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

Title	:	Reporting and Analysis Plan for A three part, non-randomised, open label study designed to assess the pharmacokinetics of GSK2982772 following administration of minitab modified release formulations in capsule relative to an immediate release reference tablet formulation (Part A), the pharmacokinetics of escalating, repeat doses of a selected minitab modified release prototype (Part B) in healthy subjects, and the pharmacokinetics of GSK2982772 following administration of modified release tablet formulations in the fed and fasted state (Part C) in healthy participants.
Compound Number	:	GSK2982772
Effective Date	:	24-JAN-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 205017.
- 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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TABLE OF CONTENTS

PAGE

1. INTRODUCTION

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

Revision Chronology:		
2017N315344_00	07-Jul-2017	Original
2017N315344_01	18-Sep-2017	Amendment 01
2017N315344_02	14-Jun-2018	Amendment 02

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: 07-Jul-2017).

Protocol amendment 1: There were no changes or deviations to the originally planned statistical analysis specified in the protocol (Dated: 18-Sep-2017).

Protocol amendment 2: Additional analyses were added for the inclusion of Part C that mirror what was specified for Part A (14-Jun-2018).

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

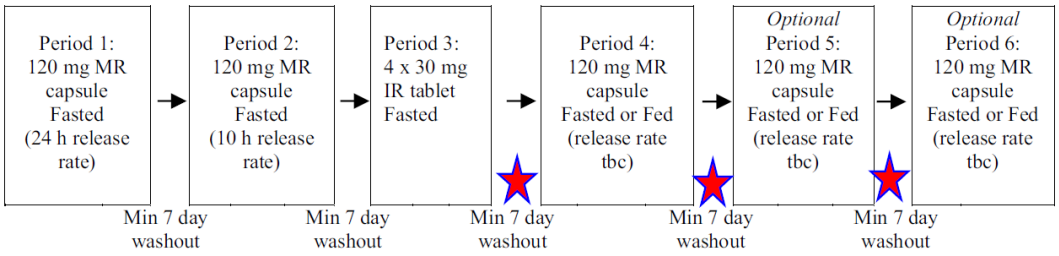
Objectives	**Endpoints**
Primary Objectives	**Primary Endpoints**
• To evaluate the single dose PK profile of GSK2982772 from each test minitab Modified Release (MR) formulation in a capsule (120 mg) compared to the IR formulation (120 mg)	• GSK2982772 area under the curve from time zero to infinity (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), area under the curve from time zero to 12 hours AUC(0-12), maximum observed concentration (Cmax), Concentration at 12 hours post-dose (C12h), Concentration at 24 hours post-dose (C24h) and ratio of Cmax : C12h and Cmax : C24h, relative bioavailability (Frelformulation) based on AUC and Cmax
• To evaluate the single dose PK profile of GSK2982772 from a (matrix monolithic) MR tablet (240mg) compared to the IR formulation (240mg).	• GSK2982772 AUC(0-inf), AUC(0-t), AUC(0-24), AUC(0-12), Cmax, C12h, C24h, Cmax:C12h and Cmax:C24h, $Frel_{formulation}$ based on AUC and Cmax.
Secondary Objectives	**Secondary Endpoints**
• To assess the impact of high fat meal on the PK of GSK2982772 following single dose	• GSK2982772 AUC(0-inf), AUC(0-t), Cmax, time to Cmax (Tmax), $Frel_{FE}$ based on AUC and Cmax,

Objectives	Endpoints
administration of the selected minitab MR formulation in a capsule (120 mg)	
• To determine if there are any dose dependant changes in the absorption of GSK2982772 following repeat dose administration of the selected minitab MR formulation in a capsule at target daily doses of 30, 60 and 240 mg	• GSK2982772 AUC(0-24), Cmax, and Tmax if once daily (QD) dosing, on Day 1 and Day 3 • GSK2982772 AUC(0-12), AUC(12-24), Cmax, and Tmax after morning dose, Cmax and Tmax after evening dose if twice daily (BID) dosing, on Day 1 and Day 3
• To assess the impact of food on the PK of GSK2982772 following single dose administration of the (matrix monolithic) MR tablet (dose corrected, as appropriate).	• GSK2982772 AUC(0-inf), AUC(0-t) or AUC(0-24), Cmax, and time to Cmax (Tmax), $Frel_{FE}$ based on AUC and Cmax (dose corrected as appropriate).
• To determine if there are any dose dependent changes in the absorption of GSK2982772 following single dose administration or BID dose administration of the (matrix monolithic) MR tablet.	• GSK2982772 AUC(0-inf), AUC(0-t), AUC(0-24), Cmax, C24, Cmax:C24, and Tmax • GSK2982772 AUC(0-12), C12, and Cmax:C12 if BID dosing
• To assess the safety and tolerability of single doses of GSK2982772 IR formulation and single and repeat doses of the (matrix monolithic) MR and minitab MR formulations in a capsule	• 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
Exploratory	
• To assess the impact of a standard meal on the PK of GSK2982772 following administration of the selected minitab MR formulation in a capsule.	• GSK2982772 AUC(0-inf), AUC(0-t), Cmax, Tmax, and $Frel_{FE}$ based on AUC and Cmax (dose corrected as appropriate).

2.3. Study Design

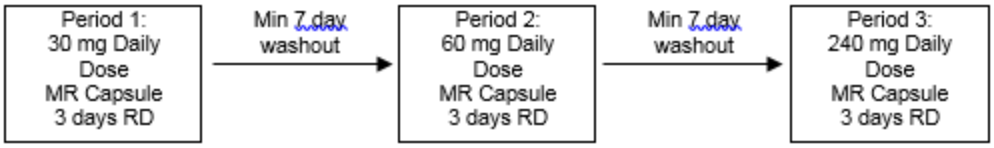
Overview of Study Design and Key Features

Part A:

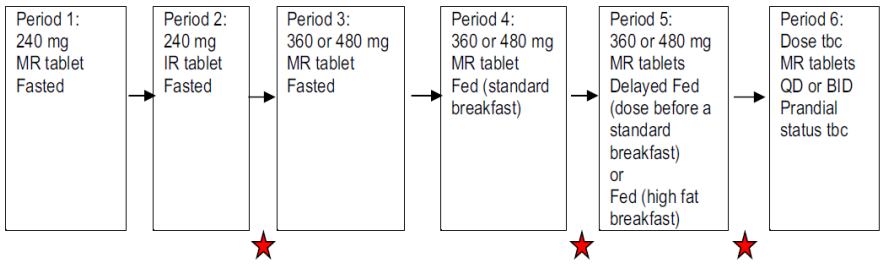


Interim decisions based on PK and safety data. Periods 4, 5 and 6 are flexible and the dosing regimen will be dependent on the outcome of the preceding periods.

Part B:



Part C:



Interim decisions based on PK and safety data. Periods 3 to 6 are flexible and the dosing regimen will be dependent on the outcome of the preceding periods.

