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

Title	:	Reporting and Analysis Plan for Study 206817: A Single Centre, Double Blind (Sponsor Open), Placebo Controlled, 3-Period Crossover, Ascending Dose Study in Japanese Healthy Elderly Male Subjects to Evaluate the Safety, Tolerability and Pharmacokinetics of Danirixin in the Fed State (Part1) and an open label, 2-way crossover to evaluate food effect on the pharmacokinetics of Danirixin (Part2).
Compound Number	:	GSK1325756
Effective Date	:	11-JUL-2017

Description:

- The purpose of this reporting and analysis plan (RAP) is to describe the planned analyses and output to be included in the clinical pharmacology study report for protocol 206817.
- This RAP is intended to describe the safety, pharmacokinetics analyses required for the study.
- This document will be provided to the study team members to convey the content of the statistical analysis complete (SAC) deliverable.

Author's Name and Functional Area:

PPD Biostatistics Group 1 Manager, Biomedical Data Sciences Department, Japan.	5-Jul-2017
PPD Clinical Pharmacology & Science Promotion Office, Medicines Development, Japan.	5-Jul-2017

Approved:

PPD Department Manager, Biomedical Data Sciences Department, Japan.	11-Jul-2017

TABLE OF CONTENTS

PAGE

1. REPORTING & ANALYSIS PLAN SYNPOSIS

Overview	Key Elements of the Reporting and Analysis Plan
Purpose	• The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 206817.
Protocol	• Reporting and Analysis Plan is based on original protocol (Dated:11-Apr-2017) for study GSK1325756 / 206817 [GlaxoSmithKline Document Number:2016N309585_0]
Objectives	Part 1 • To assess the safety, tolerability and PK following single doses of GSK1325756H 10, 50 and 100 mg in the fed state in healthy Japanese subjects of over 65 years of age inclusive. Part 2 • To investigate the safety, tolerability and food effect on PK of GSK1325756 following a single dose of 50 mg in the fed and fasted state, in healthy Japanese subjects of over 65 years of age inclusive.
Endpoints	Part 1 and 2. • Adverse events (AEs) • Change from baseline of clinical laboratory values, vital signs, and electrocardiogram (ECG) parameters • Blood concentration of GSK1325756 • Cmax, AUC(0-t), AUC(0-inf), AUC(0-24), tmax, t1/2, tlag, tlast of the blood concentration of GSK1325756, as data permit
Study Design	This study consists of two parts. • Part 1 is a double blind, placebo-controlled, 3-period crossover, ascending dose, single oral administration in the fed condition • Part 2 is an open label, 2-way crossover, single oral dose in the fed and fasted state.
Analysis Population	• Screened: Consisting of all subjects screened in the study • Screening Failure: Subjects who screened in the study but are never subsequently randomized. • Safety: All randomized subjects who take at least one dose of study treatment. • Pharmacokinetic: This population is defined as all subjects administered at least one dose of study treatment and who have PK sample taken and analysed.
Hypothesis	• The objectives of this study are to evaluate safety and tolerability of GSK1325756 and to estimate GSK1325756 Pharmacokinetic parameters. No formal statistical hypotheses will be tested in Part 1 and Part 2. Descriptive statistics will be used to assess safety and tolerability objectives. An estimation approach will be used to address the pharmacokinetic study objectives, where point estimates and corresponding 90% confidence intervals will be constructed.
Safety Analyses	• Safety data will be presented in tabular and/or graphical format and summarized descriptively according to GSK's Integrated Data Standards Library (IDSL) standards.
Pharmacokinetic Analyses	• Individual GSK1325756 blood concentration-time profiles (by part, treatment and subject) and median/mean (±SD) profiles by part and treatment will be plotted and listed. Treatment indicates dose group in Part 1 and the fed and fasted condition in Part 2. • Blood concentration time data for GSK1325756 will be analyzed by non-compartmental methods using WinNonlin and derived PK parameters graphically present, summarised

Overview	Key Elements of the Reporting and Analysis Plan
	and listed. No formal statistical analyses will be conducted. • Statistical analyses will be carried out to explore the dose proportionality of GSK1325756 as assessed by AUC(0-t) and Cmax using the Power Model (Part 1). • Statistical analyses will be carried out to explore the food effect of GSK1325756 as assessed by AUC(0-t) and Cmax using a mixed effects mode (Part 2).

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: 11/APR/2017].

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

Objectives	Endpoints
Part 1 • To assess the safety, tolerability and PK following single doses of GSK1325756H 10, 50 and 100 mg in the fed state in healthy Japanese subjects of over 65 years of age inclusive. Part 2 • To investigate the safety, tolerability and food effect on PK of GSK1325756 following a single dose of 50 mg in the fed and fasted state, in healthy Japanese subjects of over 65 years of age inclusive.	Part 1 and Part 2 • Adverse events (AEs) • Change from baseline of clinical laboratory values, vital signs, and electrocardiogram (ECG) parameters • Blood concentration of GSK1325756 • Cmax, AUC(0-t), AUC(0-inf), AUC(0-24), tmax, t1/2, tlag, tlast of the blood concentration of GSK1325756, as data permit

2.3. Study Design

Overview of Study Design and Key Features

Subjects will be divided into Part 1 and 2, and receive the following study treatment doses shown in Table below.

Part 1:

Group	n	Period 1	Washout	Period 2	Washout	Period 3
A	6	10 mg	at least 7 days	50 mg	at least 7 days	Placebo
B	6	10 mg		Placebo		100 mg
C	6	Placebo		50 mg		100 mg

Part 2:

Group	n	Period 1	Washout	Period 2
D	8	50 mg, fed	at least 7 days	50 mg, fasted
E	8	50 mg, fasted		50 mg, fed

Design Features	Part 1: This is a double blind, placebo-controlled, 3-period crossover, ascending dose, single oral administration in the fed condition. Part 2: This is an open label, 2-way crossover, single oral dose in the fed and fasted state study.
Dosing	Part 1: Subjects will have a screening visit within 30 days prior to the first dose of study. A minimum washout period of 7 days will be required between each treatment period. Subjects will receive three treatment periods in the study. Subjects will be housed in the Clinical Research Unit from Day -1 (the day before dosing) through Day 3 for Period 1 and 2, and from Day -1 (the day before dosing) through Day 4 for Period 3. Subjects will return to the clinic 7 days (at least) after the previous administration day for Period 1 and 2, and subjects will visit the unit on Day 8 (+/- 1 day) of the last dosing for Period 3 for follow-up. Part 2: Subjects will have a screening visit within 30 days prior to the first dose of study treatment, two treatment periods separated by at least 7 days, and follow-up. Subjects will be housed in the Clinical Research Unit from Day -1 (the day before dosing) through Day 3 (for Period 1 and 2), and re-visit 7 (±1) days after the last dose of Period 2 for follow-up.
Treatment Assignment	• Sufficient participants will be randomised such that approximately 18 in Part 1and 16 in Part 2 evaluable participants complete the study of

Overview of Study Design and Key Features	
	each part. • If participants prematurely discontinue the study, additional participants may be enrolled as replacement participants and assigned to the same treatment sequence, if applicable, at the discretion of the sponsor in consultation with the investigator. • On Day 1 of each Part, participants will be assigned a unique number (randomization number) in ascending numerical order. The randomization number encodes the participant's assignment to one of the 3 sequences in Part 1 and one of the 2 sequences in Part 2, according to the randomization schedule generated prior to the study by the Biomedical Data Sciences Department at GSK. • Participants will be randomized in a 1:1:1 ratio to receive sequence (A:B:C) for Part 1, or will be randomized in a 1:1 ratio to receive sequence (D:E) for Part 2. • Each participant will be dispensed blinded study treatment, labeled with his unique randomization number, throughout the study. • Investigators, participants and sponsor will remain blinded to each participant's assigned study treatment throughout the course of the study. For the concentration evaluation after Period 2 of Part 1, the pre-specified sponsor's person who is responsible for the confirmation of the concentration will review blood drug concentration data under unblended.
Interim Analysis	• No formal statistical analysis is planned. • A blind review of preliminary safety data (AE, clinical laboratory values, vital signs, ECG) and blood concentration will be conducted between Period 2 and Period 3 in Part 1 and prior to Part 2. • After completion of Part 1, formal analysis for Part 1 is to be conducted.

2.4. Statistical Hypotheses

The objectives of this study are to evaluate safety, tolerability and PK profile of single dose of GSK1325756H and to investigate food effect of PK profile of single dose of GSK1325756H in healthy Japanese elderly subjects. No formal statistical hypotheses will be tested in Part 1 and Part 2. Descriptive statistics will be used to assess safety and tolerability objectives. An estimation approach will be used to address the PK study objectives, where point estimates and corresponding 95% confidence intervals will be constructed, unless otherwise stated.

3. PLANNED ANALYSES

3.1. Interim Analyses

No formal statistical analysis is planned. However, following Period 1 and Period 2 of Part 1, a blind review of preliminary safety data (AE, clinical laboratory values, vital signs, ECGs) will be conducted between Period 2 and Period 3 in Part 1 and prior to Part 2. Furthermore, the sponsor's person who is responsible for the confirmation of the concentration will review blood drug concentration data under unblended.

3.2. Final Analyses

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

1. All subjects in each part have completed the study as defined in the protocol.
2. All required database cleaning activities in each part have been completed and final database release and database freeze has been declared by Data Management for each part.
3. All criteria for unblinding the randomisation codes have been met for Part 1.
4. Randomisation codes have been distributed according to RandAll NG procedures.

After completion of Part 1, formal analysis for Part 1 is to be conducted.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Endpoint(s) Evaluated
Screened	• Consisting of all subjects screened in the study. Note: This definition indicates the same meaning as 'All subjects who have subject number' in a programming point of view.	• Study Population
Screening Failure	• Subjects who screened in the study but are never subsequently randomized. All participants who sign the ICF have the screening test in the study. Note: This definition indicates the same meaning as 'Subjects who have subject number but are never subsequently randomized' in a programming point of view.	• Study Population
Safety	• All randomized subjects who take at least one dose of study treatment. Participants will be analyzed according to the treatment they actually received.	• Study Population • Safety
Pharmacokinetic	• This population is defined as all subjects	• PK

Population	Definition / Criteria	Endpoint(s) Evaluated
	administered at least one dose of study treatment and who have PK sample taken and analysed. Participants will be analyzed according to the treatment they actually received.	

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.
    - Data will be reviewed prior to freezing the database to ensure all important deviations and deviations which may lead to exclusion from the analysis are captured and categorised on the protocol deviations dataset.
    - This dataset will be the basis for the summaries and listings of protocol deviations.
- A separate listing of all inclusion/exclusion criteria deviations will also be provided. This will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

Table 1 provides an overview of appendices within the RAP for outlining general considerations for data analyses and data handling conventions.

Table 1 Overview of Appendices

Section	Component
10.1	Appendix 1: Protocol Deviation Management
10.2	Appendix 2: Time & Events
10.3	Appendix 3: Treatment States and Phases
10.4	Appendix 4: Data Display Standards & Handling Conventions
10.5	Appendix 5: Derived and Transformed Data
10.6	Appendix 6: Premature Withdrawals & Handling of Missing Data
10.7	Appendix 7: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Analyses

The study population analyses will be based on the Safety Population, unless otherwise specified. These analyses will be performed in each part.

Table 2 provides an overview of the planned study population analyses, with full details of data displays being presented in Appendix 9: List of Data Displays.

Table 2 Overview of Planned Study Population Analyses

Display Type	Data Displays Generated		
	Table	Figure	Listing
Subject Disposition			
Subject Disposition and Reason for Study Withdrawal	Y		Y
Screening Status and Reasons for Screen Failure	Y		Y
Subjects for Whom the Treatment Blind was Broken			Y
Planned and Actual Treatments			Y
Protocol Deviations			
Important Protocol Deviations	Y		Y
Inclusion/Exclusion Criteria Deviations			Y
Populations Analysed			
Study Populations	Y		
Subjects Excluded from Any Population			Y
Demographic and Baseline Characteristics			
Demographic Characteristics	Y		Y
Demographic Characteristics for Screening Failure			Y
Age Ranges	Y		
Race and Racial Combinations	Y		Y
Race and Racial Combinations for Screening Failure			Y
Medical Conditions and Concomitant Medications			
Medical Conditions			Y
Concomitant Medications			Y
Exposure and Treatment Compliance			
Exposure to Study Treatment			Y
Meal			
Meal start and end days/times on fed treatment			Y

NOTES:

- Y = Yes display generated.

7. SAFETY ANALYSES

The safety analyses will be based on the Safety Population, unless otherwise specified. These analyses will be performed in each part.

Adverse events occurred in washout period will be included in adverse events analyses for previous period. Also adverse events occurred in follow up period will be included in safety analyses for the last period.

7.1. Overview of Planned Adverse Events Analyses

Table 3 provides an overview of the planned adverse events analyses with full details of data displays being presented in Appendix 9: List of Data Displays.

Table 3 Overview of Planned Adverse Event Analyses

Display Type	Absolute		
	Summary		Individual
	T	F	L
Adverse Events (AEs)			
All AEs by SOC and PT	Y		Y
All AEs by Maximum Intensity	Y		
Drug-Related AEs by SOC and PT	Y		
Drug-Related AEs by Maximum Intensity	Y		
Subject Numbers for Individual AEs			Y
Relationship Between AE SOCs, PT and Verbatim Text			Y
Serious and Other Significant AEs			
Serious AEs			Y
AEs Leading to Withdrawal from Study			Y

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated, SOC = System Organ Class, PT = Preferred Term.
- Summary = Represents TF related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

7.2. Overview of Planned Clinical Laboratory Analyses

Table 4 provides an overview of the planned analyses, with further details of data displays being presented in Appendix 9: List of Data Displays.

Table 4 Overview of Planned Clinical Laboratory Analyses

Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
Chemistry						
Chemistry Data	Y		Y	Y		Y

Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
Chemistry Results Relative to Normal Range				Y		
All Chemistry Data for Subjects with any Value of Potential Clinical Concern/PCI			Y			Y
Hematology						
Hematology Data	Y		Y	Y		Y
Hematology Results Relative to Normal Range				Y		
All Hematology Data for Subjects with any Value of Potential Clinical Concern/PCI			Y			Y
Urinalysis						
Dipstick Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen)	Y		Y*			
Gravity and pH	Y		Y			
Hepatobiliary (Liver)						
Liver Monitoring/Stopping Event Reporting			Y			
Medical Conditions for Subjects with Liver Stopping Events			Y			
Substance Use for Subjects with Liver Stopping Events			Y			

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated, PCI = Potential Clinical Importance
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

*: If blood or protein is abnormal, microscopic examination will be included.

7.3. Overview of Planned Other Safety Analyses

Table 5 provides an overview of the planned analyses, with further details of data displays being presented in Appendix 9: List of Data Displays.

Table 5 Overview of Planned Other Safety Analyses

Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
ECG						
ECG Findings	Y		Y			
ECG Values	Y		Y	Y		Y
All ECG Values for Subjects with any Value of PCI			Y			
Vital Signs						
Vitals Values	Y		Y	Y		Y
All Vital Signs for Subjects with any Value of PCI			Y			

Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
Ophthalmic examinations						
Ophthalmic examinations			Y			

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated, PCI = Potential Clinical Importance
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

8. PHARMACOKINETIC ANALYSES

8.1. Overview of Planned Pharmacokinetic Analyses

The pharmacokinetic (PK) analyses will be based on the Pharmacokinetic population, unless otherwise specified. These analyses will be performed in each part.

Table 6 provides an overview of the planned analyses, with full details being presented in Appendix 9: List of Data Displays.

Table 6 Overview of Planned Pharmacokinetic Analyses

Display Type	Untransformed				Log-Transformed				
	Summary		Individual		Stats analysis	Summary		Individual	
	F	T	F	L		F	T	F	L
Descriptive statistics									
Blood Drug Concentrations	Y [1] [2]	Y	Y [1]	Y					
Derived PK Parameters	Y	Y		Y			Y		
Statistical Analysis of PK Parameters									
Power model (Part 1)					Y				
Food effect (Part 2)					Y				

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated.
- Summary = Represents TFL related to any summaries (descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

1. Linear and Semi-Log plots will be created on the same display.
2. Separate Mean (+ SD) and Median plots will be generated.

8.2. Drug Concentration Measures

Blood concentrations of GSK1325756 will be listed and summarised by part, treatment and nominal time. Standard summary statistics will be calculated (i.e. mean, standard deviation, median, minimum and maximum).

Individual blood concentration-time profiles and median/mean profiles by treatment will be plotted. Each of the figures will contain one plot on the untransformed scale (i.e. a linear plot) and one plot on the log transformed scale (i.e. log-linear plot).

Refer to Appendix 4: Data Display Standards & Handling Conventions (Section 10.4.4 Reporting Process & Standards).

8.3. Pharmacokinetic Parameters

8.3.1. Deriving Pharmacokinetic Parameters

- Derivation of pharmacokinetic parameters will be performed by, or under the direct auspices of, Clinical Pharmacology & Science Promotion Office, GlaxoSmithKline K.K.
- Refer to Appendix 4: Data Display Standards & Handling Conventions (Section 10.4.4 Reporting Process & Standards).
- The pharmacokinetic parameters will be calculated by standard non-compartmental analysis using WinNonlin (version 6.3 or higher)
- All calculations of non-compartmental parameters will be based on actual sampling times recorded during the study.
- Pharmacokinetic parameters described in Table 7 will be determined from blood GSK1325756 concentration-time data, as data permits.

Table 7 Derived Pharmacokinetic Parameters

Parameter	Parameter Description
AUC(0-24) (h*ng/mL)	Area under the concentration-time curve will be calculated to fixed nominal time 24 hours after administration (AUC(0-24)),using the combination of linear and logarithmic trapezoidal methods (i.e., Linear Up/Log Down calculation method in Phoenix WinNonlin Professional). If a sampling time deviation occurred at nominal time 24 hours after administration (and 24 < t), AUC(0-24) will be calculated using the concentration at time 24 hours after administration post-dose estimated by the method of interpolation. If nominal time 24 hours after administration > t (or if the concentration at time 24 hours after administration was below then limit of quantification), then the concentration (y) at time 24 hours after administration is estimated using lambda_z and last observed Ct according to the formula: y=Ct(obser) x e-lambda_z(24-t) Then the following equation will be used to calculate (AUC(0-24)) where t is the time of last quantifiable blood concentration.

Parameter	Parameter Description
	AUC(0-24) = AUC(0-t) + AUC(t-24) If lambda_z is not estimable, a partial AUC is not calculated (when 24 > t).
AUC(0-t) (h*ng/mL)	Area under the concentration-time curve from zero time (pre-dose) to the time of the last quantifiable concentration (AUC(0-t)) will be calculated by a combination of linear and logarithmic trapezoidal methods. The linear trapezoidal method will be employed for all incremental trapezoids arising from increasing concentrations and the logarithmic trapezoidal method will be used for those arising from decreasing concentrations (i.e., Linear Up/Log Down calculation method in Phoenix WinNonlin Professional).
AUC(0-inf) (h*ng/mL)	Area under the concentration-time curve from zero time (pre-dose) extrapolated to infinite time (AUC(0-inf)) will be calculated as follows: AUC(0-inf) = AUC(0-t) + Ct / lambda_z
Cmax (ng/mL)	Maximum observed concentration will be obtained directly from the concentration-time data.
Tmax (h)	Time to first occurrence of Cmax will be obtained directly from the concentration-time data.
t1/2 (h)	Terminal phase half-life will be calculated as follows: t1/2 = ln2 / lambda_z
tlag (h)	Lag time before observation of drug concentrations in sampled matrix.
tlast (h)	The time of the last measurable (positive) concentration.
%AUCex (%)	The area under the curve (AUC) from the last predicted non-zero concentration value to infinity as a percentage of the area under the curve extrapolated to infinity.
lambda_z (/h)	The first order rate constant associated with the terminal (log-linear) portion of the curve.
lambda_z_lower (h)	The lower limit on time for values to be included in the calculation of Lambda z.
lambda_z_upper (h)	The upper limit on time for values to be included in the calculation of Lambda z.
#pts	The number of time points used in computing Lambda z.
R2	The goodness of fit statistic for the terminal elimination phase.

NOTES:

- Additional parameters may be included as required.
- Lambda_z is the terminal phase rate constant.
- Ct is the last observed quantifiable concentration.

8.3.2. Summary of Pharmacokinetic Parameters

- For each of these parameters, except for tmax, tlag and tlast, the following summary statistics will be calculated for each treatment:
    - Non-transformed: arithmetic mean, median, maximum, minimum, 95% confidence interval for the arithmetic mean and standard deviation
    - Loge-transformed: geometric mean, 95% confidence interval for the geometric mean, standard deviation of logarithmically transformed data and between geometric coefficient of variation (CVb (%))
- Median, maximum, minimum, arithmetic mean, 95% confidence interval and standard deviation will be calculated for tmax, tlag and tlast.

8.3.3. Statistical Analysis of Pharmacokinetic Parameters

8.3.3.1. Dose proportionality

For Part 1, the PK-dose relationship will be investigated graphically in order to assess dose proportionality of GSK1325756. Plots of AUC (0-t) and Cmax versus dose will be plotted.

Also statistical analyses will be carried out to explore the dose proportionality of GSK1325756 as assessed by AUC(0-t) and Cmax, using the Power Model:

$\log_e (Y_{ij}) = \mu + S_i + \beta * \log_e (D_j) + \varepsilon_{ij}$

Y_{ij}: PK parameter (AUC(0-t), Cmax) on the *j*th dose for *i*th subject

μ: Overall mean (Intercept)

S_i: Random effect for subject i following normal distribution $N(0, \sigma_b^2)$

β: Slope for $\log_e$ transformed dose

D_j: Dose (j=1:10mg, 2:50mg, 3:100mg)

ε_{ij}: Random error following normal distribution $N(0, \sigma_w^2)$

Following loge-transformation, AUC (0-t) and Cmax will be separately analyzed, if data permitted. A mixed effect model will be fitted with the loge transformed dose and period as fixed effects. Subject will be fitted as a random effect. The Kenward & Roger (KR) degrees of freedom approach will be used. Point estimates and their associated 90% confidence intervals will be constructed.

8.3.3.2. Food effect

For Part 2, statistical analyses will be carried out to assess treatment (food effect) of GSK1325756 for AUC(0-t) and Cmax using Mixed effect model:

$\log_e (Y_{ij}) = \mu + S_i + t_j + p_k + \varepsilon_{ij}$

Y_{ij}: PK parameter (AUC(0-t), Cmax) on the *j*th treatment for *i*th subject

μ: Overall mean (Intercept)

S_i: Random effect for subject i following normal distribution $N(0, \sigma_b^2)$

t_i : Treatment effect (j=fasted, fed)

p_k: Period effect (k=period 1, period 2)

ε_{ij}: Random error following normal distribution $N(0, \sigma_w^2)$

Following loge-transformation, AUC (0-t) and Cmax will be separately analysed using a mixed effects model fitting terms for treatment and period as fixed effects, and subject as a random effect in order to assess food effect of GSK1325756 (Fed vs. Fasted). The Kenward & Roger (KR) degrees of freedom approach will be used.

Point estimates for the adjusted means on the loge scale, the mean difference between treatments and associated 90% confidence interval will be constructed using the residual variance. The point estimate and confidence interval will then be exponentially back-transformed to obtain adjusted (least square) geometric means for each treatment, and point estimates and associated 90% confidence interval for the ratio of fasted/fed.

Estimates of within-subject variability (CVw (%)) for AUC (0-t) and Cmax will also be provided. CVw (%) will be calculated based on the loge-normal distribution where:

CVw (%)= SQRT(exp(MSE)-1) * 100. (MSE is the residual mean squared error from the model)

9. REFERENCES

GlaxoSmithKline Document Numbers 2016N309585_01: Study Protocol of 206817. A Single Centre, Double Blind (Sponsor Open), Placebo Controlled, 3-Period Crossover, Ascending Dose Study in Japanese Healthy Elderly Male Subjects to Evaluate the Safety, Tolerability and Pharmacokinetics of Danirixin in the Fed State (Part1) and an open label, 2-way crossover to evaluate food effect on the pharmacokinetics of Danirixin (Part2).

10. APPENDICES

Section	Appendix
RAP Section 4 : Analysis Populations	
Section 10.1	Appendix 1: Protocol Deviation Management
RAP Section 5 : General Considerations for Data Analyses & Data Handling Conventions	
Section 10.2	Appendix 2: Time and Events
Section 10.3	Appendix 3: Treatment States & Phases
Section 10.4	Appendix 4: Data Display Standards & Handling Conventions • Study Treatment • Baseline Definitions & Derivations • Reporting Process & Standards
Section 10.5	Appendix 5: Derived and Transformed Data • General • Study Population • Safety • Pharmacokinetics
Section 10.6	Appendix 6: Premature Withdrawals & Handling of Missing Data • General • Study Population & Safety
Section 10.7	Appendix 7: Values of Potential Clinical Importance • Laboratory Values • ECG • Vital Signs
Other RAP Appendices	
Section 10.8	Appendix 8: Abbreviations & Trade Marks
Section 10.9	Appendix 9: List of Data Displays
Section 10.10	Appendix 10: Example Mock Shells for Data Displays

10.1. Appendix 1: Protocol Deviation Management

Details will be referred latest Protocol Deviation Management Plan and data handling will be decided prior to final data base release.

10.2. Appendix 2: Time & Events

Part 1, Period 1-2

Day	Screening	Day-1	Day 1													Day 2	Day 3
Time post-dose			Pre-dose	0 h	0.25 h	0.5 h	0.75 h	1 h	2 h	3 h	4 h	6 h	8 h	10 h	12 h	24 h	48 h
Informed consent	X																
Subject demography /Medical history	X																
Height, Weight, BMI	X																
Urine drug screen	X																
Serological test	X																
Physical examination	X	X	X								X					X	X
Vital signs (PR, BP, temp)	X	X	X								X					X	X
12-lead ECG	X	X	X								X					X	X
Ophthalmic examination	X[3]																
SAEs[2]	<==========																==========>
AEs[2]	<==========																==========>
Con Med review	<==========																==========>
Hematology, clinical chemistry and urinalysis	X	X															X
Administration				X													
PK sampling			X		X	X	X	X	X	X	X	X	X	X	X	X	X
Admission		X															
Discharge																	X

1. Screening visit will occur only prior to the first dosing. Treatment Period 2 will occur after at least 7-days wash-out period. High fat meal will be started and completed before within 30 minutes of GSK1325756H/Placebo dosing.
2. All SAEs will be collected from the signing of the ICF until the follow-up visit at the time points specified. All AEs will be collected from the start of treatment until the follow-up visit at the time points specified (see Section 9.1 Adverse Events).

3. Ophthalmic examinations are conducted on the day between Screening and Day-1. However, it is not carried out for those who are ineligible due to other screening criteria.

Part 1, Period 3

Day	Day-1	Day 1													Day 2	Day 3		Day 4	Follow up [2,3]
Time post-dose		Pre-dose	0 h	0.25 h	0.5 h	0.75 h	1 h	2 h	3 h	4 h	6 h	8 h	10 h	12 h	24 h	48 h	60 h	72 h	
Physical examination	X	X								X					X	X		X	X
Vital signs (PR, BP, temp)	X	X								X					X	X		X	X
12-lead ECG	X	X								X					X	X		X	X
Ophthaimic examination																			X
SAEs	<==========>																		
AEs	<==========>																		
Con Med review	<==========>																		
Hematology, clinical chemistry and urinalysis	X																	X	X
Administration			X																
PK sampling		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Admission	X																		
Discharge																		X	

1. Treatment Period 3 will occur after at least 7-days wash-out period. High fat meal will be started and completed before within 30 minutes of GSK1325756/Placebo dosing.
2. Follow up visit will occur after 7 days (+/- 1day) of the last dosing.
3. In the case where the subject has discontinued the study prematurely, the assessments for follow up will be carried out.

