5%)	10 (5%)
BORTEZOMIB	5 (5%)	5 (5%)	10 (5%)
CARFILZOMIB	5 (5%)	5 (5%)	10 (5%)
IXAZOMIB	5 (5%)	5 (5%)	10 (5%)
Chemotherapy	5 (5%)	5 (5%)	10 (5%)
Stem Cell Transplant	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
Monoclonal Antibody	5 (5%)	5 (5%)	10 (5%)
CXCR4	5 (5%)	5 (5%)	10 (5%)
DARATUMUMAB	5 (5%)	5 (5%)	10 (5%)
ELOTUZUMAB	5 (5%)	5 (5%)	10 (5%)
SILTUXIMAB	5 (5%)	5 (5%)	10 (5%)
HDAC Inhibitor	5 (5%)	5 (5%)	10 (5%)
Not Classified	5 (5%)	5 (5%)	10 (5%)
Immunomodulator and Proteasome Inhibitor	5 (5%)	5 (5%)	10 (5%)

This table is summarized per subject level

PPD

Example: POP_F2
Protocol: BMA117159
Population: Part 2 MM (Data as of: 30MAY2001)

Figure x.xxxx
Plot of Dose Reduction of GSK28557916 by Cycle (Part 2 MM)



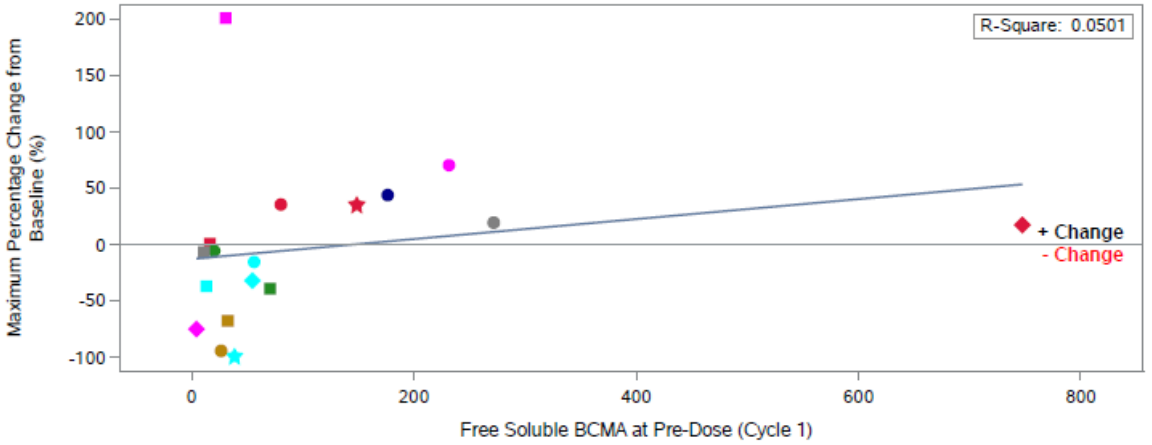
Doses 1.9 mg/kg and 1.7 mg/kg are combined and represented by 1.7 mg/kg.

PPD

Example: EFF_F1
Protocol: BMA117159
Population: Part 2 MM

(Data as of: 30MAY2001)

Figure 12.0020
Correlation of Free Soluble BCMA at Pre-Dose (Cycle 1) and
Maximum Percentage Change from Baseline
in Serum M-Protein, Urine M-Protein or Serum FLC



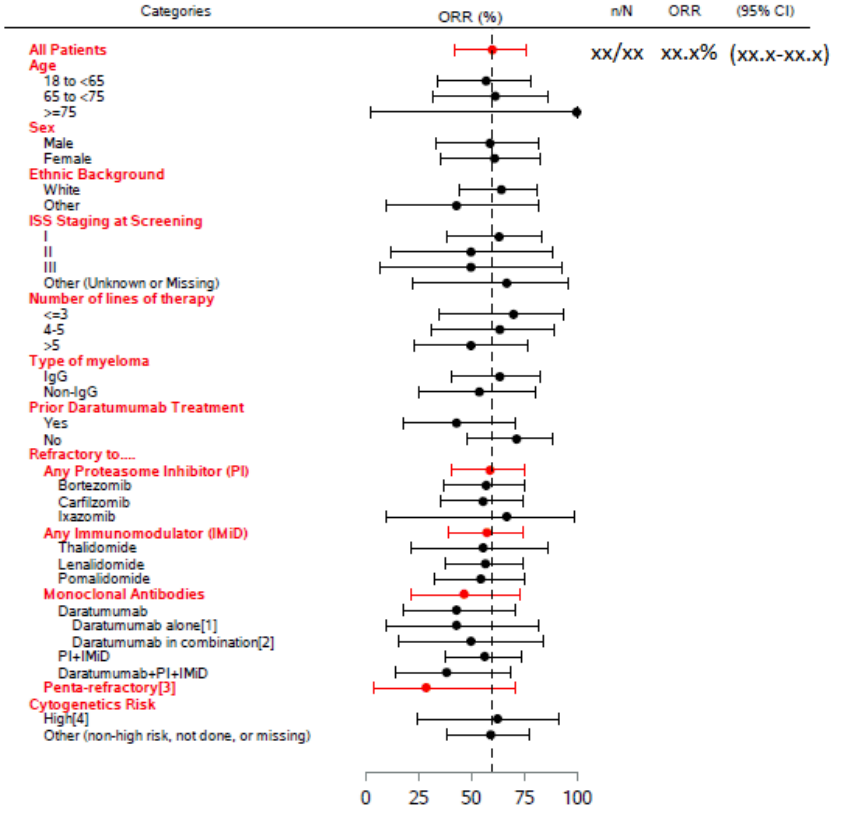
Serum M-protein depicted for subjects with serum M-Protein values;
Urine M-Protein depicted for subjects without serum M-Protein values.
Changes in affected FLC depicted in subjects with no available Serum M-protein values nor Urine M-Protein.

PPD

Example: EFF_F2
Protocol: BMA117159
Population: Part 2 MM

(Data as of: 30MAY2001)

Figure x.xxxx
Forest Plot - Overall Response Rate (ORR) (Part 2 MM)



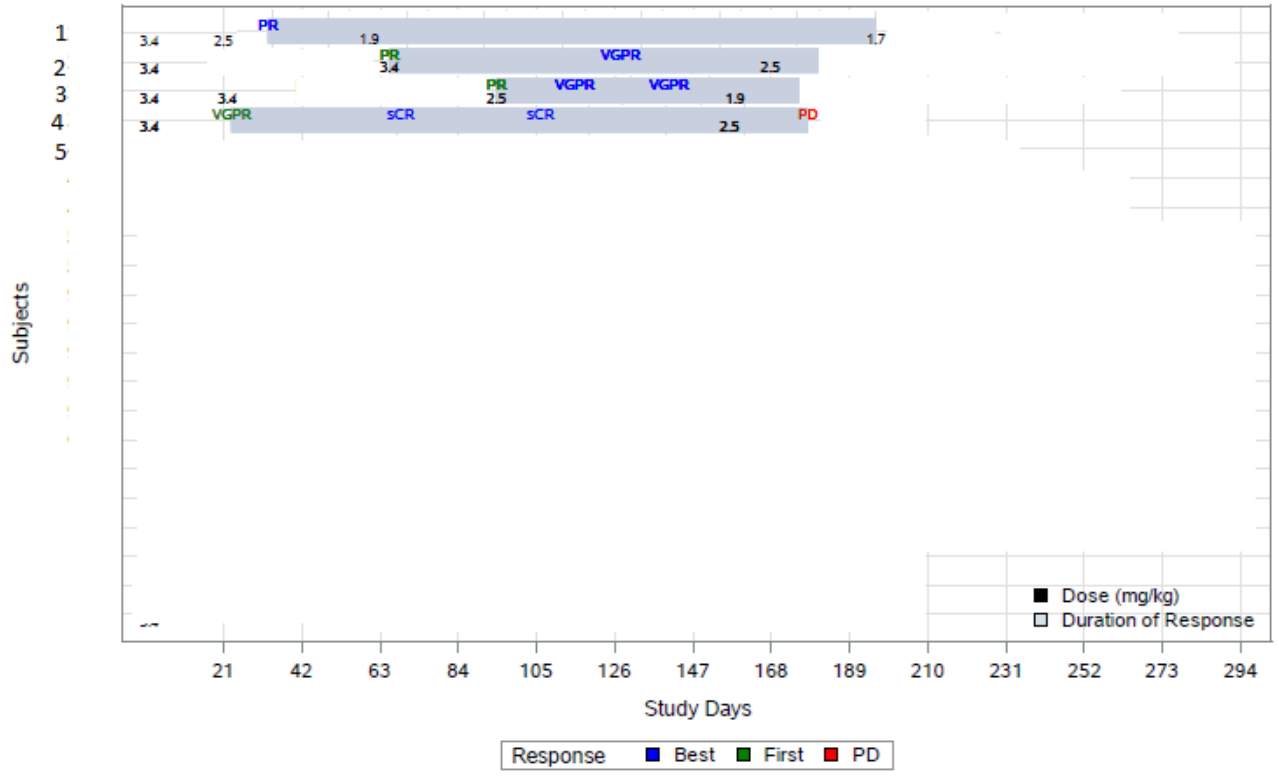
[1] Defined as prior CTX regimen with Daratumumab as the only drug in the regimen.
[2] Defined as prior CTX regimen with Daratumumab and other drugs in the regimen.
[3] Penta-refractory= refractory to: Bortezomib and Carfilzomib and Lenalidomide and Pomalidomide and Daratumumab.
[4] A subject is considered as high risk if the subject has any of the following cytogenetics: t(4;14), del17p, t(14;16).

PPD

Example: EFF_F3
Protocol: BMA117159
Population: Part 2 MM

(Data as of: 30MAY2001)

Figure x.xxxx
Profile Plot of Responders (Part 2 MM)



sCR: Stringent Complete Response, CR: Complete Response, VGPR: Very Good Partial Response, PR: Partial Response,

PPD

Example: SAFE_T1
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Subjects Experiencing Corneal Clinical Signs (Part 1)

	0.03 mg/kg (N=10)	0.06 mg/kg (N=20)	Total (N=30)
Number of Subjects Experiencing Corneal Clinical Signs	5 (50%)	15 (75%)	20 (67%)
Corneal Epithelium Finding			
Abnormal, epithelial edema	5 (50%)	12 (60%)	17 (57%)
Abnormal, epithelial edema -subtle epithelial haze	3 (30%)	11 (55%)	14 (47%)
Abnormal, epithelial edema - diffuse microcystic changes	2 (20%)	8 (40%)	10 (33%)
Abnormal, epithelial edema - mild patchy microcystic changes	1 (30%)	9 (45%)	10 (33%)
……			
Abnormal, punctate keratopathy	4 (40%)	13 (65%)	17 (57%)
Abnormal, punctate keratopathy - mild	3 (30%)	11 (55%)	14 (47%)
Abnormal, punctate keratopathy - moderate	3 (30%)	10 (50%)	13 (43%)
Abnormal, punctate keratopathy - severe	2 (20%)	7 (35%)	9 (30%)
……			
Corneal Stroma Finding			
Abnormal, active	4 (40%)	13 (65%)	17 (57%)
Abnormal, active edema - trace	3 (30%)	11 (55%)	14 (47%)
Abnormal, active edema - 1+	3 (30%)	10 (50%)	13 (43%)
Abnormal, active edema - 2+	2 (20%)	7 (35%)	9 (30%)
Abnormal, active opacity - mild	1 (10%)	6 (30%)	7 (23%)
Abnormal, active opacity - moderate	1 (10%)	5 (25%)	6 (20%)
Number of Subjects Experiencing Corneal Clinical Signs at End of Study Treatment	5 (50%)	15 (75%)	20 (67%)
Corneal Epithelium Finding			
Abnormal, epithelial edema	5 (50%)	12 (60%)	17 (57%)
Abnormal, epithelial edema -subtle epithelial haze	3 (30%)	11 (55%)	14 (47%)
Abnormal, epithelial edema - diffuse microcystic changes	2 (20%)	8 (40%)	10 (33%)
Abnormal, epithelial edema - mild patchy microcystic changes	1 (30%)	9 (45%)	10 (33%)
……			
Abnormal, punctate keratopathy	4 (40%)	13 (65%)	17 (57%)
Abnormal, punctate keratopathy - mild	3 (30%)	11 (55%)	14 (47%)
Abnormal, punctate keratopathy - moderate	3 (30%)	10 (50%)	13 (43%)
Abnormal, punctate keratopathy - severe	2 (20%)	7 (35%)	9 (30%)
……			

Corneal Stroma Finding			
Abnormal, active	4 (40%)	13 (65%)	17 (57%)
Abnormal, active edema - trace	3 (30%)	11 (55%)	14 (47%)
Abnormal, active edema - 1+	3 (30%)	10 (50%)	13 (43%)
Abnormal, active edema - 2+	2 (20%)	7 (35%)	9 (30%)
Abnormal, active opacity - mild	1 (10%)	6 (30%)	7 (23%)
Abnormal, active opacity - moderate	1 (10%)	5 (25%)	6 (20%)
Number of Subjects Experiencing Corneal Clinical Signs at Last Follow-up Exam	5 (50%)	15 (75%)	20 (67%)
Corneal Epithelium Finding			
Abnormal, epithelial edema	5 (50%)	12 (60%)	17 (57%)
Abnormal, epithelial edema -subtle epithelial haze	3 (30%)	11 (55%)	14 (47%)
Abnormal, epithelial edema - diffuse microcystic changes	2 (20%)	8 (40%)	10 (33%)
Abnormal, epithelial edema - mild patchy microcystic changes	1 (30%)	9 (45%)	10 (33%)
……			
Abnormal, punctate keratopathy	4 (40%)	13 (65%)	17 (57%)
Abnormal, punctate keratopathy - mild	3 (30%)	11 (55%)	14 (47%)
Abnormal, punctate keratopathy - moderate	3 (30%)	10 (50%)	13 (43%)
Abnormal, punctate keratopathy - severe	2 (20%)	7 (35%)	9 (30%)
……			
Corneal Stroma Finding			
Abnormal, active	4 (40%)	13 (65%)	17 (57%)
Abnormal, active edema - trace	3 (30%)	11 (55%)	14 (47%)
Abnormal, active edema - 1+	3 (30%)	10 (50%)	13 (43%)
Abnormal, active edema - 2+	2 (20%)	7 (35%)	9 (30%)
Abnormal, active opacity - mild	1 (10%)	6 (30%)	7 (23%)
Abnormal, active opacity - moderate	1 (10%)	5 (25%)	6 (20%)
……			
Number of Subjects Experiencing Corneal Clinical Signs			
n	5	15	20
Also reported corneal toxicity AE	3 (60%)	9 (60%)	12 (60%)
Did not report corneal toxicity AE	2 (40%)	6 (40%)	8 (60%)

PPD

Example: SAFE_T2
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Best Corrected Visual Acuity Test Scores (logMAR score)(Part 1)

Timepoint	Eye	BCVA Score	0.03 mg/kg (N=xx)	0.06 mg/kg (N=xx)	Total (N=xx)
Baseline	Right	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
	Left	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
End of study treatment	Right	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
	Left	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
Change from baseline to	Right	n	xx	xx	xx

end of study treatment		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
	Left	n	xx	xx	xx
		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
Last follow-up exam	Right	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
	Left	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
Change from baseline to last follow-up exam	Right	n	xx	xx	xx
		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
	Left	n	xx	xx	xx
		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
Maximum (worst) change from baseline	Right	n	xx	xx	xx
		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)

Left	N	xx	xx	xx
	No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
	Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
	Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)

Note: High scores are associated with worse vision, and low scores with better vision. No change/improved vision is defined as a change from baseline <0.12; a possible worsened vision is defined as a change from baseline >=0.12 to <0.3; a definite worsened vision is defined as a change from baseline >=0.3 logMAR score. For "End of study Treatment", summarize for subjects with ocular exam results at the end of study treatment; ocular assessment For "Change from baseline to end of study treatment", summarize for subjects with ocular exam results at baseline and the end of study treatment. For "Maximum (worst) change from baseline", summarize for subjects with ocular exam results at baseline and at least one post-baseline visit.

Subjects with "worse than 20/400" results will not be included in the summary.

PPD

Example: SAFE_T3
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Symptom Impact and HRQoL Item Scores Part 1)

Item Score=Bone Pain Worst
Treatment: 0.03 mg/kg (N=200)

Planned Time		n	Mean	SD	Median	Min.	Max.
Baseline	Score	xx	xx.x	xx.xx	xx	xx	xx
Cycle 1 Day 1 to Day 8 Average	Score	xx	xx.x	xx.xx	xx	xx	xx
	Change from Baseline	xx	xx.x	xx.xx	xx	xx	xx
Cycle 1 Day 15	Score	xx	xx.x	xx.xx	xx	xx	xx
	Change from baseline	xx	xx.x	xx.xx	xx	xx	xx

Note: This mock up will be used for both summary of item scores and change from baseline. For summary of change from baseline, include baseline scores. Include Bone Pain Worst, Bone Pain Average, Fatigue worst in one summary table. This note dose not need to be included in the final output. Will add the notes to programming notes

Example: SAFE_T4
Protocol: BMA117159 Page 1 of 1
Population: Part 1 (Data as of: 30MAY2001)

Table X.XXXX
Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time

Visit Category Results	Cohort 1 (x mg/kg) (N=X)
CYCLE 1 WEEK 1	
Screening ADA Result	
n	X
POSITIVE	X (X%)
NEGATIVE	X (X%)
Confirming ADA Result	
n	X
POSITIVE	X
NEGATIVE	X (X%)
Conclusive	
n	X
NEGATIVE,CONCLUSIVE	X (X%)

Note: Negative, Conclusive is a Negative result in ADA assay (either negative screening or negative confirming assay result) and GSK2857916 total antibody concentration <=25000 ng/mL in pharmacokinetic sample collected at same time or same day prior to dosing as the ADA sample. Negative ADA results, either negative screening or negative confirming assay results, are not considered conclusive when the GSK2857916 total antibody concentration was >25000 ng/mL or no GSK2857916 total antibody concentration was available at same time or same day prior to dosing as the ADA sample.

PPD

Example: SAFE_T5
Protocol: BMA117159 Page 1 of 1
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Anti-GSK2857916 Antibodies (ADA)

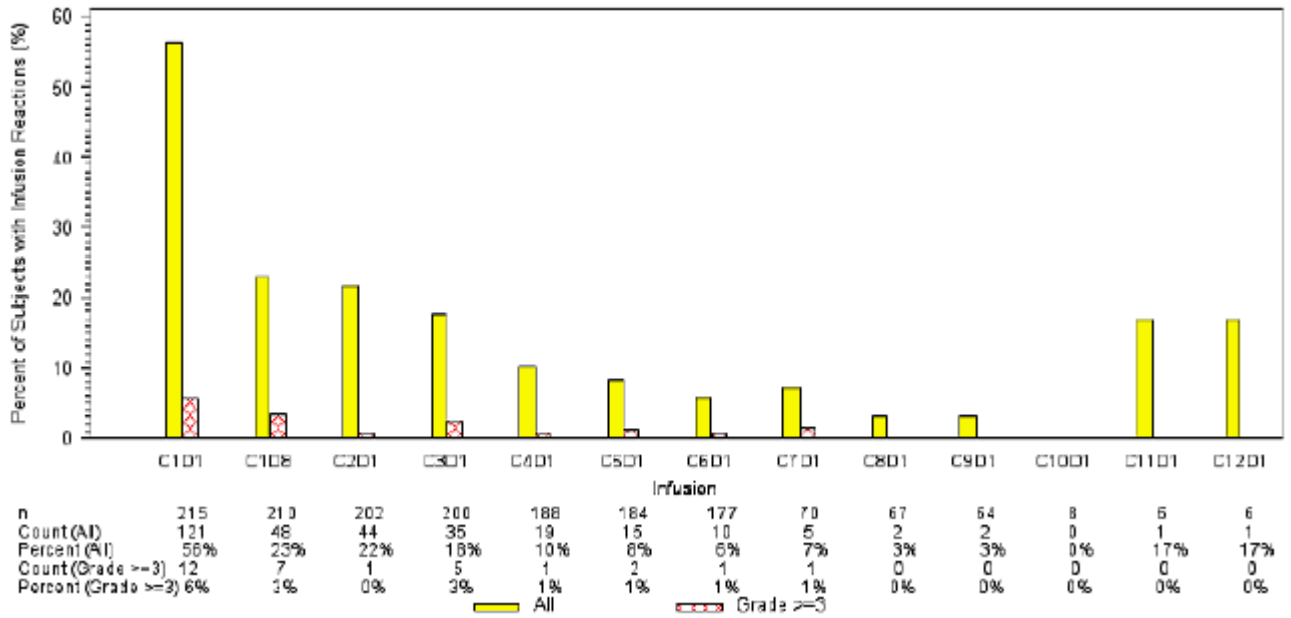
	X mg/kg (N=X)
Number of subjects with baseline ADA results	
n	X
Number of subjects with negative baseline ADA results	X (X%)
Number of subjects with confirmed positive baseline ADA results	X (X%)
Number of subjects with post-baseline ADA results	X
n	X
Number of subjects with at least one confirmed positive post-baseline ADA result	X (X%)
Number of subjects with all negative post-baseline ADA results and at least one GSK2857916 total antibody concentration ≤ 25000 ng/mL	X (X%)
Number of subjects with all negative post-baseline ADA results and all GSK2857916 total antibody concentration >25000 ng/mL or missing	X (X%)

Note a subject is considered to have a positive ADA result if they have a positive screening assay, a positive confirmation assay and a titer value. A baseline ADA result is the closest ADA sample (i.e. either Screening Visit or Cycle 1 Day 1 Visit) prior to the subject receiving the first dose of GSK2857916.

PPD

Example: SAFE_F1
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

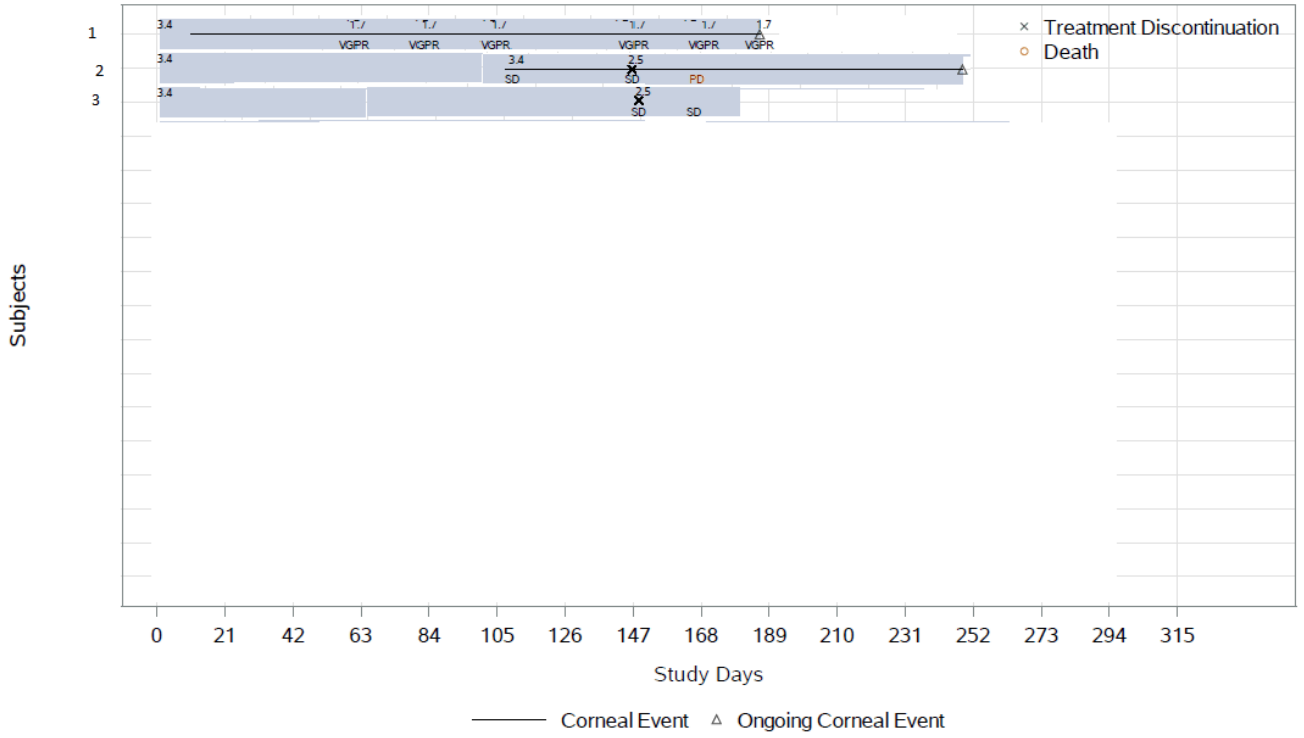
Figure x.xxxx
Proportions of Subjects with Infusion-related Reactions (Part 1)



PPD

Example: SAFE_F2
Protocol: BMA117159 Page 1 of 1
Population: All Treated MM (Data as of: 30MAY2001)

Figure x.xxxx
Profile plot for patients with No Corneal Event or Grade 1 Corneal Event (Part 2 MM)



a. sCR: Stringent Complete Response, CR: Complete Response, VGPR: Very Good Partial Response, PR: Partial Response, MR: Minimal Response, SD: Stable Disease, PD: Progressive Disease, NE: Not evaluable.
b. Dose reduction/delays can be due to non-corneal AEs.

PPD

Example SAFE_L1
Protocol: BMA117159
Population: Part 2 MM (Data as of: 30MAY2003)

Listing x.xxxx
Listing of Disease Characteristics, Prior Treatment, Dose Modification and Response to GSK2857916
(Part 2 MM)

Part: 2
Treatment: 3.40 MM

Centre ID/ Subj.	ISS Stage at Screening	Number of Prior Lines of Therapy	Refractory to Last line of Therapy	Prior Daratumumab?	Refractory to both Immunomodulators and Proteasome Inhibitors?	Best Confirmed Response
PPD	III	6 Lines	Yes	Yes	Yes	Progressive disease
	II	7 Lines	Yes		Yes	Very Good Partial Response (VGPR)
	I	8 Lines	Yes		Yes	Very Good Partial Response (VGPR)

PPD

Example SAFE_L2
Protocol: BMA117159
Population: All Treated MM (Data as of: 30MAY2003)

Listing x.xxxx
Listing of Visual Acuity and Abnormal Corneal Exam Results

Part 1
Treatment: 0.01 mg/kg

Centre/ Subj.	Age(y)/ Sex/ Race	Experienced Corneal Clinical Signs / Reported Corneal Toxicity AE	Cycle/Visit	Time Since 1st Dose / Time Since Last Dose	Eye	Visual Acuity	Corneal Exam Test/Result/ Represent a Corneal Clinical Sign
PPD	65/ F/ White - White/Caucasian/European Heritage	Y / Y	3 / DAY 1	43d / 1d	R	20/40	Corneal epithelium / Abnormal, punctate keratopathy - mild / Y
					L	20/60	Corneal epithelium / Abnormal, punctate keratopathy - mild / Y
			4 / DAY 1	64d / 1d	R	20/40	Corneal endothelium / Abnormal, guttata / N
					L	20/40	Corneal endothelium / Abnormal, guttata / N
			5 / DAY 1	85d / 1d	R	20/25	Corneal epithelium / Abnormal, epithelial edema - mild patchy microcystic changes / Y
					L	20/40	Corneal epithelium / Abnormal, epithelial edema - mild patchy microcystic changes / Y
PPD							

Example: SAFE_L3
Protocol: BMA117159
Population: All Treated MM (Data as of: 30MAY2001)

Listing x.xxxx
Listing of Anti-GSK2857916 antibody results (All Treated MM)

Treatment: X

Centre ID/ Subj.	Age (y) Sex Race	Visit	Study Date	Day	Screening Assay	Confirming Assay	Titer	GSK2857916 Concentration (ADC) (ng/mL)	GSK2857916 Concentration (Total mAb) (ng/mL)
XXXX/ X	X X X	CYCLE X WEEK X	DDMMMYYYY	X	X	X	X	X	x

PPD

Example: PK_T1
Protocol: BMA117159
Population: PK

(Data as of: 30MAY2001)

Table xx.xxx
Summary of Results of Dose Proportionality Analysis for ADC PK Parameters (AUC(0-inf), AUC(0-t), Cmax, and AUC(0-τ)) Using Power Model

Parameter	Doses	Adjusted mean slope	Standard error	DF	90% C.I.
AUCIFO (ng*hr/mL)	0.03 mg/kg	0.98	0.036	17	(0.92, 1.05)
	0.06 mg/kg	0.97	0.034	17	(0.93, 1.06)
	……				
AUCLST (ng*hr/mL)	0.03 mg/kg	0.99	0.037	17	(0.92, 1.05)
	0.06 mg/kg	0.99	0.037	17	(0.92, 1.05)
	……				
CMAX (ng/mL)	0.03 mg/kg	0.92	0.057	17	(0.82, 1.01)
	0.06 mg/kg	0.92	0.057	17	(0.82, 1.01)
	……				

PPD

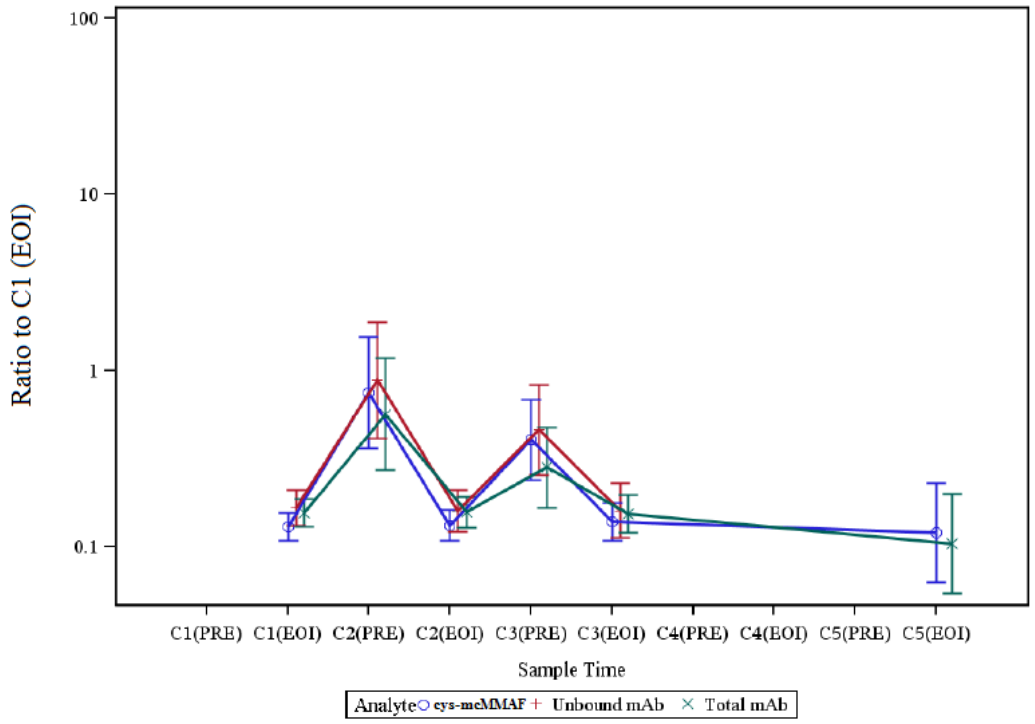
Example: PK_F1
Protocol: BMA117159
Population: PK

(Data as of: 30MAY2001)

Figure x.xxxx

Plot of Geometric Mean and 95%CI of Analyte Ratios for GSK2857916 Analytes by cycle (Linear and Semi-Log)
(Part 1)

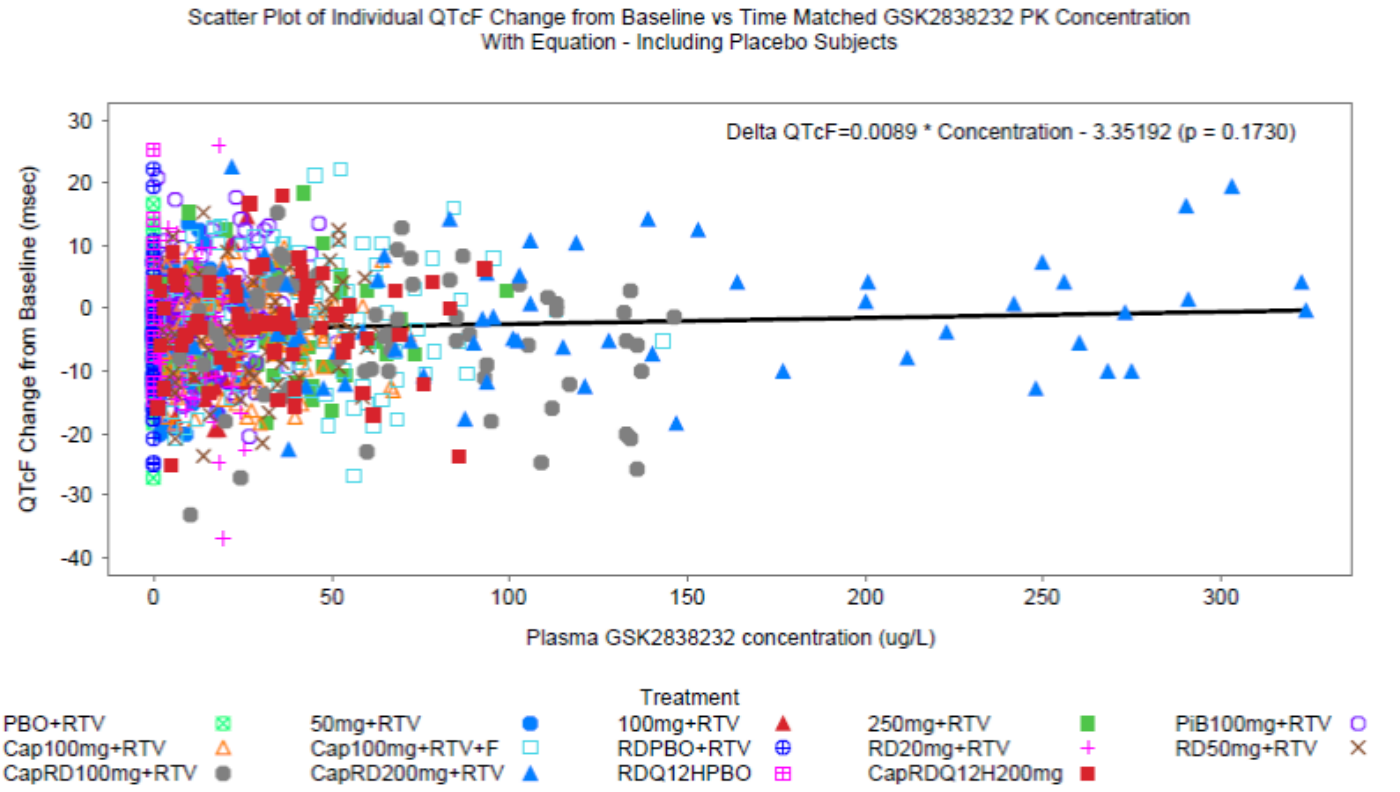
Treatment: X



Example: PK_F2
Protocol: BMA117159
Population: PK

(Data as of: 30MAY2001)

Figure x.xxxx



Note: All the placebo groups (PBO+RTV for Part 1a, RDPBO+RTV and RDQ12HPBO for Part 2) are included in the plot; the Plasma GSK2838232 concentrations of these placebo groups are imputed as 0.

PPD

Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)

Title	:	DREAMM-1: A Phase I Open-label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity and Clinical Activity of the Antibody Drug Conjugate GSK2857916 in Subjects with Relapsed/Refractory Multiple Myeloma and Other Advanced Hematologic Malignancies Expressing BCMA
Compound Number	:	GSK2857916
Effective Date	:	26-JUN-2018

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol GSK Document Number 2012N155299_05.
- This RAP is intended to describe the safety, clinical activity and pharmacokinetic analyses required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

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PAGE

1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Study Report for Protocol:

Revision Chronology:		
2012N155299_00	2013-DEC-26	Original
2012N155299_01	2014-MAR-01	Amendment No. 1. Country specific Amendment for the United Kingdom to address required changes per MHRA. Updated Exclusion Criteria to exclude subjects with current corneal disease or history of corneal disease. Updated QTc withdrawal criterion to modify QTc withdrawal for QTc >500msec and to include > 60 msec increase from baseline. Updated Data Management Section 12 to include details on dissemination of data and communication plan.
2012N155299_02	2014-MAR-20	Amendment No. 2. Global Amendment to address required changes per the FDA. Updated Inclusion Criteria with minimum weight requirement. Updated Blood Volumes. Revised Time and Events Tables. Corrected typographical errors.
2012N155299_03	2014-MAY-05	Amendment No. 3. Country specific Amendment for Canada to address required changes per Health Canada. Updated preparation instructions of GSK2857916.
2012N155299_04	2016-MAY-05	Amendment No. 4. Global Amendment to include patient reported outcome instruments in the Part 2 multiple myeloma cohort and refine the lymphoma histologies eligible in Part 2 BCMA-expressing lymphoma cohort. Additionally, the requirement for 60% of tumor cells staining positive for BCMA expression was removed. The total number of subjects that may be enrolled is presented by a range of 80 to 95 to provide an updated estimate based on the number of subjects who enrolled at the time of the amendment. Additional modifications include: changing the time-point specific blood specimens are collected for baseline/pre-treatment immunogenicity and biomarker measurements, and the visit window for certain assessments.
2012N155299_05	2017-NOV-02	Global amendment to include additional follow up of multiple myeloma subjects for ocular exams (for those whose corneal signs or symptoms have not resolved), additional patient reported outcome instruments, addition of time-to-event endpoints as exploratory objectives. Subjects who have completed treatment or the 3 month follow up visit (end of study) prior to amendment 5 will be reconsented for further follow up and survival status. Other administrative changes are also included

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

Changes from the originally planned statistical analysis specified in the protocol are outlined in Table 1.

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
• Time to response (TTR) is defined as the time between the date of first dose and the first documented evidence of response (PR or better). Subjects without confirmed response (PR or better) will be censored at the censoring date for TTP.	• Time to response (TTR) is defined as the time between the date of first dose and the first documented evidence of response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).	• To be consistent with GSK Integrated Data Standards Library (IDSL) standard
• Time to best response (TTBR) analyses was not planned.	• Time to best response (TTBR), defined as the time between the date of first dose and the best response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better), was added as an exploratory endpoint.	• To further evaluate clinical activity of GSK2857916.
• The 'Pharmacokinetic (PK) Population' is defined as those subjects in the "All Treated" population from whom at least one PK sample was obtained, analyzed, and was measurable.	• All subjects in the 'All Treated' population who had at least 1 non-missing PK assessment (Non-quantifiable [NQ] values will be considered as non-missing values).	• To be consistent with the latest GSK (IDSL) standard.
• Descriptive statistics (mean, standard deviation, median, range) will be used to summarize observed laboratory values and change from baseline in observed value at each scheduled visit, as appropriate	• Descriptive statistics (mean, standard deviation, median, range) will be used to summarize change from baseline in observed value at each scheduled visit, as appropriate	• To be consistent with the latest GSK (IDSL) standard.