Design Features	• An open label, single centre, three part, single and repeat dose study in healthy male and female participants to assess (matrix monolithic) MR and minitab MR formulations of GSK2982772 in a capsule and impact of food on absorption. • Part A – 6 period, sequential, 6-way fixed sequence design, with up to 4 MR minitab formulations evaluated after single dose of GSK2982772 120mg in the fasted state. • Part B – open-label, repeat dose to evaluate selected minitab MR formulation

Overview of Study Design and Key Features	
	(from Part A) following a 3 day repeat dosing of GSK2982772 at target daily doses of 30, 60 and 240mg (120mg, 240mg, 300mg actual daily doses). • Part C – 6 period, sequential, 6-way fixed sequence design, with MR (matrix monolithic) formulations evaluated after single dose of GSK2982772 240mg in the fasted state.
Dosing	Part A: • Single dose of GSK2982772 120mg will be evaluated. Periods 1, 2 and 3 will evaluate a slow minitab MR release duration, a fast minitab MR release formulation and IR tablet respectively. Periods 4, 5 and 6 will be flexible and depend on outcomes from Periods 1 to 3 and may be used to optimise the MR release durations and/or to evaluate the food effect. Part B: • Target total daily doses of GSK2982772 30, 60 and 120mg QD or BID (depending on Part A findings) will be evaluated for 3 days. This corresponds to actual daily doses of 120, 240, and 300mg, respectively. Administration of the minitab MR formulation will either be in fasted state or with a standard meal (depending on Part A findings) Part C: • Single dose of GSK2982772 240mg will be evaluated. Periods 1 and 2 will evaluate a (matrix monolithic) MR formulation and an IR tablet, respectively. Periods 3 through 6 will be flexible and the dosing regimen will be dependent on the outcome of Periods 1 and 2, and may evaluate higher doses, the impact of a high-fat meal, and/or standard meal after dosing or BID dosing.
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• This is an open-label, non-randomised study. A treatment allocation list will take the place of the randomisation schedule, which will be developed by the sponsor using RandAll NG.
Interim Analysis	• No formal interim analysis is planned for the study. • Analysed PK data will be reviewed after completion of Periods 1 to 3 of part A which will guide Periods 4, 5 and 6. • In Part C, there will be an interim review following completion of Periods 1 and 2 to determine the dose for Periods 3 and 4 (360 mg or 480 mg). Similarly, there will be an interim review following Periods 4 and 5 to determine dose, prandial state and and dosing regimen (QD or BID). • Data will be reviewed following completion of Part A to determine the formulation, doses, dosing frequency (QD or BID) and prandial state for Part B.

2.4. Statistical Hypotheses / Statistical Analyses

No formal hypothesis will be tested. However, point estimates and corresponding 90% confidence intervals will be derived for the ratio between each minitab MR formulation relative to the IR formulation for the geometric mean of Cmax, Cmin, C12, C24, peak-to-trough ratio, AUC(0-inf), AUC(0-12), and AUC(0-24). PK parameters at the 12 hour time point will only be included if BID dosing is used.

3. PLANNED ANALYSES

3.1. Interim Analyses

No formal statistical analyses are planned.

Part A

After Periods 1 to 3 are complete, the PK and safety 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 of preceding periods. There will be the option to either optimise the MR release duration and/or to evaluate the impact of food on the selected MR minitab formulation in a capsule. There will also be the option to cancel Periods 5 and 6 if an optimal formulation is determined in Periods 1 or 2.

There will be an interim data review following final period of Part A to determine the formulation, doses, dosing frequency (QD or BID) and prandial state for Part B. The data, consisting of summary report of PK and safety endpoints will be sent to the sponsor by Quotient, from which the decision on formulation and prandial state selection or stopping the study will be made by the Quotient study team (i.e., PI, scientific lead and pharmacokineticist) and sponsor study team (as a minimum the sponsor's medical monitor, CPMS and GCSP). The decision will be documented and signed by the PI as per Quotient Clinical current SOP. Evidence of the decision will be retained in the ISF and GSK Trial Master File.

Part B

There will be no interim analysis during Part B of the study.

Part C

In Part C, there will be an interim review following completion of Periods 1 and 2 to determine the dose for Periods 3 and 4 (360 mg or 480 mg). Similarly, there will be an interim review following Periods 4 and 5 to determine dose, prandial state and dosing regimen (QD or BID). The data, consisting of summary report of PK and safety endpoints will be sent to the sponsor by Quotient, from which the decision on formulation and prandial state selection or stopping the study will be made by the Quotient study team (i.e., PI, scientific lead and pharmacokineticist) and sponsor study team (as a minimum the sponsor's medical monitor, CPMS and GCSP). The decision will be documented and signed by the PI as per Quotient Clinical current SOP. Evidence of the decision will be retained in the ISF and GSK Trial Master File.

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 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.	• Safety and Study 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 11: 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) 25-Sep-2018 Version 001. 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 120mg minitab MR RR1 oral single dose	MT-12h 120mg Fasted	2
B	GSK2982772 120mg minitab MR RR2 oral single dose	MT-8h 120mg Fasted	3
C	GSK2982772 120mg IR oral single dose	IR 120mg Fasted	1
D	GSK2982772 120mg minitab MR RR3 oral single dose	MT-12h 120mg Fed (Standard)	4
E	GSK2982772 120mg minitab MR RR4 oral single dose	n/a	5
F	GSK2982772 120mg minitab MR fed state	n/a	6
Part B			
G	GSK2982772 minitab MR Repeat Dose 1	MT-12h 120mg Fasted	1
H	GSK2982772 minitab MR Repeat Dose 2	MT-12h 240mg Fasted	2
J	GSK2982772 minitab MR Repeat Dose 3	MT-12h 300mg Fed (Standard)	3
Part C			
K	GSK2982772 240mg (matrix monolithic) MR oral single dose	MM-12h 240mg Fasted	2
L	GSK2982772 240mg IR oral single dose	IR 240mg Fasted	1
M	GSK2982772 360mg or 480mg (matrix monolithic) MR oral single dose	MM-12h 480mg Fasted	3
N*	GSK2982772 240mg (matrix monolithic) MR fed state	MM-12h 480mg Fed (Standard)	4
P	GSK2982772 360mg or 480mg (matrix monolithic) MR delayed fed (standard meal) or fed (high-fat meal)	MM-12h 480mg Delayed Fed (Standard)	5
Q	GSK2982772 dose tbd (matrix monolithic) MR QD or BID prandial state tbd.	MM-12h 240 mg Delayed Fed (High-Fat)	6

* The randomization description for Period 4 of Part C (code N) indicates 240 mg, but the label has been updated to 480 mg to reflect the actual treatment administered.

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.

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. 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
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 and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 11: 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 (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 11: 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 in Appendix 11: List of Data Displays.

In additional to GSK Core Data Standards, Lipids (Total Cholesterol and Triglycerides) outside the normal range will be summarised. 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) and Possible Suicidality Related Adverse Event (PSRAE) will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 11: List of Data Displays.

8. PHARMACOKINETIC ANALYSES

8.1. Primary Pharmacokinetic Analyses – Part A (Periods 1 – 3) and Part C (Periods 1 & 2)

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 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
Parts A and C Relative Bioavailability of MR vs IR	
$AUC_{(0\text{-}inf)}$	Area under the curve from time zero to infinity
$AUC_{(0\text{-}t)}$[1]	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
$AUC_{(0\text{-}12)}$[2]	Area under the curve from time zero to 12 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_{max}	Time of maximum observed concentration
C_{max}	Maximum observed concentration
C_{24h}	Concentration at 24 hours post-dose
C_{12h}[2]	Concentration at 12 hours post-dose
C_{max}:C_{12h}[2]	Ratio of maximum and 12 hour concentrations
C_{max}:C_{24h}	Ratio of maximum and 24 hour concentrations

NOTES:

- Additional parameters may be included as required.
- No log transformation for Tmax nor any ratio (relative) endpoint.
- [1]: $AUC_{(0\text{-}t)}$ if $AUC_{(0\text{-}inf)}$ cannot be derived
- [2]: If BID

8.1.2. Summary Measure

For each release rate in Periods 1 through 3 of Part A, and Periods 1 and 2 of Part C, 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 $\%CV_b$ will be provided, where $\%CV_b = (100 * \sqrt{(\exp(SD2) - 1)})$ and 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

- Participant 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 participant 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 and the minimum washout period will be respected with regard to the timing of dosing of the IR formulation.
- 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.

8.1.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 11: 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).

