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

Title	:	Reporting and Analysis Plan for a two part, non-randomised, open label study designed to assess the pharmacokinetic profile of modified release prototype coated tablet formulations of GSK2982772 relative to an immediate release reference tablet formulation at a fixed strength (Part A) and the pharmacokinetic profile of alternative tablet strengths of the selected modified release prototype coated tablet formulation (Part B, optional) in healthy participants.
Compound Number	:	GSK2982772
Effective Date	:	18-JUN-2019

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 209261.
- This RAP is intended to describe the PK, safety, and tolerability 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:

Revision Chronology:		
2018N367092_00	23-JUL-2018	Original
2018N367092-01	08-Aug-2018	Follow up call changed to follow up visit
2018N367092-02	28-Aug-2018	Grounds for Non-Acceptance regarding SAEs
2018N367092-03	26-Feb-2019	New investigational medicinal product to compare type of coating of GSK2982772.
2018N367092-04	10-Apr-2019	Additional optional Period 7in Part B to explore prandial states.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

There were no changes or deviations to the originally planned statistical analysis specified in the protocol (Dated: 23/JUL/2018).

C_{8h} has been collected as a PK endpoint since dosing in the PoC studies (203167 (psoriasis), 203168 (rheumatoid arthritis) and 202152 (ulcerative colitis)) was changed from BID to TID dosing with the immediate release (IR) formulation of GSK2982772. On further reflection, comparisons of C_{8h} and C_{12h} following single dose are not relevant comparisons and will not be included in the analyses.

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

Objectives	**Endpoints**
Primary Objectives	**Primary Endpoints**
• To evaluate the single dose PK profile of GSK2982772 from each MR prototype coated tablet formulation (240 mg) compared to the IR formulation (240 mg) (Part A)	• GSK2982772 area under the curve from time zero to infinity (AUC(0-inf)), area under the curve from time zero to the last measurable concentration (AUC(0-t)), area under the curve from time zero to 24 hours (AUC(0-24)), maximum observed concentration (Cmax), concentration at 24 hours post-dose (C24h), time to Cmax (Tmax), terminal half-life (t1/2).
• To assess the impact of a high-fat breakfast on the PK of GSK2982772 following single dose administration of one or more selected MR prototype coated tablet formulations (240 mg) (Part A or Optional Part B)	• GSK2982772 AUC(0-inf), AUC(0-t), Cmax, Tmax, C24h, and t1/2, relative bioavailability (FrelFE), relative bioavailability (FrelFormulation) to IR based on AUC and Cmax
Secondary Objectives	**Secondary Endpoints**
• To assess the safety and tolerability	• Adverse events (AEs)

Objectives	Endpoints
of single doses of GSK2982772 (Part A)	• Clinical laboratory values (clinical chemistry, haematology and urinalysis) • Vital sign measurements (blood pressure, heart rate, respiratory rate and body temperature) • 12-Lead electrocardiogram (ECG) • monitoring
• To determine the bioavailability of GSK2982772 MR prototype coated tablet formulations relative to the IR reference, as appropriate (Part A) [1]	• Relative bioavailability (Frelformulation) based on AUC and Cmax
Exploratory Objectives	**Exploratory Endpoints**
• To assess the safety and tolerability of single doses of GSK2982772 (Optional Part B)	• Adverse events (AEs) • Clinical laboratory values (clinical • chemistry, haematology and urinalysis) • Vital sign measurements (blood pressure, heart rate, respiratory rate and body temperature) • 12-Lead electrocardiogram (ECG) monitoring
• To evaluate the PK profile of alternative tablet strengths of selected GSK2982772 MR prototype coated tablet formulations (Optional Part B)	• GSK2982772 AUC(0-inf), AUC(0-t), AUC(0-24), Cmax, C24h, t1/2, AUC/Dose and Cmax/Dose
• To evaluate the impact of dosing 2 or more MR prototype coated tablets on the PK profile of GSK2982772 (Optional Part B)	• GSK2982772 AUC(0-inf), AUC(0-t) or AUC(0-24), Cmax, Tmax and t1/2
• To determine if there are any dose dependent changes in the absorption of GSK2982772 following single dose administration selected GSK2982772 MR prototype coated tablet formulations (Optional Part B)	• GSK2982772 AUC(0-inf), AUC(0-t), AUC(0-24), Cmax, C24h and Tmax
• To assess the impact of a standard breakfast on the PK of GSK2982772 following single dose administration of one or more selected MR prototype coated tablet formulations (240 mg) (Part A - optional)	• GSK2982772 AUC(0-inf), AUC(0-t), Cmax, Tmax and t1/2, relative bioavailability (FrelFE), relative bioavailability (FrelFormulation), based on AUC and Cmax
• To assess the impact of a delayed meal on the PK of GSK2982772 following single dose administration of one or more selected MR prototype coated tablet formulations (240 mg) (Part A - optional)	• GSK2982772 AUC(0-inf), AUC(0-t), Cmax, Tmax and t1/2, relative bioavailability (FrelFE), relative bioavailability (FrelFormulation), based on AUC and Cmax

2.3. Study Design

See Section 5 of the protocol for the study design.

2.4. Statistical Hypotheses / Statistical Analyses

No formal hypothesis will be tested. However, point estimates and corresponding 90% confidence intervals will be derived for Cmax, AUC(0-t), AUC(0-inf) and C24h.

3. PLANNED ANALYSES

3.1. Interim Analyses

No formal statistical analyses are planned. However, after Period 3 of Part A is complete, the PK data will be analysed which will guide Periods 4, 5 and 6. Periods 4, 5 and 6 will be flexible and the dosing regimen will be dependent on the outcome (safety and PK) of preceding periods. There will be the option to optimise the MR release duration and/or to evaluate the impact of a high-fat, standard, or delayed meal on the selected MR formulation(s). If an optimal formulation is identified in Part A, Part B will proceed. If none of the MR prototype coated tablet formulations are suitable, then Part B of the study may not be conducted or Part B may be used to continue to optimise the MR prototype coated tablet formulations. This will be based upon identifying a formulation that has an appropriate exposure profile that does not show a significant food effect.

In Part B, there will be an interim review following completion of each of Periods 1 to 5 to determine the dose level, formulation and prandial status, as appropriate, to be used in subsequent periods.

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.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Subjects	• All participants who were screened for eligibility and allocated a subject number.	• Selected Study Population
Safety	• All participants who receive at least 1 dose of study	• Safety and Study

Population	Definition / Criteria	Analyses Evaluated
	treatment and will be the population for reporting of safety and study population data. Participants will be analyzed according to the treatment they actually received.	Population
PK	• Participants in the 'Safety Population' for whom a PK sample was obtained and analysed will be the population for reporting of PK data.	• PK

Refer to Appendix 10: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

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

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan (PDMP) [26-APR-2019 version 1.01]. See Section 10.1 for further details.