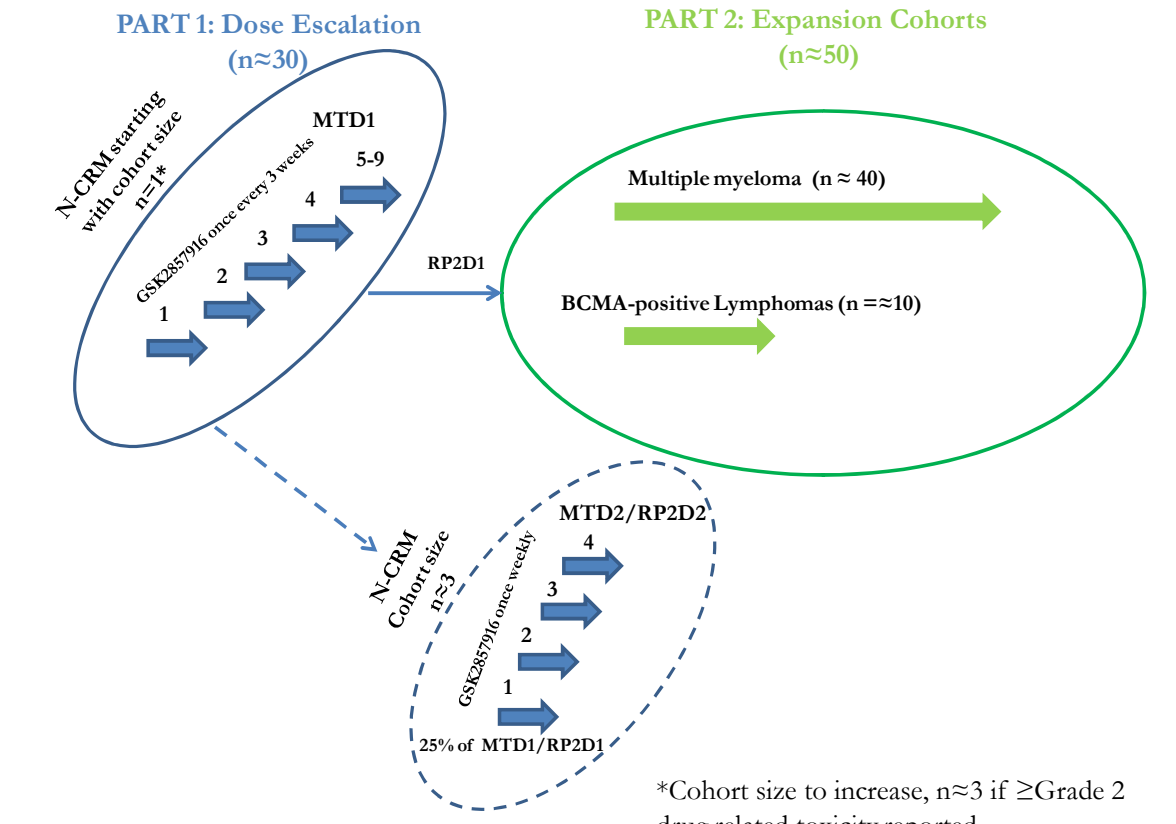
2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To determine safety, tolerability, maximum tolerated dose (MTD), and recommended phase (RP2) dose and schedule of GSK2857916 administered	• Adverse events (AE) and changes in clinical signs and laboratory parameters
Secondary Objectives	**Secondary Endpoints**
• To evaluate the pharmacokinetic (PK) profile of GSK2857916 and the breakdown product cys-mcMMAF after intravenous (IV) single and repeat dose administration in subjects with relapsed/refractory MM and BCMA expressing lymphomas	• GSK2857916 and cys-mcMMAF PK parameters following IV single and repeat dose administration during dose escalation as data permit (e.g., AUCs Cmax, tmax, CL, V_{SS}, t½ [single dose], Cmax and Ctrough [repeat dose]). GSK2857916 population PK parameters in expansion cohorts at the RP2 dose (e.g. clearance (CL), volume of distribution (Vd)), and relevant covariates which may influence exposure (e.g. age, weight, or disease-related covariates e.g. BCMA expression)
• To assess anti-drug antibody (ADA) formation after IV single and repeat dose administration of GSK2857916	• ADA incidence and titers after single and repeat IV dosing of GSK2857916
• To explore the initial anti-tumor activity of GSK2857916 in subjects with relapsed/refractory MM and BCMA expressing lymphomas	• Clinical activity measured as Overall Response Rate (ORR) which is defined as follows: ○ For MM: the percentage of subjects achieving confirmed partial response or better (≥PR) ○ In addition, the percentage of subjects with minimal response (MR) will be assessed for clinical benefit rate (CBR) (Appendix 1 of protocol) • For Lymphomas: the percentage of subjects achieving PR or better (≥PR) (Appendix 2 of protocol)
Exploratory Objectives	**Exploratory Endpoints**
• To evaluate PD markers in MM after treatment with GSK2857916	• sBCMA levels, BCMA receptor occupancy and cell death markers in subjects with MM.
• To explore relationships of GSK2857916 plasma concentrations/exposure with pharmacodynamics (PD), safety and clinical activity	• Relationship between receptor occupancy, tumor cell death markers, sBCMA and GSK2857916 plasma PK parameters; • Relationship between safety/clinical activity (e.g. ORR) and GSK2857916 PK parameters
• To characterize the relationship between clinical response and other biologic tumor characteristics (DNA, protein analysis)	• BCMA expression levels on malignant cells as measured by IHC and/or flow cytometry in tumor tissue, serum sBCMA levels and their relationship to clinical response
• To investigate the relationship between genetic variants in the host and response to study medicine, or susceptibility, severity and progression of disease	• Relationship between host genetic variation and response to study medicine or susceptibility, severity and progression of disease

Objectives	Endpoints
• To explore the effect of GSK2857916 on symptoms (including bone pain, fatigue and visual symptoms) and impacts on HRQoL in subjects with relapsed/refractory MM (Part 2)	• Changes from baseline in bone pain/fatigue and analgesic use as measured by the eDiary • Interviews with subjects to further characterize changes in symptoms (including bone pain/, fatigue and visual symptoms) and impacts on HRQoL
• To explore changes in visual symptoms and function following discontinuation of treatment with GSK2857916	• Changes in visual symptoms and impacts as measured by the OSDI and NEI-VFQ-25 following treatment discontinuation • Follow-up telephone interviews conducted to further understand subjects experience with visual symptoms and changes in symptoms and related impacts following treatment discontinuation
• To explore the initial anti-tumor activity of GSK2857916 in subjects with relapsed/refractory MM in terms of time-to-event (TTE) endpoints (Part 2 MM)	• **Time to progression (TTP)**, defined as: the time from first dose until the earliest date of PD per International Multiple Myeloma Working Group (IMWG), or death due to PD. • **Duration of response (DOR)**, defined as: the time from first documented evidence of PR or better; until the time when disease progression (PD) is documented per IMWG; or death due to PD occurs in subjects who achieve a response, i.e. confirmed PR or better. • **Time to response (TTR)**, defined as: the time between the date of first dose and the first documented evidence of response (PR or better), among subjects who achieve a response, i.e. confirmed PR or better. • **Time to best response (TTBR)**, defined as the time between the date of first dose and first documented evidence of the best response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better). • **Progression-free survival (PFS)**, defined as: the time from first dose until the earliest date of disease progression (PD) per IMWG, or death due to any cause. • **Number of deaths.**

2.3. Study Design

Overview of Study Design and Key Features



Design Features	• **Part 1 Dose Escalation**
	  ○ Population: Subjects with relapsed/refractory MM (originally planned to enrol up to 30 subjects. However, additional subjects were enrolled to explore a new intermediate dose group)
	  ○ Objective: characterize safety, PK, PD, immunogenicity and establish RP2 dose of GSK2857916
	  ○ Two dosing schedules (Schedule 1 and Schedule 2) may be explored:
	  ▪ Schedule 1: GSK2587916 once every 3 weeks (21-day cycle) (n=~20)
	  ▪ Schedule 2: GSK2587916 once weekly for 3 consecutive weeks, 1-week rest (28-day cycle) (n=~9). Schedule 2 was not actually explored.
	  ○ Serial PK samples will be collected from all subjects in Part 1
	• **Part 2 Expansion Cohort(s) (n=~50 subjects)**
	  ○ Population:
	  ▪ Subjects with relapsed/refractory MM (up to 40 subjects)
	  ▪ Subjects with lymphomas expressing BCMA (up to 10 subjects)
	  ○ Objective: Further evaluate the safety, PK, immunogenicity, and clinical activity of GSK2857916 at the RP2 dose identified in Part 1
	  ○ MM and Lymphoma expansion cohorts will be analyzed separately
	  ○ Sparse PK samples will be collected from all subjects
	• Genetics research samples will be collected predose from all subjects

Overview of Study Design and Key Features	
Dosing	• **Part 1 Dose Escalation** Initially, GSK2857916 will be administered (IV) via 60 min infusion once every three weeks (21 days = 1 cycle) on Schedule 1. Once an MTD1 or RP2D has been established on the once every 21-day (Schedule 1), the safety, tolerability, PK, and PD of once-weekly dosing (Schedule 2) of GSK2857916 may be explored as an additional cohort(s). • **Part 2: Dose Expansion Phase** Subjects enrolled in Part 2 dose expansion phase will be administered GSK2857916 at recommended phase 2 dose (RP2D) established based on Part 1 outcomes.
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• This is a non-randomized open-label study.
Interim Analysis	• **Part 1: Dose Escalation Phase** No formal interim analysis is planned for Part 1. Safety, pharmacokinetic and pharmacodynamic marker data will be examined on an ongoing basis to support dose escalation decisions. • **Part 2: Dose Expansion Phase** ○ For MM cohort, one futility analysis based on ORR data was performed after approximately 30 subjects are evaluable (originally 3 futility analyses are planned after approximately 15, 22 and 30 subjects are evaluable). The number of confirmed responses (PR or better) observed will be compared with the stopping rules provided in Section 13.6.2 of the protocol. ○ For the lymphomas expressing BCMA cohort, no interim analyses will be performed, though consideration would be given to closing the cohort should the enrolment be stopped in the MM cohort.

2.4. Statistical Hypotheses / Statistical Analyses

No formal statistical hypotheses will be tested in Part 1. Analysis of the data obtained from Part 1 will only utilize descriptive methods. In Part1, dose escalation/de-escalation decisions will be informed by the Bayesian approach: N-CRM (Neuenschwander-Continuous Reassessment Method) [Neuenschwander, 2008]. Details of the N-CRM model used for this study is described in Section 3.1.1.

The assumption for ORR in part 2 MM cohort is:

The null hypothesis H0: ORR $\leq$ 20%

The alternative hypothesis HA: ORR $\geq$ 40%.

No hypothesis testing is planned for part 2 MM cohort. The methodology utilized is based on the predictive probability of success if enrollment continues to 40 subjects [Lee, 2008]. The predictive probability design is similar to a Green-Dahlberg design in that it allows for early stopping for futility. The differences are that the predictive probability design allows for evaluation of stopping rules as often as after each subject, rather than at only two stages. While the two designs have similar type I and type II error rates, the

probability of early termination is greater with the predictive probability design. In this particular study, one futility analysis based on ORR data was performed after approximately 30 subjects are evaluable (originally 3 futility analyses are planned after approximately 15, 22 and 30 subjects are evaluable).

3. PLANNED ANALYSES

3.1. Interim Analyses

3.1.1. Part 1: Dose Escalation Phase

While no formal interim analysis is planned for Part 1, safety, pharmacokinetic and pharmacodynamic marker data will be examined on an ongoing basis to support dose escalation decisions. Prior to determining the GSK2857916 dose for the next cohort enrolled, exploratory analysis will be conducted to assess the relationship of GSK2857916 dose levels with safety, PK and PD parameters using all data from available cohorts.

Dose escalation/de-escalations decisions will take into account all available data, including but not limited to the safety parameters, PD and PK data of all cohorts assessed. Dose escalation/de-escalation decisions will be informed by the N-CRM (Neuenschwander-Continuous Reassessment Method) [Neuenschwander, 2008]. The N-CRM model used for Schedule 1 is described in detail in Section 3.1.1.1 and Section 3.1.1.2. The method is fully adaptive and makes use of all DLT information available at the time of each dose assignment.

3.1.1.1. Description of the New Continual Reassessment Method

The N-CRM is a type of Bayesian adaptive dose-escalation scheme that estimates the parameters of a statistical model relating dose and toxicity, and is expected to locate the MTD efficiently while minimizing the number of subjects exposed to pharmacologically inactive or unsafe dose levels. The method is fully adaptive and makes use of all the toxicity information available at the time of each dose assignment. N-CRM estimates may be provided at dose escalation meetings as supportive material to the primary 3+3 dose escalation design.

The N-CRM estimates, for each potential dose, the (Bayesian) posterior probabilities that the DLT rate lies in each of four predefined toxicity ranges:

- A dose falls in the **Under-dosing** range if the rate of a DLT at the dose is in the interval [0%, 16%).
- A dose falls in the **Target** toxicity range if the rate of a DLT at the dose is in the interval [16%, 33%).
- A dose falls in the **Excessive** toxicity range if the rate of a DLT at the dose is in the interval [33%, 60%).

- A dose falls in the **Unacceptable** toxicity range if the rate of a DLT at the dose is in the interval [60%, 100%].

Additionally, the following over-dose constraints for the recommended dose will be maintained:

- The posterior probability of the DLT rate lying in the Excessive Toxicity or Unacceptable Toxicity range is 0.25 or less.
- The recommended dose is no more than 2 times that of the previous dose.
- Note that a de-escalation recommendation is possible using this method. At the time of each dose-escalation decision, the dose with the highest posterior probability of lying in the Target Toxicity range (subject to the given constraints) will be the model-recommended dose for the next cohort.

The N-CRM procedure for Schedule 1 will utilize a single subject/cohort run-in phase.

The single subject (small cohort) run-in will be halted when the first ≥ Grade 2 toxicity for which relationship to the investigational agent cannot be ruled out occurs in one subject in Cycle 1 (21 days). At this point, the cohort will be expanded to 3 or more subjects at the same dose level and the escalation will continue to follow the N-CRM procedure as outlined in Table 2

Table 2 Single Subject (Small Cohort) Run-In Procedure for GSK2857916 given on Schedule 1 (once every 21 days)

Dose Level	Number of subjects with ≥G2 toxicity	Dose Escalation/Action
Dose Level 1/Cohort 1	0 out of 1 subject (Sentinel subject)	Predicted starting dose 0.03 mg/kg every 21 days
Dose Level 2/Cohort 2	0 out of 1 subject	Escalate to the next dose level with increase ≤100% of the starting dose
Dose Level 3 and beyond/Cohort 3 and beyond	0 out of 1 subject	Escalate to the next dose level with increase of ≤100% of the dose tested in the previous cohort
	1 out of 1 subject*	Switch to Cohort size of 3 or more subjects

*Increase of doses **up to** 100% of the previous dose may continue until the first ≥ Grade 2 toxicity for which relationship to the investigational agent cannot be ruled out occurs in one subject in Cycle 1 (21 days). At this point the single subject (small cohort) run-in is halted. Continue with N-CRM, with cohort sizes of 3 or more subjects. Increase of doses ≤100% will be considered for subsequent cohorts of 3 or more subjects.

3.1.1.2. Prior Probability Distribution

Elicited prior probabilities of a DLT at each dose were used to determine the prior distribution of the parameters of an explicit logistic dose-toxicity model, namely

m,

where p_d is the probability of a DLT at dose d, and d_m is a reference dose.

The prior distribution of (α, ln(β)) will be assumed to be bivariate normal with means (standard deviations): E[α]=−1.3281 (1.7153), E[ln(β)]=-0.795 (1), with correlation between α and ln(β) set to ρ=−0.9352 and d_m=0.72 mg/kg.

3.1.1.3. Displays To Be Created For Dose Escalation Review

Review of preliminary data will be performed after completion of each dosing cohort in Part 1. Preliminary safety and study population data may include a demographic summary, adverse event (AE) summary, AE summary by maximum toxicity category, SAE listing, listing of AEs that are reported to be DLT's, and listing of AEs leading to dose modification. Spreadsheets containing relevant study data may also be supplied by the study data manager.

Further, after single subject run-in was halted, after each expanded cohort in dose escalation, the recommended dose from the N-CRM method and updated posterior estimates of the probabilities of being in each dose-toxicity range may be provided. The Fixed and Adaptive Clinical Trial Simulator (FACTS) (Version 2.4 or higher) software from Tessella will be used to make N-CRM calculations.

Prior to determining a dose for the next cohort, exploratory analyses will be conducted to assess the relationship of dose levels with safety, PK, and pharmacodynamic parameters using all data from available cohorts.

The GSK study team, in collaboration with study investigators, will review all relevant data to support:

- whether the current dose had acceptable toxicity, and
- the decision regarding the next dose level based on the totality of the data

3.1.2. Part 2 Expansion Phase

3.1.2.1. Multiple Myeloma Expansion Cohort

During Part 2 (Expansion Cohort), futility analyses of response data will be conducted in order to determine whether the futility criteria for stopping have been met. The study will not be stopped early for efficacy, but is designed to stop early for futility if the predictive probability of success is less than 5%.

For Multiple Myeloma cohort, response data will be reviewed once approximately 30 subjects are evaluable at the RP2D dose and the number of confirmed responses (PR, VGPR, CR, and sCR) will be compared with the stopping rules provided in Table 3 based on predictive probability design of Lee et al. [Lee, 2008].

In addition to considering the recommendations of the futility analyses, final decisions on stopping enrolment in the MM cohort will depend on the totality of the data collected. Should the recommendation to stop for futility be disregarded in favour of a decision to

continue the trial based on the totality of the data, the overall type I error rate of the expansion phase will be inflated.

Table 3 Futility Stopping Region for Multiple Myeloma Expansion Cohort

	Number of Overall Responses												
Number of Evaluable Subjects	0	1	2	3	4	5	6	7	8	9	10	11	>11
15	■	■	■										
16	■	■	■										
17	■	■	■										
18	■	■	■	■									
19	■	■	■	■									
20	■	■	■	■									
21	■	■	■	■									
22	■	■	■	■	■								
23	■	■	■	■	■								
24	■	■	■	■	■								
25	■	■	■	■	■	■							
26	■	■	■	■	■	■							
27	■	■	■	■	■	■							
28	■	■	■	■	■	■							
29	■	■	■	■	■	■	■						
30	■	■	■	■	■	■	■						
31	■	■	■	■	■	■	■						
32	■	■	■	■	■	■	■	■					
33	■	■	■	■	■	■	■	■					
34	■	■	■	■	■	■	■	■	■				
35	■	■	■	■	■	■	■	■	■				
36	■	■	■	■	■	■	■	■	■				
37	■	■	■	■	■	■	■	■	■	■			
38	■	■	■	■	■	■	■	■	■	■			
39	■	■	■	■	■	■	■	■	■	■	■		
40	■	■	■	■	■	■	■	■	■	■	■	■	

3.1.2.1.1. Operating Characteristics of the Stopping Rules for Futility

The stopping rule in Table 3 is based on the methodology of Lee et al. [Lee, 2008]. For the MM expansion cohort, starting with 15 subjects and allowing for a maximum sample size of 40, this design will have a type I error rate of 0.075 and 89.8% power. Under the null hypothesis, if the true response rate is 20%, the expected sample size of the design is 23.4 subjects and probability of early termination (PET) is 88.9%. Under the alternative hypothesis, if the true response rate is 40%, the expected sample size of the design is 38.6 subjects and probability of early termination (PET) is 8.5%.

3.1.2.2. Lymphoma Expansion Cohort

No interim analyses will be performed on the BCMA positive lymphomas cohort; though consideration would be given to closing the cohort should the enrolment be stopped in the MM cohort.

3.2. Administrative Interim Analyses

Additional administrative interim analysis may be performed to inform patient safety and efficacy of the drug as needed.

3.3. Final Analyses

The final planned primary analyses will be performed after the completion of the following sequential steps:

1. All participants have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.

A final analysis of the MM population can be done separately, before the NHL cohort completes, and will necessitate separate DBR/DBF activities.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All participants who were screened for eligibility	• Study Population
Enrolled	• All participants who passed screening and entered the study. • Note screening failures (who never passed screening even if rescreened) and subjects screened but never enrolled into the study (Reserve, Not Used) are excluded from the Enrolled population as they did not enter the study.	• Study Population
All Treated	• All eligible subjects who receive at least 1 dose of study treatment. An incorrect treatment schedule or drug administration or an early termination of treatment will not result in exclusion of subjects from this population. • **Sub-populations:** o Part 1: all Part 1 subjects of All Treated population. Note, subjects in Part 1 are exclusively multiple myeloma patients. (2.5 mg/kg will be included in Part 1) o Part 2 MM: all Part 2 MM subjects of All Treated population o All Treated MM: comprise of subjects in Part 1 and Part 2 MM. o Part 2 NHL: all Part 2 lymphoma subjects of All Treated population.	• Study Population • Safety • Efficacy
Evaluable (MM)	• This population is a subset of the 'All Treated' population, who were initially treated at RP2D in the expansion cohort and have at least two post-baseline disease assessments or they have progressed or died or permanently discontinued treatment.	• futility analyses of MM Expansion cohort only
DLT Evaluable	• All subjects fulfilling the 'All Treated' population criteria, and having met the following adequate exposure criteria: o For Schedule 1 (once every 3 weeks dosing) subjects received a complete infusion in cycle 1. o For Schedule 2 (once weekly dosing for 3 consecutive weeks, 1 week rest) subjects receive three infusions, two of which must be complete infusions, in cycle 1. (as increases up to ≤30% are implemented between cohorts, less than 2 complete infusions would result in a total dose closer to the previous dose investigated). (Schedule 2 was not explored in the study) o Any subject in the "All Treated" population who experiences a DLT, as defined in Section 3.3.3 of the protocol will also be included in the DLT evaluable population regardless of exposure.	• Summary of DLT, for Part 1 only

Population	Definition / Criteria	Analyses Evaluated
Pharmacodynamic	• The 'Pharmacodynamic (PD) Population' is defined as those subjects in the "All Treated" population from whom at least one PD sample was obtained, analyzed, and was measurable.	• PD
Pharmacokinetic (PK)	• All subjects in the 'All Treated' population who had at least 1 non-missing PK assessment (Non-quantifiable [NQ] values will be considered as non-missing values).	• PK

Refer to Appendix 12: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarised and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan [08May2017, Version 6.0].

- Data will be reviewed prior to freezing the database to ensure all important deviations are captured and categorised on the protocol deviations dataset.
- This dataset will be the basis for the summaries and listings of protocol deviations.

A separate summary and listing of all inclusion/exclusion criteria deviations will also be provided. This summary will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions				
RandAll NG		Data Displays for Reporting		
Code	Description [1]	Description [2]	Data Display	Order in TLF
A	Active Treatment	GSK2857916 0.03 mg/kg (Part 1 MM)	0.03 mg/kg	1
		GSK2857916 0.06 mg/kg (Part 1 MM)	0.06 mg/kg	2
		GSK2857916 0.12 mg/kg (Part 1 MM)	0.12 mg/kg	3
		GSK2857916 0.24 mg/kg (Part 1 MM)	0.24 mg/kg	4
		GSK2857916 0.48 mg/kg (Part 1 MM)	0.48 mg/kg	5
		GSK2857916 0.96 mg/kg (Part 1 MM)	0.96 mg/kg	6
		GSK2857916 1.92 mg/kg (Part 1 MM)	1.92 mg/kg	7
		GSK2857916 2.50 mg/kg (Part 1 MM)	2.50 mg/kg	8
		GSK2857916 3.40 mg/kg (Part 1 MM)	3.40 mg/kg	9
		GSK2857916 4.60 mg/kg (Part 1 MM)	4.60 mg/kg	10
		GSK2857916 3.40 mg/kg (Part 2 MM)	3.40 MM	11
		GSK2857916 3.40 mg/kg (Part 2 NHL)	3.40 NHL	12

Notes:
[1] This is a single-arm study and only active treatment is planned for the study.
[2] Part 1: dose escalation phase; Part 2: Expansion Cohort; MM: multiple myeloma; NHL: Lymphoma.

5.2. Baseline Definitions

For all endpoints (except as noted in baseline definitions) the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as baseline.

For subjects who did not receive study treatment during the study, baseline will be defined as the latest, non-missing collected value.

For ECG analyses, subject level baseline is defined as the mean of triplicate baseline assessments.

Unless otherwise stated, if baseline data is missing no derivation will be performed and baseline will be set to missing.

5.2.1. Examination of Subgroups

The list of subgroups may be used in descriptive summaries. Additional subgroups of clinical interest may also be considered.

Subgroup	Categories
Age	18 to <65, 65 to <75, >=75
Sex	Male, Female
Ethnic Background	White, Other
ISS Staging at Screening	I, II, III, Other (Unknown or Missing)
Number of prior lines of therapy	<=3,4-5, >5
Type of myeloma	IgG, Non-IgG
Prior Daratumumab Treatment	Yes, No
Refractory to prior anti-cancer therapy	Any Proteasome Inhibitor (PI) Bortezomib Carfilzomib Ixazomib Any Immunomodulator (IMiD) Thalidomide Lenalidomide Pomalidomide Monoclonal Antibodies Daratumumab Daratumumab alone [2] Daratumumab in combination [3] PI+IMiD Daratumumab+PI+IMiD
Cytogenetics Risk [1] [3]	High, Other (non-high risk, not done, or missing)
Prior anti-cancer therapy of interest	• With prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors. • Without prior Daratumumab Treatment. • Refractory to Both IMiDs and Proteasomes Inhibitors.

NOTES:

[1] A subject is considered as high risk if the subject has any of the following cytogenetics: t(4;14), del17p, t(14;16).

[2] Defined as prior CTX regimen with Daratumumab as the only drug the regimen.

[3] Defined as prior CTX regimen with Daratumumab and other drugs.

5.3. Other Considerations for Data Analyses and Data Handling Conventions

Other considerations for data analyses and data handling conventions are outlined in the appendices:

Section	Component
16.3	Appendix 3: Assessment Windows
16.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
16.5	Appendix 5: Data Display Standards & Handling Conventions
16.6	Appendix 6: Derived and Transformed Data
16.7	Appendix 7: Reporting Standards for Missing Data
16.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the "All Treated" population, unless otherwise specified.

Study population analyses including analyses of subject's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 12: List of Data Displays.

6.2. Disposition of Subjects

A summary of the number of subjects in each of the analysis populations described in Section 4 will be provided (for final analysis, Evaluable population will not be included). In addition, the number of subjects enrolled by center will be summarized by Study Part and Tumor Type using the "Enrolled" population. A separate summary for exclusions from each study population will be displayed (for final analysis, Evaluable population will not be included). A listing of subjects excluded from analysis populations will also be provided.

A summary of subject status and reason for study withdrawal will be provided. This display will show the number and percentage of subjects who withdrew from the study, including primary reasons for study withdrawal. Reasons for study withdrawal will be presented in the order they are displayed in the eCRF.

A summary of study treatment status will be provided. This display will show the number and percentage of subjects who are ongoing or discontinued study treatment and a summary of the primary reasons for discontinuation of study treatment. Reasons for study treatment discontinuation will be presented in the order they are displayed in the eCRF. A listing of study treatment discontinuation will be generated. The listing will include last dose date, and reasons for study treatment discontinuation.

6.3. Demographic and Baseline Characteristics

The demographic characteristics (e.g., age, race, ethnicity, sex, baseline height, and baseline body weight and baseline BMI will be summarized and listed. Age, height, weight and BMI will be summarized using the mean, standard deviation, minimum, median, and maximum. The count and percentage will be computed for sex and ethnicity.

Race and racial combinations will be summarized and listed.

Disease history and characteristics (e.g. time since initial diagnosis in years, stage at initial diagnosis, date of initial diagnosis) at initial diagnosis and screening will be listed. Separate summaries of disease characteristics at initial diagnosis and screening will be provided. Disease characteristics for multiple myeloma subjects at screening, including stage, lines of prior therapy regimens, type of multiple myeloma, myeloma light chain and myeloma immunoglobulin will be summarized and listed.

Medical conditions present at screening will be listed and will be summarized by past and current and by cancer-related and non-cancer related categories.

Genetic characteristics for multiple myeloma subjects at screening will be summarized and listed. Cytogenetic risk for multiple myeloma subjects at screening will be summarized. A subject is considered as having high cytogenetic risk if the subject has any of the following cytogenetics: t(4;14), del17p, t(14;16).

Substance use, including smoking history and alcohol use will be summarized and listed.

Prior anti-cancer therapy will be coded using GSK Drug coding dictionary, then summarized by type of therapy and listed. A listing of prior anti-cancer therapy will show the relationship between ATC Level 1, Ingredient, and verbatim text. A summary of the best response to the most recent prior anti-cancer therapy will be provided. A summary of the number of prior anti-cancer therapy regimens will also be produced.

Prior anti-cancer therapy for multiple myeloma subjects will also be summarized by type of therapy, drug class and subclass. A summary of multiple myeloma subjects refractory to prior anti-cancer therapy by drug class will be provided.

A multiple myeloma subject is defined to be refractory to prior anti-cancer therapy if

[1] the subject's best response to prior anti-cancer therapy is PD or SD, **OR**

[2] the subject's most recent response to prior anti-cancer therapy is PD or SD, **OR**

[3] the subject progress within 60 days of completion of prior anti-cancer therapy.

Summary of subjects with multiple myeloma double refractory to prior Immunomodulator (IMID) and Proteasome Inhibitor (PI) will also be provided. For definition of "double refractory", IMID and PI are not necessary to be in the same regimen.

Anti-cancer radiotherapy will be listed. Prior cancer and non-cancer related surgeries will be summarized. Prior and on treatment cancer and non-cancer related surgeries will be listed.

6.4. Treatment Compliance

Summaries of study treatment exposure and dose modifications (e.g., number of dose reductions, number of dose interruptions) will further characterize compliance. These analyses are described in Section 6.5 'Extent of Exposure'.

6.5. Extent of Exposure

Extent of exposure to GSK2857916 will be summarized.

The number of cycles administered to study treatment will be summarised with mean, median, standard deviation, minimum, and maximum. The number and percentage of subjects who received a given number of cycles (<4, 4, and >4 cycles) will be reported.

Dose intensity (dose delivered per cycle) will be summarized using mean, median, standard deviation, minimum, and maximum by cycle and overall. Dose intensity is the cumulative actual dose divided by the total number of cycles across the entire treatment period. A by subject summary listing of data on exposure to all study treatments will be produced.

Dose reductions will be summarised by number of reductions and reasons for reductions. Dose delays will be summarised by number of delays, reasons for the delays, and delay duration (days). The number and percentage of the delays 1-21, 22-42 and >42 days will be computed. Primary reasons for dose reductions and dose delays will also be summarized by cycle.

Duration of delays is defined as period from the expected start date of dose to actual start date of current dose. Calculation: (actual start date of current dose - expected start date of dose). Expected start date of dose = actual start date of previous dose + 21.

The summaries of dose modifications will be provided only if the data warrant.

All the dose reductions, dose escalations, infusion interruptions, incomplete infusions and dose delays will be listed separately.

A plot showing the number and percentage of subjects treated at different dose levels over time will be provided.

The duration of exposure to study treatment in days (from first day to last day of treatment) will be calculated. A horizontal bar graph of duration of treatment will be produced that displays duration of treatment in days for each subject.

6.6. Concomitant Medications

Concomitant medications will be coded using GSK Drug coding dictionary, summarized, and listed. The summary of concomitant medications will show the number and percentage of subjects taking concomitant medications by Ingredient. Multi-ingredient products will be summarized by their separate ingredients rather than as a combination of ingredients. Anatomical Therapeutic Chemical (ATC) classification Level 1 (Body System) information will be included in the dataset created but will not appear on the listing or summary.

Prophylactic Medication for Infusion-Related Reactions will be summarized by drug class and drug name and listed separately. Eye medications will be listed.

In the summary of concomitant medications, each subject is counted once within each unique ingredient. For example, if a subject takes Amoxycillin on two separate occasions, the subject is counted only once under the ingredient “Amoxycillin”. In the summary of concomitant medications, the ingredients will be summarized by the base only, using CMBASECD and CMBASE. Note: In order to be considered a concomitant medication, the concomitant medication must have been taken at some point during the on-therapy window.

Blood products or blood supportive care products with onset date within the on-therapy window will be included in the summary tables. The frequency and percentage of subjects using blood products and blood supportive care products after the start of study medication will be provided. Supporting listings will also be provided.

6.7. Subsequent Anti-Cancer Therapies

The number and percentage of subjects that received chemotherapy, immunotherapy, hormonal therapy, biologic therapy, radioactive therapy, small molecule targeted therapy, as post study treatment anti-cancer therapy will be summarized. Time from study treatment discontinuation to the first post study treatment anti-cancer therapy will also be included in this summary table.

Follow-up anti-cancer therapy will be coded using GSK Drug coding dictionary, then summarized by ingredient. A listing of the type of follow-up anti-cancer therapy received (chemotherapy, immunotherapy, hormonal therapy, biologic therapy, radioactive therapy, and small molecule targeted therapy for each subject will be provided).

7. EFFICACY ANALYSES

7.1. Primary Efficacy Analyses

No primary efficacy analyses were planned.

7.2. Secondary Efficacy Analyses

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1.1 and Section 7.2.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.2.1. Multiple Myeloma

7.2.1.1. Endpoint / Variables

7.2.1.1.1. Overall Response Rate

Overall Response Rate (ORR), is defined as the percentage of responders (subjects with confirmed stringent complete response (sCR), complete response (CR), very good partial response (VGPR), and partial response (PR) as assessed according to 2011 International Myeloma Working Group (IMWG) criteria (Appendix 1 in the protocol)). Only the assessments from the start of treatment up to the earlier of disease progression or the start of new anti-cancer therapy will be considered. Only new systemic anti-cancer drugs taken are considered as anti-cancer therapy (radiotherapy and surgeries are not considered as systemic anti-cancer therapy for the purpose of this analysis). .

Subjects with only one assessment (therefore not confirmed), or assessments of Not Evaluable or missing response will be treated as non-responders; i.e. they will be included in the denominator when calculating the percentage.

7.2.1.1.2. Response Confirmation Algorithm

The definitions and details to derive unconfirmed and confirmed response are outlined below. For both confirmed and unconfirmed response derivations, only responses assessments from the start of treatment up to the earlier of disease progression or the start of new anti-cancer therapy will be considered. Date associated with response was defined in Section 16.5.5

Definitions:

1. The hierarchy of response classifications from high to low is as following: sCR, CR, VGPR, PR, MR, SD, PD and NE. Response was assessed according to the 2011 Uniform Criteria Consensus recommendations of the International Myeloma Working Group (See Appendix 1 of protocol).

2. Definition of two consecutive assessments: the two consecutive assessments should be taken from two different samples, and NOT based upon the splitting of a single sample.
    a. No minimum time separation between two consecutive assessments is required to confirm response.
    b. If there are two assessments separated by not evaluable (NE) or Missing assessment(s), collapse data by ignoring NE or Missing assessments.
    c. If two consecutive assessments are on different dates, it is assumed that the two assessments are from different samples
    d. If there are multiple assessments on the same date and there is no data to show that they are from different samples, it is assumed these assessments are from the same sample. Then only the response with the lowest magnitude will be selected as the response for that date.

Two-step algorithm for determining the best confirmed response

Step1. Determine the confirmed response sequentially at each time of disease assessment.

A. For confirmed sCR, CR, VGPR, PR, MR, SD, two consecutive assessments are required.
    a. For any two consecutive assessments with different magnitudes, the confirmed response is the response of lower magnitude.
    b. For any two consecutive assessments with the same magnitude, the confirmed response is the response of that magnitude.
    c. Although the response will be confirmed at the time of the second one of the two consecutive assessments, the date of the first one of the two consecutive assessments will be the date of this confirmed response.

Table 4 Summary of the criteria for confirmation of sCR, CR, VGPR, PR, MR, SD

Response at one time-point of two consecutive assessments	Response at the other time-point of two consecutive assessments	Confirmed Response
sCR/CR/VGPR/PR/MR/SD	SD	SD
sCR/CR/VGPR/PR/MR	MR	MR
sCR/CR/VGPR/PR	PR	PR
sCR/CR/VGPR	VGPR	VGPR
sCR/CR	CR	CR
sCR	sCR	sCR

B. For PD, since for this study, no confirmation of PD is required, only one PD assessment is required. Any PD assessment will be confirmed by itself at the time of the PD's assessment.

C. If the subject has only one non-PD /non-NE assessment then the confirmed response is NE at the date of that assessment.

D. If all assessments were NE then the confirmed response is NE at the date for each assessment.

Step 2. Determine the best overall confirmed response in Step 1. If assessments at all visits are missing then the best confirmed response is NE.

Examples:

Example 1.

Step1.

Visit	Response	Confirmed response
1	PR	
2	SD	SD
3	SD	SD

Step 2.

The best overall confirmed response is SD

Example 2.

Step1.

Visit	Response	Confirmed response
1	VGPR	
2	NE	
3	NE	
4	PR	PR

Step 2.

The best overall confirmed response is PR

Example 3.

Step1.

Visit	Response	Confirmed response
1	sCR	
2	sCR	sCR
3	CR	CR
4	PR	PR

Step 2.

The best overall confirmed response is sCR

Example 4.

Step1.

Visit	Response	Confirmed response
1	sCR	
2	CR	CR
3	CR	CR
4	PR	PR

Step 2.

The best overall confirmed response is CR

Example 5.

Step1.

Visit	Response	Confirmed response
1	CR	
2	VGPR	VGPR

Step 2.

The best overall confirmed response is VGPR.

7.2.1.2. Summary Measure

Overall response rate (ORR) and the associated 2-sided 95% exact confidence intervals will be provided by dose level and study part. In addition, Clinical Benefit Rate (CBR), defined as the percentage of subjects with minimal response (≥ MR) will be summarized in the same way as ORR by dose level and study part. Unconfirmed response summaries may be provided for interim analyses. A list of investigator-assessed response at each visit will be listed.

7.2.1.3. Population of Interest

The secondary efficacy analyses will be based on the "All Treated" population, unless otherwise specified. Response data for multiple myeloma will be summarized by Study Part using the All Treated MM population and in subgroup: Prior anti-cancer therapy of interest as defined in Section 5.2.1.

7.2.2. Lymphoma

7.2.2.1. Endpoint / Variables

7.2.2.1.1. Overall Response Rate

For lymphoma patients, clinical activity for lymphomas will be calculated based on ORR defined as the percentage of subjects with confirmed CR or PR, as described in the Revised Response Criteria for Malignant Lymphoma (RRCML, Appendix 2 in the protocol) from the start of treatment until disease progression or the start of new anti-cancer therapy.

A summary of investigator-assessed best response with confirmation will be presented. Subjects with Not Evaluable or missing response will be treated as non-responders; and they will be included in the denominator when calculating the percentage. To be assigned a status of complete response or partial response, all responses must be confirmed by repeat assessments performed no less than four weeks after the criteria for CR or PR were met (RRCML, Appendix 2 in the protocol).

7.2.2.2. Summary Measure

Overall response rate and the associated 2-sided 95% exact confidence intervals will be provided. A list of investigator-assessed response at each visit will be listed.

7.2.2.3. Population of Interest

The secondary efficacy analyses will be based on the "All Treated" population, unless otherwise specified. Response data for lymphoma will be summarized using the Part 2 NHL population.

7.2.3. Strategy for Intercurrent (Post-Randomization) Events

Not applicable to this study.

7.2.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.3. Exploratory Efficacy Analyses

7.3.1. Multiple Myeloma

7.3.1.1. Endpoint / Variables

Time-to-event endpoint - Multiple Myeloma	
Progression-Free Survival (PFS)	defined as the time from first dose until the earliest date of confirmed disease progression (PD) per IMWG (2011), or death due to any cause.
Time to Progression (TTP)	defined as the time from first dose until the earliest date of PD per IMWG (2011), or death due to PD.
Duration of Response (DOR)	defined as the time from first documented evidence of confirmed PR or better until the time when disease progression (PD) is documented per IMWG (2011), or death due to PD among subjects who achieve a response (i.e. confirmed PR or better).
Time to Response (TTR)	defined as the time between the date of first dose and the first documented evidence of confirmed response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).
Time to Best Response (TTBR)	defined as the time between the date of first dose and the best confirmed response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).
Overall survival (OS)	defined as the time from the date of first dose until death from any cause.

In addition, monoclonal protein and serum free light chain lab test values will be plotted. Subgroup analysis for ORR will be performed

7.3.1.2. Summary Measure

7.3.1.2.1. Progression-Free Survival

PFS is defined as the interval of time between the date of first dose and the earlier of the date of first disease progression and the date of death due to any cause. Disease progression will be based on the assessments by the Investigator.

If there is no adequate baseline assessment, the subjects will be censored at their date of first dose. Subjects without any adequate post-baseline tumor assessments will be censored at the date of first dose.

Subjects who progressed or died after an extended period without adequate assessment will be censored at their date of last adequate assessment prior to progression or death even if subsequent information is available regarding progression or death. An adequate assessment is defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR or SD. The date of response at that assessment will be used for censoring. As the assessment schedule may change through the course of the protocol, specific rules for identifying extended loss to follow-up or extended time without an adequate assessment are provided in Section 16.5.4.

For subjects who receive subsequent anti-cancer therapy the following rules will apply:

- If the start date of the anti-cancer therapy is partial (i.e. either missing the day but has the month and year available or missing both day and month), the imputation rules described in Section 16.7.2.1 will be applied. No imputation will be made for completely missing dates.
- If anti-cancer therapy is started without documented disease progression or death OR is started prior to documented disease progression or death, then PFS will be censored at the date of the last adequate assessment that is no later than the date of initiation of anti-cancer therapy (i.e. if an assessment occurs on the same day as the start of new anti-cancer therapy the assessment will be used - as it will be assumed the assessment occurred prior to the administration of new anti-cancer therapy). The date of response at the last adequate assessment will be used as the censoring value.
- If a subject has only a baseline visit or does not have an adequate assessment that is no later than the date of initiation of anti-cancer therapy, PFS will be censored at the date of first dose.
- If a subject has neither progressed nor died nor started new anti-cancer therapy, then PFS will be censored at the date of the last adequate assessment defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR or SD. The date of response will be used as the censoring date.

A summary of the assignments for progression and censoring dates for PFS are specified in Table 5.

