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

Title	:	Reporting and Analysis Plan for A Two-Part, Randomized, Open-Label, Single Dose, Crossover Clinical Study to Assess the Relative Bioavailability of Fixed-Dose Combinations of GSK3640254 and Dolutegravir and to Assess the Effect of Food on the Select Fixed Dose Combination of GSK3640254 and Dolutegravir in Healthy Participants
Compound Number	:	GSK3640254, GSK4107821
Clinical Study Identifier	:	GSK 213055
Effective Date	:	22/06/2021

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report (CSR) for Protocol 213055.
- This RAP is intended to describe the full analyses required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

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1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the CSR for Protocol: 213055.

Revision Chronology:		
Original Protocol 213055	25-MAR-2021	Original
Amendment 1	05-MAY -2021	

2. SUMMARY OF KEY PROTOCOL INFORMATION

This study will compare the relative bioavailability (BA) of 2 Fixed-Dose Combinations (FDCs) of GSK3640254 / Dolutegravir (DTG) with GSK3640254 and DTG administered together as single agents (Part 1). In addition, this study will investigate the effect of food on the pharmacokinetics (PK) of the selected FDC of GSK3640254 / DTG. This study will investigate the effect of a high fat and calorie meal on the PK, safety, and tolerability of the FDC of GSK3640254 + DTG, in comparison with administration under fasting conditions (Part 2).

2.1. Changes to the Protocol Defined Statistical Analysis Plan

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

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
• This is an open-label study	• Biostatistics and Programming teams from both GSK and PPD will remain blinded to the actual randomization schedule. Other teams including PPD Clinical Pharmacology team will remain open-label	• Biostatistics and Programming teams remain blinded following GSK's requirement

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

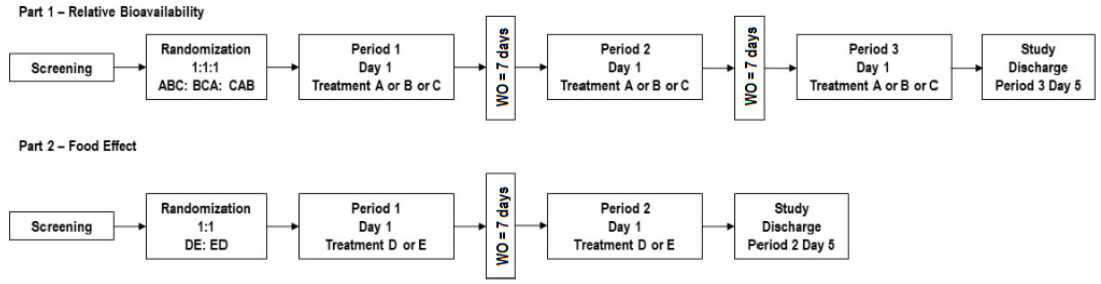
Objectives	Endpoints
Primary	
Part 1 • To assess the relative BA of FDCs of GSK3640254 / DTG compared with GSK3640254 / DTG administered together as single agents when administered with a moderate fat and calorie meal **Part 2** • To assess the effect of food on the PK of the selected FDC of GSK3640254 / DTG when administered with a high fat and calorie meal compared to fasted conditions	**Parts 1 and 2** • Plasma AUC(0-∞), AUC(0-t), and Cmax for GSK3640254 and DTG
Secondary	**Secondary**
Part 1 • To assess the safety and tolerability of FDCs of GSK3640254 / DTG compared with GSK3640254 and DTG administered together as single agents	**Parts 1 and 2** • Safety and tolerability parameters for AEs or SAEs, observed and change from baseline clinical laboratory assessments, ECGs, and vital sign measurements

Objectives	Endpoints
Part 2 • To assess the safety and tolerability of selected FDC of GSK3640254 / DTG following single oral administration to healthy participants under fasted or fed conditions	