Part 2, Period 1-2

Day	Screening	Day-1	Day 1													Day 2	Day 3	Follow up[3,5]
Time post-dose			Pre-dose	0 h	0.25 h	0.5 h	0.75 h	1 h	2 h	3 h	4 h	6 h	8 h	10 h	12 h	24 h	48 h	
Informed consent	X																	
Subject demography /Medical history	X																	
Height, Weight, BMI	X																	
Urine drug screen	X																	
Serological test	X																	
Physical examination	X	X	X								X					X	X	X
Vital signs (PR, BP, temp)	X	X	X								X					X	X	X
12-lead ECG	X	X	X								X					X	X	X
Ophthalmic examination	X[6]																	X
SAEs[4]	<==========																	==========>
AEs[4]			<==========															==========>
Con Med review	<==========																	==========>
Hematology, clinical chemistry and urinalysis	X	X															X	X
Administration				X														
PK sampling			X		X	X	X	X	X	X	X	X	X	X	X	X	X	
Admission		X																
Discharge																	X	

1. Screening visit will occur only prior to the first dosing. Treatment Period 2 will occur after at least 7-days wash-out period.
2. For the fed condition, meal will be started and completed before within 30 minutes of GSK1325756H dosing.
3. Follow up visit will occur after 7-days (+/- 1day) of the last dosing.
4. All SAEs will be collected from the signing of the ICF until the follow-up visit at the time points specified. All AEs will be collected from the start of treatment until the follow-up visit at the time points specified (see Section 9.1.Adverse Events).
5. In the case where the subject has discontinued the study prematurely, the assessments for follow up will be carried out.
6. Ophthalmic examinations are conducted on the day between Screening and Day-1. However, it is not carried out for those who are ineligible due to other screening criteria.

10.3. Appendix 3: Treatment States and Phases

10.3.1. Treatment Phases

Assessments and events will be classified according to the time of occurrence relative to the assessment date.

Treatment Phase	Definition
Part 1: Period 1	Assessment Date < Previous Day of Dosing Start Date in Period 2 (Part 1)
Part 1: Period 2	Previous Day of Dosing Start Date in Period 2 ≤ Assessment Date < Previous Day of Dosing Start Date in Period 3 (Part 1)
Part 1: Period 3	Previous Day of Dosing Start Date in Period 3 ≤ Assessment Date (Part 1)
Part 2: Period 1	Assessment Date < Previous Day of Dosing Start Date in Period 2 (Part 2)
Part 2: Period 2	Previous Day of Dosing Start Date in Period 2 ≤ Assessment Date (Part 2)

10.3.2. 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.

10.3.2.1. Treatment States for AE Data

Treatment State	Definition
Pre-Treatment	AE Start Date and Time < Dosing Start Date and Time
Part 1: Period 1	Dosing Start Date and Time in Period 1 ≤ AE Start Date and Time < Dosing Start Date and Time in Period 2 (Part 1)
Part 1: Period 2	Dosing Start Date and Time in Period 2 ≤ AE Start Date and Time < Dosing Start Date and Time in Period 3 (Part 1)
Part 1: Period 3	Dosing Start Date and Time in Period 3 ≤ AE Start Date and Time (Part 1)
Part 2: Period 1	Dosing Start Date and Time in Period 1 ≤ AE Start Date and Time < Dosing Start Date and Time in Period 2 (Part 2)
Part 2: Period 2	Dosing Start Date and Time in Period 2 ≤ AE Start Date and Time (Part 2)
Onset Time Since First Dose (Minute)	If Dosing Start Date and Time > AE Onset Date and Time = AE Onset Date and Time – Dosing Start Date and Time If dosing Start Date and Time ≤ AE Onset Date and Time = AE Onset Date and Time - Dosing Start Date and Time +1 Missing otherwise
Onset Time Since Last Dose (Minute)	AE Start Date and Time – Most Recent Treatment Start Date and Time + 1
Duration (Minute)	AE Resolution Date and Time – AE Onset Date and Time + 1
Drug-related	If relationship is marked 'YES' on eCRF

10.4. Appendix 4: Data Display Standards & Handling Conventions

10.4.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions			
Part1 (Scedule1)			
RandAll NG		**Data Displays for Reporting**	
Code	**Description**	**Description**	**Order [1]**
P	Placebo, Fed	Placebo, Fed	1
X1	GSK1325756H 10 mg, Fed	GSK1325756H 10 mg, Fed	2
X2	GSK1325756H 50 mg, Fed	GSK1325756H 50 mg, Fed	3
X3	GSK1325756H 100 mg, Fed	GSK1325756H 100 mg, Fed	4
Part2 (Scedule2)			
X2	GSK1325756H 50 mg, Fed	GSK1325756H 50 mg, Fed	1
X4	GSK1325756H 50 mg, Fasted	GSK1325756H 50 mg, Fasted	2

NOTES:

1. Order in which treatments are to be presented in Listings. Note that the order in which treatments are to be presented in Tables, active treatment (X1, X2, X3 in Part 1, X2, X4 in Part 2) is shown in the first and placebo (P in Part 1) in the second.

10.4.2. Sequence group Display Descriptors

Sequence Group Descriptions			
RandAll NG		**Data Displays for Reporting**	
Code	**Description**	**Description [1]**	**Order**
A	X1/X2/P	A	1
B	X1/P/X3	B	2
C	P/X2/X3	C	3
D	X2/X4	D	4
E	X4/X2	E	5

NOTES:

1. Footnote will be added in displays as follows.
   A: 10mg (Fed) / 50mg (Fed) / Placebo (Fed), B: 10mg (Fed) / Placebo (Fed) / 100mg (Fed), C: Placebo (Fed) / 50mg (Fed) / 100mg (Fed), D: 50mg (Fed) / 50mg (Fasted) , E: 50mg (Fasted) / 50mg (Fed)

10.4.3. Baseline Definition & Derivations

10.4.3.1. Baseline Definitions

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Day -1	Day 1 (Pre-Dose)	
Safety				
12 Lead ECG & Vital Signs	X	X	X	Day 1 (Pre Dose)
Haematology	X	X		Day -1
Clinical Chemistry	X	X		Day -1

NOTES:

- The baseline will be defined for each period in Part 1 and Part 2.

10.4.3.2. Derivations and Handling of Missing Baseline Data

Definition	Reporting Details
Change from Baseline	= Post-Dose Visit Value – Baseline

NOTES:

- Unless otherwise specified, the baseline definitions specified in Section 10.4.3.1 Baseline Definitions will be used for derivations for endpoints / parameters and indicated on summaries and listings.
- Unless otherwise stated, if baseline data is missing no derivation will be performed and will be set to missing.
- The baseline definition will be footnoted on all change from baseline displays.

10.4.4. Reporting Process & Standards

Reporting Process	
Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: uk1salx00175
HARP Area	Part1:/arenv/arprod/gsk1325756/mid206817/primary_01 Part2:/arenv/arprod/gsk1325756/mid206817/final_01
QC Spreadsheet	Part1:/arenv/arprod/gsk1325756/mid206817/primary_01/qc Part2:/arenv/arprod/gsk1325756/mid206817/final_01/qc
Analysis Datasets	
• Analysis datasets will be created according to GSK IDSL A&R dataset standards	
Generation of RTF Files	
• N/A	

Reporting Standards	
General	
• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated: o 4.03 to 4.23: General Principles o 5.01 to 5.08: Principles Related to Data Listings o 6.01 to 6.11: Principles Related to Summary Tables o 7.01 to 7.13: Principles Related to Graphics	
Formats	
• All data will be reported according to the actual treatment the subject received unless otherwise stated. • GSK IDSL Statistical Principles (4.24) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected. • Numeric data will be reported at the precision collected on the eCRF. • The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP's.	
Planned and Actual Time	
• Reporting for tables, figures and formal statistical analyses: o Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated. o 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: o Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1). o Unscheduled or unplanned readings will be presented within the subject's listings. o Visits outside the protocol defined time-windows (i.e. recorded as protocol deviations) will be included in listings but omitted from figures, summaries and statistical analyses.	
Unscheduled Visits	
• Unscheduled visits will not be included in summary tables. • Unscheduled visits will not be included in 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)

Reporting Standards	
Reporting of Pharmacokinetic Parameters	
Descriptive Summary Statistics. (Log Transformed)	N, n, geometric mean, 95% CI of geometric mean, standard deviation (SD) of logged data and between geometric coefficient of variation (CVb/w (%)) will be reported. CVb (%) = SQRT (exp(SD^2) - 1) * 100 (SD = SD of loge-transformed data) CVw (%) =SQRT (exp(MSE) - 1) * 100 (MSE = mean square error from mixed effect model of loge-transformed data).
Parameters Not Being Log Transformed	tmax, tlag, tlast
Parameters Not Being Summarised	The following PK parameters will not be summarised but listed: %AUCex, lambda_z, lambda_z_lower, lambda_z_upper, #pts, R2.
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

10.5. Appendix 5: Derived and Transformed Data

10.5.1. General

Multiple Measurements at One Time Point

- Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented.
- If there are two values within a time window 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.
- Subjects having both High and Low values for Normal Ranges at any post-baseline visits 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 start of dosing date:
  - Ref Date = Missing → Study Day = Missing
  - Ref Date < of start of dosing Date → Study Day = Ref Date – of start of dosing Date
  - Ref Data ≥ of start of dosing Date → Study Day = Ref Date – (of start of dosing Date) + 1

10.5.2. Study Population

Demographics

Age

- GSK standard IDSL algorithms will be used for calculating age where birth date will be imputed as:
  - 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'.
- Reference will be Randomization date for Part 1 and Part 2
- Reference date for calculation of age at screening will be from visit 1 (Screening visit) date, however this will be from screen failure date for a screen failure subject.
- Analysis age group will be categorized (Years):

  <=18, 19-64, 65-74, >=75
- Age will be categorized for EudraCT:

  <=17 years, 18-64 years, 65-84 years, >=85 years

Body Mass Index (BMI)

- Calculated as Weight (kg) / [Height $(m)^2$]

10.5.3. Safety

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

Laboratory Assessments	
Haematology	Platelet Count, RBC Count, Haemoglobin, Hematocrit, RBC Indices (MCV, MCH, %Reticulocytes), WBC count with Differential (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils)
Clinical Chemistry	BUN, Creatinine, Glucose (fasting), Uric acid, HDL-cholesterol, Amylase, Potassium, Sodium, Calcium, TG, LDH, Chloride, Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline phosphatise, Total Cholesterol, GGT, Phosphorus, Total and direct bilirubin, Total Protein, Albumin, LDL-cholesterol, CK (CPK)
Routine Urinalysis	• Specific gravity, pH (assessed by dipstick) • glucose, protein, blood, ketones, bilirubin, urobilinogen by dipstick • Microscopic examination (if blood or protein is abnormal)

ECG (12-lead ECG)
ECG findings, ECG values (Heart rate, PR interval, QRS duration, QT interval and QTcF intervals)

Vital Signs
Pulse rate, Blood pressure (Systolic, Diastolic),Temperature

Ophthalmic examinations
Ophthalmic examinations

10.5.4. Pharmacokinetics

PK Parameters
• If one or more non-quantifiable (NQ) values occur in a profile before the first measurable concentration, they will be assigned a value of zero concentration. For linear plots, zero concentration value(s) before the first measurable concentration will be included in the plot. For log-linear plots, zero concentration value(s) before the first measurable concentration will be assigned a missing value. • If a single NQ value occurs between measurable concentrations in a profile, the NQ should generally be set to missing in the derivation of pharmacokinetic parameters, statistical analysis, and the individual subject plots. • If two or more NQ values occur in succession between measurable concentrations, the profile will be deemed to have terminated at the last measurable concentration prior to these NQs. For the purpose of individual subject plots, these NQs will be set to 0, and the subsequent measurable concentrations will be retained. For the derivation of pharmacokinetic parameters, these NQs and any subsequent measurable concentrations will be set to missing. • NQs which occur after the last measurable concentration will be omitted (set to missing) in the derivation of pharmacokinetic parameters and from the individual subject plots. • Individual's PK parameters reported as 'NC' (Not Calculable) or 'ND' (Not Determined) will be included in listings but omitted (set to missing) from figures, summaries and statistical analyses.

10.6. Appendix 6: Premature Withdrawals & Handling of Missing Data

10.6.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion was defined as a participant has completed all periods of the study including the last visit or the last scheduled procedure (Follow-up) for each period as described in the protocol. • Withdrawn subjects maybe replaced in the study. • All available data from subjects who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

10.6.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o These data will be indicated by the use of a “blank” in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as “Not applicable” and “Not evaluable” are not considered to be missing data and should be displayed as such.

10.6.3. Handling of Partial Dates

Element	Reporting Detail
Concomitant Medications	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: o If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month o 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.

10.6.4. Handling of Missing Data for Statistical Analysis

Element	Reporting Detail
Imputation	• No imputation will be performed for missing data

10.7. Appendix 7: Values of Potential Clinical Importance

10.7.1. Laboratory Values (Healthy Volunteers)

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
While Blood Cell Count (WBC)	$x10^9$/ L		3	20

Clinical Chemistry				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Albumin	G/L		30	
Calcium	mmol/L		2	2.75
Creatinine	µmol/L	Δ from BL		↑ 44.2
Glucose	mmol/L		3	9
Phosphorus	mmol/L		0.8	1.6
Potassium	mmol/L		3	5.5
Sodium	mmol/L		130	150

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

10.7.2. ECG (Healthy Volunteers)

ECG Parameter	Units	Clinical Concern Range	
		Lower	Upper
Absolute			
Absolute QTc Interval	msec		> 450 [1]
Absolute PR Interval	msec	< 110 [1]	> 220 [1]
Absolute QRS Interval	msec	< 75 [1]	> 110 [1]
Change from Baseline			
Increase from Baseline QTc	msec	> 60 [1]	

NOTES:
1. Represent standard ECG values of PCI for HV studies

10.7.3. Vital Signs (Healthy Volunteers)

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

10.8. Appendix 8 - Abbreviations & Trade Marks

10.8.1. Abbreviations

Abbreviation	Description
AE	Adverse Event
A&R	Analysis and Reporting
AUC(0-24)	Area under the concentration-time curve from pre-dose to 24 hours
AUC(0-inf)	Area under the concentration-time curve from time zero (pre-dose) extrapolated to infinite time
AUC(0-t)	Area under the concentration-time curve from time zero (pre-dose) to last time of quantifiable concentration within a subject across all treatments
BMI	Body mass index
BP	Blood pressure
CI	Confidence Interval
Cmax	Maximum observed concentration
CSR	Clinical Study Report
CVb	Coefficient of variation (Between)
CVw	Coefficient of Variation (Within)
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
GSK	GlaxoSmithKline
HR	Heart rate
hrs	Hours
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
LLN	Lower Limit of Normal
LLQ	Lower Limit of Quantification
MedDRA	Medical Dictionary for Regulatory Activities
MG	Milligrams
msec	Milliseconds
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
RAP	Reporting and Analysis Plan
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event(s)
SAS	Statistical Analysis Software
SD	Standard Deviation
ULN	Upper Limit of Normal
SOP	Standard Operation Procedure
t1/2	Terminal half-life
Tmax	Time to maximum observed blood drug concentration
TFL	Tables, Figures & Listings

10.8.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
None

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS
WinNonlin

10.9. Appendix 9: List of Data Displays

10.9.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.14	N/A
Safety	2.1 to 2.34	N/A
Pharmacokinetic	3.1 to 3.8	3.1 to 3.10
Section	**Listings**	
ICH Listings	1 to 70	
Other Listings	N/A	

10.9.2. Mock Example Referencing

Non IDSL specifications will be referenced as indicated and if required an example mock-up displays provided in Appendix 10: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln

NOTES:

- Indicate display is Non-Standard in the 'IDSL/TST ID / Example Shell' or 'Programming Notes' column.

10.9.3. Deliverable [Priority]

Delivery [Priority] [1]	Description
PR [1]	Primary Report (Part 1 only)
SAC [2]	Statistical Analysis Complete (Part 2 only)

NOTES:

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

10.9.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	Safety	CP_ES1	Summary of Subject Disposition (Part 1)	Completed or withdrawn and the reason for withdrawal.	PR [1]
1.2.	Safety	ES4	Summary of Subject Disposition at each period (Part 1)	Completed or withdrawn at each period.	PR [1]
1.3.	Safety	CP_ES1	Summary of Subject Disposition (Part 2)	Completed or withdrawn and the reason for withdrawal.	SAC [2]
1.4.	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure	The number (%) of Randomized or screening failure subjects as the screening status, and the reason for screening failure.	SAC [2]
Protocol Deviation					
1.5.	Safety	DV1	Summary of Important Protocol Deviations (Part 1)	Data is from DV1 dataset.	PR [1]
1.6.	Safety	DV1	Summary of Important Protocol Deviations (Part 2)	Data is from DV1 dataset.	SAC [2]
Population Analysed					
1.7.	Safety	SP1	Summary of Study Populations (Part 1)	Only PK population (Yes or No) is summarized.	PR [1]
1.8.	Safety	SP1	Summary of Study Populations (Part 2)	Only PK population (Yes or No) is summarized.	SAC [2]
Demographic and Baseline Characteristics					
1.9.	Safety	DM3	Summary of Demographic Characteristics (Part 1)		PR [1]
1.10.	Safety	DM3	Summary of Demographic Characteristics (Part 2)		SAC [2]
1.11.	Screened	DM11	Summary of Age Ranges (Part 1)	<=17 years, 18-64 years, 65-84 years, >=85 years	PR [1]

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.12.	Screened	DM11	Summary of Age Ranges (Part 2)	<=17 years, 18-64 years, 65-84 years, >=85 years	SAC [2]
1.13.	Safety	DM5	Summary of Race and Racial Combinations (Part 1)		PR [1]
1.14.	Safety	DM5	Summary of Race and Racial Combinations (Part 2)		SAC [2]

10.9.5. Safety Tables

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 1)		PR [1]
2.2.	Safety	AE5A	Summary of All Adverse Events by Maximum Intensity (Part 1)		PR [1]
2.3.	Safety	AE1	Summary All Drug-Related Adverse Events by System Organ Class and Preferred Term (Part 1)		PR [1]
2.4.	Safety	AE5A	Summary All Drug-Related Adverse Events by Maximum Intensity (Part 1)		PR [1]
2.5.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term (Part 2)		SAC [2]
2.6.	Safety	AE5A	Summary of All Adverse Events by Maximum Intensity (Part 2)		SAC [2]
2.7.	Safety	AE1	Summary All Drug-Related Adverse Events by System Organ Class and Preferred Term (Part 2)		SAC [2]
2.8.	Safety	AE5A	Summary All Drug-Related Adverse Events by Maximum Intensity (Part 2)		SAC [2]
Laboratory: Chemistry					
2.9.	Safety	LB1	Summary of Chemistry (Part 1)		PR [1]
2.10.	Safety	LB1	Summary of Chemistry Changes from Baseline (Part 1)		PR [1]
2.11.	Safety	LB4	Summary of Chemistry Data Shifts from Baseline with Respect to the Normal Range (Part 1)		PR [1]
2.12.	Safety	LB1	Summary of Chemistry (Part 2)		SAC [2]
2.13.	Safety	LB1	Summary of Chemistry Changes from Baseline (Part 2)		SAC [2]

Safety: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.14.	Safety	LB4	Summary of Chemistry Data Shifts from Baseline with Respect to the Normal Range (Part 2)		SAC [2]
Laboratory: Hematology					
2.15.	Safety	LB1	Summary of Hematology (Part 1)		PR [1]
2.16.	Safety	LB1	Summary of Hematology Changes from Baseline (Part 1)		PR [1]
2.17.	Safety	LB4	Summary of Hematology Data Shifts from Baseline with Respect to the Normal Range (Part 1)		PR [1]
2.18.	Safety	LB1	Summary of Hematology (Part 2)		SAC [2]
2.19.	Safety	LB1	Summary of Hematology Changes from Baseline (Part 2)		SAC [2]
2.20.	Safety	LB4	Summary of Hematology Data Shifts from Baseline with Respect to the Normal Range (Part 2)		SAC [2]
Laboratory: Urinalysis					
2.21.	Safety	UR3b	Summary of Urinalysis Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen) (Part 1)		PR [1]
2.22.	Safety	LB1	Summary of Urinalysis Data (Specific Gravity and pH) (Part 1)		PR [1]
2.23.	Safety	UR3b	Summary of Urinalysis Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen) (Part 2)		SAC [2]
2.24.	Safety	LB1	Summary of Urinalysis Data (Specific Gravity and pH) (Part 2)		SAC [2]
ECG					
2.25.	Safety	EG1	Summary of ECG Findings (Part 1)		PR [1]
2.26.	Safety	EG2	Summary of ECG Value (Part 1)		PR [1]
2.27.	Safety	EG2	Summary of Change from Baseline in ECG Values (Part 1)		PR [1]
2.28.	Safety	EG1	Summary of ECG Findings (Part 2)		SAC [2]

Safety: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.29.	Safety	EG2	Summary of ECG Value (Part 2)		SAC [2]
2.30.	Safety	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 2)		SAC [2]
Vital Signs					
2.31.	Safety	VS1	Summary of Vital Signs (Part 1)		PR [1]
2.32.	Safety	VS1	Summary of Change from Baseline in Vital Signs (Part 1)		PR [1]
2.33.	Safety	VS1	Summary of Vital Signs (Part 2)		SAC [2]
2.34.	Safety	VS1	Summary of Change from Baseline in Vital Signs (Part 2)		SAC [2]

10.9.6. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part 1					
3.1.	PK	PK01: pkct1	Summary of GSK1325756 Blood Concentration (Part 1)		PR [1]
3.2.	PK	PK03: pkpt1	Summary of GSK1325756 Pharmacokinetic Parameters (non-transformed) (Part 1)		PR [1]
3.3.	PK	PK05: pkpt3	Summary of GSK1325756 Pharmacokinetic Parameters (loge-transformed) (Part 1)		PR [1]
3.4.	PK	Study Specific (PK_T1)	Analysis of Power Model Analysis for GSK1325756 Dose Proportionality of Pharmacokinetic Parameters (AUC(0-t), Cmax) (Part 1)	Parameter, Effect, n, Point estimate of Slope, SE, 90% CI	PR [1]
Part 2					
3.5.	PK	PK01: pkct1	Summary of GSK1325756 Blood Concentration (Part 2)		SAC [2]
3.6.	PK	PK03: pkpt1	Summary of GSK1325756 Pharmacokinetic Parameters (non-transformed) (Part 2)		SAC [2]
3.7.	PK	PK05: pkpt3	Summary of GSK1325756 Pharmacokinetic Parameters (loge-transformed) (Part 2)		SAC [2]
3.8.	PK	Study Specific (PK_T2)	Analysis of food effect for Pharmacokinetic Parameters (AUC(0-t), Cmax) (Part 2)	n, Geometric mean of Fasted and Fed, ratio (Fasted/Fed), 90% CI and CVw(%)	SAC [2]

10.9.7. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part 1					
3.1.	PK	PK16b: pkcf1x	Individual GSK1325756 Blood Concentration-Time Plots by Subject (Part 1)	By Subject (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	PR [1]
3.2.	PK	PK24: pkcf6	Individual GSK1325756 Blood Concentration-Time Plots by treatment (Part 1)	By Treatment (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	PR [1]
3.3.	PK	Study Specific (PK_F1)	Mean (+SD) GSK1325756 Blood Concentration-Time Plots (Part 1)	Unit of x-axis is Hours	PR [1]
3.4.	PK	PK18: pkcf3	Median GSK1325756 Blood Concentration-Time Plots (Part 1)	Unit of x-axis is Hours	PR [1]
3.5.	PK	PK28	Plot of GSK1325756 Treatment and PK Parameters (AUC (0-t), Cmax) (Part 1)		PR [1]
Part 2					
3.6.	PK	PK16b: pkcf1x	Individual GSK1325756 Blood Concentration-Time Plots by Subject (Part 2)	By Subject (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	SAC [2]
3.7.	PK	PK24: pkcf6	Individual GSK1325756 P Blood Concentration-Time Plots by Treatment (Part 2)	By Treatment (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	SAC [2]
3.8.	PK	Study Specifics (PK_F1)	Mean (+SD) GSK1325756 Blood Concentration-Time Plots (Part 2)	Unit of x-axis is Hours	SAC [2]
3.9.	PK	PK18: pkcf3	Median GSK1325756 Blood Concentration-Time Plots (Part 2)	Unit of x-axis is Hours	SAC [2]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.10.	PK	PK28	Plot of GSK1325756 Treatment and PK Parameters (AUC(0-t), Cmax) (Part 2)		SAC [2]

10.9.8. ICH Listings

Note: 'Inv.' in the standard displays will be replaced to 'Centre'.