Endpoint (log scale)
• $AUC_{(0\text{-}inf)}$
• $AUC_{(0\text{-}t)}$ if $AUC_{(0\text{-}inf)}$ cannot be derived
• $AUC_{(0\text{-}12)}$ if BID
• $AUC_{(0\text{-}24h)}$

• C_{max} • C_{12h} if BID • C_{24h}
Model Specification
• For each endpoint a mixed model will be fit with 3 observations per participant expected in Part A, and 2 observations per participant in Part C. The model will contain formulation 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. • If outliers are detected, an additional table will be produced with outlying observations omitted.
Model Results Presentation
• Point estimates and corresponding 90% CI will be computed for the differences in the endpoint for each GSK2982772 MR formulation vs GSK2982772 IR formulation. • The relative bioavailability ratio, $Frel_{formulation}$,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

8.2. Secondary Pharmacokinetic Analyses - Part A (Periods 4-6), Part B, and Part C (Periods 3-6)

8.2.1. Endpoint / Variables

8.2.1.1. Drug Concentration Measures

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

8.2.1.2. 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
Part A - Food Effect	
$AUC_{(0\text{-}inf)}$	Area under the curve from time zero to infinity
$AUC_{(0\text{-}t)}$[1]	Area under the curve from time zero to last quantifiable concentration
$AUC_{(0\text{-}12)}$[2]	Area under the curve from time zero to 12 hours
$AUC_{(0\text{-}24)}$[3]	Area under the curve from time zero to 24 hours
C_{max}	Maximum observed concentration
C_{12h}[2]	Concentration at 12 hours post-dose
C_{24h}	Concentration at 24 hours post-dose
C_{max}:C_{12h}[2]	Ratio of maximum and 12 hour concentrations
C_{max}:C_{24h}	Ratio of maximum and 24 hour concentrations
T_{max}	Time of maximum observed concentration
Part B – Repeat Dose	
$AUC_{(0\text{-}12)}$[2]	Area under the curve from time zero to 12 hours
$AUC_{(12\text{-}24)}$[2]	Area under the curve from time 12hours to 24 hours
$AUC_{(0\text{-}24)}$[3]	Area under the curve from time zero to 24 hours
C_{max}	Maximum observed concentration
C_{12h}[2]	Concentration at 12 hours post-dose
C_{24h}	Concentration at 24 hours post-dose
C_{max}:C_{12h}[2]	Ratio of maximum and 12 hour concentrations
C_{max}:C_{24h}	Ratio of maximum and 24 hour concentrations
T_{max}	Time of maximum observed concentration
Part C – High Dose Food Effect	
$AUC_{(0\text{-}inf)}$	Area under the curve from time zero to infinity
$AUC_{(0\text{-}t)}$[1]	Area under the curve from time zero to the last quantifiable concentration
$AUC_{(0\text{-}24)}$[3]	Area under the curve from time zero to 24 hours
$AUC_{(0\text{-}12)}$[1]	Area under the curve from time zero to 12 hours
T_{max}	Time of maximum observed concentration
C_{max}	Maximum observed concentration
C_{min}	Minimum observed concentration
C_{24h}	Concentration at 24 hours post-dose
C_{12h}[2]	Concentration at 12 hours post-dose

Parameter	Parameter Description
C_{max}:C_{12h}[2]	Ratio of maximum and 12 hour concentrations
C_{max}:C_{24h}	Ratio of maximum and 24 hour concentrations

NOTES:

- Additional parameters may be included as required.
- No log transformation for Tmax nor any ratio (relative) endpoint.
- [1]: $AUC_{(0-t)}$ if $AUC_{(0-inf)}$ cannot be derived
- [2]: If BID formulation.
- [3]: QD formulation only.

8.2.2. Summary Measure

For each fed/fasted state in Parts A and C, and for day 1 and day 3 of every dose (period) in Part B, 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 $\%CV_b$ will be provided, where $\%CV_b = (100 * \sqrt{(\exp(SD2) - 1)})$ and SD is the standard deviation of log-transformed data.

For Part B, log-scale dose normalized C_{max}, $C_{12h\ (for\ BID)}$, C_{24h}, $AUC_{(0-12)}$ (for BID dosing) AUC(12-24) (for BID dosing), and $AUC_{(0-24)}$ will also be summarized. Plots of dose vs log-scale dose normalised $AUC_{(0-24)}$, ($AUC_{(0-12)}$ and $AUC_{(12-24)}$ for BID dosing), $C_{12h\ (for\ BID)}$, C_{24h}, and C_{max} (after morning and evening doses if BID dosing) will be generated to determine if there are any dose dependent changes in the absorption of GSK2982772 following repeat dose administration of the selected minitab MR formulation.

8.2.3. Population of Interest

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

8.2.4. Strategy for Intercurrent (Post-Randomization) Events

- See Section 8.1.4.

8.2.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 11: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 8.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

8.2.5.1. Statistical Methodology Specification (Part A)

Endpoint (log scale)
• $AUC_{(0\text{-}inf)}$ • $AUC_{(0\text{-}t)}$ if $AUC_{(0\text{-}inf)}$ cannot be derived • C_{max}
Model Specification
• For each endpoint a mixed model will be fit with 2 observations per subject expected. The model will contain state [[fed/fasted] as a fixed, categorical effect and a random intercept for subject. • The Kenward & Roger (KR) degreed of freedom approach will be used.
Model Checking & Diagnostics
• See Section 8.1.5.1
Model Results Presentation
• Point estimates and corresponding 90% CI will be computed for the differences in the endpoint for GSK2982772 MR formulation (120 mg) taken in the fed state (test) vs in the fasted state (reference) using the residual error from the model (MSE). • The point and interval estimates on the log-scale will then be exponentially back transformed to give estimates of the ratios of geometric means, $Frel_{FE}$,and 90% CI. See Section 10.6.4

Endpoint
• Tmax
Model Specification
• Exact non-parametric Hodges-Lehmann estimation of location shift will be fitted. • Only the dose of GSK2982772 administered under both fed and fasted conditions will be used.
Model Results Presentation
• GSK2982772 MR formulation in fed (test) will be compared to fasted (reference) state. • Median difference and 90% CI for median difference will be presented.

8.2.5.2. Statistical Methodology Specification (Part B)

Endpoint (log scale)
• $AUC_{(0\text{-}24h)}$ (QD) • $AUC_{(0\text{-}12h)}$ (if BID) • $AUC_{(12\text{-}24h)}$ (if BID) • Cmax (morning) (QD or BID) • Cmax (evening) (if BID)

Model Specification
• For each endpoint a mixed model will be fit with 6 observations per subject expected. The model will contain dose (120, 240, 300) and day (1,3) as fixed, categorical effects, and their interaction. • A direct product (UN@CS) covariance pattern will be fit using period and day (in that order) as the effects in the REPEATED statement. • The Kenward & Roger (KR) degrees of freedom approach will be used.
Model Checking & Diagnostics
• See Section 8.1.5.1. Additionally, in the event the model fails to converge a compound symmetric covariance pattern will be fit using day*dose as the effect on the REPEATED statement, with type=CS, group=period, and subject id specified in the subject= option to account for the correlation between days within period. A random intercept effect will also be included to account for the correlation between days across period. • In the event the above model fails to converge, a compound symmetric covariance pattern will be fit using day*dose as the effect on the REPEATED statement, with type=CS and subject id specified in the subject= option. A random period effect will also be included. • In the event the above model fails to converge, a compound symmetric covariance pattern will be fit using day*dose as the effect on the REPEATED statement, with type=CS and subject id specified in the subject= option. • In the event the above model fails to converge, all other covariance patterns will be explored, including unstructured. • If outliers are detected, an additional table will be produced with outlying observations omitted.
Model Results Presentation
• Point estimates and corresponding 90% CI will be computed for the differences in the endpoint between Day 1 and Day 3 for Period 1 (120mg daily), Period 2 (240mg daily), and Period 3 (300mg daily) for GSK2982772 minitab MR dose. • The point and interval estimates on the log-scale will then be exponentially back transformed to give estimates of the ratios of geometric means, $Frel_{Day}$, and 90% CI. See Section 10.6.4

