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Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 208466/ADP-04511.
- This RAP is intended to describe the planned efficacy and safety 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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3. LIST OF ABBREVIATIONS & TRADE MARKS

Abbreviation	Description
AE	Adverse Event
ATC-2	Anatomical Therapeutic Chemical 2nd level
ATC-3	Anatomical Therapeutic Chemical 3rd level
BMI	Body Mass Index
BOR	Best Overall Response
BSA	Body Surface Area
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CMV	Cytomegalovirus
CR	Complete Response
CRP	C-reactive protein
CRS	Cytokine Release Syndrome
CTCAE	Common Toxicity Criteria for Adverse Events
DOR	Duration of Respond
DOSD	Duration of Stable Disease
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
eCTD	Electronic Common Technical Document
GVHD	Graft Versus Host Disease
ICH	International Conference on Harmonisation
ITT	Intent-to-treat
KM	Kaplan-Meier
LTFU	Long-Term Follow-Up
MedDRA	Medical Dictionary for Regulatory Activities
mITT	Modified Intent-to-Treat
NCI	National Cancer Institute
NE	Not Evaluable
ORR	Overall Response Rate
OS	Overall Survival
PCR	Polymerase Chain Reaction
PD	Progression of Disease
PFS	Progression-Free Survival
PP	Per-protocol
PR	Partial Response
PT	Preferred Term
QTc	QT Interval Corrected for Heart Rate
RECIST	Response Evaluation Criteria in Solid Tumors
RCL	Replication Competent Lentovirus
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Stable Disease
SOC	System Organ Class

Abbreviation	Description
TTR	Time to Complete Response
ULN	Upper Limit of Normal
WHO	World Health Organization

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4. INTRODUCTION

This statistical analysis plan (SAP) describes the efficacy and safety analyses that will be performed for Study 208466/ADP-04511, based on the study protocol Version 15, dated 15OCT2018. The SAP should be used in conjunction with the protocol and electronic case report form (eCRF).

5. OVERALL STUDY DESIGN AND OBJECTIVES

5.1. Study Objectives

5.1.1. Primary Objectives

- Determine the response rate in subjects with unresectable, metastatic or recurrent synovial sarcoma treated with lymphodepletion and Treg depletion followed by adoptive immunotherapy with T cells engineered to recognize an HLA-A2 restricted NY-ESO-1 derived peptide (Cohort 1).
- Determine the response rate and duration of response of adoptive immunotherapy with NY-ESO-1^{c259}T cells in subjects with synovial sarcoma and low-level expression of NY-ESO-1 (Cohort 2).
- Determine the response rate and duration of response of adoptive immunotherapy with NY-ESO-1^{c259}T cells in subjects with synovial sarcoma treated with a lymphodepleting conditioning regimen containing cyclophosphamide as a single cytotoxic agent (Cohort 3).
- Determine the response rate and duration of response of adoptive immunotherapy with NY-ESO-1^{c259}T cells in subjects with synovial sarcoma treated with a lymphodepleting regimen containing cyclophosphamide and fludarabine cytotoxic agents at reduced total doses (Cohort 4).

5.1.2. Secondary Objectives

- Determine the safety of treatment with adoptively transferred NY-ESO-1^{c259}T cells.
- When possible, assess whether subjects with progressive disease following NY-ESO-1^{c259}T cell infusion or who do not respond experience a response following a second dose.

5.1.3. Exploratory Objectives

- Evaluate persistence, phenotype, and functionality of adoptively transferred NY-ESO-1^{c259}T cells and correlate with clinical response.
- Evaluate mechanisms of resistance and sensitivity to NY-ESO-1^{c259}T cells.
- Evaluate antigen spreading as a mechanism of response.

5.2. Trial Design and Study Procedures

5.2.1. Study Design

This open-label trial was designed as a four Cohort study as of Protocol Amendment 15. Study implementation (including study design) is described in detail in Section 3 of the protocol.

Subjects are eligible for the study if they test positive for HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06; are ≥4 years of age; and have NY-ESO-1 expressing unresectable, metastatic or recurrent synovial sarcoma.

Efficacy, safety, and biomarker assessments to be conducted as each visit are outlined in the Schedule of Procedures in Section 10.2 (Appendix 2) of the protocol.

5.2.2. Treatments and Assignment to Treatment

Drug administration details for each of the four cohorts are described in Section 3.3. of the protocol. Subjects in each cohort received lymphodepletion followed by infusion of transduced NY-ESO-1^{c259}T cells, then were followed for toxicity, antitumor effects, and immune endpoints. The target dose administered was $5x10^9$ with a minimum of $1x10^9$ to a maximum of $6x10^9$ transduced NY-ESO-1^{c259}T cells for subjects ≥40 kg. Subjects <40 kg were dosed per body weight with a minimum $0.025x10^9$ transduced cells/kg, with a target dose of $0.125x10^9$ transduced cells/kg.

Second infusions can occur in two settings:

1. Patients enrolled onto any cohort who have a confirmed response, or have stable disease for >3 months, then progress, were eligible for a second infusion of NY-ESO-1c259T, provided eligibility criteria are met. Patients with confirmed responses or stable disease that qualify for a second infusion will receive lymphodepleting chemotherapy and T cell infusion as received for the first infusion.

2. Patients in Cohort 3 and 4 who have progressive disease or stable disease ≤ 3 months as best response, may receive a 2nd treatment of NY-ESO-1c259T using the Regimen A lymphodepletion to determine if more intense lymphodepletion can result in an improved best response.

Patients may receive a maximum of two treatments with NY-ESO-1c259T. The second cycle (i.e. re-treatment) can be given no sooner than 60 Days from the first infusion and no later than 2 years after the first infusion. Decisions to retreat with a second infusion will be discussed with the Sponsor and Investigators.

5.3. Sample Size

The sample size for each cohort is based on clinical judgment. The study is not statistically powered to conduct hypothesis testing between cohorts.

6. GENERAL ANALYSIS CONVENTIONS

With respect to the primary objectives and endpoints, no specific statistical hypotheses will be evaluated. All analyses will be descriptive and exploratory.

In the protocol and eCRF, the date of the first T cell infusion is referred to as Day 0.For the tables, listings, and figures, the date of the first T cell infusion will be referred to as Day 1 to be consistent with CDISC data standards.

Data collected in this study will be documented using summary tables and subject data listings. Continuous variables will be summarized using descriptive statistics (number of subjects, mean, median, standard deviation, minimum, and maximum). Categorical variables will be summarized using frequencies and proportions. Time-to-event data will be summarized via Kaplan-Meier (KM) methodology using the 25th, 50th (median), and 75th percentiles with associated 2-sided 95% confidence intervals (CIs) using the complementary log-log transformation, as well as the proportion of censored observations. The 95% CIs for proportions will be calculated using Wilson and exact confidence limits.

Because of the small number of expected subjects receiving a second infusion, only select adverse events tables will be prepared for data on subjects who receive a second infusion. Efficacy data will be summarized in tables and listings.

Assessments will be displayed for each Cohort and for all Cohorts combined (i.e., overall).

Unless specified otherwise, baseline measurements should be the most recent value prior to initiating lymphodepletion and should occur within 7 days prior to initiating lymphodepletion (Table 1). If an assessment is not available, then the last assessment prior to that visit would be used.

Table 1 Definition of Baseline

Assessment/Test	Visit
Target and Non-target Lesions	Baseline within 7 days prior to initiating lymphodepletion
Demography	Date of Screening Informed Consent
Hematology, Chemistry, C-reactive protein (CRP), CMV PCR, Additional Lab	Baseline within 7 days prior to initiating lymphodepletion
Vital Signs, Physical Exam, ECOG	Baseline within 7 days prior to initiating lymphodepletion
Electrocardiograms	Baseline within 7 days prior to initiating lymphodepletion
Cytokines	Baseline within 7 days prior to initiating lymphodepletion

Algorithms for imputing partial or missing dates are shown in Table 2. If a period determination cannot be made for an adverse event, it will be attributed to the post-lymphodepletion period (described in Section 6.1), with missing dates imputed as explained in Table 2. AE end dates are imputed to facilitate calculation of AE duration. Note: Only SAEs are collected prior to leukapheresis.

Table 2 Partial or Missing Date Algorithms

Variable	Missing Day	Missing Day, Month	Missing Day, Month, Year
Date of Last Systemic Therapy/Date of Initial Diagnosis	Assign 1	Assign January 1 if prior to date of informed consent, otherwise use date of informed consent	Missing (do not impute)
Adverse Event Start Date	Assign first day of month unless it is the month of start of lymphodepletion. Otherwise, assign date lymphodepletion started.	Assign January 1 unless the year is year of start of lymphodepletion Otherwise, assign date lymphodepletion started.	Assign date lymphodepletion started.
Adverse Event End Date	Assign the last day of the month or end of study date, whichever is earlier.	Assign December 31 or end of study date, whichever is earlier.	If ongoing, end date is missing. Otherwise, assign end of study date.

Missing date information for concomitant medication will not be imputed.

Medical history, adverse events and concurrent procedures will be coded using Medical Dictionary for Regulatory Activities (MedDRA), Version 22.0 or higher. Prior and concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary (December 2015 or later).

Data for all subjects in the clinical database will be included in the data listings. Calculated (derived) variables will be listed as appropriate. All tables, listings, and figures will be programmed using SAS Version 9.3 or higher.

A list of proposed statistical tables, data listings, and figures is provided in Section 17.

BSA (m^2) will be presented as reported on the eCRF.

BMI will be computed as weight in kg/height in m^2

6.1. Study Periods

Subjects undergo leukapheresis within 7 days of the screening visit. Following leukapheresis, cells are transduced. A baseline visit occurs within 7 days prior to initiating chemotherapy for lymphodepletion. The T cell infusion occurs at most 7 days

following chemotherapy depending on the Cohort. The interventional phase is the period from initiation of chemotherapy for lymphodepletion through the date of discontinuation or up to 5 years after the last T cell infusion, whichever is earlier Subjects are followed for 15 years after infusion, or until death, lost to follow-up, or withdrawal of consent, whichever comes first.

For the purposes of adverse event reporting, the following visit intervals will apply:

- Pre-leukapheresis Period: Date screening ICF signed to the date before leukapheresis – only serious adverse events (SAEs) will be reported for screened subjects
- Date informed consent signed (Screening) to end of study (Period 1)
- Day 1 of lymphodepletion to end of study (Period 2)

Period 1 adverse events will be summarized for the intent-to-treat population unless otherwise specified. Period 2 adverse events will be summarized for the modified intent-to-treat population.

Period 2 is clinically relevant for summarizing safety in the context of lymphodepletion and T-cell therapy because Period 1 includes safety results prior to lymphodepletion and T-cell therapy.

6.2. Visit Windows

Study visits are expected to occur according to the protocol schedule. All data will be tabulated per the evaluation visit as recorded on the eCRF even if the assessment is outside of the visit window. In data listings, dates and study day relative to T cell infusion (Study Day 1) will be presented. Note: for time-to-event analyses, evaluations will be based on the actual date of the event rather than on the visit on which the event was reported.

7. ANALYSIS POPULATIONS

The number of subjects in each study population will be summarized.

7.1. Intent-to-Treat Population

The intent-to-treat (ITT) population will include all subjects who were enrolled in the trial (i.e., underwent leukapheresis). The ITT population will be used to assess the efficacy and safety of the T cell therapy regimen.

7.2. Modified Intent-to-Treat Population

The modified intent-to-treat (mITT) population will include all subjects who receive NY-ESO-1^{c259}T cell infusion. The mITT population is the primary analysis population for both safety and efficacy. If the ITT and mITT populations are the same, only analyses associated to the ITT population will be reported.

7.3. Per-Protocol Population

A per-protocol population (PP) may be included if there are subjects in the mITT population who have protocol deviations that are expected to affect efficacy assessments (e.g., subjects enrolled who do not meet key eligibility criteria) during the trial. Exclusions from the per protocol population will be identified and documented prior to database lock.

8. SUBJECT DISPOSITION

Subject disposition will be summarized by Cohort, Cohorts 2-4 combined and overall for all subjects who entered the study (i.e., signed the informed consent for the study) and will include the number of subjects in each population (ITT, mITT, PP if applicable) and reasons subjects were removed from a population. The number of subjects receiving lymphodepleting chemotherapy will also be summarized. The number and proportion of subjects who complete the trial, as well as those exiting the interventional phase for each reason specified on the eCRFs will also be summarized. A subject will be considered to have completed the trial when he/she has confirmed progression of disease or death, or when the subject is in the trial for 5 years after the last T cell infusion. Reasons for early termination from the study are:

- Disease Progression
- Unacceptable toxicity and other safety reasons
- Death
- Investigator discretion
- Subject withdrew consent
- Protocol deviation
- Lost to follow-up
- Termination by Sponsor
- Failed manufacture of cell product
- Pregnancy
- Failed to meet eligibility criteria for the second infusion.

Leukapharesed or T-cell infused subjects excluded from analysis populations will be presented in a data listing.

9. PROTOCOL DEVIATIONS

Subjects will be excluded from the per protocol population if they have protocol deviations expected to affect efficacy assessments, these may include the following, and possibly others not listed here:

- Did not meet key inclusions criteria (e.g., did not meet disease requirements)
- Received less than 1 billion transduced NY-ESO-1^{c259}T cells (or less than $0.025x10^9$ cells/kg if <40kg).
- Had a post baseline tumor resection
- Took prohibited medication

- Developed withdrawal criteria during the study but were not withdrawn
- Did not have at least one post-treatment tumor assessment
- Had different imaging methods for baseline and post-baseline assessments

Protocol deviations will be presented by Cohort and subject in a data listing.

10. DEMOGRAPHIC AND BASELINE CHARACTERISTICS

10.1. Demographic Characteristics

Demographic and baseline characteristics at study entry will be summarized by Cohort and overall for the ITT and mITT populations. Variables to be summarized are:

- Continuous variables
  - Age (years) at time of screening informed consent
  - Weight (kg, converted from pounds if necessary)
  - Height (cm, converted from inches if necessary)
  - Body surface area (BSA) (m^2)
  - BMI [(weight in kg)/(height in $m)^2$]
- Categorical variables
  - Sex
  - Race
  - Ethnicity
  - NY-ESO status
  - HLA status (HLA-A*0201, HLA-A*0205, HLA-A*0206, Other)
  - ECOG performance status at baseline
  - Primary disease site at enrollment
  - Disease stage at enrollment
  - Histology grade at enrollment

Demographic and baseline characteristics will be presented by Cohort and subject in data listings.

10.2. Medical History

Medical history will be summarized by Cohort and overall for the ITT population. Medical history information will be presented by Cohort and subject in a data listing.

10.3. Prior Cancer Therapy

All prior cancer therapies should have an end date prior to screening Informed Consent date. Additionally, all prior cancer therapies taken from after apheresis and before lymphodepletion (i.e., bridging therapies) will be summarized.

Prior systemic therapy, radiotherapy, surgery history, and bridging therapies will be summarized for the ITT and mITT populations by Cohort and overall. The following variables will be summarized:

- Prior systemic therapy (yes/no)

- Type of systemic therapy
- Time since last systemic therapy (days)
- Time since initial diagnosis (days)
- Best response to last systemic therapy
- Prior radiotherapy (yes/no)
- Prior cancer-related surgery (yes/no)
- Bridging therapy (yes/no)
- Type of bridging therapy (chemotherapy, radiation, other)

Bridging therapy is therapy administered on or after apheresis and before lymphodepletion.

Time since last systemic therapy is calculated as the date the informed consent was signed minus the latest therapy end date, expressed in days, and will be summarized using descriptive statistics. Time since initial diagnosis is calculated as the date the informed consent was signed minus the date of initial diagnosis, expressed in days, and will be summarized using descriptive statistics. Partial dates for date of last systemic therapy and time since initial diagnosis will be imputed as described in Section 6. Only positive values will be summarized for time since last systemic therapy and time since initial diagnosis. Number of lines of prior systemic therapy will be summarized using descriptive statistics and will also be categorized and summarized using counts and percentages. All other variables listed above will be summarized using counts and percentages.

Yes/no variables for prior systemic therapy, prior radiotherapy, and prior cancer-related surgery will be derived from the presence or absence of this information in the raw datasets, as there is no specific question on the eCRF for these variables.

Prior systemic therapy, radiotherapy, and surgery history information will be presented by Cohort and subject in a data listing.

11. STATISTICAL METHODS FOR EFFICACY

The study objectives are described in Section 5.1.

11.1. Primary Efficacy Analysis

The primary analysis population for primary and secondary efficacy endpoints will be the mITT population. ITT will be used as the secondary population for analysis of the primary endpoint. The primary efficacy endpoint is the overall response rate (ORR). ORR is defined as the proportion of subjects with a confirmed complete response (CR) or partial response (PR) relative to the total number of subjects in the corresponding analysis population per Response Evaluation Criteria in Solid Tumors (RECIST v1.1) as determined by the local investigators. To be assigned a status of a CR or PR, changes in tumor measurements must be confirmed by repeat assessments that should be performed

at least 4 weeks after the criteria for response are first met. Subjects with unknown or missing response will be treated as non-responders, that is, they will be included in the denominator when calculating the proportion.

Response categories are confirmed CR, confirmed PR, stable disease (SD), and progressive disease (PD). Response confirmation will be handled according to Table 3 (RECIST v1.1) in the next section.

Sensitivity analyses to be performed for ORR defined by RECIST v1.1 include:

- Two-sided 95% CIs for ORR will be calculated using both the Wilson and Clopper-Pearson methods
- ORR analyses repeated for the PP population (if a PP population is defined)
- Investigator assessed response

Listings of response data and lesion measurements per RECIST v1.1 will also be provided.

11.2. Secondary Efficacy Analyses

The key secondary efficacy endpoints are

- Time to confirmed response (TTR)
- Duration of response (DOR)
- Progression-free survival (PFS)
- Overall survival (OS)

Additional clinically relevant endpoints include best overall response (BOR) duration of stable disease (DOSD), and time on study (defined as date of last visit in study – date of informed consent +1).

The secondary efficacy analyses will be performed for the mITT population, that is, subjects who received T-cell infusion, which is the primary population for efficacy analysis. Efficacy endpoints will be based on RECIST v1.1.

Time to confirmed response (CR or PR) (reported in weeks) is defined as the interval between the date of first T-cell infusion and the earliest date of first documented confirmed CR or confirmed PR among participants with a confirmed PR or CR.

Duration of response (reported in weeks) is defined as the time from first documented evidence of confirmed CR or confirmed PR until first documented date of disease progression or death due to any cause or surgical resection or start of prohibited medications. For responders who are still alive and who do not have documented disease progression, surgical resection, or prohibited medication the date of the last disease assessment is used.

PFS (reported in weeks) is defined as the interval between the date of first T cell infusion and the earliest documented evidence of disease progression or death due to any cause or surgical resection or start of prohibited medications. Subjects who do not have a

documented date of progression, death, surgical resection, or prohibited medication will be censored at the date of the last disease assessment.

Subject will be censored for PFS and DOSD at the day 1 for the situation the censoring algorithm calls for the subject to be censored at the date of the last disease assessment but no such assessment exists.

Extended Loss to Follow-up

For the analysis of PFS, if there are two or more consecutive scheduled disease assessments which are missing and are then followed by an assessment demonstrating disease progression or death (due to any cause) or surgical resection or start of prohibited medications, PFS will be censored at the last adequate disease assessment prior to progression or death or surgical resection or start of prohibited medications. For this type of censoring due to extended loss to follow-up, the 'last adequate disease assessment' will be defined as the date of the last radiological assessment prior to the missing assessments that shows no disease progression.

As the assessment schedule changes through the course of the study (i.e. every 4 weeks during the first 12 weeks and then every 3 months until month 24 and then every 6 months after month 24), the following rules will be used for identifying extended loss to follow up.

- If PFS event is on or prior to week 12, then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 56 days (8 weeks) prior to PFS event;

- Else if PFS event is after week 12 and on or prior to the first scheduled disease assessment date (month 6, day 183) during week 12 to month 24, then a subject will be identified as an extended loss to follow up if the subject missed both week 8 and week 12 disease assessments:

    - If PFS event is after week 12 and on or prior to day 122 (month 4), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 56 days (8 weeks);

    - Else if PFS event is after week 12 and on or prior to day 153 (month 5), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 84 days (12 weeks);

    - Else if PFS event is after week 12 and on or prior to day 183 (month 6), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 112 days (16 weeks);

- Else if PFS event is after day 183 (month 6) and on or prior to the second scheduled disease assessment date (month 9, day 274) during week 12 to month

24, then a subject will be identified as an extended loss to follow up if the subject missed both week 12 and month 6 disease assessments:

  - If PFS event is after day 183 (month 6) and on or prior to day 214 (month 7), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 120 days (4 weeks + 3 months);

  - Else if PFS event is after day 183 (month 6) and on or prior to day 244 (month 8), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 150 days (4 weeks + 4 months);

  - Else if PFS event is after day 183 (month 6) and on or prior to day 274 (month 9), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 181 days (4 weeks + 5 months);

- Else if PFS event is after day 274 (month 9) and on or prior to day 731 (month 24), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 183 days (6 months);

- Else if PFS event is after day 731 (month 24) and on or prior to day 914 (24 months + 6 months), then a subject will be identified as an extended loss to follow up if the subject missed both month 21 and month 24 disease assessments;

  - If PFS event is after day 731 (month 24) and on or prior to day 822 (month 27), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 183 days (6 months);

  - Else if PFS event is after day 822 (month 27) and on or prior to day 914 (month 30), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 274 days (6 months + 3 months);

- Else if PFS event is after day 914 (month 30) and on or prior to day 1096 (month 36), then a subject will be identified as an extended loss to follow up if the subject missed both month 24 and month 30 disease assessments;

  - If PFS event is after day 914 (month 30) and on or prior to day 1005 (month 33), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 274 days (6 months + 3 months);

  - Else if PFS event is after day 1005 (month 33) and on or prior to day 1096 (month 36), then a subject will be identified as an extended loss to follow

up if the subject did not have an adequate disease assessment during the time period of 366 days (12 months);

- Else if PFS event is after day 1096 (month 36), then a subject will be identified as an extended loss to follow up if the subject did not have an adequate disease assessment during the time period of 366 days (12 months);

Overall survival (reported in weeks) is defined as the interval between the date of the first T-cell infusion and date of death from any cause. Subjects who are still alive or who are lost to follow-up will be censored at the date of last contact.

Best overall response is the best response recorded from the start of treatment (first T cell infusion) until disease progression/recurrence. Response categories from best to worst are: confirmed CR, confirmed PR, SD and confirmed PD. The handling of response confirmation will be handled according Table 3 (RECIST v1.1). Duration of stable disease must be at least 4 weeks to qualify SD as the BOR. If a subject did not have confirmed CR or PR and had stable disease for less than 4 weeks, BOR will be PD.

Table 3 Best Overall Response per RECIST v1.1.

Overall Response First time point	Overall Response Subsequent Time Point	Best Overall Response
CR	CR	CR
CR	PR	SD, PD, or PR*
CR	SD	SD provided minimum criteria for SD duration met**, otherwise PD
CR	PD	SD provided minimum criteria for SD duration met**, otherwise PD
CR	NE	SD provided minimum criteria for SD duration met**, otherwise NE
PR	CR	PR
PR	PR	PR
PR	SD	SD
PR	PD	SD provided minimum criteria for SD duration met**, otherwise PD
PR	NE	SD provided minimum criteria for SD duration met**, otherwise NE
NE	NE	NE

*If CR is truly met at first time point, then any disease seen at a subsequent time point, even disease meeting PR criteria relative to baseline, makes the disease PD at that point (since disease must have reappeared after CR). Best response would depend on whether minimum duration for SD was met. However, sometimes 'CR' may be claimed when subsequent scans suggest small lesions were likely still present and in fact the patient had PR, not CR at the first time point. Under these circumstances, the original CR should be changed to PR and the best response is PR.
** Minimum criteria for SD disease duration is at least 4 weeks to qualify SD as BOR.
Note: If Best Overall Response is CR or PR, the subject is classified as a responder for the ORR analysis.

Duration of stable disease (reported in weeks) is defined as the interval between the date of first T cell infusion and the earliest documented evidence of PD. Subjects who do not have documented evidence of PD will be censored at the date of the last assessment.

No hypothesis testing is planned for these secondary endpoints. Time to event endpoints will be summarized and displayed graphically using KM methodology to estimate the median, and the 25th and 75th percentiles and associated 2-sided 95% CIs using the complementary log-log transform. Overall survival may be assessed at fixed time points

such as 1 year and 2 years using KM methods. The proportion of censored observations will be summarized.

Sensitivity analyses will be performed for BOR, DOR, and PFS as follows:

- Summaries based on the PP population (if a PP population is defined)
- In cases where a tumor assessment has a value of NE (missing or unknown), sensitivity analyses will be performed assigning values of PD and SD (PFS only)
- For PFS, subjects who received surgical resection or prohibited medications prior to documented disease progression then PFS will be censored at the date of the last adequate disease assessment
- Based on investigator assessment
- In cases where a tumor assessment has a value of NE (missing or unknown), sensitivity analyses will be performed ignoring the assessment with a value of NE
- In cases where a tumor assessment has a value of not evaluable (NE) (i.e., missing or unknown), sensitivity analyses will be performed assigning values of SD if the assessments before and after the NE assessment are CR, PR, or SD. and will assign PD otherwise, except for PR NE CR where the assessment is improving, as shown in Table 4. (per RECIST v1.1.)

Table 4 Sensitivity Analyses for NE Responses

Responses at Time Points 1, 2, 3	Sensitivity Analysis 1: SD Replaces NE at the second time point
CR-NE-CR	SD
CR-NE-PR	SD
CR-NE-SD	SD
CR-NE-PD	PD
CR-NE-NE	PD
PR-NE-CR	SD
PR-NE-PR	SD
PR-NE-SD	SD
PR-NE-PD	PD
PR-NE-NE	PD

Other sensitivity analyses may be performed as appropriate.

Subject response characteristics and time on study will be shown on a swim lane plot. Time on study will be calculated as (date of last assessment for ongoing subjects or discontinuation date) – date of first T cell infusion).

Maximal change in target lesions from baseline will be shown in a waterfall plot. Change in target lesions from baseline over time will be shown in a spider plot.

Listings of response data and derivations for secondary endpoints will be provided, along with other relevant data collected on the eCRF.

12. STATISTICAL/ANALYTICAL ISSUES

12.1. Handling of Dropouts or Missing Data

Missing dates will be imputed as described in Section 4. Sensitivity analyses for missing data are described in Section 11.1 and Section 11.2.

12.2. Pooling of Centers in Multi-Center Studies

Data will not be summarized by study center or for groupings of study centers.

12.3. Multiple Comparisons/Multiplicity

No formal statistical testing will be performed; therefore, no adjustments for multiple comparisons or multiplicity are planned.

12.4. Examination of Subgroups

No subgroup analyses are planned.

12.5. Interim Analysis and Data Monitoring

Futility evaluation was conducted by Adaptimmune for cohorts 2, 3, and 4 after enrolling 5 subjects using stopping criteria described in Section 3.2 of the protocol.

13. STATISTICAL METHODS FOR SAFETY ENDPOINTS

Safety endpoints are:

- Adverse events (AEs), including serious AEs (SAEs) and adverse events of special events (AESI)
- Laboratory assessments, including chemistry, hematology and anti-infused cell (NY-ESO-1^{c259}T) antibodies
- Correlation of circulating cytokines with CRS

Other safety assessments include physical exams, vital signs, and concomitant medications.

All safety data will be included in data listings.

13.1. Study Drug Exposure

The total number of transduced T cells and a summary of lymphodepleting chemotherapy administration will be summarized for the mITT population by Cohort and overall using descriptive statistics. The number of transduced cells will be summarized overall for subjects with a second T cell infusion.

All dose administration data for lymphodepletion, including cyclophosphamide and fludarabine, and for T cell infusion will be presented by subject in a data listing.

13.2. Adverse Events

Adverse events (AEs) will be summarized separately for each analysis population and Period (as appropriate) as described in Section 6 and as described below. AEs with partial start or end dates will be imputed as described in Section 6.

Adverse events (AEs) will be summarized by Cohort and overall for:

- Period 1: Date informed consent signed (Screening) to end of study for ITT and mITT populations
- Period 2: Day 1 of lymphodepletion to end of study for mITT population only
- Pre-leukapheresis Period: SAEs only for screened subjects.

Adverse events will be summarized by MedDRA (version 22.0) system organ class (SOC) and preferred term (PT) in alphabetic order for SOC and PT within a SOC. AEs will be graded according to the National Cancer Institute (NCI) Common Toxicity Criteria for Adverse Events (CTCAE) version 4.0. Per the request of the clinical team, various Preferred Terms were combined and will be reported together as one term. The combined terms are listed in Appendix 2. Of note, tables that summarize AEs by SOC and PT and fatal AEs will use MedDRA preferred terms. All other AE tables will summarize AEs by the combined terms in Appendix 2.

Only SAEs occurring prior to leukapheresis for screened subjects will be reported for the pre-leukapheresis period.

AEs with partial start or end dates will be imputed as described in Section 4.

An overview summary table of Period 1 (ITT) and Period 2 (mITT) AEs will be presented by Cohort and overall, including the number and proportion of subjects reporting an AE for the following categories:

- Subjects reporting at least one AE
- Subjects reporting at least one treatment-related AE
- Subjects with ≥ Grade 3 AE
- Subjects with ≥ Grade 3 related AEs
- Subjects with ≥ Grade 3 SAE
- Subjects with ≥ Grade 3 related SAEs
- Subjects reporting at least one SAE
- Subjects reporting at least one treatment-related SAE
- Subjects with SAEs with fatal outcome

For subjects who have a second T cell infusion, an overview summary table of post-lymphodepletion AEs associated with the second infusion will be presented, including the number and proportion of subjects reporting an AE for the following categories:

- Subjects reporting at least one AE
- Subjects reporting at least one treatment-related AE
- Subjects reporting at least one SAE
- Subjects reporting at least one treatment-related SAE
- Subjects with SAEs with fatal outcome

The second infusion AE summaries will be summarized across cohorts.