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	Screening Failure	ES7	Listing of Reasons for Screen Failure		PR [1]
2.	Safety	CP-ES10x	Listing of Reasons for Study Withdrawal (Part 1)		PR [1]
3.	Safety	CP-ES10x	Listing of Reasons for Study Withdrawal (Part 2)		SAC [2]
4.	Safety	BL2	Listing of Subjects for Whom the Treatment Blind was Broken (Part 1)		PR [1]
5.	Safety	TA2	Listing of Planned and Actual Treatments (Part 1)		PR [1]
6.	Safety	TA2	Listing of Planned and Actual Treatments (Part 2)		SAC [2]
Protocol Deviations					
7.	Safety	DV2	Listing of Important Protocol Deviations (Part 1)	Column for Treatment Sequence/Period of Protocol deviation will be displayed after Centre./Subj. Period day will be displayed in the same column of Date of Deviation/Study day.	PR [1]
8.	Safety	DV2	Listing of Important Protocol Deviations (Part 2)		SAC [2]
9.	Screened	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations		SAC [2]
Populations Analysed					

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
10.	Safety	Study Specifics (POP_L1)	Listing of Subjects Excluded from PK Population (Part 1)		PR [1]
11.	Safety	Study Specifics (POP_L1)	Listing of Subjects Excluded from PK Population (Part 2)		SAC [2]
Demographic and Baseline Characteristics					
12.	Safety	DM4	Listing of Demographic Characteristics (Part 1)	"Age at Screening" is added.	PR [1]
13.	Safety	DM4	Listing of Demographic Characteristics (Part 2)	"Age at Screening" is added.	SAC [2]
14.	Screening Failure	DM4	Listing of Demographic Characteristics for Screening Failure Subjects		SAC [2]
15.	Safety	DM10	Listing of Race (Part 1)		PR [1]
16.	Safety	DM10	Listing of Race (Part 2)		SAC [2]
17.	Screening Failure	DM10	Listing of Race for Screening Failure Subjects	Treatment is not needed to display.	SAC [2]
Medical Conditions and Concomitant Medications					
18.	Screened	MH3	Listing of Medical Conditions		PR [1]
19.	Safety	CM5	Listing of Concomitant Medications (Part 1)		PR [1]
20.	Safety	CM5	Listing of Concomitant Medications (Part 2)		SAC [2]
Exposure and Treatment Compliance					
21.	Safety	EX4	Listing of Exposure Data (Part 1)		PR [1]
22.	Safety	EX4	Listing of Exposure Data (Part 2)		SAC [2]
Meal					
23.	Safety	CP_ML1x	Listing of Dosing Times, Meal Start and End Times on Fed Treatment Days (Part 1)		PR [1]

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
24.	Safety	CP_ML1x	Listing of Dosing Times, Meal Start and End Times on Fed Treatment Days (Part 2)		SAC [2]
Adverse Events					
25.	Safety	AE9CP	Listing of All Adverse Events (Part 1)		SAC [1]
26.	Safety	AE9CP	Listing of All Adverse Events (Part 2)		SAC [2]
27.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events (Part 1)		PR [1]
28.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events (Part 2)		SAC [2]
29.	Screened	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text		SAC [2]
Serious and Other Significant Adverse Events					
30.	Safety	AE9CP	Listing of Serious Adverse Events (Part 1)		PR [1]
31.	Safety	AE9CP	Listing of Serious Adverse Events (Part 2)		SAC [2]
32.	Screening Failure	AE9CP	Listing of Serious Adverse Events for Screening Failure Subject	Treatment is not needed to display.	SAC [2]
33.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study (Part 1)		PR [1]
34.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study (Part 2)		SAC [2]
Laboratory (Chemistry Data)					
35.	Safety	CP_LB6	Listing of All Chemistry Data (Part 1)	Change from baseline is included.	PR [1]
36.	Safety	CP_LB6	Listing of All Chemistry Data (Part 2)	Change from baseline is included.	SAC [2]

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
37.	Safety	CP_LB6	Listing of All Chemistry Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]
38.	Safety	CP_LB6	Listing of All Chemistry Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Laboratory (Hematology Data)					
39.	Safety	CP_LB6	Listing of All Hematology Data (Part 1)	Change from baseline is included.	PR [1]
40.	Safety	CP_LB6	Listing of All Hematology Data (Part 2)	Change from baseline is included.	SAC [2]
41.	Safety	CP_LB6	Listing of All Hematology Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]
42.	Safety	CP_LB6	Listing of All Hematology Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Laboratory (Urinalysis Data)					
43.	Safety	UR2b	Listing of All Urinalysis Dipstick Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen) (Part 1)	Time will be displayed after 'Date'.	PR [1]
44.	Safety	CP_LB6	Listing of Urinalysis Data (Gravity and pH) (Part 1)		PR [1]
45.	Safety	UR2b	Listing of All Urinalysis Dipstick Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen) (Part 2)	Time will be displayed after 'Date'.	SAC [2]
46.	Safety	CP_LB6	Listing of Urinalysis Data (Gravity and pH) (Part 2)		SAC [2]
Hepatobiliary (Liver)					
47.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 1)	Column for Treatment/Period will be displayed after the column for Age/Sex/Race Detail.	PR [1]
48.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 2)		SAC [2]

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
49.	Safety	MH3	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 1)		PR [1]
50.	Safety	MH3	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 2)		SAC [2]
51.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 1)		PR [1]
52.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 2)		SAC [2]
ECG					
53.	Safety	CP_EG4	Listing of All ECG Values (Part 1)		PR [1]
54.	Safety	CP_EG4	Listing of All ECG Values (Part 2)		SAC [2]
55.	Safety	CP_EG4	Listing of Change from Baseline in ECG Values (Part 1)		PR [1]
56.	Safety	CP_EG4	Listing of Change from Baseline in ECG Values (Part 2)		SAC [2]
57.	Safety	CP_EG6	Listing of ECG Findings (Part 1)		PR [1]
58.	Safety	CP_EG6	Listing of ECG Findings (Part 2)		SAC [2]
59.	Safety	CP_EG4	Listing of All ECG Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]
60.	Safety	CP_EG4	Listing of All ECG Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Vital Signs					
61.	Safety	CP_VS5	Listing of All Vital Signs (Part 1)	Change from baseline is included.	PR [1]
62.	Safety	CP_VS5	Listing of All Vital Signs (Part 2)	Change from baseline is included.	SAC [2]
63.	Safety	CP_VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
64.	Safety	CP_VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Others					
65.	Safety	Study Specifics (SAFE_L1)	Listing of Ophthalmic examinations (Part 1)		PR [1]
66.	Safety	Study Specifics (SAFE_L1)	Listing of Ophthalmic examinations (Part 2)		SAC [2]
PK					
67.	PK	PK08: pkcl1x	Listing of GSK1325756 Blood Concentration (Part 1)		PR [1]
68.	PK	PK08: pkcl1x	Listing of GSK1325756 Blood Concentration (Part 2)		SAC [2]
69.	PK	Study Specifics (PK_L1)	Listing of GSK1325756 Pharmacokinetic Parameters (Part 1)		PR [1]
70.	PK	Study Specifics (PK_L1)	Listing of GSK1325756 Pharmacokinetic Parameters (Part 2)		SAC [2]

10.10. Appendix 10: Example Mock Shells for Data Displays

10.10.1. Study population

Example CP_ES1 (XO studies)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)
Completion Status	
Completed	50 (50%)
Withdrawn	50 (50%)
Primary*/subreason^ for withdrawal	
Adverse event	10 (10%)
Elevated ALT levels	2 (2%)
Severe vomiting	5 (5%)
Lack of efficacy	0
Protocol deviation	0
Subject reached stopping criteria	10 (10%)
CD4 levels below continuation threshold	10 (10%)
Study closed/terminated	0
Lost to follow-up	0
Investigator discretion	0
Withdrew consent	30 (30%)
Burden of procedures	10 (10%)
Pursue alternative treatment	20 (20%)
Other	0

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: ES4
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Phase		Not Randomized (N=10)	Placebo (N=100)	Curitol 10mg (N=100)
Screening	Entered	10(100%)	100(100%)	100(100%)
	Completed	0	100(100%)	100(100%)
	Withdrawn	10(100%)	0	0
Double blind	Entered		100(100%)	100(100%)
	Completed		50 (50%)	50 (50%)
	Withdrawn		50 (50%)	50 (50%)
Follow-up	Entered		50 (50%)	50 (50%)
	Completed		50 (50%)	50 (50%)
	Withdrawn		0	0

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: ES6 (SF for CONSORT)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Screened Subjects (N=100)
Screening Status	
ENROLLED	50 (50%)
FAILED	50 (50%)
Reason(s) for Failure	
DID NOT MEED INCLUSION/EXCLUSION CRITERIA	25 (25%)
STUDY CLOSED/TERMINATED	5 (5%)
PHYSICIAN DECISION	10 (10%)
PROTOCOL DEVIATION	10 (10%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_ES10x
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Treatment Sequence/ Period of Withdrawal	Last Treatment Before Withdrawal	Date of Withdrawal/ Study Day of Withdrawal/ Period Day of Withdrawal	Primary Reason for Withdrawal	Subreason for Withdrawal	Date of Last Contact/ Study Day of Last Contact
xxxxxx/ xxx	PAB/ Period 1	A	DDMMMYYYY/ xx/ x	*Adverse Event*	*Elevated ALT levels*	DDMMMYYYY/ x
xxxxxx/ xxx	BPC/ Period 2	B	DDMMMYYYY/ x/ x			DDMMMYYYY/ x

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: ES7 (for SF)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Date of Screen Failure	Reason Term(s) for Screen Failure
xxxxxx/ xxx	DDMMMYYYY	*DID NOT MEED INCLUSION/EXCLUSION CRITERIA*
xxxxxx/ xxx	DDMMMYYYY	*PHYSICIAN DECISION* *DID NOT MEED INCLUSION/EXCLUSION CRITERIA*
xxxxxx/ xxx	DDMMMYYYY	*DID NOT MEED INCLUSION/EXCLUSION CRITERIA*
	DDMMMYYYY	*PHYSICIAN DECISION*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: BL2 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Sequence/ Treatment when Blind broken	Date Blind Broken	Time Blind Broken	Study Day	Period Day	Reason
xxxxxx	xxxx	PBC/ Treatment A	DDMMMYYYY	hh:ss	xx	*x*	*Other: PT REQUESTED TO KNOW FOR MEDICAL REASONS*
xxxxxx	xxxx	APC/ Treatment C	DDMMMYYYY	hh:ss	xx	*xx*	*Medical Emergency*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: TA2 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Country: Canada
Centre ID: PPD
Investigator: PPD

Subject ID	Randomization Number	Randomization Date	Period	Randomization Treatment	Actual Treatment	Deviation
PPD		01JAN08	1	Curital 10mg	Curital 10mg	
			2	Placebo	Placebo	
			3	Placebo	No treatment	Y
			4	Curital 20mg	No treatment	Y
		03JAN08	1	Curital 20mg	Curital 20mg	
			2	Placebo	Placebo	
			3	Curital 10mg	Curital 10mg	
			4	Placebo	Placebo	
		01FEB08	1	Placebo	Placebo	
			2	Curital 10mg	Curital 10mg	
			3	Placebo	Placebo	
			4	Curital 20mg	Curital 10mg	Y
		15FEB08	1	Curital 10mg	Curital 10mg	
			2	Placebo	Placebo	
			3	Placebo	Placebo	
			4	Curital 10mg	Curital 20mg	Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: IE4 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Treatment sequence	Type	Criterion
xxxxxx	xxx	APC	INCLUSION	*Is the subject 18 years of age or older?*
xxxxxx	xxx	PAB	EXCLUSION	*Has the subject had an asthma episode(s) requiring intubation associated with hypercapnia, respiratory arrest, or hypoxic seizures within 12 months prior to Visit 1?*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DV1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Category/Coded Term	Total (N=200)
Any important protocol deviations	60 (30%)
Informed consent	10 (5%)
WRONG INFORMED CONSENT/ASSENT VERSION SIGNED	10 (5%)
Eligibility criteria not met	14 (7%)
Not withdrawn after developing withdrawal criteria	18 (9%)
Not discontinued from study treatment	10 (5%)
Not withdrawn from study	8 (4%)
EXCLUDED MEDICATION, VACCINE OR DEVICE	4 (2%)
MEDICATION, EXCLUDED BY THE PROTOCOL, WAS ADMINISTERED	4 (2%)
Assessment or time point completion	2 (1%)
OUT OF WINDOW EFFICACY ASSESSMENT	2 (1%)
WRONG STUDY TREATMENT/ADMINISTRATION/DOSE	4 (2%)
STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	2 (1%)
EXPIRED STUDY TREATMET ADMINISTERED	2 (1%)
Failure to report SAFETY EVENTS PER Protocol	8 (5%)
SAE NOT REPORTED WITHIN THE EXPECTED TIME FRAME	4 (2%)
LIVER FUNCTION ABNORMALITIES PER PROTOCOL	4 (2%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DV2
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

				Deviation Requires Exclusion from		
Site Id./	Date of Deviation/	Category/ Coded Term	Term	Intent to Treat Population	Safety Population	Per Protocol Population
PPD	PPD 28	ILURE TO REPORT SAFETY EVENTS PER PROTOCOL / SAE NOT REPORTED WITHIN THE EXPECTED TIME FRAME	SAE OF FEVER WITH SEVERE CHILLS REQUIRING IV HYDRATION WAS NOT REPORTED TO GSK WITHIN 24 HOURS.			
	PPD 31	ELIGIBILITY CRITERIA NOT MET / ELIGIBILITY CRITERIA NOT MET	SUBJECT SCREEN FAILED BUT WAS RANDOMIZED IN ERROR.		Y	Y
	PPD 1	WRONG STUDY TREATMENT/ ADMINISTRATION/DOSE / STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	SUBJECT MISSED WEEK 8 TREATMENT			
	PPD 2	WRONG STUDY TREATMENT/ ADMINISTRATION/DOSE / STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	INTERRUPTION OF IP FOR GREATER THAN 20 PERCENT OF TIME			Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: SP1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Population	No Treatment (N=50)	Placebo (N=xxx)	Treatment 1 (N=200)	Treatment 2 (N=250)	Total (N=500)
Screened	50 (100%)	xx (xxx%)	200 (100%)	250 (100%)	500 (100%)
Enrolled	10 (20%)	xx (xxx%)	200 (100%)	250 (100%)	460 (92%)
Randomized	5 (10%)	xx (xx%)	200 (100%)	250 (100%)	455 (91%)
Safety		xx (xx%)	195 (98%)	245 (98%)	440 (88%)
PK		xx (xx%)	200 (100%)	250 (100%)	455 (91%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: POP_L1
Protocol: GSK123456
Population: xxxxx (Randomised subjects)

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Treatment sequence	PK population
xxxxxx/ xxx	ABC	Y
xxxxxx/ xxx	CBA	Y
xxxxxx/ xxx	BAC	Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM3 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)
Sex	
n	100
F	50 (50%)
M	50 (50%)
Age (YEARS)[1]	
n	100
Mean	50.0
SD	10.00
Median	50.0
Min.	18
Max.	65
Age Group(YEARS)[1]	
<=18	5 (5%)
19-64	50 (50%)
>=65	45 (45%)
Ethnicity	
n	100
HISPANIC OR LATINO	10 (10%)
NOT HISPANIC OR LATINO	90 (90%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM3 (continued)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)	
Race Detail		
AMERICAN INDIAN OR ALASKA NATIVE	1	(1%)
ASIAN - CENTRAL/SOUTH ASIAN HERITAGE	3	(3%)
ASIAN - EAST ASIAN HERITAGE	4	(4%)
ASIAN - JAPANESE HERITAGE	3	(3%)
ASIAN - SOUTH EAST ASIAN HERITAGE	1	(1%)
BLACK OR AFRICAN AMERICAN	2	(2%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	59	(59%)
WHITE - ARABIC/NORTH AFRICAN HERITAGE	26	(26%)
WHITE - WHITE/CAUSASIAN/EUROPEAN HERITAGE	1	(1%)
MIXED ASIAN RACE	1	(1%)
MIXED WHITE RACE	1	(1%)
MULTIPLE	1	(1%)
Height (cm)		
n	100	
Mean	150.0	
SD	10.00	
Median	50.0	
Min.	18	
Max.	65	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM3 (continued)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)
Weight (kg)	
n	100
Mean	50.0
SD	10.00
Median	50.0
Min.	18
Max.	65
Options (units)	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM4 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Treatment Sequence	Partial Date of Birth	Age (YEARS) [1]	Sex	Ethnicity	Height (cm)	Weight (kg)	Option (unit)
xxxxxx/ xxx	ABC	--MMYYYY	xx	*F*	*HISPANIC OR LATINO*	xxx	xx	
xxxxxx/ xxx	BCA	--MMYYYY	xx	*M*	*NOT HISPANIC OR LATINO*	xxx	xx	
xxxxxx/ xxx	CAB	----YYYY	xx	*M*	*NOT HISPANIC OR LATINO*	xxx	xx	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM5
Protocol: GSK123456
Population: xxxxx

Table x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

		Treatment A (N=XXX)		Treatment B (N=XXX)		Total (N=XXX)	
Race	n	100		100		200	
	African American/African Heritage	30	(30%)	30	(30%)	60	(30%)
	American Indian or Alaskan Native	0		0		0	
	Asian	15	(15%)	15	(15%)	30	(15%)
	Central/South Asian Heritage	3	(3%)	3	(3%)	6	(3%)
	Japanese/East Asian Heritage/South East Asian Heritage	11	(11%)	11	(11%)	22	(11%)
	Mixed Asian Heritage	1	(1%)	1	(1%)	2	(1%)
	Native Hawaiian or other Pacific Islander	10	(10%)	10	(10%)	20	(10%)
	White	35	(35%)	35	(35%)	70	(35%)
	Native Hawaiian or other Pacific Islander & American Indian or Alaskan Native	2	(2%)	2	(2%)	4	(4%)
	White & African American/African Heritage	3	(3%)	3	(3%)	6	(3%)
	White & Asian	5	(5%)	5	(5%)	10	(5%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM11
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	No Treatment (N=1)	Total (N=201)
Age Ranges [1]		
In utero	0	4 (2%)
Preterm newborn infants (gestational age <37 weeks)	0	2 (1%)
Newborns (0-27 days)	0	6 (3%)
Infants and toddlers (28 days-23 months)	0	8 (4%)
Children (2-11 years)	0	6 (3%)
Adolescents (12-17 years)	0	2 (1%)
Adult (18-64 years)	0	118 (59%)
>=65-84 years	0	52 (26%)
>=85 years	1 (100%)	3 (1%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM10 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Treatment sequence	Race	Race Detail
xxxxxx	xxx	ABC	*BLACK OR AFRICAN AMERICAN*	*BLACK OR AFRICAN AMERICAN*
	xxx	BCA	*Mixed race*	*ASIAN – EAST ASIAN HERITAGE* *ASIAN – JAPANESE HERITAGE*
	xxx	CAB	*WHITE – ARABIC/NORTH AFRICAN HERITAGE*	*WHITE – ARABIC/NORTH AFRICAN HERITAGE*
	xxx	ABC	*WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAGE*	*WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAGE*
xxxxxx	xxx	ABC	*Mixed race*	*WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAG* *ASIAN – JAPANESE HERITAGE*
	xxx	BCA	*NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER*	*NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER*
	xxx	CAB	*BLACK OR AFRICAN AMERICAN*	*BLACK OR AFRICAN AMERICAN*
	xxx	ABC	*WHITE - ARABIC/NORTH AFRICAN HERITAGE*	*WHITE - ARABIC/NORTH AFRICAN HERITAGE*
xxxxxx	xxx	BCA	*AMERICAN INDIAN OR ALASKA NATIVE*	*AMERICAN INDIAN OR ALASKA NATIVE*
	xxx	CAB	*Mixed race*	*BLACK OR AFRICAN AMERICAN* *WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAGE*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: MH3
Protocol: GSK123456 Page 1 of n
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv.	Subject	Treatment Sequence	Classification	Condition	Status
PPD		AB	Hepatobiliary	HEPATITIS A	Current
			Psychiatric	PARANOIA COMBINED WITH MANIA.	Past
		AB	Eye	ASTIGMATISM	Current
		BA	Metabolism and nutrition	RICKETS	Current

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CM5
Protocol: GSK123456
Population: xxxxx

Listing x.x

Inv./ Subj./ Seq	Treat- ment/ Period	ATC Level 1/ Ingredient/ Verbatim Text/ Indication	Dose/ Units/ Freq/ Route	Start Date/Time Study Day/ Period Day	Stop Date/Time Study Day/ Period Day	Started Pre- Trial?	Ongoing Medi- cation?
PPD ABC	Tmt A/ Per 1	Endocrine & metabolic/ Fluticasone propionate/ FLIXOTIDE/ Asthma	2/ MG/ 2XD/ IH	PPD 12:30/ 15/ 7			Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EX4
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Treatment	Start Date/ Start Time of Dose	Stop Date/ Stop Time of Dose	Duration (days)	Dose	Dose Unit	Formulation/ Route	Frequency	Cumulative Dose
xxxxxx	xxx	Treatment A	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Placebo	DDMMMYYYY/ hh:ss		xx	xx	mg	Tablet/ Oral	1xday	
		Treatment C	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
	PPD	Placebo	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Treatment B								
		Treatment C	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Treatment A	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Placebo								
		Treatment B	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_ML1x
Protocol: GSK123456
Population: xxxxx

Listing x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Cohort (Optional)	Investigator OR Centre ID (Optional)	Subj.	Treatment	Meal type (Optional)	Period (Optional) /Visit	Visit Date	Dose Time	Meal Start Time	Meal End Time (Optional)	Meal ended within 20 minutes of Meal Start Time (Optional)	Time from Start of Meal to Dosing (min) (Optional)
1	PPD		50mg GSK123456	High-fat breakfast	Period 2/Day 4	PPD	8:13	7:30	7:41	Y	43
			25mg GSK123456	High-fat breakfast	Period 2/Day 4		8:12	7:28	7:42	Y	44
			10mg GSK123456	High-fat breakfast	Period 2/Day 4		8:10	7:27	7:35	Y	43
2			50mg GSK123456	High-fat breakfast	Period 2/Day 4		8:09	7:28	7:50	N	41
			50mg GSK123456	High-fat breakfast	Period 2/Day 4		8:11	7:30	7:41	Y	41
			25mg GSK123456	High-fat breakfast	Period 2/Day 4		8:09	7:25	7:42	Y	44
			10mg GSK123456	High-fat breakfast	Period 2/Day 4		8:10	7:27	7:36	Y	43

USER ID: directory/program.sas DDMMMYYYY hh:mm

10.10.2. Safety population

Example: AE1
Protocol: GSK123456
Population: xxxxx

Table x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

System Organ Class Preferred Term	Placebo (N=78)	Drug A (N=78)	Drug B (N=78)
ANY EVENT	58 (74%)	64 (82%)	64 (85%)
Gastrointestinal disorders			
Any event	xx (xx%)	xx (xx%)	xx (xx%)
Dyspepsia	xx (xx%)	xx (xx%)	xx (xx%)
Nausea	xx (xx%)	xx (xx%)	xx (xx%)
Vomiting Nos	xx (xx%)	xx (xx%)	xx (xx%)
Constipation	xx (xx%)	xx (xx%)	xx (xx%)
Diarrhoea Nos	xx (xx%)	xx (xx%)	xx (xx%)
Toothache	xx (xx%)	xx (xx%)	xx (xx%)
Abdominal Pain Upper	xx (xx%)	xx (xx%)	xx (xx%)
Dry Mouth	xx (xx%)	xx (xx%)	xx (xx%)
Flatulence	xx (xx%)	xx (xx%)	xx (xx%)
Gastrointestinal Upset	xx (xx%)	xx (xx%)	xx (xx%)
Haemorrhoids	xx (xx%)	xx (xx%)	xx (xx%)
Loose Stools	xx (xx%)	xx (xx%)	xx (xx%)
Abdominal Pain Nos	xx (xx%)	xx (xx%)	xx (xx%)
Faecal Incontinence	xx (xx%)	xx (xx%)	xx (xx%)
Gastritis Nos	xx (xx%)	xx (xx%)	xx (xx%)
Lip Disorder Nos	xx (xx%)	xx (xx%)	xx (xx%)
Lip Dry	xx (xx%)	xx (xx%)	xx (xx%)
Stomach Discomfort	xx (xx%)	xx (xx%)	xx (xx%)
Nervous system disorders			
Any event	xx (xx%)	xx (xx%)	xx (xx%)
Headache	xx (xx%)	xx (xx%)	xx (xx%)
Dizziness	xx (xx%)	xx (xx%)	xx (xx%)
Extrapyramidal Disorder	xx (xx%)	xx (xx%)	xx (xx%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE5A
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treatment: Treatment A (N=200)

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	MODERATE /SEVERE	UNKNOWN	Total
ANY EVENT	30 (15%)	40 (20%)	40 (20%)	80 (40%)	1 (<1%)	151 (76%)
Cardiovascular						
Any Event	20 (10%)	40 (20%)	40 (20%)	80 (40%)	0	140 (70%)
Hypertension	0	20 (10%)	20 (10%)	20 (10%)	0	40 (20%)
Syncope	0	0	0	0	0	0
Hypotension	20 (10%)	0	0	40 (20%)	0	60 (30%)
Nervous system disorders	10 (5%)	0	0	0	1 (<1%)	11 (6%)
Any Event	10 (5%)	0	0	0	1 (<1%)	11 (6%)
Dizziness	10 (5%)	0	0	0	1 (<1%)	11 (6%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: LB1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Test (units)	Treatment	N	Planned Time	n	Mean	SD	Median	Min.	Max.
Alkaline Phosphatase (IU/L)	Trt A	202	Week 8	150	2.1	7.95	1	-25	32
			Week 12	133	0.4	10.05	1	-64	33
			Week 24	55	-1.6	18.22	0	-339	44
	Trt B	220	Week 8	150	2.1	7.95	1	-25	32
			Week 12	133	0.4	10.05	1	-64	33
			Week 24	55	-1.6	18.22	0	-339	44
Alanine Aminotransferase (IU/L)	Trt A	202	Week 8	150	-1.2	16.32	0	-320	38
			Week 12	133	0.7	10.55	1	-64	32
			Week 24	55	-3.3	29.50	0	-235	36
	Trt B	220	Week 8	150	-1.2	16.32	0	-320	38
			Week 12	133	0.7	10.55	1	-64	32
			Week 24	55	-3.3	29.50	0	-235	36

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: LB4
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Test= Alanine Aminotransferase (IU/L), Treatment=Treatment A

Planned Time	N	n	Baseline Value	Time Period Value: High	Normal	Low	Total
Week 1	100	100	High	0	1 (1%)	3 (3%)	4 (4%)
			Normal	10 (10%)	84 (84%)	2 (2%)	96 (96%)
			Low	0	0	0	0
			Total	10 (10%)	85 (85%)	5 (5%)	100 (100%)
Week 4	100	100	High	0	1 (1%)	3 (3%)	4 (4%)
			Normal	10 (10%)	84 (84%)	2 (2%)	96 (96%)
			Low	0	0	0	0
			Total	10 (10%)	85 (85%)	5 (5%)	100 (100%)
Worst Case Post-Baseline	100	100	High	0	1 (1%)	3 (3%)	4 (4%)
			Normal	10 (10%)	84 (84%)	2 (2%)	96 (96%)
			Low	0	0	0	0
			Total	10 (10%)	85 (85%)	5 (5%)	100 (100%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: UR3b
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Test	Period/Planned Relative Time	Result	Treatment A (N=100)	Treatment B (N=100)
Urine General Dipstick	SCREENING/ SCREENING	Positive	30 (30%)	60 (60%)
		Negative	40 (40%)	30 (30%)
		No Result	30 (30%)	10 (10%)
	PERIOD 1/DAY 1	Positive	40 (40%)	50 (50%)
		Negative	30 (30%)	40 (40%)
		No Result	30 (30%)	10 (10%)
Urine Occult Blood (Dipstick)	SCREENING/ SCREENING	None	40 (40%)	40 (40%)
		Trace	25 (25%)	25 (25%)
		1+	10 (10%)	15 (15%)
		2+	0	0
		3+	0	0
		No Result	10 (10%)	20 (20%)
	PERIOD 1/DAY 1	None	40 (40%)	40 (40%)
		Trace	30 (30%)	30 (30%)
		1+	5 (5%)	5 (5%)
		2+	2 (2%)	4 (4%)
		3+	0	0

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EG1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment A (N=157)		Treatment B (N=160)	
Time Period 1				
n	156		160	
Normal	81	(52%)	90	(56%)
Abnormal, not clinically significant	75	(48%)	69	(43%)
Abnormal, clinically significant	0		1	(<1%)
Time Period 2				
n	117		123	
Normal	50	(43%)	67	(54%)
Abnormal, not clinically significant	64	(55%)	55	(45%)
Abnormal, clinically significant	2	(2%)	1	(<1%)
n	117		122	
Clinically significant change from baseline	2	(2%)	1	(<1%)
Not a clinically significant change	115	(98%)	121	(>99%)
Not applicable	0		0	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EG1 (continued)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment A (N=157)		Treatment B (N=160)	
Any time post-baseline				
n	117		123	
Normal	50	(43%)	67	(54%)
Abnormal, not clinically significant	65	(56%)	55	(45%)
Abnormal, clinically significant	2	(2%)	1	(<1%)
No result (not available)	0		0	
n	117		122	
Clinically significant change from baseline	2	(2%)	1	(<1%)
Not a clinically significant change	115	(98%)	121	(>99%)
Not applicable	0		0	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EG2
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
PR Interval (msec)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: VS1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
Diastolic BP (mmHg)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE7
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

System Organ Class Preferred Term	Treatment	No. with Event	Unique Subject Id.
Gastrointestinal disorders Dyspepsia	Placebo	9	PPD
	Treatment A	11	
	Treatment B	4	
Nausea	Placebo	6	
	Treatment A	8	
	Treatment B	4	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE9CP
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Site Id./ Unique Subject Id./ /Arm	Treatment/ Period	Age(YEARS)/ Sex/ Race Detail/ Weight (kg)	System Organ Class/ Preferred Term/ VERBATIM TEXT	Outcome/ Onset Datetime/ Datetime of Resolution/ Duration	Time since Study 1st Dose/ Period 1st Dose/ Last Dose	Maximum Intensity/ Maximum Grade/ Serious/ Withdrawal	Frequency/ Action Taken/ Relation to Study Treatment
PPD AB-BA-BA	Tmt A/ Per 1	57/ F/ ASIAN - JAPANESE HERITAGE/ 62.0	Gastrointestinal Disorders/ Internal spasm/ ENTERO - SPASM	RECOVERED/RESOLVED/ PPD T06:05/ T09:35/ 22d 13h 6m	31d 26h 4m/ 31d 26h 4m/ -29d 7h 0m	MILD/ 1 N/ N	INTERMITTENT/ DOSE REDUCED/ Y
	Tmt B/ Per 2	65/ M/ MIXED WHITE RACE/ 75.0	Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN IN RIGHT SHOULDER	RECOVERED/RESOLVED/ PPD T05:50/ T21:55/ 71d 9h 45m	83d 1h 12m/ 83d 1h 12m/ -17d 2h 5m	MODERATE/ 2/ N/ N	SINGLE EVENT/ DOSE NOT CHANGED/ N

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE2
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

System Organ Class	Preferred Term	Verbatim Text
Blood and lymphatic system disorders	Lymphadenopathy	ENLARGED LYMPH NODE
Cardiac disorders	Palpitations	CLOGGED EARS WITH EAR WAX
	Ear pain	EARACHES IN BOTH EARS
		RIGHT EAR PAIN
	Tinnitus	RINGING IN RIGHT EAR
Eye disorders	Asthenopia	TIRED EYES
	Conjunctivitis	BILATERAL ACUTE CONJUNCTIVITIS
		CONJUNCTIVITIS
	Dry eye nos	DRY EYES
	Eye redness	REDDENED EYES
	Vision blurred	BLURRED VISION
		BLURRY VISION
		WORSENING OF BLURRED VISION
Gastrointestinal disorders	Abdominal pain nos	ABDOMEN PAIN
	Abdominal pain upper	MID-EPIGASTRIC AREA PAIN
		STOMACH ACHE
.	.	.
.	.	.