8.2.5.3. Statistical Methodology Specification (Part C)

Bioavailability of Food Effect

Endpoint (log scale)
• AUC(0-inf) • AUC(0-t) if AUC(0-inf) not available • Cmax •
Model Specification
• For each endpoint a mixed model will be fit with 5 observations per subject expected. The model will contain dose (240mg, 480mg) and prandial state [fed (standard)/delayed fed

(standard)/delayed fed (high-fat)/fasted] as a fixed, categorical effect and a random intercept for subject. • A direct product (UN@CS) covariance pattern will be fit using dose and state (in that order) as the effects in the REPEATED statement. • The Kenward & Roger (KR) degrees of freedom approach will be used.
Model Checking & Diagnostics
• See Section 8.1.5.1.
Model Results Presentation
• Point estimates and corresponding 90% CI will be computed for the differences in the endpoint for GSK2982772 MR formulation (240 mg or 480 mg) taken in the fed state (test) vs in the fasted state (reference) using the residual error from the model (MSE). • The point and interval estimates on the log-scale will then be exponentially back transformed to give estimates of the ratios of geometric means, $Frel_{FE}$,and 90% CI. See Section 10.6.4

Endpoint
• Tmax
Model Specification
• Exact non-parametric Hodges-Lehmann estimation of location shift will be fitted. • Only the dose of GSK2982772 administered under both fed and fasted conditions will be used.
Model Results Presentation
• GSK2982772 MR formulation in fed (test) state will be compared to fasted (reference) state. • Median difference and 90% CI for median difference will be presented.

Bioavailability of Dose

Endpoint (log scale)
• AUC(0-inf) • AUC(0-t) if AUC(0-inf) not available • AUC(0-24) • Cmax • C24
Model Specification
• For each endpoint a mixed model will be fit with 2 observations per subject expected. The model will contain dose (480 mg and 240 mg in the fasted state) 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
• See Section 8.1.5.1.
Model Results Presentation
• Point estimates and corresponding 90% CI will be computed for the differences in the endpoint for GSK2982772 MR dose (480 mg vs 240 mg) using the residual error from the model (MSE). • The point and interval estimates on the log-scale will then be exponentially back transformed to give estimates of the ratios of geometric means, $Frel_{DOSE}$,and 90% CI. See Section 10.6.4

Endpoint
• Tmax
Model Specification
• Exact non-parametric Hodges-Lehmann estimation of location shift will be fitted. • Only GSK2982772 administered at 240 mg and 480 mg.
Model Results Presentation
• GSK2982772 MR formulation at 480 mg (test) state will be compared to 240 mg (reference). • Median difference and 90% CI for median difference will be presented.

9. REFERENCES

GlaxoSmithKline Document Number 2017N315344_02. A three part, non-randomised, open label study designed to assess the pharmacokinetics of GSK2982772 following administration of minitab modified release formulations in a capsule relative to an immediate release reference tablet formulation (Part A), the pharmacokinetics of escalating, repeat doses of a selected minitab modified release prototype (Part B), and the pharmacokinetics of GSK2982772 following administration of modified release tablet formulations in the fed and fasted state (Part C) in healthy participants. Effective Date: 14-JUN-2018

Hauschke D1, Steinijans VW, Diletti E. A distribution-free procedure for the statistical analysis of bioequivalence studies. *Int J Clin Pharmacol Ther Toxicol*, 1990;28(2):72-8.

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

Schedule of Activities for Parts A and C

Procedure	Screening (up to 28 days before Day 1)	Treatment Period 1, 2, 3, 4, 5, 6 Day			Follow-up/Study Discontinuation (7 days post last dose)	Notes[a]
		–1	1	2		
Informed consent	X					
Inclusion and exclusion criteria[1]	X					1. Recheck clinical status before 1st dose of study medication.
Demography	X					
Demonstrate ability to swallow size 0-00 capsules	X					
Full physical examination including height and weight	X					
Brief physical examination		X		X[2]	X	2. Discharge (32 h post-dose for Treatment Period 1, 2, 4, 5 and 6 in Part A and Treatment Period 1, 3, 4, 5 and 6 in Part C 24 h post-dose for Treatment Period 3 in Part A and Treatment Period 2 Part C)
Medical history (includes substance usage)[3]	X					3. Substances: Drugs, Alcohol, tobacco and caffeine
Past and current medical conditions	X					

Procedure	Screening (up to 28 days before Day 1)	Treatment Period 1, 2, 3, 4, 5, 6 Day			Follow-up/Study Discontinuation (7 days post last dose)	Notes[a]
		–1	1	2		
Follicle Stimulating Hormone (FSH) (as needed in women of non-childbearing potential only)	X					
Serum pregnancy test (WOCBP only)	X				X	
Urine pregnancy test (WOCBP only)		X				
Human Immunodefeciency Virus (HIV), Hepatitis B and C screening[4]	X					4. 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	X[5]	X[5]	X	5. Pre-dose (Treatment Period 1 only) and 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/Study Discontinuation (7 days post last dose)	Notes[a]
		–1	1	2		
12-lead ECG	X[6]	X	X[7]	X[8]	X	6. In triplicate 7. Pre-dose and 2 and 12 h post-dose 8. 24 h post-dose Allowable windows in Section 9.4.3
Vital signs	X	X	X[9]	X[10]	X	9. Pre-dose and 2 and 12 h post-dose 10. 24 h post-dose Allowable windows in Section 9.4.2
Study treatment			X			
AE review		←==========		==========→	X	
Serious AE (SAE) review	X	←==========		==========→	X	
Concomitant medication review		←==========		==========→	X	
PK blood sample collection			X[11]	X[11]		11. Time points in Table 2

[a] The timing of assessments may be amended in Part C if BID dosing is selected for any of the regimens.

Pharmacokinetic Blood Sample Collection Times for Parts A and C

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

[a] PK sampling schedule may be amended in Part C if BID dosing is selected for any of the regimens. If BID dosing is employed the number of PK samples may be reduced i.e. some of the samples between 14 and 24 h may not be required. In addition, the 12 h sample will be taken prior to administering the second daily dose.

Schedule of Activities for Part B

Procedure	**Screening (up to 28 days before Day 1)**	**Treatment Period 1, 2, 3 Day**					**Follow-up/Study Discontinuation (7 days post last dose)**	**Notes**
		–1	**1**	**2**	**3**	**4**		
Informed consent	X							
Inclusion and exclusion criteria[1]	X							1. Recheck clinical status before 1st dose of study medication.
Demography	X							
Demonstrate ability to swallow size 0-00 capsules	X							
Full physical examination including height and weight	X							
Brief physical examination		X				X[2]	X	2. Discharge (24 h after the last dose)
Medical history (includes substance usage)[3]	X							3. Substances: Drugs, Alcohol, tobacco and caffeine
Past and current medical conditions	X							
FSH (as needed in women of non-childbearing potential only)	X							
Serum pregnancy test (WOCBP only)	X						X	
Urine pregnancy test (WOCBP only)		X						

