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

Title	:	Reporting and Analysis Plan for 205184: A single-centre, randomized, double-blind (sponsor-unblinded), placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of GSK2982772 in repeat oral doses in healthy subjects
Compound Number	:	GSK2982772
Effective Date	:	30-NOV-2018

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 205184.
- This RAP is intended to describe the safety, tolerability and PK 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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1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Study Report for Protocol 205184:

Revision Chronology:		
2017N326600_00	31-JUL-2017	Original
2017N326600_01	07-DEC-2017	Amendment 01
2017N326600_02	15-FEB-2018	Amendment 02
2017N326600_03	26-FEB-2018	Republished Amendment 02

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

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

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
An interim analysis may be performed during the study on completed cohorts in Part A and Part B of the study to aid internal decision making only. The RAP will describe the planned interim analyses in greater detail.	No formal IA will be conducted during the study.	The DEC make decisions on proceeding to higher dose strengths based on assessment of safety, tolerability and pharmacokinetic data at the preceding dose only.
Protocol Section 10.3 references an 'Enrolled population'.	RAP uses the 'Randomised Population'.	The population was renamed to match the current IDSL guidance.

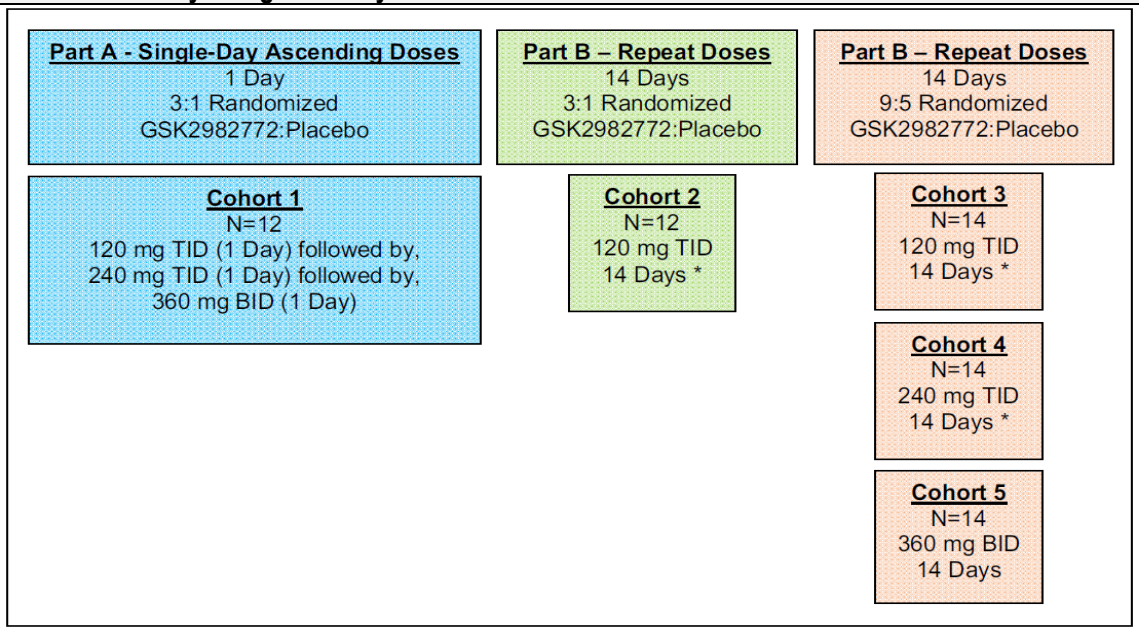
2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To investigate the safety and tolerability of repeat doses of GSK2982772 in healthy subjects.	• Adverse events. • Clinical laboratory values (clinical chemistry, haematology and urinalysis). • Vital sign measurements (blood pressure, heart rate, respiratory rate and body temperature). • Physical examinations. • 12-Lead ECG monitoring.

Objectives	Endpoints
Secondary Objectives	**Secondary Endpoints**
• To characterise the pharmacokinetic (PK) profile of repeat doses of GSK2982772 in healthy subjects.	• A 24 hr profile to be collected on Day 1 of Part A and Day 14 of Part B. On Day 1 of Part B, the PK profile will be evaluated following the first dose only. Derived PK parameters for GSK2982772, including area under the plasma drug concentration versus time curve over 24 hr ($AUC_{(0-24)}$) and AUC over each dose interval (i.e. $AUC_{(0-7)}$, $AUC_{(7-14)}$ and $AUC_{(14-24)}$ for TID and $AUC_{(0-12)}$ and $AUC_{(12-24)}$ for BID). Maximum observed plasma drug concentration (C_{max}) following each dose, time to maximum observed plasma drug concentration (T_{max}) following each dose, observed trough plasma drug concentrations (C_0, C_7, C_{14} and C_{24} for TID dosing and C_0, C_{12} and C_{24} for BID dosing).
• To assess the impact of food on the PK of repeat doses of GSK2982772 in healthy subjects at steady state	• Derived PK parameters for GSK2982772, including $AUC_{(0-7)}$, $AUC_{(7-14)}$, C_{max}, after 1st dose of day and T_{max} after 1st dose of day.
• To assess potential effect of repeat doses of GSK2982772 on CYP3A4 enzyme activity	• Plasma 4β-hydroxycholesterol to cholesterol ratio pre-treatment and following 14 days of repeat dosing of GSK2982772.
Exploratory Objectives	**Exploratory Endpoints**
• To investigate the levels of circulating glucuronide metabolite (M8; GSK3562183) and desmethyl metabolite (M9; GSK2997852) in healthy subjects after single-day and repeat dosing of GSK2982772.	• Quantify M8 (GSK3562183) and M9 (GSK2997852) in select plasma PK samples at pre-dose and 2 hr following Day 14 of repeat dosing of GSK2982772.

2.3. Study Design

Overview of Study Design and Key Features



*With Food Effect Treatment

Design Features	• This is a single-centre, randomized, double-blind (sponsor-unblinded), placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of GSK2982772 in repeat oral doses in healthy participants.
	• This study consists of 2 parts:
	  • Part A (Cohort 1) – single ascending dose, randomized, placebo-controlled, 3-way crossover.
	  • Part B (Cohorts 2, 3, 4 and 5) – repeat dose, randomized, placebo-controlled, sequential-group.

Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• The study is planned to enrol approximately 66 participants with approximately 12 participants (9 active, 3 placebo) in Cohorts 1 and 2 (up to approximately 24 in total) and 14 participants (9 active, 5 placebo) in Cohorts 3, 4 and 5 (up to approximately 42 in total). • If participants prematurely discontinue the study, additional replacement participants may be randomized in order to guarantee that sufficient participants are treated with GSK2982772 at any given dose before escalating to the following dose. Replacement participants will be assigned to the same treatment sequence (Cohort 1) or treatment (Cohorts 2-5). • All participants will be centrally randomized using an Interactive Voice/Web Response System (IVRS/IWRS). Study treatment is dispensed at the study visits summarized in the Schedule of Activities (SoA). Each participant is dispensed blinded study treatment, labelled with his/her unique randomization number, throughout the study. Returned study treatment should not be re-dispensed to the participants.

Overview of Study Design and Key Features	
	• In Cohorts 1 and 2, participants will be randomized in a 3:1 ratio to either GSK2982772 or placebo. In Cohorts 3, 4 and 5, participants will be randomized in a 9:5 ratio to either GSK2982772 or placebo. • The randomization will reflect the fact that at least 2 of the 12 participants in Cohorts 1 and 2 and at least 2 of the 14 participants in Cohort 4 and 5 (one participant will receive GSK2982772 and one participant will receive matched-placebo) will be dosed first (on Day 1) in each part to enable dose staggering. • In Cohort 1, the participants will be randomized to one of four sequences (ABC, ABP, APC, PBC), where the treatments are: A 120 mg TID B 240 mg TID C 360 mg BID P Placebo • Once a treatment allocation number has been assigned to a participant, it cannot be reassigned to any other participant.
Dosing	• For TID dosing, GSK2982772 or placebo will be administered using a 7hr and 7hr dosing interval in Part A and a 7hr, 7hr and 10hr dosing interval in Part B. • For BID dosing, GSK2982772 or placebo will be administered using a 12hr dosing interval.
Interim Analysis	• No interim analyses will be performed. • The decision to proceed to higher dose strengths will be made by the Dose Escalation Committee (DEC) based on assessment of safety, tolerability and pharmacokinetic data at the preceding dose.

2.4. Statistical Hypotheses / Statistical Analyses

- The objectives of this study are to assess the safety and tolerability of single and repeat ascending doses of GSK2982772. No formal hypotheses will be tested.

- An estimation approach will be used to describe pharmacokinetics of GSK2982772, where point estimates and corresponding 90% confidence intervals will be constructed, unless otherwise stated.

3. PLANNED ANALYSES

3.1. Interim Analyses

No interim analyses will be performed. The decision to proceed to higher dose strengths will be made by the Dose Escalation Committee (DEC) based on assessment of safety, tolerability and pharmacokinetic data at the preceding dose.