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_LB6
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq	Age(y)/ Sex/ Race	Treat-ment/ Period	Lab test (units)	Planned Relative Time	Date/Time	Study Day/ Period Day	Converted Data Value	Converted Data Normal Range	Flag[1] NR	Flag[1] CI	Flag[1] BL
PPD	63/ Male/ White	Trt A/ Per 1	Alk Phos (U/L)	Screening	PPD 12:05	-1/-1	64.00	32.0- 92.0			
				Week 12	PPD 13:45	85/85	84.00	32.0- 92.0			
			ALT (U/L)	Screening	PPD 13:32	-1/-1	29.00	10.0- 40.0			
				Week 12	PPD 09:55	85/85	70.00	10.0- 40.0	H	H	H

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: UR2b
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv.	Subject	Treatment	Period	Visit	Sample Date	Study Day	Period Day	Urinalysis Test	Result
PPD		Trt A	1	1	PPD	1	1	Blood	++ or 2+
		Trt B	2	8		137	1	Blood	+ or 1+
		Trt B	1	1		1	1	Blood	+ or 1+
								Protein	+++ or 3+
		Trt A	2	8		137	1	Blood	+ or 1+

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: LIVER5
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treatment: Treatment A

Site Id./ Unique Subject Id.	Age(YEARS)/ Sex/ Race Detail	Maximum Status of the Liver Event	Date First Detected/ Study Day	Time Since First Dose (days)	Time Since Last Dose (days)	Restart/Re-challenge After Stopping Criteria Was Met	Resolved?/ Date resolved
PPD	63/ M/ WHITE - WHITE/CAUSASIAN/EUROPEAN HERITAGE	LIVER MONITORING CRITERIA	PPD 101	101	1	N	Y/ 2010-02-19
	61/ F/ ASIAN - JAPANESE HERITAGE	LIVER EVENT STOPPING CRITERIA	PPD 68	68	1	Y	Y/ 2010-04-10
		LIVER EVENT STOPPING CRITERIA	PPD 134	134	7	N	N

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: SU2
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treat-ment	Inv./ Subj.	Visit	Study Day	Assess-ment Date	Smoking History	Cur-rently Smoke	Last Smoked	Smoked Since Last Visit	Days Smoked Since Last Visit	Years Smoked	Ciga-rettes /day	Smoking Pack Years *
Trt A	PPD	Visit 1	1	PPD	Never	No		No	Zero			
		Visit 1	1		Current	Yes		Yes	A few	5	20	5
Trt B		Visit 1	1		Former	No	31DEC1990	No	Zero	18	30	27

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_EG4
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj. /Seq.	Age (y)/ Sex/ Race	Treat- ment/ Period	Planned Relative Time	ECG Date/Time	Study Day /Period Day	Actual Relative Time (optional)	Heart Rate (bpm)	PR Int. (msec)	QRS Dur. (msec)	RR Int. (msec)	QT Int. (msec)	QTcB (msec)	QTcF (msec)
PPD /AB	65/ White/ Female	Trt A/ Per 1	Time 1	PPD 14:00	1/1	-30m	60 L	150	350	750	450	520	495
			Time 2	PPD 15:00	7/7	26m	80	150	350	750	450	520	495
		Trt B/ Per 2	Time 1	PPD 19:00	14/1	-30m	80	150	390 H	750	450	520	495
			Time 2	PPD 20:00	21/7	26m	80	150	350	750	450	520	495
PPD /BA	58 Male/ White/	Trt A/ Per 2	Time 1	PPD 14:00	1/1	-30m	80	90 L	350	800 H	450	520	495
			Time 2	PPD 15:00	7/7	26m	80	150	350	750	450	520	495

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_EG6
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq.	Age (y)/ Sex/ Race	Treat-ment/ Period	Planned Relative Time/ECG Date/Time	Study Day/ Period Day	ECG Finding	Clinically Significant Change from Baseline?	Clinically Significant Abnormality
PPD A/B	65/ Female/ White	Trt A/ Per 1	Visit 1/ PPD /14:00	1/1	Normal		
			Visit 2/ PPD /12:00	4/4	Abnormal-not clinically significant	No	
		Trt B/ Per 2	Visit 3/ PPD /19:00	8/1	Abnormal-clinically significant		Sinus tachycardia
			Visit 4/ PPD /13:00	12/4	No result (not available)		
PPD B/A	58 Male/ White	Trt B/ Per 1	Visit 1/ PPD /14:00	16/1	Abnormal-clinically significant		Ectopic ventricular beats

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_VS5
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq.	Age(y)/ Sex/ Race	Treat-ment/ Period	Planned Relative Time	Actual Date/Time	Study Day/ Period Day	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Vital Sign 3 (units)
PPD	23/	Tmt B/	Time 1	PPD	1/1	190 H	60	xx H
	Male/	Per 1	Time 2	PPD	5/5	95	50 L	xx H
B/C/A	White		Time 3	PPD	10/10	95	60	xx
		Tmt C/	Time 1	PPD	15/1	185 H	90 H	xx H
		Per 2	Time 2	PPD	20/5	95	50	xx H
			Time 3	PPD	25/10	95	60	xx
		Tmt A/	Time 1	PPD	30/1	200 H	45 L	xx H
		Per 3	Time 2	PPD	35/5	95	60	xx H
			Time 3	PPD	40/10	95	85 H	xx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: SAFE_L1
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq.	Age(y)/ Sex/ Race	Treat-ment/ Period	Planned Relative Time	Actual Date/Time	Study Day/ Period Day	Location/ Category	Test type	Side	Test Result
PPD	23/	Tmt B/	Time 1	PPD	1/	Eye/	Indirect fundoscopic exam	Left	Normal
	Male/	Period x			1	Ophthalmological examination		Right	xxxxx
B/C/A	White						Slit lamp	Left	xxxxxx
								Right	xxxxxx
			Time 2		5/		xxxxxxxxxx	xxxxx	xxxxxxx
					5			xxxxx	xxxxxxx
							xxxxxxxxxx	xxxxx	xxxxxxx
								xxxxx	xxxxxxx
		Tmt C/	Time 1		15/		xxxxxxxxxx	xxxxx	xxxxxxx
		Period 2			1			xxxxx	xxxxxxx

USER ID: directory/program.sas DDMMMYYYY hh:mm

10.10.3. PK population

Example: PK01
Protocol: GSK123456 Page 1 of n
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treatment	N	{Add. time var.}	Planned Relative Time	n	No. Imputed	Mean	{95% CI (Lower,Upper)}	SD	Median	Min.	Max.
50mg	24		Pre-dose	24	20	xxxx.x	(xxxx.x,xxxx.x)		xxxx.x	xxxx	xxxx
			30 min	24	1	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			1 hr	23	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			2 hr	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
100mg	24		Pre-dose	24	3	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			30 min	21	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			1 hr	21	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			2 hr	21	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
200mg	24		Pre-dose	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			30 min	23	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			1 hr	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			2 hr	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK03
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Treatment	N	{Additional time variables}	n	Mean	{95% CI (Lower,Upper)}	SD	Median	Min.	Max.
AUC(0-t) (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
Cmax (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	21	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK05
Protocol: GSK123456
Population: xxxxx

Table x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Treatment	N	{Additional time variables}	n	Geom. Mean	95% CI (Lower,Upper)	SD (logs)	{%CVb}
AUC(0-t) (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	200mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	21	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
Cmax (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	200mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	21	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK_T1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Effect	n	Slope Point Estimate	SE	90% CI
Parameter1 (unit)	Log(dose levels)	xx	xxx	xxx	(xx,xx)
Parameter2 (unit)	Log(dose levels)	xx	xxx	xxx	(xx,xx)
.	.	.	.	.	
.	.	.	.	.	
.	.	.	.	.	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK_T2
Protocol: GSK123456
Population: xxxxx

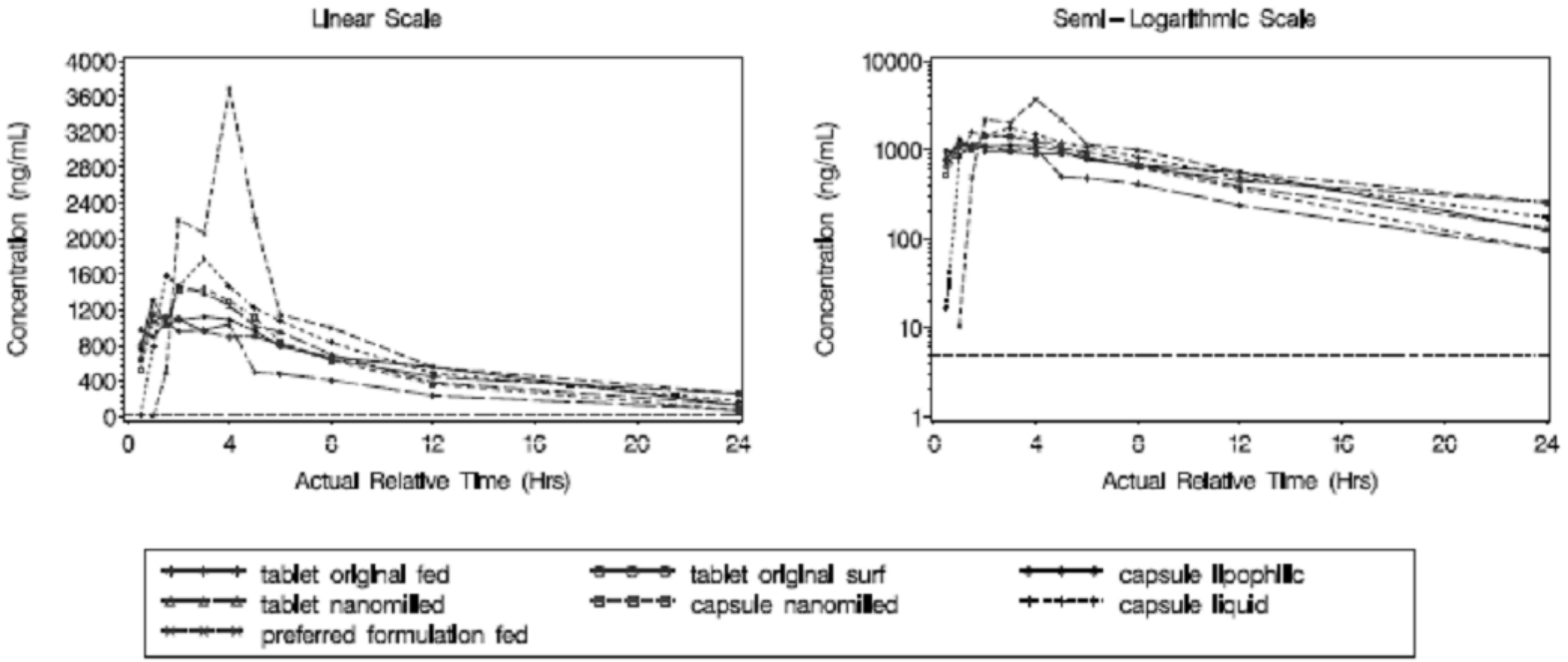
Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Treatment	N	n	Geometric LS Mean	Ratio (Fasted/Fed)	90% CI	CVw(%)[1]
Parameter1 (unit)	Trt1	xx	xx	xxx	Xxx	(xx,xx)	xx
	Trt2	xx	xx	xxx			
Parameter2 (unit)	Trt1	xx	xx	xxx	xxx	(xx,xx)	xx
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
ParameterX (unit)	xx	xx	xx	xxx	xxx	(xx,xx)	xx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK16b
Protocol: GSK123456
Population: xxxxx

Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

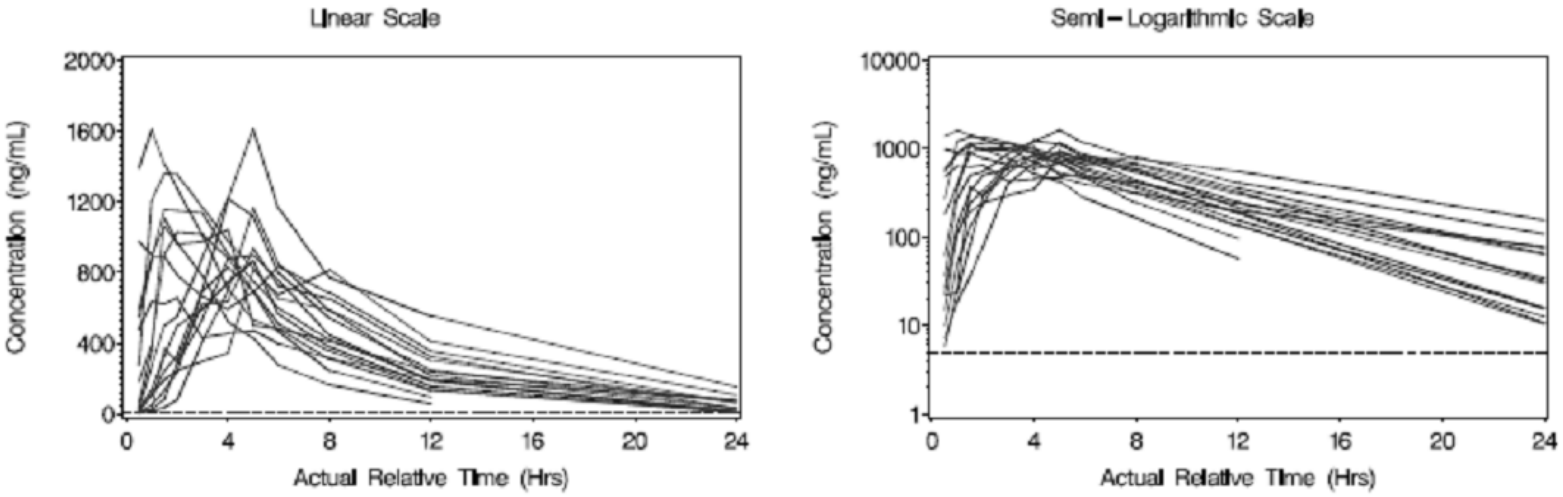


USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK24
Protocol: GSK123456
Population: xxxxx

Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

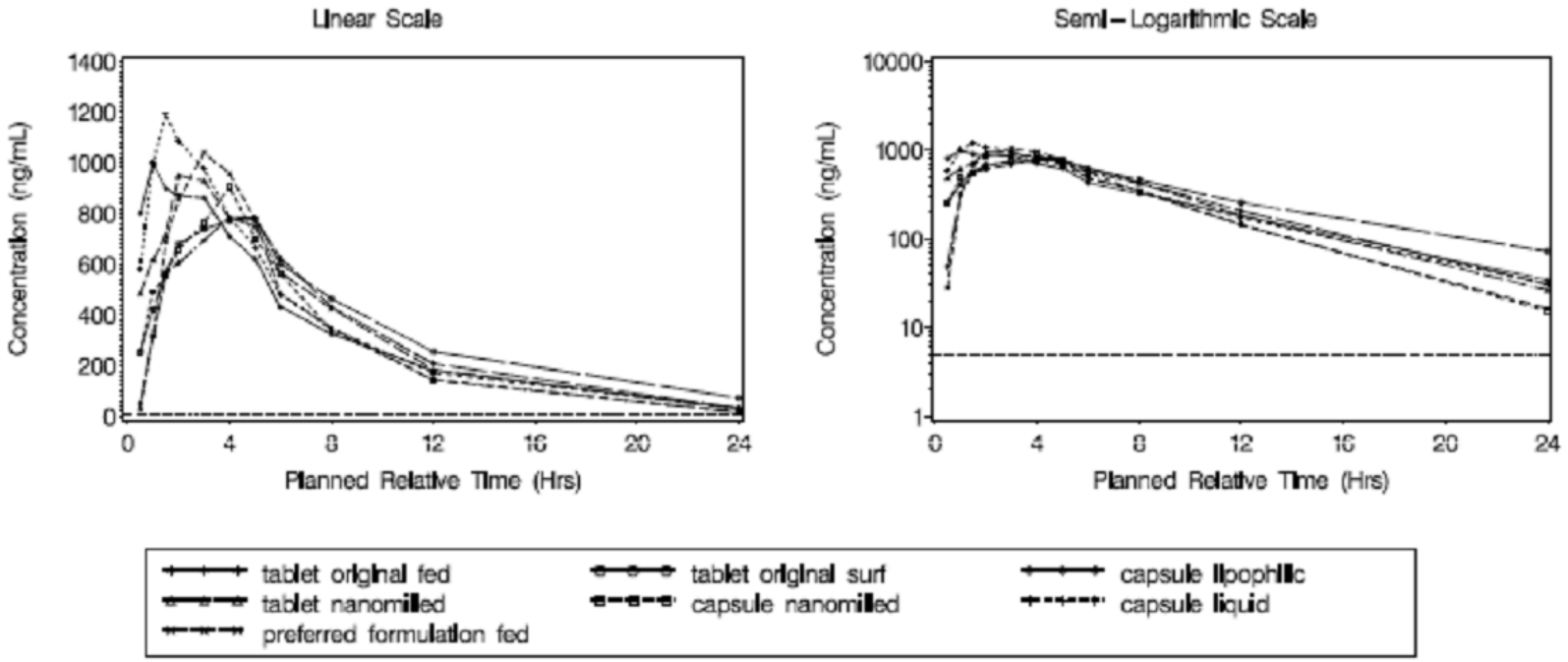
Treatment = tablet original fed



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK18
Protocol: GSK123456
Population: xxxxx

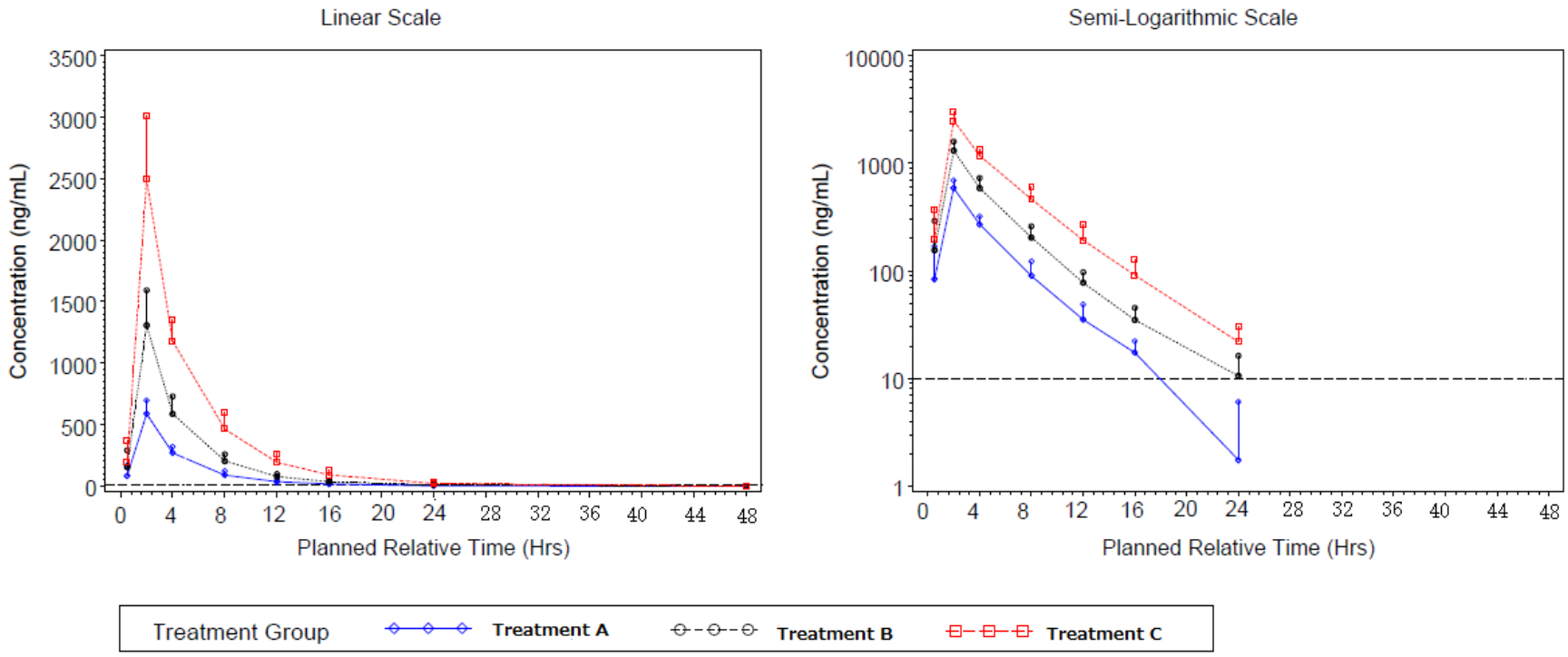
Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK_F1
Protocol: GSK123456
Population: xxxxx

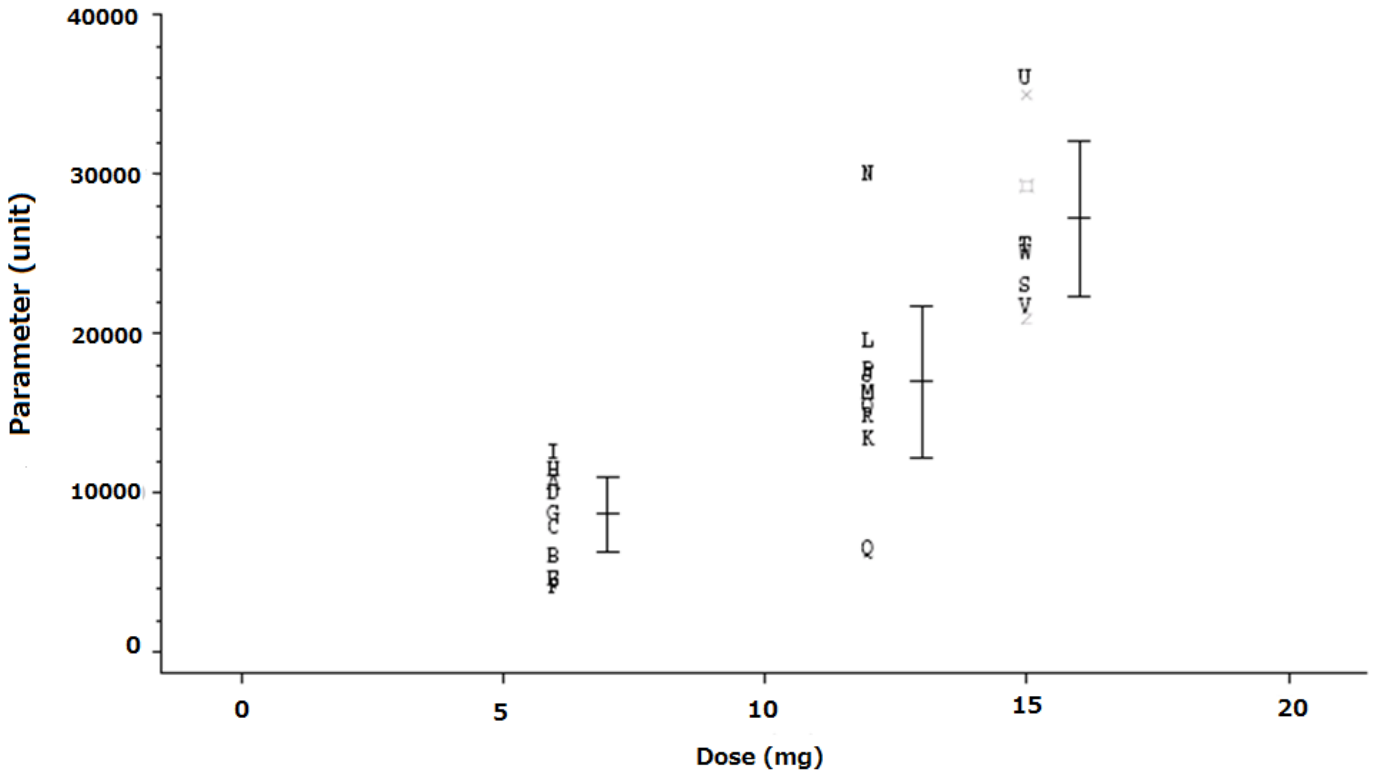
Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK28
Protocol: GSK123456
Population: xxxxx

Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK08 (pkcl1x)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

{Inv./} Subj.	{Age(y)/ Sex/ Race}	Period /Tmt.	Date	Study Day / Period Day	Planned Relative Time	Actual time	Time dev. (units)	Actual Relative Time	Concentration (units)
PPD	36/ M/ Mixed Race	1/ 50mg	PPD	1/1	pre-dose	11:55	0	0h 0m 0s	123
					5m	12:05	0	0h 5m 0s	1434
					1h	13:00	0	1h 0m 0s	NQ (<0.23)
					1h 30m	13:30	0	1h 30m 0s	30
		2/ 100mg		17/1	pre-dose	11:57	0	0h 0m 0s	435
					5m	12:10	0.83	0h 10m 0s	34566
					1h	12:56	-0.67	0h 56m 0s	3452
					1h 30m	13:30	0	1h 30m 0s	30
	33/ M/ Mixed Race	1/ 50mg		1/1	pre-dose	11:58	0	0h 0m 0s	2345
					5m	12:04	-0.17	0h 4m 0s	234
					1h	12:35	0.83	1h 0m 0s	NR
					1h 30m	13:30	0	1h 30m 0s	30

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK_L1
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

{Inv./} Subj.	{Age(y)/ Sex/ Race}	Parameter (units)	Period/ Tmt.	Value
PPD	36/ M/ Mixed Race	Parameter1(unit)	1/ 50mg	xx.xx
			2/ 100mg	xx.xx
		Parameter2(unit)	1/ 50mg	xx
			2/ 100mg	xx
	29/ M/ Mixed Race	Parameter1(unit)	1/ 100mg	xx.xx
			2/ 50mg	xx.xx
		Parameter2(unit)	1/ 100mg	xx

USER ID: directory/program.sas DDMMMYYYY hh:mm

11. REVISION HISTORIY

Version	Date	Amendment
00	11-Jul-2017	Issued version 00

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

Title	:	Reporting and Analysis Plan for Study 206817: A Single Centre, Double Blind (Sponsor Open), Placebo Controlled, 3-Period Crossover, Ascending Dose Study in Japanese Healthy Elderly Male Subjects to Evaluate the Safety, Tolerability and Pharmacokinetics of Danirixin in the Fed State (Part1) and an open label, 2-way crossover to evaluate food effect on the pharmacokinetics of Danirixin (Part2).
Compound Number	:	GSK1325756
Effective Date	:	26-JUL-2017

Description:

- The purpose of this reporting and analysis plan (RAP) is to describe the planned analyses and output to be included in the clinical pharmacology study report for protocol 206817.
- This RAP is intended to describe the safety, pharmacokinetics analyses required for the study.
- This version includes amendments to the originally approved RAP.
- This document will be provided to the study team members to convey the content of the statistical analysis complete (SAC) deliverable.