Procedure	Screening (up to 28 days before Day 1)	Treatment Period 1, 2, 3 Day					Follow-up/Study Discontinuation (7 days post last dose)	Notes
		–1	1	2	3	4		
HIV, Hepatitis B and C screening[4]	X							4. If test otherwise performed within 3 months prior to first dose of study treatment, testing at screening is not required
Tuberculosis 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	X[5]			X[6]	X	5. Pre-dose 6. 24 h after the last dose Allowable windows in Section 9.4.4
Glomerular filtration rate	X							
CRP	X							
ANA	X					X[7]		7. 24 h after the last dose
12-lead ECG	X[8]	X	X[9]	X[10]	X[9]	X[11]	X	8. In triplicate 9. Pre-dose and 2 and 12 h post-dose 10. Pre-dose 11. 24 h after the last dose Allowable windows in Section 9.4.3 Time points may be subject to change depending on results from Part A
Vital signs	X	X	X[12]	X[13]	X[12]	X[14]	X	12. Pre-dose and 2 and 12 h post-dose 13. Pre-dose 14. 24 h after the last dose Allowable windows in Section 9.4.2 Time points may be subject to change depending on results from Part A
Columbia Suicide Risk questionnaire	X		X[15]			X[16]		15. Pre-dose 16. 24 h after last dose of each period
Study treatment			X	X	X			
AE review		←==========				==========→	X	
SAE review	X	←==========				==========→	X	
Concomitant medication review		←==========				==========→	X	
PK blood sample collection			X[17]	X[17]	X[17]	X[17]		17. Time points in Table 4

Pharmacokinetic Blood Sample Collection Times for Part B

	Periods 1, 2 and 3													
	Days 1 and 3													
Time (h)	Pre-dose	0	2	4	6	8	10	12	14	16	18	20	22	24
Dosing[a]		X												
PK sampling[b]	X		X	X	X	X	X	X	X	X	X	X	X	X[c]

[a] Subjects will be dosed on Days 1, 2 and 3; however, no PK samples will be taken post-dose on Day 2

[b] PK sampling schedule may be amended based upon the PK data from Part A and/or if BID dosing is selected for Part B. If BID dosing is employed the number of PK samples may be reduced i.e. some of the samples between 14 and 24 h may not be required. In addition, the 12 h sample will be taken prior to administering the second daily dose.

[c] Day 1 24 h post-dose sample should be taken prior to dosing on Day 2.

PK samples should take priority over other procedures scheduled at the same time point. As guidance, the preferred order of assessments is:

ECGs → Vital Signs → PK blood sampling (nominal time) → Other assessments eg physical exams,

Electrocardiograms (ECGs) should be taken prior to vital signs when both measurements are scheduled at the same time point. Other assessments, e.g. physical examinations etc, will be performed within the required time windows. All safety assessments will be timed and performed relative to the start of dosing.

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/Treatment Phases and Adverse Events

10.4.1. Treatment 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

10.4.2. Treatment States

Assessments and events will be classified according to time of occurrence relative to the start and/or stop date of the study treatment.

10.4.3. Treatment States for AE Data

Treatment State	Definition
Pre-Treatment	AE Start Date < Study Treatment Start Date
On-Treatment	If AE onset date is on or after treatment start date & on or before treatment stop date. Study Treatment Start Date ≤ AE Start Date ≤ Study Treatment Stop Date
Post-Treatment	If AE onset date is after the treatment stop date. AE Start Date > Study Treatment Stop Date
Onset Time Since 1st Dose (Days)	If Treatment Start Date > AE Onset Date = AE Onset Date - Treatment Start Date If Treatment Start Date ≤ AE Onset Date = AE Onset Date - Treatment Start Date +1 Missing otherwise.
Duration (Days)	AE Resolution Date – AE Onset Date + 1
Drug-related	If relationship is marked 'YES' on [Inform/CRF OR value is missing].

NOTES:

- If the study treatment stop date is missing then the AE will be considered to be On-Treatment.

10.4.4. Treatment 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.

10.5. 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\ mid205017\final_01
QC Spreadsheet	: \arwork\gsk2982772\mid205017\documents
Analysis Datasets	
• Analysis datasets will be created according to Legacy GSK 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
• 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 subject receives unless otherwise states. • 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. • 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, %
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)
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

10.6. Appendix 6: Derived and Transformed Data

10.6.1. General

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

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

10.6.2. Study Population

Demographics
Age

• GSK standard IDSL algorithms will be used for calculating age where birth date will be imputed as follows:
  ○ Any subject with a missing day will have this imputed as day '15'.
  ○ Any subject with a missing date and month will have this imputed as '30th June'.
• Birth date will be presented in listings as 'YYYY'.

Body Mass Index (BMI)
• Calculated as **Weight (kg) / [Height (m)^2**

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 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 $$QTcB = \frac{QT}{\sqrt{\frac{RR}{1000}}} \qquad QTcF = \frac{QT}{\sqrt[3]{\frac{RR}{1000}}}$$

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

10.6.4. Pharmacokinetic

10.6.4.1. Non-Compartmental Analysis

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.

Pharmacokinetic Endpoints
AUC(0-∞) (Day 1)
• 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.
AUC(0-24) for QD dosing
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(0-12) for BID dosing
Area under the concentration-time curve from time zero to 12 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(12-24) for BID dosing
Area under the concentration-time curve from time 12 h 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_{12h} for BID dosing
Observed concentration at 12 hours, 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.
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 $AUC_{(0\text{-}inf)}$ and C_{max}. If for any reason the $AUC_{(0\text{-}inf)}$ is not calculable then an alternative AUC such as $AUC_{(0\text{-}last)}$, $AUC_{(0\text{-}\tau)}$ or AUC over a partial area may be used. The following comparisons will be made: o MR Formulation (test) vs IR Formulation (reference) o Fed (test) vs Fasted (reference) o Day 3 vs Day 1 (reference)

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.

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 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	umol/L			1.3 X ULN
Creatinine	umol/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	
		> 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	
	msec	> 30	<60f
	msec	≥ 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

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: Pharmacokinetic Analyses

10.9.1. Systems

N/A

10.10. Appendix 10: Abbreviations & Trade Marks

10.10.1. Abbreviations

Abbreviation	Description
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
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
eCRF	Electronic Case Record Form
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
GCSP	Global Clinical Safety and Pharmacovigilance
GSK	GlaxoSmithKline
IA	Interim Analysis
ICH	International Conference on Harmonization
IDSL	Integrated Data Standards Library
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
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings

10.10.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
None

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS
WinNonlin

10.11. Appendix 11: List of Data Displays

10.11.1. 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	

10.11.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided.

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.'

10.11.3. 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

10.11.4. Study Population Tables

10.11.4.1. 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.	All Subjects	SP1	Summary of Study Populations and Exclusions: Part A	IDSL	SAC
Demographic and Baseline Characteristics					
1.34.	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').	SAC
1.6.	Safety	DM1	Summary of Demographic Characteristics: Part A	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.7.	Safety	DM5	Summary of Race and Racial Combinations: Part A	ICH E3, FDA, GSK CTR, FDAAA, EudraCT	SAC
1.8.	Safety	DM6	Summary of Race and Racial Combination Details: Part A	ICH E3, FDA	SAC

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

10.11.4.2. Study Population Tables Part B

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.12.	Safety	ES1A	Summary of Subject Disposition: Part B	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.13.	All Subjects	ES6	Summary of Reasons for Screen Failure: Part B	Journal Requirements	SAC
Protocol Deviation					
1.14.	Safety	DV1	Summary of Important Protocol Deviations: Part B	ICH E3	SAC
1.15.	All Subjects	IE2	Summary of Inclusion/Exclusion Criteria Deviations: Part B	IDSL	SAC
Population Analysed					
1.16.	All Subjects	SP1	Summary of Study Populations and Exclusions: Part B	IDSL	SAC
Demographic and Baseline Characteristics					
1.35.	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
1.17.	Safety	DM1	Summary of Demographic Characteristics: Part B	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.18.	Safety	DM5	Summary of Race and Racial Combinations: Part B	ICH E3, FDA, GSK CTR, FDAAA, EudraCT	SAC
1.19.	Safety	DM6	Summary of Race and Racial Combination Details: Part B	ICH E3, FDA	SAC