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
Part A			
A	GSK2982772 240mg MR RR1 oral single dose	MR-12h 240mg Fasted	2
B*	GSK2982772 240mg MR RR2 oral single dose	IR 240mg Fasted	1
C*	GSK2982772 240mg IR oral single dose	MR-18h 240mg Fasted	3
D	GSK2982772 240mg MR RR3 oral single dose	MR-18h 240mg Fed (High-Fat)	5
E	GSK2982772 240mg MR RR4 oral single dose	MR-12h 240mg Fed (High-Fat)	4
F	GSK2982772 240mg MR fed state	MR-16h 240mg Fasted	6
Part B			
G	GSK2982772 120mg MR oral single dose	MR-16h 480mg Fasted	1
H	GSK2982772 480mg MR oral single dose	MR-16h 960mg Fasted	5
J	GSK2982772 MR oral single dose 1	MR-16h 480mg Fed (High-Fat)	3
K	GSK2982772 MR oral single dose 2	MR-16h 120mg Fasted	6
L	GSK2982772 MR oral single dose 3	MR-16h 480mg Fed (High-Fat) (Enteric Coated)	4
M	GSK2982772 MR oral single dose 4	MR-16h 480mg Fed (Standard)	2

* In Part A, the treatments for Period 2 and 3 were reversed in order due to availability of the drug at site. For Period 2 participants received "GSK2982772 240mg IR oral single dose" and Period 3 participants received "GSK2982772 240mg MR RR2 oral single dose".

Safety listings may be presented chronologically instead of in the order suggested above.

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. Unless otherwise stated, the mean of replicate assessments at any given time point will be used as the value for that time point.

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Day -1	Day 1 (Pre-Dose)	
Safety				
Vital signs	X	X	X	Day 1 (Pre-Dose)
12-lead ECG	X	X	X	Day 1 (Pre-Dose)
Laboratory (Haematology, clinical chemistry and urinalysis)	X	X	X	Day 1 (Pre-Dose)

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

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
10.3	Appendix 3: Assessment Windows
10.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events

Section	Component
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

6. STUDY POPULATION ANALYSES

6.1. 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 subject's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 10: List of Data Displays.

7. SAFETY ANALYSES

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

7.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious Adverse Events (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.

7.2. 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 provided in Appendix 10: List of Data Displays.

In additional to GSK Core Data Standards, Lipids (Total Cholesterol and Triglycerides) outside the normal range will be summarised.

7.3. 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. The details of the planned displays are provided in Appendix 10: List of Data Displays.

8. PHARMACOKINETIC ANALYSES

8.1. Primary, Secondary, and Exploratory Pharmacokinetic Analyses – Part A and Part B

8.1.1. Endpoint / Variables

8.1.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 10.5.2 Reporting Standards)

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
$AUC_{(0\text{-}inf)}$	Area under the curve from time zero to infinity
$AUC_{(0\text{-}t)}$	Area under the curve from time zero to the last quantifiable concentration
$AUC_{(0\text{-}24)}$	Area under the curve from time zero to 24 hours
AUC%extrap	Percentage of AUC extrapolated beyond the last measured time point.
$t_{1/2}$	Terminal half-life
T_{lag}	Time from dosing to first quantifiable concentration.
T_{last}	Time of last measurable concentration
T_{max}	Time of maximum observed concentration
C_{max}	Maximum observed concentration
C_{24h}	Concentration at 24 hours post-dose

NOTES:

- Additional parameters may be included as required.
- No log transformation for Tmax nor any ratio (relative) endpoint.

8.1.2. Summary Measure

For each period in Part A and Part B period, descriptive statistics (n, arithmetic mean, standard deviation [SD], 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 %CVb (100 * √ (exp(SD2) -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

- Subject study completion (i.e. as specified in the protocol) was defined as completing all phases of the study including the follow-up visit.
- Withdrawn subjects may be replaced in the study. Replacement subjects enrolled will be dosed with the next planned treatment of the withdrawn subject, and they will not receive any treatment that the withdrawn subject has already received with the exception of the need to increase subject numbers to obtain the minimum number of evaluable subjects required for interim decisions, and to obtain data in any other treatment that is required for a valid comparison. Replacement subjects will receive the required treatments in the same order as planned for the original subject and the minimum washout period will be respected with regard to the timing of dosing of the IR formulation.
- All available data from subjects 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.

8.1.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 8.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

8.1.5.1. Statistical Methodology Specification

The following pharmacokinetic statistical analyses will only be performed if sufficient data is available (i.e. if participants have well defined plasma profiles).

Parts A and B

Model Specification: AUC, C_{max}, C_{24h} in log scale
• Include covariates and handling of multicentre studies (if appropriate), additional information can be included in other relevant sections of the RAP and cross reference provided. • For each study part and each endpoint a mixed model will be fit with up to 6 observations per participant expected in Part A, corresponding to periods 1 through 6. Similarly for Part B. The model will contain formulation (PATRTGRP) as a fixed, categorical effect, and a random intercept for subject. • The Kenward and Roger method for approximating the denominator degrees of freedom and correcting for bias in the estimated variance-covariance of the fixed effects will be used.

Model Checking & Diagnostics
• Model assumptions will be applied, but appropriate adjustments may be made based on the data. • In the event the model fails to converge, the RANDOM statement will be removed and alternative covariance structures such as CS, CSH, or UN for the R matrix will be used by specifying 'type=' on the REPEATED line. Akaike's Information Criteria (AIC) will be used to assist with the selection of covariance structure. • Distributional assumptions underlying the model used for analysis will be examined by obtaining a normal probability plot of the residuals and a plot of the residuals versus the fitted values (i.e. checking the normality assumption and constant variance assumption of the model respectively) to gain confidence that the model assumptions are reasonable. • If there are any departures from the distributional assumptions, alternative models will be explored using appropriate transformed data.
Model Results Presentation
• Point estimates and corresponding 90% CI will be computed for the differences in the endpoint for each treatment period. • The relative bioavailability ratio, Frel, and 90% CI will be calculated by back-transforming the difference between the least square means for each of the two formulation comparisons. See Section 10.6.4

Model Specification: Tmax
• Include covariates and handling of multicentre studies (if appropriate), additional information can be included in other relevant sections of the RAP and cross reference provided. • Exact non-parametric Hodges-Lehmann estimation of location shift will be fitted.
Model Results Presentation
• For each relative bioavailability, the median difference and 90% CI for median difference will be presented.