Author's Name and Functional Area:

PPD Biostatistics Group 2 Associate Manager, Biomedical Data Sciences Department, Japan.	21-Jul-2017
PPD Clinical Pharmacology & Science Promotion Office, Medicines Development, Japan.	21-Jul-2017

Approved:

PPD Department Manager, Biomedical Data Sciences Department, Japan.	26-Jul-2017

TABLE OF CONTENTS

PAGE

1. REPORTING & ANALYSIS PLAN SYNOPSIS

Overview	Key Elements of the Reporting and Analysis Plan
Purpose	• The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 206817.
Protocol	• Reporting and Analysis Plan is based on original protocol (Dated:11-Apr-2017) for study GSK1325756 / 206817 [GlaxoSmithKline Document Number:2016N309585_01]
Objectives	Part 1 • To assess the safety, tolerability and PK following single doses of GSK1325756H 10, 50 and 100 mg in the fed state in healthy Japanese subjects of over 65 years of age inclusive. Part 2 • To investigate the safety, tolerability and food effect on PK of GSK1325756 following a single dose of 50 mg in the fed and fasted state, in healthy Japanese subjects of over 65 years of age inclusive.
Endpoints	Part 1 and 2. • Adverse events (AEs) • Change from baseline of clinical laboratory values, vital signs, and electrocardiogram (ECG) parameters • Blood concentration of GSK1325756 • Cmax, AUC(0-t), AUC(0-inf), AUC(0-24), tmax, t1/2, tlag, tlast of the blood concentration of GSK1325756, as data permit
Study Design	This study consists of two parts. • Part 1 is a double blind, placebo-controlled, 3-period crossover, ascending dose, single oral administration in the fed condition • Part 2 is an open label, 2-way crossover, single oral dose in the fed and fasted state.
Analysis Population	• Screened: Consisting of all subjects screened in the study • Screening Failure: Subjects who screened in the study but are never subsequently randomized. • Safety: All randomized subjects who take at least one dose of study treatment. • Pharmacokinetic: This population is defined as all subjects administered at least one dose of study treatment and who have PK sample taken and analysed.
Hypothesis	• The objectives of this study are to evaluate safety and tolerability of GSK1325756 and to estimate GSK1325756 Pharmacokinetic parameters. No formal statistical hypotheses will be tested in Part 1 and Part 2. Descriptive statistics will be used to assess safety and tolerability objectives. An estimation approach will be used to address the pharmacokinetic study objectives, where point estimates and corresponding 90% confidence intervals will be constructed.
Safety Analyses	• Safety data will be presented in tabular and/or graphical format and summarized descriptively according to GSK's Integrated Data Standards Library (IDSL) standards.
Pharmacokinetic Analyses	• Individual GSK1325756 blood concentration-time profiles (by part, treatment and subject) and median/mean (±SD) profiles by part and treatment will be plotted and listed. Treatment indicates dose group in Part 1 and the fed and fasted condition in Part 2. • Blood concentration time data for GSK1325756 will be analyzed by non-compartmental methods using WinNonlin and derived PK parameters graphically present, summarised

	and listed. No formal statistical analyses will be conducted. • Statistical analyses will be carried out to explore the dose proportionality of GSK1325756 as assessed by AUC(0-t) and Cmax using the Power Model (Part 1). • Statistical analyses will be carried out to explore the food effect of GSK1325756 as assessed by AUC(0-t) and Cmax using a mixed effects mode (Part 2).

1.1. RAP Amendments

Revision chronology:

RAP Section	Amendment Details
Reporting and Analysis Plan_206817_Final [11-Jul-2017	
Reporting and Analysis Plan_206817_Final_Amend 1 [DD-Jul-2017]	
1.1 RAP Amendments	• added the section
10.9.1. Data Display Numbering	• corrected number of ICH Listings
10.9.3. Deliverable [Priority]	• deleted "(Part 2 only)" for SAC [2]
10.9.4. Study Population Tables	• deleted "(Yes or No)" in the Programing Notes for No. 1.7 and No. 1.8
10.9.6. Pharmacokinetic Tables	• added unit in the title for No. 3.1 and No. 3.5
10.9.8. ICH Listings	• corrected "Deliverable [Priority]" column for No. 1, No. 18, and No. 26 • added " Listing of Relationship between ATC Level 1, Ingredient and Verbatim Text" as No. 21 • corrected the title for No. 44 and No. 46 • corrected "IDSL / TST ID / Example Shell" column for No. 70 and No. 71
10.10.1. Study population	• added CM6
10.10.3. PK population	• deleted "(unit)" in "Parameter" column for PK_T1 • deleted PK_L1 • added PK14
11. Revision History	• deleted the section

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: 11/APR/2017].

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

Objectives	Endpoints
Part 1 • To assess the safety, tolerability and PK following single doses of GSK1325756H 10, 50 and 100 mg in the fed state in healthy Japanese subjects of over 65 years of age inclusive. Part 2 • To investigate the safety, tolerability and food effect on PK of GSK1325756 following a single dose of 50 mg in the fed and fasted state, in healthy Japanese subjects of over 65 years of age inclusive.	Part 1 and Part 2 • Adverse events (AEs) • Change from baseline of clinical laboratory values, vital signs, and electrocardiogram (ECG) parameters • Blood concentration of GSK1325756 • Cmax, AUC(0-t), AUC(0-inf), AUC(0-24), tmax, t1/2, tlag, tlast of the blood concentration of GSK1325756, as data permit

2.3. Study Design

Overview of Study Design and Key Features

Subjects will be divided into Part 1 and 2, and receive the following study treatment doses shown in Table below.

Part 1:

Group	n	Period 1	Washout	Period 2	Washout	Period 3
A	6	10 mg	at least 7 days	50 mg	at least 7 days	Placebo
B	6	10 mg		Placebo		100 mg
C	6	Placebo		50 mg		100 mg

Part 2:

Group	n	Period 1	Washout	Period 2
D	8	50 mg, fed	at least 7 days	50 mg, fasted
E	8	50 mg, fasted		50 mg, fed

Design Features	Part 1: This is a double blind, placebo-controlled, 3-period crossover, ascending dose, single oral administration in the fed condition. Part 2: This is an open label, 2-way crossover, single oral dose in the fed and fasted state study.
Dosing	Part 1: Subjects will have a screening visit within 30 days prior to the first dose of study. A minimum washout period of 7 days will be required between each treatment period. Subjects will receive three treatment periods in the study. Subjects will be housed in the Clinical Research Unit from Day -1 (the day before dosing) through Day 3 for Period 1 and 2, and from Day -1 (the day before dosing) through Day 4 for Period 3. Subjects will return to the clinic 7 days (at least) after the previous administration day for Period 1 and 2, and subjects will visit the unit on Day 8 (+/- 1 day) of the last dosing for Period 3 for follow-up. Part 2: Subjects will have a screening visit within 30 days prior to the first dose of study treatment, two treatment periods separated by at least 7 days, and follow-up. Subjects will be housed in the Clinical Research Unit from Day -1 (the day before dosing) through Day 3 (for Period 1 and 2), and re-visit 7 (±1) days after the last dose of Period 2 for follow-up.

Overview of Study Design and Key Features	
Treatment Assignment	• Sufficient participants will be randomised such that approximately 18 in Part 1and 16 in Part 2 evaluable participants complete the study of each part. • If participants prematurely discontinue the study, additional participants may be enrolled as replacement participants and assigned to the same treatment sequence, if applicable, at the discretion of the sponsor in consultation with the investigator. • On Day 1 of each Part, participants will be assigned a unique number (randomization number) in ascending numerical order. The randomization number encodes the participant's assignment to one of the 3 sequences in Part 1 and one of the 2 sequences in Part 2, according to the randomization schedule generated prior to the study by the Biomedical Data Sciences Department at GSK. • Participants will be randomized in a 1:1:1 ratio to receive sequence (A:B:C) for Part 1, or will be randomized in a 1:1 ratio to receive sequence (D:E) for Part 2. • Each participant will be dispensed blinded study treatment, labeled with his unique randomization number, throughout the study. • Investigators, participants and sponsor will remain blinded to each participant's assigned study treatment throughout the course of the study. For the concentration evaluation after Period 2 of Part 1, the pre-specified sponsor's person who is responsible for the confirmation of the concentration will review blood drug concentration data under unblended.
Interim Analysis	• No formal statistical analysis is planned. • A blind review of preliminary safety data (AE, clinical laboratory values, vital signs, ECG) and blood concentration will be conducted between Period 2 and Period 3 in Part 1 and prior to Part 2. • After completion of Part 1, formal analysis for Part 1 is to be conducted.

2.4. Statistical Hypotheses

The objectives of this study are to evaluate safety, tolerability and PK profile of single dose of GSK1325756H and to investigate food effect of PK profile of single dose of GSK1325756H in healthy Japanese elderly subjects. No formal statistical hypotheses will be tested in Part 1 and Part 2. Descriptive statistics will be used to assess safety and tolerability objectives. An estimation approach will be used to address the PK study objectives, where point estimates and corresponding 95% confidence intervals will be constructed, unless otherwise stated.

3. PLANNED ANALYSES

3.1. Interim Analyses

No formal statistical analysis is planned. However, following Period 1 and Period 2 of Part 1, a blind review of preliminary safety data (AE, clinical laboratory values, vital signs, ECGs) will be conducted between Period 2 and Period 3 in Part 1 and prior to Part 2. Furthermore, the sponsor's person who is responsible for the confirmation of the concentration will review blood drug concentration data under unblended.

3.2. Final Analyses

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

1. All subjects in each part have completed the study as defined in the protocol.
2. All required database cleaning activities in each part have been completed and final database release and database freeze has been declared by Data Management for each part.
3. All criteria for unblinding the randomisation codes have been met for Part 1.
4. Randomisation codes have been distributed according to RandAll NG procedures.

After completion of Part 1, formal analysis for Part 1 is to be conducted.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Endpoint(s) Evaluated
Screened	• Consisting of all subjects screened in the study. Note: This definition indicates the same meaning as 'All subjects who have subject number' in a programming point of view.	• Study Population
Screening Failure	• Subjects who screened in the study but are never subsequently randomized. All participants who sign the ICF have the screening test in the study. Note: This definition indicates the same meaning as 'Subjects who have subject number but are never subsequently randomized' in a programming point of view.	• Study Population
Safety	• All randomized subjects who take at least one dose of study treatment. Participants will be analyzed according to the treatment they actually received.	• Study Population • Safety

Population	Definition / Criteria	Endpoint(s) Evaluated
Pharmacokinetic	• This population is defined as all subjects administered at least one dose of study treatment and who have PK sample taken and analysed. Participants will be analyzed according to the treatment they actually received.	• PK

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.
    - Data will be reviewed prior to freezing the database to ensure all important deviations and deviations which may lead to exclusion from the analysis are captured and categorised on the protocol deviations dataset.
    - This dataset will be the basis for the summaries and listings of protocol deviations.
- A separate listing of all inclusion/exclusion criteria deviations will also be provided. This will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

Table 1 provides an overview of appendices within the RAP for outlining general considerations for data analyses and data handling conventions.

Table 1 Overview of Appendices

Section	Component
10.1	Appendix 1: Protocol Deviation Management
10.2	Appendix 2: Time & Events
10.3	Appendix 3: Treatment States and Phases
10.4	Appendix 4: Data Display Standards & Handling Conventions
10.5	Appendix 5: Derived and Transformed Data
10.6	Appendix 6: Premature Withdrawals & Handling of Missing Data
10.7	Appendix 7: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Analyses

The study population analyses will be based on the Safety Population, unless otherwise specified. These analyses will be performed in each part.

Table 2 provides an overview of the planned study population analyses, with full details of data displays being presented in Appendix 9: List of Data Displays.

Table 2 Overview of Planned Study Population Analyses

Display Type	Data Displays Generated		
	Table	Figure	Listing
Subject Disposition			
Subject Disposition and Reason for Study Withdrawal	Y		Y
Screening Status and Reasons for Screen Failure	Y		Y
Subjects for Whom the Treatment Blind was Broken			Y
Planned and Actual Treatments			Y
Protocol Deviations			
Important Protocol Deviations	Y		Y
Inclusion/Exclusion Criteria Deviations			Y
Populations Analysed			
Study Populations	Y		
Subjects Excluded from Any Population			Y
Demographic and Baseline Characteristics			
Demographic Characteristics	Y		Y
Demographic Characteristics for Screening Failure			Y
Age Ranges	Y		
Race and Racial Combinations	Y		Y
Race and Racial Combinations for Screening Failure			Y
Medical Conditions and Concomitant Medications			
Medical Conditions			Y
Concomitant Medications			Y
Exposure and Treatment Compliance			
Exposure to Study Treatment			Y
Meal			
Meal start and end days/times on fed treatment			Y

NOTES:

- Y = Yes display generated.

7. SAFETY ANALYSES

The safety analyses will be based on the Safety Population, unless otherwise specified. These analyses will be performed in each part.

Adverse events occurred in washout period will be included in adverse events analyses for previous period. Also adverse events occurred in follow up period will be included in safety analyses for the last period.

7.1. Overview of Planned Adverse Events Analyses

Table 3 provides an overview of the planned adverse events analyses with full details of data displays being presented in Appendix 9: List of Data Displays.

Table 3 Overview of Planned Adverse Event Analyses

Display Type	Absolute		
	Summary		Individual
	T	F	L
Adverse Events (AEs)			
All AEs by SOC and PT	Y		Y
All AEs by Maximum Intensity	Y		
Drug-Related AEs by SOC and PT	Y		
Drug-Related AEs by Maximum Intensity	Y		
Subject Numbers for Individual AEs			Y
Relationship Between AE SOCs, PT and Verbatim Text			Y
Serious and Other Significant AEs			
Serious AEs			Y
AEs Leading to Withdrawal from Study			Y

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated, SOC = System Organ Class, PT = Preferred Term.
- Summary = Represents TF related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

7.2. Overview of Planned Clinical Laboratory Analyses

Table 4 provides an overview of the planned analyses, with further details of data displays being presented in Appendix 9: List of Data Displays.

Table 4 Overview of Planned Clinical Laboratory Analyses

Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
Chemistry						
Chemistry Data	Y		Y	Y		Y
Chemistry Results Relative to Normal Range				Y		
All Chemistry Data for Subjects with any Value of Potential Clinical Concern/PCI			Y			Y
Hematology						
Hematology Data	Y		Y	Y		Y
Hematology Results Relative to Normal Range				Y		
All Hematology Data for Subjects with any Value of Potential Clinical Concern/PCI			Y			Y
Urinalysis						
Dipstick Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen)	Y		Y*			
Gravity and pH	Y		Y			
Hepatobiliary (Liver)						
Liver Monitoring/Stopping Event Reporting			Y			
Medical Conditions for Subjects with Liver Stopping Events			Y			
Substance Use for Subjects with Liver Stopping Events			Y			

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated, PCI = Potential Clinical Importance
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

*: If blood or protein is abnormal, microscopic examination will be included.

7.3. Overview of Planned Other Safety Analyses

Table 5 provides an overview of the planned analyses, with further details of data displays being presented in Appendix 9: List of Data Displays.

Table 5 Overview of Planned Other Safety Analyses

Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
ECG						
ECG Findings	Y		Y			
ECG Values	Y		Y	Y		Y
All ECG Values for Subjects with any Value of PCI			Y			
Vital Signs						
Vitals Values	Y		Y	Y		Y
All Vital Signs for Subjects with any Value of PCI			Y			
Ophthalmic examinations						
Ophthalmic examinations			Y			

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated, PCI = Potential Clinical Importance
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

8. PHARMACOKINETIC ANALYSES

8.1. Overview of Planned Pharmacokinetic Analyses

The pharmacokinetic (PK) analyses will be based on the Pharmacokinetic population, unless otherwise specified. These analyses will be performed in each part.

Table 6 provides an overview of the planned analyses, with full details being presented in Appendix 9: List of Data Displays.

Table 6 Overview of Planned Pharmacokinetic Analyses

Display Type	Untransformed				Log-Transformed				
	Summary		Individual		Stats analysis	Summary		Individual	
	F	T	F	L		F	T	F	L
Descriptive statistics									
Blood Drug Concentrations	Y [1] [2]	Y	Y [1]	Y					
Derived PK Parameters	Y	Y		Y			Y		
Statistical Analysis of PK Parameters									
Power model (Part 1)					Y				
Food effect (Part 2)					Y				

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated.
- Summary = Represents TFL related to any summaries (descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

1. Linear and Semi-Log plots will be created on the same display.
2. Separate Mean (+ SD) and Median plots will be generated.

8.2. Drug Concentration Measures

Blood concentrations of GSK1325756 will be listed and summarised by part, treatment and nominal time. Standard summary statistics will be calculated (i.e. mean, standard deviation, median, minimum and maximum).

Individual blood concentration-time profiles and median/mean profiles by treatment will be plotted. Each of the figures will contain one plot on the untransformed scale (i.e. a linear plot) and one plot on the log transformed scale (i.e. log-linear plot).

Refer to Appendix 4: Data Display Standards & Handling Conventions (Section 10.4.4 Reporting Process & Standards).

8.3. Pharmacokinetic Parameters

8.3.1. Deriving Pharmacokinetic Parameters

- Derivation of pharmacokinetic parameters will be performed by, or under the direct auspices of, Clinical Pharmacology & Science Promotion Office, GlaxoSmithKline K.K.
- Refer to Appendix 4: Data Display Standards & Handling Conventions (Section 10.4.4 Reporting Process & Standards).
- The pharmacokinetic parameters will be calculated by standard non-compartmental analysis using WinNonlin (version 6.3 or higher)
- All calculations of non-compartmental parameters will be based on actual sampling times recorded during the study.
- Pharmacokinetic parameters described in Table 7 will be determined from blood GSK1325756 concentration-time data, as data permits.

Table 7 Derived Pharmacokinetic Parameters

Parameter	Parameter Description
AUC(0-24) (h*ng/mL)	Area under the concentration-time curve will be calculated to fixed nominal time 24 hours after administration (AUC(0-24)),using the combination of linear and logarithmic trapezoidal methods (i.e., Linear Up/Log Down calculation method in Phoenix WinNonlin Professional). If a sampling time deviation occurred at nominal time 24 hours after administration (and 24 < t), AUC(0-24) will be calculated using the concentration at time 24 hours after administration post-dose estimated by the method of interpolation. If nominal time 24 hours after administration > t (or if the concentration at time 24 hours after administration was below then limit of quantification), then the concentration (y) at time 24 hours after administration is estimated using lambda_z and last observed Ct according to the formula: y=Ct(obser) x e-lambda_z(24-t) Then the following equation will be used to calculate (AUC(0-24)) where t is the time of last quantifiable blood concentration. AUC(0-24) = AUC(0-t) + AUC(t-24) If lambda_z is not estimable, a partial AUC is not calculated (when 24 > t).
AUC(0-t) (h*ng/mL)	Area under the concentration-time curve from zero time (pre-dose) to the time of the last quantifiable concentration (AUC(0-t)) will be calculated by a combination of linear and logarithmic trapezoidal methods. The linear trapezoidal method will be employed for all incremental trapezoids arising from increasing concentrations and the logarithmic trapezoidal method will be used for those arising from decreasing concentrations (i.e., Linear Up/Log Down calculation method in Phoenix WinNonlin Professional).
AUC(0-inf) (h*ng/mL)	Area under the concentration-time curve from zero time (pre-dose) extrapolated to infinite time (AUC(0-inf)) will be calculated as follows: AUC(0-inf) = AUC(0-t) + Ct / lambda_z
Cmax (ng/mL)	Maximum observed concentration will be obtained directly from the concentration-time data.
Tmax (h)	Time to first occurrence of Cmax will be obtained directly from the concentration-time data.
t1/2 (h)	Terminal phase half-life will be calculated as follows: t1/2 = ln2 / lambda_z
tlag (h)	Lag time before observation of drug concentrations in sampled matrix.

Parameter	Parameter Description
tlast (h)	The time of the last measurable (positive) concentration.
%AUCex (%)	The area under the curve (AUC) from the last predicted non-zero concentration value to infinity as a percentage of the area under the curve extrapolated to infinity.
lambda_z (/h)	The first order rate constant associated with the terminal (log-linear) portion of the curve.
lambda_z_lower (h)	The lower limit on time for values to be included in the calculation of Lambda z.
lambda_z_upper (h)	The upper limit on time for values to be included in the calculation of Lambda z.
#pts	The number of time points used in computing Lambda z.
R2	The goodness of fit statistic for the terminal elimination phase.

NOTES:

- Additional parameters may be included as required.
- Lambda_z is the terminal phase rate constant.
- Ct is the last observed quantifiable concentration.

8.3.2. Summary of Pharmacokinetic Parameters

- For each of these parameters, except for tmax, tlag and tlast, the following summary statistics will be calculated for each treatment:
    - Non-transformed: arithmetic mean, median, maximum, minimum, 95% confidence interval for the arithmetic mean and standard deviation
    - Loge-transformed: geometric mean, 95% confidence interval for the geometric mean, standard deviation of logarithmically transformed data and between geometric coefficient of variation (CVb (%))
- Median, maximum, minimum, arithmetic mean, 95% confidence interval and standard deviation will be calculated for tmax, tlag and tlast.

8.3.3. Statistical Analysis of Pharmacokinetic Parameters

8.3.3.1. Dose proportionality

For Part 1, the PK-dose relationship will be investigated graphically in order to assess dose proportionality of GSK1325756. Plots of AUC (0-t) and Cmax versus dose will be plotted.

Also statistical analyses will be carried out to explore the dose proportionality of GSK1325756 as assessed by AUC(0-t) and Cmax, using the Power Model:

$\log_e (Y_{ij}) = \mu + S_i + \beta * \log_e (D_j) + \varepsilon_{ij}$

Y_{ij}: PK parameter (AUC(0-t), Cmax) on the *j*th dose for *i*th subject

μ: Overall mean (Intercept)

S_i: Random effect for subject i following normal distribution $N(0, \sigma_b^2)$

β: Slope for $\log_e$ transformed dose

D_j: Dose (j=1:10mg, 2:50mg, 3:100mg)

ε_{ij}: Random error following normal distribution $N(0, \sigma_w^2)$

Following loge-transformation, AUC (0-t) and Cmax will be separately analyzed, if data permitted. A mixed effect model will be fitted with the loge transformed dose and period as fixed effects. Subject will be fitted as a random effect. The Kenward & Roger (KR) degrees of freedom approach will be used. Point estimates and their associated 90% confidence intervals will be constructed.

8.3.3.2. Food effect

For Part 2, statistical analyses will be carried out to assess treatment (food effect) of GSK1325756 for AUC(0-t) and Cmax using Mixed effect model:

$\log_e (Y_{ij}) = \mu + S_i + t_j + p_k + \varepsilon_{ij}$

Y_{ij}: PK parameter (AUC(0-t), Cmax) on the *j*th treatment for *i*th subject

μ: Overall mean (Intercept)

S_i: Random effect for subject i following normal distribution $N(0, \sigma_b^2)$

t_i : Treatment effect (j=fasted, fed)

p_k: Period effect (k=period 1, period 2)

ε_{ij}: Random error following normal distribution $N(0, \sigma_w^2)$

Following loge-transformation, AUC (0-t) and Cmax will be separately analysed using a mixed effects model fitting terms for treatment and period as fixed effects, and subject as a random effect in order to assess food effect of GSK1325756 (Fed vs. Fasted). The Kenward & Roger (KR) degrees of freedom approach will be used.

Point estimates for the adjusted means on the loge scale, the mean difference between treatments and associated 90% confidence interval will be constructed using the residual variance. The point estimate and confidence interval will then be exponentially back-transformed to obtain adjusted (least square) geometric means for each treatment, and point estimates and associated 90% confidence interval for the ratio of fasted/fed.

Estimates of within-subject variability (CVw (%)) for AUC (0-t) and Cmax will also be provided. CVw (%) will be calculated based on the loge-normal distribution where:

CVw (%)= SQRT(exp(MSE)-1) * 100. (MSE is the residual mean squared error from the model)

9. REFERENCES

GlaxoSmithKline Document Numbers 2016N309585_01: Study Protocol of 206817. A Single Centre, Double Blind (Sponsor Open), Placebo Controlled, 3-Period Crossover, Ascending Dose Study in Japanese Healthy Elderly Male Subjects to Evaluate the Safety, Tolerability and Pharmacokinetics of Danirixin in the Fed State (Part1) and an open label, 2-way crossover to evaluate food effect on the pharmacokinetics of Danirixin (Part2).

10. APPENDICES

Section	Appendix
RAP Section 4 : Analysis Populations	
Section 10.1	Appendix 1: Protocol Deviation Management
RAP Section 5 : General Considerations for Data Analyses & Data Handling Conventions	
Section 10.2	Appendix 2: Time and Events
Section 10.3	Appendix 3: Treatment States & Phases
Section 10.4	Appendix 4: Data Display Standards & Handling Conventions • Study Treatment • Baseline Definitions & Derivations • Reporting Process & Standards
Section 10.5	Appendix 5: Derived and Transformed Data • General • Study Population • Safety • Pharmacokinetics
Section 10.6	Appendix 6: Premature Withdrawals & Handling of Missing Data • General • Study Population & Safety
Section 10.7	Appendix 7: Values of Potential Clinical Importance • Laboratory Values • ECG • Vital Signs
Other RAP Appendices	
Section 10.8	Appendix 8: Abbreviations & Trade Marks
Section 10.9	Appendix 9: List of Data Displays
Section 10.10	Appendix 10: Example Mock Shells for Data Displays

10.1. Appendix 1: Protocol Deviation Management

Details will be referred latest Protocol Deviation Management Plan and data handling will be decided prior to final data base release.

10.2. Appendix 2: Time & Events

Part 1, Period 1-2

Day	Screening	Day-1	Day 1													Day 2	Day 3
Time post-dose			Pre-dose	0 h	0.25 h	0.5 h	0.75 h	1 h	2 h	3 h	4 h	6 h	8 h	10 h	12 h	24 h	48 h
Informed consent	X																
Subject demography /Medical history	X																
Height, Weight, BMI	X																
Urine drug screen	X																
Serological test	X																
Physical examination	X	X	X								X					X	X
Vital signs (PR, BP, temp)	X	X	X								X					X	X
12-lead ECG	X	X	X								X					X	X
Ophthalmic examination	X[3]																
SAEs[2]	<==========																==========>
AEs[2]	<==========																==========>
Con Med review	<==========																==========>
Hematology, clinical chemistry and urinalysis	X	X															X
Administration				X													
PK sampling			X		X	X	X	X	X	X	X	X	X	X	X	X	X
Admission		X															
Discharge																	X

1. Screening visit will occur only prior to the first dosing. Treatment Period 2 will occur after at least 7-days wash-out period. High fat meal will be started and completed before within 30 minutes of GSK1325756H/Placebo dosing.
2. All SAEs will be collected from the signing of the ICF until the follow-up visit at the time points specified. All AEs will be collected from the start of treatment until the follow-up visit at the time points specified (see Section 9.1 Adverse Events).

3. Ophthalmic examinations are conducted on the day between Screening and Day-1. However, it is not carried out for those who are ineligible due to other screening criteria.

Part 1, Period 3

Day	Day-1	Day 1												Day 2	Day 3		Day 4	Follow up [2,3]
Time post-dose		Pre-dose	0 h	0.25 h	0.5 h	0.75 h	1 h	2 h	3 h	4 h	6 h	8 h	10 h	12 h	24 h	48 h	60 h	72 h	
Physical examination	X	X								X					X	X		X	X
Vital signs (PR, BP, temp)	X	X								X					X	X		X	X
12-lead ECG	X	X								X					X	X		X	X
Ophthaimic examination																			X
SAEs	<==========>																		
AEs	<==========>																		
Con Med review	<==========>																		
Hematology, clinical chemistry and urinalysis	X																	X	X
Administration			X																
PK sampling		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Admission	X																		
Discharge																		X	

1. Treatment Period 3 will occur after at least 7-days wash-out period. High fat meal will be started and completed before within 30 minutes of GSK1325756/Placebo dosing.
2. Follow up visit will occur after 7 days (+/- 1day) of the last dosing.
3. In the case where the subject has discontinued the study prematurely, the assessments for follow up will be carried out.