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

10.11.4.3. Study Population Tables Part C

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.23.	Safety	ES1A	Summary of Subject Disposition: Part C	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.24.	All Subjects	ES6	Summary of Reasons for Screen Failure: Part C	Journal Requirements	SAC
Protocol Deviation					
1.25.	Safety	DV1	Summary of Important Protocol Deviations: Part C	ICH E3	SAC
1.26.	All Subjects	IE2	Summary of Inclusion/Exclusion Criteria Deviations: Part C	IDSL	SAC
Population Analysed					
1.27.	All Subjects	SP1	Summary of Study Populations and Exclusions: Part C	IDSL	SAC
Demographic and Baseline Characteristics					
1.36.	All Subjects	DM11	Summary of Age Ranges: Part C	ICH E3, GSK CTR, FDAAA, EudraCT Only include age ranges applicable to the study ('Adult (18-64 years)' and '>=65-84 years').	SAC
1.28.	Safety	DM1	Summary of Demographic Characteristics: Part C	ICH E3, GSK CTR, FDAAA, EudraCT	SAC
1.29.	Safety	DM5	Summary of Race and Racial Combinations: Part C	ICH E3, FDA, GSK CTR, FDAAA, EudraCT	SAC
1.30.	Safety	DM6	Summary of Race and Racial Combination Details: Part C	ICH E3, FDA	SAC

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

10.11.5. Safety Tables

10.11.5.1. 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 Table 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
2.66.	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					
2.11.	Safety	LB1	Summary of Hematology Changes From Baseline: Part A	ICH E3 Includes baseline values.	SAC
2.12.	Safety	LB1	Summary of Hematology Values: Part A	ICH E3 Includes baseline values.	SAC
2.13.	Safety	LB3	Summary of Emergent Hematology Results by Potential Clinical Importance Criteria: Part A		SAC
Laboratory: Urinalysis					
2.14.	Safety	UR3	Summary of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part A	ICH E3 Includes Baseline values.	SAC
Laboratory: Hepatobiliary (Liver)					
2.15.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting: Part A	IDSL	SAC
2.16.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities: Part A		SAC
ECG					
2.17.	Safety	EG1	Summary of ECG Findings: Part A	IDSL	SAC
2.18.	Safety	EG2	Summary of Change from Baseline in ECG Values by Visit: Part A	IDSL	SAC
2.19.	Safety	CP_EG12	Summary of Maximum Change from Baseline in QTc Values by Category: Part A	IDSL	SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Vital Signs					
2.20.	Safety	VS1	Summary of Change From Baseline in Vital Signs by Visit: Part A	ICH E3 Includes Baseline values.	SAC
2.21.	Safety	VS1	Summary of Vital Signs by Visit: Part A		SAC

10.11.5.2. Safety Tables Part B

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
2.22.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term: Part B	See Table 2.02 from 200975	SAC
2.23.	Safety	AE5a	Summary of All Adverse Events by System Organ Class and Maximum Intensity: Part B	ICH E3	SAC
2.24.	Safety	AE3	Summary of Common (>10%) Adverse Events by Overall Frequency: Part B	GSK CTR	SAC
2.25.	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					
2.26.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class: Part B	IDSL / GSK CTR	SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.27.	Safety	AE3	Summary of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment by Overall Frequency: Part B	IDSL	SAC
2.28.	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					
2.29.	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
2.30.	Safety	LB1	Summary of Clinical Chemistry Values: Part B		SAC
2.31.	Safety	LB3	Summary of Emergent Clinical Chemistry Results by Potential Clinical Importance Criteria: Part B		SAC
2.67.	Safety	LB17	Summary of Worst Case Lipids Outside Laboratory Normal Range Post-Baseline Relative to Baseline: Part B		SAC
Laboratory: Hematology					
2.32.	Safety	LB1	Summary of Hematology Changes From Baseline: Part B	ICH E3 Includes baseline values.	SAC
2.33.	Safety	LB1	Summary of Hematology Values: Part B	ICH E3 Includes baseline values.	SAC
2.34.	Safety	LB3	Summary of Emergent Hematology Results by Potential Clinical Importance Criteria: Part B		SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Urinalysis					
2.35.	Safety	UR3	Summary of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part B	ICH E3 Includes Baseline values.	SAC
Laboratory: Hepatobiliary (Liver)					
2.36.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting: Part B	IDSL	SAC
2.37.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities: Part B		SAC
ECG					
2.38.	Safety	EG1	Summary of ECG Findings: Part B	IDSL	SAC
2.39.	Safety	EG2	Summary of Change from Baseline in ECG Values by Visit: Part B	IDSL	SAC
2.40.	Safety	CP_EG12	Summary of Maximum Change from Baseline in QTc Values by Category: Part B	IDSL	SAC
Vital Signs					
2.41.	Safety	VS1	Summary of Change From Baseline in Vital Signs by Visit: Part B	ICH E3 Includes Baseline values.	SAC
2.42.	Safety	VS1	Summary of Vital Signs by Visit: Part B		SAC
CSSRS					
2.43.	Safety	CSSRS1	Summary of Subjects with C-SSRS Suicidal Ideation or Behaviour during Treatment: Part B		SAC

10.11.5.3. Safety Tables Part C

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
2.44.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term: Part C	See Table 2.02 from 200975	SAC
2.45.	Safety	AE5a	Summary of All Adverse Events by System Organ Class and Maximum Intensity: Part C	ICH E3	SAC
2.46.	Safety	AE3	Summary of Common (>10%) Adverse Events by Overall Frequency: Part C	GSK CTR	SAC
2.47.	Safety	AE5a	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Intensity: Part C	GSK CTR	SAC
Serious and Other Significant Adverse Events					
2.48.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class: Part C	IDSL / GSK CTR	SAC
2.49.	Safety	AE3	Summary of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment by Overall Frequency: Part C	IDSL	SAC
2.50.	Safety	AE16	Summary of Subjects and Number of Occurrences of Serious, Drug-Related Serious, Fatal Serious, and Drug-Related Fatal Serious Adverse Events: Part C	FDAAA, EudraCT	SAC
Laboratory: Chemistry					
2.51.	Safety	LB1	Summary of Clinical Chemistry Changes from Baseline: Part C	ICH E3 Includes Baseline values. Includes pre-specified parameters repeated in conventional units.	SAC
2.52.	Safety	LB1	Summary of Clinical Chemistry Values: Part C		SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.53.	Safety	LB3	Summary of Emergent Clinical Chemistry Results by Potential Clinical Importance Criteria: Part C		SAC
2.68.	Safety	LB17	Summary of Worst Case Lipids Outside Laboratory Normal Range Post-Baseline Relative to Baseline: Part C		SAC
Laboratory: Hematology					
2.54.	Safety	LB1	Summary of Hematology Changes From Baseline: Part C	ICH E3 Includes baseline values.	SAC
2.55.	Safety	LB1	Summary of Hematology Values: Part C	ICH E3 Includes baseline values.	SAC
2.56.	Safety	LB3	Summary of Emergent Hematology Results by Potential Clinical Importance Criteria: Part C		SAC
Laboratory: Urinalysis					
2.57.	Safety	UR3	Summary of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part C	ICH E3 Includes Baseline values.	SAC
Laboratory: Hepatobiliary (Liver)					
2.58.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting: Part C	IDSL	SAC
2.59.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities: Part C		SAC
ECG					
2.60.	Safety	EG1	Summary of ECG Findings: Part C	IDSL	SAC
2.61.	Safety	EG2	Summary of Change from Baseline in ECG Values by Visit: Part C	IDSL	SAC