3.2. Final Analyses

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

1. All participants have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.
3. All criteria for unblinding the randomization codes have been met.
4. Randomization codes have been distributed according to RandAll NG procedures.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Subjects	• Comprises of all participant who were screened and allocated a subject number.	• Screen Failure • Population Analysed.
Randomised	• All participants who were randomly assigned to treatment in the study. • This population will be based on the treatment the participant was randomized to.	• Age ranges
Safety	• Comprises of all randomised participants who received at least one dose of study treatment. • This population will be based on the treatment the subject was randomised to.	• All other Study Population • Safety
Pharmacokinetic	• Participants in the 'Safety' population for whom a pharmacokinetic sample was obtained and analysed.	• PK

Refer to Appendix 10: List of Data Displays which details the population used for each display.
Note: All data displays (Tables, Figures & Listings) will use the term "Subject" which reflects CDISC and GSK Data Display Standards terminology.

4.1. Protocol Deviations

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

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan (Version 4.0, 01 Feb 18)

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

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

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions			
RandAll NG		Data Displays for Reporting	
Code	Description	Description	Order in TLF
P	Placebo TID Single Dose	Placebo	1
Q	Placebo BID Single Dose	Placebo	1
A	GSK2982772 120 mg TID Single Dose	GSK 120 mg TID	2
B	GSK2982772 240 mg TID Single Dose	GSK 240 mg TID	3
C	GSK2982772 360 mg BID Single Dose	GSK 360 mg BID	4
R	Placebo TID Repeat Dose	Placebo	1
S	Placebo BID Repeat Dose	Placebo	1
D	GSK2982772 120 mg TID Repeat Dose	GSK 120 mg TID	2
E	GSK2982772 240 mg TID Repeat Dose	GSK 240 mg TID	3
F	GSK2982772 360 mg BID Repeat Dose	GSK 360 mg BID	4
G	GSK2982772 Cohort 3 Repeat Dose	GSK 120 mg TID	2
H	GSK2982772 Cohort 4 Repeat Dose	GSK 240 mg TID	3
J	GSK2982772 Cohort 5 Repeat Dose	GSK XX mg TID/BID [1]	3 or 4
T	Placebo Cohort 3 Repeat Dose	Placebo	1
U	Placebo Cohort 4 Repeat Dose	Placebo	1
V	Placebo Cohort 5 Repeat Dose	Placebo	1

NOTES:

[1] Dose level not required as the study met the PK stopping criteria at the end of Cohort 4.

5.2. Baseline Definitions

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

For Part A, baseline definitions defined in the table are applicable to each treatment period.

Unless otherwise stated, if baseline data is missing no derivation will be performed and baseline will be set to missing. The mean of triplicate measurements at any given time point will be used as the value for that time point unless otherwise stated.

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Day -1	Day 1 (Pre-Dose)	
Safety				
Clinical Chemistry/ Haematology/ Urinalysis	X	X	X	Day 1
12-lead ECG [1]	X	X	X	Day 1
Vital Signs	X	X	X	Day 1
C-SSRS (Part B only)	X	X		Day -1/Day 1
Pharmacokinetic				
PK Concentrations/ Parameters			X	Day 1

NOTES:

[1] ECG recordings will be performed in triplicate at screening. Use the mean of the triplicate measurements.

5.3. Multicentre Studies

This is a single centre study.

5.4. Examination of Covariates, Other Strata and Subgroups

There are no covariates, strata or subgroups to be investigated in this study.

5.5. Multiple Comparisons and Multiplicity

No adjustments for multiplicity will be required.

5.6. Other Considerations for Data Analyses and Data Handling Conventions

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

Section	Component
10.1	Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population
10.2	Appendix 2: Schedule of Activities
10.3	Appendix 3: Assessment Windows
10.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
10.5	Appendix 5: Data Display Standards & Handling Conventions
10.6	Appendix 6: Derived and Transformed Data
10.7	Appendix 7: Reporting Standards for Missing Data
10.8	Appendix 8: Values of Potential Clinical Importance
10.9	Appendix 9: Abbreviations & Trademarks
10.10	Appendix 10: List of Data Displays
10.11	Appendix 11: Example Mock Shells for Data Displays

6. SAFETY ANALYSES

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

6.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 10: List of Data Displays.

6.2. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 10: List of Data Displays.

Additionally, plasma 4β-hydroxycholesterol to cholesterol ratio pre-treatment and following 14 days of repeat dosing of GSK2982772 will be summarised and listed.

In addition to GSK Core Data Standards, lipids (Total Cholesterol, Triglycerides, HDL cholesterol, LDL cholesterol and Total Cholesterol/HDL ratio) outside the normal range and percent change in lipids will be summarised. The fasting lipid status will be included in listings.

6.3. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs and vital signs will be based on GSK Core Data Standards, unless otherwise specified. Suicide risk monitoring including analyses of Colombia Suicide Severity Rating Scale (C-SSRS) will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 10: List of Data Displays.

7. STUDY POPULATION ANALYSES

7.1. Overview of Planned Study Population Analyses

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

Study population analyses including analyses of participant's disposition, protocol deviations, demographic and baseline characteristics, concomitant medication, and exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 10: List of Data Displays.

8. PHARMACOKINETIC ANALYSES

8.1. Primary Pharmacokinetic Analyses

8.1.1. Endpoint / Variables

8.1.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 10.5.3 Reporting Standards for Pharmacokinetic).

8.1.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters will be calculated by standard non-compartmental analysis according to current working practices and using the currently supported version of WinNonlin. All calculations of non-compartmental parameters will be based on actual sampling times. Pharmacokinetic parameters listed will be determined from the plasma concentration-time data, as data permits.

Parameter	Parameter Description
$AUC_{(0-24)}$	Area under the curve from time zero hours to 24 hours
$AUC_{(0-7)}$	Area under the curve from time zero hours to 7 hours (TID only)
$AUC_{(7-14)}$	Area under the curve from time 7 hours to 14 hours (TID only)
$AUC_{(14-24)}$	Area under the curve from time 14 hours to 24 hours (TID only)
$AUC_{(0-12)}$	Area under the curve from time zero hours to 12 hours (BID only)
$AUC_{(12-24)}$	Area under the curve from time 12 hours to 24 hours (BID only)
Cmax	Maximum observed concentration after 1st, 2nd and 3rd dose in Part A and on Day 14 in Part B
Tmax	Time to maximum observed concentration after 1st, 2nd and 3rd dose in Part A and on Day 14 in Part B
C_0	Concentration at zero hours (pre-dose)
C_7	Concentration at 7 hours post-dose (TID only)
C_{12}	Concentration at 12 hours post-dose (BID only)
C_{14}	Concentration at 14 hours post-dose (TID only)
C_{24}	Concentration at 24 hours post-dose

NOTES:

- Additional parameters may be included as required.

8.1.2. Summary Measure

- The PK of TID and BID dosing on Day 1 in Part A will be evaluated. In Part B the comparisons of interest will be:
  - The PK profile following the 1st dose of the day following administration in the fed state (standard meal on Day 9 and high fat meal on Day 11) or in the fasted state (Day 14).
  - The pharmacokinetic profile following the 1st dose on Day 14 (fasted) and the 1st dose on Day 1 (fasted);

- Descriptive statistics (n, arithmetic mean, standard deviation [SD] standard error [SE], 95% CI, minimum, median and maximum) will be calculated by treatment for all PK concentrations over time and for the derived PK parameters. In addition, for loge-transformed PK parameter variables geometric mean, 95% CI and $\%CV_b$ ($100 * \sqrt{(\exp(SD^2) - 1)}$) will be provided, where the SD is the standard deviation of log-transformed data.

8.1.3. Population of Interest

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

8.1.4. Strategy for Intercurrent (Post-Randomization) Events

- Study completion (i.e. as specified in the protocol) was defined as completing all phases of the study including the follow-up visit.
- Withdrawn participants may be replaced in the study. Replacement participants, enrolled will be dosed with the next planned treatment of the withdrawn participant, and they will not receive any treatment that the withdrawn participant has already received with the exception of the need to increase participants numbers to obtain the minimum number of evaluable participants required for interim decisions, and to obtain data in any other treatment that is required for a valid comparison. Replacement participants will receive the required treatments in the same order as planned for the original participant.
- All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

8.2. Secondary Pharmacokinetic Analyses

8.2.1. Endpoint / Variables

8.2.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 10.5.3 Reporting Standards for Pharmacokinetic).

- Descriptive statistics (n, arithmetic mean, standard deviation, standard error, 95% CI, minimum, median and maximum) of circulating glucuronide metabolite (M8; GSK3562183) and des-methyl metabolite (M9; GSK2997852) will be investigated in healthy participants after single-day and repeat dosing of GSK2982772

9. REFERENCES

- PKOne and relevant information on Standards for the Transfer and Reporting of PK Data using HARP available within IDSL standards.

10. APPENDICES

10.1. Appendix 1: Protocol Deviation Management

- Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan.
    - Data will be reviewed prior to freezing the database to ensure all important deviations are captured and categorised on the protocol deviations dataset.
    - This dataset will be the basis for the summaries and listings of protocol deviations.