2.3. Study Design

Overview of Study Design and Key Features

Figure 1 Study Design Schematic



FDC = fixed dose combination; WO = washout

Design Features	A Phase 1, 2-part, randomized, open-label, crossover study.
	The study will consist of a screening period and a treatment period.
	• Screening Period: within 28 days before the first dose of study intervention
	  ○ Part 1: 3-period, 3-treatment, crossover design, with a washout period of at least 7 days (-4 hours) between doses
	  ○ Part 2: 2-period, 2-treatment crossover design, with a washout period of at least 7 days (-4 hours) between doses

Dosing	• Part 1:
	  ○ Treatment A = A single oral dose of GSK3640254 25 mg (2 x tablets), GSK3640254 100 mg (1 x tablet) and DTG 50 mg (1 x tablet) administered together under moderate fat and calorie conditions
	  ○ Treatment B = A single oral dose of GSK3640254 / DTG, 150 mg / 50 mg (1 x monolayer tablet) FDC administered under moderate fat and calorie conditions.
	  ○ Treatment C = A single oral dose of GSK3640254 / DTG, 150 mg / 50 mg (1 x bilayer tablet) FDC administered under moderate fat and calorie conditions.
	
	• Part 2:
	  ○ Treatment D = A single oral dose of selected FDC of GSK3640254 / DTG, 150 mg /50 mg administered under high fat and calorie conditions
	  ○ Treatment E = A single oral dose of selected FDC of GSK3640254 / DTG, 150 mg / 50 mg administered under fasted conditions

Time & Events	• Refer to Appendix 1: Schedule of Activities
Treatment Assignment	• This is a randomized study. Biostatistics and Programming teams from both GSK and PPD will remain blinded to the actual randomization schedule. Other teams including PPD Clinical Pharmacology team will remain open-label.

Overview of Study Design and Key Features	
	• In Part 1, participants will be randomly assigned to 1 of 3 treatment sequences in 1:1:1 ratio; in Part 2, participants will be randomly assigned to 1 of 2 treatment sequences in 1:1 ratio. • Site pharmacy group will use a computer-generated randomization schedule for treatment assignments. • The computer-generated randomization schedule will be produced by SAS software (Version 9.4).
Interim Analysis	• After completion of Part 1 the study, preliminary safety & PK data will be analyzed by PPD under the oversight of Clinical Pharmacology Modeling & Simulation within VH/GSK to determine the formulation to be used in Part 2. • GSK Clinical Pharmacology Modeling and Simulation and the study team will inform the principal investigator of the formulation decision. • The interim outputs will be produced by WinNonlin (8.0 or higher).

2.4. Statistical Hypotheses

There is no formal research hypothesis that will be statistically tested in this study.

2.5. Sample Size

As there is no formal research hypothesis being statistically tested in this study, the sample size was not selected based on statistical considerations but determined using feasibility. For each part, approximately 18 participants will be enrolled to ensure that 14 evaluable participants complete the study. If participants prematurely discontinue the study, additional participants may be enrolled after consultation with the sponsor to ensure that the required number of evaluable participants complete the study.

Since it was expected that coadministration of GSK3640254 and DTG would increase the exposure of DTG, ranges for point estimate for a ratio of 1.0, 1.1, and 1.2 were explored. It was expected that coadministration of GSK3640254 with DTG would have no significant impact on the exposure of GSK3640254, thus ranges for point estimate for a ratio of 0.9, 1.0, and 1.1 were explored. The details of the results of these analyses can be found in the protocol Section 9.2.

2.6. Study Blinding

The Biostatistics and Programming teams for GSK will be blinded during this study. PPD will work with ADaM datasets and table, listing, and figures (TLFs) based on the surrogate randomization schedule, and not having access to the actual randomization schedule until unblinding process in the final analysis.

Once Medidata RaveDatabase Hard Lock occurs, Source Data Lock is achieved, at which point the PPD team will switch from surrogate to actual randomization. The unblinded SDTM datasets will be transferred to the GSK Data Management team, who will authorize Database Freeze (DBF). At this point the entire GSK study team is officially unblinded.