Table 5 Assignments for Progression and Censoring Dates for PFS Analysis

Situation	Date of Event (Progression/Death) or Censoring	Outcome Event (Progression/Death) Or Censored
No *(or inadequate)* baseline tumor assessments [1] and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
No post-baseline assessments and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
Progression documented between scheduled visits	Date of assessment of progression [1]	Event
No progression *(or death)*	Date of last 'adequate' assessment of response [2]	Censored
New anticancer treatment started *(prior to documented disease progression or death)* [3].	Date of last 'adequate' assessment of response [2] *(on or prior to starting anti-cancer therapy)*	Censored
Death before first PD assessment (or Death at baseline or prior to any adequate assessments)	Date of death	Event
Death between adequate assessment visits	Date of death	Event
Death or progression after an extended loss-to-follow-up time (two or more missed cycles + 7 day window) [4]	Date of last 'adequate' assessment of response [2] *(prior to missed assessments)*	Censored

[1] **In part 1**, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein or b. Urine M-protein or c. Serum FLC assay or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit).
In part 2, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein ≥0.5 g/dL (≥5 g/L) or b. Urine M-protein ≥200 mg/24h or c. Serum FLC assay: Involved FLC level ≥5 mg/dL (≥50 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65) or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit and no later than the first dose date).
[2] An adequate assessment is defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR, or SD.
[3] If PD or death and New anti-cancer therapy occur on the same day assume the progression or death was documented first (e.g., outcome is progression or death and the date is the date of the assessment of progression or death). If anti-cancer therapy is started prior to any adequate assessments, censoring date should be the date of first dose.
[4] Refer to section 16.5.4 "Extended Loss to Follow-up or Extended Time without an Adequate Assessment".

PFS will be summarized using Kaplan-Meier curves. If there are a sufficient number of progressions or deaths, median PFS, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A figure and listing of PFS time will also be provided. Summary and figure of PFS will be based on

Part 2 MM sub-population and subgroup prior anti-cancer therapy of interest; listing of PFS will be based on All Treated MM population.

7.3.1.2.2. Time to Progression

TTP is defined as the interval of time between the date of first dose and the earlier of the date of first documented evidence of PD, or death due to PD, whichever occurs first.

A summary of the assignments for progression and censoring dates for TTP are specified in Table 6

Table 6 Assignments for Progression and Censoring Dates for TTP Analysis

Situation	Date of Event (Progression/Death) or Censoring	Outcome Event (progression/Death) Or Censored
No *(or inadequate)* baseline tumor assessments [1] and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
No post-baseline assessments and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	First dose date	Censored
Progression documented at or between scheduled visits	Date of assessment of progression [1]	Event
No progression *(or death)*	Date of last 'adequate' assessment of response [2]	Censored
New anticancer treatment started *(prior to documented disease progression or death)* [3].	Date of last 'adequate' assessment of response [2] *(on or prior to starting anti-cancer therapy)*	Censored
Death from causes other than progression	Date of death	Censored
Death or progression after an extended loss-to-follow-up time (two or more missed cycles + 7 day window) [4]	Date of last 'adequate' assessment of response [2] *(prior to missed assessments)*	Censored

[1] **In part 1**, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein or b. Urine M-protein or c. Serum FLC assay or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit).
In part 2, adequate baseline assessment is defined as at baseline, a patient has at least one of the following measurements: a. Serum M-protein ≥0.5 g/dL (≥5 g/L) or b. Urine M-protein ≥200 mg/24h or c. Serum FLC assay: Involved FLC level ≥5 mg/dL (≥50 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65) or d. Biopsy proven plasmacytoma (should be measured within 28 days of Screening Visit and no later than the first dose date).
[2] An adequate assessment is defined as an assessment where the Investigator determined response is sCR, CR, VGPR, PR, MR, or SD.
[3] If PD and New anti-cancer therapy occur on the same day assume the progression was documented first e.g., outcome is progression and the date is the date of the assessment of progression). If anti-cancer therapy is started prior to any adequate assessments, censoring date should be the date of first dose. Refer to Section 16.5.4 "Extended Loss to Follow-up or Extended Time without an Adequate Assessment".

TTP will be summarized using Kaplan-Meier curves. If there are a sufficient number of progressions or death due to PD, median TTP, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A figure and listing of TTP time will also be provided. Summary and figure of TTP will be based on Part 2 MM population; listing of TTP will be based on All Treated MM population.

7.3.1.2.3. Duration of Response

Duration of Response (DOR) is defined, for subjects with a confirmed response (PR or better) as the time between first documented evidence of confirmed response and disease progression or death due to PD, whichever occurs first.

- Duration of response is derived for patients with a confirmed PR or better only.
- Censoring rules will follow those of the TTP analysis.

DOR will be summarized using Kaplan-Meier curves. If there are a sufficient number of progressions or death due to PD among the responders, median DOR, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A figure and listing of DOR time will also be provided. Summary and figure of DOR will be based on Part 2 MM population and subgroup: prior anti-cancer therapy of interest; listing of DOR will be based on All Treated MM population.

7.3.1.2.4. Time to Response

Time to Response (TTR) is defined as the time from first dose to the first documented evidence of confirmed PR or better, among subjects who achieve a response (i.e., confirmed PR or better).

TTR will be summarized using Kaplan-Meier method. If data permits, median TTR, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A listing of TTR time will also be provided. Summary of TTR will be based on Part 2 MM population; listing of TTR will be based on All Treated MM population.

7.3.1.2.5. Time to Best Response

Time to Response (TTBR) is defined as the time from first dose to the best confirmed response (PR or better), among subjects who achieve a response (i.e., confirmed PR or better).

TTBR will be summarized using Kaplan-Meier method. If data permits, median TTBR, first and third quartiles and 95% CI, will be estimated using the Brookmeyer-Crowley method [Brookmeyer, 1982]. A listing of TTBR time will also be provided. Summary of TTBR will be based on Part 2 MM population; listing of TTBR will be based on All Treated MM population.

7.3.1.2.6. Overall Survival

Overall survival (OS) is defined as the time from the date of first dose until death from any cause. For subjects who do not die, time of death will be censored at the date of last contact.

The protocol is amended to collect long-term survival data (i.e. up to 1 year after last subject completes or discontinues treatment). Subjects who are already completed the study will be contacted to request re-consent.

If all the patients (who were alive at the time of study completion) can be re-consented, OS landmark analysis may be performed at 9 and 12 months using Kaplan-Meier analysis as data permits. A listing of OS will also be provided. The OS landmark analysis will be based on Part 2 MM population; listing of OS will be based on All Treated MM population.

Otherwise, only descriptive analysis (number and % of deaths and lost to follow-up) will be performed.

7.3.1.3. Monoclonal Protein and Serum Free Light Chain

A waterfall plot showing the maximum percent reduction from baseline in Serum M-protein, or Urine M-protein, or difference between two types Serum FLC [Kappa light chain (Kappa LC) and Lambda light chain (Lambda LC)] for each subject will be produced using Part1 and Part 2 MM populations. Only the assessments from the start of treatment up to the start of new anti-cancer therapy will be considered. Only new systemic anti-cancer drugs taken are considered as anti-cancer therapy (radiotherapy and surgeries are not considered as systemic anti-cancer therapy for the purpose of this analysis). The maximum percent reduction will be plotted in the following hierarchical order:

[1] Plot Serum M-protein maximum percent reduction from baseline if data is available;

[2] If [1] is not feasible, plot Urine M-protein maximum percent reduction from baseline if data is available;

[3] If both [1] and [2] are not feasible, plot maximum percent reduction from baseline for difference between two types of Serum FLC if data is available;

Difference between two types Serum FLC

The percent change from baseline for difference between two types of Serum FLC is defined as:

(post-baseline difference-baseline difference) / baseline difference *100%

To calculate the difference, the “involved” and “non-involved” light chains must be determined at first based on the ratio of non-missing values for Serum Kappa LC protein and Serum Lambda LC protein at baseline.

Detailed algorithm is provided as below:

- If the baseline ratio of (Kappa LC/Lambda LC)>1.65, then Kappa LC is defined as involved FLC, and Lambda LC is defined as non-involved FLC. Then
    - Difference between involved and uninvolved = Kappa LC-Lambda LC
- If the baseline ratio of (kappa/lambda)<0.26, then Lambda light chain is defined as involved FLC, and Kappa light chain is defined as non-involved FLC
    - Difference between involved and uninvolved = Lambda LC-Kappa LC
- If the baseline ratio of (Kappa LC/Lambda LC) ≤ 1.65 and ≥ 0.26, then "involved" and "non-involved" FLC can not be determined (ratio is normal), and maximum percent reduction from baseline for difference between two types of Serum FLC won't be available.

In addition, a scatter plot of free soluble BCMA at pre-dose (cycle 1) and maximum percent change from baseline in Serum M-protein, Urine M-protein or difference between two types Serum FLC will be provided following the hierarchical order specified above.

7.3.1.4. Subgroup Analysis of ORR

A forest plot of ORR analysis will be provided for the following subgroups: Age, Sex, Ethnic Background, ISS Staging at Screening, Number of prior lines of therapy, Type of myeloma, Prior Daratumumab Treatment, Refractory to prior anti-cancer therapy, Cytogenetics Risk as defined in Section 5.2.1.

7.3.1.5. Population of Interest

The secondary efficacy analyses will be based on the "All Treated" population, unless otherwise specified (as in Section 4).

7.3.2. Strategy for Intercurrent (Post-Randomization) Events

Not applicable to this study.

7.3.3. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

8. SAFETY ANALYSES

The safety analyses will be based on the "All Treated" population, unless otherwise specified.

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 12: List of Data Displays.

An overview summary of AEs, including counts and percentages of subjects with any AE, AEs related to study treatment, AEs leading to permanent discontinuation of study treatment, AE leading to dose reductions, AEs leading to dose delays OR interruptions, SAEs, SAEs related to study treatment, fatal SAEs, and fatal SAEs related to study treatment will be produced.

A summary of non-serious AEs that occurred in strictly 5% of the subjects or above will be provided (no rounding for the percentage will be used in terms of 5% threshold, e.g., event with 4.9% incidence rate should not be included in this table). The summary will be displayed by SOC and PT.

The relationship between MedDRA SOC, PT, and Verbatim Text will be displayed.

Adverse events (AEs) will be graded according to the CTCAE, Version 4.0. Adverse events will be coded to the preferred term (PT) level using the Medical Dictionary for Regulatory Affairs (MedDRA dictionary).

A summary of number and percentage of subjects with any adverse events by maximum grade will be produced. AEs will be sorted by Preferred term (PT) in descending order of total incidence. The summary will use the following algorithms for counting the subject:

- **Preferred term row**: Subjects experiencing the same AE preferred term several times with different grades will only be counted once with the maximum grade.

- **Any event row**: Each subject with at least one adverse event will be counted only once at the maximum grade no matter how many events they have.

In addition, the frequency and percentage of AEs (all grades) will be summarized and displayed in two ways: 1) in descending order of total incidence by PT only and 2) in descending order of total incidence by System Organ Classes (SOC) and PT and Maximum Grade. In the SOC row, the number of subjects with multiple events under the same system organ class will be counted once.

A separate summary will be provided for study treatment-related AEs. A study treatment-related AE is defined as an AE for which the investigator classifies the relationship to study treatment as "Yes". A worst-case scenario approach will be taken to handle missing relatedness data, i.e. the summary table will include events with the relationship to study

treatment as 'Yes' or missing. The summary table will be displayed in descending order of total incidence by SOC and PT and Maximum Grade.

All AEs will be listed. Additionally, a listing of subject IDs for each individual AE will be produced.

A listing of adverse events recorded as dose-limiting toxicities will be provided. Additionally, a summary of the number of patients experiencing DLT's in each cohort will be provided.

The summary of adverse event by SOC and PT and maximum grade, and AE by PT will also be produced for the following subgroups:

Prior anti-cancer therapy of interest:

- With prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors
- Without prior Daratumumab Treatment
- Refractory to Both IMiDs and Proteasomes Inhibitors

8.2. Adverse Events of Interest Analyses

There are no pre-defined Adverse Events of Special Interest in the protocol, as it was a first time in human (FTIH) trial. During the course of the study, the analyses of the following adverse events of interest were included upon the safety review team (SRT) requests.

- Corneal events
- Thrombocytopenia
- Neutropenia
- Hematologic Toxicity
- Infusion-related Reactions as collected in the eCRF

For Corneal events, Thrombocytopenia, Neutropenia Hematologic Toxicity, a comprehensive list of MedDRA terms based on clinical review will be used to identify each type of event. Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional adverse events of interest, therefore the list of terms to be used for each event of interest and the specific events of interest will be based on the SRT agreements in place at the time of reporting. The details of the planned displays are provided in Appendix 12: List of Data Displays.

Summaries of the number and percentage of subjects with these events will be provided for each type of events separately by preferred term and maximum grade. The time of

onset and duration of first occurrence of each type of events will be summarized using summary statistics mean, standard deviation, median, minimum value, and maximum. The number and percentage of subjects who have time of onset of first occurrence (1-21, 22-42, 43-63, >63 days) will be reported. The number and percentage of subjects who have duration of first occurrence (1-21, 22-42, >42 days) will be reported.

The summary of event characteristics will also be provided, including number of subjects with any event, number of events, number of subjects with any event that is serious, number of subjects with any event that is related to study treatment, number of occurrences (One, Two, Three or more), maximum grade and the action taken for the event. The percentage will be calculated in two ways, one with number of subjects with event as the denominator and the other with total number of subjects as the denominator. The worst-case approach will be applied at subject level for the maximum grade, i.e. a subject will only be counted once as the worst case from all the events experienced by the subject. For action taken to an event, subject will be counted once under each action, e.g. if a subject has an event leading to both study treatment discontinuation and dose reduction, the subject will be counted once under both actions.

8.3. Deaths and Serious Adverse Events

In the event that a subject has withdrawn consent, no data after the withdrawal of consent date from this subject including death is supposed to appear in the database, which should be part of the data cleaning process. All deaths will be summarised based on the number and percentage of subjects. This summary will classify subjects by time of death relative to the last dose of medication (>30 days or ≤30 days) and primary cause of death (disease under study, SAE related to study treatment, or other). A supportive listing will be generated to provide subject-specific details on subjects who died.

All SAEs will be tabulated based on the number and percentage of subjects who experienced the event. Separate summaries will also be provided for study treatment-related SAEs. The summary tables will be displayed in descending order of total incidence by SOC and PT.

A study treatment-related SAE is defined as an SAE for which the investigator classifies the relationship to study treatment as “Yes”. A worst-case scenario approach will be taken to handle missing data, i.e. the summary table will include events with the relationship to study treatment as ‘Yes’ or missing.

SAEs are included in the listing of all adverse events. Separate supportive listings with subject-level details will be generated for

- Fatal SAEs
- Non-Fatal SAEs.

AEs of maximum grade of 3 or higher will be summarized separately by SOC and PT.

8.4. Adverse Events Leading to Discontinuation of Study Treatment and/or Withdrawal from the Study and Other Significant Adverse Events

The following categories of AEs will be summarized separately in descending order of total incidence by SOC and PT and separate supportive listings will be generated with subject level details for those subjects:

- AEs Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study
- AEs Leading to Discontinuation of Study Treatment
- AEs Leading to Dose Interruptions or Delays
- AEs Leadings to Dose Reductions

8.5. Pregnancies

While pregnancy itself is not considered to be an AE or SAE, any pregnancy complication or elective termination of a pregnancy for medical reasons will be recorded as an AE or SAE as described in the protocol. If subjects and subjects' partner become pregnant while on the study, the information will be included in the narratives and no separate table or listing will be produced.

8.6. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 12: List of Data Displays.

Summary of change from baseline by scheduled visits using mean, median, standard deviation, minimum and maximum will be provided.

Summaries of worst case grade increase from baseline grade will be provided for all the lab tests that are gradable by CTCAE v4.0. These summaries will display the number and percentage of subjects with a maximum post-baseline grade increasing from their baseline grade. Any increase in grade from baseline will be summarized along with any increase to a maximum grade of 3 and any increase to a maximum grade of 4. Missing baseline grade will be assumed as grade 0. For laboratory tests that are graded for both low and high values, summaries will be done separately and labelled by direction, e.g., sodium will be summarized as hyponatremia and hypernatremia.

For lab tests that are not gradable by CTCAE v4.0, summaries of worst case changes from baseline with respect to normal range will be generated. Decreases to low, changes to normal or no changes from baseline, and increases to high will be summarized for the worst case post-baseline. If a subject has a decrease to low and an increase to high during the same time interval, then the subject is counted in both the "Decrease to Low" categories and the "Increase to High" categories.

Separate summary tables for hematology, and chemistry laboratory tests will be produced. Liver function laboratory tests will be included with chemical chemistry.

A supporting listing of laboratory data for subjects with abnormalities of potential clinical concern will be provided. A separate listing of laboratory data with character values will also be provided. For lab test values that can be graded, values of grade 1 or above are defined as values of potential clinical concern. For lab test values that can not be graded, values out of the normal range are defined as values of potential clinical concern.

Detailed derivation of baseline assessment is specified in Section 5.2.

Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of subjects with non-missing value at each particular visit.

8.6.1. Analyses of Liver Function Tests

Summaries of hepatobiliary laboratory events including possible Hy's law cases will be provided in addition to what has been described above.

A plot of maximum total bilirubin versus maximum ALT will be generated. Plots of maximum AST versus maximum LDH and maximum AST versus maximum Creatinine Kinase will be generated.

A Summary of Liver Monitoring/Stopping Event Reporting will be provided. The medical conditions data for subjects with liver stopping events will be listed. The substance use data for subjects with liver stopping events will be listed.

8.7. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs and vital signs will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 12: List of Data Displays.

Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of subjects with non-missing value at each particular visit.

Performance Status

ECOG performance status will be summarized at baseline and each post-baseline scheduled visit. Summaries will use frequency and percentage of subjects at each planned assessment time. A summary of change from baseline by scheduled visits will be performed, as well as the worst case post-baseline and the best case post-baseline changes during the study (improved, no change, deteriorated).

A supporting listing will also be provided.

ECG

A summary of the number and percentage of subjects who had normal and abnormal (clinically significant and not clinically significant) ECG findings will be displayed by scheduled visits as well as for the worst case post-baseline.

The QTc values based on Fridericia formula will be rounded to the integer and the values will be categorized into the following ranges: Grade 0 (<450), Grade 1 (450-480), Grade 2 (481-500), and Grade 3 (≥501). Summaries of grade increase will be provided. These summaries will display the number and percentage of subjects with any grade increase, increase to grade 2 and increase to grade 3 in the worst case post-baseline only.

The changes in QTc values will be categorized into the clinical concern ranges which are specific to changes in QTc: 31-60 and >60 msec. A summary of change in QTc value will display the number and percentage of subjects with a change within each range in the worst case post-baseline only. Subjects with missing baseline values will be excluded from this summary.

A listing of QTc values of potential clinical importance will be provided

The summaries and listing of QTc will use the collected values based on Fridericia formula.

A figure plotting the baseline QTc and the worst-case post-baseline values will be produced. The figure will have reference lines at 480 and 500 msec for both the ordinate and the abscissa axes. There will be diagonal reference lines at equality (i.e. a 45 degree line), at equality plus 30 msec, and at equality plus 60 msec.

LVEF

Absolute change from baseline in LVEF will be summarized in the worst case post-baseline only. Only the post-baseline assessments that used the same method (ECHO or MUGA) as the baseline assessments will be used to derive the change from baseline. The change from baseline will be categorized as follows:

- No change or any increase
- Any decrease
- >0-<10 decrease
- 10-19 decrease
- >=20 decrease
- >=10 decrease and >= LLN
- >=10 decrease and < LLN
- >=20 decrease and >= LLN
- >=20 decrease and < LLN

LVEF results will also be listed with subject level details including absolute change from baseline.

Ocular Exams

For best corrected visual acuity (BCVA), summary statistics for the logMAR score at baseline and end of study treatment will be displayed separately by eye using mean, median, standard deviation, minimum and maximum. Changes of logMAR score from baseline to end of treatment visit, and maximum (worst) change from baseline will be summarized based on the following categories: no change/improved vision: a change from baseline <0.12; a possible worsened vision: a change from baseline >=0.12 to <0.3; a definite worsened vision: a change from baseline >=0.3. Subjects with character values of visual acuity exam results will not be included in this summary.

Number and percentage of subjects who experienced corneal clinical signs will be summarized. Among subjects who experienced corneal clinical signs, number and percentage of subjects with/without reported corneal events will be provided. Visual acuity/ abnormal corneal exam results (eye level) at each visit, and incidence of corneal clinical signs and reported corneal events (subject level) during the study will be listed. The findings considered 'corneal clinical signs' were identified from the pre-defined list of choices in the eCRF.

Listing of abnormal conjunctival exam results, listing of abnormal slit lamp Lens and slit lamp anterior chamber exam results and listing of indirect fundoscopic exam and intra-ocular pressure results will be provided separately.

Constitutional Symptoms (or B-Symptoms)

A summary of the number and percentage of subjects with any constitutional symptom /B-symptom will be displayed by scheduled visits. A summary of improvement, i.e. number of subjects who had no symptoms at each post-baseline scheduled visit and had at least one at baseline, will also be provided.

A supporting listing will be provided.

Organ Examination

The number and percentage of subjects with normal or enlarged organs based on liver and spleen examination by palpation/CT scan will be summarized by scheduled visits.

A supporting listing will also be provided.

9. PHARMACOKINETIC ANALYSES

The pharmacokinetic (PK) analyses will be based on the Pharmacokinetic population, unless otherwise specified.

Pharmacokinetic data from Part 1 of the study will be analyzed using standard non-compartmental methods, and combined data from Part 1 and Part 2 of the study will be analyzed in a population approach using nonlinear mixed effects modeling. Full details are presented in Appendix 12: List of Data Displays.

9.1. Endpoint / Variables

9.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 16.5.3 Reporting Standards for Pharmacokinetic)

9.1.2. Derived Pharmacokinetic Parameters

9.1.2.1. Non-compartmental Analysis

- The pharmacokinetic parameters for Part 1 will be calculated by standard non-compartmental analysis according to current working practices and using Phoenix WinNonlin, version 6.3 or later.
- All calculations of non-compartmental parameters will be based on actual sampling times.
- Pharmacokinetic parameters described in Table 7 will be determined from the Cycle 1 plasma concentration-time data in Part 1 of the study separately for each analyte, as data permit.

Table 7 Derived Pharmacokinetic Parameters

Parameter	Parameter Description
AUC(0-t)	Area under the concentration-time curve from time zero to the time of the last quantifiable concentration (C(t)) will be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
AUC(0-τ)	Area under the concentration-time curve during the dosing interval
AUC(0-∞)	Area under the concentration-time curve extrapolated to infinity will be calculated as: **AUC = AUC(0-t) + C(t) / lambda_z**
%AUCex	The percentage of AUC (0-∞) obtained by extrapolation (%AUCex) will be calculated as: **[AUC(0-inf) – AUC(0-t)] / AUC(0-inf) x 100**
Cmax	Maximum observed concentration, determined directly from the concentration-time data for each cycle
tmax	Time to reach Cmax, determined directly from the concentration-time data for each cycle
Cτ, Ctrough	Trough concentration prior to the next dose for each cycle

Parameter	Parameter Description
t½	Apparent terminal half-life will be calculated as: **t½ = ln2 / lambda_z**
tlast	Time of last observed quantifiable concentration
CL	Clearance
Vss	Volume of distribution at steady state
λz, lambda_z	Terminal phase rate constant
Ae(0-24)	Urinary recovery of cys-mcMMAF within the 24-h collection period will be calculated as: **Urine cys-mcMMAF concentration x 24-h urine volume**
Fe	Fraction of cys-mcMMAF dose excreted in the 24-h collection period will be calculated as: **Ae(0-24) / cys-mcMMAF dose**

9.2. Population of Interest

The primary pharmacokinetic analyses will be based on the "Pharmacokinetic" population, unless otherwise specified.

9.3. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK Data Standards and statistical principles. Unless otherwise specified, endpoints / variables defined in Section 9.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

9.3.1. Statistical Methodology Specification

The following pharmacokinetic statistical analyses will only be performed if sufficient data are available.

9.3.1.1. Exploratory assessment of dose proportionality:

The PK-dose relationship initially will be examined graphically by plotting AUC(0-∞), AUC(0-τ), and Cmax as a function of the dose levels administered; AUC(0-t) may be used for cys-mcMMAF. Plots of PK parameters versus dose will be produced, with two plots for each PK parameter. The first will be on a linear scale, and the second will use the logarithmic scale for both axes.

In practice, at least three dose levels are required to assess dose proportionality. Hence, if more than two dose cohorts are required to reach MTD (or recommended dose based on available safety, PK, and response data), dose proportionality of GSK2857916, unbound antibody, total antibody, and cys-mcMMAF following administration in Cycle 1 will be evaluated, if data permit, using the power model.

Dose Proportionality Analysis
Endpoint(s)
• Log_e-transformed single dose PK parameters (AUC(0-∞), AUC(0-τ), and Cmax; AUC(0-t) for cys-mcMMAF) will be investigated.
Model Specification

• Endpoints for each analyte will be separately analyzed using appropriate methods for GSK2857916 doses.
• Power Model
  • Dose proportionality of PK parameters AUC(0-∞), AUC(0-τ), and Cmax (AUC(0-t) for cys-mcMMAF) will be assessed following single dose administration of GSK2857916 between 0.03 mg/kg and 4.6 mg/kg, using the power model as described below:
  $y = \alpha * dose^{\beta}$
  where y denotes the PK parameter being analyzed and α depends on subject.
  • Dose proportionality implies that β=1 and will be assessed by estimating β along with its 90% confidence interval. The exponent, β, in the power model will be estimated by regressing the log_e-transformed PK parameter on log_e-transformed dose.
  • The power model will be fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. A power model with only subject as a random effect power model will be fitted. The mean slope will be estimated from the power model and the corresponding 90% confidence interval calculated.
  • If the 90% confidence interval for the slope regressing dose against exposure is contained within the interval (0.8, 1.25), the exposure will be considered to be dose proportional.

Model Checking & Diagnostics
• Refer to Section 9.3.2.
Model Results Presentation

• Power Model
  • The mean slope and the corresponding 90% confidence interval for each parameter will be produced in tabular format.
  • Comparative plots of individual PK parameters will be generated by treatment on linear and semi-logarithmic scales.
  • Supportive SAS output from statistical analysis will be generated.

9.3.1.2. Assessment of Accumulation Ratio:

To assess the extent of accumulation following GSK2857916 repeat dosing, the observed accumulation ratio (Ro) for GSK2857916, total antibody, unbound antibody, and cys-mcMMAF will be determined as ratio of Cmax and Ctrough at steady-state to Cmax and Ctrough after the first dose, respectively, adjusted for any change in GSK2857916 dose.

Ro (Cmax) = Cmax CxD1/Cmax C1D1;
x = 3, 5;

Ro (Ctrough) = Ctrough CxD1/Ctrough C1D1;
x = 3, 5;

Preliminary pharmacokinetic data indicate that the pharmacokinetics for the third consecutive dose given at the planned interval will be at steady state. Therefore, based

on the study design, subjects who meet one of the following criteria will be at steady state:

- Subjects who receive the same dose without delay or change for Cycles 1, 2, and 3 (i.e., with dosing delays of ≤3 days). In this case, Cycle 3 represents steady state. Accumulation ratios are calculated as Cycle 3/Cycle 1.
- Subjects who receive the same dose without delay or change to Cycle 5. Accumulation ratio = Cycle 5/Cycle1.
- Subjects who have a dose reduction or two by Cycle 3, but then dose is maintained at the same level and interval through Cycle 5. Cycle 5 represents steady-state pharmacokinetics, but dose adjustment is needed. Dose adjustment: multiply Cmax/Ctrough values by the ratio (starting dose level/Cycle 3-5 dose level). Accumulation ratio = adjusted Cycle 5/Cycle 1.

For the purpose of accumulation ratio analysis, Cmax is defined as the EOI concentration at each cycle.

Exploratory analysis might be performed considering the effect of dose delay on the ratio.

Accumulation Ratio Assessment (Part 1 and Part 2)
Endpoint(s)
• Accumulation ratio (Ro). The observed accumulation ratio (Ro) will be calculated for each analyte by determining the ratio of Cmax at steady state to Cmax on Day 1 (Ro(Cmax)) and the ratio of Ctrough at steady state to Ctrough on Day 1 (Ro(Ctrough)).
Model Specification
• A mixed effect model will be fitted for each parameter by actual dose at each cycle as fixed effect and subject as random effect. The model will be adjusted by actual dose and dose delay status in each cycle. The ratio will be calculated by back-transforming the difference between the Least Squares means. Using the pooled estimate of variance, 90% confidence intervals will be calculated for the difference and then back-transformed. • The Kenward & Roger degrees of freedom approach will be used.
Model Checking & Diagnostics
• Refer to Section 9.3.2.
Model Results Presentation
• Geometric least-squares means for each treatment, point estimates and associated 90% confidence intervals for the ratios for each parameter will be produced in tabular format. • Plots of mean Accumulation Ratio will be generated by dose group on linear and semi-logarithmic scales. • The accumulation ratio will be listed and summarized along with other PK parameters. • Supportive SAS output from statistical analysis will be generated.

9.3.1.3. Assessment of Analyte Ratios:

Following natural log-transformation, Cmax and Ctau of ADC, unbound and total antibody, and cys-mcMMAF will be analysed using a mixed effects model with fixed effect terms for treatment, visit, and log(body weight). Subject will be treated as a

random effect in the model. Point estimates and their associated 90% confidence intervals will be constructed for the differences of Cmax and Ctau in analytes and comparison with cys-mcMMAF at each cycle. The point estimates and their associated 90% confidence intervals then will be back-transformed to provide point estimates and 90% confidence intervals for the ratios of analytes to cys-mcMMAF at each cycle.

Ratio of analytes at each cycle versus cys-mcMMAF at Cycle X:
Ra (Cmax) = Cmax (ADC, unbound anti-body, total anti-body) Cycle X /
Cmax (cys-mcMMAF) Cycle X
X = 1, 2, 3, 5;

Ra (Ctrough) = Ctrough (ADC, unbound anti-body, total anti-body) Cycle X /
Ctrough (cys-mcMMAF) Cycle X
X = 1, 2, 3, 5;

For the purpose of analyte ratio analysis, Cmax is defined as the EOI concentration at each cycle, and Ctrough is defined as the concentration immediately prior to the next cycle dose.

To fit into the analysis model, the units of the analytes need to be converted from ng/mL or pg/mL to nM as below.

	Original unit	Operation	Converted unit
ADC	ng/mL	/152.1	nM
Total Antibody	ng/mL	/152.1	nM
Unbound Antibody	ng/mL	/152.1	nM
cys-mcMMAF	pg/mL	/1045	nM

Pharmacokinetic Statistical Analyses
Endpoint(s)
• Cmax, Ctau by analyte and cycle
Model Specification
• Repeated measures mixed effects analysis
Model Checking & Diagnostics
• Refer to Section 9.3.2
Model Results Presentation
• Graphical ratios at Cycle 1 • Graphical ratio of analyte to cys-mcMMAF by cycle

9.3.2. Model Checking & Diagnostics

Endpoint(s)	• For Dose Proportionality Analysis (Parts 1), Log_e-transformed single dose PK parameters (AUC(0-∞), AUC(0-τ), and Cmax; AUC(0-t) for cys-mcMMAF) in Cycle 1, as applicable. • For Accumulation Ratio Assessment (Part 1 and Part 2), Log_e-transformed accumulation ratio (Ro) for Cmax at steady state to Cmax on Day 1 (Ro(Cmax)) and the ratio of Ctrough after the dose at steady state to Ctrough after the dose on Day 1 (Ro(Ctrough)). • For Analyte Ratio Assessment (Part 1 and Part 2), Log_e-transformed Cmax and Ctau
Analysis	• Mixed Effects

Assumptions:

- Model assumptions will be applied, but appropriate adjustments may be made based on the data.
- The Kenward and Roger method for approximating the denominator degrees of freedom and correcting for bias in the estimated variance-covariance of the fixed effects will be used.
- An unstructured covariance structure for the G matrix will be used by specifying 'type=UN' on the RANDOM line.
    - In the event that this model fails to converge, alternative correlation structures may be considered such as VC or CS.
    - Akaike's Information Criteria (AIC) will be used to assist with the selection of covariance structure.
- Distributional assumptions underlying the model used for analysis will be examined by obtaining a normal probability plot of the residuals and a plot of the residuals versus the fitted values (i.e., checking the normality assumption and constant variance assumption of the model respectively) to gain confidence that the model assumptions are reasonable.
- If there are any departures from the distributional assumptions, alternative models will be explored using appropriate transformed data.

10. POPULATION PHARMACOKINETIC (POPPK) ANALYSES

The primary goal of this analysis is to characterize the population pharmacokinetics of GSK2857916 and associated analytes after intravenous of GSK2857916 in participants with multiple myeloma. The influence of subject demographics, baseline characteristics including disease activity, and other covariates on the pharmacokinetics of GSK2857916 will be investigated. The individual subject pharmacokinetic parameters will be estimated and documented for the purposes of any subsequent exposure-response (PK/PD) analyses. This analysis will be performed by CPMS and reported separately.

A summary of the planned population pharmacokinetic analyses is outlined below:

- Plasma concentration-time data for GSK2857916 ADC will be subjected to nonlinear mixed effects modelling using the program NONMEM to develop a population pharmacokinetic model. A similar approach may be used on the data from the three analytes (ADC, total antibody, and cys-mcMMAF) together.

- Individual *post hoc* estimated pharmacokinetic parameters will be summarized descriptively.
- To support this analysis, a population PK dataset will be generated. The details for the dataset specifications are provided in Appendix 9: Population Pharmacokinetic (PopPK) Analyses.

Detailed population PK methodology is presented in Appendix 9: Population Pharmacokinetic (PopPK) Analyses.

11. PHARMACODYNAMIC (AND / OR BIOMARKER) ANALYSES

The pharmacodynamic analyses will be documented in a separate RAP.

12. PHARMACOKINETIC / PHARMACODYNAMIC ANALYSES

12.1. Exposure-Response for Efficacy and Corneal Events

The primary goal of this analysis is to characterize the pharmacokinetic/pharmacodynamic relationships for GSK2857916 administered IV in subjects with multiple myeloma for efficacy and corneal toxicity. In these analyses, drug plasma concentration (or pharmacokinetic parameter) data and pharmacodynamic data will be subjected to nonlinear mixed effects modelling using suitable software. The influence of subject demographics and baseline characteristics, including disease activity, in this population may be investigated. Detailed PK/PD methodology is provided in Appendix 10: Pharmacokinetic / Pharmacodynamic Analyses. This analysis will be performed by CPMS and reported separately. Concentration-QTc Analyses.

12.2. Concentration-QTc Analyses

For each ECG assessment, the individual subject's QTcF change from baseline will be calculated and will be merged with time-matched PK concentration values for the timepoints at which they are available. QTcF change from baseline (y-axis) will be plotted against the PK concentration data (x-axis) separately for each analyte (ADC, unbound mAb, total mAb, and cys-mc-MMAF). If appropriate, linear regression analyses may be performed for each analyte-ΔQTcF plot.

13. HEALTH OUTCOMES ANALYSES

Symptom impact and HRQoL will be assessed using the e-Diary. The Pain (average and worst) and Fatigue (worst) items will be scored as individual items. Baseline will be calculated for each item as the mean of all of the assessments captured in the period prior to Cycle 1 Day 1 (treatment start date) (patients can only start the diary 2 to 4 days prior to Cycle 1 Day 1). There will be no minimum number of data points required to calculate a baseline, if only one day has been completed in this time period then this will be used as Baseline value.

Scores will be created for each pain (bone pain worst, bone pain average) and fatigue item (worst) during the treatment cycle. The mean for each item will be calculated from the available data for assessments on Day 1 through to Day 8 in each cycle (for a score to be calculated, at least 4 of the 8 days must be completed, otherwise data to be set to missing). For the assessment at Day 15 the stand-alone value will be the score for that item for that day. If not completed, then data for Day 15 is set to missing. Change from baseline for all pain and fatigue items will be assessed at each cycle. Change will be calculated for both time points (Day 1-Day 8 average and Day 15).

Visual Functioning Questionnaires (NEI VFQ-25 and OSDI): Data will be collected from end of treatment (EOT) visit as baseline. Additional data will be collected in follow-up visits on a monthly basis for subjects with ongoing corneal events or signs at EOT for 1 year or until resolution, whichever occurs first. These data will not be collected for subjects who already completed the treatment. Due to limited number of on-treatment subjects at the time of protocol amendment, only individual subject data will be listed. Data for both measures will be scored as outlined in the User Manuals.

For the NEI VFQ-25 data will be presented for the overall composite score and the 11 vison-targeted sub-scores: global vision rating, difficulty with near vision activities; difficulty with distance vision activities; limitations in social functioning due to vision; role limitations due to vision; dependency on others due to vision; mental health symptoms due to vision; driving difficulties; limitations with peripheral vision, limitations with color vision; and corneal pain. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Sub-scales with at least one item answered can be used to generate a sub-scale score. Hence scores represent the average for all items in the sub-scale that the respondent answered. Only individual subject data will be listed.

For the OSDI, the total score will be calculated as well as scores for the subscales (ocular symptom, visual related function and environmental triggers). The total OSDI score = ([sum of scores for all questions answered × 100]/[total number of questions answered × 4]). Subscale scores are computed similarly with only the questions from each subscale used to generate its own score. Only individual subject data will be listed.

14. ANTI-DRUG ANTIBODY ANALYSES

For each subject, the results and titers of anti-GSK2857916 binding antibodies, and also ADC and total antibody concentration will be listed for each assessment time point. The frequency and percentage of subjects with positive and negative results will be summarized for each assessment time and overall for each subject by dose cohort. The conclusive results will be based on the total antibody concentration.

15. REFERENCES

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16. APPENDICES

16.1. Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population

This study does not have per protocol population.

16.2. Appendix 2: Schedule of Activities

16.2.1. Protocol Defined Schedule of Events

Please see Section 7.1 of Protocol (Version: GSK Document Number 2012N155299_05). Weekly Dosing Schedule (Dose Escalation) for Multiple Myeloma and Dose Expansion Weekly Dosing Schedule for Multiple Myeloma were not explored in this study.

Weekly dosing schedule was not explored.