Safety : Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.62.	Safety	CP_EG12	Summary of Maximum Change from Baseline in QTc Values by Category: Part C	IDSL	SAC
Vital Signs					
2.63.	Safety	VS1	Summary of Change From Baseline in Vital Signs by Visit: Part C	ICH E3 Includes Baseline values.	SAC
2.64.	Safety	VS1	Summary of Vital Signs by Visit: Part C		SAC

10.11.6. Safety Figures

10.11.6.1. 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	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 va Maximum Total Bilirubin: Part A		SAC

10.11.6.2. 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	SAC
Hepatobilary (Liver)					
2.5.	Safety	LIVER14	Scatter Plot of Maximum vs Baseline for ALT: Part B		SAC
2.6.	Safety	LIVER9	Scatter Plot for Maximum ALT va Maximum Total Bilirubin: Part C		SAC

10.11.6.3. Safety Figures Part C

Safety : Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
2.7.	Safety	AE10	Plot of Common Adverse Events and Relative Risk: Part C	IDSL	SAC
Hepatobilary (Liver)					
2.8.	Safety	LIVER14	Scatter Plot of Maximum vs Baseline for ALT: Part C		SAC
2.9.	Safety	LIVER9	Scatter Plot for Maximum ALT va Maximum Total Bilirubin: Part C		SAC

10.11.7. Pharmacokinetic Tables

10.11.7.1. 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 Pharmacokinetic Concentration-Time Data by Formulation: Part A	Includes fed state.	SAC
PK Derived Parameters					
3.2.	PK	PKPT1	Summary Statistics of Derived Plasma GSK2982772 Pharmacokinetic Parameters by Formulation: Part A	Parameters with units. Includes fed state.	SAC
3.3.	PK	PKPT3	Summary Statistics of Log-Transformed Derived Plasma GSK2982772 Pharmacokinetic Parameters by Formulation: Part A	Parameters with units. Includes fed state.	SAC
PK Analyses					
3.4.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & C) Assessing Relative Bioavailability of Formulation: Part A		SAC
3.5.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Relative Bioavailability of Formulation: Part A	Tmax	SAC

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.6.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & C) Assessing Relative Bioavailability of Food Effect: Part A		SAC
3.7.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Relative Bioavailability of Food Effect: Part A	Tmax	SAC
3.23.	PK	PK_T1	Sensitivity: Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & C) Assessing Relative Bioavailability of Formulation: Part A Excluding Subject PPD		SAC
3.24.	PK	PK_T1	Sensitivity: Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Relative Bioavailability of Formulation: Part A Excluding Subject PPD	Tmax	SAC
3.25.	PK	PK_T1	Sensitivity: Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & C) Assessing Relative Bioavailability of Food Effect: Part A Excluding Subject PPD		SAC
3.26.	PK	PK_T1	Sensitivity: Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Relative Bioavailability of Food Effect: Part A Excluding Subject PPD	Tmax	SAC

10.11.7.2. 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 Pharmacokinetic Concentration-Time Data by Dose and Day: Part B		SAC
PK Derived Parameters					
3.9.	PK	PKPT1	Summary Statistics of Derived Plasma GSK2982772 Pharmacokinetic Parameters by Dose and Day: Part B	Parameters with units	SAC
3.10.	PK	PKPT3	Summary Statistics of Log-Transformed Derived Plasma GSK2982772 Pharmacokinetic Parameters by Dose and Day: 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 Day: Part B	Parameters with units	SAC
PK Analyses					
3.12.	PK	PK_T2	Summary of Statistical Analysis of Plasma GSK2982772 PK Parameters (AUC & C) Assessing Relative Bioavailability of Repeat Dose: Part B		SAC

10.11.7.3. Pharmacokinetic Tables Part C

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK Concentration					
3.13.	PK	PK01	Summary of Plasma GSK2982772 Pharmacokinetic Concentration-Time Data by Formulation/Prandial State: Part C	Includes fed state.	SAC
PK Derived Parameters					
3.14.	PK	PKPT1	Summary Statistics of Derived Plasma GSK2982772 Pharmacokinetic Parameters by Formulation/Prandial State: Part C	Parameters with units. Includes fed state.	SAC
3.15.	PK	PKPT3	Summary Statistics of Log-Transformed Derived Plasma GSK2982772 Pharmacokinetic Parameters by Formulation/ Prandial State: Part C	Parameters with units. Includes fed state.	SAC
3.16.	PK		Summary Statistics of Log-Transformed Derived Plasma GSK2982772 Dose-Normalized Pharmacokinetic Parameters by Formulation/Prandial State: Part C		
PK Analyses					
3.17.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & C) Assessing Relative Bioavailability of Formulation: Part C		SAC
3.18.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Relative Bioavailability of Formulation: Part C	Tmax	SAC

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.19.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & C) Assessing Relative Bioavailability of Food Effect: Part C		SAC
3.20.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Relative Bioavailability of Food Effect: Part C	Tmax	SAC
3.21.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (AUC & C) Assessing Relative Bioavailability of Dose: Part C		SAC
3.22.	PK	PK_T1	Summary of Statistical Analysis of Plasma GSK2982772 Parameters (Tmax) Assessing Relative Bioavailability of Dose: Part C		SAC

10.11.8. Pharmacokinetic Figures

10.11.8.1. 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 Plot by Subject (Linear and Semi-Log): Part A	Paginate by Subject	SAC
3.2.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time Plot by Formulation (Linear and Semi-Log): Part A	Paginate by Formulation. This includes the fed state.	SAC
Mean / Median Concentration Plots					
3.3.	PK	PKCF2	Mean Plasma GSK2982772 Concentration-Time Plots by Formulation (Linear and Semi-log): Part A	Paginate by Formulation. This includes the fed state.	SAC
3.4.	PK	PKCF3	Median Plasma GSK2982772 Concentration-Time Plots by Formulation (Linear and Semi-log): Part A	Paginate by Formulation. This includes the fed state.	SAC
3.5.	PK	PK_F1	Plot of Individual Subject (+Geometric Mean and 95% CI) Plasma GSK2982772 PK Parameters vs Formulation: Part A		SAC
3.6.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Relative Bioavailability of Formulation: Part A		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 Relative Bioavailability of Food Effect: Part A		SAC

10.11.8.2. 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 Plot by Subject (Linear and Semi-Log): Part B	Paginate by Subject	SAC
3.9.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time Plot by Dose (Linear and Semi-Log): Part B	Paginate by Dose	SAC
Mean / Median Concentration Plots					
3.10.	PK	PKCF2	Mean Plasma GSK2982772 Concentration-Time Plots by Dose (Linear and Semi-log): Part B	Paginate by Dose	SAC
3.11.	PK	PKCF3	Median Plasma GSK2982772 Concentration-Time Plots by Dose (Linear and Semi-log): Part B	Paginate by Dose	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		SAC
3.13.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Relative Bioavailability of Repeat Dose: Part B		SAC

10.11.8.3. Pharmacokinetic Figures Part C

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Individual Concentration Plots					
3.14.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time Plot by Subject (Linear and Semi-Log): Part C	Paginate by Subject	SAC
3.15.	PK	PKCF1P	Individual GSK2982772 Plasma Concentration-Time Plot by Formulation (Linear and Semi-Log): Part C	Paginate by Formulation. This includes the fed state.	SAC
Mean / Median Concentration Plots					
3.16.	PK	PKCF2	Mean Plasma GSK2982772 Concentration-Time Plots by Formulation (Linear and Semi-log): Part C	Paginate by Formulation. This includes the fed state.	SAC
3.17.	PK	PKCF3	Median Plasma GSK2982772 Concentration-Time Plots by Formulation (Linear and Semi-log): Part C	Paginate by Formulation. This includes the fed state.	SAC
3.18.	PK	PK_F1	Plot of Individual Subject (+Geometric Mean and 95% CI) Plasma GSK2982772 PK Parameters vs Formulation: Part C		SAC
3.19.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Relative Bioavailability of Formulation: Part C		SAC
3.20.	PK	PK_F2	Plot of Geometric Mean Ratio and 90% CI of Plasma GSK2982772 PK Parameters Assessing Relative Bioavailability of Food Effect: Part C		SAC