Part A - Formulation

Endpoint (AUC, C_{max}, C_{24h} in log scale)
• $AUC_{(0-inf)}$ • $AUC_{(0-t)}$ • $AUC_{(0-24h)}$ • C_{max} • C_{24h} • T_{max}
Relative Bioavailability
• MR-12h 240mg Fasted vs IR 240mg Fasted • MR-18h 240mg Fasted vs IR 240mg Fasted

• MR-16h 240mg Fasted vs IR 240mg Fasted • MR-18h 240mg Fed (High-Fat) vs MR-12h 240mg Fed (High-Fat)

Part A – Food Effect

Endpoint (AUC, C_{max} in log scale)
• $AUC_{(0\text{-}inf)}$ • $AUC_{(0\text{-}t)}$ • C_{max} • T_{max}
Relative Bioavailability
• MR-18h 240mg Fed (High-Fat) vs MR-18h 240mg Fasted • MR-12h 240mg Fed (High-Fat) vs MR-12h 240mg Fasted

Part B – Dose Effect

Endpoint (AUC, C_{max}, C_{24h} in log scale)
• $AUC_{(0\text{-}inf)}$ • $AUC_{(0\text{-}t)}$ • $AUC_{(0\text{-}24h)}$ • C_{max} • C_{24h} • T_{max}
Relative Bioavailability
• MR-16h 960mg Fasted vs MR-16h 120mg Fasted • MR-16h 480mg Fasted vs MR-16h 120mg Fasted • MR-16h 960mg Fasted vs MR-16h 480mg Fasted

Part B – Food Effect

Endpoint (AUC, C_{max} in log scale)
• $AUC_{(0\text{-}inf)}$ • $AUC_{(0\text{-}t)}$ • C_{max} • T_{max}
Relative Bioavailability
• MR-16h 480mg Fed (High-Fat) vs MR-16h 480mg Fasted

Part B – Enteric Coating Effect

Endpoint (AUC, C_{max}, C_{24h} in log scale)
• $AUC_{(0\text{-}inf)}$ • $AUC_{(0\text{-}t)}$ • C_{max} • C_{24h} • T_{max}
Relative Bioavailability
• MR-16h 480mg Fed (High-Fat) (Enteric Coating) vs MR-16h 480mg Fed (High-Fat)

9. REFERENCES

GlaxoSmithKline Document Number 2018N367092_02. A two part, non-randomised, open label study designed to assess the pharmacokinetic profile of modified release prototype coated tablet formulations of GSK2982772 relative to an immediate release reference tablet formulation at a fixed strength (Part A) and the pharmacokinetic profile of alternative tablet strengths of the selected modified release prototype coated tablet formulation (Part B, optional) in healthy participants. Effective Date: 28-AUG-2018.

SAS Institute Inc. 2017. SAS/STAT® 14.3 User's Guide. Cary, NC: SAS Institute Inc.

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

Procedure	Screening (up to 28 days before Day 1)	Treatment Period 1, 2, 3, 4, 5, 6 Day				Follow-up Visit (7 to 9 days post last dose)	Notes
		–1	1	2	3		
Informed consent	X						
Inclusion and exclusion criteria[1]	X						1. Recheck clinical status before 1st dose of study medication.
Demography	X						
Full physical examination including height and weight	X						
Brief physical examination		X		X[2]	X[2]	X	2. Discharge (48 h post-dose for Part B, and Treatment Periods 1, 2, 4, 5 and 6 for Part A; 24 h post-dose for Part A Treatment Period 3 only)
Medical history (includes substance usage)[3]	X						3. Substances: Drugs, Alcohol, tobacco and caffeine
Past and current medical conditions	X						
Follicle Stimulating Hormone (FSH) and estradiol (as needed in women of non-childbearing potential only)	X						
Serum pregnancy test (WOCBP)	X					X	

Procedure	Screening (up to 28 days before Day 1)	Treatment Period 1, 2, 3, 4, 5, 6 Day				Follow-up Visit (7 to 9 days post last dose)	Notes
		–1	1	2	3		
Urine pregnancy test (WOCBP)		X		X[4]	X[4]		4. Discharge (48 h post-dose for Part B, and Treatment Periods 1, 2, 4, 5 and 6 for Part A; 24 h post-dose for Part A Treatment Period 3 only)
Human Immunodeficiency Virus (HIV), Hepatitis B and C screening[5]	X						5. If test otherwise performed within 3 months prior to first dose of study treatment, testing at screening is not required
Tuberculosis (TB) Test	X						
Urine drug screen	X	X					
Alcohol breath test	X	X					
Carbon monoxide breath test	X	X					
Laboratory assessments (haematology, clinical chemistry and urinalysis)	X	X[6]		X[7]		X	6. Results must be available prior to dosing on Day 1 7. 24 h post-dose Allowable windows in Section 9.4.4
Glomerular filtration rate	X						
C-reactive protein (CRP)	X						

Procedure	Screening (up to 28 days before Day 1)	Treatment Period 1, 2, 3, 4, 5, 6 Day				Follow-up Visit (7 to 9 days post last dose)	Notes
		–1	1	2	3		
12-lead ECG	X[8]	X	X[9]	X[10]		X	8. In triplicate 9. Pre-dose and 2 and 12 h post-dose 10. 24 h post-dose Allowable windows in Section 9.4.3
Vital signs	X	X	X[11]	X[12, 13]	X[13]	X	11. Pre-dose and 2 and 12 h post-dose 12. 24 h post-dose Allowable windows in Section 9.4.2 13. Discharge (48 h post-dose for Part B, and Treatment Periods 1, 2, 4, 5 and 6 for Part A; 24 h post-dose for Part A Treatment Period 3 only)
Genetics blood sample collection (optional)			X[14]				14. A blood sample is collected at the Day 1 visit, after the participant has been randomised 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. Subjects that decline to provide a sample will still be eligible for this study

Procedure	Screening (up to 28 days before Day 1)	Treatment Period 1, 2, 3, 4, 5, 6 Day				Follow-up Visit (7 to 9 days post last dose)	Notes
		–1	1	2	3		
Study treatment			X				
AE review		←==========→					
Serious AE (SAE) review	X	←==========→					
Concomitant medication review		←==========→					
PK blood sample collection			X[15]	X[15]	X[15]		15. Time points in Table 2

Table 2 from Protocol

	Treatment Periods 1, 2, 4, 5 and 6 (MR Formulations) and Part B (All Periods)																			
Time	Pre-dose	0 h	2 h	4 h	6 h	8 h	10 h	12 h	14 h	16 h	18 h	20 h	22 h	24 h	26 h	28 h	30 h	32 h	36 h	48 h
Dosing		X																		
PK sampling	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Part A: Treatment Period 3 (IR Formulation)																				
Time	Pre-dose	0 h	0.33 h	0.66 h	1 h	1.5 h	2 h	3 h	4 h	5 h	6 h	8 h	10 h	12 h	24 h					
Dosing		X																		
PK sampling	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 dosing.

Treatment Phase	Definition
Pre-Treatment	Date[1] ≤ Study Treatment Start Date[1]
On-Treatment	Study Treatment Start Date[1] < Date[1] ≤ Study Treatment Stop Date[1]
Post-Treatment	Date[1] > Study Treatment Stop Date[1]

[1] Datetime if Time is present for assessments or events

10.4.1.1. Study Phases for Concomitant Medication

Study Phase	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. (plus washout or protocol-specified time limit (e.g. half-life of drug, certain number of days, etc.). • Study Treatment Start Date ≤ AE Start Date ≤ Study Treatment Stop Date. • 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.