13.2.1. Adverse Events

The number and proportion of subjects by Cohort and overall with the following categories of AEs will be summarized in tables by system organ class and preferred term for Period 1 (ITT and mITT) and Period 2 (mITT):

- Any AE
- Any AE by toxicity grade
- Any AE by relationship to study treatment

- Any AE ≥ Grade 3
- Any treatment-related AE ≥ Grade 3
- Any SAE ≥ Grade 3 SAE
- Any treatment-related SAE ≥ Grade 3
- Any SAE
- Any treatment-related SAE
- Any SAE with fatal outcome AEs by descending order of PTs (ordered by overall incidence)
- SAEs by descending order of PTs (ordered by overall incidence)

In addition, the following summaries will be provided for the pre-leukapheresis period (all screened subjects):

- Any SAE
- Any SAE with fatal outcome
- Any SAE ≥ Grade 3

The number and percentage of subjects who experienced at least one AE will be summarized overall and for each SOC and each PT. The proportion will be based on the number of subjects in the relevant population by Cohort and overall. Each subject will contribute at most one count per summarization category. In other words, if a subject has more than one AE with the same PT, the subject will be counted only once for that PT. Similarly, if a subject has more than one AE for a SOC, the subject will be counted only once in that SOC, listing out all the PTs.

AE toxicity grade will be classified using NCI CTCAE version 4 criteria into 5 categories: Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe, Grade 4 = life threatening and Grade 5 = fatal. If a subject has multiple occurrences of the same SOC or PT, then only the most severe event will be summarized in the tables for that SOC and PT. AEs of grade 3 or higher will also be summarized. A missing toxicity grade will not be imputed.

The relationship of the AE to T cell infusion will be classified into 5 categories: definitely related, probably related, possibly related, unlikely (Cohort 1 only), and not related. AEs will be summarized in the tables as ‘related’ or ‘not related’ and listings will display all categories. Treatment-related AEs include definitely related, probably related, unlikely, and possibly related. If a subject has multiple occurrences of the same SOC or PT, only the most related event will be summarized in the tables for that SOC and PT.

For subjects who have a second T cell infusion, the number and proportion of subjects with the following categories of AEs will be summarized in tables by system organ class and preferred term for AEs associated with the second infusion for the post-lymphodepletion period.

- Any AE
- Any AE by toxicity grade
- Any AE by relationship to study treatment

- Any SAE

No formal hypothesis-testing analysis of AE incidence rates will be performed. All reported AEs will be listed in data listings, with a separate listing for AEs associated with a second T cell infusion. By-subject listings also will be provided for all subjects for the following: all AEs, serious AEs, and AEs with intensity grade 3 or above; the listings will identify which AEs are associated with the first T cell infusion and which are associated with the second T cell infusion. In addition, deaths and cause of death will be presented in a data listing.

13.3. Adverse Events of Special Interest (AESI)

An adverse event of special interest is a grouping of adverse events that are of scientific and medical concern specific to NY-ESO-1^{c259}T cell infusion. As changes to the MeDRA dictionary may occur between the time of the start of the study and the time of the final reporting, the list of terms to be used for each event of interested will be based on the latest listing provided by safety team.

Summaries of the number and percentage of subjects with these events will be provided for each type of events separately. 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, the outcome of the event, maximum grade. The worst-case approach will be applied at subject level for the event outcome, maximum graded, i.e. a subject will only be conted once as the worst case from all the events that subject had. In addition, onset and duration of the first/last occurences for each type of events will be summarized. AE preferred terms will be 'collapsed' (refer to Appendix 3 for the specific rules) when reporting the onset and duration. Of note, if the AE start date is before the lymphodepletion date and the end date is on or after the lymphodepletion date then the start date for calculating the onset of the AE is still the start date of the AE but the start date for calculating the duration of the AE is the lymphodepletion start date.

Additionally, by-subject listings for subjects experiencing AESIs of CRS, GVHD, GBS, Encephalopathy syndrome and Recurrent pancytopenia with bone marrow failure/Aplastic anemia will be provided (MEdDRA preferred terms are listed in Appendix 2). The time course of CRS and Recurrent pancytopenia with bone marrow failure/Aplastic anemia indicating the severity will be graphically displayed.

Boxplots of select cytokines may also be provided for subjects with and without CRS. A timeline plot of CRS indicating the severity of CRS will be created.

13.4. Laboratory Tests

13.4.1. Clinical Laboratory Tests

Quantitative clinical laboratory results for hematology and clinical chemistry will be summarized at baseline (as defined in Table 1), each scheduled post-baseline visit, and change from baseline to each scheduled visit using descriptive statistics (number of subjects, mean, median, standard deviation, and minimum and maximum values) for each Cohort and overall. Refer to Appendix 1 for a list of safety laboratory tests by category.

Laboratory data will be summarized for the post-lymphodepletion period (mITT population).
Shift tables that present changes from baseline to worst post-baseline values relative to NCI CTCAE version 4 classification ranges will be produced for each Cohort and overall for laboratory parameters with quantitative CTCAE criteria

The number and percentage of subjects with potentially clinically significant post-baseline elevations in hepatic parameters (Table 5) will be summarized by Cohort and overall.

A listing of the subjects with clinically significant post-baseline hepatic elevations will be provided. The listing will contain all of a subject's values for parameters meeting the criteria.

Table 5 Potentially Clinically Significant Elevations in Hepatic Parameters

Parameter*	Criterion
ALT, AST and Total Bilirubin Elevations	≥3 xULN AST and/or ALT and ≥2 xULN total BIL
	≥3 xULN AST and/or ALT and ≥1.5 xULN total BIL
ALT Elevations	≥20 xULN
	≥10 xULN
	≥5 xULN
	≥3 xULN
Total Bilirubin Elevations	>2 xULN
	>1.5 xULN

*ALT = Alanine aminotransferase, ALK = Alkaline Phosphatase, AST = Aspartate aminotransferase, BIL = Total bilirubin, ULN = upper limit of normal.

All laboratory parameters will be included in data listings, and values outside of the reference range will be flagged as high or low on the listings.

13.4.2. Persistence of NY-ESO-1 ^{c259}T and Replication Competent Lentivirus (RCL)

Persistence of gene-modified cells is an indicator of exposure and expansion of T cell therapy. Persistence will be monitored in peripheral blood mononuclear cell (PBMC) samples using a PCR-based method for the presence of the specific WPRE or Psi sequences, which are part of the lentiviral vector used to transduce the T cells. Note, vector with WPRE sequence utilized for subjects dosed before 12-Dec-2016 with exception of Subject PPD, who was dosed with Psi vector.

Persistence data is reported from the analysis vendor as:

- Copies/well
- Copies/ug DNA
- Copies/cell

Copies/ug DNA and copies/cell are calculated by analysis vendor as follows:

- copies/µg DNA=copies per well/µg DNA per well

- copies/cell=(copies/µg)x(0.0000063 µg DNA/cell)

In addition, the following calculations will be performed, where Psi is the persistence result from the eCRF:

Cell Persistence = Absolute peripheral gene-marked cell number / µL = (Psi result number / 151515) x (lymphocyte count + monocyte count) x 1000

Percent of gene marked cells per total lymphocyte compartment = ((Absolute peripheral gene marked cell number / µL) / (Lymphocyte count x 1000)) x 100

OF note, for the data directly from vendor post GSK-Adaptimmune transition, the following calculation will be performed: Cell persistence=Absolute peripheral gene-marked cell number/µL= copies/cell × (lymphocyte count + monocyte count) × 1000, where copies/cell is reported by analysis vendor.

For persistence value below LLOQ, the following rules will be applied:

Reported Copies per cell Result	Reported Copies per ug DNA Result	Reported Result	Set Value for Copies per cell	Set Value for Copies per ug DNA
<0.0003	<50.0	Negative	0	0
<0.0003	<50.0	Detectable, <LLOQ	0.0003	50

Note, sometimes values for copies per cell and copies per ug DNA might be different than above as it depends on the input of DNA, but rule would be the same:

- If interpretive reported result is negative, set values at 0.

- If interpretive reported result is “Detectable, <LLOQ”, set values at LLOQ (If <XXX, set at XXX)

Spider plots of persistence (copies/ug DNA) will be used to graphically summarize persistence over time for each subject by responders and non-responders. Maximum persistence during the study and time to maximum persistence will be summarized overall and for responders and non-responders using descriptive statistics and boxplots.

A listing of persistence will be provided and will include coefficient of variation, number of positive replicates, copies/DNA, interpretive result, duration of detectible persistence and time to loss of 25%/50%/75% peak persistence.

Duration of detectable persistence is defined as time from T-cell infusion until persistence is no longer detectable. Persistence above the assay limit of detection but below the lower limit of quantitation is considered for the duration determination, i.e. the time window from infusion until the first instance persistence falls below the detection limit and the interpretive reported result is “Negative.” If persistence for a given subject

remains detectable at their last sample collection timepoint, the last observed time is reported and considered as right-censored with a "+" appended to the numerical result. Note, transduced T-cells frequently persist beyond the follow-up period, and hence, the reported duration is directly influenced by length of time the patient is on-study.

Time to loss of 25% of peak persistence will be calculated as the time since T-cell infusion corresponding to observing at least 25% loss of peak persistence. If time to 25% loss of peak persistence is not observed, the last observed time will be reported with a "+". The same procedure will be followed for 50% and 75%.

The proportion of subjects who are RCL positive will be summarized for the mITT population. RCL is reported as "Negative" if copies of VSV-G are <50 copies/ugDNA

RCL and persistence results (raw and derived) will be presented by Cohort and subject in a data listing.

13.4.3. Cytokines

Boxplots of the maximum post-baseline value for select cytokines including IFN gamma IL6, IL8, IL12, IL13, and TNF alpha will be provided for subjects with none or non-serious CRS vs. serious CRS for the mITT population and for responders vs. non-responders. One spider plot and boxplot will be presented per cytokine.

Cytokine results will be presented by subject in a data listing. Subjects with an adverse event of cytokine release symptom (CRS) will be flagged in the listing. If the reported result is "Fail QC" or "CV>25%", then the value will be set to missing. For values deemed < lower limit of quantitation, a value of the laboratory specified lower limit of quantitation divided by 3 will be used. Laboratory specified upper limit of quantitation values will be used for values > upper limit of quantitation. If there are multiple baseline values, the earliest value will be used as baseline.

The missing data rules for cytokines are as follows:

Reported Result	**Set Value**
Fail QC	Missing
CV>25%	Missing
<LLOQ (ex. <0.25)	LLOQ/3 (ex: 0.0833 calculated from 0.25/3)

13.5. Vital Signs

A listing of the subjects with potentially clinically significant post-baseline vital signs will be provided. The listing will contain all of a subject's values for parameters meeting the criteria (Table 6).

Table 6 Potentially Clinically Significant Vital Signs Values

Parameter	Criterion
Heart Rate	< 60 bpm
	> 100 bmp
Systolic blood pressure	≥ 140 mmHg
Diastolic	≥ 90 mmHg

Vital signs will be presented by Cohort and subject in a data listing.

13.6. Physical Exams

Physical exam results will be presented by Cohort and subject in a data listing.

13.7. Electrocardiograms

All ECG, ECHO, MUGA results will be presented by Cohort and subject in data listings.

13.8. Eastern Cooperative Oncology Group (ECOG) Performance Status

ECOG performance status results will be summarized by Cohort and overall at baseline, each scheduled post-baseline visit with counts and proportion of subjects with each score for the mITT population. For subjects less than 10 years of age, Lansky scores will be listed instead of ECOG.

If there are multiple assessments on the same visit the worst ECOG status will be used.

13.9. Concomitant Medications

Concomitant medications will be summarized by the WHO Drug Dictionary Anatomical Therapeutic Chemical 3rd level (ATC-3) and preferred name by Cohort and overall for the mITT population. If the 3rd level term is not available, the next available level (e.g., ATC-2) will be used.

The number and proportion of the subjects who took each medication will be tabulated by the ATC-3 level and preferred name for concomitant medications. A subject will only be counted once within each ATC-3 code and within each preferred name.

All concomitant medication data will be listed by subject.

14. QUALITY CONTROL

All data displays and analyses will adhere to the International Conference on Harmonisation (ICH) *Harmonized Tripartite Guideline: Structure and Content of Clinical Study Reports (ICH Topic E3)*.

GSK will review all tables, listings, and figures prior to final database lock. Final SAS datasets, programs and outputs will be transferred to GSK at project completion.

15. TABLES AND LISTINGS CONVENTIONS

Mock-ups for statistical tables and listings will be provided. Final formats for the statistical tables and listings may deviate from these mock-ups upon agreement with GSK.. Footnotes will be used as needed to clarify the information that is presented in the tables and listings. Unless otherwise requested by GSK the term 'subject' will be used in all tables and listings, in accordance with CDISC standards.

The general layout of tables and listings will be as follows:

GlaxoSmithKline Page x of y

Protocol: GSK208466/ADP-04511 Run Date: DDMMMYY-HH:MM

<Population>

Listing 16.2_x (or Table 14.x_x)

<Title>

Col 1 Col 2 Col 3 etc

<Any footnotes>

File Name: <pathname for SAS program>

All tables and listings will use landscape orientation. Margins will be at least 2.0 cm at the top and bottom and at least 0.8 cm on the left and right, excluding headers and

footers, in accordance with electronic Common Technical Document (eCTD) guidelines. Font will be Courier New, unless otherwise specified, with an 8-point font size in most cases. Page numbering will be sequential within each table, listing, and figure. Column headers should be in initial capital letters. Units for numeric data will be included when appropriate.

Tables and data listings will be created from different SAS programs. A single program may produce multiple tables or multiple data listings from the same dataset (e.g., all clinical chemistry data listings may be generated by a single program).

Statistical Table Conventions

Mock-ups for statistical tables will include headers, title numbers, titles, column headers and footers, and a proposed layout for the display of data. The final decision on the precision (i.e., number of decimal places) for presentation of descriptive statistics will be made by GSK after review of draft statistical tables and before database freeze.

Data Listing Conventions

Mock-ups for data listings will include headers, title numbers, titles, column headers, and footers. Data listings will provide all data collected on the corresponding eCRF page or provided by external vendors, unless otherwise indicated. If there are too many fields to be fit into a single page, data should be grouped logically and the listings will be generated as Part I, Part II, etc.

In general, data listings should include all subjects with data. However, if only subjects who meet a certain condition are listed (e.g., subjects with SAEs) and no subjects meet the condition, the data listing will so indicate.

The sort order for data presented in data listings will be Cohort and subject ID, unless otherwise requested by Updated... Within a subject, data will be listed in chronological order. Whenever possible, formatted values will be displayed (i.e., decoded). Where applicable, calendar date and study day of evaluations/events will be provided in the data listings.

16. REFERENCES

Eisenhauer EA, et al. New response evaluation criteria in solid tumors: Revised RECIST guideline (version 1.1) 2009; Eur J Ca 45:228-247.

Wolchok JD, Hoos A, O'Day S, Weber JS, Hamid O, Lebbé C et al. Guidelines for the Evaluation of Immune Therapy Activity in Solid Tumors: Immune-Related Response Criteria Clin Cancer Res 2009;15:7412-7420.

17. PRELIMINARY LIST OF TABLES, LISTINGS, AND FIGURES TO BE PROGRAMMED

17.1. Statistical Tables

Table Number	Table Title	Analysis Population
6.1001	Subject Enrollment and Disposition	ITT
6.2001	Demographic and Baseline Characteristics	ITT
6.2002	Demographic and Baseline Characteristics	mITT
6.3001	Summary of Medical History	ITT
6.4001	Summary of Prior Cancer Therapy	ITT
6.4002	Summary of Prior Cancer Therapy	mITT
7.1001	Summary of Overall Response Rate and Best Overall Response for the First Infusion	mITT
7.1002	Summary of Overall Response Rate and Best Overall Response for the Second Infusion	Subjects with a Second T Cell Infusion
7.2001	Time in Study, Time to Response, Duration of Response, and Kaplan-Meier Estimate of Duration of Stable Disease	mITT
7.2002	Kaplan-Meier Estimate of Progression-Free Survival and Overall Survival	mITT
7.2101	Sensitivity Analyses for Best Overall Response for the First Infusion	mITT
7.2103	Sensitivity Analyses for Progression-Free Survival	mITT
8.0001	Summary of Lymphodepleting Chemotherapy Administration for the First Infusion	mITT
8.0002	Summary of the First T Cell Infusion	mITT
8.0003	Summary of the Second T Cell Infusion	Subjects with a Second T Cell Infusion
8.1001	Overall Summary of Adverse Events for Period 1	ITT
8.1003	Overall Summary of Adverse Events for Period 2	mITT
8.1101	Incidence of Adverse Events by System Organ Class and Preferred Term for Period 1	ITT
8.1103	Incidence of Adverse Events by System Organ Class and Preferred Term for Period 2	mITT
8.1104	Summary of Adverse Events Grouped by Similarity of Preferred Terms for Period 1	ITT
8.1106	Summary of Adverse Events Grouped by Similarity of Preferred Terms for Period 2	mITT

Table Number	Table Title	Analysis Population
8.1201	Incidence of Adverse Events by Toxicity Grade and Preferred Term for Period 1	ITT
8.1203	Incidence of Adverse Events by Toxicity Grade and Preferred Term for Period 2	mITT
8.1204	Incidence of Treatment Related Adverse Events by Toxicity Grade and Preferred Term for Period 2	mITT
8.1205	Incidence of Treatment Related Adverse Events by System Organ Class and Preferred Term for Period 1	mITT
8.1206	Incidence of Treatment Related Adverse Events by System Organ Class and Preferred Term for Period 2	mITT
8.1301	Incidence of Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 1	ITT
8.1303	Incidence of Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 2	mITT
8.1305	Incidence of Treatment Related Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 1	mITT
8.1306	Incidence of Treatment Related Adverse Eventswith Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 2	mITT
8.1401	Incidence of Serious Adverse Events by System Organ Class and Preferred Term for the Pre-leukapheresis Period	ITT
8.1402	Incidence of Serious Adverse Events by System Organ Class and Preferred Term for Period 1	ITT
8.1404	Incidence of Serious Adverse Events by System Organ Class and Preferred Term for Period 2	mITT
8.1502	Incidence of Treatment Related Serious Adverse Events by System Organ Class and Preferred Term for Period 1	mITT
8.1503	Incidence of Treatment Related Serious Adverse Events by System Organ Class and Preferred Term for Period 2	mITT
8.1504	Incidence of Serious Adverse Events by Toxicity Grade and Preferred Term for Period 1	ITT
8.1505	Incidence of Serious Adverse Events by Toxicity Grade and Preferred Term for Period 2	mITT
8.1506	Incidence of Treatment Related Serious Adverse Events by Toxicity Grade and	mITT

Table Number	Table Title	Analysis Population
	Preferred Term for Period 2	
8.1601	Incidence of Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for the Pre-leukapheresis Period	ITT
8.1602	Incidence of Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 1	ITT
8.1604	Incidence of Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 2	mITT
8.1606	Incidence of Treatment Related Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for the Period 1	mITT
8.1607	Incidence of Treatment Related Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for the Period 2	mITT
8.1608	Incidence of Serious Adverse Events Resulting in Death by System Organ Class and Preferred Term for the Pre-leukapheresis Period	ITT
8.2101	Incidence of Serious Adverse Events Resulting in Death by System Organ Class and Preferred Term for Period 1	ITT
8.2103	Incidence of Serious Adverse Events Resulting in Death by System Organ Class and Preferred Term for Period 2	mITT
8.3001	Overall Summary of Adverse Events for the Post-lymphodepletion Period for the Second T Cell Infusion	Subjects with a Second T Cell Infusion
8.3002	Incidence of Adverse Events by System Organ Class and Preferred Term for the Post-lymphodepletion Period for the Second T Cell Infusion	Subjects with a Second T Cell Infusion
8.3003	Incidence of Adverse Events by Toxicity Grade and Preferred Term for the Post-lymphodepletion Period for the Second T-Cell Infusion	Subjects with a Second T-Cell Infusion
8.3004	Incidence of Treatment Related Adverse Events by System Organ Class and Preferred Term for the Post- lymphodepletion Period for the Second T-Cell Infusion	Subjects with a Second T-Cell Infusion
8.3005	Incidence of Serious Adverse Events by System Organ Class and Preferred Term for the Post-	Subjects with a Second T-Cell

Table Number	Table Title	Analysis Population
	lymphodepletion Period for the Second T-Cell Infusion	Infusion
8.3006	Incidence of Treatment Related Adverse Events by Toxicity Grade and Preferred Term for the Post- lymphodepletion Period for the Second T-Cell Infusion	Subjects with a Second T-Cell Infusion
8.3007	Incidence of Serious Adverse Events by Toxicity Grade and Preferred Term for the Post- lymphodepletion Period for the Second T-Cell Infusion	Subjects with a Second T-Cell Infusion
8.3008	Incidence of Treatment Related Serious Adverse Events by Toxicity Grade and Preferred Term for the Post- lymphodepletion Period for the Second T-Cell Infusion	Subjects with a Second T-Cell Infusion
8.3101	Summary of Adverse Events of Special Interest by Cohort (All Infusions)	mITT
8.3102	Summary of Adverse Events of Special Interest for the First Infusion	mITT
8.3103	Summary of Adverse Events of Special Interest by Cohort for the Second Infusion	Subjects with a Second T-Cell Infusion
8.3104	Summary of Characteristics of Guillain-Barre Syndrome (All Infusions)	mITT
8.3105	Summary of Characteristics of Graft versus Host Disease (All Infusions)	mITT
8.3106	Summary of Characteristics of Cytokine Release Syndrome (All Infusions)	mITT
8.3107	Summary of Characteristics of Recurrent Pancytopenia/Aplastic Anaemia (All Infusions)	mITT
8.3108	Summary of Characteristics of Encephalopathy (All Infusions)	mITT
8.3109	Summary of Characterisics of Guillain-Barre Syndrome (Second Infusion)	Subjects with a Second T-Cell Infusion
8.3110	Summary of Characteristics of Graft versus Host Disease (Second Infusion)	Subjects with a Second T-Cell Infusion
8.3111	Summary of Characteristics of Cytokine Release Syndrome (Second Infusion)	Subjects with a Second T-Cell Infusion
8.3112	Summary of Characteristics of Recurrent Pancytopenia/Aplastic Anaemia (Second Infusion)	Subjects with a Second T-Cell Infusion
8.3113	Summary of Characteristics of Encephalopathy	Subjects with a

Table Number	Table Title	Analysis Population
	(Second Infusion)	Second T-Cell Infusion
8.3114	Summary of Onset and Duration of the First Occurrence of Guillain-Barre Syndrome	mITT
8.3115	Summary of Onset and Duration of the First Occurrence of Graft versus Host Disease	mITT
8.3116	Summary of Onset and Duration of the First Occurrence of Cytokine Release Syndrome	mITT
8.3117	Summary of Onset and Duration of the First Occurrence of Recurrent Pancytopenia/Aplastic Anaemia	mITT
8.3118	Summary of Onset and Duration of the Last Occurrence of Encephalopathy	mITT
8.3119	Summary of Onset and Duration of the Last Occurrence of Guillain-Barre Syndrome	mITT
8.3120	Summary of Onset and Duration of the Last Occurrence of Graft versus Host Disease	mITT
8.3121	Summary of Onset and Duration of the Last Occurrence of Cytokine Release Syndrome	mITT
8.3122	Summary of Onset and Duration of the Last Occurrence of Recurrent Pancytopenia/Aplastic Anaemia	mITT
8.3123	Summary of Onset and Duration of the Last Occurrence of Encephalopathy	mITT
8.3124	Summary of Adverse Events of Special Interest by Cohort (Comprehensive List - All Infusions)	mITT
8.3125	Summary of Adverse Events of Special Interest for the First Infusion (Comprehensive List)	mITT
8.3126	Summary of Adverse Events of Special Interest by Cohort for the Second Infusion (Comprehensive List)	Subjects with a Second T-Cell Infusion
8.3127	Summary of Characteristics of Haematopoietic Cytopenias (Comprehensive List-All Infusions)	mITT
8.3128	Summary of Characteristics of Haematopoietic Cytopenias (Comprehensive List-Second Infusion)	Subjects with a Second T-Cell Infusion
8.3129	Summary of Onset and Duration of the First Occurrence of Haematopoietic Cytopenias (Comprehensive List)	mITT
8.3201	Time to Resolution of Grade >= 3 Haematopoietic Cytopenias (Comprehensive List)	mITT
8.3202	Time to Resolution of Grade >=3 Recurrent Pancytopenia/Aplastic Anaemia	mITT

Table Number	Table Title	Analysis Population
8.3203	Time to Resolution of Grade >=3 Graft versus Host Disease	mITT
8.3204	Time to Resolution of Grade >=3 Cytokine Release Syndrome	mITT
8.4101	Change from Baseline to Each Scheduled Visit for Hematology Parameters for the Post-lymphodepletion Period	mITT
8.4102	Change from Baseline to Each Scheduled Visit for Chemistry Parameters for the Post-lymphodepletion Period	mITT
8.4201	Shifts from Baseline to Worst Post-Baseline NCI-CTCAE Grade for Hematology Parameters for the Post-lymphodepletion Period	mITT
8.4202	Shifts from Baseline to Worst Post-Baseline NCI-CTCAE Grade for Chemistry Parameters for the Post-lymphodepletion Period	mITT
8.4301	Number and Proportion of Subjects with Potentially Clinically Significant Hepatic Post-Baseline Results for the Post-lymphodepletion Period	mITT
8.5001	Maximum Persistence and Time to Maximum Persistence for Responders, Non-responders, and Overall	mITT
8.5002	Number and Proportion of RCL Positive Subjects	mITT
8.5003	Number and Percentage of Subjects with Potentially Clinically Significant Post-Baseline Vital Signs Results	mITT
8.6101	Summary of ECOG Performance Status at Each Visit	mITT

17.2. Data Listings

Number	Title
26.0001	Subject Disposition
26.0002	Study Visits
Protocol Deviations	
26.1401	Inclusion and Exclusion Criteria Not Met Prior to Leukapheresis
26.1403	Protocol Deviations

Number	Title
Demographic Data	
26.1101	Demographics and Baseline Characteristics
26.3101	Medical History
26.3102	HLA and NY-ESO Antigen
26.2101	Disease Characteristics
26.4001	Prior Cancer Surgery
26.4002	Prior Oncology Treatment
Study Drug Administration	
28.0001	Dates of Leukapheresis, Lymphodepleting Chemotherapy, and T-Cell Infusion
28.0002	Lymphodepleting Chemotherapy
28.0003	T Cell Infusion
Individual Efficacy Response Data	
27.0001	Lesion Measurements and Assessments by RECIST 1.1
27.0003	Response Assessments and Overall Response by RECIST v1.1 for the First Infusion
27.0004	Response Assessments and Overall Response by RECIST v1.1 Following a Second T Cell Infusion
27.0005	Investigator RECIST v1.1 Response Assessments and Overall Response for the First Infusion
27.00051	Investigator RECIST v1.1 Response Assessments and Overall Response Following a Second T Cell Infusion
27.0007	Progression-Free Survival and Overall Survival
27.0008	Time to Confirmed Response, Duration of Response, and Duration of Stable Disease, and Best Overall Response
Adverse Event Listings	
28.1001	Adverse Events for First T-Cell Infusion
28.1002	Adverse Events for Second T-Cell Infusion
28.1003	Adverse Events with CTCAE Grade 3 or Higher
28.2001	Serious Adverse Events
28.3001	Cytokine Release Syndrome (CRS)
28.3002	Graft Versus Host Disease (GVHD)
28.3003	Recurrent pancytopenia with bone marrow failure/Aplastic anemia
28.3004	Guillain-Barre syndrome
28.3005	Encephalopathy syndrome
Listings of Individual Laboratory Measurements	
28.3101	Hematology Evaluations - Part 1
28.3111	Hematology Evaluations - Part 2

Number	Title
28.3121	Hematology Evaluations - Part 3
28.3131	Clinically Significant Hematology Findings
28.3132	Listing of Subjects with Potentially Clinically Significant Hepatic Post-Baseline Results the Post-lymphodepletion Period
28.3201	Clinical Chemistry Evaluations - Part 1
28.3211	Clinical Chemistry Evaluations – Part 2
28.3221	Clinical Chemistry Evaluations – Part 3
28.3231	Clinically Significant Clinical Chemistry Findings
28.3301	Urinalysis Evaluations – Part 1
28.3311	Urinalysis Evaluations – Part 2
28.3321	Urinalysis Evaluations – Part 3
28.3331	Clinically Significant Urinalysis Findings
28.3341	Additional Laboratory Assessments
28.3342	Clinically Significant Additional Laboratory Findings
28.3343	Renal Function Findings
28.4001	Replication Competent Lentivirus (RCL)
28.4002	Persistence
28.4101	Cytokines – Part 1
28.4102	Cytokines – Part2
28.4201	Biopsy – Tumor Antigen Results
28.4301	Flow Cytometry
28.5001	Pregnancy Test Results
28.5101	Vital Signs
28.5102	Listing of Subjects with Potentially Clinically Significant Post-Baseline Vital Signs Results
28.5201	ECOG Performance Status, Karnofsky Score, and Lansky Score
28.6101	Electrocardiogram
28.6201	Physical Examination
28.6301	Concomitant Medications
28.6401	Bridging Therapies
28.6402	On-study Surgery
28.6403	On-study Oncology Treatment
28.6404	Echocardiogram or Multigated Acquisition Scan (MUGA)
28.6502	EBV and Anti-CMV Status
28.6503	Infectious Disease Testing