16.2.2. Dose Escalation

16.2.2.1. Every 3 Weeks Dosing Schedule for Multiple Myeloma

Time and Events Table for Full Study (Cycle = 21 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X				X	At the start of each cycle	X	
Ocular Exam	X[3]					X[4]	At the start of each cycle[4]	X[4]	
ECOG Performance Status	X					X	At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]		X	X	X[5]	At the start of each cycle[5]	X	
Weight and Height	X	Weight only				Weight only	Weight only - At the start of each cycle	Weight only	
Hematology	X	X[6]		X	X	X	At the start of each cycle	X	
Clinical chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]				X	At the start of each cycle	X	
INR, PTT	X	X[6]		X	X	X	At the start of each cycle		
HBV/HCV tests	X								
CK-MB, Troponin	X[7]			X[7]		X[7]	At the start of each cycle[7]	X[7]	
BNP	X[8]								
UPEP and urine Immunofixation	X					X	At the start of each cycle		
SPEP and serum Immunofixation, Serum M-protein Calculation	X					X	At the start of each cycle		
Kappa, lambda free LC, FLC ratio	X					X	At the start of each cycle		
24 hr urine protein and albumin	X					X	At the start of each cycle		

Time and Events Table for Full Study (Cycle = 21 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
IgG, IgM, IgA	X					X	At the start of each cycle		
CRP, beta2 microglobulin	X					X	At the start of each cycle		
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]		X[11]	X[11]	X[11]	At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	
Extramedullary plasmacytoma imaging	X[13]						At the start of cycles 5[13], 9[13], 13[13]	X[13]	
BM Aspirate (see below for each test required within procedure)**:**									
Disease assessment	X[14]						At the time of Complete Response		
BCMA assessment and PD (flow)	X[15]			X[15]					
FISH testing	X[16]								
BM biopsy for disease assessment and BCMA expression (IHC)	X[17]						At the time of CR (disease assessment only)		
Serum (soluble BCMA)		X[18]	X[18]	X[18]	X[18]	X[18]	Predose at the start of each cycle	X[18]	
Serum (cytokines/chemokines)		X[19]	X			X[19]	At predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)	X					X[20]	At the start of cycles 3[20], 6[20], 9[20], 12[20] and 16[20]	X	
Plasma-cfDNA	X							X	
Peripheral blood (flow for TBNK)	X[15]					X[15]	At the start of each cycle[15]	X[15]	
Serial Pharmacokinetics (blood)		X[21]	X[21]	X[21]	X[21]	X[21]	C3D1 only[21]	X[22]	
Urine PK	X[23]					X[23]	Day 1 of cycles 4[23], 7[23], 10[23], 13[23], 16[23]		
Premedication if needed		X				X	At the start of each cycle		
GSK2857916 administration		X[24]				X[24]	X[24]		
Steroid eye drops		X[25]				X[25]	X[25]		
Adverse Events		Continuous							

Time and Events Table for Full Study (Cycle = 21 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Concomitant Medications	X	Continuous							
Survival Status									X[26]
Subsequent Treatment									X[26]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be ± 3 days of scheduled occurrence unless otherwise specified.
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes (±5 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. The Sentinel Subject must be observed for at least 24 hours post EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local lab (troponin I or T) and a central lab (troponin I). CK-MB at the local lab or if not possible by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine;
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. On dosing days, ECG to be performed in triplicate at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 21).** At screening, on interim visits (C1D8 and C1D15) and End of Study obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 5 days before dosing. All ECHOs to be done locally and sent to GSK for central imaging storage.
13. May be performed up to 21 days prior to C1D1 as screening value. Needs to be performed by the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
14. Samples from within 14 days prior to first dose are acceptable.
15. Sample(s) collected for analysis by central lab. The same sample will be used for BCMA (flow) and PD during Screening. On D8 only postdose PD assessment will be performed

16. FISH testing at least for: t(4;14), t(14;16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
17. Archival tissue from up to 60 days prior to study is acceptable
18. A single sample for sBCMA will be collected at C1D8, C1D15 and at the End of Study visit. sBCMA samples will also be collected on C1D1 at predose (within 30 minutes prior to SOI), at EOI (±5 minutes) and on C1D2 24h post SOI. On C2D1 sBCMA will be collected pre-dose (within 30 minutes prior to SOI) and at the EOI (±5 minutes)
19. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction)
20. All ADA samples will be collected prior to each infusion
21. PK samples to be taken (in all subjects) for both GSK2857916 and cys-mcMMAF measurement: C1D1 at pre-dose (within 30 minutes prior to SOI), 0.5 h after the start of the infusion (SOI) (±5 min), at the end of infusion (EOI) just before EOI), 1 h after EOI, 3 h after EOI (±5 min), 8 h after EOI (±15 min), 24h after EOI (±1h) (Day 2); C1D8 1 sample; C1D15 1 sample; C2D1, at pre-dose (within 30 minutes prior to SOI) and at the EOI (just before EOI); C3D1 at pre-dose (within 30 minutes prior to SOI) and at the EOI (just before EOI).
22. Collect 1 PK sample at each subject's final visit.
23. Pre-specified amounts of urine will be collected for PK analysis from the 24 hour urine collection at Screening, C2D1, C4D1, C7D1, C10D1, C13D1, and C16D1. Refer to Section 7.4.2 of the protocol for details.
24. Study drug administration ±3 day window only
25. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
26. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.2.2. Weekly Dosing Schedule (Dose Escalation) for Multiple Myeloma

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X				X	At the start of each cycle	X	
Ocular Exam	X[3]					X[4]	At the start of each cycle[4]	X[4]	
ECOG Performance Status	X					X	At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]		X	X	X[5]	At the start of each cycle[5]	X	
Weight and Height	X	Weight only				Weight only	Weight only - At the start of each cycle	Weight only	
Hematology	X	X[6]		X	X	X	At the start of each cycle	X	
Clinical Chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]				X	At the start of each cycle	X	
INR, PTT	X	X[6]		X	X	X	At the start of each cycle		
HBV/HCV tests	X								
CK-MB , Troponin	X[7]			X[7]		X[7]	At the start of each cycle[7]	X[7]	
BNP	X[8]								
UPEP and urine Immunofixation	X					X	At the start of each cycle		
SPEP and serum Immunofixation and Serum-M protein Calculation	X					X	At the start of each cycle		
Kappa, lambda free LC, FLC ratio	X					X	At the start of each cycle		
24 hr urine protein and albumin	X					X	At the start of each cycle		
IgG, IgM, IgA	X					X	At the start of each cycle		
CRP, beta2 microglobulin	X			X		X	At the start of each cycle		

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]		X[11]	X[11]	X[11]	At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	
Extramedullary Plasmacytoma Imaging	X[13]						At the start of cycles 5[13], 9[13], 13[13]	X[13]	
BM Aspirate (see below for each test required within procedure)**:**									
Disease assessment	X[14]						At the time of Complete Response		
BCMA assessment and PD (flow)	X[15]			X[15, 17]					
FISH testing	X[16]								
BM biopsy for disease assessment	X[18]						At the time of Complete Response (disease assessment only)		
Serum (soluble BCMA)		X[19]	X[19]	X[19]	X[19]	X[19]	Predose at the start of each cycle	X	
Serum (cytokines/chemokines)		X[20]	X	X[20]	X[20]	X[20]	At predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)		X[21]			X[21]	X[21]	At the start of cycles 3[21], 6[21], 9[21], 12[21] and 16[21]	X	
Plasma-cfDNA		X						X	
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[15]		X[15]		X[15]	At the start of each cycle[15]	X[15]	
Serial Pharmacokinetics (blood)		X[22]	X[22]	X[22]	X[22]	X[22]	C3D1 only[22]	X[23]	
Urine PK	X[24]					X[24]	Day 1 of cycles 4[24], 7[24], 10[24], 13[24], 16[24]		
Premedication if needed		X		X	X	X	Each dosing week		
GSK2857916 administration		X[25]		X[25]	X[25]	X[25]	Each dosing week[25]		
Steroid eye drops		X[26]		X[26]	X[26]	X[26]	Each dosing week[26]		
Adverse Events		Continuous							

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 2 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Concomitant Medications	X	Continuous							
Survival Status									X[27]
Subsequent Treatment									X[27]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified.
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, dilated fundoscopic examination may be performed within 21 days prior to first dose
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes (±5 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign time points align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hours prior to first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab. CK-MB at the local lab or if not available by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine.
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. On dosing days, ECG to be performed in triplicate at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn** (PK sample should be taken at the exact nominal time; refer to footnote 22). At screening and at End of Study, obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to fi**rst dose;** All ECHOs indicated on dosing days may be performed up to 5 days before dosing**. ECHOs to be done locally and sent to GSK for central imaging storage.**
13. **May be performed up to 21 days prior to** C1D1 as screening value. Needs to be performed by the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
14. Samples from within 14 days prior to first dose are acceptable.
15. Sample(s) collected for analysis by central lab. The same sample collected on Day 1 of cycle 1 prior to dosing will be used for BCMA (flow) and PD u.
16. FISH testing at least for t(4;14), t(14/16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
17. Collect sample prior to dosing.

18. Archival tissue from up to 60 days prior to study is acceptable.
19. A single sample for sBCMA will be collected at C1D8 predose, and at the End of Study visit. sBCMA samples will also be collected on C1D1 at predose (within 30 minutes prior to SOI), at EOI (±5 minutes) and on C1D2 24h post SOI. On C1D15 and C2D1 collect at predose (within 30 minutes prior to SOI) and EOI (±5 minutes)
20. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction
21. All ADA samples will be collected prior to each infusion
22. PK samples to be taken (in all subjects) for both GSK2857916 and cys-mcMMAF measurement: C1D1 at predose (within 30 minutes prior to SOI), 0.5 h after the start of the infusion, at EOI (just before EOI), 1 h after EOI (±5 min), 3 h after EOI (±5 min), 8 h after EOI (± 15 min), and 24h after EOI (±1 h) (Day 2); C1D8 at predose (within 30 minutes prior to SOI), and at EOI (just before EOI); C1D15 at predose (within 30 minutes prior to SOI) and at EOI (just before EOI); C2D1 at predose (within 30 minutes prior to SOI), at EOI (just before EOI); C3D1 at predose (within 30 minutes prior to SOI) and at EOI (just before EOI).
23. Collect 1 PK sample at each subject's final visit.
24. Pre-specified amounts of urine will be collected for PK analysis from the 24 hour urine collection at Screening, C2D1, C4D1, C7D1, C10D1, C13D1, and C16D1. Refer to Section 7.4.2 of the protocol for details.
25. Study drug administration ±1 day window only.
26. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
27. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.

Abbreviations:

ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.3. Dose Expansion

16.2.3.1. Every 3 Weeks Dosing Schedule for Multiple Myeloma

	Time and Events Table for Full Study (Cycle = 21 days)								
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment[34]**	**Monthly Follow up[35]**	
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X	At the start of each cycle	X		
Ocular Exam	X[3]				X[4]	At the start of each cycle[4]	X[4]	X[35]	
ECOG Performance Status	X				X	At the start of each cycle	X		
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X	X	X[5]	At the start of each cycle[5]	X		
Weight and Height	X	Weight only			Weight only	Weight only - At the start of each cycle	Weight only		
Hematology	X	X[6]	X	X	X	At the start of each cycle	X		
Clinical chemistry	X	X[6]	X	X	X	At the start of each cycle	X		
Urine Dipstick	X	X[6]			X	At the start of each cycle	X		
INR, PTT	X	X[6]	X	X	X	At the start of each cycle			
HBV/HCV tests	X								
CK-MB , Troponin	X[7,8]		X[7,8]		X[7,8]	At the start of each cycle[7, 8]	X[7,8]		
BNP	X[9]								
UPEP and urine Immunofixation	X				X	At the start of each cycle			
SPEP and serum immunofixation and Serum M-protein Calculation	X				X	At the start of each cycle			
Kappa, lambda free LC, FLC ratio	X				X	At the start of each cycle			

	Time and Events Table for Full Study (Cycle = 21 days)								
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment[34]**	**Monthly Follow up[35]**	
24 hr urine protein and albumin	X				X	At the start of each cycle			
IgG, IgM, IgA	X				X	At the start of each cycle			
CRP, beta2 microglobulin	X				X	At the start of each cycle			
Pregnancy Test	X[10]					At the start of cycles 5[10], 9[10], 13[10]	X[10]	X[11]	
Chest X-ray	X								
12-lead ECG	X[12]	X[12]	X[12]	X[12]	X[12]	At the start of each cycle[12]	X[12]		
LVEF and valves assessment (ECHO)	X[13]					At the start of cycles 4[13], 9[13]	X[13]		
Extramedullary Plasmacytoma Imaging	X[14]					At the start of cycles 5[14], 9[14], 13[14]	X[14]		
	BM Aspirate (see below for each test required within procedure)**:**								
Disease assessment	X[15]					At the time of Complete Response			
BCMA assessment and PD (flow)	X[16]		X[16, 18]						
FISH testing	X[17]								
BM biopsy for disease assessment	X[19]					At the time of CR (disease assessment only)			
Serum (soluble BCMA)		X[20]			X[20]	Predose at the start of each cycle	X		
Serum (cytokines/chemokines)		X[21]			X[21]	Predose and EOI on D1 of each cycle	X		
Serum (anti-drug-antibodies)		X[22]			X[22]	At the start of cycles 3[22], 6[22], 9[22], 12[22] and 16[22]	X		
Plasma-cfDNA		X					X		
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[23]	X		X[23]	At the start of each cycle[23]	X[23]		
Sparse PK (blood)		X[24]			X[24]	C3D1[24] and C5D1[24] only	X[25]		
Genetics sample		X[26]							

	Time and Events Table for Full Study (Cycle = 21 days)								
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment[34]**	**Monthly Follow up[35]**	
Premedication if needed		X			X	X			
GSK2857916 administration		X[27]			X[27]	X[27]			
Steroid eye drops		X[28]			X[28]	X[28]			
Adverse Events			Continuous						
Concomitant Medications	X		Continuous						
e-Diary	X	X	X	X	X[30]	X[30]	X		
OSDI							X[31]	X[31]	
NEI-VFQ-25							X[31]	X[31]	
Exit Interview							X[32]		
Follow-up Interview								X[33]	
Survival Status								X[29]	
Subsequent Treatment								X[29]	

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing. In the event that a subject has a dose delay due to a non-ocular toxicity and an ocular exam has been performed for that cycle, a repeat ocular exam 3 days prior to dosing may be omitted if the participant did not have corneal signs on the previous exam and does not have any new corneal symptoms.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes, +30 minutes (±15 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for a comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab.
8. CK-MB at the local lab or if not available by a central laboratory.
9. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.

10. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine.
11. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
12. ECGs to be performed in triplicate. On dosing days, ECG to be performed at predose (within 30 minutes prior to SOI) and EOI. At screening, on interim visits (C1D8 and C1D15) and End of Study, obtain a single ECG measurement. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 24)**
13. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 5 days before dosing. ECHOs to be done locally and sent to GSK for central imaging storage.
14. May be performed up to 21 days prior to C1D1 as screening value. Needs to be performed with the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
15. Samples from within 14 days prior to first dose are acceptable.
16. Sample(s) collected for analysis at central lab. The same sample will be used for BCMA (flow) and PD. On D8 only postdose PD assessment will be performed, if applicable (refer to footnote 18).
17. FISH testing at least for: t(4;14), t(14;16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
18. **Additional samples may be collected in some subjects (up to 6) for further exploration of PD.**
19. Archival tissue from up to 60 days prior to study is acceptable.
20. Collect sBCMA at C1D1 predose (within 30 minutes prior to SOI) and at EOI (±5 minutes), C2D1 at predose (within 30 minutes prior to SOI) and at EOI (+- 5 minutes).
21. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction
22. All ADA samples will be collected prior to each infusion
23. Flow cytometry performed central laboratory.
24. PK samples to be taken for both GSK2587916 and cys-mcMMAF measurement on C1D1, C2D1, C3D1, and C5D1 at predose (within 30 minutes prior to SOI) and at EOI (just before EOI).
25. Collect 1 PK sample at each subject's final visit.
26. Informed consent for optional genetics research should be obtained before collecting a sample.
27. Study drug administration ±3 day window only.
28. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
29. All participants should be followed for survival for 1 year from last subject last dose. and whether subsequent treatment for disease was given. Subject does not need to come in for visit. Participants who have completed treatment or the 3 month follow up visit (end of study) prior to amendment 5 will be reconsented for further follow up and survival status.
30. e-Diary to be completed at screening, then Days 1-7, 8, 15 of each treatment cycle. Upon implementation of the e-Diary, these assessments will be required.
31. OSDI and NEI-VFQ-25 to be administered during end of study treatment visit. Additional assessments for subjects who are experiencing corneal symptoms to be completed via telephone on a monthly basis for up to 1 year, or until resolution of symptoms (whichever comes first) during the follow-up period.
32. Exit interview to be performed within 21 days of end of study visit
33. Optional follow-up telephone interview to explore visual symptoms and changes in symptoms and related impacts following treatment discontinuation be performed at least 6 months following the End of Study Treatment visit. This interview would only be for those subjects who experienced corneal symptoms during treatment and consent to participate.
34. End of treatment visit should be performed within 30 days (+7 days) after the last dose or prior to the start of new anti-cancer treatment, whichever is earlier. In cases where more than 30 days (+7 days) have elapsed from the date of the subject's last dose due to dosing delays and a subsequent decision to take the subject off treatment, the end of study treatment visit should be scheduled as soon as possible to allow the final assessments to be performed at the earliest date.

35. Participants with corneal signs or symptoms at the end of study treatment visit should be monitored by ophthalmic exam once a month after the last study dose until deemed clinically stable by an eye care professional complete resolution or for 12 months (whichever comes first). Corneal exams to include BCVA and slit lamp examination (with special focus on cornea). Participants who have completed treatment or the 3 month follow up visit (end of study) will be reconsented for additional ophthalmology follow up.
Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.3.2. Dose Expansion Weekly Dosing Schedule for Multiple Myeloma

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X		At the start of each cycle	X	
Ocular Exam	X[3]				X[4]		At the start of each cycle[4]	X[4]	
ECOG Performance Status	X				X		At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X[5]	X[5]	X[5]		At the start of each cycle[5]	X	
Weight and Height	X	Weight only			Weight only		Weight only - At the start of each cycle	Weight	
Hematology	X	X[6]	X	X	X		At the start of each cycle	X	
Clinical chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]			X		At the start of each cycle	X	
INR, PTT	X	X[6]	X	X	X		At the start of each cycle		
HBV/HCV tests	X								
CK-MB , Troponin	X[7]		X[7]		X[7]		At the start of each cycle[7]	X[7]	
BNP	X[8]								
UPEP and urine immunofixation	X				X		At the start of each cycle		
SPEP and serum immunofixation and Serum M-protein Calculation	X				X		At the start of each cycle		
Kappa, lambda free LC, FLC ratio	X				X		At the start of each cycle		
24 hr urine protein and albumin	X				X		At the start of each cycle		
IgG, IgM, IgA	X				X		At the start of each cycle		

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
CRP, beta2 microglobulin	X		X		X		At the start of each cycle		
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]	X[11]	X[11]	X[11]		At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	
Extramedullary Plasmacytoma Imaging	X[13]						At the start of cycles 5[13], 9[13], 13[13]	X[13]	
BM Aspirate (see below for each test required within procedure)**:**									
Disease assessment	X[14]						At the time of Complete Response		
BCMA assessment and PD (flow)	X[15]		X[15, 17]						
FISH testing	X[16]								
BM biopsy for disease assessment	X[18]						At the time of Complete Response (disease assessment only)		
Serum (soluble BCMA)		X[19]	X[19]	X[19]	X[19]		Predose at the start of each cycle	X	
Serum (cytokines/chemokines)		X[20]	X[20]	X[20]	X[20]		Predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)		X[21]		X[21]	X[21]		At the start of cycles 3[21], 6[21], 9[21], 12[21] and 16[21]	X	
Plasma-cfDNA		X	X					X	
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[15]	X		X[15]		At the start of each cycle[15]	X[15]	
Sparse PK (blood)		X[22]	X[22]	X[22]	X[22]	X[22]	C3D1[22], C3D15[22], and C5D1[22] only	X[23]	
Genetics sample		X[24]							
Premedication if needed		X	X	X	X	X	Each dosing week		
GSK2857916 administration		X[25]	X[25]	X[25]	X[25]	X[25]	Each dosing week[25]		
Steroid eye drops		X[26]	X[26]	X[26]	X[26]	X[26]	Each dosing week[26]		
Adverse Events		Continuous							

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Concomitant Medications	X	Continuous							
e-Diary	X	X	X	X	X		X[28]	X	
Exit Interview								X[29]	
Survival Status									X[27]
Subsequent Treatment									X[27]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing.
5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes (±5 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab. CK-MB at the local lab, or if not available by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. ECGs to be performed in triplicate. On dosing days, ECG to be performed at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 22).** At screening and End of Study, obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 7 days before dosing. ECHOs to be done locally and sent to GSK for central imaging storage.
13. May be performed up to 21 days prior to C1D1 as screening value. Needs to be performed with the same method throughout the study as was done at baseline (i.e. if PET scan was used as baseline, subject needs to be followed by PET scans). Selected target lesion needs to be measured and followed over time.
14. Samples from within 14 days prior to first dose are acceptable.
15. Sample(s) collected for analysis at central lab. The same sample collected on Day 1 of cycle1 prior to dosing will be used for BCMA (flow) and PD (refer to footnote 17).

16. FISH testing at least for: t(4;14), t(14;16), 17p13del. FISH results from samples taken within 60 days prior to first dose are acceptable.
17. Additional samples may be collected from 6 subjects in the MM cohort. Collect sample prior to dosing.
18. Archival tissue from up to 60 days prior to study is acceptable
19. A single sBCMA sample will be collected at C1D1 predose (within 30 minutes prior to SOI) unless otherwise specified. On C1D15 and C2D1 collect samples at predose (within 30 minutes prior to SOI) and at EOI (±5 minutes).
20. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction
21. All ADA samples will be collected prior to each infusion
22. PK samples to be taken for both GSK2857916 and cys-mcMMAF measurement at C1D1 predose (within 30 minutes prior to SOI), EOI (just before EOI), 1 hour post EOI (±5 min), and 3 hours post EOI (±5 min); predose (within 30 minutes prior to SOI) and EOI (just before EOI) on C1D8, C1D15, C2D1, C2D15, C3D1, C3D15, and C5D1
23. Collect 1 PK sample at each subject's final visit
24. Informed consent for optional genetics research should be obtained before collecting a sample.
25. Study drug administration ±1 day window only
26. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drop QID x 4 days starting 1 day prior to treatment
27. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.
28. e-Diary to be completed at screening, then Days 1-7, 8, 15 of each treatment cycle. Upon implementation of the e-Diary, these assessments will be required.
29. 29.Exit interview to be performed within 14 days of end of study visit

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatinine kinase; CRP = C-reactive protein; EM = extramedullary; EOI = End of Infusion; FLC = free light chain; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion; SPEP = serum protein electrophoresis; UPEP = urine protein electrophoresis

16.2.3.3. Dose Expansion Every 3 Weeks Dosing Schedule for Lymphomas

Study Assessments[1]	Screen[2]	Day 1 C1	Day 8 C1	Day 15 C1	Day 1 C2	D1 of C3-C16	End of Study Treatment[26]	Monthly Follow up[27]	
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X	At the start of each cycle	X		
Ocular Exam	X[3]				X[4]	At the start of each cycle[4]	X[4]	X[27]	
ECOG Performance Status	X				X	At the start of each cycle	X		
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X	X	X[5]	At the start of each cycle[5]	X		
Weight and Height	X	Weight only			Weight only	Weight only - At the start of each cycle	Weight only		
Hematology	X	X[6]	X	X	X	At the start of each cycle	X		
Clinical chemistry	X	X[6]	X	X	X	At the start of each cycle	X		
Urine Dipstick	X	X[6]			X	At the start of each cycle	X		
INR, PTT	X	X[6]	X	X	X	At the start of each cycle			
HBV/HCV tests	X								
CK-MB, Troponin	X[7,8]		X[7,8]		X[7,8]	At the start of each cycle[7]	X[7,8]		
BNP	X[9]								
24 hr urine protein and albumin	X				X	At the start of each cycle			
IgG, IgM, IgA	X				X	At the start of each cycle			
CRP, beta2 microglobulin	X				X	At the start of each cycle			
Pregnancy Test	X[10]					At the start of cycles 5[10], 9[10], 13[10]	X[10]	X[11]	
Chest X-ray	X								
12-lead ECG	X[12]	X[12]	X[12]	X[12]	X[12]	At the start of each cycle[12]	X[12]		
LVEF and valves assessment (ECHO)	X[13]					At the start of cycles 4[13], 9[13]	X[13]		
Serum (soluble BCMA)		X[14]			X[14]				

Study Assessments[1]	**Screen**[2]	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**D1 of C3-C16**	**End of Study Treatment**[26]	**Monthly Follow up**[27]	
Serum (cytokines/chemokines)		X[15]			X[15]	Predose and EOI on D1 of each cycle	X		
Serum (anti-drug-antibodies)		X[16]			X[16]	At the start of cycles 3[16], 6[16], 9[16], 12[16] and 16[16]	X		
Plasma-cfDNA		X					X		
Peripheral blood (flow for TBNK and intracellular cytokine testing)		X[17]	X[17]		X[17]	At the start of each cycle[17]	X[17]		
Sparse PK (blood)		X[18]			X[18]	C3D1[18] and C5D1[18]	X[19]		
Genetics sample		X[20]							
CT Scan/PET Scan for disease assessments	X[21]					At the start of cycles 4, 7, 10, 13, and 16			
Premedication if needed		X			X	At the start of each cycle			
GSK2857916 administration		X[22]			X[22]	X[22]			
Steroid eye drops		X[23]			X[23]	At the start of each cycle[23]			
Tumor biopsy for BCMA expression	X[24]								
Adverse Events				Continuous					
Concomitant Medications	X			Continuous					
Survival Status								X[25]	
Subsequent Treatment								X[25]	

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days of scheduled occurrence unless otherwise specified.
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing. In the event that a subject has a dose delay due to a non-ocular toxicity and an ocular exam has been performed for that cycle, a repeat ocular exam 3 days prior to dosing may be omitted if the participant did not have corneal signs on the previous exam and does not have any new corneal symptoms.

5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes, +30 minutes (±15 min) after SOI, EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI. **On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to **Table 15 of the protocol** for a comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab.
8. CK-MB at the local lab, or if not available by a central laboratory.
9. BNP to be measured locally at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
10. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine.
11. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
12. On dosing days, triplicate ECGs to be performed at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 18).** At screening, on interim visits (C1D8 and C1D15) and End of Study, obtain a single ECG measurement.
13. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 5 days. ECHOs to be done locally and sent to GSK for central imaging storage.
14. A single sBCMA sample will be collected at C1D1 predose (within 30 minutes prior to SOI). On C2D1 sBCMA will be collected at predose (within 30 minutes prior to SOI) and at EOI (±5 minutes).
15. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction.
16. All ADA samples will be collected prior to each infusion.
17. Sample(s) collected for analysis by central lab.
18. PK samples to be taken for both GSK2587916 and cys-mcMMAF measurement on C1D1 at pre-dose (within 30 minutes prior to SOI), at EOI (just before EOI), 1 h after EOI (±5 min), 3 h after EOI (±5 min); C2D1, C3D1, and C5D1 at pre-dose (within 30 minutes prior to SOI) and at EOI (just before EOI).
19. Collect 1 PK sample at each subject's final visit.
20. Informed consent for optional genetics research should be obtained before collecting a sample.
21. CT/PET or CT scans from within 21 days prior to first dose are acceptable. CT scans are acceptable at all restaging assessments unless CR is suspected, in which case a PET/CT scan will be obtained to confirm CR.
22. Study drug administration ±3 day window only.
23. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drops QID x 4 days starting 1 day prior to treatment.
24. Archived or fresh tissue required for BCMA testing. Refer to Section 5.2.1 of the protocol Inclusion Criterion #4 for eligibility criteria.
25. Record subject's survival status until last subject completes or discontinues treatment and whether subsequent treatment for disease was given. Subject does not need to come in for visit.
26. End of treatment visit should be performed within 30 days (+7 days) after the last dose or prior to the start of new anti-cancer treatment, whichever is earlier. In cases where more than 30 days (+7 days) have elapsed from the date of the subject's last dose due to dosing delays and a subsequent decision to take the subject off treatment, the end of study treatment visit should be scheduled as soon as possible to allow the final assessments to be performed at the earliest date.
27. All participants should be followed for survival for 1 year from last dose. Participants with corneal signs or symptoms at the end of study treatment visit should be monitored by ophthalmic exam every month after the last study dose until deemed clinically stable by an eye care professional or for 12 months (whichever comes first). Corneal exams to include BCVA and slit lamp examination (with special focus on cornea).

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatine kinase; CRP = C-reactive protein; EOI = End of Infusion; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion

16.2.3.4. Dose Expansion Weekly Dosing Schedule for Lymphomas

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Informed Consent	X								
Baseline Demographics	X								
Medical History	X								
Physical Exam	X	X			X		At the start of each cycle	X	
Ocular Exam	X[3]				X[4]		At the start of each cycle[4]	X[4]	
ECOG Performance Status	X				X		At the start of each cycle	X	
Vital Signs (BP, HR, Body Temperature)	X	X[5]	X[5]	X[5]	X[5]		At the start of each cycle[5]	X	
Weight and Height	X	Weight only			Weight only		Weight only - At the start of each cycle	Weight	
Hematology	X	X[6]	X	X	X		At the start of each cycle	X	
Clinical chemistry	X	X[6]	X	X	X	X	At the start of each cycle	X	
Urine Dipstick	X	X[6]			X		At the start of each cycle	X	
INR, PTT	X	X[6]	X	X	X		At the start of each cycle		
HBV/HCV tests	X								
CK-MB , Troponin	X[7]		X[7]		X[7]		At the start of each cycle[7]	X[7]	
BNP	X[8]								
24 hr urine protein and albumin	X				X		At the start of each cycle		
IgG, IgM, IgA	X				X		At the start of every other cycle		
CRP, beta2 microglobulin	X				X		At the start of each cycle		
Pregnancy Test	X[9]						At the start of cycles 5[9], 9[9], 13[9]	X[9]	X[10]
Chest X-ray	X								
12-lead ECG	X[11]	X[11]	X[11]	X[11]	X[11]		At the start of each cycle[11]	X[11]	
LVEF and valves assessment (ECHO)	X[12]						At the start of cycles 4[12], 9[12]	X[12]	

Time and Events Table for Full Study (Cycle = 28 days)									
Study Assessments[1]	**Screen[2]**	**Day 1 C1**	**Day 8 C1**	**Day 15 C1**	**Day 1 C2**	**Day 15 C2**	**D1 of C3-C16**	**End of Study Treatment**	**3-Month Off-study Follow-up**
Serum (soluble BCMA)		X[13]	X[13]	X[13]	X[13]			X[13]	
Serum (cytokines/chemokines)		X[14]	X[14]	X[14]	X[14]		Predose and EOI on D1 of each cycle	X	
Serum (anti-drug-antibodies)		X[15]		X[15]	X[15]		At the start of cycles 3[15], 6[15], 9[15], 12[15] and 16[15]	X	
Plasma-cfDNA		X						X	
Peripheral blood (flow for TBNK)		X[16]	X[16]		X[16]		At the start of each cycle[16]	X[16]	
Sparse PK (blood)		X[17]	X[17]	X[17]	X[17]	X[17]	C3D1[17], C3D15[17] and C5D1[17] only	X[18]	
Genetics sample		X[19]							
CT/PET Scan for disease assessments	X[20]						At the start of Cycles 3, 5, 7, 9, 11, 13, and 16		
Premedication if needed		X	X	X	X[24]	X	Each dosing week		
GSK2857916 administration		X[21]	X[21]	X[21]	X[21, 24]	X	Each dosing week[21]		
Steroid eye drops		X[22]	X[22]	X[22]	X[22, 24]	X[22]	Each dosing week[22]		
Tumor biopsy for BCMA expression	X[23]								
Adverse Events		Continuous							
Concomitant Medications	X	Continuous							
Survival Status									X[25]
Subsequent Treatment									X[25]

1. Assessments scheduled on days of dosing should be done prior to drug administration, unless otherwise specified. All other assessments can be done ± 3 days unless otherwise specified
2. All Screening assessments must be performed within 14 days prior to first dose unless otherwise specified. Informed Consent must be signed before any study-specific assessments are performed.
3. Screening examination to include BCVA (best-corrected visual acuity), slit lamp examination (with special focus on cornea), intraocular pressure, and dilated fundoscopic examination may be performed within 21 days prior to first dose.
4. On-study exams, to include BCVA (best-corrected visual acuity) and slit lamp examination (with special focus on cornea); window for exams is up to 3 days prior to dosing. In the event that a subject has a dose delay due to a non-ocular toxicity and an ocular exam has been performed for that cycle, a repeat ocular exam 3 days prior to dosing may be omitted if the participant did not have corneal signs on the previous exam and does not have any new corneal symptoms.

5. On initial (first infusion) dosing day, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +10 minutes and +30 minutes after SOI (±5 min), EOI, and 1 hour post EOI. On subsequent dosing days, vital signs must be assessed at pre-dose (within 30 minutes prior to SOI), +30 minutes after SOI, and EOI**. On days where vital sign timepoints align with PK sampling timepoints, vital signs should be assessed prior to PK samples being drawn.**
6. If completed within 72 hrs prior to the first dose, this assessment need not be repeated on Day 1 of Cycle 1. Refer to Table 15 of the protocol for comprehensive list of lab tests.
7. Troponin will be measured at the local (troponin I or T) and central (troponin I) lab. CK-MB at the local lab, or if not available by a central laboratory.
8. BNP to be measured locally, or if not available by a central laboratory, at screening; if cardiac workup is required due to safety concerns during the study, BNP should be measured.
9. Perform only in women of child-bearing potential. A serum pregnancy test should be performed at screening, and subsequent pregnancy tests may be either serum or urine
10. Final pregnancy test (serum or urine) must be performed in women of childbearing potential 60 days after last study treatment.
11. On dosing days, perform triplicate ECGs at predose (within 30 minutes prior to SOI) and EOI. **On days where ECG timepoints align with PK sampling timepoints, ECGs should be performed prior to PK samples being drawn (PK sample should be taken at the exact nominal time; refer to footnote 17).** At screening and End of Study, obtain a single ECG measurement.
12. At Screening, LVEF may be performed within 30 days prior to first dose. All ECHOs indicated on dosing days may be performed up to 7 days before dosing. ECHOs to be done locally and sent to GSK for central imaging storage.
13. A single sample for sBCMA will be collected at C1D8 predose, and at the End of Study visit. sBCMA samples will also be collected on C1D1 at predose (within 30 minutes prior to SOI) and EOI (±5 minutes). On C1D15 and C2D1 collect at predose (within 30 minutes prior to SOI) and EOI (±5 minutes)
14. Collect cytokines at predose (within 30 minutes prior to SOI) and EOI (±5 min) (even when infusion is interrupted or halted) to assess allergic reaction.
15. All ADA samples will be collected prior to each infusion.
16. Sample(s) collected for analysis by central lab.
17. PK samples to be taken for both GSK2857916 and cys-mcMMAF measurement at C1D1 predose (within 30 minutes prior to SOI), EOI (just before EOI), 1 hour post EOI (±5 min), and 3 hours post EOI (±5 min); predose (within 30 minutes prior to SOI) and EOI (just before EOI) on C1D8, C1D15, C2D1, C2D15, C3D1, C3D15, and C5D1.
18. Collect 1 PK sample at each subject's final visit.
19. Informed consent for optional genetics research should be obtained before collecting a sample.
20. CT/PET scans from within 21 days prior to first dose are acceptable.
21. Study drug administration ±1 day window only.
22. Prophylaxis with prednisolone phosphate 1% or dexamethasone 0.1% 1 drops QID x 4 days starting 1 day prior to treatment.
23. Archived or fresh tissue required for BCMA testing. Refer to Section 5.2.1 of the protocol Inclusion Criterion #4 for eligibility criteria.
24. Also applies to C2D8.
25. Record subject's survival status and whether subsequent treatment for disease was given. Subject does not need to come in for visit.

Abbreviations:
ADA = Antibody Drug Antibody; ALP = alkaline phosphatase; BCVA = best corrected visual acuity; BNP = B-type natriuretic peptide; C1D1 = Cycle 1 Day 1, etc.; cfDNA = Circulating free DNA; CK = creatine kinase; CRP = C-reactive protein; EOI = End of Infusion; PD = Pharmacodynamics; PK = Pharmacokinetics; QID = 4 times a day; SOI = start of infusion

16.3. Appendix 3: Assessment Windows

No assessment windows will be applied.

16.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events

16.4.1. Study Phases

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date
On-Treatment	Study Treatment Start Date < Date

Some datasets include the first dosing day as On-Treatment and some exclude the first dosing date as On-Treatment. The first dosing day (Day 1) is considered Pre-Treatment for ECOG, ECG, vital signs, liver events, lab tests, cardiac scan, and other safety domains. The first dosing day (Day 1) is considered to be On-Treatment for adverse events and concomitant medications.

16.4.1.1. Study Time Periods for Concomitant Medications and Blood and Blood Supportive Care Products

Concomitant Medication and Blood and Blood Supportive Care Product start and end dates will be assigned to study time periods in relation to first dose of study treatment as defined below. The start date references time flag variables and end date reference time flag variables will be added to the concomitant medications and blood and blood supportive products datasets, respectively.

- Start **relative to treatment:** Assign to 'BEFORE' if start date is prior to study treatment start date or if subject has not taken any study treatment or (start date is missing and end date is before study treatment start date). Else assign to 'DURING' if the start date falls into the on-therapy period as defined above or if subject is ongoing (not all study treatment discontinuation records completed) or start date is missing. Else assign to 'AFTER' if start date is after the on-therapy period.
- **End relative to** treatment: Assign to 'BEFORE' if end date is prior to study treatment start date or if subject has not taken any study treatment. Else assign to 'DURING' if start date falls into the on-therapy period or if subject is ongoing (not all study treatment discontinuation records completed) or (end date is missing and start relative to treatment not 'AFTER'). Else assign to 'AFTER' if start date is after the on-therapy period or (end date is missing and start relative to treatment='AFTER').

Only on-therapy blood and blood supportive care products that start after the start of study treatment are included in the Blood Products and Blood Supportive Care Product summaries. Therefore, for summary tables, include blood and blood supportive care product records where start relative to treatment in ('DURING') and end relative to treatment in ('DURING','AFTER'). All data will be reported in listings.

Concomitant medication start relative to treatment and end relative to treatment flags are used to select data to include in the Concomitant Medication summaries as follows:

- Summary of Concomitant Medications: This summary will contain medications including those with start date prior to study treatment start date and continue

(missing end date or end date after study treatment start date) on therapy. Note that any medications with start date and end date prior to study treatment start date will be excluded. In addition, any medication that was started during post-therapy will be excluded. Include concomitant medication records where start relative to treatment in ('BEFORE','DURING') and end relative to treatment in ('DURING','AFTER').

- Summary of Concomitant Medications with On-Therapy Onset: This summary will contain medications with start date after study treatment start date. In addition, any medication that was started during post-therapy (see above for definition of post-therapy) will be excluded. Include concomitant medication records where start relative to treatment in ('DURING') and end relative to treatment in ('DURING','AFTER').

16.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	• Study Treatment Start Date ≤ AE Start Date • AE Start Date is missing

NOTES:

- If the study treatment stop date is missing, then the AE will be considered to be On-Treatment.
- Time of study treatment dosing and start/stop time of AEs should be considered, if collected.

16.5. Appendix 5: Data Display Standards & Handling Conventions

16.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: US1SALX00259
HARP Compound	: arprod\gsk2859716\bma117159\
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.1.3 & ADaM IG Version 1.0.	
Generation of RTF Files	
• RTF files will be generated for all tables.	

16.5.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics
• Do not include subject level listings in the main body of the GSK Clinical Study Report. All subject level listings should be located in the modular appendices as ICH or non-ICH listings

Formats
• GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF. The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP's.
Planned and Actual Time

• Reporting for tables, figures and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the subject's listings.

Unscheduled Visits	
• Unscheduled visits will not be included in summary tables and/or figures. For by planned time analysis, unscheduled visits will not be included; For worst-case analysis, unscheduled visits will be included. • All unscheduled visits will be included in listings.	
Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

16.5.3. Reporting Standards for Pharmacokinetic

Pharmacokinetic Concentration Data	
PC Windows Non-Linear (WNL) File	PC WNL file (CSV format) for the non compartmental analysis by Clinical Pharmacology Modelling and Simulation function will be created according to [Insert document name]. Note: Concentration values will be imputed as per GUI_51487
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to IDSL Statistical Principle 6.06.1. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
NONMEM/Pop PK File	Pop-PK file (CSV format) for the POP-PK analysis by Clinical Pharmacology Modelling and Simulation function will be created according to the data specification detailed in Section 16.9.1 Population Pharmacokinetic (PopPK) Dataset Specification.
NONMEM/PK/PD File	PK/PD file (CSV format) for the PK/PD analysis by Clinical Pharmacology Modelling and Simulation function will be created according to the data specification detailed in Section 16.10.1 Pharmacokinetic/Pharmacodynamic Dataset Specification.
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	The following PK parameters will be derived by the Programmer:
Pharmacokinetic Parameter Data	
Is NQ impacted PK Parameters Rule Being Followed	Yes, refer to [Standards for Handling NQ Impacted PK Parameters].
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards.

16.5.4. Extended Loss to Follow-up or Extended Time without an Adequate Assessment

For subjects, if two or more scheduled disease assessments are missed and are then followed by an assessment of PD or death, PFS will be censored at the last adequate assessment prior to PD or death. When the scheduled disease assessment is every 3 weeks, a window of 49 days (6 weeks + 7 day window) will be used to determine whether there was an extended time without adequate assessment. That is, if the time difference between PD/death and last adequate assessment is more than 49 days, then PFS will be censored at the last adequate assessment prior to PD/death.

16.5.5. Date Associated with Response

Investigator assessment of disease is entered in the eCRF on the VISIT form. The date of the VISIT is captured but the date of the response assessment is not captured separately. The date associated with response will be the visit date for the VISIT on which the investigator assessed disease. A disease assessment may occur at an unscheduled visit. The date of the unscheduled visit would be assigned to any response assessed on that date. In the following section, unless otherwise specified, the disease assessment denotes post-baseline assessment.