NOTES:

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

10.5. Appendix 5: Data Display Standards & Handling Conventions

10.5.1. Reporting Process

Software	
• The currently supported versions of SAS software and WIN-NonLin will be used.	
Reporting Area	
HARP Server	: UK1SALX00175
HARP Area	**Final** : \arprod\gsk2982772\ mid209261\final_01
QC Spreadsheet	: \arwork\gsk2982772\mid209261\final_01\documents
Analysis Datasets	
• Analysis datasets will be created according to Legacy GSK Integrated Data Standards Library (IDSL) A&R dataset standards.	
Generation of RTF Files	
• RTF files will be generated for SAC tables.	

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 subject level listings in the main body of the GSK Clinical Study Report. All subject level listings should be located in the modular appendices as ICH or non-ICH listings

Formats
• GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF. • The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP's.   • PK Summary Statistics: 3 significant figures for the lowest value of each PK parameter. The summary statistics for higher values will be reported to the same number of decimal places as the lowest value
Planned and Actual Time

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

• Unscheduled or unplanned readings will be presented within the subject's listings.	
Unscheduled Visits	
• Unscheduled visits will not be included in summary tables and/or figures, except where appropriate. • 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.	
Reporting of Pharmacokinetic Concentration Data	
Descriptive Summary Statistics	Refer to IDSL Statistical Principle 6.06.1 Assign zero to NQ values (Refer to GUI_51487 for further details)

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. • If there are two values within a time window (as per Section 10.3.1) 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

Demographics
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 1 for QD. Treatment compliance could be greater than 100% if there are events of overdose. Cumulative compliance (since Day 1) at each visit will be calculated.
Extent of Exposure
• Number of days of exposure to study drug will be calculated based on the formula:

Treatment Compliance
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. Efficacy

N/A

10.6.4. Safety

ECG Parameter
RR Interval
• IF RR interval (msec) is not provided directly, then RR can be derived as : [1] If QTcB is machine read & QTcF is not provided, then : $$RR = \left[\left(\frac{QT}{QTcB}\right)^2\right] * 1000$$ [2] If QTcF is machine read and QTcB is not provided, 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 Bazett's (QTcB) and Fridericia's (QTcF) formulas will be calculated, in msec, depending on the availability of other measurements. • IF RR interval (msec) is provided then missing QTcB and/or QTcF will be derived as $$QTcB = \frac{QT}{\sqrt{\frac{RR}{1000}}} \qquad QTcF = \frac{QT}{\sqrt[3]{\frac{RR}{1000}}}$$

ECG Parameter	Units	QTc Categories	
		Lower	Upper
Absolute			
Absolute QTc Interval	msec	≤ 450	
		> 450	≤ 480
		> 480	≤ 500
		> 500	
Change from Baseline			

ECG Parameter	Units	QTc Categories	
		Lower	Upper
Increase from Baseline QTc	msec	≤ 30	
		> 30	≤ 60
		> 60	

See Section 8.1.2 of the protocol for QTc stopping criteria. In addition to the two stopping criteria outlined in the protocol,

- QTc >500 msec
- Change from baseline (pre-dose Day 1) of QTc >60 msec

a third criteria will be flagged for summary purposes:

- Change from triplicate screening of QTc >60 msec

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 decimal places in the observed values will be used to determine how much to add or subtract in order to impute the corresponding numeric value. o Example 1: 2 Decimal Places= '< x ' becomes x – 0.01 o Example 2: 1 Decimal Places = '> x' becomes x + 0.1 o Example 3: 0 Decimal Places = '< x' becomes x – 1

10.6.5. Pharmacokinetic

The pharmacokinetic parameters will be calculated by standard non-compartmental analysis according to current working practices using WinNonlin Version 6.3 or higher.

Pharmacokinetic Endpoints
AUC(0-t)
• Area under the concentration-time curve from time zero to the time of the last quantifiable concentration (C(t)) will be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
AUC(0-∞)
• Area under the concentration-time curve extrapolated to infinity will be calculated as: **AUC = AUC(0-t) + C(t) / lambda_z** where lambda_z is the terminal phase rate constant.

Pharmacokinetic Endpoints
AUC(0-24)
Area under the concentration-time curve from time zero to 24 h post dose will be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
AUC%extrap
Percentage of AUC extrapolated beyond the last measured time point
C_{max}
Maximum observed concentration, determined directly from the concentration-time data
C_{24h}
Observed concentration at 24 hours, determined directly from the concentration-time data
Tmax
Time to reach Cmax, determined directly from the concentration-time data.
Tlast
Time of last measurable concentration
Tlag
Time from dosing at which GSK2982772 was first quantifiable in a concentration vs time profile
t1/2
Terminal half-life
Notes • Additional parameters may be included as required

Relative Bioavailability (Frel)
• Frel will be calculated as follows: $Frel = \frac{GeoMean\{AUC\ or\ C_{max}(test)\}}{GeoMean\{AUC\ or\ C_{max}(reference)\}}\ x\ 100$ Frel will be calculated using $AUC_{(0\text{-}inf)}$, AUC(0-last), C_{24h}, and C_{max}. o MR Formulation (test) vs IR Formulation (reference) o MR Fed (test) vs MR Fasted (reference) o Enteric Coated (test) vs MR (reference)

MR refers to DiffCORE

10.7. Appendix 7: Reporting Standards for Missing Data

10.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion (i.e. as specified in the protocol) was defined as one who completes all phases of the study including the last scheduled procedure shown in the SoA i.e. the follow-up visit. • Withdrawn subjects may be replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

See study protocol for liver chemistry, QTc, and nervous system early stopping criteria.

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: ○ These data will be indicated by the use of a "blank" in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. ○ 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 subject 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

Element	Reporting Detail
	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	
Hemoglobin	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
White 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	µmol/L			1.3 X ULN
Creatinine	µmol/L	Δ from BL		↑ 44.2
Glucose	mmol/L		3	9
Potassium	mmol/L		3	5.5
Sodium	mmol/L		130	150
Total CO2	mmol/L		18	32

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	≥ 1.5x ULN
T. Bilirubin + ALT	µmol/L U/L	High	1.5xULN T. Bilirubin + ≥ 2x ULN ALT

10.8.2. ECG

ECG Parameter	Units	Clinical Concern Range	
		Lower	Upper
Absolute			
Absolute QTc Interval	msec	> 450	≤ 480
		> 480	≤ 500
		> 500	
Absolute PR Interval	msec	< 110	> 220
Absolute QRS Interval	msec	< 75	> 110
Change from Baseline			
Increase from Baseline QTc	msec	> 30	≤ 60
	msec	> 60	

E.g. H1=">450 - <=480" H2=">480 - <=500" H3=">500" to be used as the flagging for Absolute QTc Interval in the corresponding displays.