17.3. Figures

Number	Figure Title	Analysis Population
17.0001	Maximal Reduction in Sum of Diameters of Target Lesions from Baseline through Progression or Prior to Subsequent Anti-Cancer Therapy for the First Infusion	mITT
17.0002	Maximal Reduction in Sum of Diameters of Target Lesions from the Second Infusion through Progression or Subsequent Anti-Cancer Therapy	mITT
17.1001	Kaplan-Meier Plot of Progression-Free Survival	mITT
17.1002	Kaplan-Meier Plot of Overall Survival	mITT
17.2001	Response Characteristics via RECIST 1.1 and Follow-up	mITT
17.3001	Boxplots for Peak Expansion by Responders vs. Non-Responders for the First Infusion	mITT
17.4001	Spider Plots for Persistence Results over Time (Truncated at 60 Days) for Responders vs. Non-Responders for the First Infusion	mITT
17.4002	Spider Plots for Persistence Results over Time (Truncated at 100 Days) by Responders vs. Non-Responders for the First Infusion	mITT
17.4003	Spider Plots for Persistence Results over Time by Responders vs. Non-Responders for the First Infusion	mITT
17.4004	Spider Plots of Change from Baseline in Target Lesion through Progression and Prior to Subsequent Anti-Cancer Therapy Over Time by Response Status for the First Infusion	mITT
17.4005	Spider Plots for Persistence Results over Time (Truncated at 60 Days) by Responders vs. Non-Responders for the Second Infusion	mITT
17.4006	Spider Plots for Persistence Results over Time (Truncated at 100 Days) by Responders vs. Non-Responders for the Second Infusion	mITT
17.4007	Spider Plots for Persistence Results over Time by Responders vs. Non-Responders for the Second Infusion	mITT
17.4008	Spider Plots of Change from Baseline in Target Lesion through Progression and Prior to Subsequent Anti-Cancer Therapy Over Time by Response Status for the Second Infusion	mITT
18.5003	Characteristics of CRS Plot for the First Infusion	mITT
18.5004	Characteristics of CRS Plot for the Second Infusion	Subjects with a Second T-Cell Infusion
18.5005	Characteristics of Recurrent Pancytopenia with Bone Marrow Failure/Aplastic Anemia Plot for the First Infusion	mITT
18.5006	Characteristics of Recurrent Pancytopenia with Bone Marrow Failure/Aplastic Anemia Plot for the Second	Subjects with a Second T-

Number	Figure Title	Analysis Population
	Infusion	Cell Infusion
18.5101	Profile of INF-Gamma by CRS Status and Subject (First Infusion)	mITT
18.5102	Profile of IL-6 by CRS Status and Subject (First Infusion)	mITT
18.5103	Profile of IL-8 by CRS Status and Subject (First Infusion)	mITT
18.5104	Profile of IL-12 by CRS Status and Subject (First Infusion)	mITT
18.5105	Profile of IL-13 by CRS Status and Subject (First Infusion)	mITT
18.5106	Profile of TNF-Alpha by CRS Status and Subject (First Infusion)	mITT
18.5107	Profile of INF-Gamma by Response and Subject (First Infusion)	mITT
18.5108	Profile of IL-6 by Response and Subject (First Infusion)	mITT
18.5109	Profile of IL-8 by Response and Subject (First Infusion)	mITT
18.5110	Profile of IL-12 by Response and Subject (First Infusion)	mITT
18.5111	Profile of IL-13 by Response and Subject (First Infusion)	mITT
18.5112	Profile of TNF-Alpha by Response and Subject (First Infusion)	mITT
18.5113	Peak Cytokine Expression of INF-Gamma by CRS Status (First Infusion)	mITT
18.5114	Peak Cytokine Expression of IL-6 by CRS Status (First Infusion)	mITT
18.5115	Peak Cytokine Expression of IL-8 by CRS Status (First Infusion)	mITT
18.5116	Peak Cytokine Expression of IL-12 by CRS Status (First Infusion)	mITT
18.5117	Peak Cytokine Expression of IL-13 by CRS Status (First Infusion)	mITT
18.5118	Peak Cytokine Expression of TNF-Alpha by CRS Status (First Infusion)	mITT
18.5119	Peak Cytokine Expression of INF-Gamma by Response (First Infusion)	mITT
18.5120	Peak Cytokine Expression of IL-6 by Response (First Infusion)	mITT
18.5121	Peak Cytokine Expression of IL-8 by Response (First Infusion)	mITT
18.5122	Peak Cytokine Expression of IL-12 by Response (First Infusion)	mITT
18.5123	Peak Cytokine Expression of IL-13 by Response (First Infusion)	mITT
18.5124	Peak Cytokine Expression of TNF-Alpha by Response (First Infusion)	mITT

18. APPENDICES

18.1. Appendix 1 Safety Laboratory Tests by Category

Urinalysis

- Specific gravity
- Urine glucose
- Urine protein
- Urine biliburin
- Urine ketones
- Urine blood
- PH
- Urine leukocytes

Hematology

- WBC
- RBC
- Hemaglobin
- Hematocrit
- Platelet count
- Absolute neturophil count
- Absolute lymphocyte count
- Absolute monocyte count
- Absolute eosinophil count
- Reticulocyte count

Chemistry

- Creatinine clearance
- BUN
- Creatinine
- Sodium
- Potassium
- Chloride
- CO2
- Calcium
- Magnesium
- Albumin
- Total Bilirubin
- Alkaline Phosphatase
- AST
- ALT
- LDH
- Phosphorus

- Ferritin
- C-reactive protein
- Direct Bilirubin
- Uric Acid
- Amylase
- Lipase

Coagulation

- PT
- PTT

Pregnancy Test

- Urine pregnancy test
- serum pregnancy test

Additional Lab

- TSH
- T3
- T4

18.2. Appendix 2 List of PTs to Be Combined

The following synonyms will be combined under the PT as shown below. The combined term will be used when reporting AE data in tables by PT.

Synonymous terms will be combined regardless of body system.

Synonym	**MedDRA Preferred terms (System Organ Class)**
Anaemia/Red blood cell count decreased	Anaemia (Blood and lymphatic system disorders)
Cytokine Release Syndrome (CRS)	Cytokine Release Syndrome (Immune System Disorders) Cytokine Storm (Immune System Disorders)
Acute GVHD – Skin	Acute graft versus host disease in skin
Acute GVHD - Gut (Liver and Intestine)	Acute graft versus host disease in liver Acute graft versus host disease in intestine
Acute GVHD - Other (Lung, Bone Marrow, not specified)	Acute graft versus host disease
Chronic GVHD - Skin	Chronic graft versus host disease in skin
Acute GVHD - Gut (Liver and Intestine)	Acute graft versus host disease in liver Acute graft versus host disease in intestine
Acute GVHD - Other (Lung, Bone Marrow, not specified)	Acute graft versus host disease
Chronic GVHD - Skin	Chronic graft versus host disease in skin
Chronic GVHD - Gut (Liver and Intestine)	Chronic graft versus host disease in liver

Synonym	**MedDRA Preferred terms (System Organ Class)**
	Chronic graft versus host disease in intestine
Chronic GVHD Other - (Lung, Bone Marrow, not specified)	Chronic graft versus host disease
Unspecified GVHD - Skin	Graft versus host disease in skin
Unspecified GVHD - Gut (Liver and Intestine)	Graft versus host disease in liver Graft versus host disease in gastrointestinal tract
Unspecified GVHD - Other (Lung, Bone Marrow, not specified)	Graft versus host disease Graft versus host disease in eye Graft versus host disease in lung Prophylaxis against graft versus host disease Transfusion associated graft versus host disease Engraftment syndrome
Leukopenia/WBC decreased	White blood cell count decreased (Investigations) Leukopenia (Blood and lymphatic system disorders)
Lymphopenia/Lymphocyte count decreased	Lymphopenia (Investigations) Lymphocyte count decreased (Investigations) CD4 lymphocytes decreased (Investigations) CD8 lymphocytes decreased
Neutropenia/Neutrophil count decreased	Neutrophil count decreased (Investigations) Neutropenia (Blood and lymphatic system disorders)

Synonym	MedDRA Preferred terms (System Organ Class)
Rash/Rash maculo-papular	Rash maculo-papular Rash Rash erythematous
Thrombocytopenia/Platelet count decreased	Platelet count decreased (Investigations) Thrombocytopenia (Blood and lymphatic system disorders)

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The AE listing will not combine these PTs but list them out as they are reported.

18.3. Appendix 3 Specification for Collapsing Adverse Event Segments

This section provides the specification for collapsing the segments of adverse events with common preferred term and with either overlapped/or continuous start/end dates into unique adverse events (AEs) based on ADAE ADaM SAS dataset.

1. COLLAPSING AE SEGMENTS WITH A COMMON AE PREFERRED TERM (PT) INTO UNIQUE EVENTS BASED ON THE START AND END DATES

For each unique subject, the AE records (segments) with the same AE preferred term will be collapsed into one unique AE event based on the start and end dates below.

1.1 Multiple AE Segments with Overlapped or Continuous Start/End Dates

Multiple AE segments with a common preferred term (PT, variable=ADAE.AEDECOD) that occurred around the same time; defined as:

If a segment starts no more than one day (i.e., ≤ 1 day) prior, on, or after the previous segment's end date, it is considered as an 'event'.

If the gap between the start date of a segment and the end date of previous segment is greater than one complete day (i.e., > 1 day), then consider these segments as different events.

If partial start or end dates for any AE segments, then consider these segments as separate events.

*** **NOTE: Handling of partial dates or completely missing dates**

Partial dates or completely missing dates will not be imputed.

The reason for not using imputed dates is due to the small number of partial / or completely missing dates. Furthermore, using imputed dates might create additional error of up to 30 days off for the AE start or AE end dates, and can be up to 60 days off for the duration of AE.

1.2 Sort Adverse Events (AE)

For any AE event identified above:

- Sort the AEs segments by study ID (ADAE.STUDYID), unique subject ID (ADAE.USUBJID), AE preferred term (ADAE.AEDECOD), AE start date (ADAE.AESTDTC), and AE end date (ADAE.AEENDTC). The

sorting will include all AE segments with complete or partial start / end dates.

1.3 Create Derived Variables in ADAE ADaM SAS Dataset

Based on the ADAE dataset sorted above under Section 1.2, for each unique subject, create the following derived variables in the ADAE ADaM SAS data set:

1) **ANL01FL: Flag for the unique AE**

   a) Collapsed AE Segments

   For collapsed AE segments. based on the ADAE data set sorted above under Section 1.2:

   - derive the flag variable: **ANL01FL="Y" on the first record for each collapsed AE (i.e. the earliest segment within each collapsed AE with the same ADAE.AEDECOD)** .
   - **Otherwise ANL01FL="" (Missing).**

   b) AE Events Comprised of a Single Row (No Collapsing Needed)

   - derive the flag variable: **ANL01FL="Y" for each single segment AE event**.

2) **EVTSEQ: Sequence number of each unique AE with the same PT**

   Create a sequence number, EVTSEQ, for each unique AE within the same ADAE.AEDECOD.

   For each unique subject within each unique AE preferred term, this variable will be recorded as **the sequential number to identify all unique adverse events (including both single segment events (i.e., no collapsing needed) and collapsed events from multiple segments) based on the sorting order chronologically addressed above under Section 1.2.**

   a) Collapsed AE Segments

   Each collapsed AE and its corresponding composed segments will have the same sequence numbers (i.e., if multiple segments/records are qualified for being collapsed into one unique AE (i.e, all those records will have same value for the derived variable EVTSEQ for that corresponding subject within the same collapsed AE).

b) Single Segment AE Records

Each single segment AE event (i.e., un-collapsed event) will have different unique sequence number separately

c) AE Segments with partial start or end dates

Each AE segment with partial start or end dates will have different unique sequence number starting from 99XXX, where

XXX=001, 002, ...

*** NOTE:**

For those subjects who received 2 T-cell infusions, the sequential number will be based on both infusion periods combined

(i.e., the assigned sequential number will be independent of T-cell infusion periods).

- **Example:**

Original ADAE Dataset:

SUBJID	ADECODE	APERIOD	ASTDT	AENDT
PPD	Cytokine Release Syndrome	1	PPD	PPD
	Cytokine Release Syndrome	1	PPD	PPD
	Cytokine Release Syndrome	1	PPD	PPD
	Cytokine Release Syndrome	2	PPD	PPD

Derived ADAE Dataset:

SUBJID	ADECODE	APERIOD	ASTDT	AENDT	ANL01FL	EVTSEQ
PPD	Cytokine Release Syndrome	1	PPD	PPD	Y	**1**
	Cytokine Release Syndrome	1	PPD	PPD		**1**
	Cytokine Release Syndrome	1	PPD	PPD		**1**
	Cytokine Release Syndrome	2	PPD	PPD	Y	**2**

3) **EVTENDT: End Date for each unique AE**

   a) **Collapsed AE Segments**

   - **=ADAE.AENDT (end date) of the last segment of the collapsed event** (i.e., the segment with the latest ADAE.AENDT within the same collapsed AE for each unique subject)
   - **This should be populated on the segment with ANL01FL='Y' only (i.e., the segment with earliest ADAE.ASTDT of each collapsed AE).** .
   - **Note:**
     If any of the segments have missing end date (i.e., unresolved) then the derived EVTENDT will be missing, and hence cannot calculate duration of event (please see derived variable: EVTDUR under item 4) below).

   b) **Single Segment AE Records**

   =ADAE.AENDT (end date) of each single segment event (i.e. un-collapsed record).

4) **EVTDUR: Duration of each unique AE**
   a) **Collapsed AE Segments**
      - Where **ANL01FL='Y' then EVTDUR = AESTDT-EVTENDT+ 1**
      - **=** Missing, if missing end date for the derived variable EVTENDT (i.e., AEOUT=unresolved with missing AEENDTC for any of the segments within the same collapsed AE)

   b) **Single Segment AE records**
      - **EVTDUR = AESTDT-EVTENDT (i.e., = AEENDT) + 1**
      - **=** Missing, if missing end date (i.e., missing AEENDT and hence EVTENDT due to AEOUT=unresolved for the corresponding, single segment record (i.e., un-collapsed AE record).

2. ADDITIONAL NOTES

- **For any collapsed AEs and single segment records with missing or partial start and/or end dates,**
  - **EVTDUR= missing and will be excluded from the calculation for the summary statistics of AE duration.**

- **AOCCPFL: Flag for the first occurrence of preferred term**
  - This variable is a GSK standard variable in the ADAE ADaM SAS data set, which can be used to capture the first AE onset date for each unique AE preferred term.

3. DATA EXAMPLES

3.1 Case #1: Previous AE End Date is Same as Next AE Start Date

Original ADAE Dataset

USUBJID	AEDECOD	ASTDT	AENDT	APERIOD	ATOXGRN	AREL1	AEOUT	AEACN
PPD	Cytokine release syndrome	PPD	PPD	1	1	Y	RECOVERED/RESOLVED	NOT APPLICABLE
	Cytokine release syndrome	PPD	PPD	1	2	Y	RECOVERED/RESOLVED	NOT APPLICABLE
	Cytokine release syndrome	PPD	PPD	2	2	N Y	RECOVERED/RESOLVED	NOT APPLICABLE
	Cytokine release syndrome	PPD	PPD	2	3	Y	RECOVERED/RESOLVED	NOT APPLICABLE

In the above example, this subject had 4 CRS records with the first two occurred after the 1st T-cell infusion, and the last two occurred after the 2nd T-cell infusion. The first two segments can be collapsed into one single CRS event since the 2nd segment started on the same date as the end date of the 1st segment. Similarly, the 3rd and 4th segment post the 2nd T-cell infusion can be collapsed into one other CRS event due to the same reason.

Below please see **the derived variables** added into ADAE ADaM SAS dataset.

Derived ADAE Dataset

USUBJID	AEDECOD	ASTDT	AENDT	APERIOD	ATOXGRN	AREL1	AEOUT	AEACN	ANL01FL	EVTSEQ	EVTENDT	EVTDUR	AOCCPFL
PPD	Cytokine release syndrome	PPD	PPD	1	1	Y	RECOVERED/RESOLVED	NOT APPLICABLE	Y	1	PPD	3	
	Cytokine release syndrome	PPD	PPD	1	2	Y	RECOVERED/RESOLVED	NOT APPLICABLE		1			
	Cytokine release syndrome	PPD	PPD	2	2	N	RECOVERED/RESOLVED	NOT APPLICABLE	Y	2	PPD	14	
	Cytokine release syndrome	PPD	PPD	2	3	Y	RECOVERED/RESOLVED	NOT APPLICABLE		2			

3.2 Case #2: Previous AE Start Date is Same as Next AE Start Date

Unique Subject Identifier	Dictionary-Derived Term	Sequence Number	Outcome of Adverse Event	Standard Toxicity Grade	Action Taken with Study Treatment	Causality	Start Date/Time of Adverse Event	End Date/Time of Adverse Event	ANL01FL	evtseq	evtendt	evtdur
PPD	Nausea	22	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD	Y	1	PPD	9
PPD	Nausea	25	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD		1	.	.
PPD	Nausea	23	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD	Y	2	PPD	18
PPD	Nausea	24	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD		2	.	.
PPD	Nausea	26	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD		2	.	.
PPD	Nausea	27	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD		2	.	.
PPD	Vomiting	43	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD	Y	1	PPD	9
PPD	Vomiting	46	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD		1	.	.

3.3 Case #3: Next AE Start Date is One Day after Previous AE End Date

Unique Subject Identifier	Dictionary-Derived Term	Sequence Number	Outcome of Adverse Event	Standard Toxicity Grade	Action Taken with Study Treatment	Causality	Start Date/Time of Adverse Event	End Date/Time of Adverse Event	ANL01FL	evtseq	evtendt	evtdur
PPD	Neutrophil count decreased	14	RECOVERED/RESOLVED	4	NOT APPLICABLE	NOT RELATED	PPD	PPD	Y	1	PPD	9
PPD	Neutrophil count decreased	15	RECOVERED/RESOLVED	3	NOT APPLICABLE	NOT RELATED	PPD	PPD		1	.	.
PPD	White blood cell count decreased	21	RECOVERED/RESOLVED	4	DOSE NOT CHANGED	NOT RELATED	PPD	PPD	Y	1	PPD	16
PPD	White blood cell count decreased	22	RECOVERED/RESOLVED	3	NOT APPLICABLE	NOT RELATED	PPD	PPD		1	.	.
PPD	Neutrophil count decreased	12	RECOVERED/RESOLVED	3	DOSE NOT CHANGED	NOT RELATED	PPD	PPD	Y	1	PPD	6
PPD	Neutrophil count decreased	13	RECOVERED/RESOLVED	4	DOSE NOT CHANGED	NOT RELATED	PPD	PPD		1	.	.

3.4 Case #4: Previous AE End Date is Greater Than Next AE Start Date.

Unique Subject Identifier	Dictionary-Derived Term	Sequence Number	Outcome of Adverse Event	Standard Toxicity Grade	Action Taken with Study Treatment	Causality	Start Date/Time of Adverse Event	End Date/Time of Adverse Event	ANL01FL	evtseq	evtendt	evtdur
PPD	Dyspnoea	20	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD	Y	2	PPD	183
PPD	Dyspnoea	17	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD		2	.	.
PPD	Dyspnoea	18	RECOVERED/RESOLVED	2		POSSIBLE	PPD	PPD		2	.	.
PPD	Skin disorder	60	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD	Y	1	PPD	8
PPD	Skin disorder	58	RECOVERED/RESOLVED	1		NOT RELATED	PPD	PPD		1	.	.
PPD	Decreased appetite	32	RECOVERED/RESOLVED	3		NOT RELATED	PPD	PPD	Y	1	PPD	52
PPD	Decreased appetite	34	RECOVERED/RESOLVED	3		POSSIBLE	PPD	PPD		1	.	.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat
(Data as of: 24APR2018)

Table 6.1001
Subject Enrollment and Disposition
ITT Population

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 2-4 Total	Overall
ITT Population	xx	xx	xx	xx	xx	xx
MITT Population	xx	xx	xx	xx	xx	xx
Lymphodepleted	xx	xx	xx	xx	xx	xx
Subject Status at the End of the First Infusion						
Disease progression	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unacceptable toxicity and other safety reasons	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
INVESTIGATOR DISCRETION	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
subject withdrew consent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
protocol violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
termination by sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
failed manufacture of cell product	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
FAILED TO MEET ELIGIBILITY CRITERIA FOR THE SECOND INFUSION	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

ITT = Intent-to-treat, mITT = Modified ITT.
ITT Population = all subjects who were enrolled in the trial (i.e., underwent leukapheresis).
MITT Population = all subjects in the ITT population who received at least one T cell infusion.
Note 1: Denominator for percentages is based on the ITT Population.
Note 2: Subjects who have disease progression are considered to have completed the interventional phase.
Note 3: If withdrawn less than or equal to 60 days since the first infusion, the subject cannot be re-enrolled into the 2nd infusion and only required to provide the status at the end of the study.
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Table 6.1001
Subject Enrollment and Disposition
ITT Population

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 2-4 Total	Overall
Subject Status at the End of the Study						
Disease progression	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unacceptable toxicity and other safety reasons	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
INVESTIGATOR DISCRETION	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
subject withdrew consent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
protocol violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
termination by sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
failed manufacture of cell product	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
FAILED TO MEET ELIGIBILITY CRITERIA FOR THE SECOND INFUSION	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

ITT = Intent-to-treat, mITT = Modified ITT.
ITT Population = all subjects who were enrolled in the trial (i.e., underwent leukapheresis).
MITT Population = all subjects in the ITT population who received at least one T cell infusion.
Note 1: Denominator for percentages is based on the ITT Population.
Note 2: Subjects who have disease progression are considered to have completed the interventional phase.
Note 3: If withdrawn less than or equal to 60 days since the first infusion, the subject cannot be re-enrolled into the 2nd infusion and only required to provide the status at the end of the study.

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Table 6.2001
Demographic and Baseline Characteristics
ITT Population

Parameter	Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Sex	FEMALE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	MALE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Age (years)		N	x	x	x	x	x	x
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min,Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Race	BLACK OR AFRICAN AMERICAN	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	AMERICAN INDIAN OR ALASKA NATIVE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	ASIAN	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	WHITE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	OTHER	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Ethnicity	HISPANIC OR LATINO	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	NOT HISPANIC OR LATINO	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Screening Height (cm)		N	x	x	x	x	x	x
		Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
		Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x

BMI = Body Mass Index, BSA = Body Surface Area, ECOG = Eastern Cooperative Oncology Group, SD = Standard Deviation.
Note 1: Age is the age at informed consent, baseline weight is within 7 days prior to lymnphodepletion, and BMI is calculated using the baseline weight and the height at the Screening visit.
Note 2: ECOG Score: 0 – Fully active and able to carry on all pre-disease activities without restriction, 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light sedentary nature, 2 – Ambulatory and capable of all self-care but unable to carry out any work activities, 3 – Capable of only limited self-care, 4 – Completely disabled, 5 – Dead. Subjects had to have an ECOG score of 0 or 1 to be enrolled in the study.
File Name: S:\..... \&prog_name

Table 6.2001
Demographic and Baseline Characteristics
ITT Population

Parameter	Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Weight (kg)		N	x	x	x	x	x	X
		Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
		Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
BMI(kg/m^2)		N	x	x	X	X	X	X
		Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
		Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
BSA (m^2)		N	x	x	X	X	X	X
		Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
		Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
HLA Status	HLA-A*0201	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	HLA-A*0205	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	HLA-A*0206	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Other	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
NY-ESO Status	Positive High	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Positive Low	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Negative	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Not Evaluable	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

BMI = Body Mass Index, BSA = Body Surface Area, ECOG = Eastern Cooperative Oncology Group, SD = Standard Deviation.
Note 1: Age is the age at informed consent, baseline weight is within 7 days prior to T-cell infusion, and BMI is calculated using the baseline weight and the height at the Screening visit.
Note 2: ECOG Score: 0 – Fully active and able to carry on all pre-disease activities without restriction, 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light sedentary nature, 2 – Ambulatory and capable of all self-care but unable to carry out any work activities, 3 – Capable of only limited self-care, 4 – Completely disabled, 5 – Dead. Subjects had to have an ECOG score of 0 or 1 to be enrolled in the study.
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Table 6.2001
Demographic and Baseline Characteristics
ITT Population

Parameter	Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Disease Stage at Enrollment	Stage I	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Stage II							
	Stage III							
	Stage IV	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	OTHER	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	MISSING							
Type of Histology	MONOPHASIC	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	BIPHASIC	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	OTHER	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Screening ECOG Performance Status	0	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	1	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

BMI = Body Mass Index, BSA = Body Surface Area, ECOG = Eastern Cooperative Oncology Group, SD = Standard Deviation.
Note 1: Age is the age at informed consent, baseline weight is within 7 days prior to T-cell infusion, and BMI is calculated using the baseline weight and the height at the Screening visit.
Note 2: ECOG Score: 0 – Fully active and able to carry on all pre-disease activities without restriction, 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light sedentary nature, 2 – Ambulatory and capable of all self-care but unable to carry out any work activities, 3 – Capable of only limited self-care, 4 – Completely disabled, 5 – Dead. Subjects had to have an ECOG score of 0 or 1 to be enrolled in the study.
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Repeat 6.2001 format for:

Table 6.2002
Demographic and Baseline Characteristics
mITT Population

Note: mITT tables will be provided only if mITT and ITT populations differ.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat

(Data as of: 24APR2018)

Table 6.3001
Summary of Medical History
ITT Population

System Organ Class/ Preferred Term	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Any Medical History	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
SOC 1						
Preferred Term 1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Preferred Term 2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Etc.						
SOC 2						
Preferred Term 1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Preferred Term 2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Etc.						
Etc.						

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Programming note: sort by descending overall SOC and descending overall PT.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Table 6.4001
Summary of Prior Cancer Therapy
ITT Population

Characteristic/ Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Prior Systemic Therapy							
YES	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
NO	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number of Prior Systemic Therapy Regimens							
1	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
2	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Etc.							
Type of Systemic Therapy $							
CHEMOTHERAPY	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
IMMUNOTHERAPY	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
HORMONAL	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
VACCINE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
OTHER	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Time Since Last Systemic Therapy (Days) @	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
Best Response to Last Systemic Therapy							
COMPLETE RESPONSE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PARTIAL RESPONSE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
STABLE DISEASE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
DISEASE PROGRESSION	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
UNKNOWN	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
NOT DONE	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

$ A subject may have more than one response.
@ Time Since Last Systemic Therapy is calculated as the date the informed consent was signed minus the latest therapy end date. Time Since Initial Diagnosis is calculated as the date the informed consent was signed minus the date of initial diagnosis.
# Bridging therapy is therapy administered on or after apheresis and before lymphodepletion.
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Table 6.4001
Summary of Prior Cancer Therapy
ITT Population

Characteristic/ Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Prior Radiotherapy							
YES	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
NO	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Prior Cancer-Related Surgery							
YES	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
NO	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Bridging Therapy #							
YES	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
NO	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Type of Bridging Therapy #							
CHEMOTHERAPY	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
RADIATION	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
OTHER	n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Time Since Initial Diagnosis(Days) @	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x

$ A subject may have more than one response.
@ Time Since Last Systemic Therapy is calculated as the date the informed consent was signed minus the latest therapy end date. Time Since Initial Diagnosis is calculated as the date the informed consent was signed minus the date of initial diagnosis.
# Bridging therapy is therapy administered on or after apheresis and before lymphodepletion.
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Repeat 6.4001 format for:

Table 6.4002
Summary of Prior Cancer Therapy
mITT Population

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 7.1001
Summary of Overall Response Rate and Best Overall Response for the First Infusion
mITT Population

Parameter/ Category or Criterion	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Overall Response Rate (ORR) $					
Derived Response derived based on RECIST V1.1	n (%) 95% Clopper Pearson CI 95% Wilson CI	x (xx.x%) (xx.x, xx.x) (xx.x, xx.x)	x (xx.x%) (xx.x, xx.x) (xx.x, xx.x)	x (xx.x%) (xx.x, xx.x) (xx.x, xx.x)	x (xx.x%) (xx.x, xx.x) (xx.x, xx.x)
Investigator-assessed based on RECIST V1.1	n (%) 95% CI	x (xx.x%) (xx.x, xx.x)	x (xx.x%) (xx.x, xx.x)	x (xx.x%) (xx.x, xx.x)	x (xx.x%) (xx.x, xx.x)
Best Overall Response (BOR) derived based on RECIST V1.1 &					
Complete Response	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Partial Response	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Stable Disease	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progressive Disease	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Unknown or Missing	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

BOR = Best Overall Response, CI = Confidence Interval, ORR = Overall Response Rate.
$ Overall response rate is defined as the proportion of subjects with a confirmed complete response or partial response relative to the total number of subjects in the population.
& Best overall response is the best response recorded from the time of first T cell infusion until disease progression, use of prohibited medications, or surgical resection. If unconfirmed complete or partial response, then the best overall response is stable disease.
Note 1: Subject PPD had a day 3 assessment of PD that is not included in this summary because assessments prior to week 4 were not used in determination of PD.
Note 2: In cohort 2 subject PPD's derived BOR based on RECIST 1.1 is SD but PD per investigator-assessed.
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Repeat Table 7.1001 template for:

Table 7.1002
Summary of Overall Response Rate and Best Overall Response for the Second Infusion
Subjects Who Received Second Infusion

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 7.2001
Time in Study, Time to Response, Duration of Response, and Kaplan-Meier Estimate of Duration of Stable Disease
mITT Population

Parameter/ Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Time to Response (weeks)&	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x	x.x
	Min, Max	x, x	x, x	x, x	x, x
Duration of Response (weeks) @	n	x	x	x	x
	Mean	x.x	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx	x.xx
	Median	x.x	x.x	x.x	x.x
	Min, Max	x, x	x, x	x, x	x, x

CI = Confidence interval, DOR = Duration of Response, TTR = Time to Response, DOSD = Duration of Stable Disease, Q1=25th percentile, Q3=75th percentile, CR = Complete Response, PR = Confirmed Response, PD = Progressive Disease.
Note: Quartiles and 95% CI are from Kaplan-Meier estimate. CIs are from complementary log-log transformation.
& TTR is defined as the interval between the date of first T cell infusion and the earliest date of confirmed complete response (CR) or partial response (PR), and is summarized for those subjects with a confirmed CR or PR.
@ DOR is defined as the time from first documented confirmed CR or PR until first documented disease progression or death due to any cause or surgical resection or start of prohibited medications from any cause. For responders without these events, date of the last study assessment is used.
# DOSD is defined as the interval between the date of first T cell infusion and the first documented disease progression. Subjects who do not have documented disease progression are censored at the date of last disease assessment.
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Table 7.2001
Time in Study, Time to Response, Duration of Response, and Kaplan-Meier Estimate of Duration of Stable Disease
mITT Population

Parameter/ Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Duration of Stable Disease (DOSD) #					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Duration of Stable Disease (weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Time in Study(Days)					
	n	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x

CI = Confidence interval, DOR = Duration of Response, TTR = Time to Response, DOSD = Duration of Stable Disease, Q1=25th percentile, Q3=75th percentile, CR = Complete Response, PR = Confirmed Response, PD = Progressive Disease.
Note: Quartiles and 95% CI are from Kaplan-Meier estimate. CIs are from complementary log-log transformation.
& TTR is defined as the interval between the date of first T cell infusion and the earliest date of confirmed complete response (CR) or partial response (PR), and is summarized for those subjects with a confirmed CR or PR.
@ DOR is defined as the time from first documented confirmed CR or PR until first documented disease progression or death due to any cause or surgical resection or start of prohibited medications from any cause. For responders without these events, date of the last study assessment is used.
# DOSD is defined as the interval between the date of first T cell infusion and the first documented disease progression. Subjects who do not have documented disease progression are censored at the date of last disease assessment.
File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat

(Data as of: 24APR2018)

Table 7.2002
Kaplan-Meier Estimate of Progression-Free Survival and Overall Survival
mITT Population

Parameter/ Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Progression-Free Survival (PFS) &					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PFS (weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Reason for PD/Death					
Increased Tumor Burden	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Death	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Surgical Resection	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Prohibited Medication	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Overall Survival (OS) @					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
OS (weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

CI = Confidence interval, OS = Overall Survival, PFS = Progression-Free Survival, Q1=25th percentile, Q3=75th percentile.
Note: Quartiles and 95% CI are from Kaplan-Meier estimate. CIs are from complementary log-log transformation.
& PFS is defined as the interval between the date of first T cell infusion and first documented disease progression or death due to any cause or surgical resection or start of prohibited medication. Subjects without any of the aforementioned events are censored at the date of last adequate assessment.