10.2. Appendix 2: Schedule of Activities

10.2.1. Protocol Defined Schedule of Events

10.2.1.1. Part A (Cohort 1)

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)					**Follow-Up** (No more than 14 days post last dose)	**Notes**
		-1	1	2	3	4		
Outpatient Visit	X						X	
Admission to Clinical Unit		X						
Inpatient Stay at Clinical Unit			←==X==→					
Discharge from Clinical Unit						X		*Following completion of all assessments.*
Informed Consent	X							
Inclusion and Exclusion Criteria	X							
Demography	X							
Full Physical Examination	X							*Additional exams/screens may be performed, or brief exams made full exams, by the Investigator, as deemed necessary (e.g. where safety or laboratory findings indicate). Tests will be conducted within site specified standards.*
Brief Physical Examination		X		X		X		
Height	X							
Weight	X							
Drug/Alcohol/Smoking Screen	X	X						*Tests include alcohol breath test, smoking breath test and urine drug screen.*
Medical/Medication/Drug/Alcohol History	X							
HIV, Hepatitis B and C Screening	X							
Tuberculosis Test	X							*Conducted at the standard practice of the site.*
Serum Pregnancy Test (WOCBP only)	X						X	
Urine Pregnancy Test (WOCBP only)		X				X		
Highly effective contraceptive method (WOCBP only)	X	X	X	X	X	X	X	*Must use method for a minimum of 28 days prior to first dose of study medication until the follow-up visit*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)					**Follow-Up** (No more than 14 days post last dose)	**Notes**
		-1	1	2	3	4		
Contraception with male condoms (WOCBP using hormonal contraceptive method and male subjects with female partners of childbearing potential only)		X	X	X	X	X	X	
Meals		X	X[a]	X	X	X		[a] *On Day 1, subjects will fast 8hr overnight prior to dose 1. A breakfast will be served approximately 2hr after dose 1.* ***TID dosing****: On Day 1, lunch and dinner will be served between 2 to 3hr prior to doses 2 and 3, respectively.* ***BID dosing:*** *On Day 1, lunch will be served approximately 4 to 5hr after dose 1. Dinner will be served between 2 to 3hr prior to dose 2. A snack may be consumed approximately 2 to 3hr after dose 2.* *Water is permitted with dosing and at all times. Subjects will receive standardized meals scheduled at the same time in each period.*
Haem/Chem/Urinalysis Test (Include Liver Chemistries)	X	X	X	X		X	X	*Non-fasted samples can be collected on Day -1 and Follow-Up Visit.*
PK Blood Sampling			X	X				***TID Dosing:*** *PK samples to be taken pre-dose on Day 1 and then at the following time points post first-dose: 20min, 40min, 1hr, 1hr 30min, 2hr, 3hr, 5hr, 7hr, 7hr 20min, 7hr 40 min, 8hr, 8hr 30min, 9hr, 10hr, 12hr, 14hr, 14hr 20min, 14hr 40 min, 15hr, 15hr 30min, 16hr, 17hr, 19hr, 22hr, 24hr.* ***BID Dosing:*** *PK samples to be taken pre-dose on Day 1 and then at the following time points post first-dose: 20min, 40min, 1hr, 1hr 30min, 2hr, 3hr, 4hr, 6hr, 8hr, 10hr, 12hr, 12hr 20min, 12hr 40min, 13hr, 13hr 30min, 14hr, 15hr, 16hr, 19hr, 22hr, 24hr.* *Remaining PK plasma samples from Part A may be analysed for metabolite sampling.*
Neuro. Examination		←X→		X	←X→			***TID Dosing:*** *Neurological examinations to be conducted either on Day -1 or pre-dose Day 1 and then at the subsequent time points post first-dose on Day 1: 2hr, 9hr, 16hr, 24hr and 48hr. Then 24 and 48hr after the last dose administered on Day 1.* ***BID Dosing:*** *Neurological examinations to be conducted either on Day -1 or pre-dose Day 1 and then at the subsequent time points post first-dose: 2hr, 14hr, 24hr and 48hr. Then 24 and 48 hr after the last dose administered on Day 1.*
Telemetry			←X→					*Continuous at least 24hr post-evening dose. Initiate at least 15 min. prior to dosing.*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)					**Follow-Up** (No more than 14 days post last dose)	**Notes**
		-1	1	2	3	4		
12-Lead ECG	X	X	T	X	←X→			*Vital signs to include HR, BP, temperature and respiration rate.* ***TID Dosing:*** *12-Lead ECG and Vital Signs to be conducted on Day -1 and pre-dose on Day 1 and then at the subsequent time points post first-dose: 40min, 2hr, 4hr, 7hr (pre-2nd dose), 9hr, 14hr (pre-3rd dose), 16hr, 24hr and 48hr. Then 24 and 48hr after the last dose administered on Day 1.* ***BID Dosing:*** *12-Lead ECG and Vital Signs to be conducted on Day -1 and pre-dose on Day 1 and then at the subsequent time points post first-dose: 40 min, 2hr, 4hr, pre-2nd dose, 12hr 20 min, 14hr, 24hr and 48 hr. Then 24 and 48hr after the last dose administered on Day 1.* *T = Triplicate.*
Vital Signs	X	X	T	X	←X→		X	
Randomization		X						*Randomization can occur on either Day -1 or Day 1.*
Study Treatment			X[b]					[b] ***TID dosing:*** *GSK2982772 or placebo will be administered using a 7hr, 7hr dosing interval.* ***BID dosing:*** *GSK2982772 or placebo will be administered using a 12hr dosing interval.*
Pharmacogenetic Sample (PGx)			X					*A PGx blood sample is collected at the Day 1 visit, after the subject has been randomized and provided informed consent for genetic research. If the sample is not collected at the Day 1 visit, it can be collected at any time during the study after randomization.*
AE Review		←=======X======→					X	
SAE Review		←=======X======→					X	
Concomitant Medication Review	X	←=======X======→					X	

10.2.1.2. Part B (Cohorts 2-5)

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																	**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	
Outpatient Visit	X																			X	
Admission to Clinical Unit		X																			
Inpatient Stay at Clinical Unit			←==========X==========→																		
Discharge from Clinical Unit																			X		*Following completion of all assessments.*
Informed Consent	X																				
Inclusion and Exclusion Criteria	X																				
Demography	X																				
Full Physical Examination	X																		X		*Additional exams/screens may be performed, or brief exams made full exams, by the*
Brief Physical Examination		X		X		X			X			X					X			X	

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					Investigator, as deemed necessary (e.g. where safety or laboratory findings indicate). Tests will be conducted within site specified standards.
Height	X																				
Weight	X								X										X		
Drug/Alcohol/Smoking Screen	X	X																			*Tests include alcohol breath test, smoking breath test and urine drug screen.*
Medical/Medication/ Drug/Alcohol History	X																				
HIV, Hepatitis B and C Screening	X																				

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
Tuberculosis Test	X																				
Anti-Nuclear Antibody	X								X										X		
Serum Pregnancy Test (WOCBP only)	X																			X	
Urine Pregnancy Test (WOCBP only)		X																	X		
Highly effective contraceptive method (WOCBP only)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	*Must use method for a minimum of 28 days prior to first dose of study medication until the follow-up visit.*
Contraception with male condoms (WOCBP using hormonal contraceptive method and male subjects with female partners of childbearing potential only)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
C-SSRS	X	←X→							X										X	X[c]	*May be*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					completed on either Day -1 or Day 1, but no later than 1hr prior to dosing. To be completed pre-dose on Day 7. [c] *C-SSRS to be conducted on follow-up only in the instance that a subject withdraws from the study.*
Meals		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		***TID Dosing:*** *On Day 1 through 14 subjects will fast 8hr overnight. Breakfast will be served approximately*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					2hr after dosing on Days 1-8, 10, 12 and 13 and 2hr after dosing on Day 14. A "standard" and a "high fat" breakfast will be served approximately 30 minutes prior to dosing on Day 9 and Day 11, respectively. On all study days, lunch and dinner will be served between 2 to 3hr prior to dose 2 and dose 3,

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					respectively. ***BID Dosing:*** *On Day 1 through 14, subjects will fast 8hr overnight prior to dose 1. A breakfast will be served approximately 2hr after dose 1. Lunch will be served approximately 4-5hr after dose 1. Dinner will be served between 2-3hr prior to dose 2. A snack may be consumed approximately 2-3hr after dose 2.*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					Water is permitted with dosing and at all times. Subjects will receive standardized meals scheduled at the same time in each period. Meals will be served as per the site schedule on Days -1, 16 and 17.
Haem/Chem/ Urinalysis Test (Include Liver Chemistries)	X	X	X	X		X			X			X					X			X	*Collection on Day 1 no later than 1hr prior to dosing. To be drawn pre-dose on Days 2, 4, 7 and 10.*
Fasting lipid panel	X		X	X		X			X			X					X			X	*Collection on*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					Day 1 no later than 1hr prior to dosing. To be drawn pre-dose on Days 2, 4, 7 and 10.
Holter Monitoring (24-hour)	X																				
Telemetry			X		X											X					*Continuous at least 24 hr post-evening dose. Initiate at least 15 min. prior to dosing.*
PK blood sampling			X[d]	X[e]	X[e]	X[e]	X[e]		X[e]		X[f]		X[f]			X[g]					[d] *On Day 1, PK samples will be collected pre-dose and at the following time points post first-dose: 20min, 40min, 1hr, 1hr 30min, 2hr, 3hr, 5hr,*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					7hr, 9hr and 11hr. *[e] On Days 2,3 4, 5 and 7 pre-dose samples only.* *[f] Days 9, and 11: Cohort 2, 3 and Cohort 4 PK sampling will be collected pre-dose and at the following time points post first-dose: 20min, 40min, 1hr, 1hr 30min, 2hr, 3hr, 5hr, 7hr (prior to 2nd dose) 7hr 20min, 7hr 40 min, 8hr, 8hr 30min, 9hr, 10hr, 12hr.*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					Cohort 5 is currently not planned to have PK assessment but may be included depending on outcome of food effect in Cohorts 2, 3 and 4. *[g] Day 14 sampling for Cohorts 2, 3, 4 and 5 will be over 24hr according to the following schedules:* *For **TID Dosing:** PK samples to be taken pre-dose and then at the*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					*following time points post first-dose: 20min, 40min, 1hr, 1hr 30min, 2hr, 3hr, 5hr, 7hr (pre-2nd dose) 7hr 20min, 7hr 40 min, 8hr, 8hr 30min, 9hr, 10hr, 12hr, 14hr (pre 3rd dose), 14hr 20min, 14hr 40 min, 15hr, 15hr 30min, 16hr, 17hr, 19hr, 22hr, 24hr. For **BID Dosing:** PK samples to be taken pre-dose on Day 1 and then at the*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					subsequent time points post first-dose: 20min, 40min, 1hr, 1hr 30min, 2hr, 3hr, 4hr, 6hr, 8hr, 10hr, 12hr (pre 2nd dose), 12hr 20min, 12hr 40min, 13hr, 13hr 30min, 14hr, 15hr, 16hr, 19hr, 22hr, 24hr.
Metabolite sampling																X[h]					[h] *Metabolite sampling will be conducted pre-dose and 2hr post first dose on Day 14 only.*
4β-hydroxycholesterol sampling			X[i]														X[i]				[i] *Sample to be taken pre-dose on Day 1 in a*