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

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
AIC	Akaike's Information Criteria
A&R	Analysis and Reporting
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
eCRF	Electronic Case Record Form
EMA	European Medicines Agency
FDA	Food and Drug Administration
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

Abbreviation	Description
SDTM	Study Data Tabulation Model
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings

10.9.2. Trademarks

Trademarks not owned by the GlaxoSmithKline Group of Companies
[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.n	1.1 to 1.n
Safety	2.1 to 2.n	2.1 to 2.n
Pharmacokinetic	3.1 to 3.n	3.1 to 3.n
Section	**Listings**	
ICH Listings	1 to x	
Other Listings	y to z	

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	POP_Fn	POP_Tn	POP_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln

NOTES:

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

10.10.3. Deliverables

Delivery [Priority] [1]	Description
SAC	Final Statistical Analysis Complete

NOTES:

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

10.10.4. Study Population Tables

10.10.4.1. Study Population Tables Part A

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	Safety	ES1A	Summary of Subject Disposition: Part A	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.2.	All Subjects	ES6	Summary of Reasons for Screen Failure: Part A	Journal Requirements	SAC
Protocol Deviation					
1.3.	Safety	DV1	Summary of Important Protocol Deviations: Part A	ICH E3	SAC
1.4.	All Subjects	IE2	Summary of Inclusion/Exclusion Criteria Deviations: Part A	IDSL	SAC
Population Analysed					
1.5.	Safety	SP1	Summary of Study Populations and Exclusions: Part A	IDSL	SAC
Demographic and Baseline Characteristics					
1.6.	All Subjects	DM11	Summary of Age Ranges: Part A	ICH E3, GSK CTR, FDAAA, EudraCT Only include age ranges applicable to the study ('Adult (18-64 years)' and '>=65-84 years'). Additional ranges of <18 and >=85 are also included, though these should have zero counts.	SAC
1.7.	Safety	DM3	Summary of Demographic Characteristics: Part A	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.8.	Safety	DM5	Summary of Race and Racial Combinations: Part A	ICH E3, FDA, GSK CTR, FDAAA, EudraCT	SAC
1.9.	Safety	DM6	Summary of Race and Racial Combination Details: Part A	ICH E3, FDA	SAC
Prior and Concomitant Medications					

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.10.	Safety	MH4	Summary of Current/Past Medical Conditions: Part A	ICH E3 Separate summaries for Current & Past conditions, if collected.	SAC
1.11.	Safety	CM1	Summary of Concomitant Medications: Part A	ICH E3	SAC
Exposure and Treatment Compliance					
1.12.	Safety	EX1	Summary of Exposure to Study Treatment: Part A	ICH E3 Dose and/or time on treatment, as applicable.	SAC

10.10.4.2. Study Population Tables Part B

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.13.	Safety	ES1A	Summary of Subject Disposition: Part B	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.14.	All Subjects	ES6	Summary of Reasons for Screen Failure: Part B	Journal Requirements	SAC
Protocol Deviation					
1.15.	Safety	DV1	Summary of Important Protocol Deviations: Part B	ICH E3	SAC
1.16.	All Subjects	IE2	Summary of Inclusion/Exclusion Criteria Deviations: Part B	IDSL	SAC
Population Analysed					
1.17.	Safety	SP1	Summary of Study Populations and Exclusions: Part B	IDSL	SAC
Demographic and Baseline Characteristics					
1.18.	All Subjects	DM11	Summary of Age Ranges: Part B	ICH E3, GSK CTR, FDAAA, EudraCT Only include age ranges applicable to the study ('Adult (18-64 years)' and '>=65-84 years').	SAC
1.19.	Safety	DM3	Summary of Demographic Characteristics: Part B	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.20.	Safety	DM5	Summary of Race and Racial Combinations: Part B	ICH E3, FDA, GSK CTR, FDAAA, EudraCT	SAC
1.21.	Safety	DM6	Summary of Race and Racial Combination Details: Part B	ICH E3, FDA	SAC
Prior and Concomitant Medications					

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.22.	Safety	MH4	Summary of Current/Past Medical Conditions: Part B	ICH E3 Separate summaries for Current & Past conditions, if collected.	SAC
1.23.	Safety	CM1	Summary of Concomitant Medications: Part B	ICH E3	SAC
Exposure and Treatment Compliance					
1.24.	Safety	EX1	Summary of Exposure to Study Treatment: Part B	ICH E3 Dose and/or time on treatment, as applicable.	SAC

10.10.5. Safety Tables

10.10.5.1. Safety Tables Part A

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
2.1.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term: Part A	See 2.02 from 200975	SAC
2.2.	Safety	AE5a	Summary of All Adverse Events by System Organ Class and Maximum Intensity: Part A	ICH E3	SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.3.	Safety	AE3	Summary of Common (>10%) Adverse Events by Overall Frequency: Part A	GSK CTR	SAC
2.4.	Safety	AE5a	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Intensity: Part A	GSK CTR	SAC
Serious and Other Significant Adverse Events					
2.5.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class: Part A	IDSL / GSK CTR	SAC
2.6.	Safety	AE3	Summary of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment by Overall Frequency: Part A	IDSL	SAC
2.7.	Safety	AE16	Summary of Subjects and Number of Occurrences of Serious, Drug-Related Serious, Fatal Serious, and Drug-Related Fatal Serious Adverse Events: Part A	FDAAA, EudraCT	SAC
Laboratory: Chemistry					
2.8.	Safety	LB1	Summary of Clinical Chemistry Changes from Baseline: Part A	ICH E3 Includes Baseline values. Includes pre-specified parameters repeated in conventional units.	SAC
2.9.	Safety	LB1	Summary of Clinical Chemistry Values: Part A		SAC
2.10.	Safety	LB3	Summary of Emergent Clinical Chemistry Results by Potential Clinical Importance Criteria: Part A		SAC
2.11.	Safety	LB17	Summary of Worst Case Lipids Outside Laboratory Normal Range Post-Baseline Relative to Baseline: Part A		SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Hematology					
2.12.	Safety	LB1	Summary of Hematology Changes From Baseline: Part A	ICH E3 Includes baseline values.	SAC
2.13.	Safety	LB1	Summary of Hematology Values: Part A	ICH E3 Includes baseline values.	SAC
2.14.	Safety	LB3	Summary of Emergent Hematology Results by Potential Clinical Importance Criteria: Part A		SAC
Laboratory: Urinalysis					
2.15.	Safety	UR3	Summary of Urinalysis Dipstick Results: Part A	ICH E3 Includes Baseline values.	SAC
Laboratory: Hepatobiliary (Liver)					
2.16.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting: Part A	IDSL	SAC
2.17.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities: Part A		SAC
ECG					
2.18.	Safety	EG1	Summary of ECG Findings: Part A	IDSL As above for Chemistry, using ECG findings categories (and change from baseline categories, if applicable). No need to present Heart Rate (not collected with ECG data).	SAC
2.19.	Safety	EG2	Summary of Change from Baseline in ECG Values by Visit: Part A	IDSL. No need to display Heart Rate.	SAC
2.20.	Safety	EG2	Summary of Change from Triplicate Screening in ECG Values by Visit: Part A		