Part 2, Period 1-2

Day	Screening	Day-1	Day 1													Day 2	Day 3	Follow up[3,5]
Time post-dose			Pre-dose	0 h	0.25 h	0.5 h	0.75 h	1 h	2 h	3 h	4 h	6 h	8 h	10 h	12 h	24 h	48 h	
Informed consent	X																	
Subject demography /Medical history	X																	
Height, Weight, BMI	X																	
Urine drug screen	X																	
Serological test	X																	
Physical examination	X	X	X								X					X	X	X
Vital signs (PR, BP, temp)	X	X	X								X					X	X	X
12-lead ECG	X	X	X								X					X	X	X
Ophthalmic examination	X[6]																	X
SAEs[4]	<==========																	==========>
AEs[4]			<==========															==========>
Con Med review	<==========																	==========>
Hematology, clinical chemistry and urinalysis	X	X															X	X
Administration				X														
PK sampling			X		X	X	X	X	X	X	X	X	X	X	X	X	X	
Admission		X																
Discharge																	X	

1. Screening visit will occur only prior to the first dosing. Treatment Period 2 will occur after at least 7-days wash-out period.
2. For the fed condition, meal will be started and completed before within 30 minutes of GSK1325756H dosing.
3. Follow up visit will occur after 7-days (+/- 1day) of the last dosing.
4. All SAEs will be collected from the signing of the ICF until the follow-up visit at the time points specified. All AEs will be collected from the start of treatment until the follow-up visit at the time points specified (see Section 9.1.Adverse Events).
5. In the case where the subject has discontinued the study prematurely, the assessments for follow up will be carried out.
6. Ophthalmic examinations are conducted on the day between Screening and Day-1. However, it is not carried out for those who are ineligible due to other screening criteria.

10.3. Appendix 3: Treatment States and Phases

10.3.1. Treatment Phases

Assessments and events will be classified according to the time of occurrence relative to the assessment date.

Treatment Phase	Definition
Part 1: Period 1	Assessment Date < Previous Day of Dosing Start Date in Period 2 (Part 1)
Part 1: Period 2	Previous Day of Dosing Start Date in Period 2 ≤ Assessment Date < Previous Day of Dosing Start Date in Period 3 (Part 1)
Part 1: Period 3	Previous Day of Dosing Start Date in Period 3 ≤ Assessment Date (Part 1)
Part 2: Period 1	Assessment Date < Previous Day of Dosing Start Date in Period 2 (Part 2)
Part 2: Period 2	Previous Day of Dosing Start Date in Period 2 ≤ Assessment Date (Part 2)

10.3.2. 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.

10.3.2.1. Treatment States for AE Data

Treatment State	Definition
Pre-Treatment	AE Start Date and Time < Dosing Start Date and Time
Part 1: Period 1	Dosing Start Date and Time in Period 1 ≤ AE Start Date and Time < Dosing Start Date and Time in Period 2 (Part 1)
Part 1: Period 2	Dosing Start Date and Time in Period 2 ≤ AE Start Date and Time < Dosing Start Date and Time in Period 3 (Part 1)
Part 1: Period 3	Dosing Start Date and Time in Period 3 ≤ AE Start Date and Time (Part 1)
Part 2: Period 1	Dosing Start Date and Time in Period 1 ≤ AE Start Date and Time < Dosing Start Date and Time in Period 2 (Part 2)
Part 2: Period 2	Dosing Start Date and Time in Period 2 ≤ AE Start Date and Time (Part 2)
Onset Time Since First Dose (Minute)	If Dosing Start Date and Time > AE Onset Date and Time = AE Onset Date and Time – Dosing Start Date and Time If dosing Start Date and Time ≤ AE Onset Date and Time = AE Onset Date and Time - Dosing Start Date and Time +1 Missing otherwise
Onset Time Since Last Dose (Minute)	AE Start Date and Time – Most Recent Treatment Start Date and Time + 1
Duration (Minute)	AE Resolution Date and Time – AE Onset Date and Time + 1
Drug-related	If relationship is marked 'YES' on eCRF

10.4. Appendix 4: Data Display Standards & Handling Conventions

10.4.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions			
Part1 (Scedule1)			
RandAll NG		**Data Displays for Reporting**	
Code	**Description**	**Description**	**Order [1]**
P	Placebo, Fed	Placebo, Fed	1
X1	GSK1325756H 10 mg, Fed	GSK1325756H 10 mg, Fed	2
X2	GSK1325756H 50 mg, Fed	GSK1325756H 50 mg, Fed	3
X3	GSK1325756H 100 mg, Fed	GSK1325756H 100 mg, Fed	4
Part2 (Scedule2)			
X2	GSK1325756H 50 mg, Fed	GSK1325756H 50 mg, Fed	1
X4	GSK1325756H 50 mg, Fasted	GSK1325756H 50 mg, Fasted	2

NOTES:

1. Order in which treatments are to be presented in Listings. Note that the order in which treatments are to be presented in Tables, active treatment (X1, X2, X3 in Part 1, X2, X4 in Part 2) is shown in the first and placebo (P in Part 1) in the second.

10.4.2. Sequence group Display Descriptors

Sequence Group Descriptions			
RandAll NG		**Data Displays for Reporting**	
Code	**Description**	**Description [1]**	**Order**
A	X1/X2/P	A	1
B	X1/P/X3	B	2
C	P/X2/X3	C	3
D	X2/X4	D	4
E	X4/X2	E	5

NOTES:

1. Footnote will be added in displays as follows.
   A: 10mg (Fed) / 50mg (Fed) / Placebo (Fed), B: 10mg (Fed) / Placebo (Fed) / 100mg (Fed), C: Placebo (Fed) / 50mg (Fed) / 100mg (Fed), D: 50mg (Fed) / 50mg (Fasted) , E: 50mg (Fasted) / 50mg (Fed)

10.4.3. Baseline Definition & Derivations

10.4.3.1. Baseline Definitions

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Day -1	Day 1 (Pre-Dose)	
Safety				
12 Lead ECG & Vital Signs	X	X	X	Day 1 (Pre Dose)
Haematology	X	X		Day -1
Clinical Chemistry	X	X		Day -1

NOTES:

- The baseline will be defined for each period in Part 1 and Part 2.

10.4.3.2. Derivations and Handling of Missing Baseline Data

Definition	Reporting Details
Change from Baseline	= Post-Dose Visit Value – Baseline

NOTES:

- Unless otherwise specified, the baseline definitions specified in Section 10.4.3.1 Baseline Definitions will be used for derivations for endpoints / parameters and indicated on summaries and listings.
- Unless otherwise stated, if baseline data is missing no derivation will be performed and will be set to missing.
- The baseline definition will be footnoted on all change from baseline displays.

10.4.4. Reporting Process & Standards

Reporting Process	
Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: uk1salx00175
HARP Area	Part1:/arenv/arprod/gsk1325756/mid206817/primary_01 Part2:/arenv/arprod/gsk1325756/mid206817/final_01
QC Spreadsheet	Part1:/arenv/arprod/gsk1325756/mid206817/primary_01/qc Part2:/arenv/arprod/gsk1325756/mid206817/final_01/qc
Analysis Datasets	
• Analysis datasets will be created according to GSK IDSL A&R dataset standards	
Generation of RTF Files	
• N/A	

Reporting Standards	
General	
• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated: o 4.03 to 4.23: General Principles o 5.01 to 5.08: Principles Related to Data Listings o 6.01 to 6.11: Principles Related to Summary Tables o 7.01 to 7.13: Principles Related to Graphics	
Formats	
• All data will be reported according to the actual treatment the subject received unless otherwise stated. • GSK IDSL Statistical Principles (4.24) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected. • Numeric data will be reported at the precision collected on the eCRF. • The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP's.	
Planned and Actual Time	
• Reporting for tables, figures and formal statistical analyses: o Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated. o 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: o Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1). o Unscheduled or unplanned readings will be presented within the subject's listings. o Visits outside the protocol defined time-windows (i.e. recorded as protocol deviations) will be included in listings but omitted from figures, summaries and statistical analyses.	
Unscheduled Visits	
• Unscheduled visits will not be included in summary tables. • Unscheduled visits will not be included in 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)

Reporting Standards	
Reporting of Pharmacokinetic Parameters	
Descriptive Summary Statistics. (Log Transformed)	N, n, geometric mean, 95% CI of geometric mean, standard deviation (SD) of logged data and between geometric coefficient of variation (CVb/w (%)) will be reported. CVb (%) = SQRT (exp(SD^2) - 1) * 100 (SD = SD of loge-transformed data) CVw (%) =SQRT (exp(MSE) - 1) * 100 (MSE = mean square error from mixed effect model of loge-transformed data).
Parameters Not Being Log Transformed	tmax, tlag, tlast
Parameters Not Being Summarised	The following PK parameters will not be summarised but listed: %AUCex, lambda_z, lambda_z_lower, lambda_z_upper, #pts, R2.
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

Reporting Standards

10.5. Appendix 5: Derived and Transformed Data

10.5.1. General

Multiple Measurements at One Time Point

- Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented.
- If there are two values within a time window 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.
- Subjects having both High and Low values for Normal Ranges at any post-baseline visits 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 start of dosing date:
  - Ref Date = Missing → Study Day = Missing
  - Ref Date < of start of dosing Date → Study Day = Ref Date – of start of dosing Date
  - Ref Data ≥ of start of dosing Date → Study Day = Ref Date – (of start of dosing Date) + 1

10.5.2. Study Population

Demographics

Age

- GSK standard IDSL algorithms will be used for calculating age where birth date will be imputed as:
  - 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'.
- Reference will be Randomization date for Part 1 and Part 2
- Reference date for calculation of age at screening will be from visit 1 (Screening visit) date, however this will be from screen failure date for a screen failure subject.
- Analysis age group will be categorized (Years):

  <=18, 19-64, 65-74, >=75
- Age will be categorized for EudraCT:

  <=17 years, 18-64 years, 65-84 years, >=85 years

Body Mass Index (BMI)

- Calculated as Weight (kg) / [Height $(m)^2$]

10.5.3. Safety

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

Laboratory Assessments	
Haematology	Platelet Count, RBC Count, Haemoglobin, Hematocrit, RBC Indices (MCV, MCH, %Reticulocytes), WBC count with Differential (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils)
Clinical Chemistry	BUN, Creatinine, Glucose (fasting), Uric acid, HDL-cholesterol, Amylase, Potassium, Sodium, Calcium, TG, LDH, Chloride, Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline phosphatise, Total Cholesterol, GGT, Phosphorus, Total and direct bilirubin, Total Protein, Albumin, LDL-cholesterol, CK (CPK)
Routine Urinalysis	• Specific gravity, pH (assessed by dipstick) • glucose, protein, blood, ketones, bilirubin, urobilinogen by dipstick • Microscopic examination (if blood or protein is abnormal)

ECG (12-lead ECG)
ECG findings, ECG values (Heart rate, PR interval, QRS duration, QT interval and QTcF intervals)

Vital Signs
Pulse rate, Blood pressure (Systolic, Diastolic),Temperature

Ophthalmic examinations
Ophthalmic examinations

10.5.4. Pharmacokinetics

PK Parameters
• If one or more non-quantifiable (NQ) values occur in a profile before the first measurable concentration, they will be assigned a value of zero concentration. For linear plots, zero concentration value(s) before the first measurable concentration will be included in the plot. For log-linear plots, zero concentration value(s) before the first measurable concentration will be assigned a missing value. • If a single NQ value occurs between measurable concentrations in a profile, the NQ should generally be set to missing in the derivation of pharmacokinetic parameters, statistical analysis, and the individual subject plots. • If two or more NQ values occur in succession between measurable concentrations, the profile will be deemed to have terminated at the last measurable concentration prior to these NQs. For the purpose of individual subject plots, these NQs will be set to 0, and the subsequent measurable concentrations will be retained. For the derivation of pharmacokinetic parameters, these NQs and any subsequent measurable concentrations will be set to missing. • NQs which occur after the last measurable concentration will be omitted (set to missing) in the derivation of pharmacokinetic parameters and from the individual subject plots. • Individual's PK parameters reported as 'NC' (Not Calculable) or 'ND' (Not Determined) will be included in listings but omitted (set to missing) from figures, summaries and statistical analyses.

10.6. Appendix 6: Premature Withdrawals & Handling of Missing Data

10.6.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion was defined as a participant has completed all periods of the study including the last visit or the last scheduled procedure (Follow-up) for each period as described in the protocol. • Withdrawn subjects maybe replaced in the study. • All available data from subjects who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

10.6.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o These data will be indicated by the use of a “blank” in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as “Not applicable” and “Not evaluable” are not considered to be missing data and should be displayed as such.

10.6.3. Handling of Partial Dates

Element	Reporting Detail
Concomitant Medications	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: o If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month o 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.

10.6.4. Handling of Missing Data for Statistical Analysis

Element	Reporting Detail
Imputation	• No imputation will be performed for missing data

10.7. Appendix 7: Values of Potential Clinical Importance

10.7.1. Laboratory Values (Healthy Volunteers)

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
While Blood Cell Count (WBC)	$x10^9$/ L		3	20

Clinical Chemistry				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Albumin	G/L		30	
Calcium	mmol/L		2	2.75
Creatinine	µmol/L	Δ from BL		↑ 44.2
Glucose	mmol/L		3	9
Phosphorus	mmol/L		0.8	1.6
Potassium	mmol/L		3	5.5
Sodium	mmol/L		130	150

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

10.7.2. ECG (Healthy Volunteers)

ECG Parameter	Units	Clinical Concern Range	
		Lower	Upper
Absolute			
Absolute QTc Interval	msec		> 450 [1]
Absolute PR Interval	msec	< 110 [1]	> 220 [1]
Absolute QRS Interval	msec	< 75 [1]	> 110 [1]
Change from Baseline			
Increase from Baseline QTc	msec	> 60 [1]	

NOTES:
1. Represent standard ECG values of PCI for HV studies

10.7.3. Vital Signs (Healthy Volunteers)

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

10.8. Appendix 8 - Abbreviations & Trade Marks

10.8.1. Abbreviations

Abbreviation	Description
AE	Adverse Event
A&R	Analysis and Reporting
AUC(0-24)	Area under the concentration-time curve from pre-dose to 24 hours
AUC(0-inf)	Area under the concentration-time curve from time zero (pre-dose) extrapolated to infinite time
AUC(0-t)	Area under the concentration-time curve from time zero (pre-dose) to last time of quantifiable concentration within a subject across all treatments
BMI	Body mass index
BP	Blood pressure
CI	Confidence Interval
Cmax	Maximum observed concentration
CSR	Clinical Study Report
CVb	Coefficient of variation (Between)
CVw	Coefficient of Variation (Within)
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
GSK	GlaxoSmithKline
HR	Heart rate
hrs	Hours
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
LLN	Lower Limit of Normal
LLQ	Lower Limit of Quantification
MedDRA	Medical Dictionary for Regulatory Activities
MG	Milligrams
msec	Milliseconds
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
RAP	Reporting and Analysis Plan
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event(s)
SAS	Statistical Analysis Software
SD	Standard Deviation
ULN	Upper Limit of Normal
SOP	Standard Operation Procedure
t1/2	Terminal half-life
Tmax	Time to maximum observed blood drug concentration
TFL	Tables, Figures & Listings

10.8.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
None

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS
WinNonlin

10.9. Appendix 9: List of Data Displays

10.9.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.14	N/A
Safety	2.1 to 2.34	N/A
Pharmacokinetic	3.1 to 3.8	3.1 to 3.10
Section	**Listings**	
ICH Listings	1 to 71	
Other Listings	N/A	

10.9.2. Mock Example Referencing

Non IDSL specifications will be referenced as indicated and if required an example mock-up displays provided in Appendix 10: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln

NOTES:

- Indicate display is Non-Standard in the 'IDSL/TST ID / Example Shell' or 'Programming Notes' column.

10.9.3. Deliverable [Priority]

Delivery [Priority] [1]	Description
PR [1]	Primary Report (Part 1 only)
SAC [2]	Statistical Analysis Complete

NOTES:

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

10.9.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	Safety	CP_ES1	Summary of Subject Disposition (Part 1)	Completed or withdrawn and the reason for withdrawal.	PR [1]
1.2.	Safety	ES4	Summary of Subject Disposition at each period (Part 1)	Completed or withdrawn at each period.	PR [1]
1.3.	Safety	CP_ES1	Summary of Subject Disposition (Part 2)	Completed or withdrawn and the reason for withdrawal.	SAC [2]
1.4.	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure	The number (%) of Randomized or screening failure subjects as the screening status, and the reason for screening failure.	SAC [2]
Protocol Deviation					
1.5.	Safety	DV1	Summary of Important Protocol Deviations (Part 1)	Data is from DV1 dataset.	PR [1]
1.6.	Safety	DV1	Summary of Important Protocol Deviations (Part 2)	Data is from DV1 dataset.	SAC [2]
Population Analysed					
1.7.	Safety	SP1	Summary of Study Populations (Part 1)	Only PK population is summarized.	PR [1]
1.8.	Safety	SP1	Summary of Study Populations (Part 2)	Only PK population is summarized.	SAC [2]
Demographic and Baseline Characteristics					
1.9.	Safety	DM3	Summary of Demographic Characteristics (Part 1)		PR [1]
1.10.	Safety	DM3	Summary of Demographic Characteristics (Part 2)		SAC [2]
1.11.	Screened	DM11	Summary of Age Ranges (Part 1)	<=17 years, 18-64 years, 65-84 years, >=85 years	PR [1]
1.12.	Screened	DM11	Summary of Age Ranges (Part 2)	<=17 years, 18-64 years, 65-84 years, >=85 years	SAC [2]

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.13.	Safety	DM5	Summary of Race and Racial Combinations (Part 1)		PR [1]
1.14.	Safety	DM5	Summary of Race and Racial Combinations (Part 2)		SAC [2]

10.9.5. Safety Tables

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 1)		PR [1]
2.2.	Safety	AE5A	Summary of All Adverse Events by Maximum Intensity (Part 1)		PR [1]
2.3.	Safety	AE1	Summary All Drug-Related Adverse Events by System Organ Class and Preferred Term (Part 1)		PR [1]
2.4.	Safety	AE5A	Summary All Drug-Related Adverse Events by Maximum Intensity (Part 1)		PR [1]
2.5.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term (Part 2)		SAC [2]
2.6.	Safety	AE5A	Summary of All Adverse Events by Maximum Intensity (Part 2)		SAC [2]
2.7.	Safety	AE1	Summary All Drug-Related Adverse Events by System Organ Class and Preferred Term (Part 2)		SAC [2]
2.8.	Safety	AE5A	Summary All Drug-Related Adverse Events by Maximum Intensity (Part 2)		SAC [2]
Laboratory: Chemistry					
2.9.	Safety	LB1	Summary of Chemistry (Part 1)		PR [1]
2.10.	Safety	LB1	Summary of Chemistry Changes from Baseline (Part 1)		PR [1]
2.11.	Safety	LB4	Summary of Chemistry Data Shifts from Baseline with Respect to the Normal Range (Part 1)		PR [1]
2.12.	Safety	LB1	Summary of Chemistry (Part 2)		SAC [2]
2.13.	Safety	LB1	Summary of Chemistry Changes from Baseline (Part 2)		SAC [2]

Safety: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.14.	Safety	LB4	Summary of Chemistry Data Shifts from Baseline with Respect to the Normal Range (Part 2)		SAC [2]
Laboratory: Hematology					
2.15.	Safety	LB1	Summary of Hematology (Part 1)		PR [1]
2.16.	Safety	LB1	Summary of Hematology Changes from Baseline (Part 1)		PR [1]
2.17.	Safety	LB4	Summary of Hematology Data Shifts from Baseline with Respect to the Normal Range (Part 1)		PR [1]
2.18.	Safety	LB1	Summary of Hematology (Part 2)		SAC [2]
2.19.	Safety	LB1	Summary of Hematology Changes from Baseline (Part 2)		SAC [2]
2.20.	Safety	LB4	Summary of Hematology Data Shifts from Baseline with Respect to the Normal Range (Part 2)		SAC [2]
Laboratory: Urinalysis					
2.21.	Safety	UR3b	Summary of Urinalysis Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen) (Part 1)		PR [1]
2.22.	Safety	LB1	Summary of Urinalysis Data (Specific Gravity and pH) (Part 1)		PR [1]
2.23.	Safety	UR3b	Summary of Urinalysis Data (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen) (Part 2)		SAC [2]
2.24.	Safety	LB1	Summary of Urinalysis Data (Specific Gravity and pH) (Part 2)		SAC [2]
ECG					
2.25.	Safety	EG1	Summary of ECG Findings (Part 1)		PR [1]
2.26.	Safety	EG2	Summary of ECG Value (Part 1)		PR [1]
2.27.	Safety	EG2	Summary of Change from Baseline in ECG Values (Part 1)		PR [1]
2.28.	Safety	EG1	Summary of ECG Findings (Part 2)		SAC [2]

Safety: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.29.	Safety	EG2	Summary of ECG Value (Part 2)		SAC [2]
2.30.	Safety	EG2	Summary of Change from Baseline in ECG Values by Visit (Part 2)		SAC [2]
Vital Signs					
2.31.	Safety	VS1	Summary of Vital Signs (Part 1)		PR [1]
2.32.	Safety	VS1	Summary of Change from Baseline in Vital Signs (Part 1)		PR [1]
2.33.	Safety	VS1	Summary of Vital Signs (Part 2)		SAC [2]
2.34.	Safety	VS1	Summary of Change from Baseline in Vital Signs (Part 2)		SAC [2]

10.9.6. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part 1					
3.1.	PK	PK01: pkct1	Summary of GSK1325756 Blood Concentration (ng/mL) (Part 1)		PR [1]
3.2.	PK	PK03: pkpt1	Summary of GSK1325756 Pharmacokinetic Parameters (non-transformed) (Part 1)		PR [1]
3.3.	PK	PK05: pkpt3	Summary of GSK1325756 Pharmacokinetic Parameters (loge-transformed) (Part 1)		PR [1]
3.4.	PK	Study Specific (PK_T1)	Analysis of Power Model Analysis for GSK1325756 Dose Proportionality of Pharmacokinetic Parameters (AUC(0-t), Cmax) (Part 1)	Parameter, Effect, n, Point estimate of Slope, SE, 90% CI	PR [1]
Part 2					
3.5.	PK	PK01: pkct1	Summary of GSK1325756 Blood Concentration (ng/mL) (Part 2)		SAC [2]
3.6.	PK	PK03: pkpt1	Summary of GSK1325756 Pharmacokinetic Parameters (non-transformed) (Part 2)		SAC [2]
3.7.	PK	PK05: pkpt3	Summary of GSK1325756 Pharmacokinetic Parameters (loge-transformed) (Part 2)		SAC [2]
3.8.	PK	Study Specific (PK_T2)	Analysis of food effect for Pharmacokinetic Parameters (AUC(0-t), Cmax) (Part 2)	n, Geometric mean of Fasted and Fed, ratio (Fasted/Fed), 90% CI and CVw(%)	SAC [2]

10.9.7. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Part 1					
3.1.	PK	PK16b: pkcf1x	Individual GSK1325756 Blood Concentration-Time Plots by Subject (Part 1)	By Subject (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	PR [1]
3.2.	PK	PK24: pkcf6	Individual GSK1325756 Blood Concentration-Time Plots by treatment (Part 1)	By Treatment (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	PR [1]
3.3.	PK	Study Specific (PK_F1)	Mean (+SD) GSK1325756 Blood Concentration-Time Plots (Part 1)	Unit of x-axis is Hours	PR [1]
3.4.	PK	PK18: pkcf3	Median GSK1325756 Blood Concentration-Time Plots (Part 1)	Unit of x-axis is Hours	PR [1]
3.5.	PK	PK28	Plot of GSK1325756 Treatment and PK Parameters (AUC (0-t), Cmax) (Part 1)		PR [1]
Part 2					
3.6.	PK	PK16b: pkcf1x	Individual GSK1325756 Blood Concentration-Time Plots by Subject (Part 2)	By Subject (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	SAC [2]
3.7.	PK	PK24: pkcf6	Individual GSK1325756 P Blood Concentration-Time Plots by Treatment (Part 2)	By Treatment (Linear and Semi-Log). Actual time is used. Unit of x-axis is Hours.	SAC [2]
3.8.	PK	Study Specifics (PK_F1)	Mean (+SD) GSK1325756 Blood Concentration-Time Plots (Part 2)	Unit of x-axis is Hours	SAC [2]
3.9.	PK	PK18: pkcf3	Median GSK1325756 Blood Concentration-Time Plots (Part 2)	Unit of x-axis is Hours	SAC [2]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.10.	PK	PK28	Plot of GSK1325756 Treatment and PK Parameters (AUC(0-t), Cmax) (Part 2)		SAC [2]

10.9.8. ICH Listings

Note: 'Inv.' in the standard displays will be replaced to 'Centre'.