Procedure	Screening (Up to 28 days before Day 1)	Study Period (Days)																		Follow-up (No more than 14 days post last dose)	Notes
		-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17		
																					fasted state. [j] *Sample to be taken at 24hr post first dose on Day 14. Sample should be in a fasted state.*
Neuro. examination			X		X	X				X									X		***TID Dosing:*** *Neurological examinations to be conducted either on Day-1 or pre-dose Day 1 and then at the subsequent time points post first dose: 2hr, 9hr, 16hr, 24hr and 48hr. To be completed pre-dose on Day 7*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					and then 48 hr post-last dose on Day 14. ***BID Dosing:*** *Neurological examinations to be conducted pre-dose either on Day-1 or Day 1 and then at the subsequent time points post first dose: 2hr, 14hr, 24hr and 48hr. To be completed pre-dose on Day 7 and then 48hr post-last dose on Day 14.*
12-Lead ECG	X	X	T	X		X			X							X				X	*Vital signs to include HR, BP,*
Vital signs	X	X	T	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					temperature and respiration rate. *On Day 1:* ***TID Dosing:*** *12-Lead ECG and Vital Signs to be conducted on Day-1 and pre-dose Day 1 and then at the subsequent time points post first-dose: 40min, 2hr, 4hr, 7hr (pre-2nd dose), 9hr, 14hr (pre-3rd dose), 16hr, 24hr, 48hr. Then 24 and 48hr after the first dose and last dose*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					administered on Day 14. ***BID Dosing:*** *12-Lead ECG and Vital Signs to be conducted pre-dose either on Day-1 or Day 1 and then at the subsequent time points post first-dose: 40 min, 2hr, 4hr, 12hr (pre-2nd dose), 14hr, 24hr, 48hr. Then 24 and 48hr after the first and last dose administered on Day 14. On Days 3 to 14, pre-dose*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					samples only. T = Triplicate.
Randomization		X																			*Randomization can occur on either Day -1 or Day 1.*
Study Treatment			X	X	X	X	X	X	X	X	X	X	X	X	X	X					***TID dosing:*** *GSK2982772 or placebo will be administered using a 7hr, 7hr and 10hr dosing interval.* ***BID dosing:*** *GSK2982772 or placebo will be administered using a 12hr dosing interval.*
Pharmacogenetic Sample (PGx)			X																		*A PGx blood sample is collected at the Day 1 visit,*

Procedure	**Screening** (Up to 28 days before Day 1)	**Study Period** (Days)																		**Follow-up** (No more than 14 days post last dose)	**Notes**
		-1	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**		
																					after the subject has been randomized and provided informed consent for genetic research. If the sample is not collected on Day 1, it can be collected at any time during the study after randomization.
AE review		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
SAE review		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Concomitant medication review	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

10.3. Appendix 3: Assessment Windows

10.3.1. Definitions of Assessment Windows for Analyses

No Assessment Windows will be defined for Analysis, and summaries and analyses will be based on nominal visits.

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

10.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to the start and/or stop date/time of the study treatment within the period for Part A and the start and/or stop date/time of the study treatment for Part B.

Study Phase	Definition
Pre-Treatment	Date/Time ≤ Study Treatment Start Date/Time
On-Treatment	Study Treatment Start Date/Time < Date/Time ≤ Study Treatment Stop Date/Time
Post-Treatment	Date/Time > Study Treatment Stop Date/Time

10.4.1.1. Study Phases for Concomitant Medications

Treatment State	Definition
Prior	If medication end date is not missing and is before 28 days prior to screening visit
Concomitant	Any medication that is not a prior

NOTES:

- Please refer to Appendix 7: Reporting Standards for Missing Data for handling of missing and partial dates for concomitant medication. Use the rules in this table if concomitant medication date is completely missing

10.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	• If AE onset date is on or after treatment start date & on or before treatment stop date +1. • Study Treatment Start Date ≤ AE Start Date ≤ Study Treatment Stop Date + 1 days. • For studies with greater than one treatment period (e.g., crossover study), if AE onset is during one period and worsens during a later period it would be counted in both periods. For the initial period the logic would be as above. For the later period the logic would use the treatment dates associated with the later period: Treatment Period Start Date ≤ AE Worsening Date ≤ Study Treatment Stop Date + 1 days.

NOTES:

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

10.5. Appendix 5: Data Display Standards & Handling Conventions

10.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: UK1SALX00175
HARP Compound	One reporting effort will be set up for this study which combines Part A and Part B: \ arenv \ arprod \ gsk2982772 \ mid205184 \final_01
Analysis Datasets	
• Analysis datasets will be created according to Integrated Data Standards Library (IDSL) GSK A&R dataset standards	
Generation of RTF Files	
• RTF files will be generated for all tables within the final_01 reporting effort.	

10.5.2. Reporting Standards

General

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

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

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

• Unscheduled or unplanned readings will be presented within the participant's listings.
Unscheduled Visits
• Unscheduled visits will not be included in summary tables and/or figures. • All unscheduled visits will be included in listings.
Descriptive Summary Statistics

Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %

Graphical Displays
• Refer to IDSL Statistical Principals 7.01 to 7.13.

10.5.3. Reporting Standards for Pharmacokinetic

Pharmacokinetic Concentration Data	
PC Windows Non-Linear (WNL) File	PC WNL file (CSV format) for the non-compartmental analysis by Clinical Pharmacology Modelling and Simulation function will be created according to PKOne. Note: Concentration values will be imputed as per GUI_51487.
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to IDSL Statistical Principle 6.06.1. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	The following PK parameters will be derived by the Programmer: C_0, C_7, C_{12}, C_{14}, C_{24}.
Pharmacokinetic Parameter Data	
Is NQ impacted PK Parameters Rule Being Followed	Yes, refer to Standards for Handling NQ Impacted PK Parameters.
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to PKOne.

10.6. Appendix 6: Derived and Transformed Data

10.6.1. General

Multiple Measurements at One Analysis Time Point
• Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented except for blood pressure measurements as only the average of the 3 blood pressure readings will be recorded on the CRF. • If there are two values within a time window the value closest to the target day for that window will be used. If values are the same distance from the target, then the mean will be taken. • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of "Any visit post-baseline" row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Study Day

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

10.6.2. Study Population

Date of Birth
• Only the year of birth will be captured, and therefore the date of birth is then derived as follows: Year of birth = YYYY → Date of birth = 30th June YYYY
Age
• • Calculated as the integer part of (date of screening – date of birth) Age = integer part (date of screening – 30th June YYYY) / 365.25. • Birth date will be presented in listings as 'YYYY'.
Body Mass Index (BMI)
• Calculated as Weight (kg) / [Height (m) 2]
Treatment Compliance
• Treatment compliance will be calculated based on the formula: **Treatment Compliance = Number of Actual Doses / (Planned Treatment Duration in Days * Frequency)** • Frequency is 2 for BID and 3 for TID. Treatment compliance could be greater than 100% if there are events of overdose. Cumulative compliance (since Day 1) at each visit will be calculated. • Planned Treatment Duration is defined as 1 day in Part A in each period and 14 days in Part B.
Extent of Exposure
• Number of days of exposure to study drug will be calculated based on the formula: **Duration of Exposure in Days = Treatment Stop Date – (Treatment Start Date) + 1** • Participants who were randomized but did not report a treatment start date will be categorised as having zero days of exposure. • The cumulative dose will be based on the formula: **Cumulative Dose = Sum of (Number of Days x Total Daily Dose)** • If there are any treatment breaks during the study, exposure data will be adjusted accordingly.