16.6. Appendix 6: Derived and Transformed Data

16.6.1. General

Multiple Measurements at One Analysis Time Point
• Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented. • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of Any visit post-baseline row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Study Day

• Calculated as the number of days from First Dose Date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < First Dose Date → Study Day = Ref Date – First Dose Date
  • Ref Data ≥ First Dose Date → Study Day = Ref Date – (First Dose Date) + 1

16.6.2. Study Population

Extent of Exposure
• Number of days of exposure to study drug will be calculated based on the formula: **Duration of Exposure in Days = Treatment Stop Date – (Treatment Start Date) + 1** • Participants who were randomized but did not report a treatment start date will be categorised as having zero days of exposure. • The cumulative dose will be based on the formula: **Cumulative Dose = Sum of Dose at Each Cycle** • Dose intensity per cycle will be based on the formula: **Dose intensity Per Cycle = Cumulative Dose / Total Number of Cycles**

16.6.3. Efficacy

Laboratory Parameters
Serum M-protein, Urine M-protein, Serum FLC

• If a laboratory value which is expected to have a numeric value for summary purposes, has a non-detectable level reported in the database, where the numeric value is missing, but typically a character value starting with '<x' or '>x' (or indicated as less than x or greater than x in the comment field) is present, the number of significant digits in the observed values will be used to determine how much to add or subtract in order to impute the corresponding numeric value.
  ○ Example 1: 2 Significant Digits = '< x ' becomes x – 0.01
  ○ Example 2: 1 Significant Digit = '> x' becomes x + 0.1
  ○ Example 3: 0 Significant Digits = '< x' becomes x – 1

16.6.4. Safety

Adverse Events
AE'S OF Interest
• Corneal events • Thrombocytopenia • Neutropenia • Hematologic Toxicity • Infusion-related Reactions as collected in the eCRF

16.7. Appendix 7: Reporting Standards for Missing Data

16.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion (i.e. as specified in the protocol) was defined as: o For Part 1 (dose-escalation phase), a completed subject is one who has completed at least 1 cycle of study treatment and an End of Study Visit without events causing them to withdraw or discontinue from the study for reasons listed in Section 6.3 of the protocol. o For Part 2 (expansion cohort), a completed subject is one who has received at least one dose of study treatment without events causing them to withdraw or discontinue study treatment for reasons listed in Section 6.3 of the protocol and completed an End of Study Visit. o A participant will be considered to have completed the study if he or she has received at least one dose of the study treatment and, has died before the end of the study, has not been lost to follow-up, or has not withdrawn consent from study participation. • Withdrawn subjects may be replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

16.7.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o These data will be indicated by the use of a blank in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as “Not applicable” and “Not evaluable” are not considered to be missing data and should be displayed as such.
Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.
Responder Analysis	• For endpoints which determine the percentage of responders, subjects with unknown/not evaluable or missing best overall response will be assumed to be non-responders, and will be included in the denominator when calculating the percentages.
Time to Event	• Because study treatment is dependent on the study endpoints (e.g., progression, i.e. not a fixed treatment duration), the length of treatment for each subject will depend on the efficacy and toxicity of the treatment, so the duration of treatment will vary across subjects. Similarly the duration of follow up will also vary. All available time-to-event data will be analyzed using suitable statistical methods; subjects with shorter treatment and follow-up due to the natural history of their disease or medical necessities of the treatment of their disease will not be considered to have missing time-to-event data.

16.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in subject listing displays. • Imputed partial dates will not be used to derive study day, duration (e.g. duration of adverse events), or elapsed time variables. In addition, imputed dates are not used for deriving the last contact date in the overall survival analysis dataset. The imputed AE dates will only to be used in the figures "Profile Plot for Patients with No Corneal Event or Grade 1 Corneal Event" and "Profile Plot for Patients with Grade 2 or Higher Corneal Events". • Imputed dates will not be displayed in listings. However, where necessary, display macros may impute dates as temporary variables for the purpose of sorting data in listings only. In addition, partial dates may be imputed for 'slotting' data to study time periods or for specific analysis purposes as outlined below.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. ○ The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.
Concomitant Medications	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. • The recorded partial date will be displayed in listings.

Element	Reporting Detail
Anti-Cancer Therapy (Where applicable), Radiotherapy and Surgical Procedures for Time-to-Event Endpoint and Response	• Start dates for follow-up anti-cancer therapy, radiotherapy (where applicable), and surgical procedures (where applicable) will be temporarily imputed in order to define event and censoring rules for progression-free survival, response rate, time to progression, duration of response or time to response (i.e. start date for new anti-cancer therapy). The imputed dates will not be stored on the anti-cancer therapy, radiotherapy, or surgical procedure datasets. • If missing start day, month, and year, then no imputation for completely missing dates • If missing start day and month, then no imputation should be done • If missing start day, then do the following: • If partial date falls in the same month as the last dose of study treatment, then assign to earlier of (date of last dose of study treatment+1, last day of month). • If partial date falls in the same month as the subject's last assessment and the subject's last assessment is PD, then assign to earlier of (date of PD+1, last day of month). • If both rules above apply, then assign to latest of the 2 dates • Otherwise, impute missing day to the first of the month. • If missing end date, then no imputation should be done.

16.8. Appendix 8: Values of Potential Clinical Importance

16.8.1. Laboratory Parameters

Reference ranges for all laboratory parameters collected throughout the study are provided by the laboratory. A laboratory value that is outside the reference range is considered either high abnormal (value above the upper limit of the reference range) or low abnormal (value below the lower limit of the reference range). Note: a high abnormal or low abnormal laboratory value is not necessarily of clinical concern. The laboratory reference ranges will be provided on the listings of laboratory data. Clinical laboratory test results outside of the reference range will be flagged in the listings.

To identify laboratory values of potential clinical importance, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v4.0) will be used to assign grades to the relevant laboratory parameters. NCI-CTCAE v4.0 can be found at http://ctep.cancer.gov/reporting/ctc.html.

For laboratory data which are not listed in the NCI CTCAE v4.0, a summary of values outside the normal range will be provided.

16.8.2. ECG Parameters and vital signs

For ECG and vital signs, the most updated IDSL standard up to the RAP effective date will be followed

16.9. Appendix 9: Population Pharmacokinetic (PopPK) Analyses

16.9.1. Population Pharmacokinetic (PopPK) Dataset Specification

Any deviations between the dataset specification and the final dataset will be documented in the population pharmacokinetic analysis report.

General Description:

1. The type of variables should be either NUM or DATE/TIME unless specified otherwise

2. The dataset is sorted by ID, RTFDD, ANALN, ASCENDING EVID unless specified otherwise

3. The data items (columns) in the analysis-ready data file will be in the same order as follows.

4. Exclude observations with DTYPE=IMPUTE

5. Include PKFL=Y (applicable to all datasets)

6. Same rules are applied for other baseline covariates. Baseline rules are as follows:

   • Use baseline value as defined by Stats in the lab test datasets;

   • If not defined by Stats, set to measurement nearest to, but prior to, time of first dose

   • Only in cases where Day 1 measurement is not available, but screening measurement is, the screening values will be used.

7. 3 significant figures for all values.

Column Header	Data Item	Codes	Derivation/Comments	Source data set
C	Line number/exclusion identifier	Row Number STM DRM PFD	Set to line/row number unless one or more of the following conditions are met, then set to code: • STM = If a PK sample was taken but the date and/or time of the sample is missing and cannot be derived • DRM= PK samples for which dosing records are missing • PFD=PK samples with CONC reported as NA/NR/NQ/BQL/missing at pre-dose in CYCLE =1	derived
STUDY	Study ID		1 = BMA117159	adpc
SUBJID	Subject identifier from source data		SUBJID = SUBJID	adsl
ID	NONMEM subject identifier		Sequential subject identifier across studies after data is sorted by SUBJID. Starting with P	derived

Column Header	Data Item	Codes	Derivation/Comments	Source data set
AMT	Amount of GSK2857916 given (in mg)		AMT = ALTDOSE, where PARAMCD=ALTDOSE only on the dosing line. For all other lines use "."	adex
INFD	Infusion Duration (day)		(AENDTM-ASTDTM)/60/60/24 This value will only be used on the dosing line. For all other lines use "."	adex
INFH	Infusion Duration (h)		(AENDTM-ASTDTM)/60/60 This value will only be used on the dosing line. For all other lines use "."	adex
RATED	Rate of infusion (mg/day)		RATED = AMT/INFD; where INFD is the infusion duration and is computed from start and stop time of infusion (in days) This value will only be used on the dosing line. For all other lines use "."	derived
RATEH	Rate of infusion (mg/h)		RATEH = AMT/INFH; where INFH is the infusion duration and is computed from start and stop time of infusion (in h) This value will only be used on the dosing line. For all other lines use "."	derived
RTFDD	Relative time from start of first infusion on study (day)		RTFDH=((ADTM-ASTDTM)/60/60/24)	adpc, adex
RTFDH	Relative time from start of first infusion on study (h)		RTFDD=((ADTM-ASTDTM)/60/60));	adpc, adex
RTLDD	Relative time from start of the most recent dose on study (day)		RTLDD= RTLDD/24	derived
RTLDH	Relative time from start of the most recent dose on study (h)		AWNLRT= RTLDH	adpc
NOMTLDD	Planned nominal time relative to start of most recent infusion (day)		NOMTLDH/24	adpc

NOMTLDH	Planned nominal time relative to start of most recent infusion (h)		Derive from PCTPT
			when (PCTPT ='PRE-DOSE), NOMTLDH=0;
			when (PCTPT='DOSE'), NOMTLDH =0;
			when (PCTPT ="30M POST START OF INFUSION (SOI)"), NOMTLDH =0.5;
			when (PCTPT ="END OF INFUSION (EOI)"), NOMTLDH =1;
			when (PCTPT ="1 HOUR POST-EOI"), NOMTLDH =2;
			when (PCTPT ="3 HOURS POST-EOI"), NOMTLDH =4;
			when (PCTPT ="8 HOURS POST-EOI"), NOMTLDH =9;
			when (PCTPT ="24 HOURS POST-EOI"), NOMTLDH =25;
			when (PCTPT ="7 DAYS POST-EOI"), NOMTLDH =168;
			when (PCTPT ="14 DAYS POST-EOI"), NOMTLDH
				adpc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			=336; when (PCTPT ="END OF STUDY"), NOMTLDH =10000; otherwise NOMTLDH =.;	
CTIME	Clock time sample was obtained	Clock time (24 h) '00:00'	TIMEPART (EVENT) Format TIME5.	all dataset
DATE	Date of event (MM/DD/YYYY)		DATEPART (EVENT) Format DATE9.	all dataset
ANALN	Analyte	1= ADC(antibody-drug conjugate) 2= TOTALMAB(total antibody including complex) 3= MMAF(cys-mcMMAF)	This value will be used on all lines except for dosing record line where missing "." will be used. EXCLUDE MAB PARAMCD in (P1RES, P5RES, P7RES), assign ANALN =3, 1, 2 respectively	adpc
DV	Plasma concentration (ng/mL) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If AVALC=NA/NR/NQ/BQL/missing, set DV= "." Else DV=AVAL When PARAMCD=P1RES, then DV=AVAL/1000 [Convert cys-mcMMAF from pg/mL to ng/mL precision (3 significant figures).For example, 0.111 pg/mL= 0.000111 ng/mL]	adpc
DNDV	Dose-normalized plasma concentration[(ng/mL)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		DNDV = DV (ng/mL)/AVAL; where AVAL=adex.PARAMCD=ADOSE (mg/kg) For DV = ".", set DNDV = "."	adpc, adex
DVNM	Plasma concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		For ANALN = 1, DVNM = DV(ng/mL)/152.1 For ANALN = 2, DVNM = DV(ng/mL)/152.1 For ANALN = 3, DVNM = DV(ng/mL)/1.045 For DV = ".", set DVNM = "."	adpc
DNDVNM	Dose-normalized plasma concentration[(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including		DNDVNM = DVNM (nM)/ AVAL; where AVAL=adex.PARAMCD=ADOSE (mg/kg) For DVNM = ".", set DNDVNM = "."	adpc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	complex) and cys-mcMMAF			
LNDV	Natural logarithm of the plasma concentration of GSK2857916 (ng/mL) (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		• If DV = "." then LNDV = "." • Else LNDV = loge(DV)	adpc
LNDNDV	Natural logarithm of dose-normalized plasma concentration[(ng/mL)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DNDV = "." then LNDNDV = "." Else LNDNDV = loge(DNDV)	adpc
LNDVNM	Natural logarithm of plasma concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DVNM = "." then LNDVNM = "." Else LNDVNM = loge(DVNM)	adpc
LNDNDVNM	Natural logarithm of dose-normalized plasma concentration[(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DNDVNM = "." then LNDNDVNM = "." Else LNDNDVNM = loge(DNDVNM)	adpc
DV2	Plasma concentration (ng/mL) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If adpc.AVALC=NA/NR/missing, set DV2= "." If AVALC=NQ/BQL, set DV2 = "LLOQ/2" When PARAMCD=P1RES, then DV2=AVAL/1000; [Convert cys-mcMMAF from pg/mL to ng/mL precision (3 significant figures). For example, 0.111 pg/mL= 0.000111 ng/mL]	adpc
DNDV2	Dose-normalized plasma concentration[(ng/m		DNDV2 = DV2(ng/mL)/ AVAL; where AVAL=adex.PARAMCD=ADOSE (mg/kg)	adpc, adex

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	L)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		For DV2 = ".", set DNDV2 = "."	
DVNM2	Plasma concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		For ANALN = 1, DVNM2 = DV2(ng/mL)/152.1 For ANALN = 2, DVNM2 = DV2(ng/mL)/152.1 For ANALN = 3, DVNM2 = DV2(ng/mL)/1.045 For DV2 = ".", set DVNM2 = "."	adpc
DNDVNM2	Dose-normalized plasma concentration[(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		DNDVNM2 = DVNM2 (nM)/ADOSE (mg/kg) For DVNM2 = ".", set DNDVNM2 = "."	adpc
LNDV2	Natural logarithm of the plasma concentration of GSK2857916 (ng/mL) (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		• If DV2 = "." then LNDV2 = "." • Else LNDV2 = loge(DV2)	adpc
LNDNDV2	Natural logarithm of dose-normalized plasma concentration[(ng/mL)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DNDV2 = "." then LNDNDV2 = "." Else LNDNDV2 = loge(DNDV2)	adpc

Column Header	Data Item	Codes	Derivation/Comments	Source data set
LNDVNM2	Natural logarithm of plasma concentration (nM) of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DVNM2 = "." then LNDVNM2 = "." Else LNDVNM2 = loge(DVNM2)	adpc
LNDNDVNM2	Natural logarithm of dose-normalized plasma concentration[(nM)/(mg/kg)] of GSK2857916 (antibody-drug conjugate), total antibody (including complex) and cys-mcMMAF		If DNDVNM2 = "." then LNDNDVNM2 = "." Else LNDNDVNM2 = loge(DNDVNM2)	adpc
BQL	Flag for BQL concentration	0 or 1	Set to 1 if adpc.AVALC= NQ/BQL; Else set to 0	adpc
MDV	Missing dependent variable flag.	0 or 1	1 for DV = "." and dosing line. 0 otherwise	adpc
MDV2	Missing dependent variable flag 2	0 or 1	1 for DV2= "."and dosing line. 0 otherwise	adpc
EVID	Flag indicating whether it is dosing admin info or drug concentration data.	0 or 1	1 on dosing line Set to 0 for all other lines	adex, adpc
OCC	Cycle number	>0	1 = Cycle 1, 2 = Cycle 2, 3 = Cycle 3 ,4 = Cycle 4,5 = Cycle 5,… etc EOT=999 Derive from AVISIT	adpc
IDOSE	GSK2857916 initial cycle dose (mg/kg)	>0	IDOSE=adex.TRT01A; strip off units	adex
ADOSE	GSK2857916 actual cycle dose (mg/kg)	>0	ADOSE= AVAL; where AVAL=adex.PARAMCD=ADOSE	adex
CMT	Compartment	>0	1 = Central Compartment for antibody-drug conjugate (Plasma concentration of antibody-drug conjugate ANALN=1) 3 = Central Compartment for total antibody (including complex) (Plasma concentration (DV) of total antibody for ANALN=2) 5 = Central Compartment for cys-mcMMAF (Plasma concentration(DV) of cys-mcMMAF for ANALN=3) On Dosing line CMT= 1	

Column Header	Data Item	Codes	Derivation/Comments	Source data set
AGE	Age (years)		• Use value as defined by Stats; • If not defined by Stats, AGE = date of first dose – date of birth • If date of birth is missing, AGE = -99	adsl
GENDER	Gender	0 or 1	Male = 1 Female = 0 • If sex is missing, GENDER = -99	adsl
BWT	Baseline Weight (kg)		Baseline rules: • Use baseline value as defined by Stats in the lab test datasets; • If not defined by Stats, set to weight measurement nearest to, but prior to, time of first dose • Only in cases where Day 1 weight is not available, but screening weight is, the screening values will be used. Fill in BWT in all rows for each subject **Same rules are applied for other baseline covariates**	adsl
HT	Height (cm)		Height at baseline in cm Fill in HT in all rows for each subject	adsl
LNWT	Ln transformed weight (kg)		LNWT = loge(BWT) Fill in LNWT in all rows for each subject	adsl
LWT	Lean Weight (kg)		Male: 0.32810• BWT(kg) + 0.33929• HT(cm) - 29.5336 Female: 0.29569• BWT (kg) + 0.41813• HT (cm) - 43.2933 Ref: Hume, 1966 Fill in LWT in all rows for each subject	adsl
LNLWT	Ln transformed lean Weight (kg)		LNLWT= loge(LWT) Fill in LNLWT in all rows for each subject	adsl
BBSA	Baseline Body Surface Area (m^2)		Baseline BSA (m^2) BBSA = $0.024265 \cdot HT(cm)^{0.3964} \cdot BWT(kg)^{0.5378}$ Fill in BBSA in all rows for each subject	adsl
BBMI	Baseline Body Mass Index (kg/m^2)		BBMI = $BWT(kg)/(HT(cm)/100)^2$ Assign BBMI = -99 if negative values would be derived for any of BBMI Fill in BBMI in all rows for each subject	adsl
BFFM	Baseline fat-free mass (kg)		• If Male, BFFM = (9270*BWT(kg))/(6680+(216*BBMI(kg/m^2))) • If Female, BFFM = (9270*BWT(kg))/(8780+(244*BBMI(kg/m^2))) Assign FFM = -99 if negative values are derived for any of BMI, BSA, FFM or IBW. Fill in BFFM in all rows for each subject	adsl
CANCER	Cancer type	0 or 1	0=Multiple Myeloma, 1=BCMA positive Lymphomas If TRT01AN = 12, then CANCER=1, else CANCER=0 Fill in CANCER in all rows for each subject	all datasets
BSBCMA	sBCMA level at baseline (ng/mL)		Baseline value is pre-dose on Cycle 1 Day 1. For PARAMCD = SBCMAG, get the values from AVAL column. When AVAL is missing: • and AVALC = ALQ: set to LBULOQ • and AVALC = BLQ: set to LBLLOQ/2	adbiomrk PARAMCD = SBCMAG when ABLFL=Y.

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			• and AVALC = missing: set to -99 Fill in the BSBCMA in all rows for each subject	
SBCMA	sBCMA level (ng/mL)		For PARAMCD = SBCMAG, get the values from AVAL column. SBCMA is propagated forward from the most recent measurement for all observations up to the next sBCMA measurement (LOCF). When AVAL is missing: • and AVALC = ALQ: set to LBULOQ • and AVALC = BLQ: set to LBLLOQ/2 • and AVALC = missing: propagate prior SBCMA value forward until the next measured SBCMA Please capture the values corresponding to the PK time points.	adbiomrk PARAMCD = SBCMA
SBCMA GC	Complex BCMA (ng/mL)		For PARAMCD = SBCMAGC, get the values from AVAL column. SBCMAGC is propagated forward from the most recent measurement for all observations up to the SBCMAGC measurement (LOCF). When AVAL is missing: • and AVALC = ALQ: set to LBULOQ • and AVALC = BLQ: set to LBLLOQ/2 • and AVALC = missing: propagate prior SBCMAGC value forward until the next measured SBCMAGC Please capture the values corresponding to the PK time points.	adbiomrk PARAMCD = SBCMAGC
BCRCL	Baseline Creatinine Clearance (mL/min/1.73 m^2)		eGFR = 175 × $(Scr)^{-1.154}$ × $(Age)^{-0.203}$ × (0.742 if female) × (1.212 if African American) Scr = AVAL; AVAL=adlab.PARAMCD =LB1404 and ABLFL=Y Convert units (µmol/L) to (mg/dL) using the following formula: To convert µmol/L to mg/dL, multiply by 0.0113. Age is expressed in years. Fill in the BCRCL in all rows for each subject Assign-99 if missing	adlab; PARAMCD=LB1404
CRCL	Creatinine Clearance (mL/min/1.73 m^2)		eGFR = 175 × $(Scr)^{-1.154}$ × $(Age)^{-0.203}$ × (0.742 if female) × (1.212 if African American) Scr = AVAL; AVAL=adlab.PARAMCD = PARAMCD=LB1404. Convert units (µmol/L) to (mg/dL) using the following formula: To convert µmol/L to mg/dL, multiply by 0.0113. Age is expressed in years.If AGE is changing during the course of treatment, then use baseline AGE. CRCL is propagated forward from the most recent measurement for all observations up to the next CRCL measurement (LOCF). Please capture the values corresponding to the PK time points.	adlab
BALT	Baseline ALT (IU/L)		BALT = AVAL; AVAL=adlab.PARAMCD =LB1227 and ABLFL=Y Fill in BALT in all rows for each subject	adlab

Column Header	Data Item	Codes	Derivation/Comments	Source data set
BAST	Baseline AST (IU/L)		BAST = AVAL; AVAL=adlab.PARAMCD =LB1273 and ABLFL=Y Fill in BAST in all rows for each subject	adlab
BALB	Baseline Albumin (g/L)		BALB = AVAL; AVAL=adlab.PARAMCD =LB1216 and ABLFL=Y Fill in BALB in all rows for each subject	adlab
BBILI	Baseline Total Bilirubin (mg/dL)		BALB = AVAL; AVAL=adlab.PARAMCD =LB1282 and ABLFL=Y Fill in BBILI in all rows for each subject	adlab
BIGG	Baseline serum IgG (g/L)		BIGG = AVAL; AVAL=adlab.PARAMCD =LB1566 and ABLFL=Y If a prior-to-first-dose-of- GSK2857916 lab test value was not available, set as -99 Fill in BIGG in all rows for each subject	adlab
IGG	Serum IgG (g/L)		BIGG = AVAL; AVAL=adlab.PARAMCD =LB1566 Missing values use -99. IGG is propagated forward from the most recent measurement for all observations up to the next IGG measurement (LOCF). Please capture the values corresponding to the PK time points.	adlab
MAXPRED	Maximum reduction in M-protein or FLC		Obtain AVAL for PARAMCD=MAXPRED. When AVAL is missing, MAXPRED = -999	adrs
RESPRATIO	Transform MAXRED to a ratio to baseline		RESPRATIO = max((100+MAXPRED)/100,0.001) • When MAXRED is missing, MAXPRED = -999 and RESPRATIO= -99 • When MAXPRED is less than -100 e.g. -100.15, RESPRATIO = negative (It is negative but greater than -8.99), then update RESPRATIO = 0.001 • When MAXPRED is equal to -100, RESPRATIO = 0, then update RESPRATIO = 0.001	adrs
RACE	Subject race	1=White, or White/Caucasian, or White/Caucasian - European Heritage 2=Asian 3= Black or African American, or Black/African American, or Black - African American or African Heritage 4= American	If race is missing, set to other (use CRF/Stats coding for other) Fill in RACE in all rows for each subject	adsl

Column Header	Data Item	Codes	Derivation/Comments	Source data set
		Indian or Alaska Native, or Alaska Native or American Indian, or Alaksa Native or American Indian from North/Central /South America 5= Native Hawaiian or Other Pacific Islander 6= Multi-racial: White Caucasian + Alaksa Native or American Indian		
ETHN	Subject ethnicity	1 = Hispanic or Latino 2 = Non-Hispanic -99 = Missing	• Same coding as CRF/Stats • Fill in ETHN in all rows for each subject	adsl
CNC	Country code	1 = Canada, 2 = UK 3 = US	Fill in CNC in all rows for each subject	adsl

<table>
<tr><th>Column Header</th><th>Data Item</th><th>Codes</th><th>Derivation/Comments</th><th>Source data set</th></tr>
<tr><td>IMMU</td><td>Immunogenicity Outcome by Collection Time</td><td>0 = negative
1 = positive</td><td>
<table>
<tr><th></th><th colspan="2">PARAMCD</th><th rowspan="2">IMMU</th></tr>
<tr><th></th><th>PARAMCD = AGBABDS</th><th>PARAMCD = AGBABDC</th></tr>
<tr><td>AVALC</td><td>NEGATIVE</td><td>MISSING</td><td>0</td></tr>
<tr><td>AVALC</td><td>POSITIVE</td><td>POSITIVE</td><td>1</td></tr>
<tr><td>AVALC</td><td>POSITIVE</td><td>NEGATIVE</td><td>0</td></tr>
<tr><td>AVALC</td><td>POSITIVE</td><td>MISSING</td><td>-99</td></tr>
<tr><td>AVALC</td><td>MISSING</td><td>ANY</td><td>-99</td></tr>
</table>
IMMU may not have been assayed at all PK visits. For visits between IMMU visits, imputation rules are as follows:
(1) When there is no change in IMMU between IMMU visits, all PK visits in between will be imputed with the same IMMU

(2) When IMMU changes from 0 to 1, impute IMMU=1 from the first record after the record known to be IMMU=0
When IMMU changes from 1 to 0, impute IMMU = 1 until the record known to be IMMU=0
</td><td>adis</td></tr>
<tr><td>IMM</td><td>Overall Immunogenicity Outcome

0=anti-GSK3174998 negative, 1=anti-GSK3174998 positive (at least one postdose)</td><td>0 = negative
1 = positive
-99 = missing</td><td>
• If IMMU = 1 at any observation for a subject, IMM = 1
• else if all IMMU = -99, IMM = -99
Else IMM = 0

Fill in IMM in all rows for each subject
</td><td></td></tr>
</table>

16.9.2. Population Pharmacokinetic (PopPK) Methodology

The primary goal of this analysis is to characterize the population pharmacokinetics of GSK2857916 and associated analytes after intravenous administration of GSK2857916 in subjects with multiple myeloma. This analysis will be performed by CPMS and reported separately.

A summary of the planned population pharmacokinetic analyses is outlined below:

- Exploratory data analyses will be performed to understand the content of the analysis dataset with respect to the anticipated models, to search for extreme values and/or potential outliers, to examine the correlation between covariates, and to assess possible trends in the data.
- Drug concentration-time data will be subjected to nonlinear mixed effects modelling using appropriate validated software to develop a population PK model.
- Based on the preliminary analysis, log-transformed drug concentration data for GSK2857916 ADC will be subjected to analysis using a two-compartment IV infusion model parameterized using either clearances and distribution volumes, micro-constants or macro-constants (A, B, ALPHA and BETA), depending on parameters to be estimated. A similar approach may be used on the data from the three analytes (ADC, total antibody, and cys-mcMMAF) together.
- Inter-individual or between-subject variability (IIV or BSV) will be initially modeled using an exponential random effects model. Random effects for clearances and volumes or A and B and BETA will be incorporated, depending on model parameterization used. If the goodness-of-fit plots reveal potential biases in the random effects model, alternative random effects models may be considered.
- An additive error model on a log-transformed data scale reflecting an exponential error residual variability model will initially be used to describe the residual variability. If the goodness-of-fit plots reveal potential biases in the residual variability model, other residual error models will be considered as appropriate.
- Covariate analysis will be performed to explore measurable sources of PK variability. Different approaches may be evaluated for covariate model building including a step-wise process consisting of a forward and a backward selection procedure and/or a full-model approach. Some of the prospectively identified covariates are listed below:
    - Continuous covariates such as age, albumin, measures of body size (e.g., body weight, body surface area, body mass index, lean body mass);
    - Categorical covariates such as gender, race, disease status, immunogenicity status, and geographic region.
- Non-parametric bootstrapping may be performed to test model robustness. The model performance may be evaluated by performing predictive check.
- Individual *post hoc* estimated PK parameters will be summarized descriptively.
- Individual subject PK parameters and exposure measures for Cycle 1 will be estimated and documented for the purposes of any subsequent exposure-response (PK/PD) analyses.

Any analyses not described *a priori* but undertaken based on emerging data will be described in detail in the report.

Data handling considerations are summarized below:

- Drug concentration data which are below the lower limit of quantification, LLQ, (NQ or BLQ) are not reported as a numeric value. Such NQ observations will be either discarded or handled in a special way. When the frequency of NQ is small, the NQ values will be excluded, since discarding NQ values in this case introduces little bias [Beal, 2001]. In situations where there are a large percentage of NQ values, other strategies which may reduce estimation bias will be considered [Beal, 2001; Hing, 2001; Ahn, 2008]. The total number and percentage of NQ values will be calculated and the rationale for the method for handling these NQ values will be documented in the final report. In situations with large number of NQ values, the predictive performance of the model will be assessed to compare the agreement between observed versus predicted proportion of samples below the LLQ.
- Concentrations that are inconsistent pharmacokinetically with the drug concentration-time profile within an individual may be considered as outliers and subsequently excluded from the dataset or analysis. Visual inspection of individual and pooled data and weighted residuals during analysis may be used to identify such outliers. Any such exclusion will be reported and discussed in the analyses summary.
- Missing data will be handled in the following way:
- Subjects who withdrew from the study and did not provide any PK samples and do not have adequate sampling and/or covariate information will be excluded from the analysis.
- If dosing and/or sampling times are missing, the relevant concentrations may be excluded from the analysis dataset and summarized in an exclusion listing file. Alternatively, the nominal times of the respective doses and/or samples may be utilized.
- Imputations of any covariate value will only be performed if the variable is missing for less than 10% of the subjects. For continuous covariates, missing values for an individual subject will be imputed as the gender-specific median value for the study. Any changes to the imputation methods will be justified and documented. If the percentage of missing data is greater than 10%, the variable will only be evaluated in exploratory graphical displays and not in the population analyses. Subjects from race categories with an insufficient number for analysis (typically less than 10% of the subject population) may be re-grouped and/or defined as race “Other.”

16.10. Appendix 10: Pharmacokinetic / Pharmacodynamic Analyses

16.10.1. Pharmacokinetic / Pharmacodynamic Dataset Specification

Dataset specifications for exposure-response analyses of efficacy and of corneal toxicity are provided. Any deviations between the dataset specifications and the final datasets will be documented in the population pharmacokinetic analysis report.

For corneal toxicity

Column Header	Data Item	Codes	Derivation/Comments	Source data set
C	Line number/exclusion identifier	Row Number	Set to line/row number	adae
STUDY	Study ID		1 = BMA117159	adsl
SUBJID	Subject identifier from source data		SUBJID = SUBJID	adsl
ID	NONMEM subject identifier		Sequential subject identifier across studies after data is sorted by SUBJID. Starting with PP	
TOXTYPE	This variable is created to separate out Grade 1 toxicity from Grade 2 and higher.	1,2	2 separate datasets with one line per subject: TOXTYPE = 1 for 1st occurrence of corneal event (CQ01NAM = Corneal Event). If CQ01NAM = missing, add 1 line for that subject. TOXTYPE = 2 for 1st occurrence of corneal event (CQ01NAM = Corneal Event) with AETOXGRN ≥ 2. If CQ01NAM = missing, add 1 line for that subject. After these 2 datasets are complete, merge them.	adae
CORTOX	Presence or Absence of Corneal toxicity	0 or 1	When CQ01NAM ="Corneal Event", then CORTOX=1. When CQ01NAM =missing, then CORTOX=0.	adae
AETOXGRN	Standard Toxicity Grade	0,1,2,3		adae
TTECORTOX	Time to corneal toxicity event (day)		• For TOXTYPE = 1 and CORTOX = 1, then TTECORTOX = AESTDY • When TOXTYPE = 1 and CORTOX = 0, then TTECORTOX = (TRTSDT, LSTCTDT is coming from adsl dataset) • For TOXTYPE = 2 and CORTOX = 1, then	adae, adsl

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			TTECORTOX = AESTDY • When TOXTYPE = 2 and CORTOX=0, then TTECORTOX = LSTCTDT – TRTSDT+ 1	
DOAE	Duration of adverse event (days)		• When CQ01NAM = Corneal Event and AONGO=N and AENDT= blank, then DOAE = ADURN; • When CQ01NAM = Corneal Event and AONGO = N and AENDT= D, then DOAE = -99; • When CQ01NAM = Corneal Event and AONGO=Y, then DOAE = LSTCTDT – AESTDY + 1; • When CQ01NAM = missing, then DOAE = 0;	adae, adsl
DOAECFLCD	DOAE Censoring Flag Code	0 or 1	When AONGO=N, then DOAECFLCD=0 When AONGO=Y, then DOAECFLCD=1	adae
LNDOAE	Log of duration of adverse event		LNDOAE = Log(DOAE); When DOAE=-99, LNDOAE =-99; When DOAE=0, LNDOAE=0	adae
CUMAMTCT	Cumulative dose to TTECORTOX (mg)		For corneal toxicity that occurred on dosing days, the dose on the corneal toxicity day was not included in the cumulative dose calculation.	adex. adae
Q4CUMAMTCT	Quartile of CUMAMTCT	0,1,2,3		derived
Q5CUMAMTCT	Quintile of CUMAMTCT	0,1,2,3,4		derived
CUMAUCCT	Cumulative AUC to TTECORTOX (ug.day/mL)		(Cumulative dose to TTECORTOX)/Individual Clearance of ADC	popPK output, adae
Q4CUMAUCCT	Quartile of CUMAUCCT	0,1,2,3		derived
Q5CUMAUCCT	Quintile of CUMAUCCT	0,1,2,3,4		derived
TAAUCCT	Time-average AUC till TTECORTOX (AUC/day)		The area under the plasma ADC concentration–time curve (AUC) per day (AUC/day) will be derived for each patient using the available ADC dosing information, individual patient oral clearance (CL/F) values from the population pharmacokinetic model, and the time to the occurrence of the corneal toxicity.	popPK output, adae
Q4TAAUCCT	Quartile of TAAUCCT	0,1,2,3		derived
Q5TAAUCCT	Quintile of TAAUCCT	0,1,2,3,4		derived
CANCER	Cancer type	0 or 1	0=Multiple Myeloma, 1=BCMA positive Lymphomas If TRT01AN = 12, then CANCER=1, else	adsl

Column Header	Data Item	Codes	Derivation/Comments	Source data set
			CANCER=0	
AMT	Amount (in mg) of GSK2857916 given in first cycle		AMT = AVAL when PARAMCD=ALTDOSE and AVISIT= CYCLE 1 DAY 1	adex
Q4AMT	Quartile of AMT	0,1,2,3		derived
Q5AMT	Quintile of AMT	0,1,2,3,4		derived
TOTAMT	Total dose received (mg)		TOTAMT = AVAL* WEIGHTBL; Get AVAL for PARAMCD=CUMDOSE	adex,adsl
Q4TOTAMT	Quartile of TOTAMT	0,1,2,3		derived
Q5TOTAMT	Quintile of TOTAMT	0,1,2,3,4		derived
IDOSE	GSK2857916 initial cycle dose (mg/kg)	>0	IDOSE=adex.TRT01A; strip off units	adex
Q4IDOSE	Quartile of IDOSE	0,1,2,3		derived
Q5IDOSE	Quintile of IDOSE	0,1,2,3,4		derived
CMAX	First dose Cmax of ADC – Observed EOI on Cycle 1 (ng/mL)			popPK output
Q4CMAX	Quartile of CMAX	0,1,2,3		derived
Q5CMAX	Quintile of CMAX	0,1,2,3,4		derived
MMAFCMAX	First dose Cmax of MMAF – Observed EOI on Cycle 1 (ng/mL)			popPK output
Q4MMAFCMAX	Quartile of MMAFCMAX	0,1,2,3		derived
Q5MMAFCMAX	Quintile of MMAFCMAX	0,1,2,3,4		derived
CTAU	First dose C_{tau} of ADC– Observed pre-dose on Cycle 2			popPK output
Q4CTAU	Quartile of CTAU	0,1,2,3		derived
Q5CTAU	Quintile of CTAU	0,1,2,3,4		derived
AUC	First dose AUC(0-inf) of ADC (ug.day/mL)		First dose (mg)/Individual Clearance of ADC	popPK output
Q4AUC	Quartile of AUC	0,1,2,3		derived
Q5AUC	Quintile of AUC	0,1,2,3,4		derived
TOTAUC	Total AUC (ug.day/mL)		(Total dose received)/Individual Clearance of ADC	popPK output
Q4TOTAUC	Quartile of TOTAUC	0,1,2,3		derived
Q5TOTAUC	Quintile of TOTAUC	0,1,2,3,4		derived
MMAFAUC	First dose AUC(0-inf) of MMAF (ug.day/mL)		First dose (mg)/Individual Clearance of MMAF	popPK output
Q4MMAFAUC	Quartile of MMAFAUC	0,1,2,3		derived
Q5MMAFAUC	Quintile of MMAFAUC	0,1,2,3,4		derived
MMAFTOTAUC	Total AUC (ug.day/mL)		(Total dose received)/Individual Clearance of MMAF	popPK output
Q4MMAFTOTAUC	Quartile of MMAFTOTAUC	0,1,2,3		derived
Q5MMAFTOTAUC	Quintile of MMAFTOTAUC	0,1,2,3,4		derived

For efficacy

Column Header	Data Item	Codes	Derivation/Comments	Source data set
C	Exclusion identifier	Row Number DORDM	Set to line/row number unless one or more of the following conditions are met, then set to code: • DORDM: If DORD is missing	adtte
STUDY	Study ID		1 = BMA117159	adsl
SUBJID	Subject identifier from source data		SUBJID = SUBJID	adsl
ID	NONMEM subject identifier		Sequential subject identifier across studies after data is sorted by SUBJID. Starting with P	derived
PFSCFLCD	PFS Censoring Flag Code	0 or 1	For PARAMCD=PFS_D, CNSR value is assigned to PFSCFLCD 0=Event 1=Censor	adtte
PFSD	PFS (Days)		For PARAMCD=PFS_D, AVAL value is assigned to PFSD	adtte
PFSM	PFS (Months)		For PARAMCD=PFS_M, AVAL value is assigned to PFSM	adtte
PFSY	PFS (Years)		For PARAMCD=PFS_D, (AVAL/365) value is assigned to PFSY	derived
TTRCFLCD	TTR Censoring Flag Code	0 or 1	For PARAMCD=TTR_D, Assign 1 to TTRCFLCD. For subjects where TTR_D is missing, assign 0 to TTRCFLCD.	adtte
TTRD	TTR (Days)		For PARAMCD=TTR_D, AVAL value is assigned to TTRD. For subjects where TTR_D is missing, assign PFSD to TTRD.	adtte
TTRM	TTR (Months)		For PARAMCD=TTR_M, AVAL value is assigned to TTRM. For subjects where TTR_M is missing, assign PFSM to TTRM.	adtte
TTRY	TTR (Years)		For PARAMCD=TTR_D, (AVAL/365) value is assigned to TTRY. For subjects where TTR_D is missing, assign PFSY to TTRY.	derived
DORCFLCD	DOR Censoring Flag Code	0 or 1	For PARAMCD=DOR_D, CNSR value is assigned to DORCFLCD 0=Event 1=Censor Assign "." for missing.	adtte
DORD	DOR (Days)		For PARAMCD=DOR_D, AVAL value is assigned to DORD. For subjects where DOR_D is missing, assign "."	adtte

Column Header	Data Item	Codes	Derivation/Comments	Source data set
DORM	DOR (Months)		For PARAMCD=DOR_M, AVAL value is assigned to DORM. For subjects where DOR_M is missing, assign "."	adtte
DORY	DOR (Years)		For PARAMCD=DOR_D, (AVAL/365) value is assigned to DORY For subjects where DOR_Y is missing, assign "."	derived
ORDRESP		0,1,2,3,4,5,6	For PARAMCD=BCRSP, assign 0 for PD 1 for SD 2 for MR 3 for PR 4 for VGPR 5 for CR 6 for sCR	adrs
MAXPRED			Obtain AVAL for PARAMCD=MAXPRED. When AVAL is missing, MAXPRED = -999	adrs
RESPRATIO	Transform MAXRED to a ratio to baseline		RESPRATIO = max((100+MAXPRED)/100,0.001) • When MAXRED is missing, MAXRED = -999 and RESPRATIO= -99 • When MAXRED is less than -100 e.g. -100.15, RESPRATIO = negative (It is negative but greater than -8.99), then update RESPRATIO = 0.001 • When MAXRED is equal to -100, RESPRATIO = 0, then update RESPRATIO = 0.001	adrs,derived
RSPTYP	Response Type	1,2,3	1 for Serum M-Protein 2 for Serum FLC 3 for Urine M-Protein	adrs
CUMAMTP	Cumulative dose to PFS (mg)		For progression that occurred on dosing days, the dose on the progression day was not included in the cumulative dose calculation.	adex, adtte
Q4CUMAMTP	Quartile of CUMAMTP	0,1,2,3		derived
Q5CUMAMT	Quintile of CUMAMTP	0,1,2,3,4		derived
CUMAUCP	Cumulative AUC to progression (ug.day/mL)		(Cumulative dose to progression)/Individual Clearance of ADC	popPK output, adtte
Q4CUMAUCP	Quartile of CUMAUCP	0,1,2,3		derived
Q5CUMAUCP	Quintile of	0,1,2,3,4		derived

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	CUMAUCP			
TAAUCP	Time-average AUC till progression (AUC/day)		The area under the plasma ADC concentration–time curve (AUC) per day (AUC/day) will be derived for each patient using the available ADC dosing information, individual patient oral clearance (CL/F) values from the population pharmacokinetic model, and the time to the occurrence of the PFS	popPK output, adtte
Q4TAAUCP	Quartile of TAAUCP	0,1,2,3		derived
Q5TAAUCP	Quintile of TAAUCP	0,1,2,3,4		derived
CUMAMTR	Cumulative dose to Response (mg)		For response that occurred on dosing days, the dose on the response day was not included in the cumulative dose calculation.	adex, adtte
Q4CUMTAMTR	Quartile of CUMAMTR	0,1,2,3		derived
Q5CUMTAMTR	Quintile of CUMAMTR	0,1,2,3,4		derived
CUMAUCR	Cumulative AUC to response (ug.day/mL)		(Cumulative dose to response)/Individual Clearance of ADC	adex, adtte, popPK output
Q4CUMAUCR	Quartile of CUMAUCR	0,1,2,3		derived
Q5CUMAUCR	Quintile of CUMAUCR	0,1,2,3,4		derived
TAAUCR	Time-average AUC till response (AUC/day)		The area under the plasma ADC concentration–time curve (AUC) per day (AUC/day) will be derived for each patient using the available ADC dosing information, individual patient oral clearance (CL/F) values from the population pharmacokinetic model, and the time to the occurrence of the response	popPK output, adtte
Q4TAAUCR	Quartile of TAAUCR	0,1,2,3		derived
Q5TAAUCR	Quintile of TAAUCR	0,1,2,3,4		derived
CUMAMTD	Cumulative dose to DOR (mg)		For DOR that occurred on dosing days, the dose on the DOR day was not included in the cumulative dose calculation.	adex, adtte
Q4CUMTAMTD	Quartile of CUMAMTD	0,1,2,3		derived
Q5CUMTAMTD	Quintile of CUMAMTD	0,1,2,3,4		derived
CUMAUCD	Cumulative AUC to DOR (ug.day/mL)		(Cumulative dose to DOR)/Individual Clearance of ADC	adex,adtte,popPK output
Q4CUMAUCD	Quartile of CUMAUCD	0,1,2,3		derived

Column Header	Data Item	Codes	Derivation/Comments	Source data set
Q5CUMAUCD	Quintile of CUMAUCD	0,1,2,3,4		derived
TAAUCD	Time-average AUC till DOR (AUC/day)		The area under the plasma ADC concentration–time curve (AUC) per day (AUC/day) will be derived for each patient using the available ADC dosing information, individual patient oral clearance (CL/F) values from the population pharmacokinetic model, and the time to the occurrence of the duration of response	adtte, popPK output
Q4TAAUCD	Quartile of TAAUCD	0,1,2,3		derived
Q5TAAUCD	Quintile of TAAUCD	0,1,2,3,4		derived
CANCER	Cancer type	0 or 1	0=Multiple Myeloma, 1=BCMA positive Lymphomas If TRT01AN = 12, then CANCER=1, else CANCER=0	adsl
AMT	Amount (in mg) of GSK2857916 given in first cycle		AMT = AVAL when PARAMCD=ALTDOSE and AVISIT= CYCLE 1 DAY 1	adex
Q4AMT	Quartile of AMT	0,1,2,3		derived
Q5AMT	Quintile of AMT	0,1,2,3,4		derived
TOTAMT	Total dose received (mg)		TOTAMT = AVAL* WEIGHTBL; Get AVAL for PARAMCD=CUMDOSE	adex,adsl
Q4TOTAMT	Quartile of TOTAMT	0,1,2,3		derived
Q5TOTAMT	Quintile of TOTAMT	0,1,2,3,4		derived
IDOSE	GSK2857916 initial cycle dose (mg/kg)	>0	IDOSE=adex.TRT01A; strip off units	adex
Q4IDOSE	Quartile of IDOSE	0,1,2,3		derived
Q5IDOSE	Quintile of IDOSE	0,1,2,3,4		derived
CMAX	First dose Cmax of ADC – Observed EOI on Cycle 1 (ng/mL)			popPK output
Q4CMAX	Quartile of CMAX	0,1,2,3		derived
Q5CMAX	Quintile of CMAX	0,1,2,3,4		derived
MMAFCMAX	First dose Cmax of MMAF – Observed EOI on Cycle 1 (ng/mL)			popPK output
Q4MMAFCMAX	Quartile of MMAFCMAX	0,1,2,3		derived
Q5MMAFCMAX	Quintile of	0,1,2,3,4		derived

Column Header	Data Item	Codes	Derivation/Comments	Source data set
	MMAFCMAX			
CTAU	First dose C_{tau} of ADC– Observed pre-dose on Cycle 2			popPK output
Q4CTAU	Quartile of CTAU	0,1,2,3		derived
Q5CTAU	Quintile of CTAU	0,1,2,3,4		derived
AUC	First dose AUC(0-inf) of ADC (ug.day/mL)		First dose (mg)/Individual Clearance of ADC	popPK output
Q4AUC	Quartile of AUC	0,1,2,3		derived
Q5AUC	Quintile of AUC	0,1,2,3,4		derived
TOTAUC	Total AUC (ug.day/mL)		(Total dose received)/Individual Clearance of ADC	popPK output
Q4TOTAUC	Quartile of TOTAUC	0,1,2,3		derived
Q5TOTAUC	Quintile of TOTAUC	0,1,2,3,4		derived
MMAFAUC	First dose AUC(0-inf) of MMAF (ug.day/mL)		First dose (mg)/Individual Clearance of MMAF	popPK output
Q4MMAFAUC	Quartile of MMAFAUC	0,1,2,3		derived
Q5MMAFAUC	Quintile of MMAFAUC	0,1,2,3,4		derived
MMAFTOTAUC	Total AUC (ug.day/mL)		(Total dose received)/Individual Clearance of MMAF	popPK output
Q4MMAFTOTAUC	Quartile of MMAFTOTAUC	0,1,2,3		derived
Q5MMAFTOTAUC	Quintile of MMAFTOTAUC	0,1,2,3,4		derived

16.10.2. Pharmacokinetic / Pharmacodynamic Methodology

The primary goal of this analysis is to characterize the pharmacokinetic/pharmacodynamic relationships for GSK2857916 administered IV in subjects with multiple myeloma. In these analyses, drug plasma concentration (or pharmacokinetic parameter) data and pharmacodynamic data will be subjected to nonlinear mixed effects modelling using suitable software. The influence of subject demographics and baseline characteristics, including disease activity, in this population may be investigated. This analysis will be performed by CPMS and reported separately.