@ OS is defined as the interval between the date of first T cell infusion and date of death due to any cause. Subjects who are still alive or lost to follow-up are censored at the date of last contact.

File Name: S:\..... \&prog_name

Note to programmer: Denominator for each reason is number fo subjects with event.

Table 7.2101
Sensitivity Analyses for Best Overall Response for the First Infusion
mITT Population

Sensitivity Analysis/ Response Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Progressive Disease Based on Last Tumor Assessment $					
Complete Response	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Partial Response	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Stable Disease	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progressive Disease	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Unknown or Missing	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Investigator Assessment of Response					
Complete Response	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Partial Response	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Stable Disease	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progressive Disease	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Unknown or Missing	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

BOR = Best Overall Response, CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluable (Unknown or Missing), N/A = Not Applicable.
Note: Best overall response is the best response recorded from the time of first T cell infusion until disease progression, use of prohibited medications, or surgical resection, whichever came first, except as noted in $ footnote.
$ Date of last assessment is used as date of progressive disease in place of start date of prohibited medications or surgical resection.
@ Assign values of SD if the assessments before and after the NE assessment are CR, PR, or SD. Assign PD otherwise, except for PR NE CR where the assessment is improving.
Note: Subject PPD had a day 3 assessment of PD that is not included in this summary because assessments prior to week 4 were not used in determination of PD.

File Name: S:\..... \&prog_name

Table 7.2101
Sensitivity Analyses for Best Overall Response for the First Infusion
mITT Population

Sensitivity Analysis/ Response Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Replace NE with SD or PD @					
Complete Response	n (%)	N/A	x (xx.x%)	x (xx.x%)	x (xx.x%)
Partial Response	n (%)	N/A	x (xx.x%)	x (xx.x%)	x (xx.x%)
Stable Disease	n (%)	N/A	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progressive Disease	n (%)	N/A	x (xx.x%)	x (xx.x%)	x (xx.x%)
Unknown or Missing	n (%)	N/A	x (xx.x%)	x (xx.x%)	x (xx.x%)

BOR = Best Overall Response, CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluable (Unknown or Missing), N/A = Not Applicable.
Note: Best overall response is the best response recorded from the time of first T cell infusion until disease progression, use of prohibited medications, or surgical resection, whichever came first, except as noted in $ footnote.
$ Date of last assessment is used as date of progressive disease in place of start date of prohibited medications or surgical resection.
@ Assign values of SD if the assessments before and after the NE assessment are CR, PR, or SD. Assign PD otherwise, except for PR NE CR where the assessment is improving.
Note: Subject PPD had a day 3 assessment of PD that is not included in this summary because assessments prior to week 4 were not used in determination of PD.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat
Table 7.2103
Sensitivity Analyses for Progression-Free Survival
mITT Population

Sensitivity Analysis/ Response Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Progressive Disease Based on Last Tumor Assessment $					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progression-Free Survival(weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluable (Unknown or Missing).

& PFS is defined as the interval between the date of first T cell infusion and first disease progression, death due to any cause, surgical resection, or start of prohibited medication, except as noted in $ footnote. Subjects without any of the aforementioned events are censored at the date of last study assessment.
$ Subjects are censored at first surgical resection or start of prohibited medications, whichever came first.
@ Assign values of SD if the assessments before and after the NE assessment are CR, PR, or SD. Assign PD otherwise, except for PR NE CR where the assessment is improving.
^ Subjects who discontinued for disease progression but did not meet RECIST criteria for PD are classified as PD at the date of discontinuation.
File Name: S:\..... \&prog_name

Table 7.2103
Sensitivity Analyses for Progression-Free Survival
mITT Population

Sensitivity Analysis/ Response Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Investigator Assessment of Response					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progression-Free Survival(weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Ignore Assessments of NE					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progression-Free Survival(weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluable (Unknown or Missing).

& PFS is defined as the interval between the date of first T cell infusion and first disease progression, death due to any cause, surgical resection, or start of prohibited medication, except as noted in $ footnote. Subjects without any of the aforementioned events are censored at the date of last study assessment.
$ Subjects are censored at first surgical resection or start of prohibited medications, whichever came first.
@ Assign values of SD if the assessments before and after the NE assessment are CR, PR, or SD. Assign PD otherwise, except for PR NE CR where the assessment is improving.
^ Subjects who discontinued for disease progression but did not meet RECIST criteria for PD are classified as PD at the date of discontinuation.
File Name: S:\..... \&prog_name

Table 7.2103
Sensitivity Analyses for Progression-Free Survival
mITT Population

Sensitivity Analysis/ Response Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Replace NE with SD or PD @					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progression-Free Survival(weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Replace NE with SD					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progression-Free Survival(weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluable (Unknown or Missing).
& PFS is defined as the interval between the date of first T cell infusion and first disease progression, death due to any cause, surgical resection, or start of prohibited medication, except as noted in $ footnote. Subjects without any of the aforementioned events are censored at the date of last study assessment.
$ Subjects are censored at first surgical resection or start of prohibited medications, whichever came first.
@ Assign values of SD if the assessments before and after the NE assessment are CR, PR, or SD. Assign PD otherwise, except for PR NE CR where the assessment is improving.
^ Subjects who discontinued for disease progression but did not meet RECIST criteria for PD are classified as PD at the date of discontinuation.

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Table 7.2103
Sensitivity Analyses for Progression-Free Survival
mITT Population

Sensitivity Analysis/ Response Category	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)
Replace NE with PD					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progression-Free Survival(weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Progressive Disease Based on Discontinuation Date for Unconfirmed PD ^					
Subjects with Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number Censored	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Progression-Free Survival(weeks)	N	X	X	X	X
	Q1 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Median (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Q3 (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluable (Unknown or Missing).

& PFS is defined as the interval between the date of first T cell infusion and first disease progression, death due to any cause, surgical resection, or start of prohibited medication, except as noted in $ footnote. Subjects without any of the aforementioned events are censored at the date of last study assessment.
$ Subjects are censored at first surgical resection or start of prohibited medications, whichever came first.
@ Assign values of SD if the assessments before and after the NE assessment are CR, PR, or SD. Assign PD otherwise, except for PR NE CR where the assessment is improving.
^ Subjects who discontinued for disease progression but did not meet RECIST criteria for PD are classified as PD at the date of discontinuation.
File Name: S:\..... \&prog_name

Table 8.0001
Summary Lymphodepleting Chemotherapy Administration for the First Infusion
mITT Population

Regimen	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Initial Treatment @							
Regimen A	n/N	xx/XX	xx/XX	xx/XX	xx/XX	xx/XX	xx/XX
Regimen B	n/N	xx/XX	xx/XX	xx/XX	xx/XX	xx/XX	xx/XX
Regimen C	n/N	xx/XX	xx/XX	xx/XX	xx/XX	xx/XX	xx/XX

Note 1: n = number of subjects with the regimen, N = total number of subjects receiving treatment.
Note 2: Regimen A = Fludarabine 30 mg/m^2 on Days -5 to -2 and Cyclophosphamide 1800 mg/m^2 on Days -5 and -3. Regimen B = Cyclophosphamide 1800 mg/m^2 on Days -3 and -2. Regimen C = Fludarabine 30 mg/m^2 and Cyclophosphamide 600 mg/m^2 on Days -7 to -5.
@ Subjects in Cohort 1 received Regimen A, subjects in Cohort 2 received Regimen A or C, subjects in Cohort 3 received Regimen B, and subjects in Cohort 4 received Regimen C.

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Protocol: GSK208466/ADP-04511 Page 1 of 1
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.0002
Summary of the First T Cell Infusion
mITT Population

Parameter	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Total Number of Transduced Cells (x 10^9)	N	x	X	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xxx	Xxx	xxx	xxx	xxx	xxx
	Min,Max	xxx,xxx	xxx,xxx	xxx,xxx	xxx,xxx	xxx,xxx	xxx,xxx

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.0003
Summary of Second T Cell Infusion
(Subjects with a Second T Cell Infusion)

Parameter	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Total Number of Transduced Cells (x 10^9)	N	x	X	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xxx	Xxx	xxx	xxx	xxx	xxx
	Min,Max	xxx,xxx	xxx,xxx	xxx,xxx	xxx,xxx	xxx,xxx	xxx,xxx

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Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat

(Data as of: 24APR2018)

Table 8.1001
Overall Summary of Adverse Events for Period 1
ITT Population
ADAE.PER01FL = 'Y'
ITTFL = 'Y'
Do not use treatment-emergent flag.
Use ARM

Category	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Subjects with Any AEs	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any AEs Related& to T Cell Therapy RELGR1 = 'Related'	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any AEs >= Grade 3 TOXGGR1 = 'Grade 3 or Higher'	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any AEs Related& T Cell Therapy and Grade >= 3 RELGR1 = 'Related', TOXGGR1 = 'Grade 3 or Higher'	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any AEs Related& T Cell Therapy and Fatal Outcome	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any Serious AEs (SAE) AESER = 'Y'						
Subjects with Any SAEs Related& to T Cell Therapy AESER = 'Y', RELGR1 = 'Related'	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any SAEs >= Grade 3 AESER = 'Y', TOXGGR1 = 'Grade 3 or Higher'	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any SAEs Related& to T Cell Therapy and Grade >= 3 AESER = 'Y', RELGR1='Related',TOXGGR1='Grade 3 or Higher'	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Subjects with Any SAEs with Fatal Outcome AESER = 'Y', AEOUT = 'FATAL'	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

SAE = serious adverse event.
Period 1 = from date of informed consent through end of study.
& Treatment-related: definitely related, probably related, possibly related, or unlikely related to T cell infusion.
File Name: S:\..... \&prog_name
Repeat Table 8.1001 template for:

Table 8.1003
Overall Summary of Adverse Events for Period 2.
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
Do not use treatment-emergent flag.
Use ARM.

Protocol: GSK208466/ADP-04511 Page 1 of 1
Population: Intent-To-Treat (Data as of: 24APR2018)

Table 8.1101
Incidence of Adverse Events by System Organ Class and Preferred Term for Period 1
ITT Population

ADAE.PER01FL = 'Y'
ITTFL = 'Y'
Do not use treatment-emergent flag for any tables.
Use ARM for all tables

System Organ Class/ ADAE.AEBODSYS Preferred Term ADAE.AEDECOD	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Any Adverse Event	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)
SOC1	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)
Term 1	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)
Term 2	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)
SOC2	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)
Term 1	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)
Term 2	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)	xx(xx.x %)
Etc.						

Programming Note: Sort SOCs by descending frequency of subjects in Overall column, then alphabetically. Within each SOC, sort PTs by descending frequency of subjects Overall column, then alphabetically.

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency according to the Overall group.
File Name: S:\..... \&prog_name

Repeat Table 8.1101 template for:

Table 8.1103
Incidence of Adverse Events by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
Use ARM

Table 8.1104
Summary of Adverse Events Grouped by Similarity of Preferred Terms for Period 1
ITT
ADAE.PER01FL = 'Y'
ITTFL = 'Y'
Use ARM

Table 8.1106
Summary of Adverse Events Grouped by Similarity of Preferred Terms for Period 2
mITT
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
Use ARM

Footnotes for 8.1104, 8.1101:
Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each synonym and once for each preferred term
Note 2: Synonyms (and preferred terms within each) are sorted by descending frequency according to the Overall group.
File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511 Page 1 of n
Population: Intent-To-Treat (Data as of: 24APR2018)

Table 8.1201
Incidence of Adverse Events by Toxicity Grade and Preferred Term for Period 1
ITT Population
Cohort 1 (N=xxx)

	Maximum Grade							
Preferred Term	1	2	3	4	5	3+4+5	Unknown	Total
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 4	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 5	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…								

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term under the most severe toxicity grade.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Note 3: Synonymous preferred terms are combined.
Note to programmer: Include only Grades with frequency > 0 for Overall columns. Please only present synonym terms as described in appendix 2.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511 Page 1 of n

Population: Intent-To-Treat (Data as of: 24APR2018)

Table 8.1201
Incidence of Adverse Events by Toxicity Grade Preferred Term for Period 1
ITT Population
Cohort 2 (N=xxx)

	Maximum Grade							
Preferred Term	1	2	3	4	5	3+4+5	Unknown	Total
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 4	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 5	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…								

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term under the most severe toxicity grade.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Note 3: Synonymous preferred terms are combined.
Note to programmer: Include only Grades with frequency > 0 for Overall columns. Please only present synonym terms as described in appendix 2.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511 Page 1 of n
Population: Intent-To-Treat (Data as of: 24APR2018)

Table 8.1201
Incidence of Adverse Events by Toxicity Grade Preferred Term for Period 1
ITT Population
Cohort 3 (N=xxx)

	Maximum Grade							
Preferred Term	1	2	3	4	5	3+4+5	Unknown	Total
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 4	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 5	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…								

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term under the most severe toxicity grade.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Note 3: Synonymous preferred terms are combined.
Note to programmer: Include only Grades with frequency > 0 for Overall columns. Please only present synonym terms as described in appendix 2.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Table 8.1201
Incidence of Adverse Events by Toxicity Grade and Preferred Term for Period 1
ITT Population
Cohort 4 (N=xxx)

	Maximum Grade							
Preferred Term	1	2	3	4	5	3+4+5	Unknown	Total
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 4	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 5	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…								

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term under the most severe toxicity grade.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Note 3: Synonymous preferred terms are combined.
Note to programmer: Include only Grades with frequency > 0 for Overall columns. Please only present synonym terms as described in appendix 2.

Table 8.1201
Incidence of Adverse Events by Toxicity Grade and Preferred Term for Period 1
ITT Population
Cohort 2-4 (N=xxx)

	Maximum Grade							
Preferred Term	1	2	3	4	5	3+4+5	Unknown	Total
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 4	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 5	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…								

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term under the most severe toxicity grade.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Note 3: Synonymous preferred terms are combined.
Note to programmer: Include only Grades with frequency > 0 for Overall columns. Please only present synonym terms as described in appendix 2.

File Name: S:\..... \&prog_name

Table 8.1201
Incidence of Adverse Events by Toxicity Grade and Preferred Term for Period 1
ITT Population
Cohort 1-4 (N=xxx)

	Maximum Grade							
Preferred Term	1	2	3	4	5	3+4+5	Unknown	Total
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 4	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 5	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…								

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term under the most severe toxicity grade.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Note 3: Synonymous preferred terms are combined.
Note to programmer: Include only Grades with frequency > 0 for Overall columns. Please only present synonym terms as described in appendix 2.

File Name: S:\..... \&prog_name
Repeat Table 8.1201 template for:

Table 8.1203
Incidence of Adverse Events by Toxicity Grade Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
Use ARM
Include only Grades with frequency > 0 for Overall columns.

Table 8.1204
Incidence of Treatment Adverse Events by Toxicity Grade Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.1205
Incidence of Treatment Related Adverse Events by System Organ Class and Preferred Term for Period 1
mITT Population
ADAE.PER01FL = 'Y'
MITTFL = 'Y'
Use ARM
Include only related AEs (RELGR1 = 'Related').

System Organ Class/ADAE.AEBODSYS Preferred Term ADAE.AEDECOD	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
SOC1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2						
Etc.						

Period 1 = from date of informed consent through end of study.
Note 1: Subjects are counted once for each system organ class and once for each preferred term under the strongest relationship.
Note 2: Related adverse events have a relationship of definitely related, probably related, possibly related, or unlikely related to T cell infusion or lymphodepletion chemotherapy (cyclophosphamide and/or Mesna).
Note 3: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.

File Name: S:\..... \&prog_name

Use 8.1205 as a template for the following Tables:

Table 8.1206
Incidence of Treatment Related Adverse Events by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
Use ARM
Include only related AEs (RELGR1 = 'Related').

Use 8.1101 as a template for the following Tables:

Table 8.1301
Incidence of Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 1
ITT Population
ADAE.PER01FL = 'Y'
ITTFL = 'Y'
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Table 8.1303
Incidence of Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Use 8.1205 as a template for the following Tables:

Table 8.1305
Incidence of Treatment Related Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 1
mITT Population
ADAE.PER01FL = 'Y'
MITTFL = 'Y'
Use Include only related AEs (RELGR1 = 'Related').
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Table 8.1306
Incidence of Treatment Related Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
Use Include only related AEs (RELGR1 = 'Related').
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Use Table 8.1101 as a template for the following Tables:

Table 8.1401
Incidence of Serious Adverse Events by System Organ Class and Preferred Term for the Pre-leukapheresis Period
ITT Population
ADAE.PRELEUFL = 'Y'
(no pop specified)
AESER = 'Y'
Use ARM [it looks like there are no AEs meeting criteria at this point]
Programming note: Change the "Population: Modified Intent-To-Treat" in the upper left to "Population: Intent-to-Treat".

Footnotes for Table 8.1401:
Note 1: Subjects are counted once for each system organ class and once for each preferred term.
Note 2: Serious adverse events that occur after the date of informed consent and prior to date of leukapheresis are included.
Note 3: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.

Table 8.1402
Incidence of Serious Adverse Events by System Organ Class and Preferred Term for Period 1
ITT Population
ADAE.PER01FL = 'Y'
ITTFL = 'Y'
AESER = 'Y'
Use ARM

Table 8.1404
Incidence of Serious Adverse Events by System Organ Class and Preferred Term for the Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
Use ARM

Use 8.1205 as a template for the following Tables:

Table 8.1502
Incidence of Treatment Related Serious Adverse Events by System Organ Class and Preferred Term for Period 1
mITT Population
ADAE.PER01FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
RELGR1 = 'Related'
Use ARM

Table 8.1503
Incidence of Treatment Related Serious Adverse Events by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
RELGR1 = 'Related'
Use ARM

Repeat Table 8.1201 template for:

Table 8.1504
Incidence of Serious Adverse Events by Toxicity Grade and Preferred Term for Period 1
ITT population

Table 8.1505
Incidence of Serious Adverse Events by Toxicity Grade and Preferred Term for Period 2
mITT population

(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)

Table 8.1506
Incidence of Treatment Related Serious Adverse Events by Toxicity Grade and Preferred Term for Period 2
mITT population

(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)

Use 8.1101 as a template for the following Tables:

Table 8.1601
Incidence of Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for the Pre-leukapheresis Period
ITT Population

Footnotes:
Note 1: Subjects are counted once for each system organ class and once for each preferred term.
Note 2: Serious adverse events that occur after the date of informed consent and prior to date of leukapheresis are included.
Note 3: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
ADAE.PRELEUFL = 'Y'
(no pop specified)
AESER = 'Y'
TOXGGR1 = 'Grade 3 or Higher'
Use ARM [it looks like there are no AEs meeting criteria at this point]
Programming note: Change the "Population: Modified Intent-To-Treat" in the upper left to "Population: Intent-to-Treat".

Table 8.1602
Incidence of Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 1
ITT Population
ADAE.PER01FL = 'Y'
ITTFL = 'Y'
AESER = 'Y'
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Table 8.1604

Incidence of Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Use 8.1205 as a template for the following Tables:

Table 8.1606
Incidence of Treatment Related Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 1
mITT Population
ADAE.PER01FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
RELGR1 = 'Related'
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Table 8.1607
Incidence of Treatment Related Serious Adverse Events with Toxicity Grade >=3 by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
RELGR1 = 'Related'
TOXGGR1 = 'Grade 3 or Higher'
Use ARM

Use 8.1101 as a template for the following Tables:

Table 8.1608
Incidence of Serious Adverse Events Resulting in Death by System Organ Class and Preferred Term for the Pre-leukapheresis Period
ITT Population
ADAE.PRELEUFL = 'Y'
(no pop specified)
AESER = 'Y'
AEOUT = 'FATAL'
Use ARM [it looks like there are no AEs meeting criteria at this point]

Footnotes:
Note 1: Subjects are counted once for each system organ class and once for each preferred term.
Note 2: Serious adverse events that occur after the date of informed consent and prior to date of leukapheresis are included.
Note 3: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Programming note: Change the "Population: Modified Intent-To-Treat" in the upper left to "Population: Intent-to-Treat".
AESER = 'Y'
AEOUT = 'FATAL'

Table 8.2101
Incidence of Serious Adverse Events Resulting in Death by System Organ Class and Preferred Term for Period 1
ITT Population
ADAE.PER01FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
AEOUT = 'FATAL'

Table 8.2103
Incidence of Serious Adverse Events Resulting in Death by System Organ Class and Preferred Term for Period 2
mITT Population
(replace Period 1 footnote with: Period 2 = from start date of lymphodepletion through end of study.)
ADAE.PER02FL = 'Y'
MITTFL = 'Y'
AESER = 'Y'
AEOUT = 'FATAL'

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat

(Data as of: 24APR2018)

Table 8.3001
Overall Summary of Adverse Events for the Post-lymphodepletion Period for the Second T Cell Infusion
Subjects with a Second T Cell Infusion

ADAE.INF2FL = 'Y'
TRT02A = 'T-CELL' (denominator)

Category	Overall (N=xx)
Subjects with Any AEs	x (xx.x%)
Subjects with Any AEs Related& to T Cell Therapy RELGR1 = 'Related'	x (xx.x%)
Subjects with Any AEs >= Grade 3 TOXGGR1 = 'Grade 3 or Higher'	x (xx.x%)
Subjects with Any Serious AEs (SAE) AESER = 'Y'	x (xx.x%)
Subjects with Any SAEs with Fatal Outcome AESER = 'Y', AEOUT = 'FATAL'	x (xx.x%)

SAE = serious adverse event.
& Treatment-related: definitely related, probably related, or possibly related to T cell infusion.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.3002
Incidence of Adverse Events by System Organ Class and Preferred Term for the Post-lymphodepletion Period for the Second T Cell Infusion
Subjects with a Second T Cell Infusion

ADAE.INF2FL = 'Y'
TRT02A = 'T-CELL' (denominator)

System Organ Class/ ADAE.AEBODSYS Preferred Term ADAE.AEDECOD	Overall (N=xx)
Any Adverse Event	xx(xx.x %)
SOC1	xx(xx.x %)
Term 1	xx(xx.x %)
Term 2	xx(xx.x %)
SOC2	xx(xx.x %)
Term 1	xx(xx.x %)
Term 2	xx(xx.x %)
Etc.	

Note 1: Subjects are counted once for each system organ class and once for each preferred term.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency according to the Overall group.
File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.3003
Incidence of Adverse Events by Toxicity Grade and Preferred Term for the Post-lymphodepletion Period for the Second T-Cell Infusion Period
Subjects with a Second T-Cell Infusion
Total (N=xxx)

	Maximum Grade							
Preferred Term	1	2	3	4	5	3+4+5	Unknown	Total
Any Adverse Event	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 4	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Term 5	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…								

Note 1: Subjects are counted once for each system organ class and once for each preferred term under the most severe toxicity grade.
Note 2: System organ classes (and preferred terms within each) are sorted by descending frequency in the Overall group.
Note 3: Synonymous preferred terms are combined.
Note to programmer: Include only Grades with frequency > 0 for Overall columns. Please only present synonym terms as described in appendix 2.

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Use 8.3002 as a template for the following Tables:

Table 8.3004
Incidence of Treatment Related Adverse Events by System Organ Class and Preferred Term for the Post-lymphodepletion Period for the Second T-Cell Infusion
Subjects with a Second T Cell Infusion
Add footnote: Note 2: Related adverse events have a relationship of definitely related, probably related, or possibly related to T cell infusion or lymphodepletion chemotherapy (cyclophosphamide and/or Mesna).
ADAE.INF2FL = 'Y'
TRT02A = 'T-CELL' (denominator)
RELGR1 = 'Related'

Table 8.3005
Incidence of Serious Adverse Events by System Organ Class and Preferred Term for the Post-lymphodepletion Period for the Second T Cell Infusion
Subjects with a Second T Cell Infusion
ADAE.INF2FL = 'Y'
TRT02A = 'T-CELL' (denominator)
AESER = 'Y'

Use 8.3003 as a template for the following Tables:

Table 8.3006
Incidence of Treatment Related Adverse Events by Toxicity Grade and Preferred Term for the Post-lymphodepletion Period for the Second T-Cell Infusion

Population: Subjects with a Second T-Cell Infusion

Table 8.3007
Incidence of Serious Adverse Events by Toxicity Grade and Preferred Term for the Post-lymphodepletion Period for the Second T-Cell Infusion

Population: Subjects with a Second T-Cell Infusion

Table 8.3008
Incidence of Treatment Related Serious Adverse Events by Toxicity Grade and Preferred Term for the Post-lymphodepletion Period for the Second T-Cell Infusion

Population: Subjects with a Second T-Cell Infusion

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.3101
Summary of Adverse Events of Special Interest by Cohort (All Infusions)

Cohort 1 (N=xx)

AESI Category / Preferred Term	Maximum Grade 1	2	3	4	5	3+4+5	Unknown	Total
ANY EVENT	1 (1%)	4 (5%)	6 (7%)	71 (86%)	0	77 (93%)	0	82 (99%)
Potential symptoms of GVHD								
Any Event	24 (29%)	31 (37%)	26 (31%)	0	0	26 (31%)	0	81 (98%)
Nausea	40 (48%)	26 (31%)	5 (6%)	0	0	5 (6%)	0	71 (86%)
Diarrhoea	23 (28%)	14 (17%)	11 (13%)	0	0	11 (13%)	0	48 (58%)
Rash maculo-papular	17 (20%)	8 (10%)	6 (7%)	0	0	6 (7%)	0	31 (37%)
Abdominal pain	15 (18%)	6 (7%)	4 (5%)	0	0	4 (5%)	0	25 (30%)

Note 1: Subjects are counted once for each preferred term under the most severe grade.
Note 2: Preferred terms are sorted by descending frequency of 'Total' AEs.
Note 3: Adverse events with missing grade are only included in 'Unknown' and 'Total' columns.
Note 4: Synonymous preferred terms are combined.

Programming note: AESI list will be provided by GSK. Please use the AESI list and report the synonym terms as described in appendix 2.
.

Table 8.3101
Summary of Adverse Events of Special Interest by Cohort (All Infusions)

Cohort 2 (N=xx)

AESI Category / Preferred Term	Maximum Grade 1	2	3	4	5	3+4+5	Unknown	Total
ANY EVENT	1 (1%)	4 (5%)	6 (7%)	71 (86%)	0	77 (93%)	0	82 (99%)
Potential symptoms of GVHD								
Any Event	24 (29%)	31 (37%)	26 (31%)	0	0	26 (31%)	0	81 (98%)
Nausea	40 (48%)	26 (31%)	5 (6%)	0	0	5 (6%)	0	71 (86%)
Diarrhoea	23 (28%)	14 (17%)	11 (13%)	0	0	11 (13%)	0	48 (58%)
Rash maculo-papular	17 (20%)	8 (10%)	6 (7%)	0	0	6 (7%)	0	31 (37%)
Abdominal pain	15 (18%)	6 (7%)	4 (5%)	0	0	4 (5%)	0	25 (30%)

Note 1: Subjects are counted once for each preferred term under the most severe grade.
Note 2: Preferred terms are sorted by descending frequency of 'Total' AEs.
Note 3: Adverse events with missing grade are only included in 'Unknown' and 'Total' columns.
Note 4: Synonymous preferred terms are combined.

Programming note: AESI list will be provided by GSK. Please use the AESI list and report the synonym terms as described in appendix 2.

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.3101
Summary of Adverse Events of Special Interest by Cohort (All Infusions)

Cohort 3 (N=xx)

AESI Category / Preferred Term	Maximum Grade 1	2	3	4	5	3+4+5	Unknown	Total
ANY EVENT	1 (1%)	4 (5%)	6 (7%)	71 (86%)	0	77 (93%)	0	82 (99%)
Potential symptoms of GVHD								
Any Event	24 (29%)	31 (37%)	26 (31%)	0	0	26 (31%)	0	81 (98%)
Nausea	40 (48%)	26 (31%)	5 (6%)	0	0	5 (6%)	0	71 (86%)
Diarrhoea	23 (28%)	14 (17%)	11 (13%)	0	0	11 (13%)	0	48 (58%)
Rash maculo-papular	17 (20%)	8 (10%)	6 (7%)	0	0	6 (7%)	0	31 (37%)
Abdominal pain	15 (18%)	6 (7%)	4 (5%)	0	0	4 (5%)	0	25 (30%)

Note 1: Subjects are counted once for each preferred term under the most severe grade.
Note 2: Preferred terms are sorted by descending frequency of 'Total' AEs.
Note 3: Adverse events with missing grade are only included in 'Unknown' and 'Total' columns.
Note 4: Synonymous preferred terms are combined.

Programming note: AESI list will be provided by GSK. Please use the AESI list and report the synonym terms as described in appendix 2.