10.6.3. Safety

ECG Parameters
RR Interval
• IF RR interval (msec) is not provided directly, then RR can be derived as: ○ If QTcF is machine read, then: $$RR = \left[\left(\frac{QT}{QTcF}\right)^{3}\right] * 1000$$ • If ECGs are manually read, the RR value preceding the measurement QT interval should be a collected value THEN do not derive.
Corrected QT Intervals
• When not entered directly in the eCRF, corrected QT intervals by Fridericia's (QTcF) formulas will be calculated, in msec, depending on the availability of other measurements. • IF RR interval (msec) is provided then missing QTcF will be derived as: $$QTcF = \frac{QT}{\sqrt[3]{\frac{RR}{1000}}}$$

Laboratory Parameters

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

10.7. Appendix 7: Reporting Standards for Missing Data

10.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Participant study completion (i.e. as specified in the protocol) was defined as one who has completed all phases of the study including the last scheduled procedure shown in the SoA (see Appendix 2). • Withdrawn participants may be replaced in the study. Additional replacement participants may be randomized to guarantee that sufficient participants are treated with GSK2982772 at any given dose before escalating to the following dose. Replacement participants will be assigned to the same treatment sequence (Cohort 1) or treatment (Cohorts 2-5) but have different subject numbers and randomisation numbers assigned. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.
Liver Chemistry Stopping Criteria	• Discontinuation of study treatment for abnormal liver tests is required when: o in the presence of abnormal liver chemistries not meeting protocol-specified stopping rules, the investigator believes study treatment discontinuation is in the best interest of the participant. o ALT ≥ 3 x ULN. • Note: Refer to Appendix 7 of the protocol for details of the required assessments if a participant meets the above criteria.
QTc Stopping Criteria	• A participant that meets either bulleted criterion based on the average of triplicate ECG readings will be withdrawn from study treatment: o QTcF > 500 msec o Change from baseline: QTcF > 60 msec
Nervous System Stopping Criteria	• A participant will be withdrawn from the study if: o A Grade 3 or greater CTCAE Nervous System finding is observed or a significant neurologic change from a participant's baseline physical examination is observed. o Any adverse event included in the CTCAE for Nervous System, which is also considered to be clinically significant by the Principal Investigator, will be reviewed for potential participant withdrawal.

10.7.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o These data will be indicated by the use of a "blank" in participant listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such.
Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.

10.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in participant listing displays.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.
Concomitant Medications/ Medical History	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. • The recorded partial date will be displayed in listings.

10.8. Appendix 8: Values of Potential Clinical Importance

10.8.1. Laboratory Values

Haematology				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Hematocrit	Ratio of 1	Male		0.54
		Female		0.54
		Δ from BL	↓0.075	
Haemoglobin	g/L	Male		180
		Female		180
		Δ from BL	↓25	
Lymphocytes	$x10^9$/ L		0.8	
Neutrophil Count	$x10^9$/ L		1.5	
Platelet Count	$x10^9$/ L		100	550
While Blood Cell Count (WBC)	$x10^9$/ L		3	20

Clinical Chemistry				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Albumin	G/L		30	
Calcium	mmol/L		2	2.75
Creatinine	umol/L	Δ from BL		↑ 44.2
Glucose	mmol/L		3	9
Potassium	mmol/L		3	5.5
Sodium	mmol/L		130	150

Liver Function			
Test Analyte	**Units**	**Category**	**Clinical Concern Range**
ALT/SGPT	U/L	High	≥ 2x ULN
AST/SGOT	U/L	High	≥ 2x ULN
AlkPhos	U/L	High	≥ 2x ULN
T Bilirubin	µmol/L	High	≥ 1.5xULN
T. Bilirubin + ALT	µmol/L U/L	High	1.5xULN T. Bilirubin + ≥ 2x ULN ALT

10.8.2. ECG

ECG Parameter	Units	Category	Clinical Concern Range	
			Lower	Upper
Absolute				
Absolute QTc Interval	msec	H1	> 450	< 480
		H2	≥ 480	< 500
		H3	≥ 500	
Absolute PR Interval	msec	L, H	< 110	> 220
Absolute QRS Interval	msec	L, H	< 75	> 110
Change from Baseline				
Increase from Baseline QTc	msec	H1	> 30	≤ 59
		H2	≥ 60	

10.8.3. Vital Signs

Vital Sign Parameter (Absolute)	Units	Clinical Concern Range	
		Lower	Upper
Systolic Blood Pressure	mmHg	< 85	> 160
Diastolic Blood Pressure	mmHg	< 45	> 100
Heart Rate	bpm	< 40	> 110
Respiratory Rate	breaths/min	≤ 8	≥ 20
Temperature	°C	≤ 35.5	≥37.8

Vital Sign Parameter (Change from Baseline)	Units	Clinical Concern Range			
		Decrease		Increase	
		Lower	Upper	Lower	Upper
Systolic Blood Pressure	mmHg	≥ 20	≥ 40	≥ 20	≥ 40
Diastolic Blood Pressure	mmHg	≥ 10	≥ 20	≥ 10	≥ 20
Heart Rate	bpm	≥ 15	≥ 30	≥ 15	≥ 30

10.9. Appendix 9: Abbreviations & Trade Marks

10.9.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
ALT	Alanine aminotransferase
A&R	Analysis and Reporting
AUC	AUC Area under the concentration-time curve
AUC(0-7)	Area under the concentration-time curve from time zero to 7 hours post first dose (TID dosing)
AUC(7-14)	Area under the concentration-time curve from 7 to 14 hours post first dose (TID dosing)
AUC(14-24)	Area under the concentration-time curve from 14 to 24 hours post first dose (TID dosing)
AUC(0-12)	Area under the concentration-time curve from 0 to 12 hours post first dose (BID dosing)
AUC(12-24)	Area under the concentration-time curve from 12 to 24 hours post first dose (BID dosing)
AUC(0-24)	Area under the concentration-time curve from time zero to 24 hours post first dose
AUC(0-t)	Area under the concentration-time curve from time zero (pre-dose) to last time of quantifiable concentration within a participant across all treatments
AUC(0-τ)	AUC from 0 hours to the time of next dosing
BID	Twice a day
BMI	Body Mass Index
BP	Blood Pressure
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
Cmax	Maximum observed concentration
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CRF	Case Report Form
CSR	Clinical Study Report
C-SSRS	Columbia Suicide Severity Rating Scale
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
eCRF	Electronic Case Record Form
ECG	Electrocardiogram
EMA	European Medicines Agency
FDA	Food and Drug Administration

Abbreviation	Description
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
GSK	GlaxoSmithKline
IA	Interim Analysis
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
ITT	Intent-To-Treat
MMRM	Mixed Model Repeated Measures
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
PP	Per Protocol
PopPK	Population PK
QC	Quality Control
QTcF	Friderica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
SAC	Statistical Analysis Complete
SDSP	Study Data Standardization Plan
SDTM	Study Data Tabulation Model
SoA	Schedule of Activities
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings
TID	Three times a day
Tmax	Time taken to maximum observed plasma drug concentration

10.9.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
HARP

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

10.10. Appendix 10: List of Data Displays

10.10.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.23	N/A
Safety	2.1 to 2.41	2.1 to 2.6
Pharmacokinetic	3.1 to 3.10	3.1 to 3.8
Section	**Listings**	
ICH Listings	1 to 33 and 40 to 73	
Other Listings	34 to 39 and 74 to 79	

10.10.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 11: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	N/A	N/A	N/A
Safety	N/A	SAFE_T1	SAFE_L1
Pharmacokinetic	N/A	N/A	N/A

NOTES:

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

10.10.3. Deliverables

Delivery	Description
SAC	Final Statistical Analysis Complete

10.10.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Subject Disposition					
1.1.	Safety (Part A)	ES1A	Summary of Subject Disposition for the Subject Conclusion Record (Part A)	ICH E3, FDAAA, EudraCT Add footnote: Note: "Subjects" is used to refer to "Participants" in all data displays to reflect GSK display standards and CDISC SDTM/ADaM standards.	SAC
1.2.	Safety (Part A)	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part A)	ICH E3	SAC
1.3.	Safety (Part A)	ES4	Summary of Disposition at Each Study Epoch (Part A)	ICH E3	SAC
1.4.	All Subject (Part A)	ES6	Summary of Screening Status and Reasons for Screen Failure (Part A)	Journal Requirements	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Protocol Deviation					
1.5.	Safety (Part A)	DV1	Summary of Important Protocol Deviations (Part A)	ICH E3	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Population Analysed					
1.6.	All Subjects (Part A)	SP1	Summary of Study Populations (Part A)	IDSL Add the following footnotes: [1] Subjects are included in the Randomised population if they were randomly assigned to treatment in the study. [2] Subjects are included in the Safety population if they have been randomized and received at least one dose of study treatment. [3] Subjects are included in the Pharmacokinetic population if they are in the Safety Population and a pharmacokinetic sample was obtained and analysed.	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Demographic and Baseline Characteristics					
1.7.	Safety (Part A)	DM3	Summary of Demographic Characteristics (Part A)	ICH E3, FDAAA, EudraCT Do not include Weight (to be included in Vital Signs summary) Add Footnote: [1] For calculating age, birth date is imputed as June 30 in the year of birth.	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.8.	Randomised (Part A)	DM11	Summary of Age Ranges (Part A)	EudraCT Only include age ranges applicable to the study ('Adult (18-64 years)' and '>=65-84 years')) Please add footnote to say that randomised population=enrolled population.	SAC
1.9.	Safety (Part A)	DM5	Summary of Race and Racial Combinations (Part A)	ICH E3, FDA, FDAAA, EudraCT	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Medical Conditions and Prior and Concomitant Medications					
1.10.	Safety (Part A)	MH1 / MH4	Summary of Current/Past Medical Conditions (Part A)	ICH E3 Separate summaries for Current & Past conditions, if collected.	SAC
1.11.	Safety (Part A)	CM1	Summary of Concomitant Medications (Part A)	ICH E3	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Exposure and Treatment Compliance					
1.12.	Safety (Part A)	EX5	Summary of Exposure to Study Treatment (Part A)	ICH E3 Total daily dose (mg) and number of days	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Subject Disposition					
1.13.	Safety (Part B)	ES1	Summary of Subject Disposition for the Subject Conclusion Record (Part B)	ICH E3, FDAAA, EudraCT	SAC
1.14.	Safety (Part B)	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment (Part B)	ICH E3	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.15.	All Subjects (Part B)	ES6	Summary of Screening Status and Reasons for Screen Failure (Part B)	Journal Requirements	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Protocol Deviation					
1.16.	Safety (Part B)	DV1	Summary of Important Protocol Deviations (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Population Analysed					
1.17.	Safety (Part B)	SP1	Summary of Study Populations (Part B)	IDSL Add the following footnotes: [1] Subjects are included in the Randomised population if they were randomly assigned to treatment in the study. [2] Subjects are included in the Safety population if they have been randomized and received at least one dose of study treatment. [3] Subjects are included in the Pharmacokinetic population if they are in the Safety Population and a pharmacokinetic sample was obtained and analysed.	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Demographic and Baseline Characteristics					
1.18.	Safety (Part B)	DM1	Summary of Demographic Characteristics (Part B)	ICH E3, FDAAA, EudraCT Do not include Weight (to be included in Vital Signs summary) [1] For calculating age, birth date is imputed as June 30 in the year of birth.	SAC
1.19.	Randomised (Part B)	DM11	Summary of Age Ranges (Part B)	EudraCT Only include age ranges applicable to the study ('Adult (18-64 years)' and '>=65-84 years'))	SAC
1.20.	Safety (Part B)	DM5	Summary of Race and Racial Combinations (Part B)	ICH E3, FDA, FDAAA, EudraCT	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Medical Conditions and Prior and Concomitant Medications					
1.21.	Safety (Part B)	MH1 / MH4	Summary of Current/Past Medical Conditions (Part B)	ICH E3 Separate summaries for Current & Past conditions, if collected.	SAC
1.22.	Safety (Part B)	CM1	Summary of Concomitant Medications (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Exposure and Treatment Compliance					
1.23.	Safety (Part B)	EX1	Summary of Exposure to Study Treatment (Part B)	ICH E3 Total daily dose, cumulative actual dose and number of days.	SAC

10.10.5. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Adverse Events (AEs)					
2.1.	Safety (Part A)	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term (Part A)		SAC
2.2.	Safety (Part A)	AE5A	Summary of All Adverse Events by Maximum Intensity by System Organ Class and Preferred Term (Part A)	ICH E3	SAC
2.3.	Safety (Part A)	AE5A	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Intensity (Part A)	ICH E3	SAC
2.4.	Safety (Part A)	AE15	Summary of Common (>=10%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Part A)	FDAAA, EudraCT	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Serious and Other Significant Adverse Events					
2.5.	Safety (Part A)	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Part A)	FDAAA, EudraCT Only if 3 or more SAEs reported	SAC
2.6.	Safety (Part A)	AE3	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by Overall Frequency (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Laboratory: Chemistry					
2.7.	Safety (Part A)	LB1	Summary of Chemistry Changes from Baseline (Part A)	ICH E3	SAC
2.8.	Safety (Part A)	LB17	Summary of Worst Case Chemistry Results by PCI Criteria Post-Baseline Relative to Baseline (Part A)	ICH E3	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.9.	Safety (Part A)	LB17	Summary of Worst Case Lipids Outside Laboratory Normal Range Post-Baseline Relative to Baseline (Part A)		SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Laboratory: Hematology					
2.10.	Safety (Part A)	LB1	Summary of Hematology Changes from Baseline (Part A)	ICH E3	SAC
2.11.	Safety (Part A)	LB17	Summary of Worst Case Hematology Results by PCI Criteria Post-Baseline Relative to Baseline (Part A)	ICH E3	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Laboratory: Urinalysis					
2.12.	Safety (Part A)	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part A)	ICH E3	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Laboratory: Hepatobiliary (Liver)					
2.13.	Safety (Part A)	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part A)	IDSL	SAC
2.14.	Safety (Part A)	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): ECG					
2.15.	Safety (Part A)	EG1	Summary of ECG Findings (Part A)	IDSL	SAC
2.16.	Safety (Part A)	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category (Part A)	IDSL	SAC
2.17.	Safety (Part A)	EG2	Summary of Change from Baseline in ECG Values by Visit (Part A)	IDSL	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.18.	Safety (Part A)	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Vital Signs					
2.19.	Safety (Part A)	VS1	Summary of Change from Baseline in Vital Signs (Part A)	ICH E3	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Suicide Risk Monitoring					
2.20.	Safety (Part A)	CSSRS1	Summary of Subjects with C-SSRS Suicidal Ideation or Behaviour during Treatment (Part A)		SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Adverse Events (AEs))					
2.21.	Safety (Part B)	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term (Part B)	ICH E3	SAC
2.22.	Safety (Part B)	AE3	Summary of Common (>=10%) Adverse Events by Overall Frequency (Part B)	ICH E3	SAC
2.23.	Safety (Part B)	AE5A	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Intensity (Part B)	ICH E3	SAC
2.24.	Safety (Part B)	AE15	Summary of Common (>=10%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subject and Occurrences) (Part B)	FDAAA, EudraCT	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Serious and Other Significant Adverse Events					
2.25.	Safety (Part B)	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Part B)	FDAAA, EudraCT Only if 3 or more SAEs reported	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.26.	Safety (Part B)	AE3	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by Overall Frequency (Part B)	IDSL	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Laboratory: Chemistry					
2.27.	Safety (Part B)	LB1	Summary of Chemistry Changes from Baseline (Part B)	ICH E3	SAC
2.28.	Safety (Part B)	LB17	Summary of Worst Case Chemistry Results by PCI Criteria Post-Baseline Relative to Baseline (Part B)	ICH E3	SAC
2.29.	Safety (Part A)	LB17	Summary of Worst Case Lipids Outside Laboratory Normal Range Post-Baseline Relative to Baseline (Part B)		SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Laboratory: Hematology					
2.30.	Safety (Part B)	LB1	Summary of Hematology Changes from Baseline (Part B)	ICH E3	SAC
2.31.	Safety (Part B)	LB17	Summary of Worst Case Hematology Results by PCI Criteria Post-Baseline Relative to Baseline (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Laboratory: Urinalysis					
2.32.	Safety (Part B)	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Laboratory: Hepatobiliary (Liver)					
2.33.	Safety (Part B)	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Part B)	IDSL	SAC
2.34.	Safety (Part B)	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Part B)	IDSL	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Laboratory: Other					
2.35.	Pharmacokinetic (Part B)	Non-Standard SAFE_T1	Summary of Plasma 4β-hydroxycholesterol to Cholesterol Ratio (Part B)	Include SE and 95% CI.	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): ECG					
2.36.	Safety (Part B)	EG1	Summary of ECG Findings (Part B)	IDSL	SAC
2.37.	Safety (Part B)	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category (Part B)	IDSL	SAC
2.38.	Safety (Part B)	EG2	Summary of Change from Baseline in ECG Values by Visit (Part B)	IDSL	SAC
2.39.	Safety (Part B)	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category (Part B)	IDSL	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Vital Signs					
2.40.	Safety (Part B)	VS1	Summary of Change from Baseline in Vital Signs (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Suicide Risk Monitoring					
2.41.	Safety (Part B)	CSSRS1	Summary of Subjects with C-SSRS Suicidal Ideation or Behaviour during Treatment (Part B)		SAC

10.10.6. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Adverse Events					
2.1.	Safety (Part A)	AE10	Plot of Common (>=10%) Adverse Events and Relative Risk (Part A)	IDSL Common defined as >10%	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Hepatobiliary (Liver)					
2.2.	Safety (Part A)	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part A)		SAC
2.3.	Safety (Part A)	LIVER9	Scatter Plot for Maximum ALT vs. Maximum Total Bilirubin (Part A)		SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Adverse Events					
2.4.	Safety (Part B)	AE10	Plot of Common (>=10%) Adverse Events and Relative Risk (Part B)	IDSL Common defined as >10%	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Hepatobiliary (Liver)					
2.5.	Safety (Part B)	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (Part B)		SAC
2.6.	Safety (Part B)	LIVER9	Scatter Plot for Maximum ALT vs. Maximum Total Bilirubin (Part B)		SAC