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

10.11.9. ICH Listings

10.11.9.1. ICH Listing 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
Protocol Deviations					
4.	Safety	DV2	Listing of Important Protocol Deviations: Part A	ICH E3	SAC
5.	All Subjects	IE4	Listing of Subjectswith Inclusion/Exclusion Criteria Deviations: Part A	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Populations Analysed					
6.	Safety	SP3	Listing of SubjectsExcluded 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 Subjectswith Liver Stopping Events: Part A	IDSL	SAC
18.	Safety	SU2	Listing of Substance Use for Subjectswith Liver Stopping Events: Part A	IDSL	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
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
93.	Safety	LB6	Listing of All Lipid Data for Subjects with Any Value Outside of Laboratory Normal Range: Part A		SAC
21.	Safety	LB14	Listing of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part A	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
22.	Safety	EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance: Part A	IDSL	SAC
23.	Safety	EG4	Listing of ECG Values of Potential Clinical Importance: Part A	IDSL	SAC
24.	Safety	EG6	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding: Part A	IDSL	SAC
25.	Safety	EG6	Listing of Abnormal ECG Findings: Part A	IDSL .	SAC

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

10.11.9.2. ICH Listings Part B

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
28.	All Subjects	ES7	Listing of Reasons for Screen Failure: Part B	Journal Guidelines	SAC
29.	Safety	ES3	Listing of Reasons for Study Withdrawal: Part B	ICH E3	SAC
30.	Safety	TA2	Listing of Planned and Actual Treatments: Part B	IDSL	SAC
Protocol Deviations					
31.	Safety	DV2	Listing of Important Protocol Deviations: Part B	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
32.	All Subjects	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations: Part B	ICH E3	SAC
Populations Analysed					
33.	Safety	SP3	Listing of Subjects Excluded from Any Population: Part B	ICH E3	SAC
Demographic and Baseline Characteristics					
34.	Safety	DM4	Listing of Demographic Characteristics: Part B	ICH E3	SAC
35.	Safety	DM10	Listing of Race: Part B	ICH E3	SAC
Prior and Concomitant Medications					
36.	Safety	CP_CM3	Listing of Concomitant Medications: Part B	IDSL	SAC
Exposure and Treatment Compliance					
37.	Safety	EX4	Listing of Exposure Data: Part B	ICH E3	SAC
Adverse Events					
38.	Safety	AE9CP	Listing of All Adverse Events: Part B	ICH E3	SAC
39.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events: Part B	ICH E3	SAC
40.	Safety	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text: Part B	IDSL	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
41.	Safety	AE9CP	Listing of Serious Adverse Events: Part B	ICH E3	SAC
42.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event: Part B	ICH E3	SAC
43.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment: Part B	ICH E3	SAC
Hepatobiliary (Liver)					
44.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events: Part B	IDSL	SAC
45.	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					
46.	Safety	LB6	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance/Outside Normal Range: Part B	ICH E3	SAC
47.	Safety	LB6	Listing of Laboratory Values of Potential Clinical Importance: Part B		SAC
94.	Safety	LB6	Listing of All Lipid Data for Subjects with Any Value Outside of Laboratory Normal Range: Part B		SAC
48.	Safety	LB14	Listing of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part B	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
49.	Safety	EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance: Part B	IDSL	SAC
50.	Safety	EG4	Listing of ECG Values of Potential Clinical Importance: Part B	IDSL	SAC
51.	Safety	EG6	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding: Part B	IDSL	SAC
52.	Safety	EG6	Listing of Abnormal ECG Findings: Part B	IDSL	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Vital Signs					
53.	Safety	VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance: Part B	IDSL	SAC
54.	Safety	VS5	Listing of Vital Signs of Potential Clinical Importance: Part B	IDSL	SAC
C-SSRS					
55.	Safety	CSSRS4	Listing of C-SSRS Suicidal Ideation and Behavior Data: Part B	IDSL	SAC
56.	Safety	CSSRS5	Listing of C-SSRS Suicidal Behavior Details: Part B	IDSL	SAC
PSRAE					
57.	Safety	PSRAE1	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description (Section 1 - Section 2): Part B	IDSL	SAC

10.11.9.3. ICH Listing Part C

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
58.	All Subjects	ES7	Listing of Reasons for Screen Failure: Part C	Journal Guidelines	SAC
59.	Safety	ES3	Listing of Reasons for Study Withdrawal: Part C	ICH E3	SAC
60.	Safety	TA2	Listing of Planned and Actual Treatments: Part C	IDSL	SAC
Protocol Deviations					
61.	Safety	DV2	Listing of Important Protocol Deviations: Part C	ICH E3	SAC
62.	All Subjects	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations: Part C	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Populations Analysed					
63.	Safety	SP3	Listing of Subjects Excluded from Any Population: Part C	ICH E3	SAC
Demographic and Baseline Characteristics					
64.	Safety	DM4	Listing of Demographic Characteristics: Part C	ICH E3	SAC
65.	Safety	DM10	Listing of Race: Part C	ICH E3	SAC
Prior and Concomitant Medications					
66.	Safety	CP_CM3	Listing of Concomitant Medications: Part C	IDSL	SAC
Exposure and Treatment Compliance					
67.	Safety	EX4	Listing of Exposure Data: Part C	ICH E3	SAC
Adverse Events					
68.	Safety	AE9CP	Listing of All Adverse Events: Part C	ICH E3	SAC
69.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events: Part C	ICH E3	SAC
70.	Safety	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text: Part C	IDSL	SAC
Serious and Other Significant Adverse Events					
71.	Safety	AE9CP	Listing of Serious Adverse Events: Part C	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
72.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event: Part C	ICH E3	SAC
73.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment: Part C	ICH E3	SAC
Hepatobiliary (Liver)					
74.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events: Part C	IDSL	SAC
75.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events: Part C	IDSL	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
All Laboratory					
76.	Safety	LB6	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance/Outside Normal Range: Part C	ICH E3	SAC
77.	Safety	LB6	Listing of Laboratory Values of Potential Clinical Importance: Part C		SAC
95.	Safety	LB6	Listing of All Lipid Data for Subjects with Any Value Outside of Laboratory Normal Range: Part C		SAC
78.	Safety	LB14	Listing of Microscopy Results for Subjects with Abnormal Urinalysis Dipstick Results: Part C	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
79.	Safety	EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance: Part C	IDSL	SAC
80.	Safety	EG4	Listing of ECG Values of Potential Clinical Importance: Part C	IDSL	SAC
81.	Safety	EG6	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding: Part C	IDSL	SAC
82.	Safety	EG6	Listing of Abnormal ECG Findings: Part C	IDSL	SAC

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

10.11.10. Non-ICH Listings

10.11.10.1. Non-ICH Listings Part A

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

10.11.10.2. Non-ICH Listings Part B

Non-ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetic					
88.	PK	PKCL1	Listing of Plasma GSK2982772 Pharmacokinetic Concentration-Time (ng/mL) Data: Part B		IA SAC
89.	PK	PKPL1	Listing of Derived Plasma GSK2982772 Pharmacokinetic Parameters: Part B		IA SAC

10.11.10.3. Non-ICH Listings Part C

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