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.3101
Summary of Adverse Events of Special Interest by Cohort (All Infusions)

Cohort 4 (N=xx)

AESI Category / Preferred Term	Maximum Grade 1	2	3	4	5	3+4+5	Unknown	Total
ANY EVENT	1 (1%)	4 (5%)	6 (7%)	71 (86%)	0	77 (93%)	0	82 (99%)
Potential symptoms of GVHD								
Any Event	24 (29%)	31 (37%)	26 (31%)	0	0	26 (31%)	0	81 (98%)
Nausea	40 (48%)	26 (31%)	5 (6%)	0	0	5 (6%)	0	71 (86%)
Diarrhoea	23 (28%)	14 (17%)	11 (13%)	0	0	11 (13%)	0	48 (58%)
Rash maculo-papular	17 (20%)	8 (10%)	6 (7%)	0	0	6 (7%)	0	31 (37%)
Abdominal pain	15 (18%)	6 (7%)	4 (5%)	0	0	4 (5%)	0	25 (30%)

Note 1: Subjects are counted once for each preferred term under the most severe grade.
Note 2: Preferred terms are sorted by descending frequency of 'Total' AEs.
Note 3: Adverse events with missing grade are only included in 'Unknown' and 'Total' columns.
Note 4: Synonymous preferred terms are combined.

Programming note: AESI list will be provided by GSK. Please use the AESI list and report the synonym terms as described in appendix 2.

Protocol: GSK208466/ADP-04511 Page 1 of n
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.3101
Summary of Adverse Events of Special Interest by Cohort (All Infusions)

Overall (N=xx)

AESI Category / Preferred Term	Maximum Grade 1	2	3	4	5	3+4+5	Unknown	Total
ANY EVENT	1 (1%)	4 (5%)	6 (7%)	71 (86%)	0	77 (93%)	0	82 (99%)
Potential symptoms of GVHD								
Any Event	24 (29%)	31 (37%)	26 (31%)	0	0	26 (31%)	0	81 (98%)
Nausea	40 (48%)	26 (31%)	5 (6%)	0	0	5 (6%)	0	71 (86%)
Diarrhoea	23 (28%)	14 (17%)	11 (13%)	0	0	11 (13%)	0	48 (58%)
Rash maculo-papular	17 (20%)	8 (10%)	6 (7%)	0	0	6 (7%)	0	31 (37%)
Abdominal pain	15 (18%)	6 (7%)	4 (5%)	0	0	4 (5%)	0	25 (30%)

Note 1: Subjects are counted once for each preferred term under the most severe grade.
Note 2: Preferred terms are sorted by descending frequency of 'Total' AEs.
Note 3: Adverse events with missing grade are only included in 'Unknown' and 'Total' columns.
Note 4: Synonymous preferred terms are combined.

Programming note: AESI list will be provided by GSK. Please use the AESI list and report the synonym terms as described in appendix 2.

Use 8.3101 as a template for the following Table:

Table 8.3102
Summary of Adverse Events of Special Interest for the First Infusion
Programming note: Please use the AESI list and report the synonym terms as described in appendix 2.

Use 8.3101 as a template for the following Table:

Table 8.3103
Overall Summary of Adverse Events of Special Interest by Cohort for the Second Infusion
Programming note: Please use the AESI list and report the synonym terms as described in appendix 2.
Protocol: GSK208466/ADP-04511 Page 1 of 1
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.3104

Summary of Characterisics of Guillain-Barre Syndrome (All Infusions)

	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2 -4 Total (N=xx)	Overall (N=xx)
Number of Subjects with Events	50 (50%)	40 (40%)	50 (50%)	40 (40%)	50 (50%)	40 (40%)
Number of Events	60	40	60	40	60	40
Event Characteristics [1]						
n	50	40	50	40	50	40
Serious	10/50 (20%)	4/40 (10%)	10/50 (20%)	4/40 (10%)	10/50 (20%)	4/40 (10%)
Drug-related	5/50 (10%)	3/40 (8%)	5/50 (10%)	3/40 (8%)	5/50 (10%)	3/40 (8%)
Fatal	0	0	0	0	0	0
Number of occurrences						
n	50	40	50	40	50	40
One	40/50 (80%)	40/40 (100%)	40/50 (80%)	40/40 (100%)	40/50 (80%)	40/40 (100%)
Two	10/50 (20%)	0	10/50 (20%)	0	10/50 (20%)	0
Three or more	0	0	0	0	0	0
Outcome [2]						
n	50	40	50	40	50	40
Recovered/Resolved	50/50 (100%)	30/40 (75%)	50/50 (100%)	30/40 (75%)	50/50 (100%)	30/40 (75%)
Recovering/Resolving	0	6/40 (15%)	0	6/40 (15%)	0	6/40 (15%)
Not Recovered/Not Resolved	0	0	0	0	0	0
Recovered/Resolved w/sequelae	10/50 (20%)	4/40 (10%)	10/50 (20%)	4/40 (10%)	10/50 (20%)	4/40 (10%)
Fatal	0	0	0	0	0	0

[1] Subjects may be included in more than one category for 'Event Characteristics'.
[2] Outcome worst case hierarchy: Fatal > Not Recovered/Not Resolved > Recovered/Resolved with sequelae > Recovering/Resolving > Recovered/Resolved

Programming note: Please use the AESI list of Guillain-Barre Syndrome; for No. of Events, n, No. of occurrences, outcome and grade counts please follow the AE collapsing rule in the RAP AESI section.

PPD

Summary of Characterisics of Guillain-Barre Syndrome (All Infusions)

	Cohort 1 (N=200)	Cohort 2 (N=100)	Cohort 3 (N=200)	Cohort 4 (N=100)	Cohort 2 – 4 Total (N=200)	Overall (N=100)
Maximum Grade						
n	50	40	50	40	50	40
Grade 1	5/50 (10%)	4/40 (10%)	5/50 (10%)	4/40 (10%)	5/50 (10%)	4/40 (10%)
Grade 2	2/50 (4%)	0	2/50 (4%)	0	2/50 (4%)	0
Grade 3	0	0	0	0	0	0
Grade 4	40/50 (80%)	35/40 (88%)	40/50 (80%)	35/40 (88%)	40/50 (80%)	35/40 (88%)
Grade 5	3/50 (6%)	1/40 (3%)	3/50 (6%)	1/40 (3%)	3/50 (6%)	1/40 (3%)

[1] Subjects may be included in more than one category for 'Event Characteristics'.
[2] Outcome worst case hierarchy: Fatal > Not Recovered/Not Resolved > Recovered/Resolved with sequelae > Recovering/Resolving > Recovered/Resolved

Programming note: Please use the AESI list of Guillain-Barre Syndrome; for No. of Events, n, No. of occurrences, outcome and grade counts please follow the AE collapsing rule in the RAP AESI section.

PPD

Use 8.3104 as a template for the following Table:

Table 8.3105
Summary of Characteristics of Cytokine Release Syndrome (All Infusions)

Table 8.3106
Summary of Characteristics of Cytokine Release Syndrome (All Infusions)

Table 8.3107

Summary of Characteristics of Recurrent Pancytopenia/Aplastic Anaemia (All Infusions)

Table 8.3108
Summary of Characteristics of Encephalopathy (All Infusions)

Table 8.3109
Summary of Characterisics of Guillain-Barre Syndrome (Second Infusions)
Programming note: population: subjects with a second T-cell infusion

Table 8.3110
Summary of Characteristics of Graft versus Host Disease (Second Infusions)
Programming note: population: subjects with a second T-cell infusion

Table 8.3111
Summary of Characteristics of Cytokine Release Syndrome (Second Infusions)
Programming note: population: subjects with a second T-cell infusion

Table 8.3112
Summary of Characteristics of Recurrent Pancytopenia/Aplastic Anaemia (Second Infusions)
Programming note: population: subjects with a second T-cell infusion

Table 8.3113
Summary of Characteristics of Encephalopathy (Second Infusions)
Programming note: population: subjects with a second T-cell infusion

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.3114
Summary of Onset and Duration of the First Occurrence of Guillain-Barre Syndrome

	Cohort 1 (N=100)	Cohort 2 (N=100)	Cohort 3 (N=100)	Cohort 4 (N=100)	Cohort 2 – 4 Total (N=100)	Overall (N=100)
Number of Subjects with Events	50 (50%)	40 (40%)	50 (50%)	40 (40%)	50 (50%)	40 (40%)
Time of onset, days						
Subjects with event						
1-14	40	40	40	40	40	40
15-28	10	0	10	0	10	0
>28	0	0	0	0	0	0
Mean	2.5	2.1	2.5	2.1	2.5	2.1
SD	1.44	1.24	1.44	1.24	1.44	1.24
Median	4	3	4	3	4	3
Min.	1	1	1	1	1	1
Max.	8	5	8	5	8	5
Duration, days						
n	50	40	50	40	50	40
1-5	40 (80%)	40 (100%)	40 (80%)	40 (100%)	40 (80%)	40 (100%)
6-10	10 (20%)	0	10 (20%)	0	10 (20%)	0
>10	0	0	0	0	0	0
Mean	2.5	2.1	2.5	2.1	2.5	2.1
SD	1.44	1.24	1.44	1.24	1.44	1.24
Median	4	3	4	3	4	3
Min.	1	1	1	1	1	1
Max.	8	5	8	5	8	5

Note: Subjects at risk is calculated as the number at risk at the start of the interval.
PPD

Programming note: Please use the AESI list of Guillain-Barre Syndrome; for duration please follow the AE collapsing rule in the RAP AESI section.

Use 8.3114 as a template for the following Table:

Table 8.3115, Table 8.3116, Table 8.3117, Table 8.3118, Table 8.3119, Table 8.3120, Table 8.3121, Table 8.3122 and Table 8.3123

Use 8.3101 as a template for the table 8.3124 (programming note: please use the Comprehensive AESI flag)
Use 8.3102 as a template for the table 8.3125 (programming note: please use the Comprehensive AESI flag)
Use 8.3103 as a template for the table 8.3126 (programming note: please use the Comprehensive AESI flag)

Use 8.3104 as template for the table:
Table 8.3127 Summary of Characteristics of Haematopoietic Cytopenias (Comprehensive List-All Infusions)
Population: mITT
Programming note: please use AESI comprehensive AESI list and use the AESI term "Haematopoietic cytopenias" to report this table.

Use 8.3104 as template for the table:
Table 8.3128 Summary of Characteristics of Haematopoietic Cytopenias (Comprehensive List-Second Infusions)
Population: Subjects with a Second T-Cell Infusion
Programming note: please use AESI comprehensive AESI list and use the AESI term "Haematopoietic cytopenias" to report this table.

Use 8.3114 as a template for the table:
Table 8.3129 Summary of Onset and Duration of the First Occurrence of Haematopoietic Cytopenias (Comprehensive List)
Population: mITT
Programming note: please use AESI comprehensive AESI list and use the AESI term "Haematopoietic cytopenias" to report this table.

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.3201
Time to Resolution of Grade >= 3 Haematopoietic Cytopenias (Comprehensive List)

	Cohort 1 (N=100)	Cohort 2 (N=100)	Cohort 3 (N=100)	Cohort 4 (N=100)	Cohort 2 – 4 Total (N=100)	Overall (N=100)
Number of Subjects with Events	50 (50%)	40 (40%)	50 (50%)	40 (40%)	50 (50%)	40 (40%)
Time to Resolution						
Subjects with event						
≤ 28 days	40	40	40	40	40	40
29 days – 3 months	10	0	10	0	10	0
> 3 months	0	0	0	0	0	0

Note: Time to resolution is defined as time from T-cell infusion to the last date of end dates of AESI preferred terms.

Programming note: Please use the comprehensive list AESI term Haematopoietic cytopenias.

Use table 8.3201 as a template for the following tables:

Table 8.3202 Time to Resolution of Grade >=3 Recurrent Pancytopenia/Aplastic Anaemia
Population: mITT
Programming note: Please use the focused list AESI term 'Recurrent Pancytopenia/Aplastic Anaemia'
Table 8.3203 Time to Resolution of Grade >=3 Graft versus Host Disease
Population: mITT
Programming note: Please use the focused list AESI term GVHD.
Table 8.3204 Time to Resolution of Grade >=3 Cytokine Release Syndrome
Population: mITT

Programming note: Please use the focused list AESI term CRS.

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.4101
Change from Baseline to Each Scheduled Visit for Hematology Parameters for the Post-lymphodepletion Period
mITT Population
MITTFL = 'Y' and ADLB.PARCAT1 = 'HEMATOLOGY' and ADLB.ANLXXFL = 'Y' (if analysis flag for mean change tables)

Parameter Study Visit Timepoint	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Parameter 1 (units)							
Day 1							
Baseline	N	x	x	x	x	x	X
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
Visit	N	x	x	X	X	X	X
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
Change from Baseline	N	x	x	X	X	X	X
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x

Etc.
Continue for remaining scheduled visits

SD = Standard Deviation.
Note: Baseline is within 7 days prior to intitiating lymphodepletion.

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Use 8.4101 as a template for the following Table:

Table 8.4102
Change from Baseline to Each Scheduled Visit for Chemistry Parameters for the Post-lymphodepletion Period
mITT Population

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.4201
Shifts from Baseline to Worst Post-Baseline NCI-CTCAE Grade for Hematology Parameters for the Post-lymphodepletion Period
mITT Population
SAFFL = 'Y' and ADLB.PARCAT1 = 'HEMATOLOGY' and ADLB.ANLXXFL = 'Y' (if analysis flag for shift tables)

Use ADLB.SHIFT1 for record with LVOTFL = 'Y'. If SHIFT1 is not in dataset, use ADLB.ANRIND and ADLB.BNRIND.
BNRIND contains baseline value, and ANRIND contains End of Treatment Value.

		Worst On-Study Grade				
Parameter/ Cohort	Baseline Grade	0 n/N (%)	1 n/N (%)	2 n/N (%)	3 n/N (%)	4 n/N (%)
Parameter 1						
Cohort 1 (N=xx)	0	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	1	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	2	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	3	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	4	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
Cohort 2 (N=xx)	0	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	1	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	2	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	3	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	4	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
Cohort 3 (N=xx)	0	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	1	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	2	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	3	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	4	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
Cohort 4 (N=xx)	0	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	1	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	2	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	3	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	4	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
Cohort 2-4 combined (N=xx)	0	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	1	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	2	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	3	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
	4	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)	x/x (xx.x)
Cohort 1-4 conbined (N=xx)						
……..						

NCI-CTCAE = National Cancer Institute - Common Terminology Criteria for Adverse Events.
Note 1: For n/N, n=number of subjects who meet the criterion, N=number of subjects with both baseline and post-baseline results.
Note 2: Baseline is within 7 days prior to intitiating lymphodepletion.

File Name: S:\..... \&prog_name

Use 8.4201 as a template for the following Table:

Table 8.4202
Shifts from Baseline to Worst Post-Baseline NCI-CTCAE Grade for Chemistry Parameters **for the Post-lymphodepletion Period**
mITT Population

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Table 8.4301
Number and Proportion of Subjects with Potentially Clinically Significant Hepatic Post-Baseline Results for the Post-lymphodepletion Period
mITT Population
Select records with ADLB.CRITXXFL = 'Y'

Parameter ADLB.PARAM	Criterion	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
ALT, AST and BIL Elevations	(≥3xULN AST and/or ALT) and ≥2xULN BIL	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
	(≥3xULN AST and/or ALT) and ≥1.5xULN BIL	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
ALT Elevations	≥20xULN	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
	≥10xULN	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
	≥5xULN	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
	≥3xULN	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
BIL Elevations	>2 xULN	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
	>1.5 xULN	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)

ALT = Alanine aminotransferase, AST = Aspartate aminotransferase, BIL = Total bilirubin.
Note 1: Baseline is within 7 days prior to initiating lymphodepletion.
Note 2: For n/N, n=number of subjects who meet the criterion at least once, N=number of subjects with post-baseline results.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.5001
Maximum Persistence and Time to Maximum Persistence for Responders, Non-Responders, and Overall for the First Infusion
mITT Population

Parameter	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Responders							
Maximum Persistence	N	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
Time to Maximum Persistence	N	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min,Max	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
Maximum Cell Persistence (/µL)							
…							
Time to Maximum Cell Persistence (Days)							
…							
Maximum Gene marked cells per total lymphocyte (%) …							
Time to Maximum Gene marked cells per total lymphocyte (%) (Days)							
Repeast for Non-Responders and Overall.							

Note 1: Time to maximum persistence is defined as date of maximum persistence for Infusion 1 visits – date of T Cell infusion + 1.
Note 2: Cell Persistence = Absolute peripheral gene-marked cell number/µL = (Psi result number/151515) X (lymphocyte count + monocyte count) X 1000, where Psi is value collected on eCRF.
Note 3: Percent of gene marked cells per total lymphocyte compartment = ((Absolute peripheral gene marked cell number/µL)/Lymphocyte count x 1000)) X 100.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat

(Data as of: 24APR2018)

Table 8.5002
Number and Proportion of RCL Positive Subjects
mITT Population

Parameter	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
RCL Positive	n/N	xx/XX (xx.x%)	xx/XX (xx.x%)	xx/XX (xx.x%)	xx/XX (xx.x%)	xx/XX (xx.x%)	xx/XX (xx.x%)

Note: n = number of subjects who are RCL positive at any time after initial T Cell infusion, N = number of subjects tested for RCL at least once after initial T Cell infusion.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat

(Data as of: 24APR2018)

Table 8.5003
Number and Percentage of Subjects with Potentially Clinically Significant Post-Baseline Vital Signs Results
MITT Population

Parameter	Criterion	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Heart Rate	< 60 bpm	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
	> 100 bpm	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
Systolic Blood Pressure	>=140 mmHg	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
Diastolic Blood Pressure	>=90mmHg	n/N (%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)

Note 1: Baseline is within 7 days of initiating lymphodepletion.
Note 2: For n/N, n=number of subjects who meet the criterion at least once, N=number of subjects with post-baseline results.
File Name: S:\..... \&prog_name

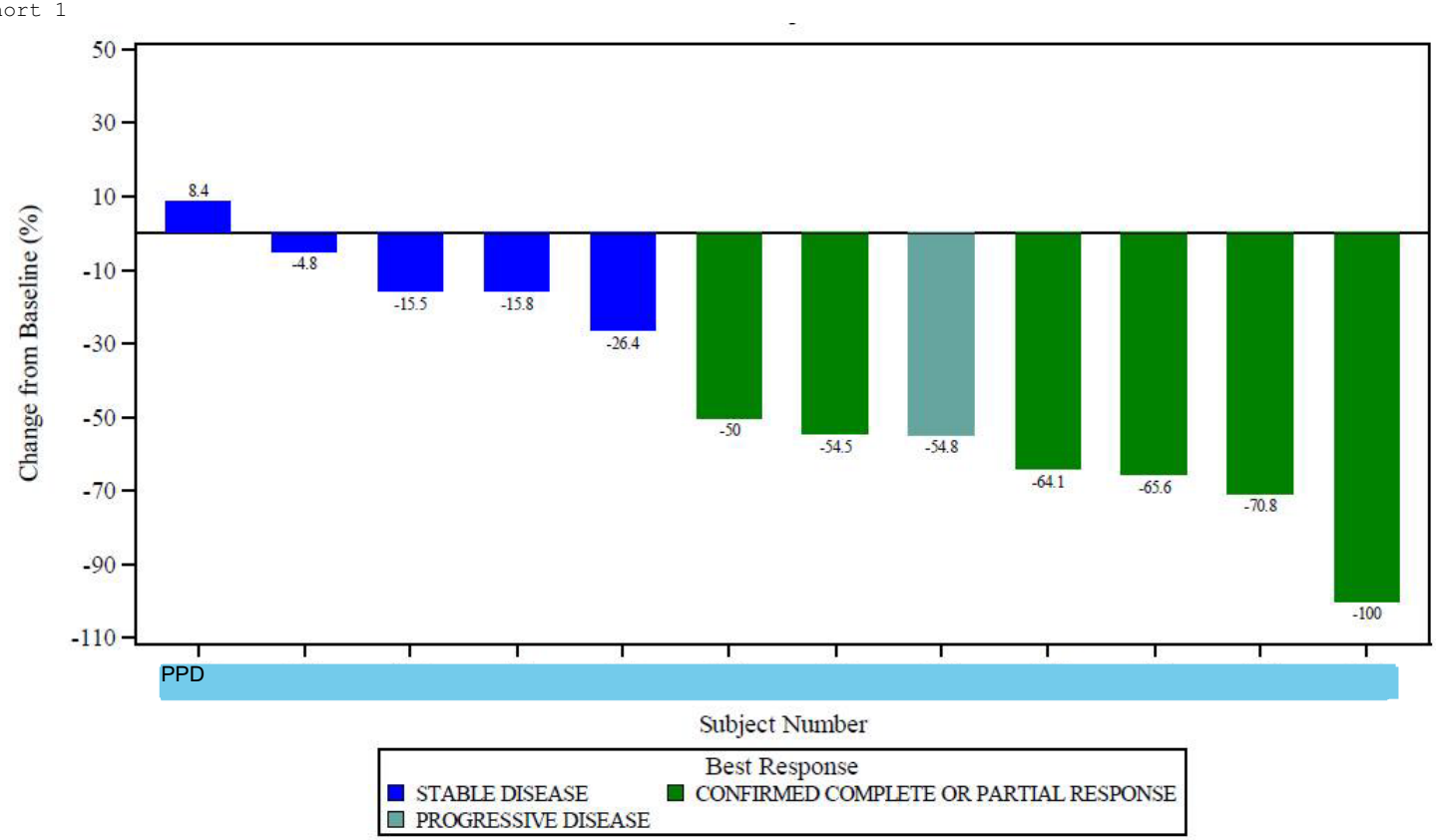
Protocol: GSK208466/ADP-04511 Page 1 of 1
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Table 8.6101
Summary of ECOG Performance Status at Each Visit
MITT Population

Visit/ Score	Statistic	Cohort 1 (N=xx)	Cohort 2 (N=xx)	Cohort 3 (N=xx)	Cohort 4 (N=xx)	Cohort 2-4 Total (N=xx)	Overall (N=xx)
Screening							
0	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
1	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
2	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
3	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
4	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
5	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
Baseline							
0	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
1	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
2	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
3	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
4	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
5	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
T-CELL INFUSION							
0	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
1	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
2	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
3	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
4	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
5	n/N(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)	xx/xx(%)
Etc. Programming note: continue for each post-baseline visit.							

ECOG = Eastern Cooperative Oncology Group.
Note 1: Baseline is within 7 days of initiating lymphodepletion.
Note 2: ECOG Score: 0 – Fully active and able to carry on all pre-disease activities without restriction, 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light sedimentary nature, 2 – Ambulatory and capable of all self-care but unable to carry out any work activities, 3 – Capable of only limited self-care, 4 – Completely disabled, 5 – Dead.
File Name: S:\..... \&prog_name
Protocol: GSK208466/ADP-04511
Page 1 of 4
Population: Modified Intent-To-Treat
(Data as of: 24APR2018)
Figure 17.0001

Maximal Reduction in Sum of Diameters of Target Lesions from Baseline through Progression or Prior to Subsequent Anti-Cancer Therapy for the First Infusion

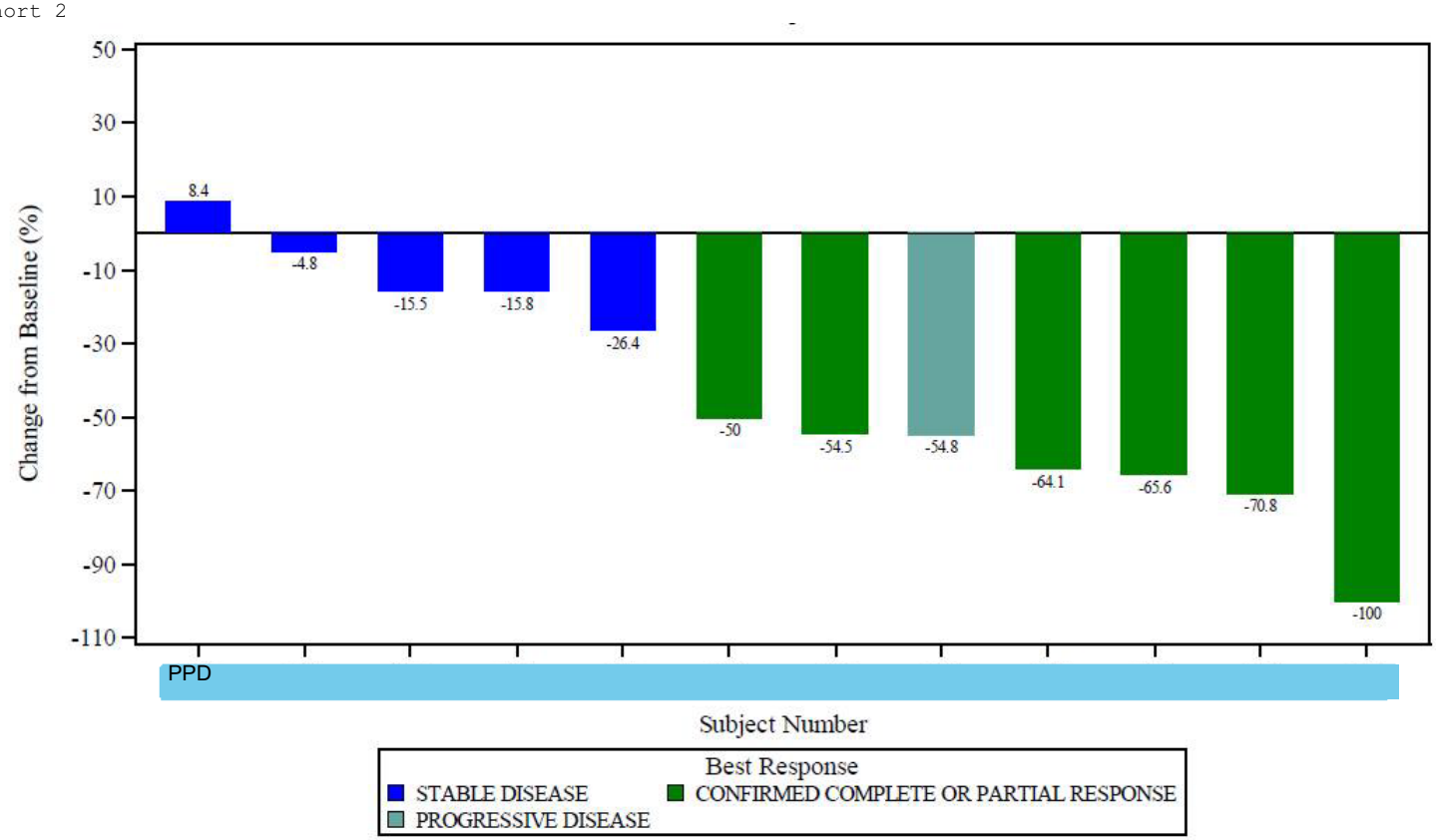
Cohort 1



Programming note: please also exclude recordes after anti-cancer treatment.

Figure 17.0001
Maximal Reduction in Sum of Diameters of Target Lesions from Baseline through Progression or Prior to Subsequent Anti-Cancer Therapy for the First Infusion

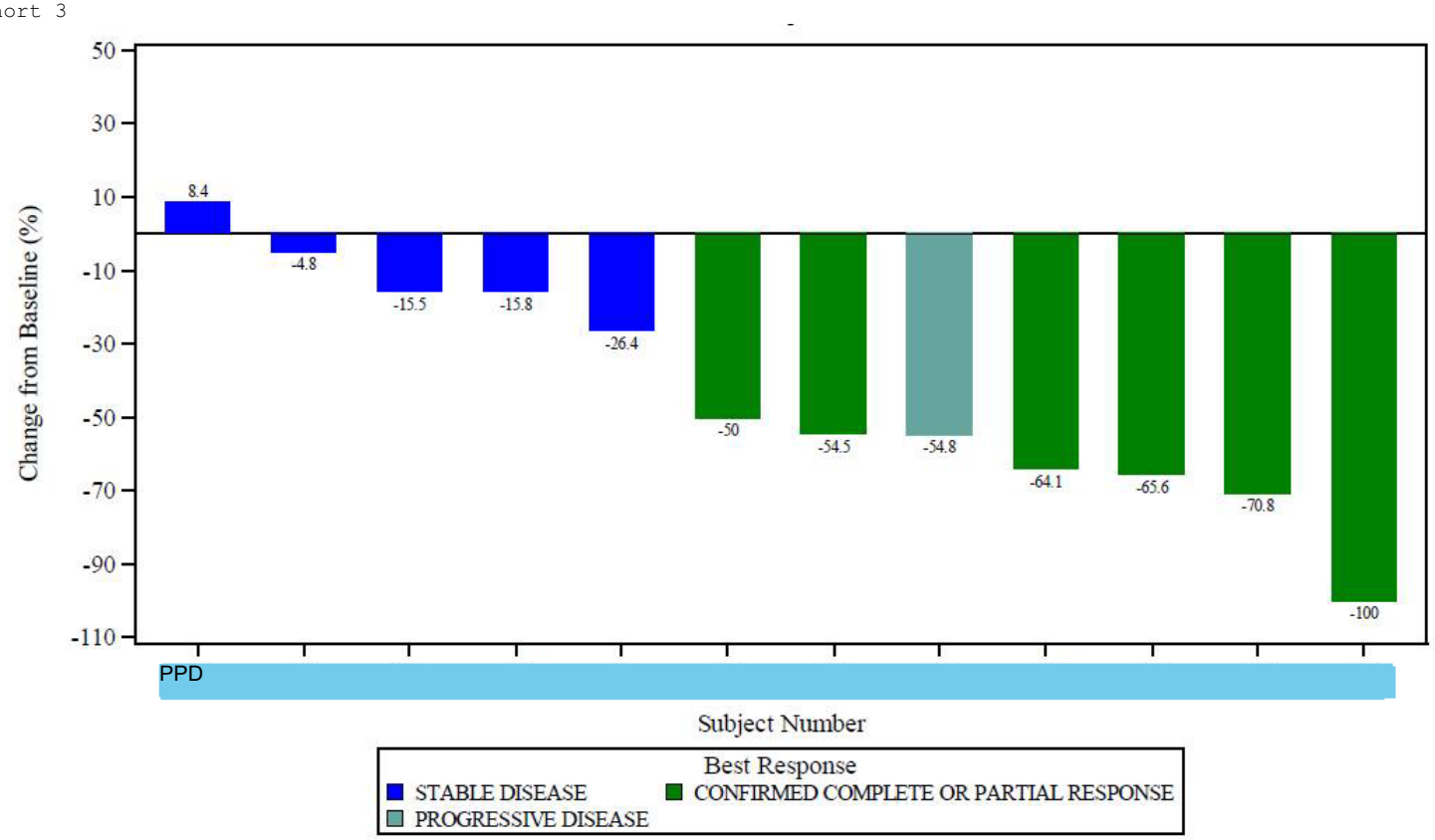
Cohort 2



Programming note: please also exclude recordes after anti-cancer treatment.