10.10.7. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Pharmacokinetic Concentrations					
3.1.	Pharmacokinetic (Part A)	PK01	Summary of Plasma GSK2982772 Pharmacokinetic Concentration-Time Data (Part A)	Include column for 95% CI.	SAC
3.2.	Pharmacokinetic (Part A)	PK01	Summary of Plasma M8 (GSK3562183) Pharmacokinetic Concentration-Time Data (Part A)	Include column for 95% CI.	SAC
3.3.	Pharmacokinetic (Part A)	PK01	Summary of Plasma M9 (GSK2997852) Pharmacokinetic Concentration-Time Data (Part A)	Include column for 95% CI.	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Pharmacokinetic Parameters					
3.4.	Pharmacokinetic (Part A)	PK03	Summary of Derived Plasma GSK2982772 Pharmacokinetic Parameters (Part A)	Include columns for parameter, period, treatment, N, n, mean, 90% CI, standard deviation [SD], standard error [SE], median, minimum and maximum.	SAC
3.5.	Pharmacokinetic (Part A)	PK05	Summary of Log-Transformed Derived Plasma GSK2982772 Pharmacokinetic Parameters (Part A)	Include columns for parameter, period, treatment, N, n, geometric mean, 90% CI of geometric mean, standard deviation [SD] of logged data and %CVb. Do not summarise Tmax.	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Pharmacokinetic Concentrations					
3.6.	Pharmacokinetic (Part B)	PK01	Summary of Plasma GSK2982772 Pharmacokinetic Concentration-Time Data (Part B)	Include column for 95% CI and the SE.	SAC

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.7.	Pharmacokinetic (Part B)	PK01	Summary of Plasma M8 (GSK3562183) Pharmacokinetic Concentration-Time Data (Part B)	Include column for 95% CI and the SE.	SAC
3.8.	Pharmacokinetic (Part B)	PK01	Summary of Plasma M9 (GSK2997852) Pharmacokinetic Concentration-Time Data (Part B)	Include column for 95% CI and the SE.	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Pharmacokinetic Parameters					
3.9.	Pharmacokinetic (Part B)	PK03	Summary of Derived Plasma GSK2982772 Pharmacokinetic Parameters (Part B)	Include columns for parameter, treatment, N, day, fed/fasted state, n, mean, 90% CI, standard deviation [SD], SE, median, minimum and maximum.	SAC
3.10.	Pharmacokinetic (Part B)	PK05	Summary of Log-Transformed Derived Plasma GSK2982772 Pharmacokinetic Parameters (Part B)	Include columns for parameter, treatment, N, day, fed/fasted state, n, geometric mean, 90% CI of geometric mean, standard deviation [SD] of logged data and %CVb. Do not summarise Tmax.	SAC

10.10.8. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Pharmacokinetic Concentrations					
3.1.	Pharmacokinetic (Part A)	PK16b	Individual Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) (Part A)		SAC
3.2.	Pharmacokinetic (Part A)	PK24	Individual Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) by Treatment (Part A)		SAC
3.3.	Pharmacokinetic (Part A)	PK19	Mean (+ SE) Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) (Part A)		SAC
3.4.	Pharmacokinetic (Part A)	PK20	Median (Range) Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) (Part A)		SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Pharmacokinetic Concentrations					
3.5.	Pharmacokinetic (Part B)	PK16a	Individual Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) (Part B)		SAC
3.6.	Pharmacokinetic (Part B)	PK24	Individual Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) by Treatment (Part B)		SAC
3.7.	Pharmacokinetic (Part B)	PK19	Mean (+ SE) Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) (Part B)		SAC
3.8.	Pharmacokinetic (Part B)	PK20	Median (Range) Plasma GSK2982772 Concentration-Time Plots (Linear and Semi-log) (Part B)		SAC

10.10.9. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Subject Disposition					
1.	All Subjects (Part A)	ES7	Listing of Reasons for Screen Failure (Part A)	Journal Guidelines	SAC
2.	Safety (Part A)	ES3	Listing of Reasons for Study Withdrawal (Part A)	ICH E3	SAC
3.	Safety (Part A)	SD3	Listing of Reasons for Study Treatment Discontinuation (Part A)	ICH E3	SAC
4.	Safety (Part A)	BL2	Listing of Subjects for Whom the Treatment Blind was Broken (Part A)	ICH E3	SAC
5.	Safety (Part A)	TA1	Listing of Planned and Actual Treatments (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Protocol Deviations					
6.	Safety (Part A)	DV2A	Listing of Important Protocol Deviations (Part A)	ICH E3	SAC
7.	Safety (Part A)	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (Part A)	ICH E3	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Populations Analysed					
8.	All Subjects (Part A)	SP3a	Listing of Subjects Excluded from Any Population (Part A)	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Demographic and Baseline Characteristics					
9.	Safety (Part A)	DM4	Listing of Demographic Characteristics (Part A)	ICH E3 Do not include Weight.	SAC
10.	Safety (Part A)	DM10	Listing of Race (Part A)	ICH E3	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Prior and Concomitant Medications					
11.	Safety (Part A)	CP_CM4	Listing of Concomitant Medications (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Exposure and Treatment Compliance					
12.	Safety (Part A)	EX4	Listing of Exposure Data (Part A)	ICH E3	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Adverse Events					
13.	Safety (Part A)	AE9CP	Listing of All Adverse Events (Part A)	ICH E3	SAC
14.	Safety (Part A)	AE7	Listing of Subject Numbers for Individual Adverse Events (Part A)	ICH E3	SAC
15.	Safety (Part A)	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Serious and Other Significant Adverse Events					
16.	Safety (Part A)	AE9CPa	Listing of Serious Adverse Events (Part A)	ICH E3 Include fatal and non-fatal status	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
17.	Safety (Part A)	AE14	Listing of Reasons for Considering as a Serious Adverse Event (Part A)	ICH E3	SAC
18.	Safety (Part A)	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (Part A)	ICH E3 Include fatal and non-fatal status	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Hepatobiliary (Liver)					
19.	Safety (Part A)	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part A)	IDSL	SAC
20.	Safety (Part A)	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): All Laboratory					
21.	Safety (Part A)	LB6	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (Part A)	ICH E3	SAC
22.	Safety (Part A)	LB6	Listing of Laboratory Values of Potential Clinical Importance (Part A)		SAC
23.	Safety (Part A)	LB6	Listing of All Lipid Data for Subjects with Any Value outside of Laboratory Normal Range (Part A)	Please include additional column after Lab Param for fasting status (if present)	SAC
24.	Safety (Part A)	LB14	Listing of Laboratory Data with Character Results (Part A)	ICH E3	SAC
25.	Safety (Part A)	UR2B	Listing of All Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (Part A)	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): ECG					
26.	Safety (Part A)	EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance (Part A)	IDSL Include absolute PCI subjects. Footnote: Note: H= High absolute value, L= Low absolute value. For QTc Interval H1= >450msec and <480msec, H2= >=480msec and <500msec, H3= >=500msec.	SAC
27.	Safety (Part A)	EG4	Listing of All ECG Changes for Subjects with Any Change of Potential Clinical Importance (Part A)	Include change from baseline PCI subjects. Footnote: Note: H=High change from baseline value, L=Low change from baseline value. For QTc Interval H1= >30msec and <=59msec, H2= >=60msec	SAC
28.	Safety (Part A)	EG4	Listing of ECG Values of Potential Clinical Importance (Part A)	IDSL Include absolute PCIs. Footnote: Note: H=High absolute value, L=Low absolute value. For QTc Interval H1= >450msec and <480msec, H2= >=480msec and <500msec, H3= >=500msec.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
29.	Safety (Part A)	EG4	Listing of ECG Changes of Potential Clinical Importance (Part A)	Include change from baseline PCIs. Footnote: Note: H=High change from baseline value, L=Low change from baseline value. For QTc Interval H1= >30msec and <=59msec, H2= >=60msec	SAC
30.	Safety (Part A)	EG6	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding (Part A)	IDSL	SAC
31.	Safety (Part A)	EG6	Listing of Abnormal ECG Findings (Part A)	IDSL	SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Vital Signs					
32.	Safety (Part A)	VS5	Listing of All Vital Signs Values for Subjects with Any Value of Potential Clinical Importance (Part A)	IDSL Footnote: Note: For absolute results: H=High, L=Low. For change from baseline: H1=Lower Increase, H2=Upper Increase, L1=Lower Decrease, L2=Upper Decrease.	SAC
33.	Safety (Part A)	VS5	Listing of Vital Signs Values of Potential Clinical Importance (Part A)	IDSL Footnote: Note: For absolute results: H=High, L=Low. For change from baseline: H1=Lower Increase, H2=Upper Increase, L1=Lower Decrease, L2=Upper Decrease.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Disposition					
40	All Subjects (Part B)	ES7	Listing of Reasons for Screen Failure (Part B)	Journal Guidelines	SAC
41	Safety (Part B)	ES2	Listing of Reasons for Study Withdrawal (Part B)	ICH E3	SAC
42	Safety (Part B)	SD2	Listing of Reasons for Study Treatment Discontinuation (Part B)	ICH E3	SAC
43	Safety (Part B)	BL1	Listing of Subjects for Whom the Treatment Blind was Broken (Part B)	ICH E3	SAC
44	Safety (Part B)	TA1	Listing of Planned and Actual Treatments (Part B)	IDSL	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Protocol Deviations					
45	Safety (Part B)	DV2	Listing of Important Protocol Deviations (Part B)	ICH E3	SAC
46	Safety (Part B)	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Populations Analysed					
47	All Subjects (Part B)	SP3	Listing of Subjects Excluded from Any Population (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Demographic and Baseline Characteristics					
48	Safety (Part B)	DM2	Listing of Demographic Characteristics (Part B)	ICH E3 Do not include Weight.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
49	Safety (Part B)	DM9	Listing of Race (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Prior and Concomitant Medications					
50	Safety (Part B)	CP_CM3	Listing of Concomitant Medications (Part B)	IDSL	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Exposure and Treatment Compliance					
51	Safety (Part B)	EX3	Listing of Exposure Data (Part B)	ICH E3	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Adverse Events					
52	Safety (Part B)	AE8CP	Listing of All Adverse Events (Part B)	ICH E3	SAC
53	Safety (Part B)	AE7	Listing of Subject Numbers for Individual Adverse Events (Part B)	ICH E3	SAC
54	Safety (Part B)	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text (Part B)	IDSL	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Serious and Other Significant Adverse Events					
55	Safety (Part B)	AE8CPa	Listing of Serious Adverse Events (Part B)	ICH E3 Include fatal and non-fatal status.	SAC
56	Safety (Part B)	AE14	Listing of Reasons for Considering as a Serious Adverse Event (Part B)	ICH E3	SAC
57	Safety (Part B)	AE8CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment (Part B)	ICH E3 Include fatal and non-fatal status.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Hepatobiliary (Liver)					
58	Safety (Part B)	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part B)	IDSL	SAC
59	Safety (Part B)	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part B)	IDSL	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): All Laboratory					
60	Safety (Part B)	LB5	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance (Part B)	ICH E3	SAC
61	Safety (Part B)	LB5	Listing of Laboratory Values of Potential Clinical Importance (Part B)		SAC
62	Safety (Part A)	LB6	Listing of All Lipid Data for Subjects with Any Value outside of Laboratory Normal Range	Please include additional column after Lab Param for fasting status (if present)	SAC
63	Safety (Part B)	LB14	Listing of Laboratory Data with Character Results (Part B)	ICH E3	SAC
64	Safety (Part B)	UR2A	Listing of All Urinalysis Data for Subjects with Any Value of Potential Clinical Importance (Part B)	ICH E3	SAC
65	Pharmacokinetic (Part B)	Non-Standard SAFE_L1	Listing of Plasma Cholesterol and 4β-hydroxycholesterol Concentration-Time (ug/mL) Data (Part B)		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): ECG					
66	Safety (Part B)	EG3	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance (Part B)	IDSL Include absolute PCI subjects. Footnote: Note: H= High absolute value, L= Low absolute value. For QTc Interval H1= >450msec and <480msec, H2= >=480msec and <500msec, H3= >=500msec.	SAC
67	Safety (Part B)	EG3	Listing of All ECG Changes for Subjects with Any Change of Potential Clinical Importance (Part B)	Include change from baseline PCI subjects. Footnote: Note: H=High change from baseline value, L=Low change from baseline value. For QTc Interval H1= >30msec and <=59msec, H2= >=60msec	SAC
68	Safety (Part B)	EG3	Listing of ECG Values of Potential Clinical Importance (Part B)	IDSL Include absolute PCIs. Footnote: Note: H=High absolute value, L=Low absolute value. For QTc Interval H1= >450msec and <480msec, H2= >=480msec and <500msec, H3= >=500msec.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
69	Safety (Part B)	EG3	Listing of ECG Changes of Potential Clinical Importance (Part B)	Include change from baseline PCIs. Footnote: Note: H=High change from baseline value, L=Low change from baseline value. For QTc Interval H1= >30msec and <=59msec, H2= >=60msec	SAC
70	Safety (Part B)	EG5	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding (Part B)	IDSL	SAC
71	Safety (Part B)	EG5	Listing of Abnormal ECG Findings (Part B)	IDSL	SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Vital Signs					
72	Safety (Part B)	VS4	Listing of All Vital Signs Values for Subjects with Any Value of Potential Clinical Importance (Part B)	IDSL Footnote: Note: For absolute results: H=High, L=Low. For change from baseline: H1=Lower Increase, H2=Upper Increase, L1=Lower Decrease, L2=Upper Decrease.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
73	Safety (Part B)	VS4	Listing of Vital Signs Values of Potential Clinical Importance (Part B)	IDSL Footnote: Note: For absolute results: H=High, L=Low. For change from baseline: H1=Lower Increase, H2=Upper Increase, L1=Lower Decrease, L2=Upper Decrease.	SAC