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.21.	Safety	CP_EG12	Summary of Maximum Change from Baseline in QTc Values by Category: Part A	IDSL. Footnote: "Increase of <=30 msec" category also includes No Change or Decreases in Change from Baseline	SAC
2.22.	Safety	CP_EG12	Summary of Maximum Change from Triplicate Screening in QTc Values by Category: Part A	IDSL. Footnote: "Increase of <=30 msec" category also includes No Change or Decreases in Change from Baseline	SAC
Vital Signs					
2.23.	Safety	VS1	Summary of Change From Baseline in Vital Signs by Visit: Part A	ICH E3 Includes Baseline values.	SAC
2.24.	Safety	VS1	Summary of Vital Signs by Visit: Part A		SAC

10.10.5.2. Safety Tables Part B

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
2.25.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term: Part B	See 2.02 from 200975	SAC
2.26.	Safety	AE5a	Summary of All Adverse Events by System Organ Class and Maximum Intensity: Part B	ICHE3	SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.27.	Safety	AE3	Summary of Common (>10%) Adverse Events by Overall Frequency: Part B	GSK CTR	SAC
2.28.	Safety	AE5a	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Intensity: Part B	GSK CTR	SAC
Serious and Other Significant Adverse Events					
2.29.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class: Part B	IDSL / GSK CTR	SAC
2.30.	Safety	AE3	Summary of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment by Overall Frequency: Part B	IDSL	SAC
2.31.	Safety	AE16	Summary of Subjects and Number of Occurrences of Serious, Drug-Related Serious, Fatal Serious, and Drug-Related Fatal Serious Adverse Events: Part B	FDAAA, EudraCT	SAC
Laboratory: Chemistry					
2.32.	Safety	LB1	Summary of Clinical Chemistry Changes from Baseline: Part B	ICH E3 Includes Baseline values. Includes pre-specified parameters repeated in conventional units.	SAC
2.33.	Safety	LB1	Summary of Clinical Chemistry Values: Part B		SAC
2.34.	Safety	LB3	Summary of Emergent Clinical Chemistry Results by Potential Clinical Importance Criteria: Part B		SAC
2.35.	Safety	LB17	Summary of Worst Case Lipids Outside Laboratory Normal Range Post-Baseline Relative to Baseline: Part B		SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Hematology					
2.36.	Safety	LB1	Summary of Hematology Changes From Baseline: Part B	ICH E3 Includes baseline values.	SAC
2.37.	Safety	LB1	Summary of Hematology Values: Part B	ICH E3 Includes baseline values.	SAC
2.38.	Safety	LB3	Summary of Emergent Hematology Results by Potential Clinical Importance Criteria: Part B		SAC
Laboratory: Urinalysis					
2.39.	Safety	UR3	Summary of Urinalysis Dipstick Results: Part B	ICH E3 Includes Baseline values.	SAC
Laboratory: Hepatobiliary (Liver)					
2.40.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting: Part B	IDSL	SAC
2.41.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities: Part B		SAC
ECG					
2.42.	Safety	EG1	Summary of ECG Findings: Part B	IDSL As above for Chemistry, using ECG findings categories (and change from baseline categories, if applicable). No need to present Heart Rate (not collected with ECG data).	SAC
2.43.	Safety	EG2	Summary of Change from Baseline in ECG Values by Visit: Part B	IDSL. No need to display Heart Rate.	SAC
2.44.	Safety	EG2	Summary of Change from Triplicate Screening in ECG Values by Visit: Part B	IDSL. No need to display Heart Rate.	SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.45.	Safety	CP_EG12	Summary of Maximum Change from Baseline in QTc Values by Category: Part B	IDSL	SAC
2.46.	Safety	CP_EG12	Summary of Maximum Change from Triplicate Screening in QTc Values by Category: Part B	IDSL	SAC
Vital Signs					
2.47.	Safety	VS1	Summary of Change From Baseline in Vital Signs by Visit: Part B	ICH E3 Includes Baseline values.	SAC
2.48.	Safety	VS1	Summary of Vital Signs by Visit: Part B		SAC

10.10.6. Safety Figures

10.10.6.1. Safety Figures Part A

Safety : Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
2.1.	Safety	AE10	Plot of Common Adverse Events and Relative Risk: Part A	IDSL Common defined as >10%	SAC
Hepatobilary (Liver)					
2.2.	Safety	LIVER14	Scatter Plot of Maximum vs Baseline for ALT: Part A		SAC
2.3.	Safety	LIVER9	Scatter Plot for Maximum ALT vs Maximum Total Bilirubin: Part A		SAC

10.10.6.2. Safety Figures Part B

Safety : Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
2.4.	Safety	AE10	Plot of Common Adverse Events and Relative Risk: Part B	IDSL Common defined as >10%	SAC
Hepatobilary (Liver)					
2.5.	Safety	LIVER14	Scatter Plot of Maximum vs Baseline for ALT: Part B		SAC
2.6.	Safety	LIVER9	Scatter Ploy for Maximum ALT vs Maximum Total Bilirubin: Part B		SAC

10.10.7. Pharmacokinetic Tables

10.10.7.1. Pharmacokinetic Tables Part A

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK Concentration					
3.1.	PK	PK01	Summary of Plasma GSK2982772 Concentration-Time (ug/mL) Data by Formulation and Prandial State: Part A		SAC
PK Derived Parameters					
3.2.	PK	PKPT1	Summary Statistics of Derived Plasma GSK2982772 Pharmacokinetic Parameters by Formulation and Prandial State: Part A	Parameters with units.	SAC
3.3.	PK	PKPT3	Summary Statistics of Log-Transformed Derived Plasma GSK2982772 Pharmacokinetic Parameters by Formulation and Prandial State: Part A	Parameters with units.	SAC
PK Analyses					
3.4.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & Cmax) Assessing Formulation Effect Relative Bioavailability: Part A	Include AUC(0-t) and AUC(0-inf)	SAC
3.5.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Formulation Effect Relative Bioavailability: Part A	Tmax	SAC
3.6.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & Cmax) Assessing Food Effect Relative Bioavailability: Part A	Include AUC(0-t) and AUC(0-inf)	SAC

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.7.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Food Effect Relative Bioavailability: Part A	Tmax	SAC