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	Screening Failure	ES7	Listing of Reasons for Screen Failure		SAC [2]
2.	Safety	CP-ES10x	Listing of Reasons for Study Withdrawal (Part 1)		PR [1]
3.	Safety	CP-ES10x	Listing of Reasons for Study Withdrawal (Part 2)		SAC [2]
4.	Safety	BL2	Listing of Subjects for Whom the Treatment Blind was Broken (Part 1)		PR [1]
5.	Safety	TA2	Listing of Planned and Actual Treatments (Part 1)		PR [1]
6.	Safety	TA2	Listing of Planned and Actual Treatments (Part 2)		SAC [2]
Protocol Deviations					
7.	Safety	DV2	Listing of Important Protocol Deviations (Part 1)	Column for Treatment Sequence/Period of Protocol deviation will be displayed after Centre./Subj. Period day will be displayed in the same column of Date of Deviation/Study day.	PR [1]
8.	Safety	DV2	Listing of Important Protocol Deviations (Part 2)		SAC [2]
9.	Screened	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations		SAC [2]
Populations Analysed					

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
10.	Safety	Study Specifics (POP_L1)	Listing of Subjects Excluded from PK Population (Part 1)		PR [1]
11.	Safety	Study Specifics (POP_L1)	Listing of Subjects Excluded from PK Population (Part 2)		SAC [2]
Demographic and Baseline Characteristics					
12.	Safety	DM4	Listing of Demographic Characteristics (Part 1)	"Age at Screening" is added.	PR [1]
13.	Safety	DM4	Listing of Demographic Characteristics (Part 2)	"Age at Screening" is added.	SAC [2]
14.	Screening Failure	DM4	Listing of Demographic Characteristics for Screening Failure Subjects		SAC [2]
15.	Safety	DM10	Listing of Race (Part 1)		PR [1]
16.	Safety	DM10	Listing of Race (Part 2)		SAC [2]
17.	Screening Failure	DM10	Listing of Race for Screening Failure Subjects	Treatment is not needed to display.	SAC [2]
Medical Conditions and Concomitant Medications					
18.	Screened	MH3	Listing of Medical Conditions		SAC [2]
19.	Safety	CM5	Listing of Concomitant Medications (Part 1)		PR [1]
20.	Safety	CM5	Listing of Concomitant Medications (Part 2)		SAC [2]
21.	Screened	CM6	Listing of Relationship between ATC Level 1, Ingredient and Verbatim Text		SAC [2]
Exposure and Treatment Compliance					
22.	Safety	EX4	Listing of Exposure Data (Part 1)		PR [1]
23.	Safety	EX4	Listing of Exposure Data (Part 2)		SAC [2]

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Meal					
24.	Safety	CP_ML1x	Listing of Dosing Times, Meal Start and End Times on Fed Treatment Days (Part 1)		PR [1]
25.	Safety	CP_ML1x	Listing of Dosing Times, Meal Start and End Times on Fed Treatment Days (Part 2)		SAC [2]
Adverse Events					
26.	Safety	AE9CP	Listing of All Adverse Events (Part 1)		PR [1]
27.	Safety	AE9CP	Listing of All Adverse Events (Part 2)		SAC [2]
28.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events (Part 1)		PR [1]
29.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events (Part 2)		SAC [2]
30.	Screened	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text		SAC [2]
Serious and Other Significant Adverse Events					
31.	Safety	AE9CP	Listing of Serious Adverse Events (Part 1)		PR [1]
32.	Safety	AE9CP	Listing of Serious Adverse Events (Part 2)		SAC [2]
33.	Screening Failure	AE9CP	Listing of Serious Adverse Events for Screening Failure Subject	Treatment is not needed to display.	SAC [2]
34.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study (Part 1)		PR [1]
35.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study (Part 2)		SAC [2]
Laboratory (Chemistry Data)					

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
36.	Safety	CP_LB6	Listing of All Chemistry Data (Part 1)	Change from baseline is included.	PR [1]
37.	Safety	CP_LB6	Listing of All Chemistry Data (Part 2)	Change from baseline is included.	SAC [2]
38.	Safety	CP_LB6	Listing of All Chemistry Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]
39.	Safety	CP_LB6	Listing of All Chemistry Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Laboratory (Hematology Data)					
40.	Safety	CP_LB6	Listing of All Hematology Data (Part 1)	Change from baseline is included.	PR [1]
41.	Safety	CP_LB6	Listing of All Hematology Data (Part 2)	Change from baseline is included.	SAC [2]
42.	Safety	CP_LB6	Listing of All Hematology Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]
43.	Safety	CP_LB6	Listing of All Hematology Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Laboratory (Urinalysis Data)					
44.	Safety	UR2b	Listing of All Urinalysis Dipstick and Microscopy Data(Part 1)	Time will be displayed after 'Date'.	PR [1]
45.	Safety	CP_LB6	Listing of Urinalysis Data (Gravity and pH) (Part 1)		PR [1]
46.	Safety	UR2b	Listing of All Urinalysis Dipstick and Microscopy Data (Part 2)	Time will be displayed after 'Date'.	SAC [2]
47.	Safety	CP_LB6	Listing of Urinalysis Data (Gravity and pH) (Part 2)		SAC [2]
Hepatobiliary (Liver)					
48.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 1)	Column for Treatment/Period will be displayed after the column for Age/Sex/Race Detail.	PR [1]
49.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 2)		SAC [2]

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
50.	Safety	MH3	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 1)		PR [1]
51.	Safety	MH3	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 2)		SAC [2]
52.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 1)		PR [1]
53.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 2)		SAC [2]
ECG					
54.	Safety	CP_EG4	Listing of All ECG Values (Part 1)		PR [1]
55.	Safety	CP_EG4	Listing of All ECG Values (Part 2)		SAC [2]
56.	Safety	CP_EG4	Listing of Change from Baseline in ECG Values (Part 1)		PR [1]
57.	Safety	CP_EG4	Listing of Change from Baseline in ECG Values (Part 2)		SAC [2]
58.	Safety	CP_EG6	Listing of ECG Findings (Part 1)		PR [1]
59.	Safety	CP_EG6	Listing of ECG Findings (Part 2)		SAC [2]
60.	Safety	CP_EG4	Listing of All ECG Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]
61.	Safety	CP_EG4	Listing of All ECG Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Vital Signs					
62.	Safety	CP_VS5	Listing of All Vital Signs (Part 1)	Change from baseline is included.	PR [1]
63.	Safety	CP_VS5	Listing of All Vital Signs (Part 2)	Change from baseline is included.	SAC [2]
64.	Safety	CP_VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance (Part 1)		PR [1]

ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
65.	Safety	CP_VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [2]
Others					
66.	Safety	Study Specifics (SAFE_L1)	Listing of Ophthalmic examinations (Part 1)		PR [1]
67.	Safety	Study Specifics (SAFE_L1)	Listing of Ophthalmic examinations (Part 2)		SAC [2]
PK					
68.	PK	PK08: pkcl1x	Listing of GSK1325756 Blood Concentration (Part 1)		PR [1]
69.	PK	PK08: pkcl1x	Listing of GSK1325756 Blood Concentration (Part 2)		SAC [2]
70.	PK	PK14: pkpl1x	Listing of GSK1325756 Pharmacokinetic Parameters (Part 1)		PR [1]
71.	PK	PK14: pkpl1x	Listing of GSK1325756 Pharmacokinetic Parameters (Part 2)		SAC [2]

10.10. Appendix 10: Example Mock Shells for Data Displays

10.10.1. Study population

Example CP_ES1 (XO studies)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)
Completion Status	
Completed	50 (50%)
Withdrawn	50 (50%)
Primary*/subreason^ for withdrawal	
Adverse event	10 (10%)
Elevated ALT levels	2 (2%)
Severe vomiting	5 (5%)
Lack of efficacy	0
Protocol deviation	0
Subject reached stopping criteria	10 (10%)
CD4 levels below continuation threshold	10 (10%)
Study closed/terminated	0
Lost to follow-up	0
Investigator discretion	0
Withdrew consent	30 (30%)
Burden of procedures	10 (10%)
Pursue alternative treatment	20 (20%)
Other	0

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: ES4
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Phase		Not Randomized (N=10)	Placebo (N=100)	Curitol 10mg (N=100)
Screening	Entered	10(100%)	100(100%)	100(100%)
	Completed	0	100(100%)	100(100%)
	Withdrawn	10(100%)	0	0
Double blind	Entered		100(100%)	100(100%)
	Completed		50 (50%)	50 (50%)
	Withdrawn		50 (50%)	50 (50%)
Follow-up	Entered		50 (50%)	50 (50%)
	Completed		50 (50%)	50 (50%)
	Withdrawn		0	0

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: ES6 (SF for CONSORT)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Screened Subjects (N=100)
Screening Status	
ENROLLED	50 (50%)
FAILED	50 (50%)
Reason(s) for Failure	
DID NOT MEED INCLUSION/EXCLUSION CRITERIA	25 (25%)
STUDY CLOSED/TERMINATED	5 (5%)
PHYSICIAN DECISION	10 (10%)
PROTOCOL DEVIATION	10 (10%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_ES10x
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Treatment Sequence/ Period of Withdrawal	Last Treatment Before Withdrawal	Date of Withdrawal/ Study Day of Withdrawal/ Period Day of Withdrawal	Primary Reason for Withdrawal	Subreason for Withdrawal	Date of Last Contact/ Study Day of Last Contact
xxxxxx/ xxx	PAB/ Period 1	A	DDMMMYYYY/ xx/ x	*Adverse Event*	*Elevated ALT levels*	DDMMMYYYY/ x
xxxxxx/ xxx	BPC/ Period 2	B	DDMMMYYYY/ x/ x			DDMMMYYYY/ x

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: ES7 (for SF)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Date of Screen Failure	Reason Term(s) for Screen Failure
xxxxxx/ xxx	DDMMMYYYY	*DID NOT MEED INCLUSION/EXCLUSION CRITERIA*
xxxxxx/ xxx	DDMMMYYYY	*PHYSICIAN DECISION* *DID NOT MEED INCLUSION/EXCLUSION CRITERIA*
xxxxxx/ xxx	DDMMMYYYY	*DID NOT MEED INCLUSION/EXCLUSION CRITERIA*
	DDMMMYYYY	*PHYSICIAN DECISION*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: BL2 (for XO studies)
Protocol: GSK123456 Page 1 of n
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Sequence/ Treatment when Blind broken	Date Blind Broken	Time Blind Broken	Study Day	Period Day	Reason
xxxxxx	xxxx	PBC/ Treatment A	DDMMMYYYY	hh:ss	xx	*x*	*Other: PT REQUESTED TO KNOW FOR MEDICAL REASONS*
xxxxxx	xxxx	APC/ Treatment C	DDMMMYYYY	hh:ss	xx	*xx*	*Medical Emergency*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: TA2 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Country: Canada
Centre ID: PPD
Investigator: PPD

Subject ID	Randomization Number	Randomization Date	Period	Randomization Treatment	Actual Treatment	Deviation
PPD		01JAN08	1	Curital 10mg	Curital 10mg	
			2	Placebo	Placebo	
			3	Placebo	No treatment	Y
			4	Curital 20mg	No treatment	Y
		03JAN08	1	Curital 20mg	Curital 20mg	
			2	Placebo	Placebo	
			3	Curital 10mg	Curital 10mg	
			4	Placebo	Placebo	
		01FEB08	1	Placebo	Placebo	
			2	Curital 10mg	Curital 10mg	
			3	Placebo	Placebo	
			4	Curital 20mg	Curital 10mg	Y
		15FEB08	1	Curital 10mg	Curital 10mg	
			2	Placebo	Placebo	
			3	Placebo	Placebo	
			4	Curital 10mg	Curital 20mg	Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: IE4 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Treatment sequence	Type	Criterion
xxxxxx	xxx	APC	INCLUSION	*Is the subject 18 years of age or older?*
xxxxxx	xxx	PAB	EXCLUSION	*Has the subject had an asthma episode(s) requiring intubation associated with hypercapnia, respiratory arrest, or hypoxic seizures within 12 months prior to Visit 1?*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DV1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Category/Coded Term	Total (N=200)
Any important protocol deviations	60 (30%)
Informed consent	10 (5%)
WRONG INFORMED CONSENT/ASSENT VERSION SIGNED	10 (5%)
Eligibility criteria not met	14 (7%)
Not withdrawn after developing withdrawal criteria	18 (9%)
Not discontinued from study treatment	10 (5%)
Not withdrawn from study	8 (4%)
EXCLUDED MEDICATION, VACCINE OR DEVICE	4 (2%)
MEDICATION, EXCLUDED BY THE PROTOCOL, WAS ADMINISTERED	4 (2%)
Assessment or time point completion	2 (1%)
OUT OF WINDOW EFFICACY ASSESSMENT	2 (1%)
WRONG STUDY TREATMENT/ADMINISTRATION/DOSE	4 (2%)
STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	2 (1%)
EXPIRED STUDY TREATMET ADMINISTERED	2 (1%)
Failure to report SAFETY EVENTS PER Protocol	8 (5%)
SAE NOT REPORTED WITHIN THE EXPECTED TIME FRAME	4 (2%)
LIVER FUNCTION ABNORMALITIES PER PROTOCOL	4 (2%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DV2
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

				Deviation Requires Exclusion from		
Site Id./	Date of Deviation/	Category/ Coded Term	Term	Intent to Treat Population	Safety Population	Per Protocol Population
PPD	PPD 28	ILURE TO REPORT SAFETY EVENTS PER PROTOCOL / SAE NOT REPORTED WITHIN THE EXPECTED TIME FRAME	SAE OF FEVER WITH SEVERE CHILLS REQUIRING IV HYDRATION WAS NOT REPORTED TO GSK WITHIN 24 HOURS.			
	PPD 31	ELIGIBILITY CRITERIA NOT MET / ELIGIBILITY CRITERIA NOT MET	SUBJECT SCREEN FAILED BUT WAS RANDOMIZED IN ERROR.		Y	Y
	PPD 1	WRONG STUDY TREATMENT/ ADMINISTRATION/DOSE / STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	SUBJECT MISSED WEEK 8 TREATMENT			
	PPD 2	WRONG STUDY TREATMENT/ ADMINISTRATION/DOSE / STUDY TREATMENT NOT ADMINISTERED PER PROTOCOL	INTERRUPTION OF IP FOR GREATER THAN 20 PERCENT OF TIME			Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: SP1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Population	No Treatment (N=50)	Placebo (N=xxx)	Treatment 1 (N=200)	Treatment 2 (N=250)	Total (N=500)
Screened	50 (100%)	xx (xxx%)	200 (100%)	250 (100%)	500 (100%)
Enrolled	10 (20%)	xx (xxx%)	200 (100%)	250 (100%)	460 (92%)
Randomized	5 (10%)	xx (xx%)	200 (100%)	250 (100%)	455 (91%)
Safety		xx (xx%)	195 (98%)	245 (98%)	440 (88%)
PK		xx (xx%)	200 (100%)	250 (100%)	455 (91%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: POP_L1
Protocol: GSK123456
Population: xxxxx (Randomised subjects)

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Treatment sequence	PK population
xxxxxx/ xxx	ABC	Y
xxxxxx/ xxx	CBA	Y
xxxxxx/ xxx	BAC	Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM3 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)
Sex	
n	100
F	50 (50%)
M	50 (50%)
Age (YEARS)[1]	
n	100
Mean	50.0
SD	10.00
Median	50.0
Min.	18
Max.	65
Age Group(YEARS)[1]	
<=18	5 (5%)
19-64	50 (50%)
>=65	45 (45%)
Ethnicity	
n	100
HISPANIC OR LATINO	10 (10%)
NOT HISPANIC OR LATINO	90 (90%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM3 (continued)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)
Race Detail	
AMERICAN INDIAN OR ALASKA NATIVE	1 (1%)
ASIAN - CENTRAL/SOUTH ASIAN HERITAGE	3 (3%)
ASIAN - EAST ASIAN HERITAGE	4 (4%)
ASIAN - JAPANESE HERITAGE	3 (3%)
ASIAN - SOUTH EAST ASIAN HERITAGE	1 (1%)
BLACK OR AFRICAN AMERICAN	2 (2%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	59 (59%)
WHITE - ARABIC/NORTH AFRICAN HERITAGE	26 (26%)
WHITE - WHITE/CAUSASIAN/EUROPEAN HERITAGE	1 (1%)
MIXED ASIAN RACE	1 (1%)
MIXED WHITE RACE	1 (1%)
MULTIPLE	1 (1%)
Height (cm)	
n	100
Mean	150.0
SD	10.00
Median	50.0
Min.	18
Max.	65

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM3 (continued)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Total (N=100)
Weight (kg)	
n	100
Mean	50.0
SD	10.00
Median	50.0
Min.	18
Max.	65
Options (units)	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM4 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID/ Subj.	Treatment Sequence	Partial Date of Birth	Age (YEARS) [1]	Sex	Ethnicity	Height (cm)	Weight (kg)	Option (unit)
xxxxxx/ xxx	ABC	--MMYYYY	xx	*F*	*HISPANIC OR LATINO*	xxx	xx	
xxxxxx/ xxx	BCA	--MMYYYY	xx	*M*	*NOT HISPANIC OR LATINO*	xxx	xx	
xxxxxx/ xxx	CAB	----YYYY	xx	*M*	*NOT HISPANIC OR LATINO*	xxx	xx	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM5
Protocol: GSK123456
Population: xxxxx

Table x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

		Treatment A (N=XXX)		Treatment B (N=XXX)		Total (N=XXX)	
Race	n	100		100		200	
	African American/African Heritage	30	(30%)	30	(30%)	60	(30%)
	American Indian or Alaskan Native	0		0		0	
	Asian	15	(15%)	15	(15%)	30	(15%)
	Central/South Asian Heritage	3	(3%)	3	(3%)	6	(3%)
	Japanese/East Asian Heritage/South East Asian Heritage	11	(11%)	11	(11%)	22	(11%)
	Mixed Asian Heritage	1	(1%)	1	(1%)	2	(1%)
	Native Hawaiian or other Pacific Islander	10	(10%)	10	(10%)	20	(10%)
	White	35	(35%)	35	(35%)	70	(35%)
	Native Hawaiian or other Pacific Islander & American Indian or Alaskan Native	2	(2%)	2	(2%)	4	(4%)
	White & African American/African Heritage	3	(3%)	3	(3%)	6	(3%)
	White & Asian	5	(5%)	5	(5%)	10	(5%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM11
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	No Treatment (N=1)	Total (N=201)
Age Ranges [1]		
In utero	0	4 (2%)
Preterm newborn infants (gestational age <37 weeks)	0	2 (1%)
Newborns (0-27 days)	0	6 (3%)
Infants and toddlers (28 days-23 months)	0	8 (4%)
Children (2-11 years)	0	6 (3%)
Adolescents (12-17 years)	0	2 (1%)
Adult (18-64 years)	0	118 (59%)
>=65-84 years	0	52 (26%)
>=85 years	1 (100%)	3 (1%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: DM10 (for XO studies)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Treatment sequence	Race	Race Detail
xxxxxx	xxx	ABC	*BLACK OR AFRICAN AMERICAN*	*BLACK OR AFRICAN AMERICAN*
	xxx	BCA	*Mixed race*	*ASIAN – EAST ASIAN HERITAGE* *ASIAN – JAPANESE HERITAGE*
	xxx	CAB	*WHITE – ARABIC/NORTH AFRICAN HERITAGE*	*WHITE – ARABIC/NORTH AFRICAN HERITAGE*
	xxx	ABC	*WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAGE*	*WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAGE*
xxxxxx	xxx	ABC	*Mixed race*	*WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAG* *ASIAN – JAPANESE HERITAGE*
	xxx	BCA	*NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER*	*NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER*
	xxx	CAB	*BLACK OR AFRICAN AMERICAN*	*BLACK OR AFRICAN AMERICAN*
	xxx	ABC	*WHITE - ARABIC/NORTH AFRICAN HERITAGE*	*WHITE - ARABIC/NORTH AFRICAN HERITAGE*
xxxxxx	xxx	BCA	*AMERICAN INDIAN OR ALASKA NATIVE*	*AMERICAN INDIAN OR ALASKA NATIVE*
	xxx	CAB	*Mixed race*	*BLACK OR AFRICAN AMERICAN* *WHITE – WHITE/CAUSASIAN/EUROPEAN HERITAGE*

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: MH3
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv.	Subject	Treatment Sequence	Classification	Condition	Status
PPD		AB	Hepatobiliary	HEPATITIS A	Current
			Psychiatric	PARANOIA COMBINED WITH MANIA.	Past
		AB	Eye	ASTIGMATISM	Current
		BA	Metabolism and nutrition	RICKETS	Current

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CM5
Protocol: GSK123456
Population: xxxxx

Listing x.x

Inv./ Subj./ Seq	Treat- ment/ Period	ATC Level 1/ Ingredient/ Verbatim Text/ Indication	Dose/ Units/ Freq/ Route	Start Date/Time Study Day/ Period Day	Stop Date/Time Study Day/ Period Day	Started Pre- Trial?	Ongoing Medi- cation?
PPD ABC	Tmt A/ Per 1	Endocrine & metabolic/ Fluticasone propionate/ FLIXOTIDE/ Asthma	2/ MG/ 2XD/ IH	PPD 12:30/ 15/ 7			Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CM6
Protocol: GSK123456
Population: xxxxx

Listing x.x

ATC Level 1	Ingredient	Verbatim Text
Endocrine & metabolic	Fluticasone Propionate	FLIXOTIDE
	Prednisolone	PREDNISOLONE
Drugs acting via the nervous system	Paracetamol	PANADOL
		CHILDREN'S PANADOL 1-5YERS

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EX4
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Centre ID	Subj.	Treatment	Start Date/ Start Time of Dose	Stop Date/ Stop Time of Dose	Duration (days)	Dose	Dose Unit	Formulation/ Route	Frequency	Cumulative Dose
xxxxxx	xxx	Treatment A	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Placebo	DDMMMYYYY/ hh:ss		xx	xx	mg	Tablet/ Oral	1xday	
		Treatment C	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
	PPD	Placebo	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Treatment B Treatment C	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Treatment A	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	
		Placebo Treatment B	DDMMMYYYY/ hh:ss	DDMMMYYYY/ hh:ss	xx	xx	mg	Tablet/ Oral	1xday	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_ML1x
Protocol: GSK123456
Population: xxxxx

Listing x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Cohort (Optional)	Investigator OR Centre ID (Optional)	Subj.	Treatment	Meal type (Optional)	Period (Optional) /Visit	Visit Date	Dose Time	Meal Start Time	Meal End Time (Optional)	Mea wi min Mea (Op
			50mg	High-fat	Period					
1	PPD		GSK123456	breakfast	2/Day 4	PPD	8:13	7:30	7:41	Y
			25mg	High-fat	Period					
			GSK123456	breakfast	2/Day 4		8:12	7:28	7:42	Y
			10mg	High-fat	Period					
			GSK123456	breakfast	2/Day 4		8:10	7:27	7:35	Y
			50mg	High-fat	Period					
2			GSK123456	breakfast	2/Day 4		8:09	7:28	7:50	N
			50mg	High-fat	Period					
			GSK123456	breakfast	2/Day 4		8:11	7:30	7:41	Y
			25mg	High-fat	Period					
			GSK123456	breakfast	2/Day 4		8:09	7:25	7:42	Y
			10mg	High-fat	Period					
			GSK123456	breakfast	2/Day 4		8:10	7:27	7:36	Y

USER ID: directory/program.sas DDMMMYYYY hh:mm

10.10.2. Safety population

Example: AE1
Protocol: GSK123456
Population: xxxxx

Table x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

System Organ Class Preferred Term	Placebo (N=78)	Drug A (N=78)	Drug B (N=78)
ANY EVENT	58 (74%)	64 (82%)	64 (85%)
Gastrointestinal disorders			
Any event	xx (xx%)	xx (xx%)	xx (xx%)
Dyspepsia	xx (xx%)	xx (xx%)	xx (xx%)
Nausea	xx (xx%)	xx (xx%)	xx (xx%)
Vomiting Nos	xx (xx%)	xx (xx%)	xx (xx%)
Constipation	xx (xx%)	xx (xx%)	xx (xx%)
Diarrhoea Nos	xx (xx%)	xx (xx%)	xx (xx%)
Toothache	xx (xx%)	xx (xx%)	xx (xx%)
Abdominal Pain Upper	xx (xx%)	xx (xx%)	xx (xx%)
Dry Mouth	xx (xx%)	xx (xx%)	xx (xx%)
Flatulence	xx (xx%)	xx (xx%)	xx (xx%)
Gastrointestinal Upset	xx (xx%)	xx (xx%)	xx (xx%)
Haemorrhoids	xx (xx%)	xx (xx%)	xx (xx%)
Loose Stools	xx (xx%)	xx (xx%)	xx (xx%)
Abdominal Pain Nos	xx (xx%)	xx (xx%)	xx (xx%)
Faecal Incontinence	xx (xx%)	xx (xx%)	xx (xx%)
Gastritis Nos	xx (xx%)	xx (xx%)	xx (xx%)
Lip Disorder Nos	xx (xx%)	xx (xx%)	xx (xx%)
Lip Dry	xx (xx%)	xx (xx%)	xx (xx%)
Stomach Discomfort	xx (xx%)	xx (xx%)	xx (xx%)
Nervous system disorders			
Any event	xx (xx%)	xx (xx%)	xx (xx%)
Headache	xx (xx%)	xx (xx%)	xx (xx%)
Dizziness	xx (xx%)	xx (xx%)	xx (xx%)
Extrapyramidal Disorder	xx (xx%)	xx (xx%)	xx (xx%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE5A
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treatment: Treatment A (N=200)

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	MODERATE /SEVERE	UNKNOWN	Total
ANY EVENT	30 (15%)	40 (20%)	40 (20%)	80 (40%)	1 (<1%)	151 (76%)
Cardiovascular						
Any Event	20 (10%)	40 (20%)	40 (20%)	80 (40%)	0	140 (70%)
Hypertension	0	20 (10%)	20 (10%)	20 (10%)	0	40 (20%)
Syncope	0	0	0	0	0	0
Hypotension	20 (10%)	0	0	40 (20%)	0	60 (30%)
Nervous system disorders	10 (5%)	0	0	0	1 (<1%)	11 (6%)
Any Event	10 (5%)	0	0	0	1 (<1%)	11 (6%)
Dizziness	10 (5%)	0	0	0	1 (<1%)	11 (6%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: LB1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Test (units)	Treatment	N	Planned Time	n	Mean	SD	Median	Min.	Max.
Alkaline Phosphatase (IU/L)	Trt A	202	Week 8	150	2.1	7.95	1	-25	32
			Week 12	133	0.4	10.05	1	-64	33
			Week 24	55	-1.6	18.22	0	-339	44
	Trt B	220	Week 8	150	2.1	7.95	1	-25	32
			Week 12	133	0.4	10.05	1	-64	33
			Week 24	55	-1.6	18.22	0	-339	44
Alanine Aminotransferase (IU/L)	Trt A	202	Week 8	150	-1.2	16.32	0	-320	38
			Week 12	133	0.7	10.55	1	-64	32
			Week 24	55	-3.3	29.50	0	-235	36
	Trt B	220	Week 8	150	-1.2	16.32	0	-320	38
			Week 12	133	0.7	10.55	1	-64	32
			Week 24	55	-3.3	29.50	0	-235	36

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: LB4
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Test= Alanine Aminotransferase (IU/L), Treatment=Treatment A

Planned Time	N	n	Baseline Value	Time Period Value: High	Normal	Low	Total
Week 1	100	100	High	0	1 (1%)	3 (3%)	4 (4%)
			Normal	10 (10%)	84 (84%)	2 (2%)	96 (96%)
			Low	0	0	0	0
			Total	10 (10%)	85 (85%)	5 (5%)	100 (100%)
Week 4	100	100	High	0	1 (1%)	3 (3%)	4 (4%)
			Normal	10 (10%)	84 (84%)	2 (2%)	96 (96%)
			Low	0	0	0	0
			Total	10 (10%)	85 (85%)	5 (5%)	100 (100%)
Worst Case Post-Baseline	100	100	High	0	1 (1%)	3 (3%)	4 (4%)
			Normal	10 (10%)	84 (84%)	2 (2%)	96 (96%)
			Low	0	0	0	0
			Total	10 (10%)	85 (85%)	5 (5%)	100 (100%)

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: UR3b
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Test	Period/Planned Relative Time	Result	Treatment A (N=100)	Treatment B (N=100)
Urine General Dipstick	SCREENING/ SCREENING	Positive	30 (30%)	60 (60%)
		Negative	40 (40%)	30 (30%)
		No Result	30 (30%)	10 (10%)
	PERIOD 1/DAY 1	Positive	40 (40%)	50 (50%)
		Negative	30 (30%)	40 (40%)
		No Result	30 (30%)	10 (10%)
Urine Occult Blood (Dipstick)	SCREENING/ SCREENING	None	40 (40%)	40 (40%)
		Trace	25 (25%)	25 (25%)
		1+	10 (10%)	15 (15%)
		2+	0	0
		3+	0	0
		No Result	10 (10%)	20 (20%)
	PERIOD 1/DAY 1	None	40 (40%)	40 (40%)
		Trace	30 (30%)	30 (30%)
		1+	5 (5%)	5 (5%)
		2+	2 (2%)	4 (4%)
		3+	0	0

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EG1
Protocol: GSK123456 Page 1 of n
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment A (N=157)		Treatment B (N=160)	
Time Period 1				
n	156		160	
Normal	81	(52%)	90	(56%)
Abnormal, not clinically significant	75	(48%)	69	(43%)
Abnormal, clinically significant	0		1	(<1%)
Time Period 2				
n	117		123	
Normal	50	(43%)	67	(54%)
Abnormal, not clinically significant	64	(55%)	55	(45%)
Abnormal, clinically significant	2	(2%)	1	(<1%)
n	117		122	
Clinically significant change from baseline	2	(2%)	1	(<1%)
Not a clinically significant change	115	(98%)	121	(>99%)
Not applicable	0		0	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EG1 (continued)
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment A (N=157)		Treatment B (N=160)	
Any time post-baseline				
n	117		123	
Normal	50	(43%)	67	(54%)
Abnormal, not clinically significant	65	(56%)	55	(45%)
Abnormal, clinically significant	2	(2%)	1	(<1%)
No result (not available)	0		0	
n	117		122	
Clinically significant change from baseline	2	(2%)	1	(<1%)
Not a clinically significant change	115	(98%)	121	(>99%)
Not applicable	0		0	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: EG2
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
PR Interval (msec)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: VS1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
Diastolic BP (mmHg)	Trt A	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125
	Trt B	200	Time 1	200	91.6	11.32	90.0	68	140
			Time 2	190	92.4	9.83	90.0	70	122
			Time 3	186	92.6	10.87	89.0	72	125

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE7
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

System Organ Class Preferred Term	Treatment	No. with Event	Unique Subject Id.
Gastrointestinal disorders Dyspepsia	Placebo	9	PPD
	Treatment A	11	
	Treatment B	4	
Nausea	Placebo	6	
	Treatment A	8	
	Treatment B	4	

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE9CP
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Site Id./ Unique Subject Id./ /Arm	Treatment/ Period	Age(YEARS)/ Sex/ Race Detail/ Weight (kg)	System Organ Class/ Preferred Term/ VERBATIM TEXT	Outcome/ Onset Datetime/ Datetime of Resolution/ Duration	Time since Study 1st Dose/ Period 1st Dose/ Last Dose	Maximum Intensity/ Maximum Grade/ Serious/ Withdrawal	Frequency/ Action Taken/ Relation to Study Treatment
PPD AB-BA-BA	Tmt A/ Per 1	57/ F/ ASIAN - JAPANESE HERITAGE/ 62.0	Gastrointestinal Disorders/ Internal spasm/ ENTERO - SPASM	RECOVERED/RESOLVE PPD T06:05/ T09:35/ 22d 13h 6m	31d 26h 4m/ 31d 26h 4m/ -29d 7h 0m	MILD/ 1 N/ N	INTERMITTENT/ DOSE REDUCED/ Y
	Tmt B/ Per 2	65/ M/ MIXED WHITE RACE/ 75.0	Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN IN RIGHT SHOULDER	RECOVERED/RESOLVE PPD T05:50/ T21:55/ 71d 9h 45m	83d 1h 12m/ 83d 1h 12m/ -17d 2h 5m	MODERATE/ 2/ N/ N	SINGLE EVENT/ DOSE NOT CHANGED/ N

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: AE2
Protocol: GSK123456 Page 1 of n
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

System Organ Class	Preferred Term	Verbatim Text
Blood and lymphatic system disorders	Lymphadenopathy	ENLARGED LYMPH NODE
Cardiac disorders	Palpitations	CLOGGED EARS WITH EAR WAX
	Ear pain	EARACHES IN BOTH EARS
		RIGHT EAR PAIN
	Tinnitus	RINGING IN RIGHT EAR
Eye disorders	Asthenopia	TIRED EYES
	Conjunctivitis	BILATERAL ACUTE CONJUNCTIVITIS
		CONJUNCTIVITIS
	Dry eye nos	DRY EYES
	Eye redness	REDDENED EYES
	Vision blurred	BLURRED VISION
		BLURRY VISION
		WORSENING OF BLURRED VISION
Gastrointestinal disorders	Abdominal pain nos	ABDOMEN PAIN
	Abdominal pain upper	MID-EPIGASTRIC AREA PAIN
		STOMACH ACHE
.	.	.
.	.	.