10.10.10. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part A (Cohort 1 – single ascending dose, 3-way crossover): Columbia Suicide Severity Rating Scale (C-SSRS)					
34	Safety (Part A)	ECSSRS4	Listing of C-SSRS suicidal Ideation and Behaviour Data (Part A)		SAC
35	Safety (Part A)	ECSSRS5	Listing of C-SSRS Suicidal Behaviour Details (Part A)		SAC
Part A (Cohort 1 – single ascending dose, 3-way crossover): Pharmacokinetic Data					
36	Pharmacokinetic (Part A)	PK08	Listing of Plasma GSK2982772 Pharmacokinetic Concentration-Time Data (Part A)		SAC
37	Pharmacokinetic (Part A)	PK07	Listing of Plasma M8 (GSK3562183) Pharmacokinetic Concentration-Time Data (Part A)		SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
38	Pharmacokinetic (Part A)	PK07	Listing of Plasma M9 (GSK2997852) Pharmacokinetic Concentration-Time Data (Part A)		SAC
39	Pharmacokinetic (Part A)	PK14	Listing of Derived Plasma GSK2982772 Pharmacokinetic Parameters (Part A)		SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Columbia Suicide Severity Rating Scale (C-SSRS)					
74	Safety (Part B)	ECSSRS4	Listing of C-SSRS suicidal Ideation and Behaviour Data (Part B)		SAC
75	Safety (Part B)	ECSSRS5	Listing of C-SSRS Suicidal Behaviour Details (Part B)		SAC
Part B (Cohorts 2, 3, 4 and 5 – repeat dose, sequential-group): Pharmacokinetic Data					
76	Pharmacokinetic (Part B)	PK07	Listing of Plasma GSK2982772 Pharmacokinetic Concentration-Time Data (Part B)		SAC
77	Pharmacokinetic (Part B)	PK07	Listing of Plasma M8 (GSK3562183) Pharmacokinetic Concentration-Time Data (Part B)		SAC
78	Pharmacokinetic (Part B)	PK07	Listing of Plasma M9 (GSK2997852) Pharmacokinetic Concentration-Time Data (Part B)		SAC
79	Pharmacokinetic (Part B)	PK13	Listing of Derived Plasma GSK2982772 Pharmacokinetic Parameters (Part B)		SAC

10.11. Appendix 11: Example Mock Shells for Data Displays

Example: SAFE_T1 Page 1 of n
Protocol: 205184
Population: Pharmacokinetic

Table x.x
Summary of Plasma 4β-hydroxycholesterol to Cholesterol Ratio (Part B)

Parameter: xxxx

Treatment	N	Study Day	Planned Relative Time	n	Mean	95% CI (Lower, Upper)	SD	SE	Median	Min.	Max.
120mg TID	24	Day -1/1	Pre-dose	24	xxxx.x	(xxxx.xx,xxxx.xx)	xx.xx	xxxx.x	xxxx.x	xxxx	xxxx
		Day 14	24 hr	23	xxxx.x	(xxxx.xx,xxxx.xx)	xx.xx	xxxx.x	xxxx.x	xxxx	xxxx
240mg TID	24	Day -1/1	Pre-dose	24	xxxx.x	(xxxx.xx,xxxx.xx)	xx.xx	xxxx.x	xxxx.x	xxxx	xxxx
		Day 14	24 hr	21	xxxx.x	(xxxx.xx,xxxx.xx)	xx.xx	xxxx.x	xxxx.x	xxxx	xxxx
360mg BID	24	Day -1/1	Pre-dose	24	xxxx.x	(xxxx.xx,xxxx.xx)	xx.xx	xxxx.x	xxxx.x	xxxx	xxxx
		Day 14	24 hr	24	xxxx.x	(xxxx.xx,xxxx.xx)	xx.xx	xxxx.x	xxxx.x	xxxx	xxxx

Example: SAFE_L1 Page 1 of n
Protocol: 205184
Population: Pharmacokinetic

Table x.x
Listing of Plasma Cholesterol and 4B-hydroxycholesterol Concentration-Time (ug/mL) Data (Part B)

Treatment: XXXXX

Inv./ Subj.	Visit/ Date/ Study Day	Planned Relative Time	Actual Time	Time Deviation (Hours)	Actual Relative Time	Analyte	Concentration (ug/mL)	Ratio [1]	Excluded from Analysis? [2]
XXXXX/ XXXXXX	Part B Day 1 DDMMMYYYY/ 1	Pre-dose	h:mm	-X.XX	-Xh XXm	4BOH CHOLESTEROL	xxxx.x	xxx.xx	
						CHOLESTEROL	xxxx.x		
	Part B Day 14 DDMMMYYYY/ 1	Pre-dose	h:mm	-X.XX	-Xh XXm	4BOH CHOLESTEROL	xxxx.x		
						CHOLESTEROL	xxxx.x		

[1] Plasma 4B-hydroxycholesterol to Cholesterol ratio.
[2] Samples excluded from analyses due to >1% haemolysis.