10.10.7.2. Pharmacokinetic Tables Part B

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK Concentration					
3.8.	PK	PK01	Summary of Plasma GSK2982772 Concentration-Time (ug/mL) Data by Dose and Prandial State: Part B		SAC
PK Derived Parameters					
3.9.	PK	PKPT1	Summary Statistics of Derived Plasma GSK2982772 Pharmacokinetic Parameters by Dose and Prandial State: Part B	Parameters with units	SAC
3.10.	PK	PKPT3	Summary Statistics of Log-Transformed Derived Plasma GSK2982772 Pharmacokinetic Parameters by Dose and Prandial State: Part B	Parameters with units	SAC
3.11.	PK	PKPT3	Summary Statistics of Log-Transformed Derived Plasma GSK2982772 Dose-Normalized Pharmacokinetic Parameters by Dose and Prandial State : Part B	Parameters with units	SAC

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK Analyses					
3.12.	PK	PK_T2	Summary of Statistical Analysis of Plasma GSK2982772 PK Parameters (AUC & Cmax) Assessing Dose Relative Bioavailability: Part B	960 mg MR fasted vs 480 mg MR fasted 960 mg MR fasted vs 120 mg MR fasted 480 mg MR fasted vs 120 mg MR fasted	SAC
3.13.	PK	PK_T2	Summary of Statistical Analysis of Plasma GSK2982772 PK Parameters (Tmax) Assessing Dose Relative Bioavailability: Part B	960 mg MR fasted vs 480 mg MR fasted 960 mg MR fasted vs 120 mg MR fasted 480 mg MR fasted vs 120 mg MR fasted	SAC
3.14.	PK	PK_T2	Summary of Statistical Analysis of Plasma GSK2982772 PK Parameters (AUC & Cmax) Assessing Food Effect Relative Bioavailability: Part B		SAC
3.15.	PK	PK_T2	Summary of Statistical Analysis of Plasma GSK2982772 PK Parameters (Tmax) Assessing Food Effect Relative Bioavailability: Part B		SAC
3.16.	PK	PK_T2	Summary of Statistical Analysis of Plasma GSK2982772 PK Parameters (AUC & Cmax) Assessing Aperture Relative Bioavailability: Part B		SAC
3.17.	PK	PK_T2	Summary of Statistical Analysis of Plasma GSK2982772 PK Parameters (Tmax) Assessing Aperture Relative Bioavailability: Part B		SAC

10.10.8. Pharmacokinetic Figures

10.10.8.1. Pharmacokinetic Figures Part A

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Individual Concentration Plots					
3.1.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time (ug/mL) Plot by Subject: Part A	Paginate by Subject. Semi-log not required.	SAC
3.2.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time (ug/mL) Plot by Formulation and Prandial State: Part A	Paginate by Formulation. This includes the fed state. Semi-log not required.	SAC
Mean / Median Concentration Plots					
3.3.	PK	PKCF2	Mean Plasma GSK2982772 Concentration-Time (ug/mL) Plots by Formulation and Prandial State: Part A	Paginate by Formulation. This includes the fed state. Semi-log not required. Page 1:240 mg IR and MR-12h, MR-16h and MR-18h Page 2: MR-12h Fasted and Fed High Fat MR-18h Fasted and Fed High Fat	SAC

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.4.	PK	PKCF3	Median Plasma GSK2982772 Concentration-Time (ug/mL) Plots by Formulation and Prandial State: Part A	Paginate by Formulation. This includes the fed state. Semi-log not required. Page 1: 240 mg IR and MR-12h, MR-16h and MR-18h Page 2: MR-12h Fasted and Fed High Fat MR-18h Fasted and Fed High Fat	SAC
3.5.	PK	PK_F1	Plot of Individual Subject (+Geometric Mean and 95% CI) Plasma GSK2982772 PK Parameters vs Formulation and Prandial State: Part A	Page 1: 240 mg IR and MR-12h, MR-16h and MR-18h Page 2: MR-12h Fasted and Fed High Fat MR-18h Fasted and Fed High Fat	SAC
3.6.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Formulation Relative Bioavailability: Part A	Page 1: MR-12h 240mg vs IR fasted MR-16h 240mg vs IR fasted MR-18h 240mg vs IR fasted Page 2: MR-18h 240mg Fed (High-Fat) vs MR-12h 240mg Fed (High-Fat)	SAC

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.7.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Food Effect Relative Bioavailability: Part A		SAC

10.10.8.2. Pharmacokinetic Figures Part B

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Individual Concentration Plots					
3.8.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time (ug/mL) Plot by Subject: Part B	Paginate by Subject. Semi-log not required.	SAC
3.9.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time (ug/mL) Plot by Dose and Prandial State: Part B	Paginate by Dose. Semi-log not required.	SAC
Mean / Median Concentration Plots					
3.10.	PK	PKCF2	Mean Plasma GSK2982772 Concentration-Time (ug/mL) Plots by Dose, Prandial State, and Aperture: Part B	Page 1: MR-16h 120 mg fasted MR-16h 480 mg fasted MR-16h 960 mg fasted Page 2: MR-16h 480 mg Fasted MR-16h 480 mg Fed (High Fat) Page 3: MR-16h 480 Fed (High Fat) MR-16h 480 Fed (High Fat) (Enteric Coated)	SAC

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.11.	PK	PKCF3	Median Plasma GSK2982772 Concentration-Time (ug/mL) Plots by Dose, Prandial State, and Aperture: Part B	Page 1: MR-16h 120 mg fasted MR-16h 480 mg fasted MR-16h 960 mg fasted Page 2: MR-16h 480 mg Fasted MR-16h 480 mg Fed (High Fat) Page 3: MR-16h 480 Fed (High Fat) MR-16h 480 Fed (High Fat) (Enteric Coated)	SAC
3.12.	PK	PK_F1	Plot of Individual Subject (+Geometric Mean and 95% CI) Plasma GSK2982772 Dose-Normalized PK Parameters vs Dose: Part B	MR-16h 120 mg fasted MR-16h 480 mg fasted MR-16h 960 mg fasted	SAC
3.13.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Dose Relative Bioavailability: Part B	960 mg MR fasted vs 480 mg MR fasted 960 mg MR fasted vs 120 mg MR fasted 480 mg MR fasted vs 120 mg MR fasted	SAC
3.14.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Food Effect Relative Bioavailability : Part B	MR-16h 480 mg Fed (High Fat) vs MR-16h 480 mg Fasted	SAC

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.15.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Aperture Relative Bioavailability: Part B	MR-16h 480 Fed (High Fat) (Enteric Coated) vs MR-16h 480 Fed (High Fat)	SAC
3.16.	PK	PKCF2	Mean Plasma GSK2982772 Concentration-Time (ug/mL) Plots by Dose in Fasted State (Semi-log): Part B	Page 1: MR-16h 120 mg fasted MR-16h 480 mg fasted MR-16h 960 mg fasted	SAC
3.17.	PK	PKCF3	Median Plasma GSK2982772 Concentration-Time (ug/mL) Plots by Dose in Fasted State (Semi-log): Part B	Page 1: MR-16h 120 mg fasted MR-16h 480 mg fasted MR-16h 960 mg fasted	SAC