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Figure 17.0001
Maximal Reduction in Sum of Diameters of Target Lesions from Baseline through Progression or Prior to Subsequent Anti-Cancer Therapy for the First Infusion

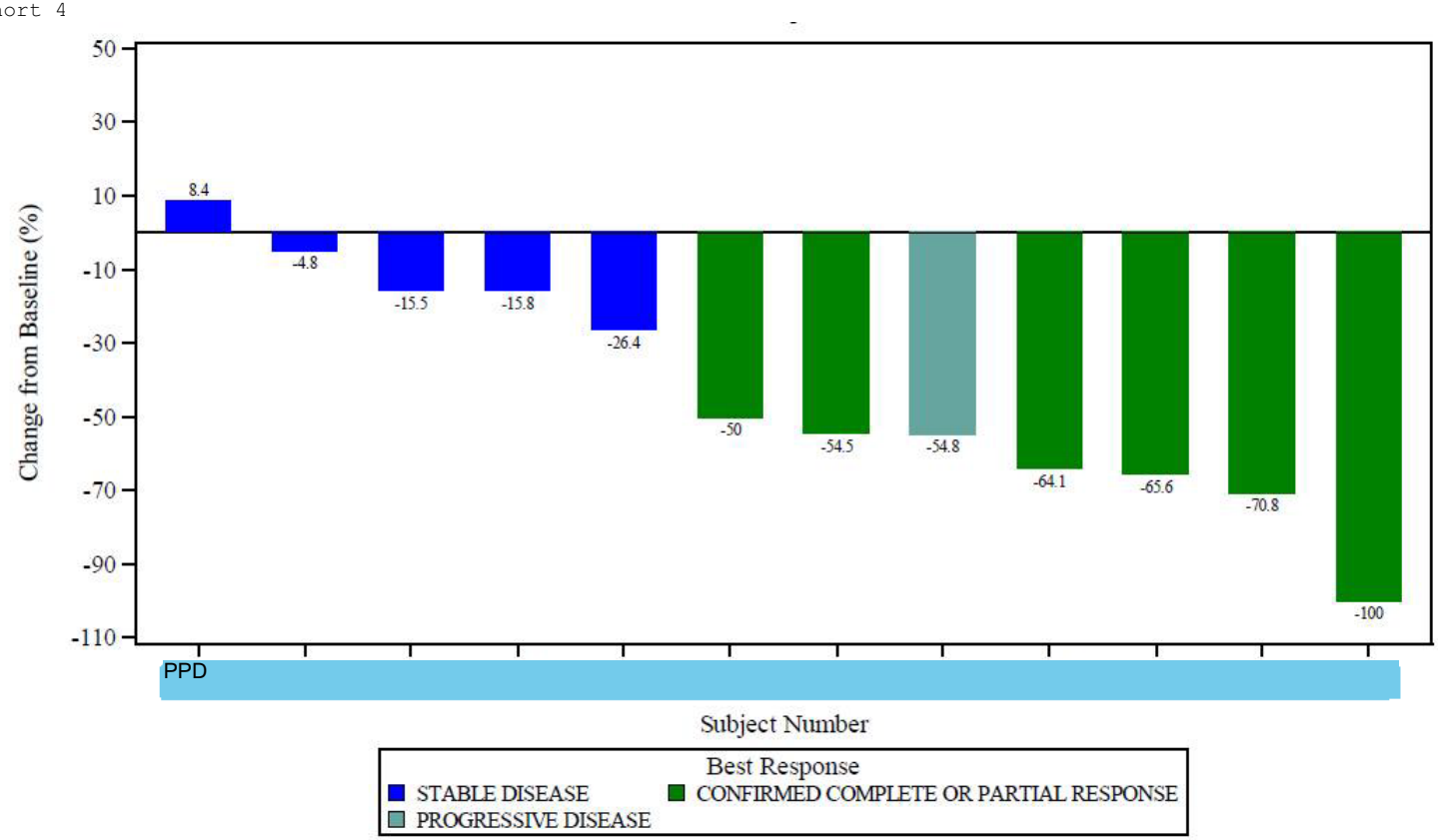
Cohort 3



Programming note: please also exclude recordes after anti-cancer treatment.

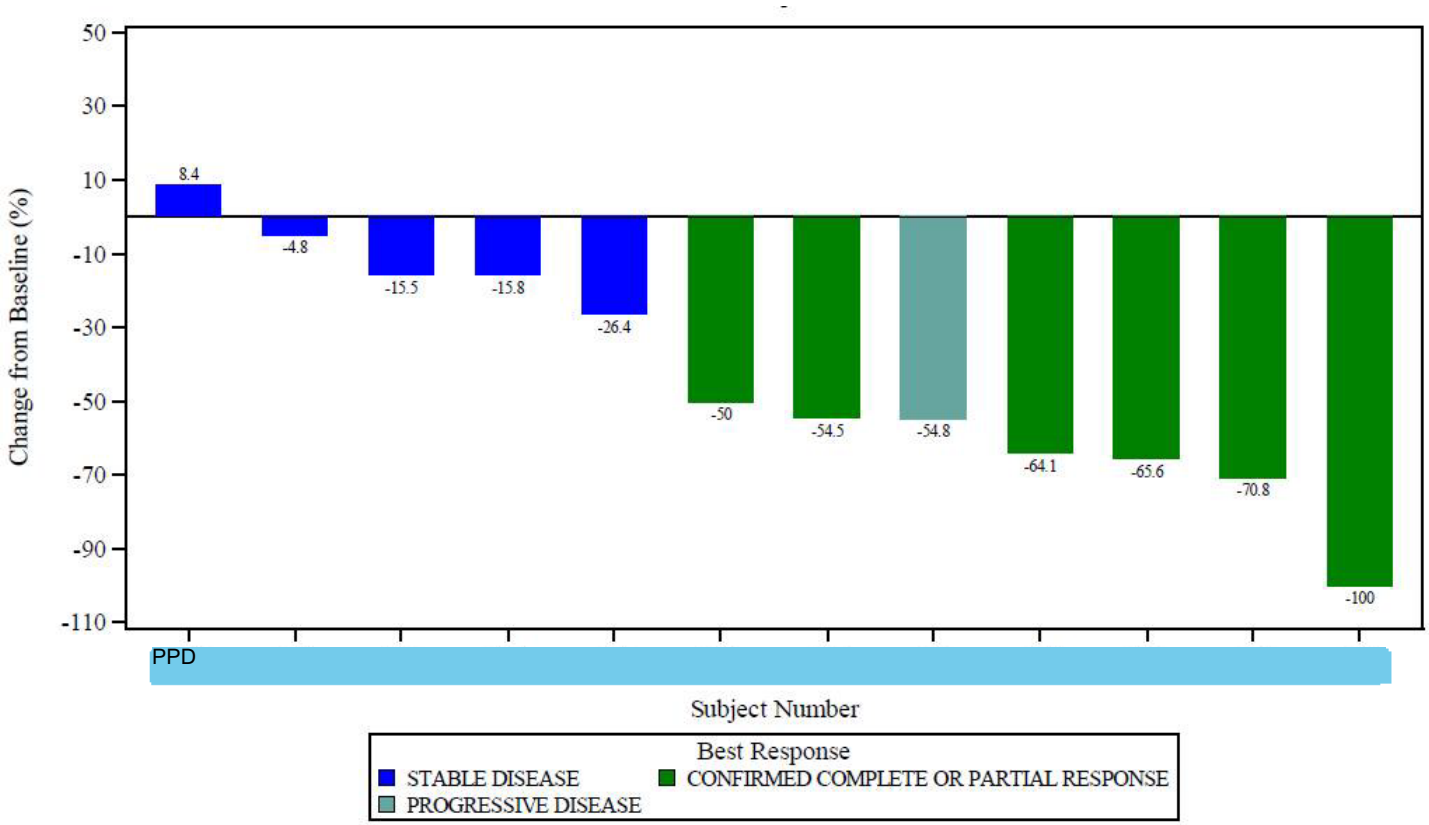
Figure 17.0001
Maximal Reduction in Sum of Diameters of Target Lesions from Baseline through Progression or Prior to Subsequent Anti-Cancer Therapy for the First Infusion

Cohort 4



Programming note: please also exclude recordes after anti-cancer treatment.

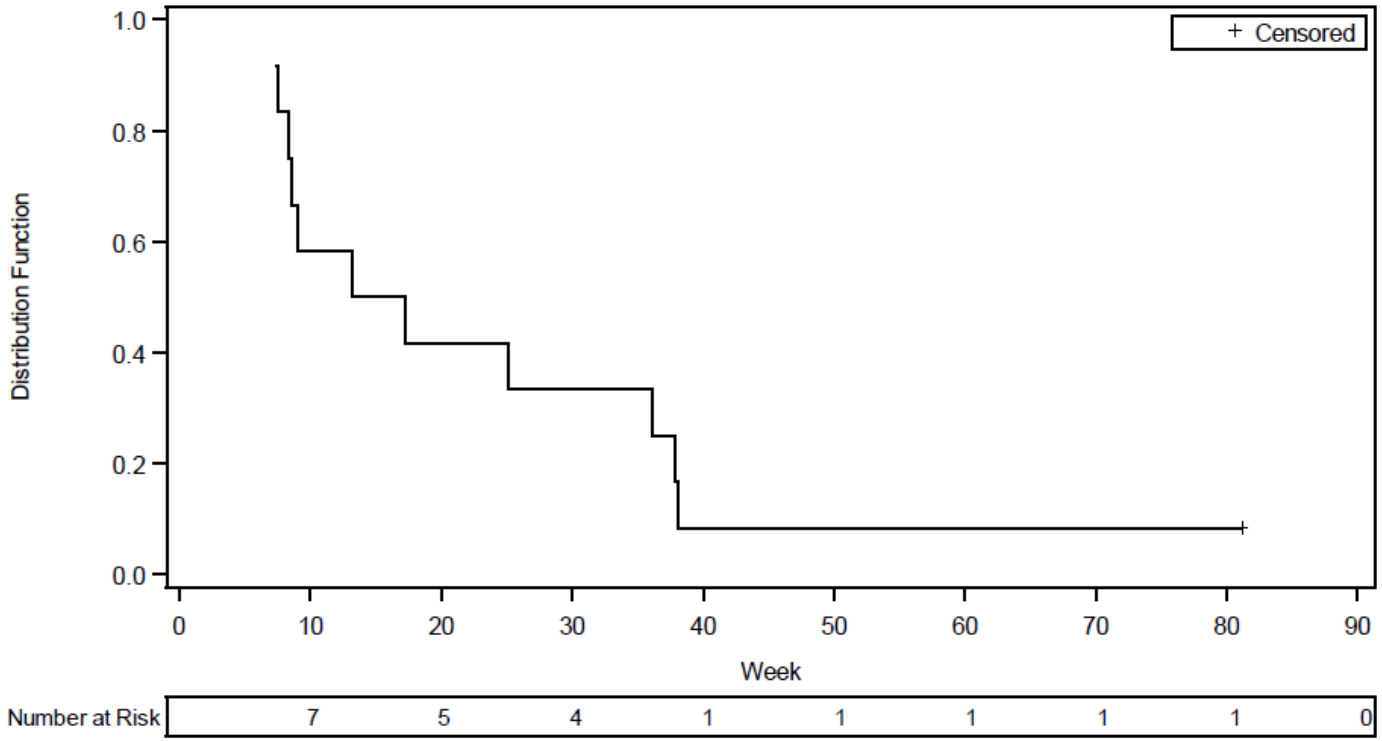
Figure 17.0002
Maximal Reduction in Sum of Diameters of Target Lesions from the Second Infusion through Progression or Prior to Subsequent Anti-Cancer Therapy



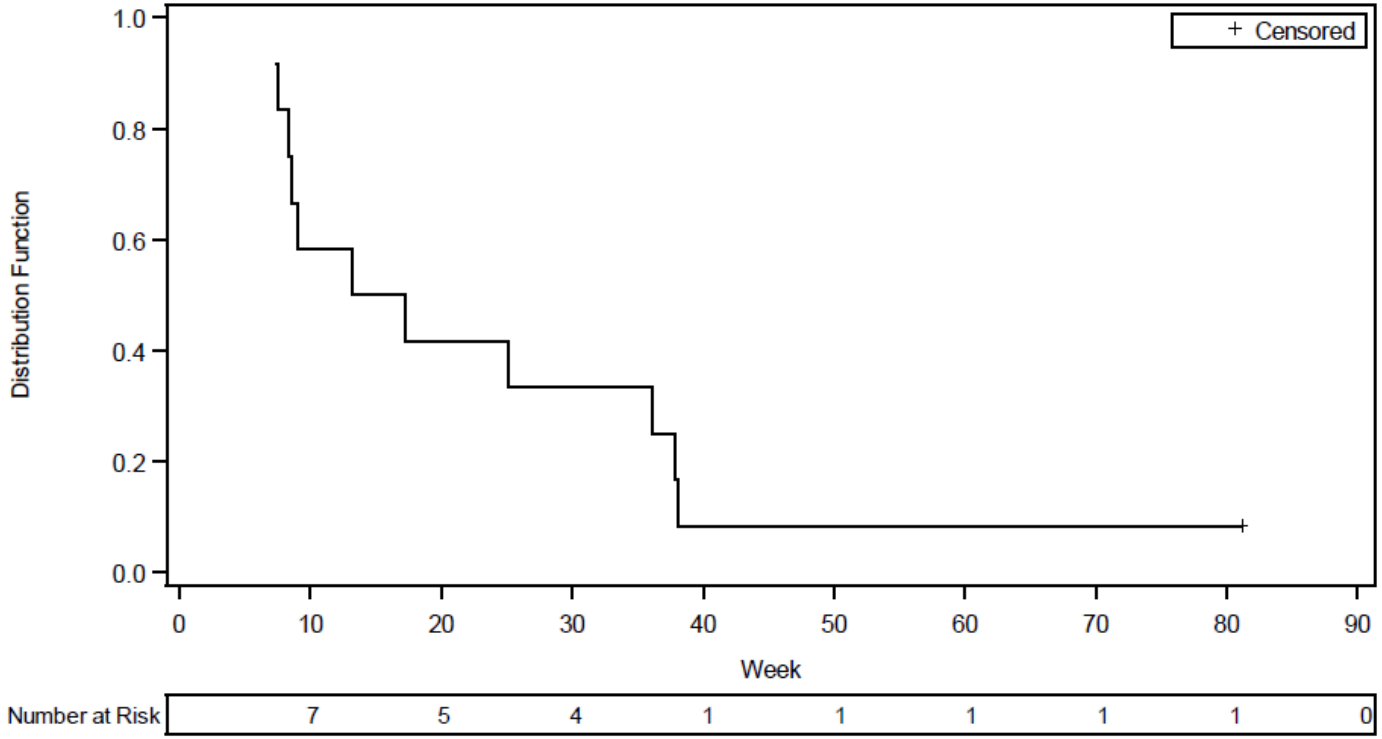
Programming note: for subjects who received 2nd infusion report them all together in in graph and if possible mark the corresponding cohort under the subject ID.
Programming note: please also exclude recordes after anti-cancer treatment.

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat
Figure 17.1001
Kaplan-Meier Plot of Progression-Free Survival

(Data as of: 24APR2018)

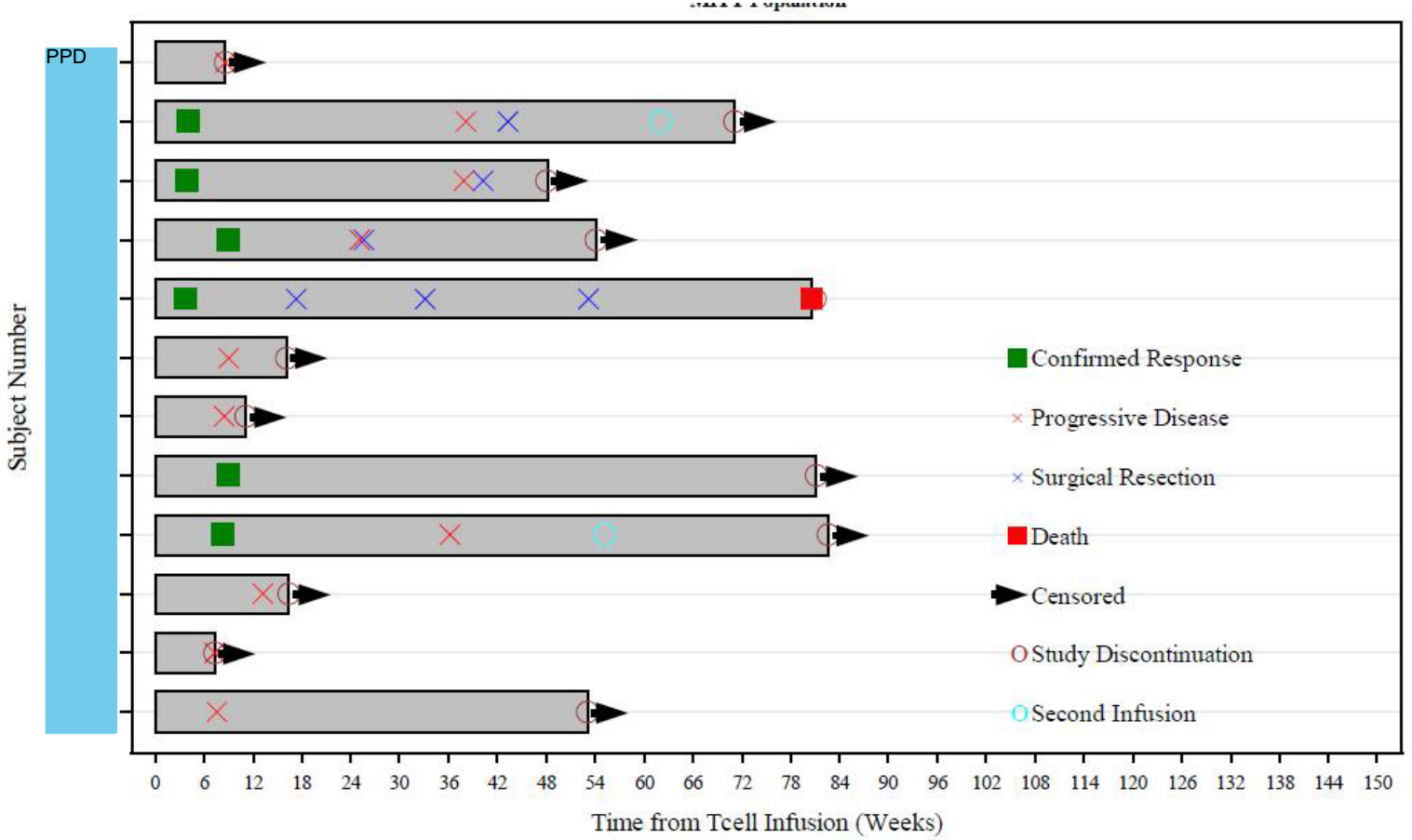


Programming note: please plot all KM curves in on graph and provide legend.



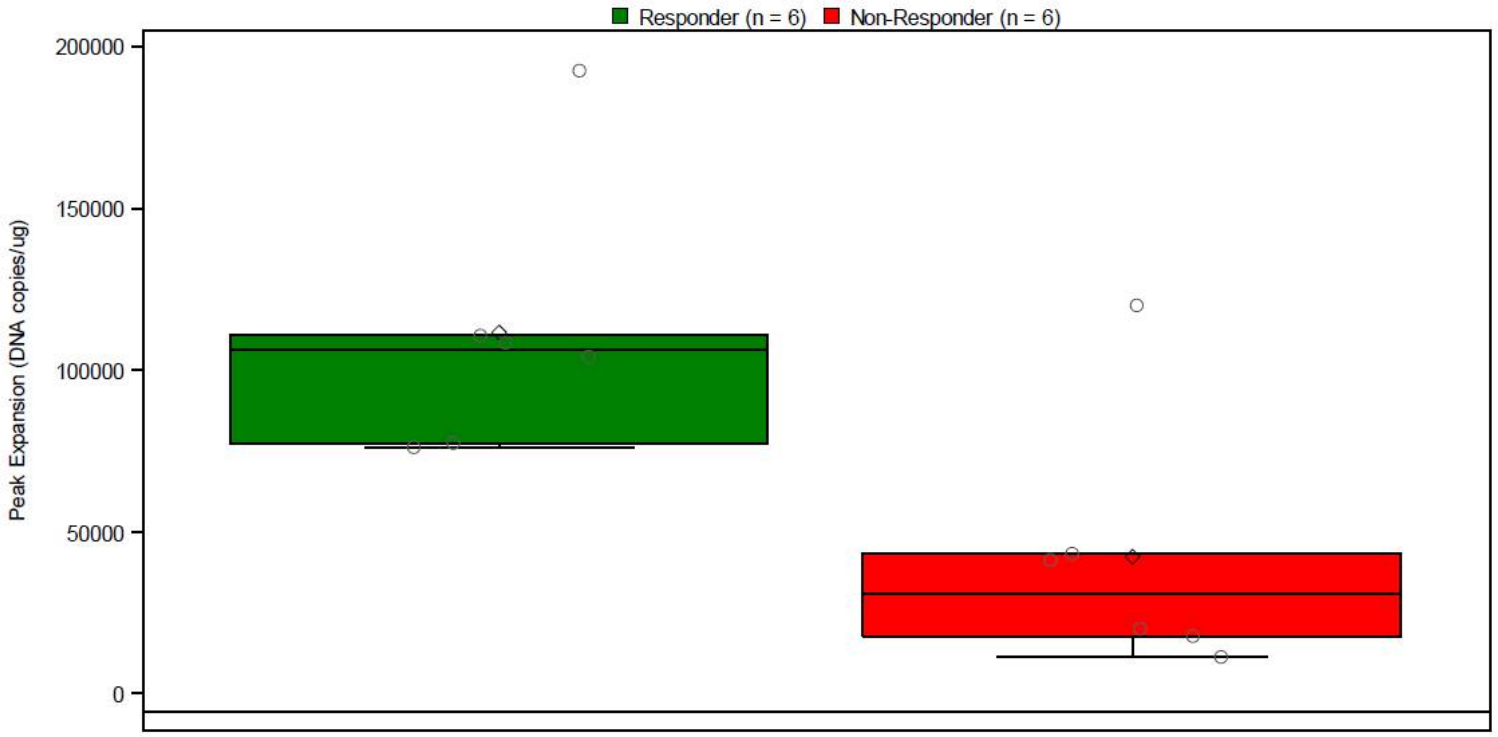
Programming note: please plot all KM curves in on graph and provide legend.

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat
Figure 17.2001
Response Characteristics via RECIST 1.1 and Follow-up
Cohort 1



Programming note: please repeat for cohort 2-4 and add 2nd infusion info. (add a symbol for the start timepoint of the 2nd infusion.) And also change the X-axis label to Time from the First Tcell Infusion (Weeks); please change "x Surgical Resection" to "x Surgical Resection/Anti-Cancer Therapy" in the lengend and so please also mark the anti-cancer therapy in the plot.

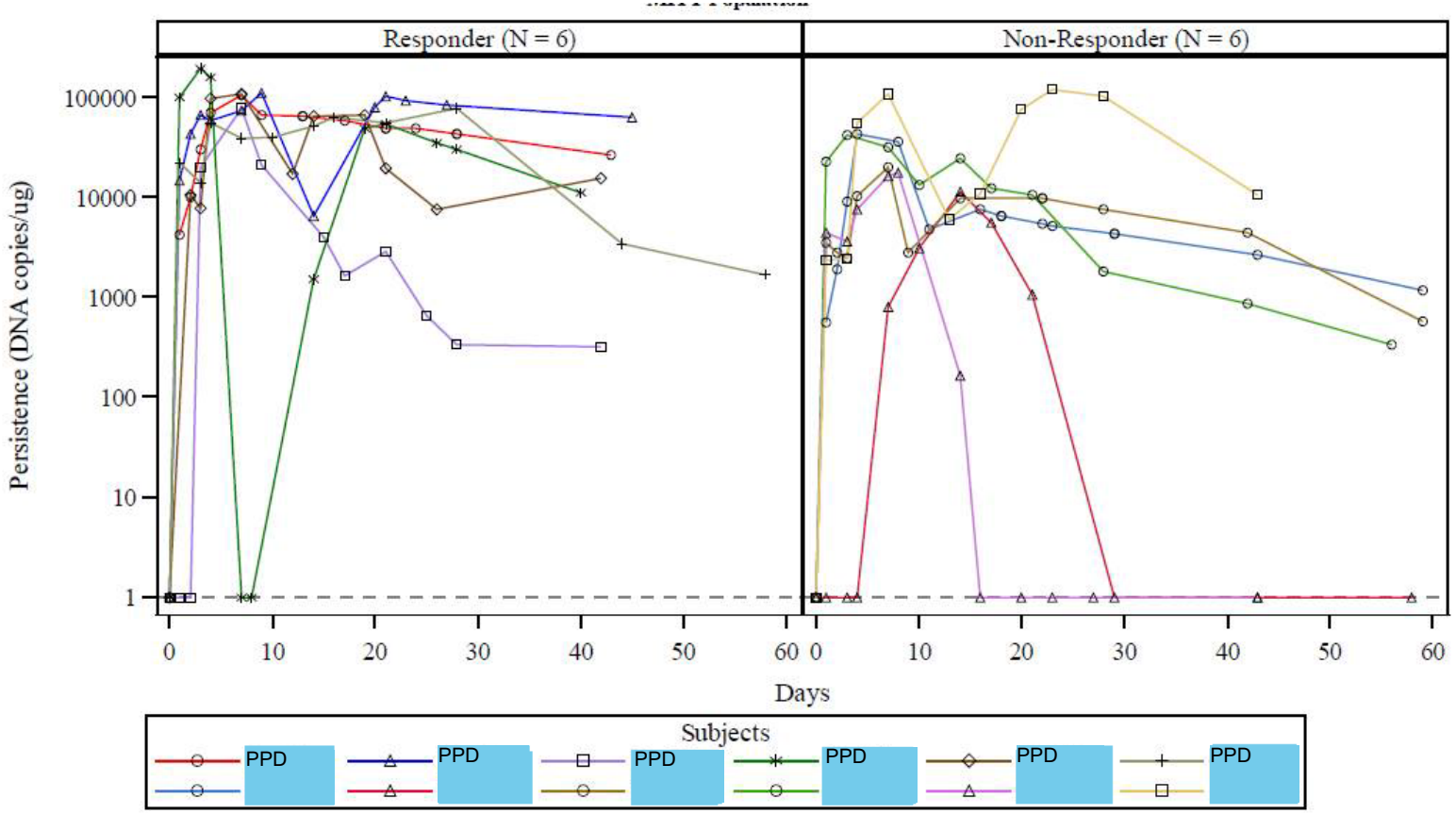
Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat
Figure 17.3001
Boxplots for Peak Expansion by Responders vs. Non-Responders for the First Infusion
Cohort 1



Note: Within each boxplot, the horizontal line is the median and the diamond is the mean.

Programming note: please repeat for cohort 2-4.

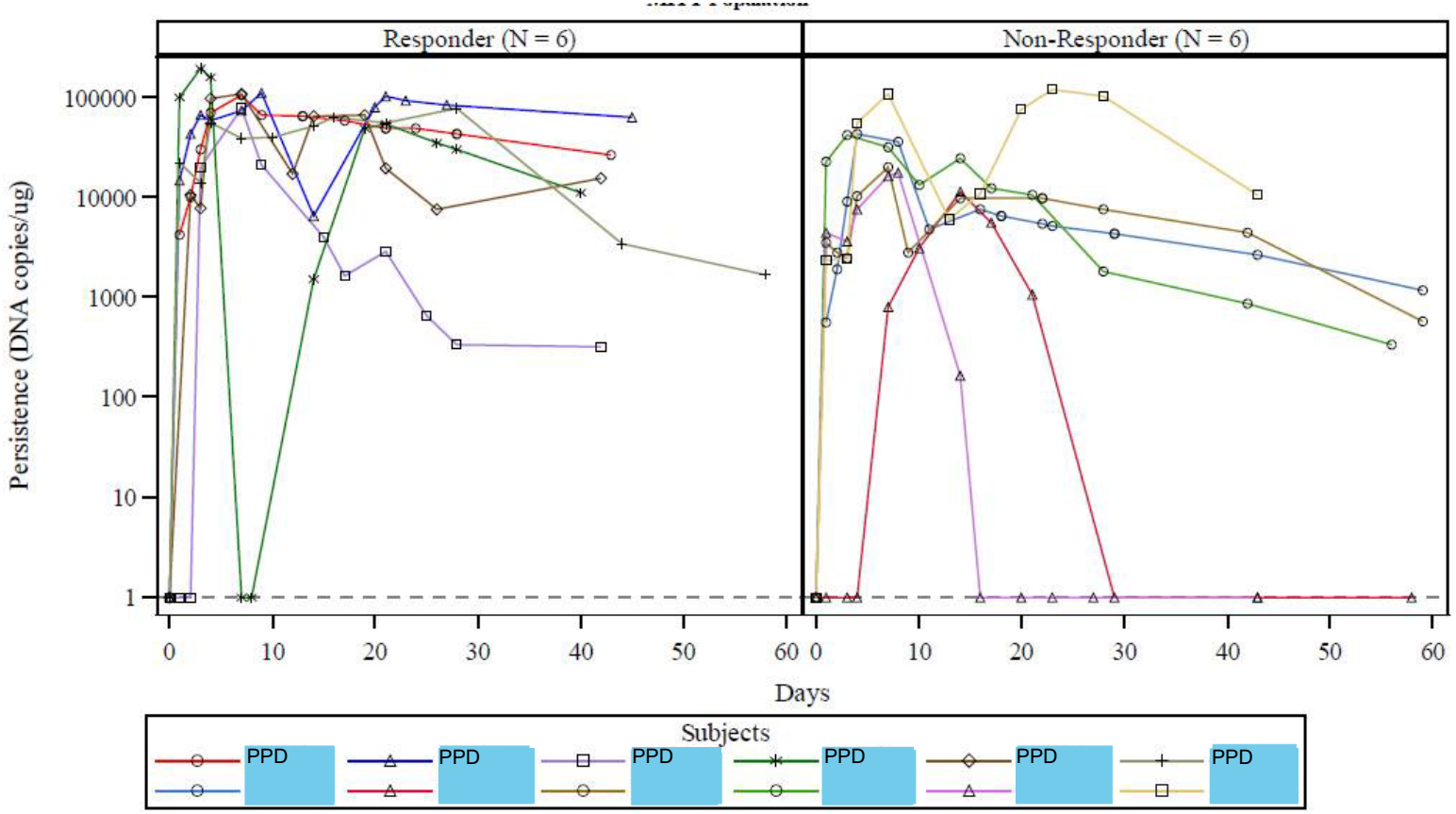
Figure 14.4001
Spider Plots for Persistence Results over Time (Truncated at 60 Days) by Responders vs. Non-Responders for the First Infusion Cohort 1



Note: Y-axis is log-transformed. Values below the lower limit of quantitation are set to 1.
The R and NR before the subject number indicate responders and non-responders, respectively.