16.10.2.1. PD Model of sBCMA Binding

Soluble and complex BCMA levels will be log-transformed and described using a conventional linear mixed effects model and planned time for Cycle 1. Ratio to pre-dose Cycle 1 will be estimated. If data permit, parameter values will be estimated. In addition, prediction of free sBCMA data using a quasi-steady-state approximation (QSSA) PK/PD reaction binding model may be conducted without parameter estimation.

16.10.2.2. Exposure-Response Analyses

16.10.2.2.1. Corneal Toxicity

Presence or absence of corneal toxicity will be described using a conventional logistic regression model for both ≥ Grade 1 and ≥ Grade 2 toxicity. Time to first corneal toxicity will be explored using Kaplan Meier plots with exposure subdivided into quartiles and quintiles. Severity of corneal toxicity will be analyzed using an ordered logistic regression model assuming Grades 0 (no toxicity), 1, 2 and 3, with exposure subdivided into quartiles and quintiles.

16.10.2.2.2. Clinical Response

Presence or absence of clinical response will be described using a conventional logistic regression model. Time to response will be explored using Kaplan Meier plots with exposure subdivided into quartiles and quintiles.

PFS will be explored using Kaplan Meier plots with exposure subdivided into quartiles and quintiles and occurrence of progression may also be described using a conventional logistic regression model.

Duration of response will be explored using Kaplan Meier plots with exposure subdivided into quartiles and quintiles.

Best clinical response will be analyzed using an ordered logistic regression, with response categorized from 0 (progressive disease) to 6 (stringent complete response). Exposure will be treated as a categorical variable subdivided into quartiles and quintiles.

In the ordered logistic regression analyses, the use of categorical measures of exposure in lieu of continuous variables will allow for non-parametric descriptions of response functions.

Best clinical response as assessed by maximum reduction in M-protein or FLC will be analyzed by exposure (continuous and/or by quartile and quintile of exposure).

16.11. Appendix 11: Abbreviations & Trade Marks

16.11.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
AIC	Akaike's Information Criteria
A&R	Analysis and Reporting
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
BCMA	B cell maturation antigen
BCVA	Best corrected visual acuity
CBR	Clinical benefit rate
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence interval
CK-MB	Creatine kinase MB-isoenzyme
CL	Clearance
Cmax	Maximum plasma drug concentration
CPMS	Clinical Pharmacology Modeling and Simulation
CR	Complete response
CRM	Continual Reassessment Method
Ctrough	Trough plasma concentration
Cys-mcMMAF	cys Monomethyl auristatin F
DLT	Dose limiting toxicity
DOB	Date of Birth
DOR	Duration of response
DP	Decimal Places
eDiary	Electronic Diary
ECOG	Eastern Cooperative Oncology Group
EOI	End of infusion
eCRF	Electronic Case Record Form
EMA	European Medicines Agency
FACTS	Fixed and adapted clinical trials simulator
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
FLC	Free light chain
FTIH	First time in human
GSK	GlaxoSmithKline

Abbreviation	Description
IA	Interim Analysis
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
ITT	Intent-To-Treat
LDH	Lactate dehydrogenase
MMRM	Mixed Model Repeated Measures
MM	Multiple Myeloma
MMAF	Monomethyl auristatin F
MR	Minimal response
MTD	Maximum Tolerated Dose
NCI-CTCAE	National Cancer Institute – Common Terminology Criteria for Adverse Events
N-CRM	A modification of the Continual Reassessment Method (CRM) proposed by Neuenschwander et al.
NEI-VFQ-25	National Eye Institute Visual Functioning Questionnaire - 25
NONMEM	Non linear mixed effects modelling
ORR	Overall response rate
OS	Overall survival
OSDI	Ocular Surface Disease Index
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PET	Probability of early termination
PFS	Progression-free survival
PK	Pharmacokinetic
PP	Per Protocol
PR	Partial response
PopPK	Population PK
QC	Quality Control
QoL	Quality of life
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
REML	Restricted maximum likelihood
Ro	Observed accumulation ratio
RP2	Recommended Phase 2
SAC	Statistical Analysis Complete
SAE	Serious adverse event
sBCMA	Soluble B-cell maturation antigen
sCR	Stringent complete response
SD	Stable disease
SDSP	Study Data Standardization Plan

Abbreviation	Description
SDTM	Study Data Tabulation Model
SOI	Start of infusion
SPEP	Serum protein electrophoresis
SOP	Standard Operation Procedure
t½	Half-life
TA	Therapeutic Area
TFL	Tables, Figures & Listings
Tmax	Time to maximum drug concentration
TTBR	Time to best response
TTP	Time to progression
TTR	Time to response
ULN	Upper limit of normal
UPEP	Urine protein electrophoresis
VGPR	Very good partial response

16.11.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
NONE

Trademarks not owned by the GlaxoSmithKline Group of Companies
FACTS
NONMEM
SAS
WinNonlin

16.12. Appendix 12: List of Data Displays

16.12.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.0010 to 1.xxxx	11.0010 to 11.xxxx
Efficacy	2.0010 to 2.xxxx	12.0010 to 12.xxxx
Safety	3.0010 to 3.xxxx	13.0010 to 13.xxxx
Pharmacokinetic	4.0010 to 4.xxxx	14.0010 to 14.xxxx
Population Pharmacokinetic (PopPK)	5.0010 to 5.xxxx	15.0010 to 15.xxxx
Pharmacodynamic and / or Biomarker	6.0010 to 6.xxxx	16.0010 to 16.xxxx
Pharmacokinetic / Pharmacodynamic	7.0010 to 7.xxxx	17.0010 to 17.xxxx
Section	**Listings**	
ICH Listings	1.0010 to 1.xxxx	
Other Listings	30.0010 to 30.xxxx	

16.12.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 13: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Population Pharmacokinetic (PopPK)	POPPK_Fn	POPPK_Tn	POPPK_Ln
Pharmacodynamic and / or Biomarker	PD_Fn	PD_Tn	PD_Ln
Pharmacokinetic / Pharmacodynamic	PKPD_Fn	PKPD_Tn	PK/PD_Ln

NOTES:

- Non-Standard displays are indicated in the 'IDSL / Example Shell' or 'Programming Notes' column as '[Non-Standard] + Reference.'

16.12.3. Deliverables

Delivery [Priority] [1]	Description
DS [X]	During Study
DE [X]	Dose Escalation
IA SAC [X]	Interim Analysis Statistical Analysis Complete
SAC [X]	Final Statistical Analysis Complete

NOTES:

1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort.

16.12.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.0010	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [1]
1.0011	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0012	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0013	All Treated	ES8	Summary of Subject Status and Reason for Study Withdrawal (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0020	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0021	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0022	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0023	All Treated	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0550	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure (Part 1)		SAC [A]
1.0551	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure (Part 2 MM)		SAC [A]
1.0552	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure (All Treated MM)		SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0553	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure (Part 2 NHL)		SAC
1.0030	Enrolled	NS1	Summary of Number of Participant by Country and Site ID (MM)	Include columns: No Treatment, Part 1, Part 2 MM, All Treated MM, Total column will be the subjects enrolled to MM cohort. Add a footnote: This summary is based on all subjects enrolled into multiple myeloma cohorts.	SAC [A]
1.0031	Enrolled	NS1	Summary of Number of Participant by Country and Site ID (NHL)	Include columns: No Treatment, Part 2 NHL, Total column will be the subjects enrolled to NHL cohort. Add a footnote: This summary is based on all subjects enrolled into lymphoma cohorts.	SAC
1.0050	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0051	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0052	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0053	All Treated	IE1	Summary of Inclusion/Exclusion Criteria Deviations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Protocol Deviation					
1.0040	All Treated	DV1	Summary of Important Protocol Deviations (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0041	All Treated	DV1	Summary of Important Protocol Deviations (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0042	All Treated	DV1	Summary of Important Protocol Deviations (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0043	All Treated	DV1	Summary of Important Protocol Deviations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Population Analysed					
1.0060	Enrolled	SP1	Summary of Study Populations (MM)	Report for: Part 1, (Summarize: by ascending dose level, Total). This table is based on subjects enrolled to MM, we do not have screen failure data, hence no screened population. For columns, include No Treatment, No Treatment for Part 1, No Treatment for Part 2 MM, Dose levels in part 1, All Treated in Part 1, All Treated in Part 2, All Treated and Total. Rows: include Enrolled, Part 1, Part 2 MM, All Treated MM, DLT Evaluable, PK, PD	SAC [A]
1.0061	Enrolled	SP1	Summary of Study Populations (NHL)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). This table is	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				based on subjects enrolled to NHL, we do not have screen failure data, hence no screened population. For columns, include No Treatment, All Treated and Total. Rows: include Enrolled, Part 2 NHL, PK, PD	
1.0430	Enrolled	SP2A	Summary of the Exclusions from the Part 1 Population		SAC [A]
1.0431	Enrolled	SP2A	Summary of the Exclusions from the Part 2 MM Population		SAC [A]
1.0432	Enrolled	SP2A	Summary of the Exclusions from the All Treated MM Population		SAC [A]
1.0433	Enrolled	SP2A	Summary of the Exclusions from the Part 2 NHL Population		SAC [A]
1.0434	Enrolled	SP2A	Summary of the Exclusions from the All Treated Population		SAC
1.04354	Enrolled	SP2A	Summary of the Exclusions from the DLT Evaluable Population		SAC [A]
1.0436	Enrolled	SP2A	Summary of the Exclusions from the Pharmacokinetic (PK) Population		SAC [A]
1.0437	Enrolled	SP2A	Summary of the Exclusions from the Pharmacodynamic (PD) Population		SAC [A]
Demographic and Baseline Characteristics					
1.0070	All Treated	DM1	Summary of Demographic Characteristics (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0071	All Treated	DM1	Summary of Demographic Characteristics (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0072	All Treated	DM1	Summary of Demographic Characteristics (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0073	All Treated	DM1	Summary of Demographic Characteristics (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0290	Enrolled	DM11	Summary of Age Ranges (MM)	Include columns "No Treatment", "Part 1", "Part 2 MM", "All Treated MM", "Total"	SAC [1]
1.0291	Enrolled	DM11	Summary of Age Ranges (NHL)	Include columns "No Treatment", "Part 2 NHL", "Total"	SAC
1.0080	All Treated	DM5	Summary of Race and Racial Combinations (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0081	All Treated	DM5	Summary of Race and Racial Combinations (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0082	All Treated	DM5	Summary of Race and Racial Combinations (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0083	All Treated	DM5	Summary of Race and Racial Combinations (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0090	All Treated	DM6	Summary of Race and Racial Combination Details (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0091	All Treated	DM6	Summary of Race and Racial Combination Details (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0092	All Treated	DM6	Summary of Race and Racial Combination Details (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0093	All Treated	DM6	Summary of Race and Racial Combination Details (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Prior and Concomitant Medications					
1.0190	All Treated	MH1	Summary of Past Medical Conditions (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0191	All Treated	MH1	Summary of Past Medical Conditions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0192	All Treated	MH1	Summary of Past Medical Conditions (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0193	All Treated	MH1	Summary of Past Medical Conditions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0200	All Treated	MH1	Summary of Current Medical Conditions (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0201	All Treated	MH1	Summary of Current Medical Conditions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0202	All Treated	MH1	Summary of Current Medical Conditions (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0203	All Treated	MH1	Summary of Current Medical Conditions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0210	All Treated	CM8	Summary of Concomitant Medications (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0211	All Treated	CM8	Summary of Concomitant Medications (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0212	All Treated	CM8	Summary of Concomitant Medications (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0213	All Treated	CM8	Summary of Concomitant Medications (Part 2 NHL)	Report for: Part 2 NHL,	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				(Summarize: only for 3.4 NHL).	
1.0380	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more than one category for 'Drug Class' and 'Drug'.	SAC [A]
1.0381	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more than one category for 'Drug Class' and 'Drug'.	SAC [A]
1.0382	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more than one category for 'Drug Class' and 'Drug'.	SAC [A]
1.0383	All Treated	CM1	Summary of Prophylactic Medication for Infusion-Related Reactions by Drug Class and Drug Name (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Please replace ATC Level 1 by 'Drug Class' and 'Ingredient' by 'Drug'. Replace the footnote as "Subjects may be included in more	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				than one category for 'Drug Class' and 'Drug'.	
1.0510	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). If the CRF does not have any coded procedures and collection of surgeries is restricted to prior cancer related surgeries, then a summary is not necessary as the number and percent of subjects with surgeries will be provided in the anticancer therapy display (see Example AC1). Otherwise a simplified version of the summary can be utilized if appropriate (see example OSP2).	SAC [A]
1.0511	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0512	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0513	All Treated	OSP2	Summary of Prior Cancer and Non-Cancer Related Surgical Procedures (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Exposure and Treatment Compliance					
1.0240	All Treated	OEX5	Summary of Exposure to GSK2857916 (Part 1)	Report for population: Part 1, (Summarize: by ascending dose level, Total). Do not need "Dose Intensity "	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				section. Use 4, <4, >4 cycles	
1.0241	All Treated	OEX5	Summary of Exposure to GSK2857916 (Part 2 MM)	Report for population: Part 2 MM, (Summarize: only for 3.4 MM). Do not need "Dose Intensity " section. Use 4, <4, >4 cycles	SAC [A]
1.0242	All Treated	OEX5	Summary of Exposure to GSK2857916 (All Treated MM)	Report for population: All Treated MM, (Summarize: Total) Do not need "Dose Intensity " section. Use 4, <4, >4 cycles	SAC [A]
1.0243	All Treated	OEX5	Summary of Exposure to GSK2857916 (Part 2 NHL)	Report for population: 3.4 NHL, (Summarize: Total) Do not need "Dose Intensity " section. Use 4, <4, >4 cycles	SAC
1.0230	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Dose Intensity(mg/kg/cycle)	SAC [A]
1.0231	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Dose Intensity(mg/kg/cycle)	SAC [A]
1.0232	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Dose Intensity(mg/kg/cycle)	SAC [A]
1.0233	All Treated	OEX6	Summary of Dose Intensity of GSK2857916 by Cycle (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Dose Intensity(mg/kg/cycle)	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0250	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0251	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0252	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0253	All Treated	ODMOD 1	Summary of Dose Reductions of GSK2857916 (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0260	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0261	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0262	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0263	All Treated	ODMOD 3	Summary of Dose Delays of GSK2857916 (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0270	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0271	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0272	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0273	All Treated	ODMOD 5	Summary of Primary Reason for Dose Reductions of GSK2857916 by Cycle (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0280	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0281	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0282	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0283	All Treated	ODMOD 6	Summary of Primary Reason for Dose Delays of GSK2857916 by Cycle (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Disease Characteristics					
1.0100	All Treated	DC2	Summary of Disease Characteristics at Screening (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summarize Stage (I, II, III, Unknown, Missing), Lines of therapy completed at screening (1-10 lines, More than 10 lines, Missing), Type of multiple myeloma (Nonsecretory, Secretory, Missing), Myeloma Light chain (Kappa Light Chain, Lambda Light Chain, Missing), Myeloma immunoglobulin (IgA, IgG, Other, Missing)	SAC [A]
1.0101	All Treated	DC2	Summary of Disease Characteristics at Screening (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summarize categories as defined in Table 1,0100.	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0102	All Treated	DC2	Summary of Disease Characteristics at Screening (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summarize categories as defined in Table 1,0100.	SAC [A]
1.0103	All Treated	DC2	Summary of Disease Characteristics at Screening (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0110	All Treated	POP_T1	Summary of Genetic Characteristics at Screening (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0111	All Treated	POP_T1	Summary of Genetic Characteristics at Screening (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0112	All Treated	POP_T1	Summary of Genetic Characteristics at Screening (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0300	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include alll optional columns.	SAC [A]
1.0301	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include all optional columns.	SAC [A]
1.0302	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include all optional columns.	SAC [A]
1.0303	All Treated	DC1	Summary of Disease Characteristics at Initial Diagnosis (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Include all optional columns.	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0390	All Treated	POP_T2	Summary of Cytogenetics Risk at Screening (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0391	All Treated	POP_T2	Summary of Cytogenetics Risk at Screening (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0392	All Treated	POP_T2	Summary of Cytogenetics Risk at Screening (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
Prior and Follow-up Anti-Cancer Therapy					
1.0120	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0121	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0122	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0123	All Treated	AC1	Summary of Prior Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0130	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0131	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0132	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0133	All Treated	CM8	Summary of Prior Dictionary Coded Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0140	All Treated	POP_T3	Summary of Prior Anti-Cancer Therapy by Drug Class of Agents (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0141	All Treated	POP_T3	Summary of Prior Anti-Cancer Therapy by Drug Class of Agents (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0142	All Treated	POP_T3	Summary of Prior Anti-Cancer Therapy by Drug Class of Agents (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0150	All Treated	POP_T4	Summary of Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0151	All Treated	POP_T4	Summary of Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0152	All Treated	POP_T4	Summary of Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0160	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Therapies should be sorted in highest to lowest incidence. Include radio therapy and surgical procedures.	SAC [A]
1.0161	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Therapies should be sorted in highest to lowest incidence. Include radio therapy and surgical procedures.	SAC [A]
1.0162	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Therapies should be sorted in highest to	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				lowest incidence. Include radio therapy and surgical procedures.	
1.0163	All Treated	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Therapies should be sorted in highest to lowest incidence. Include radio therapy and surgical procedures.	SAC
1.0170	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Only use last therapy prior to starting study,	SAC [A]
1.0171	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Only use last therapy prior to starting study	SAC [A]
1.0172	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Only use last therapy prior to starting study	SAC [A]
1.0173	All Treated	AC4	Summary of Best Response to Most Recent Prior Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0470	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0471	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0472	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0473	All Treated	FAC1	Summary of Follow-Up Anti-Cancer Therapy (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Duration of Follow-up					
1.0310	All Treated	FAC2	Summary of Duration of Follow-up (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include all optional columns.	SAC [A]
1.0311	All Treated	FAC2	Summary of Duration of Follow-up (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include all optional columns.	SAC [A]
1.0312	All Treated	FAC2	Summary of Duration of Follow-up (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include al optional columns.	SAC [A]
1.0313	All Treated	FAC2	Summary of Duration of Follow-up (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Include all optional columns.	SAC
1.0400	All Treated	FAC2	Summary of Duration of Follow-up for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0401	All Treated	FAC2	Summary of Duration of Follow-up for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0402	All Treated	FAC2	Summary of Duration of Follow-up for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0410	All Treated	FAC2	Summary of Duration of Follow-up for Subjects without Prior	Report for: Part 1, (Summarize: by	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Daratumumab Treatment (Part 1)	ascending dose level, Total).	
1.0411	All Treated	FAC2	Summary of Duration of Follow-up for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0412	All Treated	FAC2	Summary of Duration of Follow-up for Subjects without Prior Daratumumab Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0420	All Treated	FAC2	Summary of Duration of Follow-up for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0421	All Treated	FAC2	Summary of Duration of Follow-up for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0422	All Treated	FAC2	Summary of Duration of Follow-up for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
Blood and Blood Supportive Care Products					
1.0480	All Treated	BP1A	Summary of Blood Products (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0481	All Treated	BP1A	Summary of Blood Products (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
1.0482	All Treated	BP1A	Summary of Blood Products (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0483	All Treated	BP1A	Summary of Blood Products (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
1.0490	All Treated	BP1C	Summary of Blood Supportive Care Products (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
1.0491	All Treated	BP1C	Summary of Blood Supportive Care Products (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0492	All Treated	BP1C	Summary of Blood Supportive Care Products (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
1.0493	All Treated	BP1C	Summary of Blood Supportive Care Products (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL).	SAC
Substance Use					
1.0500	All Treated	SU1	Summary of Substance Use (Part 1)	Report for : Part 1, (Summarize: by ascending dose level, Total). All substance collected in eCRF	SAC [A]
1.0501	All Treated	SU1	Summary of Substance Use (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). All substance collected in eCRF	SAC [A]
1.0502	All Treated	SU1	Summary of Substance Use (All Treated MM)	Report for: All Treated MM, (Summarize: Total). All substance colleced in eCRF	SAC [A]
1.0503	All Treated	SU1	Summary of Substance Use (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). All substance colleced in eCRF	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.5. Study Population Figures

Study Population: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
11.0020	All Treated	POP_F2	Plot of Dose Reduction of GSK2857916 by Cycle (Part 2 MM)	Report for population subgroup: Part 2 MM. Combine 1.9 mg/kg and 1.7 mg/kg dose groups as 1.7 mg/kg. Sort the bar by descending dose levels. Add foot note "Doses 1.9 mg/kg and 1.7 mg/kg are combined and represented by 1.7 mg/kg."	SAC [A]
11.0030	All Treated	OEX12	Plot of Duration of Study Treatment by Response (Part 1)	Report for population subgroup: Part 1. Y axis: dose cohort. Use best confirmed response. Please add the footnote regarding treatment duration consistent with the one in OEX12.	SAC [A]
11.0031	All Treated	OEX12	Plot of Duration of Study Treatment by Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Y axis: dose cohort. Use best confirmed response. Please add the footnote regarding treatment duration consistent with the one in OEX12.	SAC [A]
11.0032	All Treated	OEX12	Plot of Duration of Study Treatment by Response (All Treated MM)	Report for population subgroup: All Treated MM. Y axis: dose cohort. Use best confirmed response. Please add the footnote regarding	SAC [A]

Study Population: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				treatment duration consistent with the one in OEX12.	

NOTES:
A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.6. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
2.0020	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate:	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				(sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0021	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (IMWG 2011) (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	SAC [A]
2.0180	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0181	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (IMWG 2011) (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.0110	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects without Prior Daratumumab treatment (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	SAC [A]
2.0111	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects without Prior Daratumumab treatment (IMWG 2011) (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE).	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0040	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects refractory to Both IMiDs and Proteasome Inhibitors (IMWG 2011) (Part 1)	Report for population subgroup: Part 1. Summarize by dose level; Do not include Total. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	SAC [A]
2.0041	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) for Subjects refractory to Both IMiDs and Proteasome Inhibitors (IMWG 2011) (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR). Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0060	All Evaluable Subjects MM	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (IMWG 2011) (All Evaluable Subjects MM)	Report for population subgroup: Part 2 MM. Summarize for 3.4 MM. Best Response: Stringent Complete Response (sCR), Complete response (CR), Very Good Partial Response (VGPR), Partial Response (PR), Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (sCR+CR+VGPR+PR). Clinical Benefit Rate: (sCR+CR+VGPR+PR+MR).	IA

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Include: Overall Response Rate and Clinical Benefit Rate (No p-value) in one table.	
2.0342	All Treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (RRMCL) (Part 2 NHL)	Report for population subgroup: Part 2 NHL. Summarize for 3.4 NHL. Best Response: Complete response (CR), Partial Response (PR). Minimal Response (MR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). Overall Response Rate: (CR+PR).	SAC
Time-to Event Endpoint					
2.0081	All Treated	TTE1a	Summary of Duration of Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.Only summarize for subjects with a confirmed PR or better.	SAC [A]
2.0201	All Treated	TTE1	Summary of Duration of Response for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0161	All Treated	TTE1	Summary of Duration of Response for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.0171	All Treated	TTE1	Summary of Duration of Response for Subjects Refractory to Both IMiDs and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0071	All Treated	TTE1	Summary of Progression-Free Survival (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0261	All Treated	TTE1	Summary of Progression-Free Survival for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0131	All Treated	TTE1	Summary of Progression-Free Survival for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0141	All Treated	TTE1	Summary of Progression-Free Survival for Subjects Refractory to Both IMiDs and Proteasome Inhibitors (Part 2 MM)	Summary of Progression-Free Survival for Subjects Refractory to Both IMiDs and Proteasome Inhibitors (Part 2 MM)	SAC [A]
2.0091	All Treated	TTE1a	Summary of Time to Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0101	All Treated	TTE1a	Summary of Time to Progression (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio	SAC [A]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				and Log-Rank P-Value.	
2.0311	All Treated	TTE1a	Summary of Time to Best Response (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Do not include Hazard Ratio and Log-Rank P-Value.	SAC [A]
2.0321	All Treated	TTE6a	Summary of Kaplan-Meier Estimates of Overall Survival at 9 Months (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Produced if all the patients (who were alive at the time of study completion) can be re-consented.	SAC [A]
2.0331	All Treated	TTE6a	Summary of Kaplan-Meier Estimates of Overall Survival at One Year (Part 2 MM)	Report for population subgroup: Part 2 MM. Summarize: only for 3.4 MM. Produced if all the patients (who were alive at the time of study completion) can be re-consented.	SAC [A]

NOTES:
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16.12.7. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
M-Protein and FLC					
12.0010	All Treated	RE8b	Percent Change at Maximum Reduction from Baseline in M-Protein (or FLC) Measurement (Part 1)	Report for population subgroup: Part 1. Include text for best confirmed response only. Remove subject ID. Include reference lines for 25%, 0, -25%, -50%, -90%, -100%.. Indicate lab test types by different symbols. Indicate dose groups by different colours of the vertical bars.	SAC [A]
12.0011	All Treated	RE8b	Percent Change at Maximum Reduction from Baseline in M-Protein (or FLC) Measurement (Part 2 MM)	Report for population subgroup: Part 2 MM. Include text for best confirmed response only. Remove subject ID. Include reference lines for 25%, 0, -25%, -50%, -90%, -100%. Indicate lab test types by different shades.	SAC [A]
12.0020	All Treated	EFF_F1	Correlation of Free Soluble BCMA at Pre-Dose (Cycle 1) and Maximum Percentage Change from Baseline in Serum M-Protein, Urine M-Protein or Serum FLC (Part 1)	Report for population subgroup: Part 1. Use best confirmed response. Colored by different dose groups. Use different symbols to indicate Serum M-protein, Urine M-protein, and Serum FLC. Do not include R square and fitted line.	SAC [A]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
12.0021	All Treated	EFF_F1	Correlation of Free Soluble BCMA at Pre-Dose (Cycle 1) and Maximum Percentage Change from Baseline in Serum M-Protein, Urine M-Protein or Serum FLC (Part 2 MM)	Report for population subgroup: Part 2 MM. Use best confirmed response. Do not include R square and fitted line.	SAC [A]
Time-to-Event Endpoint					
12.0041	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]
12.0161	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]
12.0081	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves for Subjects Refractory to Both IMiDs and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]
12.0071	All Treated	TTE10	Graph of Kaplan Meier Progression-Free Survival Curves for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]
12.0051	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response (Part 2 MM)	Report for population subgroup: Part 2 MM.and only for subjects with a confirmed PR or better.	SAC [A]
12.0171	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
12.0101	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]
12.0111	All Treated	TTE10	Graph of Kaplan Meier Curves of Duration of Response for Subjects Refractory to Both IMiDs and Proteasome Inhibitors (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]
Forest Plot					
12.0120	All Treated	EFF_F2	Forest Plot - Overall Response Rate (ORR) (Part 2 MM)		SAC [A]
Profile Plot of Responders					
12.0150	All Treated	EFF_F3	Profile Plot of Responders (Part 2 MM)	Report for population subgroup: Part 2 MM.	SAC [A]

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.8. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.0030	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0031	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0032	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0033	All Treated	OAE01	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0040	All Treated	AE3	Summary of All Adverse Events by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0041	All Treated	AE3	Summary of All Adverse Events by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0042	All Treated	AE3	Summary of All Adverse Events by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0043	All Treated	AE3	Summary of All Adverse Events by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0910	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0911	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0912	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0913	All Treated	OAE07	Summary of All Adverse Events by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0720	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0721	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0722	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0730	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects without Prior Daratumumab Treatment (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0731	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0732	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects without Prior Daratumumab Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0740	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0741	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0742	All Treated	OAE1	Summary of All Adverse Events by System Organ Class and Preferred Term and Maximum Grade for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0750	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0751	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0752	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects with Prior Daratumumab Treatment and Refractory to Both IMiDs and Proteasomes Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0760	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects without Prior Daratumumab Treatment (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0761	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects without Prior Daratumumab Treatment (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0762	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects without Prior Daratumumab Treatment (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0770	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0771	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0772	All Treated	AE3	Summary of All Adverse Events by Preferred Term for Subjects Refractory to Both IMiDs and Proteasomes Inhibitors (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0780	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0781	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0782	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0783	All Treated	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0790	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0791	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0792	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0793	All Treated	AE3	Summary of Common (>=5%) Grade 2-4 Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0060	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0061	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0062	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0063	All Treated	OAE01	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0690	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total).	SAC [A]
3.0691	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM).	SAC [A]
3.0692	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0693	All Treated	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0710	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0711	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0712	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0713	All Treated	AE3	Summary of Common (>=5%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0010	All Treated	AE13	Adverse Event Overview (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0011	All Treated	AE13	Adverse Event Overview (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0012	All Treated	AE13	Adverse Event Overview (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0013	All Treated	AE13	Adverse Event Overview (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0100	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0101	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0102	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0103	All Treated	AE1	Summary of Adverse Events of Maximum Grade 3 or Higher by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0170	DLT Evaluable	DL1	Summary of Dose-Limiting Toxicities during the Determinative Period (Part 1) (Day 1-21)	Report for: Part 1, (Summarize: by ascending dose level, Total). Section 3.3.3 of the protocol: An event will be	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				considered a DLT if its relationship to the investigational agent cannot be ruled out occurs within the DLT reporting period (first 21 days of treatment for schedule 1, and first 28 days for schedule 2)	
Serious and Other Significant Adverse Events					
3.0700	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0701	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0702	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0703	All Treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0080	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0081	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0082	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0083	All Treated	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0800	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0801	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0802	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0803	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0120	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0121	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0122	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0123	All Treated	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0130	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0131	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0132	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0133	All Treated	AE1	Summary of Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0140	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0141	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0142	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0143	All Treated	AE1	Summary of Adverse Events Leading to Dose Interruptions or Delays by System Organ Class and Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0630	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0631	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0632	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions,	Report for: All Treated MM,	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (All Treated MM)	(Summarize: Total).	
3.0633	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by System Organ Class (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0640	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0641	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0642	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0643	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLGT (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0650	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0651	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0652	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0653	All Treated	AE1	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by HLT (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0660	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0661	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0662	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0663	All Treated	AE3	Summary of Adverse Events Leading to Dose Reductions, Interruptions or Delays, Permanent Discontinuation of Study Treatment by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Adverse Events of Interest					
3.0430	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0431	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0432	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total	SAC [A]
3.0433	All Treated	OAE07	Summary of Corneal Events by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0520	All Treated	ESI1	Summary of Characteristics of Corneal Events (Part 1)	Report for: Part 1, (Summarize: by	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				ascending dose level, Total). Summary based on both all subjects and subjects with events.	
3.0521	All Treated	ESI1	Summary of Characteristics of Corneal Events (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0522	All Treated	ESI1	Summary of Characteristics of Corneal Events (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0523	All Treated	ESI1	Summary of Characteristics of Corneal Events (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Summary based on both all subjects and subjects with events.	SAC
3.0180	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0181	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0182	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				resolution: 1-21, 22-42, >42.	
3.0183	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Corneal Events (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC
3.0150	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0151	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0152	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0153	All Treated	AE3	Summary of Corneal Events Leading to Dose Reduction by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0160	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0161	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0162	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0163	All Treated	AE3	Summary of Corneal Events Leading to Dose Interruptions or Delays by Preferred Term (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0560	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0561	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and	Report for: Part 2 MM, (Summarize:	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Maximum Grade (Part 2 MM)	only for 3.4 MM)	
3.0562	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0563	All Treated	OAE07	Summary of Thrombocytopenia by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0530	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0531	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0532	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0533	All Treated	ESI1	Summary of Characteristics of Thrombocytopenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0190	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				include both 'thrombocytopenia' and 'platelet count decreased'	
3.0191	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should include both 'thrombocytopenia' and 'platelet count decreased'	SAC [A]
3.0192	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should include both 'thrombocytopenia' and 'platelet count decreased'	SAC [A]
3.0193	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Thrombocytopenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42. Thrombocytopenia should include both 'thrombocytopenia' and 'platelet count decreased'	SAC
3.0580	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0581	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0582	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0583	All Treated	OAE07	Summary of Neutropenia by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0590	All Treated	ESI1	Summary of Characteristics of Neutropenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0591	All Treated	ESI1	Summary of Characteristics of Neutropenia (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0592	All Treated	ESI1	Summary of Characteristics of Neutropenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0593	All Treated	ESI1	Summary of Characteristics of Neutropenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0860	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Neutropenia (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0861	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of	Report for: Part 2 MM, (Summarize:	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Neutropenia (Part 2 MM)	only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	
3.0862	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Neutropenia (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0863	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Neutropenia (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC
3.0550	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0551	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0552	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0553	All Treated	OAE07	Summary of Hematologic Toxicity by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: All Treated MM, (Summarize: Total).	SAC
3.0540	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0541	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				on both all subjects and subjects with events.	
3.0542	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0543	All Treated	ESI1	Summary of Characteristics of Hematologic Toxicity (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0870	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0871	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0872	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0873	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Hematologic Toxicity (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42,	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				>42.	
3.0110	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0111	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0112	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0113	All Treated	OAE07	Summary of Infusion-Related Reactions by Preferred Term and Maximum Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0600	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0601	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Summary based on both all subjects and subjects with events.	SAC [A]
3.0602	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Summary based on both all subjects and subjects with events.	SAC [A]
3.0603	All Treated	ESI1	Summary of Characteristics of Infusion-Related Reactions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Summary based on both all subjects and subjects with events.	SAC
3.0880	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of	Report for: Part 1, (Summarize: by	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Infusion-Related Reactions (Part 1)	ascending dose level, Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	
3.0881	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Infusion-Related Reactions (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0882	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Infusion-Related Reactions (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC [A]
3.0883	All Treated	ESI2b	Summary of Onset and Duration of the First Occurrence of Infusion-Related Reactions (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Time of onset: 1-21, 22-42, 43-63, >63. Duration till resolution: 1-21, 22-42, >42.	SAC
Laboratory: Chemistry					
3.0270	All Treated	LB1	Summary of Chemistry Changes from Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0271	All Treated	LB1	Summary of Chemistry Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0272	All Treated	LB1	Summary of Chemistry Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				baseline values.	
3.0273	All Treated	LB1	Summary of Chemistry Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0280	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0281	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0282	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0283	All Treated	OLB11B	Summary of Chemistry Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0290	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0291	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: by starting dose level and tumor type, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0292	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0293	All Treated	OLB9B	Summary of Chemistry Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC
3.0450	All Treated	OLB11B	Summary of LDH Laboratory Results (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				baseline'. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	
3.0451	All Treated	OLB11B	Summary of LDH Laboratory Results (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0452	All Treated	OLB11B	Summary of LDH Laboratory Results (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0453	All Treated	OLB11B	Summary of LDH Laboratory Results (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0470	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0471	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0472	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and < 5xULN, >=5xULN and < 10xULN, >=10xULN.	SAC [A]
3.0473	All Treated	OLB11B	Summary of Creatine Kinase Laboratory Results (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline. The categories for summary are: <1xULN, >=1xULN and < 2xULN, >=2xULN and <	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				5xULN, >=5xULN and < 10xULN, >=10xULN.	
Laboratory: Hematology					
3.0300	All Treated	LB1	Summary of Hematology Changes from Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0301	All Treated	LB1	Summary of Hematology Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0302	All Treated	LB1	Summary of Hematology Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0303	All Treated	LB1	Summary of Hematology Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0310	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0311	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0312	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0313	All Treated	OLB11B	Summary of Hematology Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Include only 'worst-case post-baseline'	
3.0320	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0321	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: by starting dose level and tumor type, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]
3.0322	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0323	All Treated	OLB9B	Summary of Hematology Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction. Include only 'worst-case post-baseline'	SAC
Laboratory: Urinalysis					
3.0360	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0361	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0362	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0363	All Treated	LB1	Summary of Urine Concentration Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
3.0680	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0681	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0682	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0683	All Treated	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC
Laboratory: Hepatobiliary (Liver)					
3.0200	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0201	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0202	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0203	All Treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0210	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0211	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0212	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0213	All Treated	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Coagulation					
3.0330	All Treated	LB1	Summary of Coagulation Changes from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0331	All Treated	LB1	Summary of Coagulation Changes from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0332	All Treated	LB1	Summary of Coagulation Changes from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0333	All Treated	LB1	Summary of Coagulation Changes from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0340	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0341	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include only 'worst-case post-baseline'	SAC [A]
3.0342	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0343	All Treated	OLB11B	Summary of Coagulation Changes from Baseline with Respect to the Normal Range (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL). Include only 'worst-case post-baseline'	SAC
3.0350	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Produce only for lab tests that are	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	
3.0351	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (Part 2 MM)	Report for: Part 2 MM, (Summarize: by starting dose level and tumor type, Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	SAC [A]
3.0352	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	SAC [A]
3.0353	All Treated	OLB9B	Summary of Coagulation Grade Changes from Baseline Grade (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Produce only for lab tests that are graded. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction.	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
3.0370	All Treated	EG1	Summary of ECG Findings (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0371	All Treated	EG1	Summary of ECG Findings (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0372	All Treated	EG1	Summary of ECG Findings (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0373	All Treated	EG1	Summary of ECG Findings (Part 2 NHL)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC
3.0390	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0391	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0392	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0393	All Treated	OECG1B	Summary of Worst-case Increases in Fridericia's QTc (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Include only 'worst-case post-baseline'	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0400	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0401	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0402	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0403	All Treated	OECG2B	Summary of Worst-case Amount of Increase from Baseline Value in Fridericia's QTc (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: Total). Include only 'worst-case post-baseline'	SAC
3.0380	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 1)	Report for: Part 1, (Summarize by ascending dose level, Total). Include baseline values.	SAC [A]
3.0381	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM). Include baseline values.	SAC [A]
3.0382	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (All Treated MM)	Report for: All Treated MM, (Summarize for Total). Include baseline values.	SAC [A]
3.0383	All Treated	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 2 NHL)	Report for: Part 2 NHL, (Summarize for Total). Include baseline values.	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Vital Signs					
3.0220	All Treated	VS1	Summary of Change from Baseline in Vital Signs (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Add Cycle, Visit. Include baseline values.	SAC [A]
3.0221	All Treated	VS1	Summary of Change from Baseline in Vital Signs (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Add Cycle, Visit. Include baseline values.	SAC [A]
3.0222	All Treated	VS1	Summary of Change from Baseline in Vital Signs (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Add Cycle, Visit. Include baseline values.	SAC [A]
3.0223	All Treated	VS1	Summary of Change from Baseline in Vital Signs (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Add Cycle, Visit. Include baseline values.	SAC
3.0230	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0231	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0232	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0233	All Treated	OVT1B	Summary of Changes in Heart Rate from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0240	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0241	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0242	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0243	All Treated	OVT2B	Summary of Increases in Systolic Blood Pressure from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0250	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0251	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0252	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0253	All Treated	OVT2B	Summary of Increases in Diastolic Blood Pressure from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
3.0260	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total). Include only 'worst-case post-baseline'	SAC [A]
3.0261	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM) Include only 'worst-case post-baseline'	SAC [A]
3.0262	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total). Include only 'worst-case post-baseline'	SAC [A]
3.0263	All Treated	OVT1B	Summary of Changes in Temperature from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL) Include only 'worst-case post-baseline'	SAC
ECOG Performance Status					
3.0410	All Treated	PS1A	Summary of ECOG Performance Status (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0411	All Treated	PS1A	Summary of ECOG Performance Status (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0412	All Treated	PS1A	Summary of ECOG Performance Status (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0413	All Treated	PS1A	Summary of ECOG Performance Status (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0420	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0421	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0422	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0423	All Treated	PS3A	Summary of Change in ECOG Performance Status from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Left Ventricular Ejection Fraction					
3.0480	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0481	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0482	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0483	All Treated	OLVEF1A	Summary of Left Ventricular Ejection Fraction Change from Baseline (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Ocular Exams					
3.0490	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0491	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0492	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0493	All Treated	SAFE_T 1	Summary of Subjects Experiencing Corneal Clinical Signs (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0500	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0501	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0502	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0503	All Treated	SAFE_T 2	Summary of Best Corrected Visual Acuity Test (BCVA) Scores (logMAR score) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Death					
3.0570	All Treated	DTH1a	Summary of Deaths (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0571	All Treated	DTH1a	Summary of Deaths (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0572	All Treated	DTH1a	Summary of Deaths (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.0573	All Treated	DTH1a	Summary of Deaths (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Constitutional B- Symptoms					
3.0813	All Treated	OCS1	Summary of Constitutional Symptoms over Time (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Organ Examination					
3.0823	All Treated	OOE1	Summary of Organ Examination over Time (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
Health Outcome					
3.0830	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0831	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0832	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0833	All Treated	SAFE_T 3	Summary of Symptom Impact and HRQoL Item Scores (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Anti-Drug Antibody					
3.0840	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0841	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0842	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0843	All Treated	SAFE_T 4	Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC
3.0850	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (Part 1)	Report for: Part 1, (Summarize: by ascending dose level, Total).	SAC [A]
3.0851	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (Part 2 MM)	Report for: Part 2 MM, (Summarize: only for 3.4 MM)	SAC [A]
3.0852	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (All Treated MM)	Report for: All Treated MM, (Summarize: Total).	SAC [A]
3.0853	All Treated	SAFE_T 5	Summary of Anti-GSK2857916 Antibodies (ADA) (Part 2 NHL)	Report for: Part 2 NHL, (Summarize: only for 3.4 NHL)	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.9. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory					
13.0130	All Treated	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part 1)	Report for sub-population: Part 1. Pool all subjects together.	SAC [A]
13.0131	All Treated	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
13.0133	All Treated	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
13.0120	All Treated	LIVER9	Scatter Plot of Maximum Bilirubin versus Maximum ALT - eDISH (Part 1)	Report for sub-population: Part 1. Pool all subjects together.	SAC [A]
13.0121	All Treated	LIVER9	Scatter Plot of Maximum Bilirubin versus Maximum ALT - eDISH (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
13.0122	All Treated	LIVER9	Scatter Plot of Maximum Bilirubin versus Maximum ALT - eDISH (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC [A]
13.0140	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum LDH - eDISH Plot (Part 1)	Report for sub-population: Part 1. Pool all subjects together. Bold reference lines are not needed. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]
13.0141	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum LDH - eDISH Plot (Part 2 MM)	Report for sub-population: Part 2 MM. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
13.0142	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum LDH - eDISH Plot (Part 2 NHL)	Report for sub-population: Part 2 NHL. Do not include Hy's Quadrant and Temple's Corollary.	SAC
13.0150	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum Creatinine Kinase - eDISH Plot (Part 1)	Report for sub-population: Part 1. Pool all subjects together. Bold reference lines are not needed. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]
13.0151	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum Creatinine Kinase - eDISH Plot (Part 2 MM)	Report for sub-population: Part 2 MM. Do not include Hy's Quadrant and Temple's Corollary.	SAC [A]
13.0152	All Treated	LIVER9	Scatter Plot of Maximum AST vs Maximum Creatinine Kinase - eDISH Plot (Part 2 NHL)	Report for sub-population: Part 2 NHL. Do not include Hy's Quadrant and Temple's Corollary.	SAC
Adverse Events					
13.0160	All Treated	SAFE_F1	Proportions of Subjects with Infusion-related Reactions (Part 1)	Report for sub-population: Part 1. Pool all subjects together.	SAC [A]
13.0161	All Treated	SAFE_F1	Proportions of Subjects with Infusion-related Reactions (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
ECG					
13.0200	All Treated	OECG4	Fridericia's QTc Shifts from Baseline to Worst-case Post Baseline (Part 1)	Report for sub-population: Part 1. Pool all subjects together. If machine read QTcF is missing, use the manual read QTcF and add footnote that Machine and Manual calculate values are	SAC [A]