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_LB6
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq	Age(y)/ Sex/ Race	Treat-ment/ Period	Lab test (units)	Planned Relative Time	Date/Time	Study Day/ Period Day	Converted Data		Flag[1]		
							Value	Normal Range	NR	CI	BL
PPD	63/ Male/ White	Trt A/ Per 1	Alk Phos (U/L)	Screening	PPD 12:05	-1/-1	64.00	32.0- 92.0			
				Week 12	PPD 13:45	85/85	84.00	32.0- 92.0			
			ALT (U/L)	Screening	PPD 13:32	-1/-1	29.00	10.0- 40.0			
				Week 12	PPD 09:55	85/85	70.00	10.0- 40.0	H	H	H

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: UR2b
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv.	Subject	Treatment	Period	Visit	Sample Date	Study Day	Period Day	Urinalysis Test	Result
PPD		Trt A	1	1	PPD	1	1	Blood	++ or 2+
		Trt B	2	8		137	1	Blood	+ or 1+
		Trt B	1	1		1	1	Blood	+ or 1+
								Protein	+++ or 3+
		Trt A	2	8		137	1	Blood	+ or 1+

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: LIVER5
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treatment: Treatment A

Site Id./ Unique Subject Id.	Age(YEARS)/ Sex/ Race Detail	Maximum Status of the Liver Event	Date First Detected/ Study Day	Time Since First Dose (days)	Time Since Last Dose (days)	Restart/Re-challenge After Stopping Criteria Was Met	Resolved?/ Date resolved
PPD	63/ M/ WHITE - WHITE/CAUSASIAN/EUROPEAN HERITAGE	LIVER MONITORING CRITERIA	PPD 101	101	1	N	Y/ 2010-02-19
	61/ F/ ASIAN - JAPANESE HERITAGE	LIVER EVENT STOPPING CRITERIA	PPD 68	68	1	Y	Y/ 2010-04-10
		LIVER EVENT STOPPING CRITERIA	PPD 134	134	7	N	N

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: SU2
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treat-ment	Inv./ Subj.	Visit	Study Day	Assess-ment Date	Smoking History	Cur-rently Smoke	Last Smoked	Smoked Since Last Visit	Days Smoked Since Last Visit	Years Smoked	Ciga-rettes /day	Smoking Pack Years *
Trt A	PPD	Visit 1	1	PPD	Never	No		No	Zero			
		Visit 1	1		Current	Yes		Yes	A few	5	20	5
Trt B		Visit 1	1		Former	No	31DEC1990	No	Zero	18	30	27

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_EG4
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj. /Seq.	Age (y)/ Sex/ Race	Treat- ment/ Period	Planned Relative Time	ECG Date/Time	Study Day /Period Day	Actual Relative Time (optional)	Heart Rate (bpm)	PR Int. (msec)	QRS Dur. (msec)	RR Int. (msec)	QT Int. (msec)	QTcB (msec)	QTcF (msec)
PPD /AB	65/ White/ Female	Trt A/ Per 1	Time 1	PPD 14:00	1/1	-30m	60 L	150	350	750	450	520	495
			Time 2	PPD 15:00	7/7	26m	80	150	350	750	450	520	495
		Trt B/ Per 2	Time 1	PPD 19:00	14/1	-30m	80	150	390 H	750	450	520	495
			Time 2	PPD 20:00	21/7	26m	80	150	350	750	450	520	495
PPD /BA	58 Male/ White/	Trt A/ Per 2	Time 1	PPD 14:00	1/1	-30m	80	90 L	350	800 H	450	520	495
			Time 2	PPD 15:00	7/7	26m	80	150	350	750	450	520	495

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_EG6
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq.	Age (y)/ Sex/ Race	Treat- ment/ Period	Planned Relative Time/ECG Date/Time	Study Day/ Period Day	ECG Finding	Clinically Significant Change from Baseline?	Clinically Significant Abnormality
PPD A/B	65/ Female/ White	Trt A/ Per 1	Visit 1/ PPD /14:00	1/1	Normal		
			Visit 2/ PPD /12:00	4/4	Abnormal-not clinically significant	No	
		Trt B/ Per 2	Visit 3/ PPD /19:00	8/1	Abnormal- clinically significant		Sinus tachycardia
			Visit 4/ PPD /13:00	12/4	No result (not available)		
PPD B/A	58 Male/ White	Trt B/ Per 1	Visit 1/ PPD /14:00	16/1	Abnormal- clinically significant		Ectopic ventricular beats

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: CP_VS5
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq.	Age(y)/ Sex/ Race	Treat-ment/ Period	Planned Relative Time	Actual Date/Time	Study Day/ Period Day	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Vital Sign 3 (units)
PPD	23/	Tmt B/	Time 1	PPD	1/1	190 H	60	xx H
	Male/	Per 1	Time 2		5/5	95	50 L	xx H
B/C/A	White		Time 3		10/10	95	60	xx
		Tmt C/	Time 1		15/1	185 H	90 H	xx H
		Per 2	Time 2		20/5	95	50	xx H
			Time 3		25/10	95	60	xx
		Tmt A/	Time 1		30/1	200 H	45 L	xx H
		Per 3	Time 2		35/5	95	60	xx H
			Time 3		40/10	95	85 H	xx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: SAFE_L1
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Inv./ Subj./ Seq.	Age(y)/ Sex/ Race	Treat-ment/ Period	Planned Relative Time	Actual Date/Time	Study Day/ Period Day	Location/ Category	Test type	Side	Test Result
PPD	23/	Tmt B/	Time 1	PPD	1/	Eye/	Indirect fundoscopic exam	Left	Normal
	Male/	Period x			1	Ophthalmological examination		Right	xxxxx
B/C/A	White						Slit lamp	Left	xxxxxx
								Right	xxxxxx
			Time 2		5/		xxxxxxxxxx	xxxxx	xxxxxxx
					5			xxxxx	xxxxxxx
							xxxxxxxxxx	xxxxx	xxxxxxx
								xxxxx	xxxxxxx
		Tmt C/	Time 1		15/		xxxxxxxxxx	xxxxx	xxxxxxx
		Period 2			1			xxxxx	xxxxxxx

USER ID: directory/program.sas DDMMMYYYY hh:mm

10.10.3. PK population

Example: PK01
Protocol: GSK123456 Page 1 of n
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Treatment	N	{Add. time var.}	Planned Relative Time	n	No. Imputed	Mean	{95% CI (Lower,Upper)}	SD	Median	Min.	Max.
50mg	24		Pre-dose	24	20	xxxx.x	(xxxx.x,xxxx.x)		xxxx.x	xxxx	xxxx
			30 min	24	1	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			1 hr	23	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			2 hr	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
100mg	24		Pre-dose	24	3	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			30 min	21	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			1 hr	21	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			2 hr	21	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
200mg	24		Pre-dose	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			30 min	23	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			1 hr	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx
			2 hr	24	0	xxxx.x	(xxxx.x,xxxx.x)	xx.xx	xxxx.x	xxxx	xxxx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK03
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Treatment	N	{Additional time variables}	n	Mean	{95% CI (Lower,Upper)}	SD	Median	Min.	Max.
AUC(0-t) (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
Cmax (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x
			14	21	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xxxx.xx	xxxx.x	xxxx.x

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK05
Protocol: GSK123456 Page 1 of n
Population: xxxxx

Table x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Treatment	N	{Additional time variables}	n	Geom. Mean	95% CI (Lower,Upper)	SD (logs)	{%CVb}
AUC(0-t) (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	200mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	21	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
Cmax (units)	50mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	100mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	23	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
	200mg	24	1	24	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx
			14	21	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.xx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK_T1
Protocol: GSK123456
Population: xxxxx

Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Effect	n	Slope Point Estimate	SE	90% CI
Parameter1	Log(dose levels)	xx	xxx	xxx	(xx,xx)
Parameter2	Log(dose levels)	xx	xxx	xxx	(xx,xx)
.	.		.	.	.
.	.		.	.	.
.	.		.	.	.

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK_T2
Protocol: GSK123456
Population: xxxxx

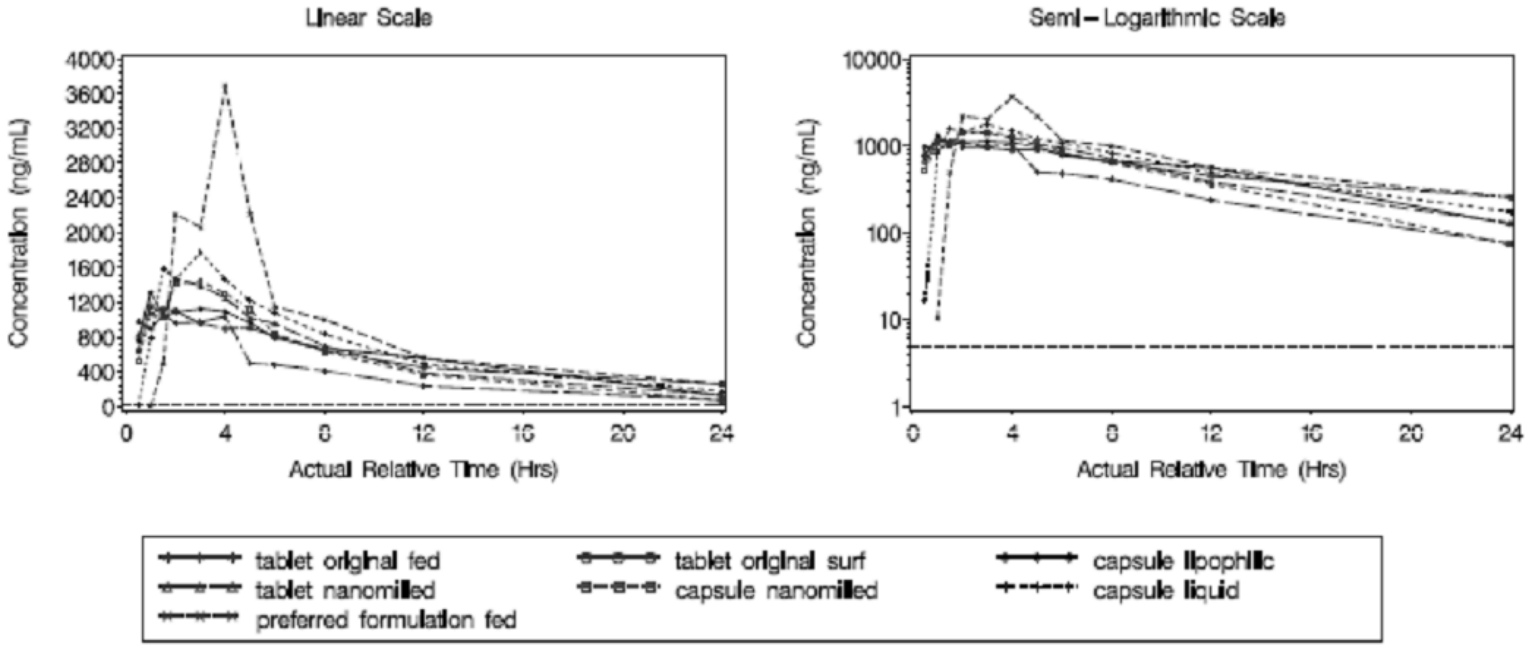
Table x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Parameter	Treatment	N	n	Geometric LS Mean	Ratio (Fasted/Fed)	90% CI	CVw(%)[1]
Parameter1 (unit)	Trt1	xx	xx	xxx	Xxx	(xx,xx)	xx
	Trt2	xx	xx	xxx			
Parameter2 (unit)	Trt1	xx	xx	xxx	xxx	(xx,xx)	xx
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
ParameterX (unit)	xx	xx	xx	xxx	xxx	(xx,xx)	xx

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK16b
Protocol: GSK123456
Population: xxxxx

Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

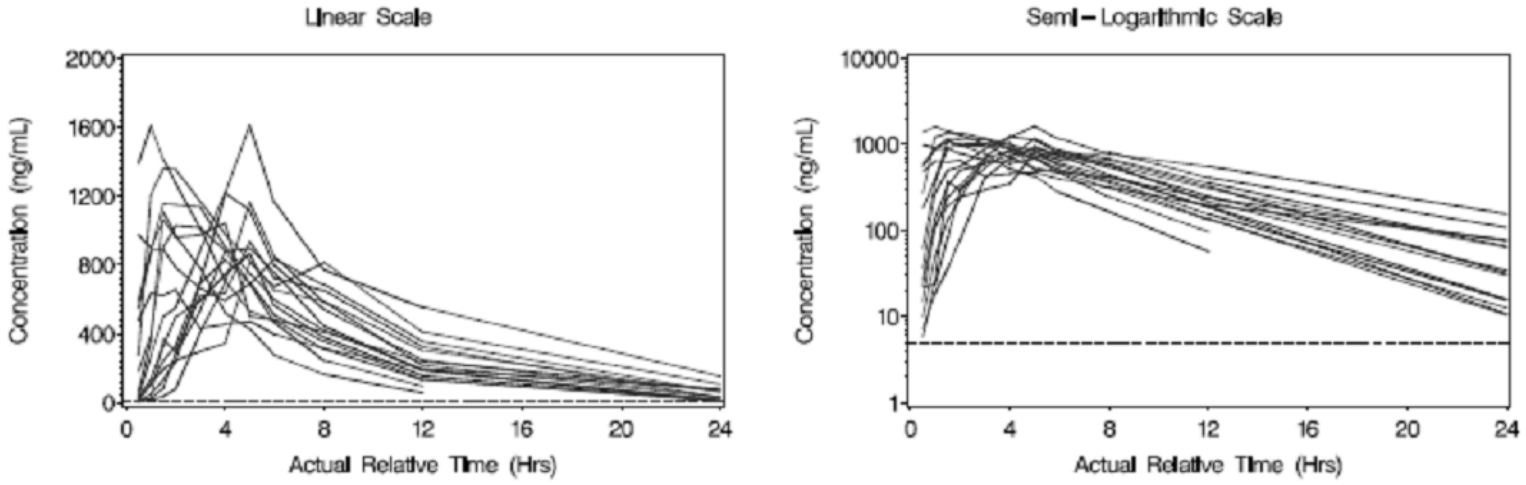


USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK24
Protocol: GSK123456
Population: xxxxx

Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

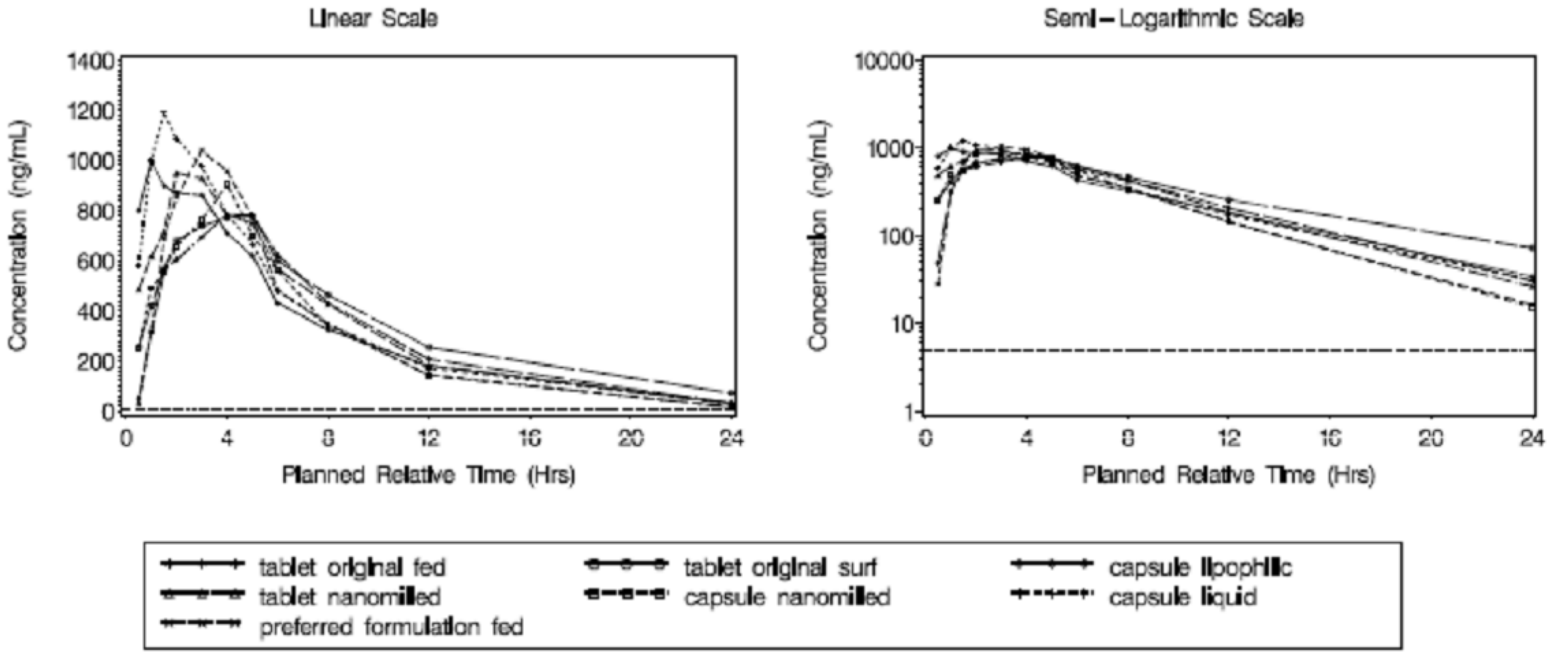
Treatment = tablet original fed



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK18
Protocol: GSK123456
Population: xxxxx

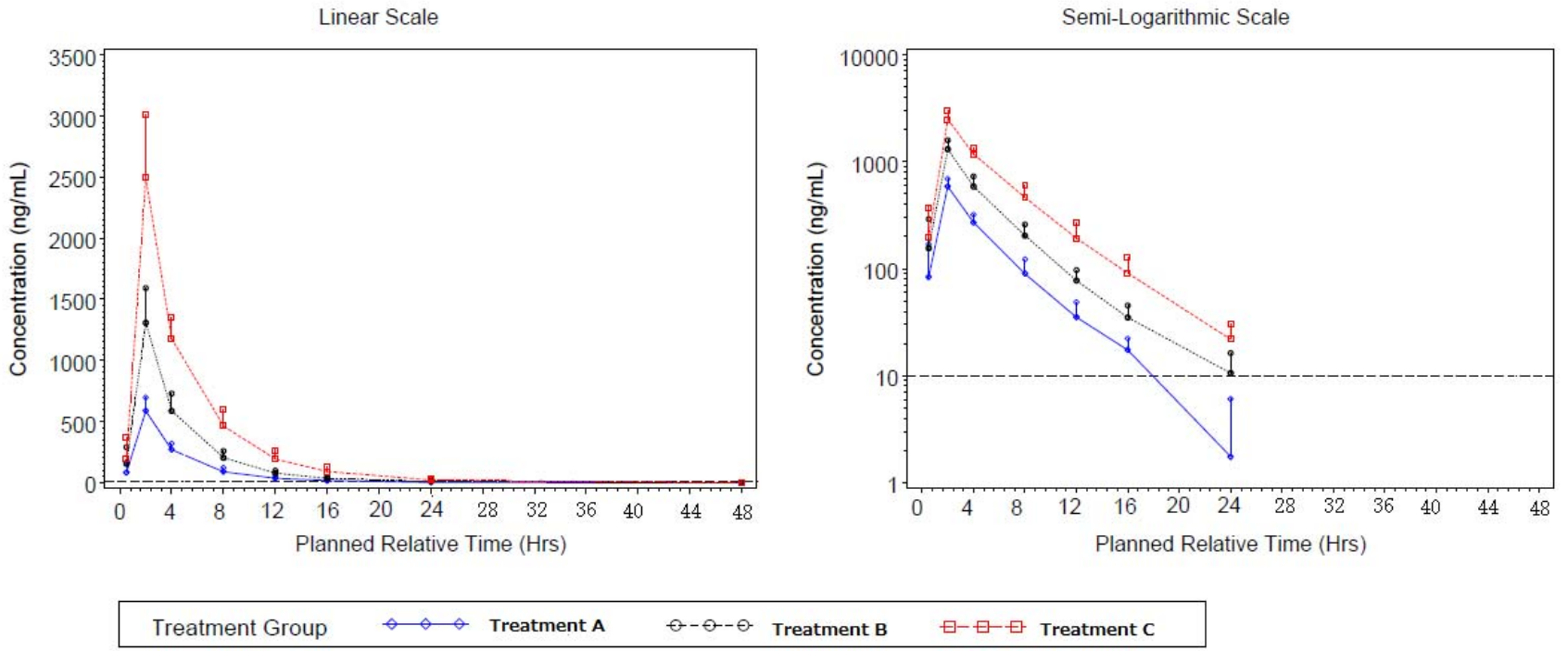
Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK_F1
Protocol: GSK123456
Population: xxxxx

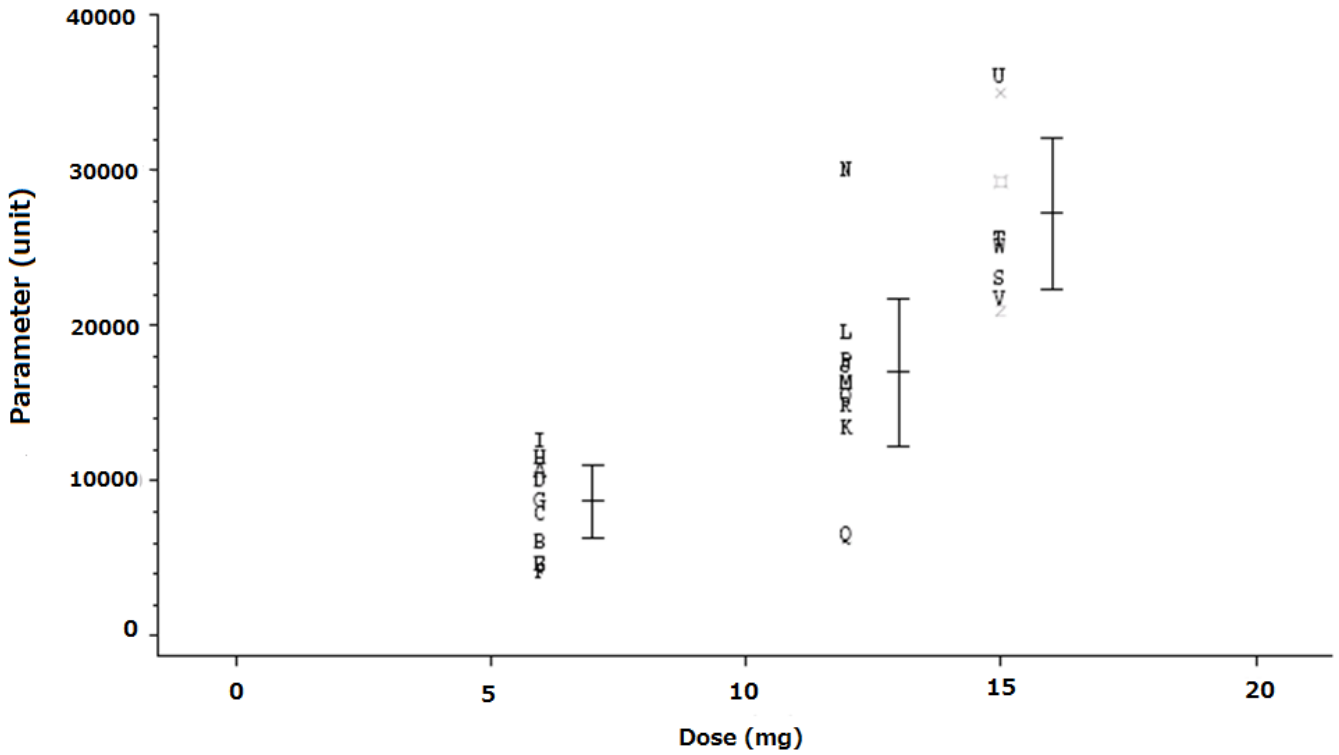
Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK28
Protocol: GSK123456
Population: xxxxx

Figure x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx



USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK08 (pkcl1x)
Protocol: GSK123456
Population: xxxxx

Listing x.x
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

{Inv./} Subj.	{Age(y)/ Sex/ Race}	Period /Tmt.	Date	Study Day / Period Day	Planned Relative Time	Actual time	Time dev. (units)	Actual Relative Time	Concentration (units)
PPD	36/ M/ Mixed Race	1/ 50mg	PPD	1/1	pre-dose	11:55	0	0h 0m 0s	123
					5m	12:05	0	0h 5m 0s	1434
					1h	13:00	0	1h 0m 0s	NQ (<0.23)
					1h 30m	13:30	0	1h 30m 0s	30
		2/ 100mg		17/1	pre-dose	11:57	0	0h 0m 0s	435
					5m	12:10	0.83	0h 10m 0s	34566
					1h	12:56	-0.67	0h 56m 0s	3452
					1h 30m	13:30	0	1h 30m 0s	30
	33/ M/ Mixed Race	1/ 50mg		1/1	pre-dose	11:58	0	0h 0m 0s	2345
					5m	12:04	-0.17	0h 4m 0s	234
					1h	12:35	0.83	1h 0m 0s	NR
					1h 30m	13:30	0	1h 30m 0s	30

USER ID: directory/program.sas DDMMMYYYY hh:mm

Example: PK14
Protocol: GSK123456
Population: xxxxx

Listing x.x
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

{Inv./} Subj.	{Age(y)/ Sex/ Race}	Period/ Tmt.	AUC(0-inf) (units)	AUC(0-t) (units)	Cmax (units)	t1/2 (units)	tmax (units)
PPD	36/ M/ Mixed Race	1/ 50mg	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		2/ 100mg	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	33/ M/ Mixed Race	1/ 50mg	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		2/ 100mg	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	24/ M/ Mixed Race	1/ 50mg	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		2/ 100mg	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

USER ID: directory/program.sas DDMMMYYYY hh:mm