10.10.9. ICH Listings

10.10.9.1. ICH Listings Part A

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	All Subjects	ES7	Listing of Reasons for Screen Failure: Part A	Journal Guidelines	SAC
2.	Safety	ES3	Listing of Reasons for Study Withdrawal: Part A	ICH E3	SAC
3.	Safety	TA2	Listing of Planned and Actual Treatments: Part A	IDSL	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Protocol Deviations					
4.	Safety	DV2A	Listing of Important Protocol Deviations: Part A	ICH E3	SAC
5.	All Subjects	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations: Part A	ICH E3	SAC
Populations Analysed					
6.	Safety	SP3	Listing of Subjects Excluded from Any Population: Part A	ICH E3	SAC
Demographic and Baseline Characteristics					
7.	Safety	DM4	Listing of Demographic Characteristics: Part A	ICH E3	SAC
8.	Safety	DM10	Listing of Race: Part A	ICH E3	SAC
Prior and Concomitant Medications					
9.	Safety	CP_CM3	Listing of Concomitant Medications: Part A	IDSL	SAC
Exposure and Treatment Compliance					
10.	Safety	EX4	Listing of Exposure Data: Part A	ICH E3	SAC
Adverse Events					
11.	Safety	AE9CP	Listing of All Adverse Events: Part A	ICH E3	SAC
12.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events: Part A	ICH E3	SAC
13.	Safety	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text: Part A	IDSL	SAC
Serious and Other Significant Adverse Events					
14.	Safety	AE9CP	Listing of Serious Adverse Events: Part A	ICH E3	SAC
15.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event: Part A	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
16.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment: Part A	ICH E3	SAC
Hepatobiliary (Liver)					
17.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events: Part A	IDSL	SAC
18.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events: Part A	IDSL	SAC
All Laboratory					
19.	Safety	LB6	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance/Outside Normal Range: Part A	ICH E3	SAC
20.	Safety	LB6	Listing of Laboratory Values of Potential Clinical Importance: Part A		SAC
21.	Safety	LB6	Listing of all Lipid Data for Subjects with Any Value Outside of Laboratory Normal Range: Part A		SAC
22.	Safety	LB14	Listing of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part A		SAC
ECG					
23.	Safety	EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance: Part A	IDSL. No need to display Heart Rate.	SAC
24.	Safety	EG4	Listing of ECG Values of Potential Clinical Importance: Part A	IDSL. No need to display Heart Rate.	SAC
25.	Safety	EG6	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding: Part A	IDSL. No need to display Heart Rate.	SAC
26.	Safety	EG6	Listing of Abnormal ECG Findings: Part A	IDSL. No need to display Heart Rate.	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Vital Signs					
27.	Safety	VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance: Part A	IDSL	SAC
28.	Safety	VS5	Listing of Vital Signs of Potential Clinical Importance: Part A	IDSL	SAC

10.10.9.2. ICH Listing Part B

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
29.	All Subjects	ES7	Listing of Reasons for Screen Failure: Part B	Journal Guidelines	SAC
30.	Safety	ES3	Listing of Reasons for Study Withdrawal: Part B	ICH E3	SAC
31.	Safety	TA2	Listing of Planned and Actual Treatments: Part B	IDSL	SAC
Protocol Deviations					
32.	Safety	DV2A	Listing of Important Protocol Deviations: Part B	ICH E3	SAC
33.	All Subjects	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations: Part B	ICH E3	SAC
Populations Analysed					
34.	Safety	SP3	Listing of Subjects Excluded from Any Population: Part B	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Demographic and Baseline Characteristics					
35.	Safety	DM4	Listing of Demographic Characteristics: Part B	ICH E3	SAC
36.	Safety	DM10	Listing of Race: Part B	ICH E3	SAC
Prior and Concomitant Medications					
37.	Safety	CP_CM3	Listing of Concomitant Medications: Part B	IDSL	SAC
Exposure and Treatment Compliance					
38.	Safety	EX4	Listing of Exposure Data: Part B	ICH E3	SAC
Adverse Events					
39.	Safety	AE9CP	Listing of All Adverse Events: Part B	ICH E3	SAC
40.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events: Part B	ICH E3	SAC
41.	Safety	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text: Part B	IDSL	SAC
Serious and Other Significant Adverse Events					
42.	Safety	AE9CP	Listing of Serious Adverse Events: Part B	ICH E3	SAC
43.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event: Part B	ICH E3	SAC
44.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment: Part B	ICH E3	SAC
Hepatobiliary (Liver)					
45.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events: Part B	IDSL	SAC
46.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events: Part B	IDSL	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
All Laboratory					
47.	Safety	LB6	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance/Outside Normal Range: Part B	ICH E3	SAC
48.	Safety	LB6	Listing of Laboratory Values of Potential Clinical Importance: Part B		SAC
49.	Safety	LB6	Listing of All Lipid Data for Subjects with Any Value Outside of Laboratory Normal Range: Part B		SAC
50.	Safety	LB14	Listing of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part B	ICH E3	SAC
ECG					
51.	Safety	EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance: Part B	IDSL	SAC
52.	Safety	EG4	Listing of ECG Values of Potential Clinical Importance: Part B	IDSL	SAC
53.	Safety	EG6	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding: Part B	IDSL	SAC
54.	Safety	EG6	Listing of Abnormal ECG Findings: Part B	IDSL	SAC
Vital Signs					
55.	Safety	VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance: Part B	IDSL	SAC
56.	Safety	VS5	Listing of Vital Signs of Potential Clinical Importance: Part B	IDSL	SAC

10.10.10. Non-ICH Listings

10.10.10.1. Non-ICH Listings Part A

Non-ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetic					
57.	PK	PKCL1X	Listing of Plasma GSK2982772 Pharmacokinetic Concentration-Time (ug/mL) Data: Part A		SAC
58.	PK	PKPL1X	Listing of Derived Plasma GSK2982772 Pharmacokinetic Parameters: Part A		SAC
Meal Times					
59.	Safety	CP_ML1x	Listing of Dosing Times, Meal Start and End Times on Fed Treatment Days: Part A		SAC

10.10.10.2. Non-ICH Listings Part B

Non-ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetic					
60.	PK	PKCL1X	Listing of Plasma GSK2982772 Pharmacokinetic Concentration-Time (ug/mL) Data: Part B		SAC
61.	PK	PKPL1X	Listing of Derived Plasma GSK2982772 Pharmacokinetic Parameters: Part B		SAC
Meal Times					
62.	Safety	CP_ML1x	Listing of Dosing Times, Meal Start and End Times on Fed Treatment Days: Part B		SAC

10.11. Appendix 11: Example Mock Shells for Data Displays

Data Display Specification will be made available on Request.