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				collapsed together.	
13.0201	All Treated	OECG4	Fridericia's QTc Shifts from Baseline to Worst-case Post Baseline (Part 2 MM)	Report for sub-population: Part 2 MM. If machine read QTcF is missing, use the manual read QTcF, and add footnote that Machine and Manual calculate values are collapsed together	SAC [A]
13.0202	All Treated	OECG4	Fridericia's QTc Shifts from Baseline to Worst-case Post Baseline (Part 2 NHL)	Report for sub-population: Part 2 NHL. If machine read QTcF is missing, use the manual read QTcF, and add footnote that Machine and Manual calculate values are collapsed together	SAC
Patient Profile Plot					
13.0190	All Treated	SAFE_F2	Profile Plot for Patients with No Corneal Event or Grade 1 Corneal Event (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]
13.0191	All Treated	SAFE_F2	Profile Plot for Patients with Grade 2 or Higher Corneal Events (Part 2 MM)	Report for sub-population: Part 2 MM.	SAC [A]

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.10. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Concentration					
4.0010	PK	PK01	Summary of Plasma GSK2857916 (ADC) PK Concentration-Time Data (Part 1)	By dose level	SAC [A]
4.0011	PK	PK01	Summary of Plasma GSK2857916 (ADC) PK Concentration-Time Data (Part 2 MM)		SAC [A]
4.0013	PK	PK01	Summary of Plasma GSK2857916 (ADC) PK Concentration-Time Data (Part 2 NHL)		SAC
4.0020	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) PK Concentration-Time Data (Part 1)	By dose level	SAC [A]
4.0021	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) PK Concentration-Time Data (Part 2 MM)		SAC [A]
4.0023	PK	PK01	Summary of Plasma GSK2857916 (Total Antibody) PK Concentration-Time Data (Part 2 NHL)		SAC
4.0030	PK	PK01	Summary of Plasma GSK2857916 (Unbound Antibody) PK Concentration-Time Data (Part 1)	By dose level	SAC [A]
4.0031	PK	PK01	Summary of Plasma GSK2857916 (Unbound Antibody) PK Concentration-Time Data (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
4.0033	PK	PK01	Summary of Plasma GSK2857916 (Unbound Antibody) PK Concentration-Time Data (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
4.0040	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data (Part 1)	By dose level	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0041	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data (Part 2 MM)		SAC [A]
4.0043	PK	PK01	Summary of Plasma cys-mcMMAF PK Concentration-Time Data (Part 2 NHL)		SAC
PK Parameter					
4.0050	PK	PK06	Summary of Derived GSK2857916 (ADC) PK Parameters (Part 1)	By dose level PK06 with both transformed and untransformed values. Also include Cmax and Ctau derived for ratio analyses.	SAC [A]
4.0051	PK	PK06	Summary of Derived GSK2857916 (ADC) PK Parameters (Part 2 MM)	PK06 with both transformed and untransformed values. Cmax and Ctau	SAC [A]
4.0053	PK	PK06	Summary of Derived GSK2857916 (ADC) PK Parameters (Part 2 NHL)	PK06 with both transformed and untransformed values. Cmax and Ctau	SAC
4.0060	PK	PK06	Summary of Derived GSK2857916 (Total Antibody) PK Parameters (Part 1)	By dose level PK06 with both transformed and untransformed values. Also include Cmax and Ctau derived for ratio analyses.	SAC [A]
4.0061	PK	PK06	Summary of Derived GSK2857916 (Total Antibody) PK Parameters (Part 2 MM)	PK06 with both transformed and untransformed values. Cmax and Ctau	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0063	PK	PK06	Summary of Derived GSK2857916 (Total Antibody) PK Parameters (Part 2 NHL)	PK06 with both transformed and untransformed values. Cmax and Ctau	SAC
4.0070	PK	PK06	Summary of Derived GSK2857916 (Unbound Antibody) PK Parameters (Part 1)	By dose level PK06 with both transformed and untransformed values. Also include Cmax and Ctau derived for ratio analyses.	SAC [A]
4.0071	PK	PK06	Summary of Derived GSK2857916 (Unbound Antibody) PK Parameters (Part 2 MM)	PK06 with both transformed and untransformed values. Cmax and Ctau. If data was not collected, present "No data to report"	SAC [A]
4.0073	PK	PK06	Summary of Derived GSK2857916 (Unbound Antibody) PK Parameters (Part 2 NHL)	PK06 with both transformed and untransformed values. Cmax and Ctau. If data was not collected, present "No data to report"	SAC
4.0080	PK	PK06	Summary of Derived cys-mcMMAF PK Parameter (Part 1)	By dose level PK06 with both transformed and untransformed values. Also include Cmax and Ctau derived for ratio analyses.	SAC [A]
4.0081	PK	PK06	Summary of Derived cys-mcMMAF PK Parameter (Part 2 MM)	PK06 with both transformed and untransformed values. Cmax and Ctau	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0083	PK	PK06	Summary of Derived cys-mcMMAF PK Parameter (Part 2 NHL)	PK06 with both transformed and untransformed values. Cmax and Ctau	SAC
4.0090	PK	PK13	Listing of Derived GSK2857916 (ADC) PK Parameters (Untransformed) (MM)		SAC [A]
4.0091	PK	PK13	Listing of Derived GSK2857916 (ADC) PK Parameters (Untransformed) (NHL)		SAC
4.0100	PK	PK13	Listing of Derived GSK2857916 (Total Antibody) PK Parameters (Untransformed) (MM)		SAC [A]
4.0101	PK	PK13	Listing of Derived GSK2857916 (Total Antibody) PK Parameters (Untransformed) (NHL)		SAC
4.0110	PK	PK13	Listing of Derived GSK2857916 (Unbound Antibody) PK Parameters (Untransformed) (MM)		SAC [A]
4.0111	PK	PK13	Listing of Derived GSK2857916 (Unbound Antibody) PK Parameters (Untransformed) (NHL)		SAC
4.0120	PK	PK13	Listing of Derived cys-mcMMAF PK Parameters (Untransformed) (MM)		SAC [A]
4.0121	PK	PK13	Listing of Derived cys-mcMMAF PK Parameters (Untransformed) (NHL)		SAC
4.0130	PK	PK03	Summary of cys-mcMMAF Pharmacokinetic Urine Excretin Data (Part 1)		SAC [A]
4.0140	PK	PK11	Listing of cys-mcMMAF Urine Excretion Data (Part 1)	replace Amount Excreted and Excretion Rate with Ae(0-24) and Fe	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Dose Proportionality Analysis					
4.0150	PK	PK_T1	Summary of Results of Dose Proportionality Analysis for GSK2857916 (ADC), GSK2857916 (Total Antibody), GSL2857916 (Unbound Antibody), and cys-mcMMAF PK Parameters Using Power Model (Part 1)	Example: PPD PPD AUC(0-inf), AUC(0-t), AUC(0- τ), Cmax, and Ctrough	SAC [A]
Accumulation Ratio					
4.0160	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 1)	By dose level	SAC [A]
4.0161	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 MM)		SAC [A]
4.0163	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 NHL)		SAC
4.0170	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 1)	By dose	SAC [A]
4.0171	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 MM)		SAC [A]
4.0173	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 NHL)		SAC

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0180	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 1)	By dose	SAC [A]
4.0181	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 MM)	If data was not collected, present "No data to report"	SAC [A]
4.0183	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 NHL)	If data was not collected, present "No data to report"	SAC
4.0190	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 1)	By dose level	SAC [A]
4.0191	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 MM)		SAC [A]
4.0193	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF PK Parameter Cmax on Day 1 of Cycle 2, 3, 5 verses Cmax on Day 1 of Cycle 1 (Part 2 NHL)		SAC
4.0200	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 1)	By dose level	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0201	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 MM)		SAC [A]
4.0203	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (ADC) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 NHL)		SAC
4.0210	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 1)	By dose	SAC [A]
4.0211	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 MM)		SAC [A]
4.0213	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Total Antibody) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 NHL)		SAC
4.0220	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 1)	By dose	SAC [A]
4.0221	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.0223	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for GSK2857916 (Unbound Antibody) PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 NHL)	If data was not collected, present "No data to report"	SAC
4.0230	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 1)	By dose	SAC [A]
4.0231	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 MM)		SAC [A]
4.0233	PK	PK_T2	Summary of Results of Accumulation Ratio Assessment for cys-mcMMAF PK Parameter Ctrough on Day 1 of Cycle 2, 3, 5 verses Ctrough on Day 1 of Cycle 1 (Part 2 NHL)		SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.11. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Concentration					
14.0010	PK	PK16	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0011	PK	PK16	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0013	PK	PK16	Individual Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0020	PK	PK16	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0021	PK	PK16	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0023	PK	PK16	Individual Plasma GSK2857916 (Total Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0030	PK	PK16	Individual Plasma GSK2857916 (Unbound Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0031	PK	PK16	Individual Plasma GSK2857916 (Unbound Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
14.0033	PK	PK16	Individual Plasma GSK2857916 (Unbound Antibody) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
14.0040	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.0041	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0043	PK	PK16	Individual Plasma cys-mcMMAF Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0050	PK	PK17	Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0051	PK	PK17	Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0053	PK	PK17	Mean Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0060	PK	PK17	Mean Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0061	PK	PK17	Mean Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0063	PK	PK17	Mean Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part NHL)		SAC
14.0070	PK	PK17	Mean Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0071	PK	PK17	Mean Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
14.0073	PK	PK17	Mean Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
14.0080	PK	PK17	Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.0081	PK	PK17	Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0083	PK	PK17	Mean Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0090	PK	PK18	Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0091	PK	PK18	Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0093	PK	PK18	Median Plasma GSK2857916 (ADC) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0100	PK	PK18	Median Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0101	PK	PK18	Median Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0103	PK	PK18	Median Plasma GSK2857916 (Total Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
14.0110	PK	PK18	Median Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]
14.0111	PK	PK18	Median Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)	If data was not collected, present “No data to report”	SAC [A]
14.0113	PK	PK18	Median Plasma GSK2857916 (Unbound Anti-body) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)	If data was not collected, present “No data to report”	SAC
14.0120	PK	PK18	Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 1)		SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.0121	PK	PK18	Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0123	PK	PK18	Median Plasma GSK2857916 (cys-mcMMAF) Concentration-Time Plots (Linear and Semi-Log) (Part 2 NHL)		SAC
Dose Proportionality					
14.0130	PK	LIVER14	Scatter Plot of GSK2857916 (ADC), GSK2857916 (Total Antibody), GSK2857916 (Unbound Antibody), and cys-mcMMAF PK Parameters by Cycle 1 Dose (Part 1)	using log transformed value. for AUC(0-tau), Cmax, PK Parameter value as y-axis and Cycle 1 dose as x-axis; label x-axis with dose value. Use the format of mock up LIVER14, no reference line is needed.	SAC [A]
Accumulation Ratio					
14.0140	PK	PK_F1	Plot of Mean Accumulation Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 1)	See example in page 7 of PPD By dose level PRE: Ctau EOI: Cmax Add a reference line at 1 Plot Ro for Ctau and Cmax on	SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				different plots. Use “Ratio to C1 (EOI)” as y-axis label for Cmax; Use “Ratio to C1 (PRE)” as y-axis label for Ctau; Plot analytes: ADC, total antibody, unbound antibody, and cys-mcMMAF on the same plot.	
14.0141	PK	PK_F1	Plot of Mean Accumulation Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 2 MM)	Add a reference line at 1	SAC [A]
14.0142	PK	PK_F1	Plot of Mean Accumulation Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 2 NHL)	Add a reference line at 1	SAC
Analyte Ratio at Each Cycle 1					
14.0180	PK	PK_F1	Plot of Mean Analyte Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 1)	See example in Page 6 of PPD  By dose PRE: Ctau EOI: Cmax Plot Ra for Ctau and Cmax on the same plot. Use “Analyte Ratio to cys-mcMMAF” as y-axis label	SAC [A]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.0181	PK	PK_F1	Plot of Mean Analyte Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 2 MM)		SAC [A]
14.0182	PK	PK_F1	Plot of Mean Analyte Ratios for GSK2857916 Analytes (Linear and Semi-Log) (Part 2 NHL)		SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.12. Pharmacokinetic / Pharmacodynamic (and / or Biomarker) Figures

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
16.0010	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (ADC) (MM)		SAC [A]
16.0011	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (ADC) (NHL)		SAC
16.0020	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Total Antibody) (MM)		SAC [A]
16.0021	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Total Antibody) (NHL)		SAC
16.0030	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Unbound Antibody) (MM)		SAC [A]
16.0031	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for GSK2857916 (Unbound Antibody) (NHL)	If data was not collected, present "No data to report"	SAC
16.0040	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for cys-mcMMAF (MM)		SAC [A]
16.0041	PK/PD	PK_F2	Plot of Fridericia's QTc Change from Baseline versus PK Concentration for cys-mcMMAF (NHL)		SAC

NOTES:
A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.13. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.0010	All Treated	ES2	Listing of Reasons for Study Withdrawal (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0011	All Treated	ES2	Listing of Reasons for Study Withdrawal (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0020	All Treated	CP_RA1p	Listing of Planned and Actual Treatments (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0021	All Treated	CP_RA1p	Listing of Planned and Actual Treatments (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0030	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0031	All Treated	SD2	Listing of Reasons for Study Treatment Discontinuation (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0750	Screened	ES7	Listing of Reasons for Screen Failure (MM)	Report for multiple myeloma subjects screened	SAC [A]
1.0751	Screened	ES7	Listing of Reasons for Screen Failure (NHL)	Report for lymphoma subjects screened	SAC
Protocol Deviations					
1.0040	All Treated	DV2	Listing of Important Protocol Deviations (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0041	All Treated	DV2	Listing of Important Protocol Deviations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0050	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0051	All Treated	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Populations Analysed					
1.0060	All Treated	SA3a	Listing of Subjects Excluded from Any Population (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0061	All Treated	SA3a	Listing of Subjects Excluded from Any Population (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Demographic and Baseline Characteristics					
1.0070	All Treated	DM2	Listing of Demographic Characteristics (All Treated MM)	Report for sub-population: All Treated MM. Add BMI (kg/m2).	SAC [A]
1.0071	All Treated	DM2	Listing of Demographic Characteristics (Part 2 NHL)	Report for sub-population: Part 2 NHL. Add BMI (kg/m2).	SAC
1.0080	All Treated	DM9	Listing of Race (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0081	All Treated	DM9	Listing of Race (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Prior and Concomitant Medications					
1.0620	All Treated	OCM1A	Listing of Concomitant Medications (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0621	All Treated	OCM1A	Listing of Concomitant Medications (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure and Treatment Compliance					
1.0090	All Treated	OEX8A	Listing of Exposure Data (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0091	All Treated	OEX8A	Listing of Exposure Data (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0100	All Treated	ODMOD10A	Listing of Dose Reductions (All Treated MM)	Report for sub-population: All Treated MM. Include Planned Time.	SAC [A]
1.0101	All Treated	ODMOD10A	Listing of Dose Reductions (Part 2 NHL)	Report for sub-population: All Treated MM. Include Planned Time.	SAC
1.0110	All Treated	ODMOD12A	Listing of Dose Delays (All Treated MM)	Report for sub-population: All Treated MM. Include Planned Time. IDSL standard does not report demographic info. PPD to check with PPD PPD regarding planned time and cycle day. If it is too much programming work to change now, we can keep it as it is.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0111	All Treated	ODMOD12A	Listing of Dose Delays (Part 2 NHL)	Report for sub-population: All Treated MM. Include Planned Time. IDSL standard does not report demographic info. PPD to check with PPD PPD regarding planned time and cycle day. If it is too much programming work to change now, we can keep it as it is.	SAC
1.0120	All Treated	ODMOD15A	Listing of Dose Escalations (All Treated MM)	Report for sub-population: All Treated MM. Include Age(y)/Sex/Race, Cycle, Visit. For C2MD, list the dose escalations where a dose escalation is indicated in the data – from the site.	SAC [A]
1.0121	All Treated	ODMOD15A	Listing of Dose Escalations (Part 2 NHL)	Report for sub-population: All Treated MM. Include Age(y)/Sex/Race, Cycle, Visit. For C2MD, list the dose escalations where a dose escalation is indicated in the data – from the site.	SAC
1.0490	All Treated	ODMOD14A	Listing of Incomplete Infusions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0491	All Treated	ODMOD14A	Listing of Incomplete Infusions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0500	All Treated	ODMOD17A	Listing of Infusion Interruptions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0501	All Treated	ODMOD17A	Listing of Infusion Interruptions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Adverse Events					
1.0140	All Treated	OAE04	Listing of All Adverse Events (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0141	All Treated	OAE04	Listing of All Adverse Events (Part 2 NHL)	Report for population subgroup: Part 2 NHL. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0150	All Treated	OAE03	Listing of Subject Numbers for Individual Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0151	All Treated	OAE03	Listing of Subject Numbers for Individual Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0160	All Treated	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0161	All Treated	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
1.0180	All Treated	OAE04	Listing of Fatal Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC [A]
1.0181	All Treated	OAE04	Listing of Fatal Serious Adverse Events (Part 2 NHL)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC
1.0190	All Treated	OAE04	Listing of Non-Fatal Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC [A]
1.0191	All Treated	OAE04	Listing of Non-Fatal Serious Adverse Events (Part 2 NHL)	Report for sub-population: All Treated MM. Include column to indicate relationship to study treatment.	SAC
1.0460	All Treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0461	All Treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0470	All Treated	OAE04	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0471	All Treated	OAE04	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0200	All Treated	OAE04	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0201	All Treated	OAE04	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0210	All Treated	OAE04	Listing of Dose-Limiting Adverse Events (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0220	DLT Evaluable	DL3	Listing of Dose-Limiting Toxicities during the Determinative Period (Day 1-21) (Part 1)	Report for population subgroup: Part 1	SAC [A]
1.0240	All Treated	OAE04	Listing of Adverse Events Leading to Dose Reduction (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0241	All Treated	OAE04	Listing of Adverse Events Leading to Dose Reduction (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0250	All Treated	OAE04	Listing of Adverse Events Leading to Dose Interruptions or Delays (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0251	All Treated	OAE04	Listing of Adverse Events Leading to Dose Interruptions or Delays (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0510	All Treated	OAE04	Listing of Adverse Events Leading to Incomplete Infusions (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0511	All Treated	OAE04	Listing of Adverse Events Leading to Incomplete Infusions (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0520	All Treated	OAE04	Listing of Adverse Events Leading to Infusion Interruptions (All Treated MM)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC [A]
1.0521	All Treated	OAE04	Listing of Adverse Events Leading to Infusion Interruptions (Part 2 NHL)	Report for population subgroup: All Treated MM. Remove onset cycle and cycle day from all AE related listings.	SAC
1.0270	All Treated	OAE04	Listing of Corneal Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0271	All Treated	OAE04	Listing of Corneal Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0530	All Treated	OAE04	Listing of Thrombocytopenia (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0531	All Treated	OAE04	Listing of Thrombocytopenia (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0540	All Treated	OAE04	Listing of Hematologic Toxicity (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0541	All Treated	OAE04	Listing of Hematologic Toxicity (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0550	All Treated	OAE04	Listing of Neutropenia (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0551	All Treated	OAE04	Listing of Neutropenia (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0260	All Treated	OAE04	Listing of Infusion Related Reactions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0261	All Treated	OAE04	Listing of Infusion Related Reactions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Hepatobiliary (Liver)					
1.0410	All Treated	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0411	All Treated	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0420	All Treated	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0421	All Treated	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
All Laboratory					
1.0330	All Treated	OLB7	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0331	All Treated	OLB7	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0320	All Treated	OLB13	Listing of Laboratory Data with Character Results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0321	All Treated	OLB13	Listing of Laboratory Data with Character Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
1.0350	All Treated	UR2A	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
1.0351	All Treated	UR2A	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
ECOG Performance Status					
1.0430	All Treated	PS5A	Listing of ECOG Performance Status (All Treated MM)	Report for sub-population: Part 2 NHL.	SAC [A]
1.0431	All Treated	PS5A	Listing of ECOG Performance Status (Part 2 NHL)	Report for sub-population: All Treated MM.	SAC
Response					
1.0560	All Treated	RE5	Listing of Investigator-Assessed Responses (All Treated MM)	Report for sub-population: All Treated MM. List investigator reported response by visit.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0561	All Treated	RE5	Listing of Investigator-Assessed Responses (Part 2 NHL)	Report for sub-population: Part 2 NHL.List investigator reported response by visit.	SAC
Time-to-Event Endpoints					
1.0440	All Treated	TTE9	Listing of Progression-Free Survival (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]
1.0570	All Treated	TTE9	Listing of Duration of Response (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0580	All Treated	TTE9	Listing of Overall Survival (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. If all patients can be reconsented.	SAC [A]
1.0590	All Treated	TTE9	Listing of Time to Progression (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]
1.0600	All Treated	TTE9	Listing of Time to Response (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0610	All Treated	TTE9	Listing of Time to Best Response (All Treated MM)	Report for sub-population: All Treated MM. Keep all optional columns. Use 'First Dose Date' in place of 'Randomization Date'. Example for endpoint description: Censor: Last adequate asmt, Event: Died, etc. Use months as unit.	SAC [A]
Death					
1.0390	All Treated	DTH3	Listing of Deaths (All Treated MM)	Report for sub-population: All Treated MM. include the time from last dose in the listing and Number of Cycles/Last Dose (optional columns in DTH3).	SAC [A]
1.0391	All Treated	DTH3	Listing of Deaths (Part 2 NHL)	Report for sub-population: Part 2 NHL. include the time from last dose in the listing and Number of Cycles/Last Dose (optional columns in DTH3).	SAC
PK					
1.0630	PK	PK07	Listing of Plasma GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data		SAC
1.0640	PK	PK07	Listing of Plasma GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data		SAC
1.0650	PK	PK07	Listing of Plasma GSK2857916 (Unbound Antibody) Pharmacokinetic Concentration-Time Data		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0660	PK	PK07	Listing of Plasma cys-mcMMAF Pharmacokinetic Concentration-Time Data (MM)		SAC [A]
1.0661	PK	PK07	Listing of Plasma cys-mcMMAF Pharmacokinetic Concentration-Time Data (NHL)		SAC
1.0670	PK	PK13	Listing of Plasma GSK2857916 (ADC) PK Parameters Data (Untransformed) (MM)		SAC [A]
1.0671	PK	PK13	Listing of Plasma GSK2857916 (ADC) PK Parameters Data (Untransformed) (NHL)		SAC
1.0680	PK	PK13	Listing of Plasma GSK2857916 (Total Antibody) PK Parameters Data (Untransformed) (MM)		SAC [A]
1.0681	PK	PK13	Listing of Plasma GSK2857916 (Total Antibody) PK Parameters Data (Untransformed) (NHL)		SAC
1.0690	PK	PK13	Listing of Plasma GSK2857916 (Unbound Antibody) PK Parameters Data (Untransformed) (MM)		SAC [A]
1.0691	PK	PK13	Listing of Plasma GSK2857916 (Unbound Antibody) PK Parameters Data (Untransformed) (NHL)		SAC
1.0700	PK	PK13	Listing of Plasma cys-mcMMAF PK Parameters Data (Untransformed) (MM)		SAC [A]
1.0701	PK	PK13	Listing of Plasma cys-mcMMAF PK Parameters Data (Untransformed) (NHL)		SAC
1.0710	PK	PK15	Listing of Derived GSK2857916 (ADC) PK Parameters Cmax and Ctough Accumulation Ratio (MM)		SAC [A]
1.0711	PK	PK15	Listing of Derived GSK2857916 (ADC) PK Parameters Cmax and Ctough Accumulation Ratio (NHL)		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.0720	PK	PK15	Listing of Derived GSK2857916 (Total Antibody) PK Parameters Cmax and Ctough Accumulation Ratio (MM)		SAC [A]
1.0721	PK	PK15	Listing of Derived GSK2857916 (Total Antibody) PK Parameters Cmax and Ctough Accumulation Ratio (NHL)		SAC
1.0730	PK	PK15	Listing of Derived GSK2857916 (Unbound Antibody) PK Parameters Cmax and Ctough Accumulation Ratio (MM)		SAC [A]
1.0731	PK	PK15	Listing of Derived GSK2857916 (Unbound Antibody) PK Parameters Cmax and Ctough Accumulation Ratio (NHL)		SAC
1.0740	PK	PK15	Listing of Derived cys-mcMMAF PK Parameters Cmax and Ctough Accumulation Ratio (MM)		SAC [A]
1.0741	PK	PK15	Listing of Derived cys-mcMMAF PK Parameters Cmax and Ctough Accumulation Ratio (NHL)		SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.12.14. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Medical Conditions					
30.0010	All Treated	MH2	Listing of Past Cancer-Related and Non-Cancer Related Medical Conditions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0011	All Treated	MH2	Listing of Past Cancer-Related and Non-Cancer Related Medical Conditions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0020	All Treated	MH2	Listing of Current Cancer-Related and Non-Cancer Related Medical Conditions (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0021	All Treated	MH2	Listing of Current Cancer-Related and Non-Cancer Related Medical Conditions (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Concomitant Medications					
30.0310	All Treated	OCM1A	Listing of Prophylactic Medication for Infusion-Related Reactions (All Treated MM)	Report for sub-population: All Treated MM. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	SAC [A]
30.0311	All Treated	OCM1A	Listing of Prophylactic Medication for Infusion-Related Reactions (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	SAC
30.0320	All Treated	OCM1A	Listing of Eye Medications (All Treated MM)	Report for sub-population: All Treated MM. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0321	All Treated	OCM1A	Listing of Eye Medications (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please replace the 2nd column as 'Drug Class/Drug Name' and the last column as 'Reason for Medication'	SAC
Blood and Blood Supportive Care Products					
30.0380	All Treated	BP4	Listing of Blood Products (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0381	All Treated	BP4	Listing of Blood Products (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0390	All Treated	BP5	Listing of Blood Supportive Care Products (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0391	All Treated	BP5	Listing of Blood Supportive Care Products (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Substance Use					
30.0370	All Treated	SU2	Listing of Substance Use (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0371	All Treated	SU2	Listing of Substance Use (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Anti-Cancer Therapy, Radiotherapy and Surgical Procedures					
30.0040	All Treated	AC6	Listing of Prior Anti-Cancer Therapy (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0041	All Treated	AC6	Listing of Prior Anti-Cancer Therapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0050	All Treated	AC7	Listing of Anti-Cancer Radiotherapy (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0051	All Treated	AC7	Listing of Anti-Cancer Radiotherapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0060	All Treated	OSP3	Listing of Prior/On Treatment Cancer and Non-Cancer Related Surgical Procedures (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0061	All Treated	OSP3	Listing of Prior/On Treatment Cancer and Non-Cancer Related Surgical Procedures (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0400	All Treated	FAC3	Listing of Follow-Up Anti-Cancer Therapy (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0401	All Treated	FAC3	Listing of Follow-Up Anti-Cancer Therapy (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Disease Characteristics					
30.0080	All Treated	DC4	Listing of Disease Characteristics at Screening (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0081	All Treated	DC4	Listing of Disease Characteristics at Screening (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0360	All Treated	DC3	Listing of Disease Characteristics at Initial Diagnosis (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0361	All Treated	DC3	Listing of Disease Characteristics at Initial Diagnosis (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0290	All Treated	OLB7	Listing of Genetic Characteristics (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0300	All Treated	SAFE_L1	Listing of Disease Characteristics, Prior Treatment, Dose Modification and Response to GSK2857916 (Part 2 MM)	Report for sub-population: Part 2 MM. Provide a line listing by	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				patient with subject identifier, ISS stage at screening, number of prior lines of therapy, refractory to last line of therapy (Y/N), prior use of daratumumab (Y/N), refractory to both IMID and PI (Y/N), Best confirmed response,	
Exposure					
30.0130	All Treated	OEX9	Summary Listing of Overall Exposure and Dose Modifications (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0131	All Treated	OEX9	Summary Listing of Overall Exposure and Dose Modifications (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Adverse Events					
30.0540	All Treated	OAE4	Listing of Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0541	All Treated	OAE4	Listing of Serious Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0550	All Treated	OAE04	Listing of Drug-Related Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0551	All Treated	OAE04	Listing of Drug-Related Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0560	All Treated	OAE4	Listing of Drug-Related Serious Adverse Events (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0561	All Treated	OAE4	Listing of Drug-Related Serious Adverse Events (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0450	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Corneal Events		SAC [A]
30.0460	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Thrombocytopenia		SAC [A]
30.0470	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Neutrupenia		SAC [A]
30.0480	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Hematologic Toxicity		SAC [A]
30.0490	All Treated	AE2	Listing of Relationship Between SOC and Verbatim Text for AEs Collapsed to Infusion related reactions		SAC [A]
Deaths					
30.0570	All Treated	DTH5	Listing of Subject Numbers for Specific Causes of Deaths (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0571	All Treated	DTH5	Listing of Subject Numbers for Specific Causes of Deaths (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Laboratory					
30.0530	All Treated	OLB7	Listing of Grade 3 and Grade 4 Laboratory Data (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0531	All Treated	OLB7	Listing of Grade 3 and Grade 4 Laboratory Data (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0580	All Treated	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0581	All Treated	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0160	All Treated	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0161	All Treated	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Constitutional Symptoms and Organ Examinations					
30.0510	All Treated	OCS3	Listing of Constitutional Symptoms (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0520	All Treated	OOE2	Listing of Organ Examinations (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Left Ventricular Ejection Fraction					
30.0500	All Treated	OLVEF2A	Listing of Left Ventricular Ejection Fraction Results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0501	All Treated	OLVEF2A	Listing of Left Ventricular Ejection Fraction Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
ECG					
30.0140	All Treated	OECG5A	Listing of Fridericia's QTc Values of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0141	All Treated	OECG5A	Listing of Fridericia's QTc Values of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
Vital Signs					
30.0440	All Treated	OVT7A	Listing of Vital Sign Values of Potential Clinical Importance (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0441	All Treated	OVT7A	Listing of Vital Sign Values of Potential Clinical Importance (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Ocular Exam					
30.0260	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0261	All Treated	SAFE_L2	Listing of Visual Acuity and Abnormal Corneal Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
30.0330	All Treated	SAFE_L2	Listing of Abnormal Conjunctival Exam Results (All Treated MM)	Report for sub-population: All Treated MM. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC [A]
30.0331	All Treated	SAFE_L2	Listing of Abnormal Conjunctival Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC
30.0340	All Treated	SAFE_L2	Listing of Abnormal Slit Lamp Anterior Chamber and Slit Lamp Lens Exam Results (All Treated MM)	Report for sub-population: All Treated MM. Please include screening results and any post-baseline abnormal results for	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	
30.0341	All Treated	SAFE_L2	Listing of Abnormal Slit Lamp Anterior Chamber and Slit Lamp Lens Exam Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Please include screening results and any post-baseline abnormal results for each patient. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC
30.0350	All Treated	SAFE_L2	Listing of Indirect Fundoscopic Exam and Intraocular Pressure Results (All Treated MM)	Report for sub-population: All Treated MM. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC [A]
30.0351	All Treated	SAFE_L2	Listing of Indirect Fundoscopic Exam and Intraocular Pressure Results (Part 2 NHL)	Report for sub-population: Part 2 NHL. Include: Centre ID/ Subj., Age(y)/ Sex/ Race, Reported Corneal Events (Y/N), Cycle/Visit, Time Since 1st Dose/ Time Since last Dose, Eye, Exam Test, Result	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Health Outcomes					
30.0590	All Treated	VS4	Listing of Symptom Impact and HRQoL Item Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List scores for Bone Pain Worst, Bone Pain Average, Fatigue	SAC [A]
30.0591	All Treated	VS4	Listing of Symptom Impact and HRQoL Item Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List scores for Bone Pain Worst, Bone Pain Average, Fatigue	SAC
30.0600	All Treated	VS4	Listing of NEI-VFQ-25 Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List overall composite score and 11 sub-scores.	SAC [A]
30.0601	All Treated	VS4	Listing of NEI-VFQ-25 Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List overall composite score and 11 sub-scores.	SAC
30.0610	All Treated	VS4	Listing of OSDI Scores (All Treated MM)	Report for sub-population: All Treated MM. Use the format of VS4, use collected visit dates. List total score and 3 sub-scores.	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0611	All Treated	VS4	Listing of OSDI Scores (Part 2 NHL)	Report for sub-population: Part 2 NHL. Use the format of VS4, use collected visit dates. List total score and 3 sub-scores.	SAC
Anti-Drug Antibody					
30.0620	All Treated	SAFE_L3	Listing of Anti-GSK2857916 antibody results (All Treated MM)	Report for sub-population: All Treated MM.	SAC [A]
30.0621	All Treated	SAFE_L3	Listing of Anti-GSK2857916 antibody results (Part 2 NHL)	Report for sub-population: Part 2 NHL.	SAC
PK					
30.0630	PK		SAS Output of Results of Dose Proportionality Analysis Using Power Model		SAC [A]
30.0640	PK		SAS Output of Results of Accumulation Ratio Assessment (Part 1)		SAC [A]
30.0641	PK		SAS Output of Results of Accumulation Ratio Assessment (Part 2 MM)		SAC [A]
30.0642	PK		SAS Output of Results of Accumulation Ratio Assessment (Part 2 NHL)		SAC
30.0650	PK		SAS Output of Results of Analyte Ratio Assessment at Cycle 1 (Part 1)		SAC [A]
30.0660	PK		SAS Output of Results of Analyte Ratio Assessment at Cycle 2 (Part 2 MM)		SAC [A]
30.0670	PK		SAS Output of Results of Analyte Ratio Assessment at Cycle 3 (Part 2 NHL)		SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0680	PK		SAS Output of Results of Analyte Ratio Assessment at Each Cycle (Part 1)		SAC [A]
30.0681	PK		SAS Output of Results of Analyte Ratio Assessment at Each Cycle (Part 2 MM)		SAC [A]
30.0682	PK		SAS Output of Results of Analyte Ratio Assessment at Each Cycle (Part 2 NHL)		SAC
PKPD					
30.0690	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (MM)	List QTc change from baseline concentration for each visit	SAC [A]
30.0691	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (ADC) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC
30.0700	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (MM)	List QTc change from baseline concentration for each visit	SAC [A]
30.0701	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Total Antibody) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC
30.0710	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Unbound Antibody) Pharmacokinetic Concentration-Time Data (MM)	List QTc change from baseline concentration for each visit	SAC [A]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.0711	PKPD		Listing of Fridericia's QTc Change from Baseline and GSK2857916 (Unbound Antibody) Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC
30.0720	PKPD		Listing of Fridericia's QTc Change from Baseline and cys-mcMMAF Pharmacokinetic Concentration-Time Data (MM)	List QTc change from baseline concentration for each visit	SAC [A]
30.0721	PKPD		Listing of Fridericia's QTc Change from Baseline and cys-mcMMAF Pharmacokinetic Concentration-Time Data (NHL)	List QTc change from baseline concentration for each visit	SAC

NOTES:

A. Indicates which displays will be generated for the reporting effort for multiple myeloma

16.13. Appendix 13: Example Mock Shells for Data Displays

Example: POP_T1
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Genetic Characteristics at Screening for Multiple Myeloma Subjects (Part 1)

Genetics	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
del13	5 (5%)	5 (5%)	10 (5%)
del17p13	5 (5%)	5 (5%)	10 (5%)
t(11:14)	5 (5%)	5 (5%)	10 (5%)
t(4:14)	5 (5%)	5 (5%)	10 (5%)
1q21	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
Missing	5 (5%)	5 (5%)	10 (5%)

PPD

Example: POP_T2
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx

Summary of Cytogenetics Risk at Screening (Part 1)

Genetics	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
High Risk [1]	5 (5%)	5 (5%)	10 (5%)
Other (non-high risk, not done, or missing)	5 (5%)	5 (5%)	10 (5%)

[1] A subject is considered as high risk if the subject has any of the following cytogenetics: t(4;14), del17p, t(14;16).