Programming note: please repeat for cohort 2-4.

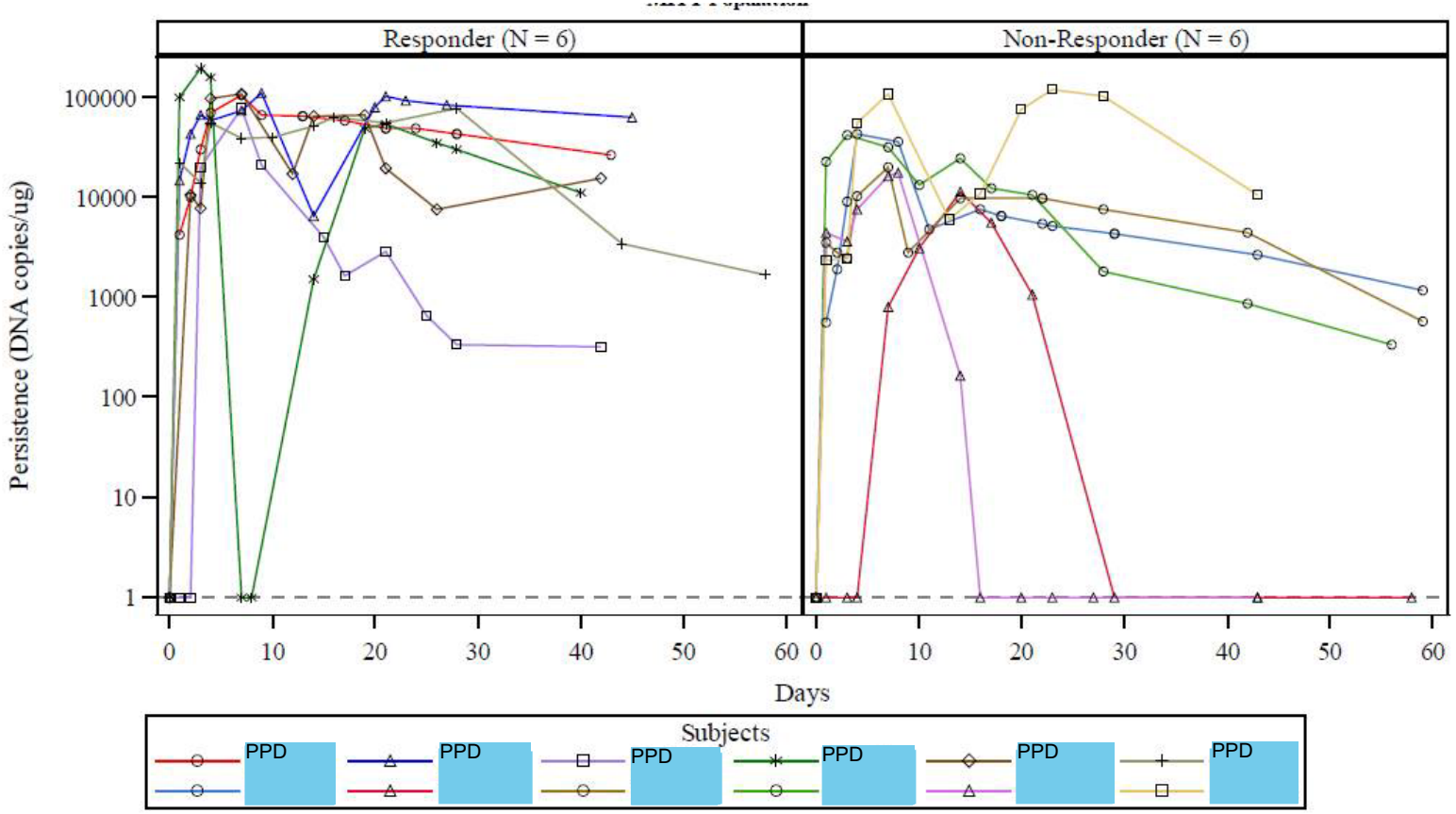
Figure 17.4002
Spider Plots for Persistence Results over Time (Truncated at 100 Days) by Responders vs. Non-Responders for the First Infusion Cohort 1



Note: Y-axis is log-transformed. Values below the lower limit of quantitation are set to 1.
The R and NR before the subject number indicate responders and non-responders, respectively.

Programming note: please repeat for cohort 2-4.

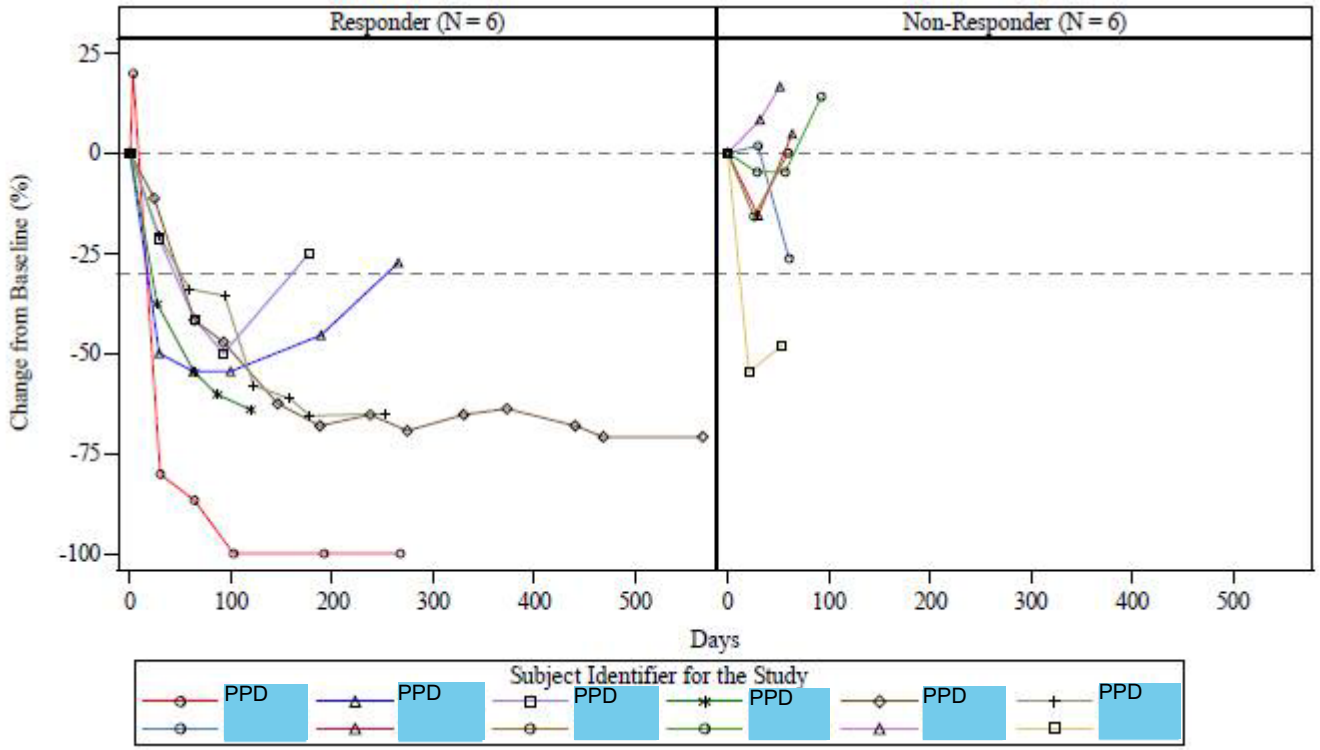
Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)
Figure 17.4003
Spider Plots for Persistence Results over Time by Responders vs. Non-Responders for the First Infusion
Cohort 1



Note: Y-axis is log-transformed. Values below the lower limit of quantitation are set to 1.
The R and NR before the subject number indicate responders and non-responders, respectively.

Programming note: please repeat for cohort 2-4.

Figure 17.4004
Spider Plots of Change from Baseline in Target Lesion through Progression and Prior to Subsequent Anti-Cancer Therapy Over Time by Response Status for the First Infusion
Cohort 1



Note: The R and NR before the subject number indicate responders and non-responders, respectively.

Programming note: please repeat for cohort 2-4. Please also exclude data after anti-cancer therapy (including anti-cancer surgery)

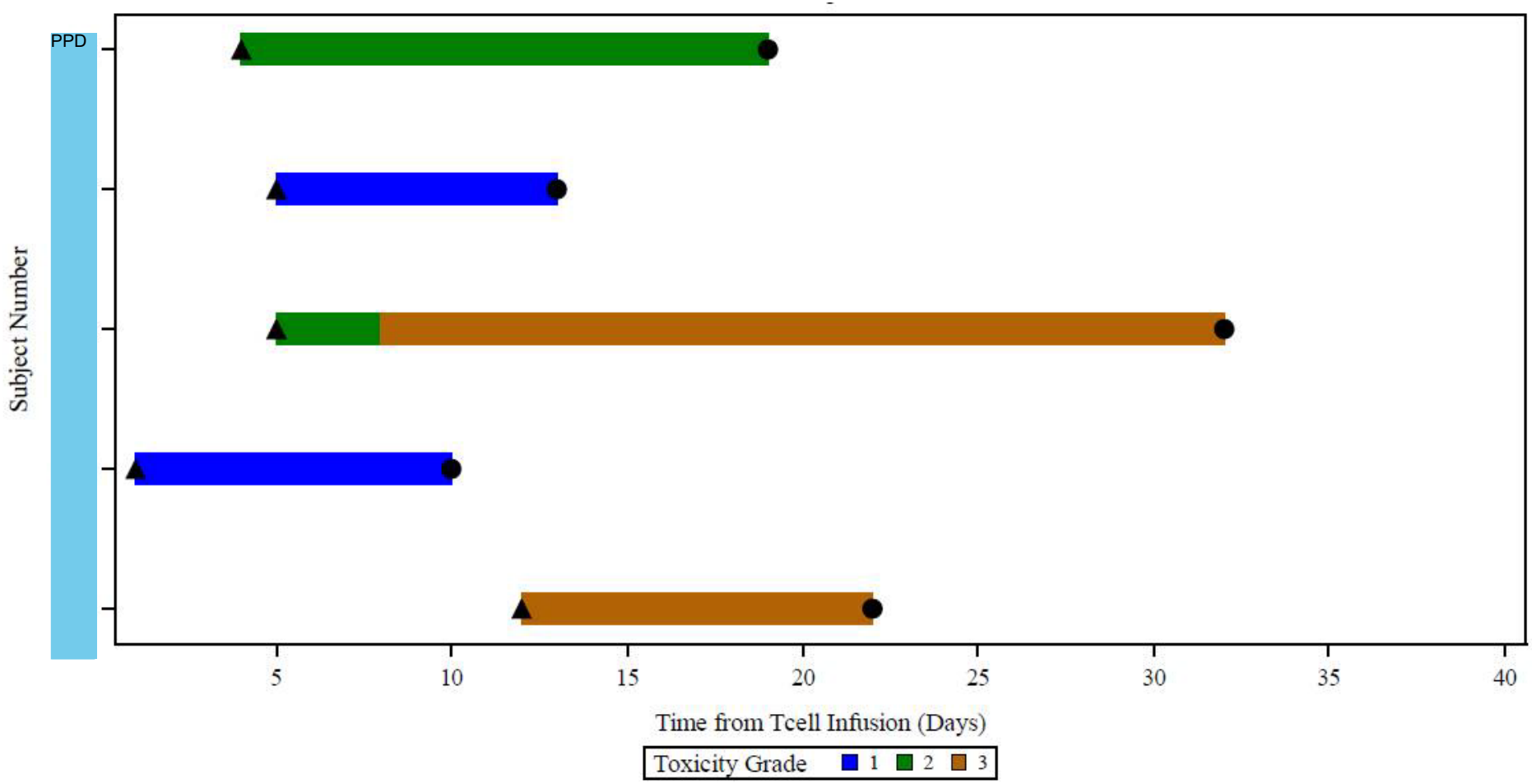
Figure 17.4005: Spider Plots for Persistence Results over Time (Truncated at 60 Days) by Responders vs. Non-Responders for the Second Infusion
Programming note: Repeat Figure 17.4001 for subjects who had 2nd infusion. Please report all subjects who received the 2nd infusion from different cohorts in one plot. Responders/non-responders are only for the 2nd infusion period. please also mark the patient cohort in the legend.

Figure 17.4006: Spider Plots for Persistence Results over Time (Truncated at 100 Days) by Responders vs. Non-Responders for the Second Infusion
Programming note: Repeat Figure 17.4002 for subjects who had 2nd infusion. Please report all subjects who received the 2nd infusion from different cohorts in one plot. Responders/non-responders are only for the 2nd infusion period. please also mark the patient cohort in the legend.

Figure 17.4007: Spider Plots for Persistence Results over Time by Responders vs. Non-Responders for the Second Infusion
Programming note: Repeat Figure 17.4003 for subjects who had 2nd infusion. Please report all subjects who received the 2nd infusion from different cohorts in one plot. Responders/non-responders are only for the 2nd infusion period. please also mark the patient cohort in the legend.

Figure 17.4008: Spider Plots of Change from Baseline in Target Lesion through Progression and Prior to Subsequent Anti-Cancer Therapy Over Time by Response Status for the Second Infusion
Programming note: Repeat Figure 17.4004 for subjects who had 2nd infusion. Please report all subjects who received the 2nd infusion from different cohorts in one plot. Responders/non-responders are only for the 2nd infusion period. please also mark the patient cohort in the legend.

Figure 18.5003
Characteristics of CRS Plot for the First Infusion
Cohort 1



Programming note: please repeat for cohort 2-4. Please use the focused scope AESI list. Change the x-axis label to "Time from the First Tcell Infusion (Days)"

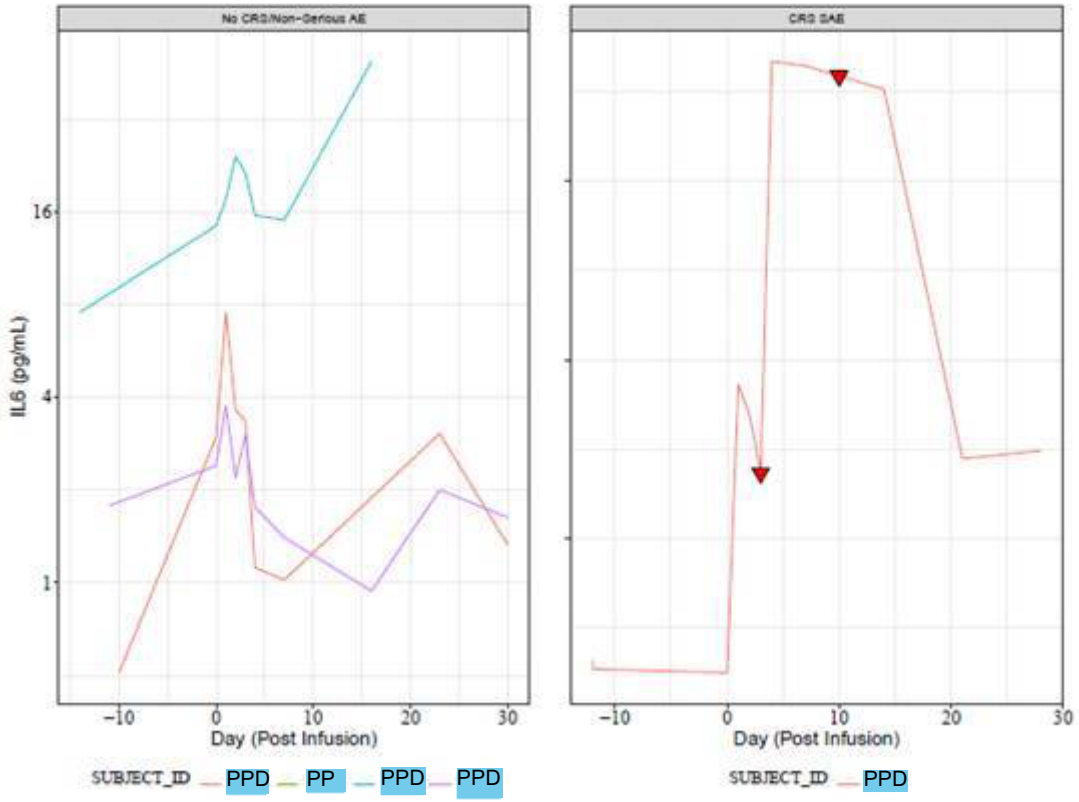
Use Figure 18.5003 as a template for the following figures:

Figure 18.5004
Characteristics of CRS Plot for the Second Infusion
Population: Subjects with a Second T-Cell Infusion
Programming note: please repeat for cohort 2-4. Please use the focused AESI list. Change the x-axis label to "Time from the Second Tcell Infusion (Days)"

Figure 18.5005
Characteristics of Recurrent Pancytopenia with Bone Marrow Failure/Aplastic Anemia plot for the First Infusion
Population: MITT
Programming note: please repeat for cohort 2-4. Please use the focused AESI list of Recurrent Pancytopenia with Bone Marrow Failure/Aplastic Anemia.

Figure 18.5006
Characteristics of Recurrent Pancytopenia with Bone Marrow Failure/Aplastic Anemia plot for the Second Infusion
Population: MITT
Programming note: please repeat for cohort 2-4. Please use the focused AESI list of Recurrent Pancytopenia with Bone Marrow Failure/Aplastic Anemia. Change the x-axis label to "Time from the Second Tcell Infusion (Days)"

Protocol: GSK208466/ADP-04511
Page 1 of 4
Population: Modified Intent-To-Treat
(Data as of: 24APR2018)
Figure 18.5101
Profile of INF-Gamma by CRS Status and Subject (First Infusion)
Cohort 1



Programming note: please repeat for cohort 2-4. Please use the focused scope AESI list. By CSR (None or Non-Serious CRS vs. Serious CRS) and add legend for start and stop of CRS event. Change color of label for end of event.

Use Figure 18.5101 as a template for the following figures:

Figure 18.5102
Profile of IL-6 by CRS Status and Subject (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5103
Profile of IL-8 by CRS Status and Subject (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5104
Profile of IL-12 by CRS Status and Subject (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5105
Profile of IL-13 by CRS Status and Subject (First Infusion)

Figure 18.5106
Profile of TNF-Alpha by CRS Status and Subject (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5107
Profile of TNF-Gamma by Response and Subject (First Infusion)
Population: Modified Intent-To-Treat
Programming note: Change the graph tile to “Responder” and “Non-Responder”

Figure 18.5108
Profile of IL-6 by Response and Subject (First Infusion)
Population: Modified Intent-To-Treat
Programming note: Change the graph tile to “Responder” and “Non-Responder”

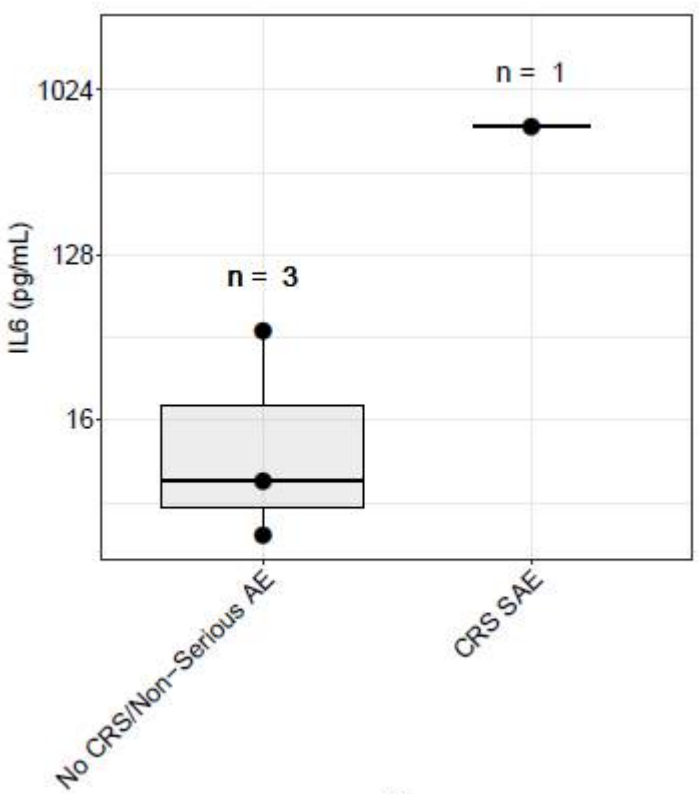
Figure 18.5109
Profile of IL-8 by Response and Subject (First Infusion)
Population: Modified Intent-To-Treat
Programming note: Change the graph tile to “Responder” and “Non-Responder”

Figure 18.5110
Profile of IL-12 by Response and Subject (First Infusion)
Population: Modified Intent-To-Treat
Programming note: Change the graph tile to “Responder” and “Non-Responder”

Figure 18.5111
Profile of IL-13 by Response and Subject (First Infusion)
Population: Modified Intent-To-Treat
Programming note: Change the graph tile to “Responder” and “Non-Responder”

Figure 18.5112
Profile of TNF-Alpha by Response and Subject (First Infusion)
Population: Modified Intent-To-Treat
Programming note: Change the graph tile to “Responder” and “Non-Responder”

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat
Figure 18.5113
Peak Cytokine Expression of INF-Gamma by CRS Status (First Infusion)
Cohort 1



Programming note: please repeat for cohort 2-4. By CSR (None or Non-Serious CRS vs. Serious CRS).

Use Figure 18.5113 as a template for the following figures:

Figure 18.5114
Peak Cytokine Expression of IL-6 by CRS Status (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5115

Peak Cytokine Expression of IL-8 by CRS Status (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5116
Peak Cytokine Expression of IL-12 by CRS Status (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5117
Peak Cytokine Expression of IL-13 by CRS Status (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5118
Peak Cytokine Expression of TNF-Alpha by CRS Status (First Infusion)
Population: Modified Intent-To-Treat

Figure 18.5119
Peak Cytokine Expression of INF-Gamma by Response (First Infusion)
Population: Modified Intent-To-Treat
Programmingn note: by responder and non-responder. Please change the x-axis labels to “Responder” and “Non-Responder”

Figure 18.5120
Peak Cytokine Expression of IL-6 by Response (First Infusion)
Population: Modified Intent-To-Treat
Programmingn note: by responder and non-responder. Please change the x-axis labels to “Responder” and “Non-Responder”

Figure 18.5121
Peak Cytokine Expression of IL-8 by Response (First Infusion)
Population: Modified Intent-To-Treat
Programmingn note: by responder and non-responder. Please change the x-axis labels to “Responder” and “Non-Responder”

Figure 18.5122
Peak Cytokine Expression of IL-12 by Response (First Infusion)
Population: Modified Intent-To-Treat
Programmingn note: by responder and non-responder. Please change the x-axis labels to “Responder” and “Non-Responder”

Figure 18.5123
Peak Cytokine Expression of IL-13 by Response (First Infusion)
Population: Modified Intent-To-Treat
Programmingn note: by responder and non-responder. Please change the x-axis labels to “Responder” and “Non-Responder”
Figure 18.5124
Peak Cytokine Expression of TNF-Alpha by Response (First Infusion)
Population: Modified Intent-To-Treat
Programmingn note: by responder and non-responder. Please change the x-axis labels to “Responder” and “Non-Responder”

Protocol: GSK208466/ADP-04511 Page 1 of 1
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.0001
Subject Disposition

Subject ADSL.SUBJID	Screening Informed Consent Date	Treatment Informed Consent Date	Protocol Version	Subject Status $	Discontinu-ation Date	Reason for Discontinuation	Second T-Cell Infusion?	Second Infusion Consent Date	Date of Death

Cohort:
ADSL.ACTARM

Programmer: If reason for discontinuation is 'Protocol Violation' or 'Failed manufacture of cell product', report this as Reason (e.g. Protocol): <specify> where the specify is from SUPPDS.
There are up to 3 Informed Consent Dates: 1) at Screening visit for study, 2) for treatment, and for second infusion.
Patient Status will be 'End of Infusion 1' or= 'Infusion 2', depending on when the subject exited the study.

Y = Yes, N = No.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
$ Subject Status = 'Infusion 1' or 'Infusion 2', depending on when subject exited the study.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.0002
Study Visits

Cohort	Subject		Visit Date	Reason for
ADSL.ACTARM	ADSL.SUBJID	Visit	(Study Day)	Unscheduled Visit

Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.1401
Inclusion and Exclusion Criteria Not Met Prior to Leukapheresis

Cohort	Subject	Criterion Type	Criterion Number
ADSL.ACTARM	ADSL.SUBJID	Violated	Violated

Note to programmer: Criterion Type Violated = 'Inclusion' or 'Exclusion'.
If all criteria were met, insert statement into listing: 'All subjects met inclusion and exclusion criteria'

Note: Only subjects who did not meet all inclusion/exclusion criteria prior to leukapheresis are listed.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.1403
Protocol Deviations

Cohort	Subject	Date Of Deviation (Study Day)	Description
ADSL.ACTARM	ADSL.SUBJID	DV.DVSTDTC	DV.DVTERM

Note to programmer: exact layout of the listing will not be known until later. Deviations not collected on eCRF.

Note 1: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 2: Only subjects with protocol deviations are listed.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.1101
Demographics and Baseline Characteristics

Cohort ADSL.ACTARM	Cohort Number	Subject ADSL.SUBJID	Date of Birth	Age (Years)	Sex	Child-Bearing Potetnial?	Race	Ethnicity	Weight (kg)	Height (cm)	BMI (kg/m2)	BSA (m2)
	Strip number from ADSL.ARCMD, this should match number in ACTARM except for subjects with treatment of 'Not Assigned'											

Note to programmer: If race is Other, report this as Other: <specify>.

BMI = Body Mass Index (calculated from weight and height), BSA = Body Surface Area (from eCRF).

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.3101
Medical History

MHCAT = 'GENERAL MEDICAL HISTORY'

Cohort	Subject	S:System Organ Class P:Preferred Term V:Verbatim Term	Start Date	End Date Or Ongoing	Treated?
ADSL.ACTARM	ADSL.SUBJID	S: MH.MHBODSYS P: MH.MHDECOD V: MH.MHTERM`	MH.MHSTDTC	MH.MHENDTC Or ONGOING	

Note to Programmer: medical history will be coded with MedDRA.

Y = Yes, N = No.
Note 1: Only subjects with medical history reported are listed.

File Name: S:\..... \&prog_name

Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.3102
HLA and NY-ESO-1 Antigen

Cohort ADSL.ACTARM	Subject ADSL.SUBJID	Sample Date for Cancer Testis Antigen Expression	HLA-A*0201	HLA-A*0205	HLA-A*0206	Other HLA Status	NY-ESO-1 Status

Note to programmer: The HLA and NY-ESO-1 status in this listing is from the Screening Enrollment CRF and the data is in S.SC.
A subject may have more than one HLA status. If HLA Status is Other, report the <specify> in the Other column. A subject will have only one NY-ESO-1 status.

Y = Yes, N = No.
File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)
Listing 26.2101
Disease Characteristics

Cohort ADSL.ACTARM	Subject ADSL.SUBJID	Primary/Original Diagnosis Date	Primary Disease Site at Screening	Disease Stage at Screening	Grade of Histology	Type of Histology

MHSTDTC when MHCAT = 'PRIMARY DIAGNOSIS'

Note to programmer: if Disease Stage or Type of Histology is Other, report this as Other: <specify>.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.4001
Prior Cancer Surgery

Cohort	Subject	Organ - Site of Surgery	Description of Surgery	Surgery Date
ADSL.ACTARM	ADSL.SUBJID			

N = No, Y = Yes.
Note: Only subjects with prior cancer surgery are listed.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 26.4002
Prior Oncology Treatment

Subject ADSL.SUBJID	Therapy Class	Therapy Description	Dose Ordered	Start Date	End Date	Best Response
Cohort: ADSL.ACTARM						

Note to programmer: All prior treatments from CM except for Radiation which is in S.PR

Note: Only subjects reporting prior oncology treatment are listed.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.0001
Dates of Leukapheresis, Lymphodepleting Chemotherapy, and T-Cell Infusion

Cohort ADSL.ACTARM	Subject ADSL.SUBJID	Visit	Treatment	Date of Treatment (Study Day)

Note to programmer: Treatment will be Leukapheresis, Lymhodepleting Chemotherapy (list which med was given), or T-Cell

Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.0002
Lymphodepleting Chemotherapy

Subject ADSL.SUBJID	Medication	Date of Med (Study Day)	Start Time	End Time	Time Point	Hospital-ized? #	Dose (mg/m^2)	Infusion Duration @

Cohort:

Note to Programmers: Include Fludarabine, Cyclophosphamide, and Mesna. Time Point is Pre-CTX or Post-CTX for Mesna.

Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
For Cyclophosphamide treatment.
@ Duration follows ISO 8601 format. P indicates that the value is a duration, T = Time, H = Hours, M = Minutes, D = Days.
File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.0003
T Cell Infusion

Subject ADSL.SUBJID	T-Cell Infusion Date (Study Day)	Start Time/ End Time	Total Cell Dose (x10^9)	Total Cells Transduced (x10^9)	Percent of Cells Infused (%) #	Reason Whole Bag Not Infused #	Duration of Infusion	Vector Copy Number (copies)	Lot Number (PCT Unit #)	Reaction To Infusion?
EXADJ	ECDUR or					EXDUR				
Cohort:										

Y = Yes, N = No.
Note 1: Only subjects who received T Cell Infusion are listed.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
If whole bag was not infused.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 27.0001
Lesion Measurements and Assessments by RECIST v1.1

										ADTRREC.						
Subject	TR. TRVISIT Visit	TR.TRDTC Assessment Date (Study Day)	Method	Lesion ID $	Organ	Site	Tumor Type	Criterion	Longest Diameter (mm)	Short Axis (mm)	PARAMCD= SDIAM Sum of Longest Diameter (mm)	% Change From Baseline	PCHG for SDIAM for BASETYPE = NADIR 1 % Change from Nadir	Assessment @		
				SUPPTU.SITE		TRCAT	TRTESTCD=						TRTESTCD =			
Cohort:			TRMETHOD	TRLNKID TULOC		TRGRPID	LDIAM	TRTESTCD= SAXIS		PCHG for SDIAM for BASETYPE =			TR.TUMSTATE			
									PRETREATMENT BASELINE 1							

Note to programmer: If Site or Modality is Other, report this as Other: <specify>. If TRSTAT = 'NOT DONE', 'ND:'<reason not done> under Assessment Date. Organ, Site, Sum of Longest Diameter and Sum of Short Axis only occur for first row per subject per visit. Tumor Type is Index,Non-Index, Target, Target Nodal, Non-Target, and New. Criterion is IRRC or RECIST v1.1. Assessment is Tumor State.

ND = Not Done.
Note 1: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 2: Sum of Longest Diameter is sum of the longest diameter for non-nodal lesions and short axis for nodal lesions. Sum of Short Axis is sum of the short axis for all nodal lesions.
Note 3: Listing includes subjects who received at least one T cell infusion.
@ Assessment was performed by investigator and applies to Non-target lesions and New lesions.
$ T = Target lesion, NT = Non-target lesion, NEW = New lesion.
File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 27.0003
Response Assessments and Overall Response by RECIST v1.1 for the First Infusion

Subject	Visit	Date of T Cell Infusion	Assessment Date (Study Day)			Target Lesion Evaluation	Non-Target Lesion Evaluation	New Lesions?	Visit Overall Response	Best Overall Response
ADSL.SUBJID	TRTSDT ADT	AVALC for TRGRESP	AVALC for NTRGRESP	AVALC for NEWLES	AVALC for VISRESP					
Cohort:										

Note to programmer: Put 'ND' under Assessment Date if tumor was NOT assessed on a visit.

N
Y = Yes, N = No, PD = Progressive Disease, SD = Stable Disease, NE = Not Evaluable, CR = Complete Response, PR = Partial Response.
RECIST = Response Evaluation Criteria in Solid Tumors.
Note 1: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 2: Evaluation of target and non-target lesions does not take into account the presence of new lesions.
The overall response does take new lesions into account.
Note 3: Subject PPD had a Day 3 assessment of PD that was not used in derivation of Best Overall Response.

File Name: S:\..... \&prog_name

Use Template for Listing 27.0003 for

Listing 27.0004
Response Assessments and Overall Response by RECIST v1.1 Following a Second T Cell Infusion
(Programming note: Please use the following footnotes:
Y = Yes, N = No, PD = Progressive Disease, SD = Stable Disease, NE = Not Evaluable, CR = Complete Response, PR = Partial Response.
RECIST = Response Evaluation Criteria in Solid Tumors.
Note 1: Listing includes only subjects who had a second T cell infusion.
Note 2: 1st Study Day is relative to the date of the first T cell infusion, 2nd study day is relative to date of the second T cell infusion.)

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 27.0005
Investigator RECIST v1.1 Response Assessments and Overall Response for the First Infusion

Subject	Visit	Date of T Cell Infusion	Assessment Date (Study Day)	Target Lesions Evaluation	Non-Target Lesions Evaluation	New Lesions?	Visit Overall Response	Best Overall Response
ADSL.SUBJID		TRTSDT	ADT	AVALC for TRGRESP	AVALC for NTRGRESP	AVALC for NEWLES	AVALC for VISRESP	
Cohort:								

Note to programmer: Put 'ND' under Assessment Date if tumor was NOT assessed on a visit.

Y = Yes, N = No, PD = Progressive Disease, SD = Stable Disease, NE = Not Evaluable, CR = Complete Response, PR = Partial Response.
RECIST = Response Evaluation Criteria in Solid Tumors.
Note 1: Listing includes subjects who received at least one T cell infusion.Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 3: Subjects PPD received anti-cancer therapy on PPD.

File Name: S:\..... \&prog_name

Use Template for Listing 27.0005 for

Listing 27.00051
Investigator RECIST v1.1 Response Assessments and Overall Response Following a Second T Cell Infusion
Programming note: Please using the following footnotes:
Y = Yes, N = No, PD = Progressive Disease, SD = Stable Disease, NE = Not Evaluable, CR = Complete Response, PR = Partial Response.
RECIST = Response Evaluation Criteria in Solid Tumors.
Note 1: Listing includes only subjects who had a second T cell infusion.
Note 2: 1st Study Day is relative to the date of the first T cell infusion, 2nd study day is relative to date of the second T cell infusion.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 27.0007
Progression-Free Survival and Overall Survival
ADTTEREC.PARAMCD = 'PFS' for Reason for PD, Death, Date of PD/Death, Progression-Free Survival.
ADTTEREC.PARAMCD = 'OS' for Date of Death or Censoring and Overall Survival

Cohort	Subject	Date of T cell Infusion	PD?	Reason For PD	Date of PD/Death or Censoring (Study Day)	Progression-Free Survival (Weeks)	Date of Death or Censoring (Study Day)	Overall Survival (Weeks)
		TRTSDT	Y/N		ADT, ADY	AVAL	ADT, ADY	AVAL
			Y if CNSR = 0 N if CNSR = 1					

From ADTTEREC

Note to programmer: there may be multiple reasons for PD. Each can go on a different row. These will be Increased Tumor Burden, Surgical Resection, Prohibited Medications

N = No, Y = Yes, OS = Overall Survival PFS = Progression-Free Survival, PD = Progressive Disease.
Note 1: PFS is defined as the interval between the date of first T cell infusion and the earliest documented evidence of disease progression or death due to any cause or surgical resection or start of prohibited medications. Subjects who do not have a documented date of progression, death, surgical resection, or prohibited medication are censored at the date of last assessment.
Note 2: OS is defined as the interval between the date of first T cell infusion and date of death from any cause. Subjects who are still alive or who are lost to follow-up are censored at the date of last contact.
Note 3: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 4: Listing includes subjects who received at least one T cell infusion.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 27.0008
Time to Confirmed Response, Duration of Response, and Duration of Stable Disease, and Best Overall Response
Note: one row per subject.

Cohort	Subject	Date of T Cell Infusion TRTSDT	AVALC for ADRSREC. PARAMCD = 'BESTRESP' And DTYPE = 'INFUSION 1 RESPONSE' Best Overall Response (BOR) CR, PR, SD, PD, NE	ADT for ADRSREC. PARAMCD = 'RSPSTUS' When AVALC = 'RESPONDER' And DTYPE = 'INFUSION 1 RESPONSE' Date of Confirmed Response (CR or PR) (Study Day)	AVAL for ADTTEREC.PARAMCD = 'TTR' and CNSR = 0. Time to Response (Weeks)	AVAL for ADTTEREC.PARAMCD = 'DOR' and CNSR = 0. Duration of Response (DOR) (Weeks)	AVAL for ADTTEREC.PARAMCD = 'DOSD' and CNSR = 0. Duration of Stable Disease (Weeks)

Programming Note: Subjects who do not have confirmed response of CR or PR will not have values for Date of Confirmed Response, Time to Response. Duration of Response.

From ADRSREC and ADTTEREC

BOR = Best Overall Response, CR = Complete Response, DOR = Duration of Response, PD = Progressive Disease, PR = Partial Response, NE = Not Evaluable, SD = Stable Disease, TTR = Time to Response.
Note 1: TTR is defined as the interval between the date of first T-cell infusion and the earliest date of first documented confirmed CR or confirmed PR among participants with a confirmed PR or CR.
Note 2: Duration of response is defined as the time from first documented evidence of confirmed CR or PR until first documented date of disease progression or death due to any cause or surgical resection or start of prohibited medications. Responders who are still alive and who do not have documented disease progression, surgical resection, or prohibited medication are censored at the date of the last assessment.
Note 3: Listing includes subjects who received at least one T-cell infusion.
Note 4: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 5: Duration of response or duration of stable disease with a "+" sign means the subject did not have documented disease progression.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.1001
Adverse Events for First T Cell Infusion

Subject ADSL.SUBJID	S:System Organ Class P:Preferred Term V:Verbatim Term	Start Date (Study Day)	End Date (Study Day) or Ongoing	Serious?/ Pre? #	Reason Serious @	Toxicity Grade $	Relationship to T Cell Infusion	Action Taken with T Cell Infusion	Other Action Taken	Outcome
			ADAE.AEENDTC							
Cohort:	ADAE.AEBODSYS		(ADAE.AEENDY)	ADAE.TRTEMFL			ADAE.AEREL			ADAE.AEOUT
ADSL.ACTARM	ADAE.AEDECOD	ADAE.AESTDTC		ADAE.AESER				ADAE.AEACN		
	ADAE.AETERM	(ADAE.AESTDY)								

Note 1: Only subjects with adverse events are listed. Includes all adverse events from date of informed consent through end of study or start of lymphodepletion for second T cell infusion, whichever is earlier.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 3: Adverse events are graded using NCI CTCAE Version 4.03.
If Serious = 'Y' and the AE started prior to leukapheresis, response to Pre? = 'Y'. Otherwise, response to Pre is missing.
@ DE = Death, DI = Disability, CA = Congenital Anomaly, LF = Life Threatening, HO = Hospitalization, MS = Medically Significant Event.
$ 'C' after the toxicity grade indicates a change in severity.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.1002
Adverse Events for Second T-Cell Infusion

Subject ADSL.SUBJID	S:System Organ Class P:Preferred Term V:Verbatim Term	Start Date (Study Day 1/ Study Day 2)	End Date (Study Day) or Ongoing	Serious?	Reason Serious @	Toxicity Grade $	Relationship to T Cell Infusion	Action Taken with T Cell Infusion	Other Action Taken	Outcome
			ADAE.AEENDTC							
Cohort:	ADAE.AEBODSYS		(ADAE.AEENDY)	ADAE.TRTEMFL			ADAE.AEREL			ADAE.AEOUT
ADSL.ACTARM	ADAE.AEDECOD	ADAE.AESTDTC		ADAE.AESER				ADAE.AEACN		
	ADAE.AETERM	(ADAE.AESTDY)								

Note to Programmer:

Note 1: Only subjects with adverse events are listed. Includes all adverse events beginning with start of lymphodepletion for second T cell infusion.
Note 2: 1st Study Day is relative to the date of the first T cell infusion, 2nd study day is relative to date of the second T cell infusion.
Note 3: Adverse events are graded using NCI CTCAE Version 4.03.
@ DE = Death, DI = Disability, CA = Congenital Anomaly, LF = Life Threatening, HO = Hospitalization, MS = Medically Significant Event.
$ 'C' after the toxicity grade indicates a change in severity.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.1003
Adverse Events with CTCAE Grade 3 or Higher

Subject ADSL.SUBJID	S:System Organ Class P:Preferred Term V:Verbatim Term	Start Date (Study Day)/ Infusion	End Date (Study Day) or Ongoing	Serious?/ Pre? #	Reason Serious @	Toxicity Grade $	Relationship to T Cell Infusion	Action Taken with T Cell Infusion	Other Action Taken	Outcome
			ADAE.AEENDTC							
Cohort:	ADAE.AEBODSYS		(ADAE.AEENDY)	ADAE.TRTEMFL			ADAE.AEREL			ADAE.AEOUT
ADSL.ACTARM	ADAE.AEDECOD	ADAE.AESTDTC		ADAE.AESER				ADAE.AEACN		
	ADAE.AETERM	(ADAE.AESTDY)								

Note to programmers: Infusion is First or Second. If there are no values for a column, omit the column.

Note 1: Only subjects with adverse events with toxicity grade of 3 or more are listed.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 3: Adverse events are graded using NCI CTCAE Version 4.03.
If Serious = 'Y' and the AE started prior to leukapheresis, response to Pre? = 'Y'. Otherwise, response to Pre is missing.
@ DE = Death, DI = Disability, CA = Congenital Anomaly, LF = Life Threatening, HO = Hospitalization, MS = Medically Significant Event.
$ 'C' after the toxicity grade indicates a change in severity.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.2001
Serious Adverse Events

Subject ADSL.SUBJID	S:System Organ Class P:Preferred Term V:Verbatim Term	Start Date (Study Day) Infusion	End Date (Study Day) or Ongoing	Serious?/ Pre? #	Reason Serious @	Toxicity Grade $	Relationship to T Cell Infusion	Action Taken with T Cell Infusion	Other Action Taken	Outcome
			ADAE.AEENDTC							
Cohort:	ADAE.AEBODSYS		(ADAE.AEENDY)	ADAE.TRTEMFL			ADAE.AEREL			ADAE.AEOUT
ADSL.ACTARM	ADAE.AEDECOD	ADAE.AESTDTC		ADAE.AESER				ADAE.AEACN		
	ADAE.AETERM	(ADAE.AESTDY)								

Note to programmers: Infusion is First or Second.

Note 1: Only subjects with serious adverse events are listed.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 3: Adverse events are graded using NCI CTCAE Version 4.03.
If the SAE started prior to leukapheresis, response to Pre? = 'Y'. Otherwise, response to Pre is missing.
@ DE = Death, DI = Disability, CA = Congenital Anomaly, LF = Life Threatening, HO = Hospitalization, MS = Medically Significant Event.
$ 'C' after the toxicity grade indicates a change in severity.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3001
Cytokine Release Syndrome (CRS)

Subject ADSL.SUBJID	S:System Organ Class P:Preferred Term V:Verbatim Term	Start Date (Study Day)/ Infusion	End Date (Study Day) or Ongoing	Serious?/ Pre? #	Reason Serious @	Toxicity Grade $	Relationship to T Cell Infusion	Action Taken with T Cell Infusion	Other Action Taken	Outcome
Cohort: ADSL.ACTARM	ADAE.AEBODSYS ADAE.AEDECOD ADAE.AETERM	ADAE.AESTDTC (ADAE.AESTDY)	ADAE.AEENDTC (ADAE.AEENDY)	ADAE.TRTEMFL ADAE.AESER			ADAE.AEREL	ADAE.AEACN		ADAE.AEOUT

Note to programmers: Infusion is First or Second. List of preferred terms to include is in Appendix 2 of SAP.

Note 1: Only subjects with adverse events coded to the MedDRA PT cytokine release syndrome or cytokine storm are listed.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 3: Adverse events are graded using NCI CTCAE Version 4.03.
If Serious = 'Y' and the AE started prior to leukapheresis, response to Pre? = 'Y'. Otherwise, response to Pre is missing.
@ DE = Death, DI = Disability, CA = Congenital Anomaly, LF = Life Threatening, HO = Hospitalization, MS = Medically Significant Event.
$ 'C' after the toxicity grade indicates a change in severity.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3002
Graft Versus Host Disease (GVHD)

Subject ADSL.SUBJID	S:System Organ Class P:Preferred Term V:Verbatim Term	Start Date (Study Day)/ Infusion	End Date (Study Day) or Ongoing	Serious?/ Pre? #	Reason Serious @	Toxicity Grade $	Relationship to T Cell Infusion	Action Taken with T Cell Infusion	Other Action Taken	Outcome
Cohort: ADSL.ACTARM	ADAE.AEBODSYS ADAE.AEDECOD ADAE.AETERM	ADAE.AESTDTC (ADAE.AESTDY)	ADAE.AEENDTC (ADAE.AEENDY)	ADAE.TRTEMFL ADAE.AESER			ADAE.AEREL	ADAE.AEACN		ADAE.AEOUT

Note to programmers: Infusion is First or Second. List of preferred terms to include is in Appendix 2 of SAP.

Note 1: Only subjects with adverse events coded to the MedDRA PT terms associated with GVHD are listed.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 3: Adverse events are graded using NCI CTCAE Version 4.03.
If Serious = 'Y' and the AE started prior to leukapheresis, response to Pre? = 'Y'. Otherwise, response to Pre is missing.
@ DE = Death, DI = Disability, CA = Congenital Anomaly, LF = Life Threatening, HO = Hospitalization, MS = Medically Significant Event.
$ 'C' after the toxicity grade indicates a change in severity.

File Name: S:\..... \&prog_name

Programming note:
Use Listing 28.3001 template for:
Listing 28.3003 Recurrent pancytopenia with bone marrow failure/Aplastic anemia
Listing 28.3004 Guillain-Barre syndrome
Listing 28.3005 Encephalopathy syndrome

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3101
Hematology Evaluations – Part 1

Subject ADSL.SUBJID	Visit LB.VIIST	Collection Date (Study Day) LB.LBDTC (LB.LBDY)	Parameter1 (unit)	Parameter2 (unit)	Parameter3 (unit)	Parameter4 (unit)	Parameter5 (unit)	Parameter6 (unit)
Cohort: ADSL.ACTARM			LB.LBSTRESC concatenated with LB.LBNRIND for 'L' or 'H' for each LBTESTCD					

Notes to programmer: If sample not collected, put ND under Collection Date. If test is not done on a parameter on a certain visit put ND as result corresponding to that parameter on that visit. Listing includes Coagulation parameters
List L or H for values outside the reference range. LB.LBNRIND
Include as many parts as needed to accommodate all parameters. If multiple parts, numbering will be 28.3101, 28.3102, etc.

ND = Not Done.
L = Below lower limit of laboratory reference range, H = Above upper limit of laboratory reference range.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Programming note:
Use Listing 28.3101 template for: Listings 28.3111, 28.3121.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat
Listing 28.3131
Clinically Significant Hematology Findings

(Data as of: 24APR2018)

Subject ADSL.SUBJID	Visit LB.VISIT	Collection Date (Study Day) LB.LBDTC (LB.LBDY)	Parameter (unit)	Result	Reference Range

Cohort:
ADSL.ACTARM

Note to programmer: Include only clinically significant values.

L = Below lower limit of laboratory reference range, H = Above upper limit of laboratory reference range.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Page 1 of 1
Population: Modified Intent-To-Treat
(Data as of: 24APR2018)

Listing 28.3132
Listing of Subjects with Potentially Clinically Significant Hepatic Post-Baseline Results for the Post-lymphodepletion Period
mITT Population

Criterion	Cohort	Subject	Visit	Collection Date/Time (Study Day)	Parameter	Value
(≥3xULN AST and/or ALT) and ≥2xULN BIL						

.

ALT = Alanine aminotransferase, AST = Aspartate aminotransferase, BIL = Total bilirubin.
Note 1: Baseline is within 7 days of initiating lymphodepletion.
Note 2: Study Day is relative to the day of the first T Cell infusion (Day 1).

File Name: S:\..... \&prog_name

Programming Note: List all of a subject's values for parameters listed in the criterion if a subject meets criterion for at least one visit.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)
Listing 28.3201
Clinical Chemistry Evaluations – Part 1

Same template as Listing 28.3101

Note to Programmer: Include as many Parts as needed to accommodate all parameters. If multiple parts, numbering will be 28.3202, 28.3203 etc.

File Name: S:\..... \&prog_name

Programming note:
Use Listing 28.3201 template for Listings 28.3211, 28.3221.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3231
Clinically Significant Clinical Chemistry Findings

Same template as Listing 28.3131

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3301
Urinalysis Evaluations – Part 1

Same template as Listing 28.3101

Note to Programmer: Include as many Parts as needed to accommodate all parameters. If multiple parts, numbering will be 28.3302, 28.3303 etc.

File Name: S:\..... \&prog_name

Programming note:
Use Listing 28.3301 template for: Listings28.3311, 28.3321.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3331
Clinically Significant Urinalysis Findings

Same template as Listing 28.3131

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3341
Additional Laboratory Assessments

Cohort	Subject	Visit	Collection Date (Study Day)	ANA	Rheumatoid Factor	TSH (units)	T3 (units)	T4 (units)

Notes to programmer: If all of the tests are not done on a visit, put 'ND' under Collection Date for that visit. If a particular test is not done on a visit, put 'ND' under that test for that visit.

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3342
Clinically Significant Additional Laboratory Findings

Same template as Listing 28.3131

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.3343
Renal Function Findings

Cohort	Subject	Visit	Collection Date (Study Day)	LBSP.TESTCD = CREATCLR Creatinine Clearance (mL/min)	LBSP.TESTCD = CREATEXR Creatinine Clearance Excretion Rate (g/day)	LBSP.TESTCD = EDTACLR EDTA GFR (mL/min)

LBSP.LBCAT = 'RENAL FUNCTION TEST' Notes to programmer: If all of the tests are not done on a visit, put 'ND' under Collection Date for that visit. If a particular test is not done on a visit, put 'ND' under that test for that visit.

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.4001
Replication Competent Lentivirus (RCL)

Cohort	Subject	Visit	Collection Date (Study Day)	Result

Notes to programmer: If test are not done on a visit, put 'ND' under Collection Date for that visit. Data to come from vendor.

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat

(Data as of: 24APR2018)

Listing 28.4002
Persistence

Cohort	Subject	Visit	Collection Date (Study Day)	Result # (copies/mcg DNA)	Lymphocytes (10^9/L)	Monocytes (10^9/L)	Cell Persistence $	% Gene Marked Cells per Lymphocyte &	Coefficient of Variation/ Number of Possitive Replicates	Interpretive Result	Peak Persistence/ Time to Peak Persistence (Days)	Time to 25% Loss of Peak Persistence (Days) / 50% / 75% / Duration of Detectable Persistence
Cohort 1	200	Baseline	01OCT2012(-28)	50.55	0.02	0.02	0.1234546	0.364748	N/A/ 1	NEGATIVE	586978.1/ 2	3/ 14/ 14/ 28+

Notes to programmer: If test are not done on a visit, put 'ND' under Collection Date for that visit. There is a pre-infusion sample on Day 0. Need to map data

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
As collected on eCRF.
$ Cell Persistence = Absolute peripheral gene-marked cell number/µL = (Psi result number/151515) x (lymphocyte count + monocyte count) x 1000, where Psi is value collected on eCRF.
& Percent of gene marked cells per total lymphocyte compartment = ((Absolute peripheral gene marked cell number/µL)/Lymphocyte count x 1000)) x 100.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.4101
Cytokines – Part 1

Cohort	Subject	Visit	Timepoint	T Cell Infusion Dates	Collection Date (Study Day)	Time Point	Param 1	Param 2	Etc.

Notes to programmer: If test are not done on a visit, put 'ND' under Collection Date for that visit. There is a pre-infusion sample on Day 0. Subjects with an AE of CRS will have # after their subject number.
Note to Programmer: Include as many Parts as needed to accommodate all parameters. If multiple parts, numbering will be 28.4102, 28.4103 etc. Data will come from vendor

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Subject has an adverse event of cytokine release syndrome (CRS).

File Name: S:\..... \&prog_name

Porgramming note:
Repeat Listing 28.4101 format for Listing 28.4102.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.4201
Biopsy-Tumor Antigen Results

Cohort	Subject	Visit	Collection Date (Study Day)	Type of Sample	Media of Sample Storage	Any Antigen Expression?	Date of Antigen Expression

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.4301
Flow Cytometry

Cohort	Subject	Visit	T Cell Infusion Dates	Collection Date (Study Day)

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.5001
Pregnancy Test Results

Cohort	Subject	Visit	Date Performed (Study Day)	Specimen Type	Result

Notes to programmer: If pregnancy test not performed, put ND under Date Performed.
Result = Positive or Negative.

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.5101
Vital Signs

Subject ADSL.SUBJID	Visit	Date/Time Performed (Study Day)	Time-point	Blood Pressure Systolic/Diastolic (mmHg)	Pulse Rate (bpm)	Temperature (C)	Respiratory Rate (Breaths/min)	Weight (kg)	BSA (m^2)	Oxygen Saturation (%)
	VS.VISIT	VS.VSDTC (VS.VSDY)	VS.VSTPT	VS.VSSTRESC for VS.VSTESTCD in 'SYSBP'/'DIABP'	VS.VSSTRESC for VS.VSTESTCD = 'HR'		VS.VSSTRESC for VS.VSTESTCD = 'RESP'		VS.VSSTRESC for VS.VSTESTCD = 'BMI'	
Cohort: ADSL.ACTARM						VS.VSSTRESC for VS.VSTESTCD = 'TEMP'		VS.VSSTRESC for VS.VSTESTCD = 'WEIGHT'		VS.VSSTRESC for VS.VSTESTCD = 'OXYSAT'

Notes to programmer: If all of the tests are not done on a visit, put ND under Date Performed for that visit. If all of the tests are not done on a time-point on a certain visit put ND under each test corresponding to that time-point. If a particular test is not done on a visit or on a time point, put 'ND' under that test for that visit or time point.

ND = Not Done.
BSA = Body Surface Area.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Modified Intent-To-Treat (Data as of: 24APR2018)

Listing 28.5102
Listing of Subjects with Potentially Clinically Significant Post-Baseline Vital Signs

Subject ADSL.SUBJID	Visit	Date/Time Performed (Study Day)	Time-point	Blood Pressure Systolic/Diastolic (mmHg)	Pulse Rate (bpm)
	VS.VISIT	VS.VSDTC (VS.VSDY)	VS.VSTPT	VS.VSSTRESC for VS.VSTESTCD in 'SYSBP''DIABP'	VS.VSSTRESC for VS.VSTESTCD = 'HR'
Cohort: ADSL.ACTARM					

Notes to programmer: If all of the tests are not done on a visit, put ND under Date Performed for that visit. If all of the tests are not done on a time-point on a certain visit put ND under each test corresponding to that time-point. If a particular test is not done on a visit or on a time point, put 'ND' under that test for that visit or time point. The listing will contain all of a subject's values for parameters meeting the criteria.

ND = Not Done.
BSA = Body Surface Area.
Note 1: Potentially clinically significant vital signs criteria: heart rate is either less than 60 bpm or greater than 100 bpm; systolic blood pressure ≥ 140 mmHg; Diastolic ≥ 90 mmHg.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.5201
ECOG Performance Status, Karnofsky Score, and Lansky Score

Cohort Subject	Visit	Date Performed (Study Day)	ECOG Score#	Karnofsky Score (%)	Lansky Score (%)

ND = Not Done, ECOG = Eastern Cooperative Oncology Group.
Note 1: The Lansky Score was assessed for children <= 10 years of age. The Karnofsky Score was optional.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1
# ECOG Score
0 = Fully active and able to carry on all pre-disease activities without restriction,
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature,
2 = Ambulatory and capable of all self-care but unable to carry out any work activities,
3 = Capable of only limited self-care,
4 = Completely disabled,
5 = Dead.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6101
Electrocardiogram

Cohort	Subject	Visit	Date/Time Performed (Study Day)	Assessment	Abnormalities	Reason for Unscheduled Assessment

Notes to programmer: If all of the tests are not done on a visit(EGTESTCD = 'EGALL'), put 'ND' under Date Performed for that visit. If a particular test is not done on a visit, put 'ND' under that test for that visit.

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6201
Physical Examination

Cohort ADSL.ACTARM	Subject ADSL.SUBJID	Visit	Date Performed (Study Day)	Body System	Abnormality

Notes to programmer: If Physical Examination is not performed, put ND under Date Performed. If Body System result was not done, put ND under Abnormality.

ND = Not Done.
Note 1: Only abnormalities and body systems not assessed are listed.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6301
Concomitant Medications

Subject ADSL.SUBJID	A:ATC-3 P:Preferred Name V:Verbatim Name	Start Date (Study Day)	End Date (Study Day) or Ongoing	Dose (units)	Frequency	Route	Indication CM.CMINDC
Cohort ADSL.ACTARM	A: QVAL when QNAM = ATC3 P: CM.CMDECOD V: CM.CMTRT	CM.CMSTDTC (CM.CMSTDY)	CM.CMENDTC (CM.CMENDY) Or CM.CMENRF				

Note to programmer: If Unit, Frequency, or Route is Other, report this as Other: <Specify>.

Note 1: Only subjects reporting medications are listed.
Note 2: Medications are coded by WHO Drug Dictionary 2015-Dec.
Note 3: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.
Note 4: If the 3rd level term is not available, the next available level is used.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6401
Bridging Therapies

Cohort ADSL.ACTARM	Subject ADSL.SUBJID	Start Date (Study Day)	Stop Date (Study Day)	Hospitalized for Therapy?	Therapy Class	Therapy Description	Dose Ordered	Disease Status

Note 1: Only subjects with cancer therapies given after apheresis and before lymphodepletion are listed.
Note 2: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6402
On-Study Surgery

Cohort	Subject	T-Cell Infusion Dates	Organ - Site of Surgery	Description of Surgery	Surgery Date
ADSL.ACTARM	ADSL.SUBJID				

N = No, Y = Yes.
Note: Only subjects with surgery following T-cell administration are listed.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6403
On-Study Oncology Treatment
CM.CMCAT = 'ON STUDY ONCOLOGY TREATMENT'
PR.PRCAT = 'ON STUDY ONCOLOGY TREATMENT'

Cohort ADSL.ACTARM	Subject ADSL.SUBJID	T-Cell Infusion Dates	Therapy Class	Therapy Description	Dose Ordered	Start Date (Study Day)	End Date (Study Day)
			'RADIATION' If from PR CM.CMSCAT	PRTRT CMTRT	PRDOSTXT CMDOSTXT		

Note to programmer: All prior treatments from CM except for Radiation which is in S.PR

Note: Only subjects reporting prior oncology treatment are listed.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6404
Echocardiogram or Multigated Acquisition Scan (MUGA)

Cohort ADSL.ACTARM	Subject ADSL.SUBJID	Visit	Date Performed (Study Day)	Test Performed	Result	Details of CS Abnormality	LVEF (%)
				ECHO MUGA			

CS = Clinically Significant, NCS = Not Clinically Significant, LVEF = Left Ventricular Ejection **Fraction.**
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat (Data as of: 24APR2018)

Listing 28.6502
EBV and Anti-CMV Status

Cohort	Subject	Visit	Collection (Study Day)	EBV Status	Anti-CMV Status
ADLBSP					

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name

Protocol: GSK208466/ADP-04511
Population: Intent-To-Treat

(Data as of: 24APR2018)

Listing 28.6503
Infection Disease Testing

Cohort	Subject	Visit	Date of Testing (Study Day)

ND = Not Done.
Note: Study Day is relative to the date of the first T cell infusion, which is Study Day 1.

File Name: S:\..... \&prog_name