PPD

Example: POP_T3
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Prior Anti-Cancer Therapy by Drug Class of Agents for Multiple Myeloma Subjects (Part 1)

Drug Class	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
Steroids	5 (5%)	5 (5%)	10 (5%)
Immunomodulator (IMID)	5 (5%)	5 (5%)	10 (5%)
LENALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
POMALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
THALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
Proteasome Inhibitor (PI)	5 (5%)	5 (5%)	10 (5%)
BORTEZOMIB	5 (5%)	5 (5%)	10 (5%)
CARFILZOMIB	5 (5%)	5 (5%)	10 (5%)
IXAZOMIB	5 (5%)	5 (5%)	10 (5%)
Chemotherapy	5 (5%)	5 (5%)	10 (5%)
Stem Cell Transplant	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
HDAC Inhibitor	5 (5%)	5 (5%)	10 (5%)
Monoclonal Antibody	5 (5%)	5 (5%)	10 (5%)
CXCR4	5 (5%)	5 (5%)	10 (5%)
DARATUMUMAB	5 (5%)	5 (5%)	10 (5%)
ELOTUZUMAB	5 (5%)	5 (5%)	10 (5%)
SILTUXIMAB	5 (5%)	5 (5%)	10 (5%)
Engineered T Cell Therapy	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
Not Classified	5 (5%)	5 (5%)	10 (5%)

PPD

Example: POP_T4
Protocol: BMA117159 Page 1 of 1
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Multiple Myeloma Subjects Refractory to Prior Anti-Cancer Therapy by Drug Class of Agents (Part 1)

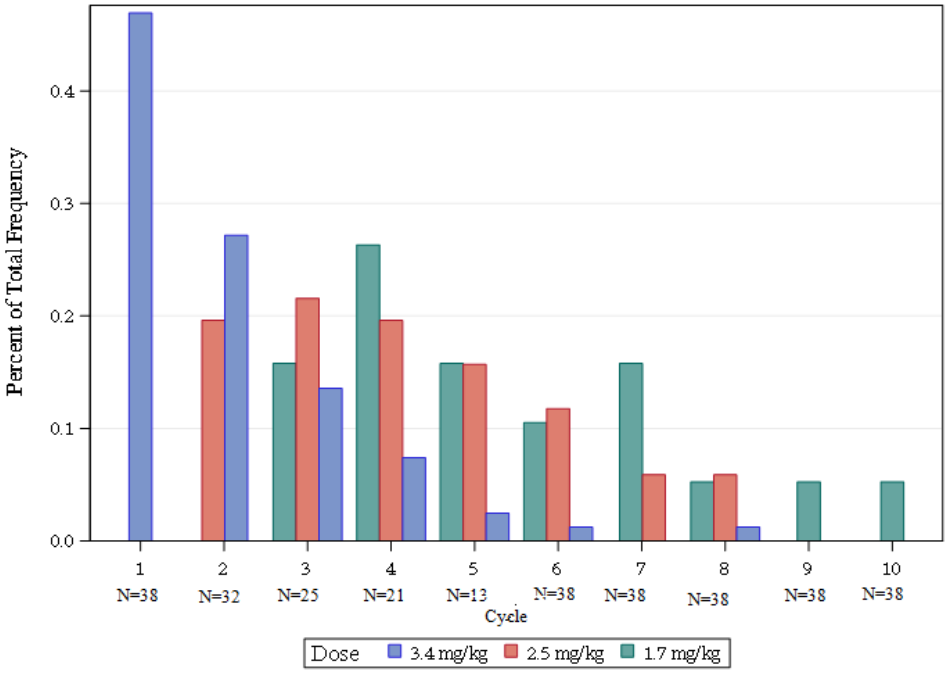
Drug Class	0.03 mg/kg (N=100)	0.06 mg/kg (N=100)	Total (N=200)
Immunomodulator	5 (5%)	5 (5%)	10 (5%)
LENALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
POMALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
THALIDOMIDE	5 (5%)	5 (5%)	10 (5%)
Steroids	5 (5%)	5 (5%)	10 (5%)
Proteasome Inhibitor	5 (5%)	5 (5%)	10 (5%)
BORTEZOMIB	5 (5%)	5 (5%)	10 (5%)
CARFILZOMIB	5 (5%)	5 (5%)	10 (5%)
IXAZOMIB	5 (5%)	5 (5%)	10 (5%)
Chemotherapy	5 (5%)	5 (5%)	10 (5%)
Stem Cell Transplant	5 (5%)	5 (5%)	10 (5%)
Other	5 (5%)	5 (5%)	10 (5%)
Monoclonal Antibody	5 (5%)	5 (5%)	10 (5%)
CXCR4	5 (5%)	5 (5%)	10 (5%)
DARATUMUMAB	5 (5%)	5 (5%)	10 (5%)
ELOTUZUMAB	5 (5%)	5 (5%)	10 (5%)
SILTUXIMAB	5 (5%)	5 (5%)	10 (5%)
HDAC Inhibitor	5 (5%)	5 (5%)	10 (5%)
Not Classified	5 (5%)	5 (5%)	10 (5%)
Immunomodulator and Proteasome Inhibitor	5 (5%)	5 (5%)	10 (5%)

This table is summarized per subject level

PPD

Example: POP_F2
Protocol: BMA117159
Population: Part 2 MM (Data as of: 30MAY2001)

Figure x.xxxx
Plot of Dose Reduction of GSK28557916 by Cycle (Part 2 MM)



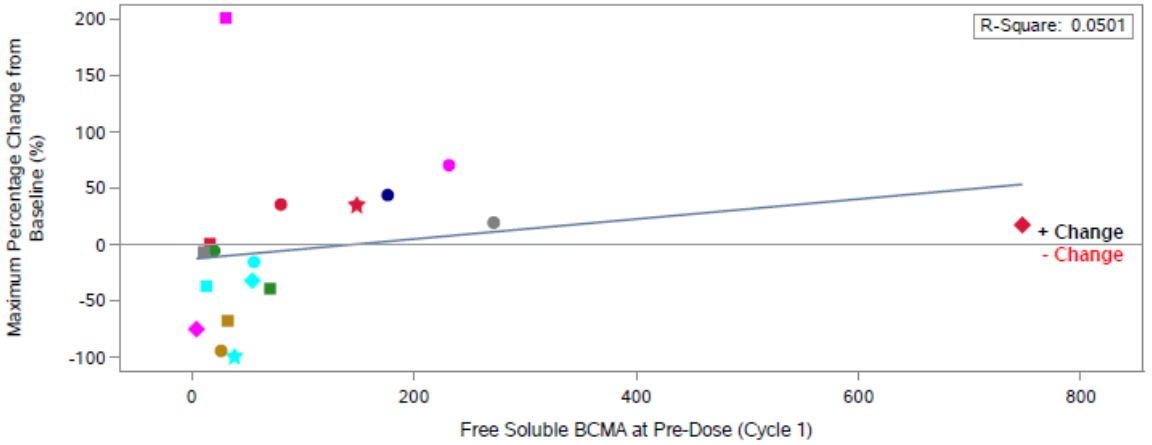
Doses 1.9 mg/kg and 1.7 mg/kg are combined and represented by 1.7 mg/kg.

PPD

Example: EFF_F1
Protocol: BMA117159
Population: Part 2 MM

(Data as of: 30MAY2001)

Figure 12.0020
Correlation of Free Soluble BCMA at Pre-Dose (Cycle 1) and
Maximum Percentage Change from Baseline
in Serum M-Protein, Urine M-Protein or Serum FLC



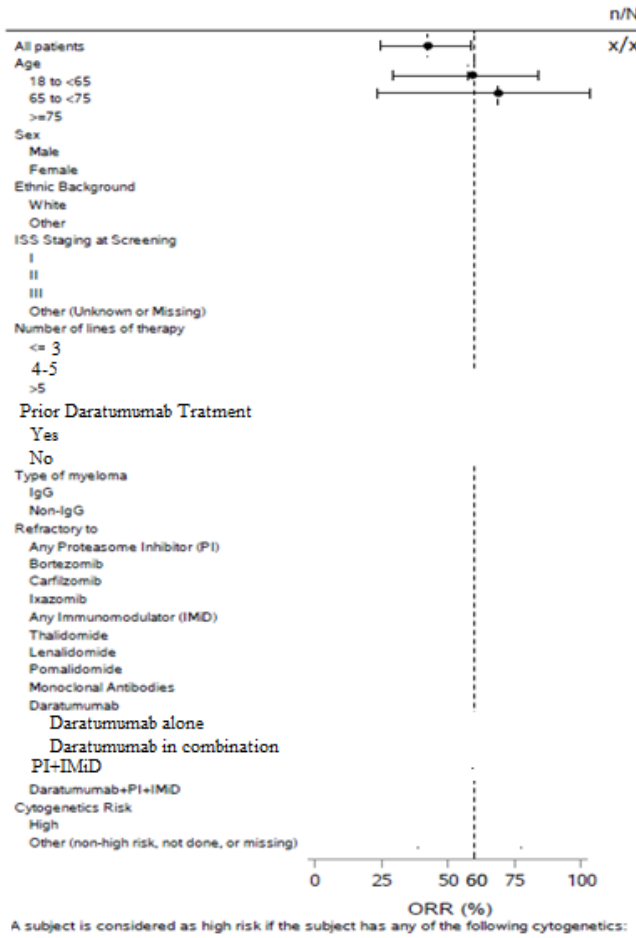
Serum M-protein depicted for subjects with serum M-Protein values;
Urine M-Protein depicted for subjects without serum M-Protein values.
Changes in affected FLC depicted in subjects with no available Serum M-protein values nor Urine M-Protein.

PPD

Example: EFF_F2
Protocol: BMA117159
Population: Part 2 MM

(Data as of: 30MAY2001)

Figure x.xxxx
Forest Plot - Overall Response Rate (ORR) (Part 2 MM)

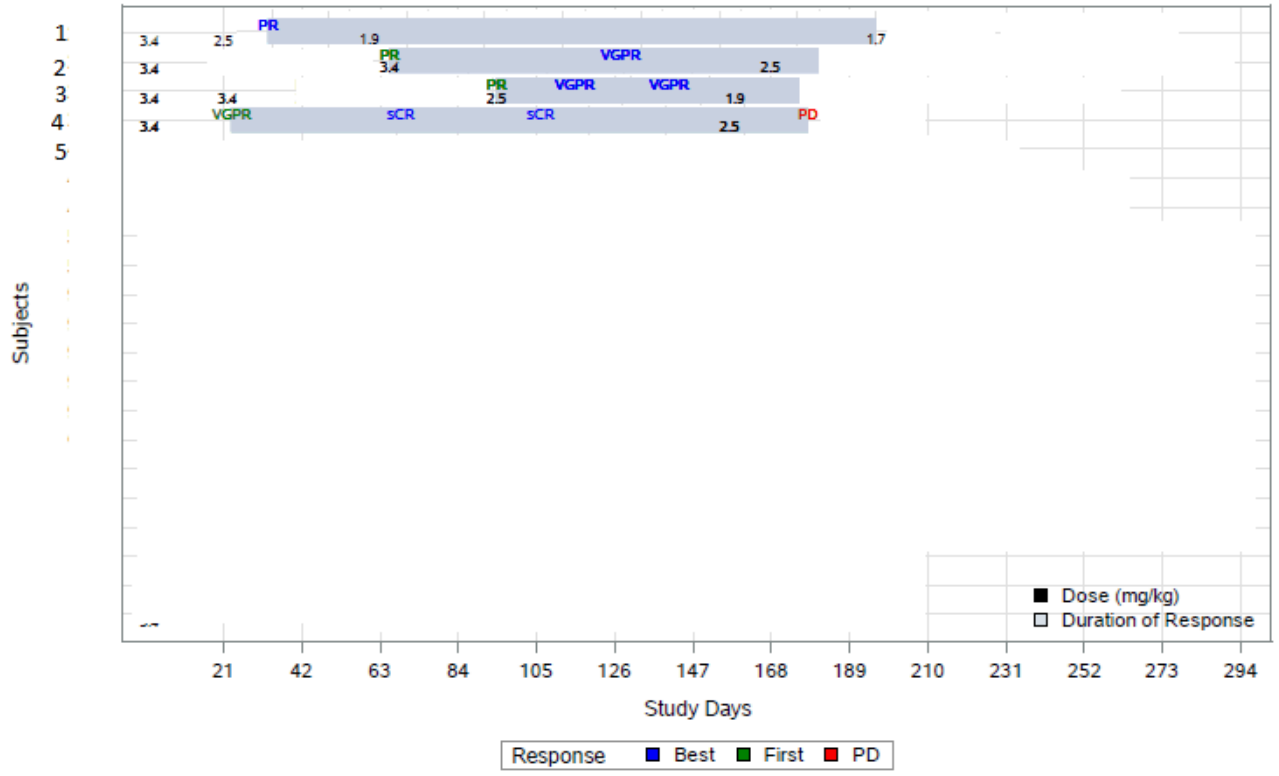


PPD

Example: EFF_F3
Protocol: BMA117159
Population: Part 2 MM

(Data as of: 30MAY2001)

Figure x.xxxx
Profile Plot of Responders (Part 2 MM)



sCR: Stringent Complete Response, CR: Complete Response, VGPR: Very Good Partial Response, PR: Partial Response,

PPD

Example: SAFE_T1
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Subjects Experiencing Corneal Clinical Signs (Part 1)

	0.03 mg/kg (N=10)	0.06 mg/kg (N=20)	Total (N=30)
Number of Subjects Experiencing Corneal Clinical Signs	5 (50%)	15 (75%)	20 (67%)
Corneal Epithelium Finding			
Abnormal, epithelial edema	5 (50%)	12 (60%)	17 (57%)
Abnormal, epithelial edema -subtle epithelial haze	3 (30%)	11 (55%)	14 (47%)
Abnormal, epithelial edema - diffuse microcystic changes	2 (20%)	8 (40%)	10 (33%)
Abnormal, epithelial edema - mild patchy microcystic changes	1 (30%)	9 (45%)	10 (33%)
……			
Abnormal, punctate keratopathy	4 (40%)	13 (65%)	17 (57%)
Abnormal, punctate keratopathy - mild	3 (30%)	11 (55%)	14 (47%)
Abnormal, punctate keratopathy - moderate	3 (30%)	10 (50%)	13 (43%)
Abnormal, punctate keratopathy - severe	2 (20%)	7 (35%)	9 (30%)
……			
Corneal Stroma Finding			
Abnormal, active	4 (40%)	13 (65%)	17 (57%)
Abnormal, active edema - trace	3 (30%)	11 (55%)	14 (47%)
Abnormal, active edema - 1+	3 (30%)	10 (50%)	13 (43%)
Abnormal, active edema - 2+	2 (20%)	7 (35%)	9 (30%)
Abnormal, active opacity - mild	1 (10%)	6 (30%)	7 (23%)
Abnormal, active opacity - moderate	1 (10%)	5 (25%)	6 (20%)
……			
Number of Subjects Experiencing Corneal Clinical Signs n	5	15	20
Also reported corneal toxicity AE	3 (60%)	9 (60%)	12 (60%)
Did not report corneal toxicity AE	2 (40%)	6 (40%)	8 (60%)

PPD

Example: SAFE_T2
Protocol: BMA117159 Page 1 of 1
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Best Corrected Visual Acuity Test Scores (logMAR score)(Part 1)

Timepoint	Eye	BCVA Score	0.03 mg/kg (N=xx)	0.06 mg/kg (N=xx)	Total (N=xx)
Baseline	Right	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
	Left	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
End of study treatment	Right	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
	Left	n	Xx	Xx	xxx
		Mean	x.xx	x.xx	x.xx
		SD	x.xxx	x.xxx	x.xxx
		Median	x.xx	x.xx	x.xx
		Min	x	x	x
		Max	x	x	x
Change from baseline to	Right	n	xx	xx	xx

end of study treatment		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
	Left	n	xx	xx	xx
		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
Maximum (worst) change from baseline	Right	n	xx	xx	xx
		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
	Left	N	xx	xx	xx
		No change/improved vision	xx (xx%)	xx (xx%)	xx (xx%)
		Possible worsened vision	xx (xx%)	xx (xx%)	xx (xx%)
		Definite worsened vision	xx (xx%)	xx (xx%)	xx (xx%)

Note: High scores are associated with worse vision, and low scores with better vision. No change/improved vision is defined as a change from baseline <0.12; a possible worsened vision is defined as a change from baseline >=0.12 to <0.3; a definite worsened vision is defined as a change from baseline >=0.3 logMAR score. For "End of study Treatment", summarize for subjects with ocular exam results at the end of study treatment; ocular assessment For "Change from baseline to end of study treatment", summarize for subjects with ocular exam results at baseline and the end of study treatment. For "Maximum (worst) change from baseline", summarize for subjects with ocular exam results at baseline and at least one post-baseline visit.

Subjects with "worse than 20/400" results will not be included in the summary.

PPD

Example: SAFE_T3
Protocol: BMA117159 Page 1 of 1
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Symptom Impact and HRQoL Item Scores Part 1)

Item Score=Bone Pain Worst
Treatment: 0.03 mg/kg (N=200)

Planned Time		n	Mean	SD	Median	Min.	Max.
Baseline	Score	xx	xx.x	xx.xx	xx	xx	xx
Cycle 1 Day 1 to Day 8 Average	Score	xx	xx.x	xx.xx	xx	xx	xx
	Change from Baseline	xx	xx.x	xx.xx	xx	xx	xx
Cycle 1 Day 15	Score	xx	xx.x	xx.xx	xx	xx	xx
	Change from baseline	xx	xx.x	xx.xx	xx	xx	xx

Note: This mock up will be used for both summary of item scores and change from baseline. For summary of change from baseline, include baseline scores. Include Bone Pain Worst, Bone Pain Average, Fatigue worst in one summary table. This note dose not need to be included in the final output. Will add the notes to programming notes

Example: SAFE_T4
Protocol: BMA117159 Page 1 of 1
Population: Part 1 (Data as of: 30MAY2001)

Table X.XXXX
Summary of Human Anti-GSK2857916 Antibodies (ADA) Over Time

Visit Category Results	Cohort 1 (x mg/kg) (N=X)
CYCLE 1 WEEK 1	
Screening ADA Result	
n	X
POSITIVE	X (X%)
NEGATIVE	X (X%)
Confirming ADA Result	
n	X
POSITIVE	X
NEGATIVE	X (X%)
Conclusive	
n	X
NEGATIVE,CONCLUSIVE	X (X%)

Note: Negative, Conclusive is a Negative result in ADA assay (either negative screening or negative confirming assay result) and GSK2857916 total antibody concentration <25 ug/mL in pharmacokinetic sample collected at same time or same day prior to dosing as the ADA sample.

PPD

Example: SAFE_T5
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

Table x.xxxx
Summary of Anti-GSK2857916 Antibodies (ADA)

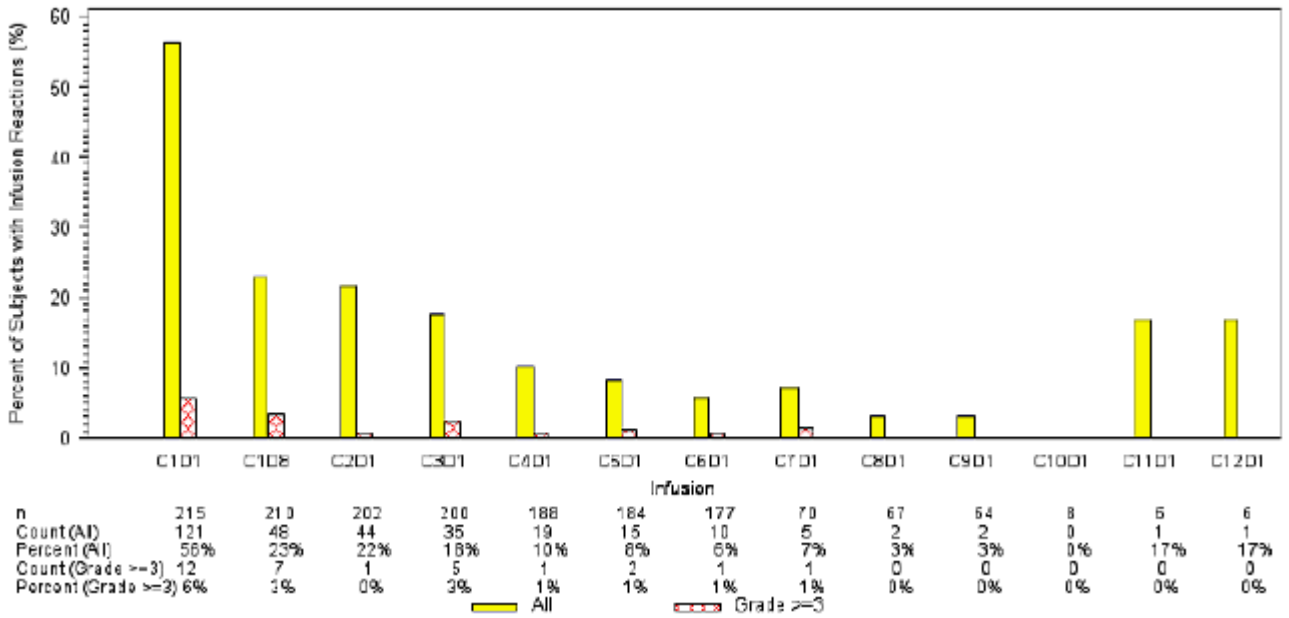
	X mg/kg (N=X)
Number of subjects with baseline ADA results	X (x%)
Number of subjects with negative baseline ADA results	X (X%)
Number of subjects with confirmed positive baseline ADA results	X (X%)
Number of subjects with post-baseline ADA results	X (X%)
Number of subjects with at least one confirmed positive post-baseline ADA result	X (X%)
Number of subjects with all negative post-baseline ADA results and at least one GSK2857916 total antibody concentration ≤ 25000 ng/mL	X (X%)
Number of subjects with all negative post-baseline ADA results and all GSK2857916 total antibody concentration >25000 ng/mL	X (X%)

Note a subject is considered to have a positive ADA result if they have a positive screening assay, a positive confirmation assay and a titer value.

PPD

Example: SAFE_F1
Protocol: BMA117159
Population: Part 1 (Data as of: 30MAY2001)

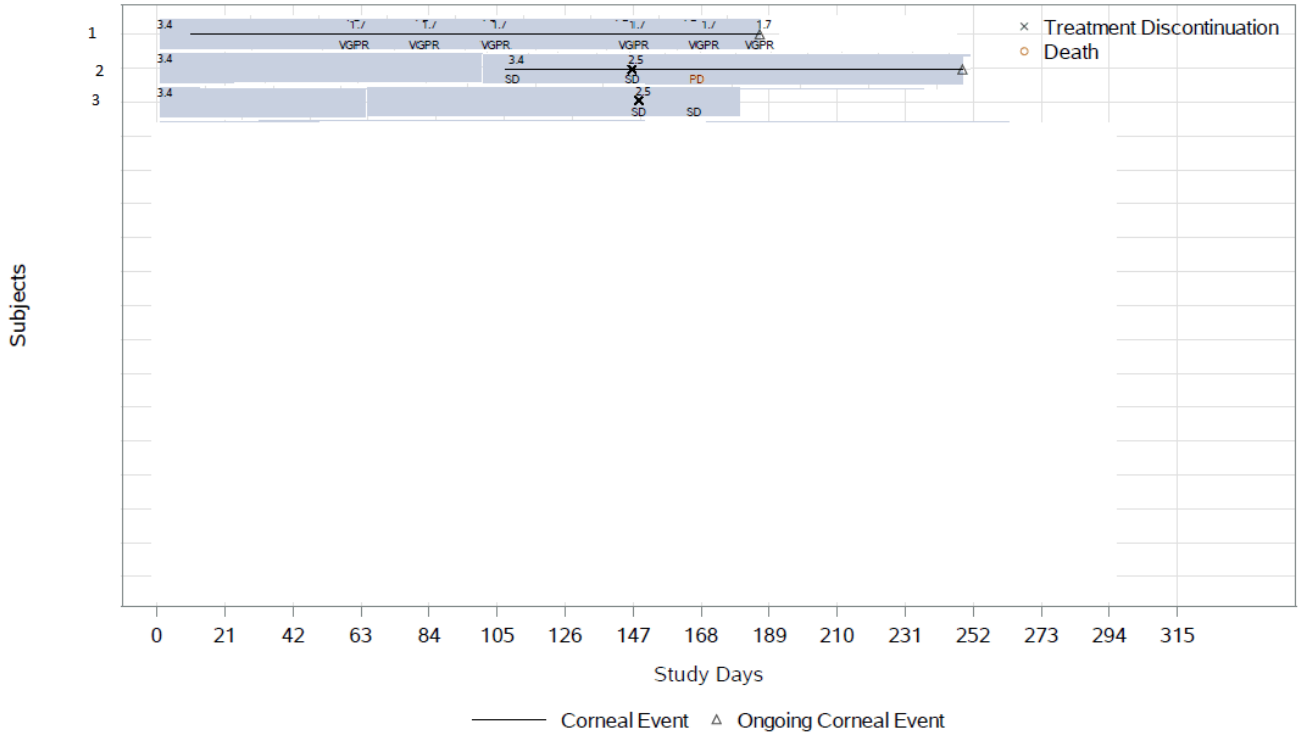
Figure x.xxxx
Proportions of Subjects with Infusion-related Reactions (Part 1)



PPD

Example: SAFE_F2
Protocol: BMA117159 Page 1 of 1
Population: All Treated MM (Data as of: 30MAY2001)

Figure x.xxxx
Profile plot for patients with No Corneal Event or Grade 1 Corneal Event (Part 2 MM)



a. sCR: Stringent Complete Response, CR: Complete Response, VGPR: Very Good Partial Response, PR: Partial Response, MR: Minimal Response, SD: Stable Disease, PD: Progressive Disease, NE: Not evaluable.
b. Dose reduction/delays can be due to non-corneal AEs.

PPD

Example SAFE_L1
Protocol: BMA117159
Population: Part 2 MM (Data as of: 30MAY2003)

Listing x.xxxx
Listing of Disease Characteristics, Prior Treatment, Dose Modification and Response to GSK2857916
(Part 2 MM)

Part: 2
Treatment: 3.40 MM

Centre ID/ Subj.	ISS Stage at Screening	Number of Prior Lines of Therapy	Refractory to Last line of Therapy	Prior Daratumumab?	Refractory to both IMiDs and Proteasome Inhibitors?	Best Confirmed Response
PPD	III	6 Lines	Yes	Yes	Yes	Progressive disease
	II	7 Lines	Yes		Yes	Very Good Partial Response (VGPR)
	I	8 Lines	Yes		Yes	Very Good Partial Response (VGPR)

PPD

Example SAFE_L2
Protocol: BMA117159
Population: All Treated MM

(Data as of: 30MAY2003)

Listing x.xxxx
Listing of Visual Acuity and Abnormal Corneal Exam Results

Part 1
Treatment: 0.01 mg/kg

Centre/ Subj.	Age(y)/ Sex/ Race	Experienced Corneal Clinical Signs / Reported Corneal Toxicity AE	Cycle/Visit	Time Since 1st Dose / Time Since Last Dose	Eye	Visual Acuity	Corneal Exam Test/Result/ Represent a Corneal Clinical Sign
PPD	65/ F/ White - White/Caucasian/European Heritage	Y / Y	3 / DAY 1	43d / 1d	R	20/40	Corneal epithelium / Abnormal, punctate keratopathy - mild / Y
					L	20/60	Corneal epithelium / Abnormal, punctate keratopathy - mild / Y
			4 / DAY 1	64d / 1d	R	20/40	Corneal endothelium / Abnormal, guttata / N
					L	20/40	Corneal endothelium / Abnormal, guttata / N
			5 / DAY 1	85d / 1d	R	20/25	Corneal epithelium / Abnormal, epithelial edema - mild patchy microcystic changes / Y
					L	20/40	Corneal epithelium / Abnormal, epithelial edema - mild patchy microcystic changes / Y
PPD							

Example: SAFE_L3
Protocol: BMA117159
Population: All Treated MM (Data as of: 30MAY2001)

Listing x.xxxx
Listing of Anti-GSK2857916 antibody results (All Treated MM)

Treatment: X

Centre ID/ Subj.	Age (y) Sex Race	Visit	Study Date	Day	Screening Assay	Confirming Assay	Titer	GSK2857916 Concentration (ADC) (ng/mL)	GSK2857916 Concentration (Total mAb) (ng/mL)
XXXX/ X	X X X	CYCLE X WEEK X	DDMMMYYYY	X	X	X	X	X	x

PPD

Example: PK_T1
Protocol: BMA117159
Population: PK

(Data as of: 30MAY2001)

Table xx.xxx
Summary of Results of Dose Proportionality Analysis for cys-mcMMAF PK Parameters (AUC(0-inf), AUC(0-t), Cmax, and AUC(0- τ) Using Power Model

Parameter	Doses	Adjusted mean slope	Standard error	DF	90% C.I.
AUCIFO (ng*hr/mL)	0.03 mg/kg	0.98	0.036	17	(0.92, 1.05)
	0.06 mg/kg	0.97	0.034	17	(0.93, 1.06)
	……				
AUCLST (ng*hr/mL)	0.03 mg/kg	0.99	0.037	17	(0.92, 1.05)
	0.06 mg/kg	0.99	0.037	17	(0.92, 1.05)
	……				
CMAX (ng/mL)	0.03 mg/kg	0.92	0.057	17	(0.82, 1.01)
	0.06 mg/kg	0.92	0.057	17	(0.82, 1.01)
	……				

PPD

Example: PK_T2
Protocol: BMA117159
Population: PK

(Data as of: 30MAY2001)

Table x.xxxx
Summary of Results of Accumulation Ratio Assessment for ADC Cmax on Day 1 of Cycle 2, 3, 5 vs Cmax on Day 1 of Cycle 1 by Dose

Treatment	n	Geometric LSMean Reference	Geometric LSMean Test	Comparison Test/Ref.	Ratio	90% Confidence Interval
0.03 mg/kg	4	11135.63	26180.71	Cycle 2 Day 1 vs Cycle 1 Day 1	2.351	(1.250, 4.424)
	3	11135.63	26180.71	Cycle 3 Day 1 vs Cycle 1 Day 1	2.351	(1.250, 4.424)
	2	11135.63	26180.71	Cycle 5 Day 1 vs Cycle 1 Day 1	2.351	(1.250, 4.424)
0.06 mg/kg	4	12457.48	28950.90	Cycle 2 Day 1 vs Cycle 1 Day 1	2.324	(1.621, 3.332)
	2	12457.48	28950.90	Cycle 3 Day 1 vs Cycle 1 Day 1	2.324	(1.621, 3.332)
	4	12457.48	28950.90	Cycle 5 Day 1 vs Cycle 1 Day 1	2.324	(1.621, 3.332)

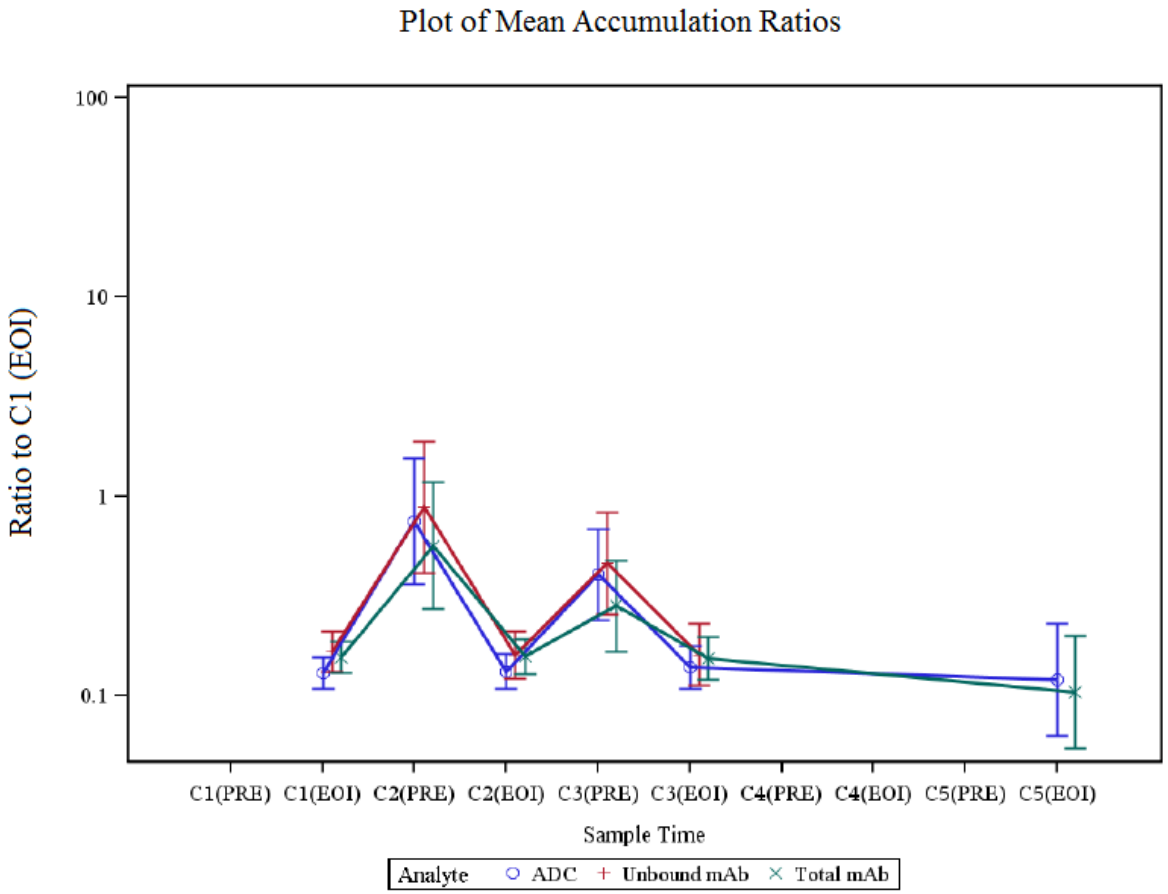
.....

Footnote: Cmax is defined as the EOI concentration at each cycle.

Example: PK_F1
Protocol: BMA117159
Population: PK

(Data as of: 30MAY2001)

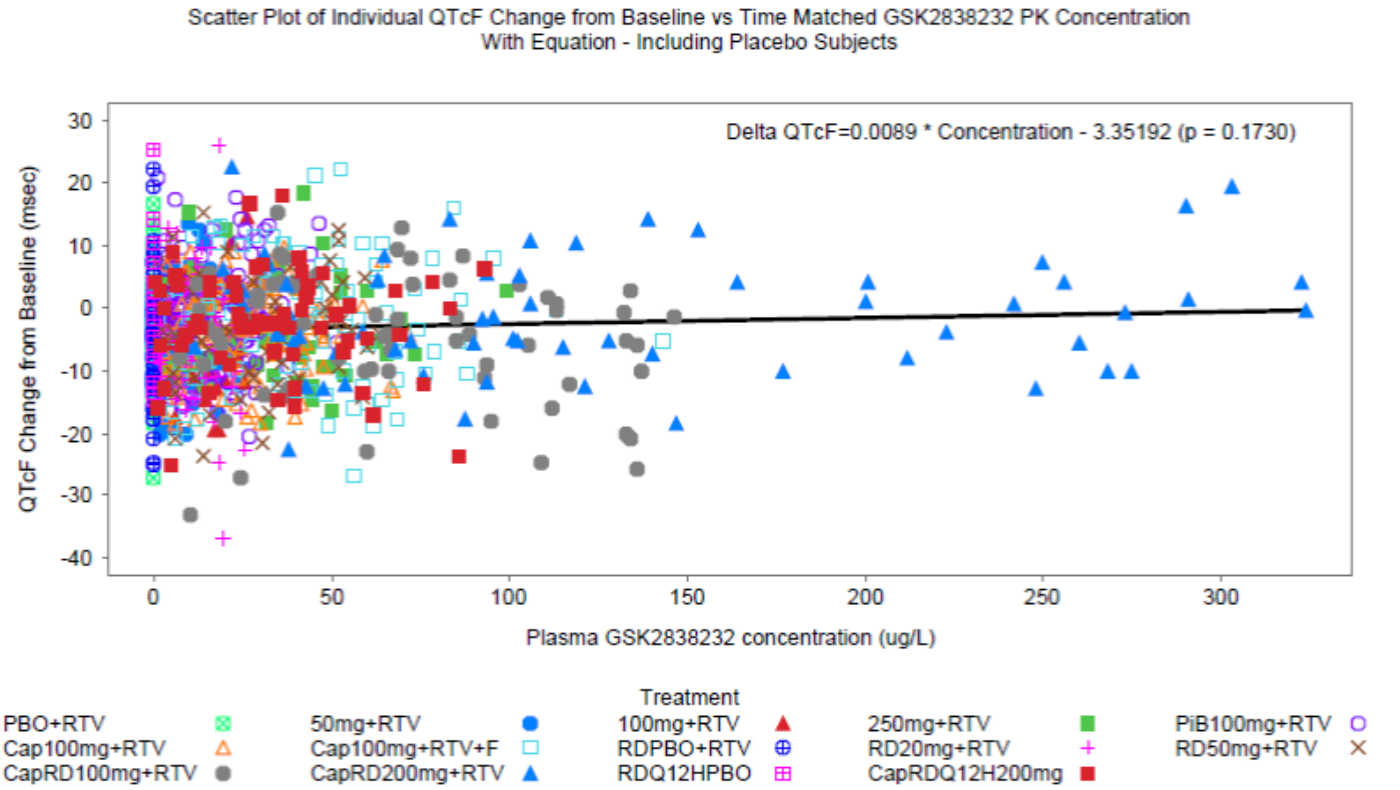
Figure x.xxxx



Example: PK_F2
Protocol: BMA117159
Population: PK

(Data as of: 30MAY2001)

Figure x.xxxx



Note: All the placebo groups (PBO+RTV for Part 1a, RDPBO+RTV and RDQ12HPBO for Part 2) are included in the plot; the Plasma GSK2838232 concentrations of these placebo groups are imputed as 0.

PPD