3. PLANNED ANALYSES

3.1. Interim Analyses

There is no formal interim analysis planned but an analysis using preliminary PK data from Part 1 will be used to determine the formulation to be used for Part 2.

GSK Clinical Pharmacology Modeling and Simulation and the study team will inform the principal investigator of the formulation decision.

The interim outputs will be produced by WinNonlin (8.0 or higher).

3.2. Final Analyses

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

1. All participants have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR).
3. All criteria for unblinding the randomization codes have been met.
4. Randomization codes have been distributed by the PPD Randomization Team to PPD Biostatistics and Programming team.
5. Database freeze has been declared by GSK Data Management after reviewing the unblinded SDTM datasets.
6. Only after DBF has been declared by GSK Data Management can GSK Biostatistics and Programming be unblinded.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All participants who signed the informed consent form • This population will be used for screen failure listing and summary.	• Study Population
Enrolled	• All participants who passed screening and entered the study. • This population will be used for summary of enrolled participants	• Study Population
Randomized	• All participants who were randomly assigned to a treatment sequence. • This population will be used for listing of randomization schedule.	• Study Population
Safety	• All participants who received at least one dose of study intervention. • This population will be used for the safety displays and baseline/demographic characteristics.	• Study Population • Safety
Pharmacokinetic Concentration	• All participants who underwent plasma PK sampling and had evaluable PK assay results. • This population will be used for the PK concentration listings, summary tables, and plotting of concentration-time data.	• PK Concentration
Pharmacokinetic Parameter	• All participants who underwent plasma PK sampling and had evaluable PK parameters estimated. • This population will be used for PK parameter listings, PK parameter summary tables, and statistical analysis tables.	• PK Parameter • PK statistical analysis

Refer to Appendix 9: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management, or patient assessment) will be summarized 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. The “significant” protocol deviation in the Protocol Deviation Management Plan is equivalent to “important” protocol deviations.

- Data will be reviewed prior to unblinding and freezing the database to ensure all significant deviations [and deviations which may lead to exclusion from the analysis populations] are captured and categorized 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 listing will be based on data as recorded on the inclusion/exclusion page of the electronic case report form (eCRF).

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions		
Data Displays for Reporting – Part 1		
By Treatment		
Description	**Code**	**Order in TLF**
A single oral dose of GSK3640254 25 mg (2 x tablets), GSK3640254 100 mg (1 x tablet) / DTG 50 mg (1 x tablet) administered together under moderate fat and calorie conditions (reference)	Treatment A	1
A single oral dose of GSK3640254 / DTG, 150 mg / 50 mg (1 x monolayer tablet) FDC administered under moderate fat and calorie conditions	Treatment B	2
A single oral dose of GSK3640254 / DTG, 150 mg / 50 mg (1 x bilayer tablet) FDC administered under moderate fat and calorie conditions	Treatment C	3
By Sequence		
Description	**Code**	**Order in TLF**
Sequence 1	ABC	1
Sequence 2	BCA	2
Sequence 3	CAB	3
Data Displays for Reporting – Part 2		
By Treatment		
Description	**Code**	**Order in TLF**
A single oral dose of selected FDC from Part 1 of GSK3640254 / DTG, 150 mg / 50 mg administered under high fat and calorie conditions	Treatment D	1
A single oral dose of selected FDC from Part 1 of GSK3640254 / DTG, 150 mg / 50 mg administered under fasted conditions	Treatment E	2
By Sequence		
Description	**Code**	**Order in TLF**
Sequence 1	DE	1
Sequence 2	ED	2

5.2. Baseline Definitions

For 12-lead ECGs and vital signs, the baseline value will be the average (for quantitative assessments) or the worst case (for interpretation) of the triplicate pre-dose assessments within each period. For clinical laboratory parameters, the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled

visits, prior to the first study drug administration in each treatment period. If there is no non-missing value prior to the first study drug administration in each treatment period, the last non-missing value in the previous treatment period will be defined as baseline..

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Day -1	Day 1 (Pre-Dose)	
Safety				
Vital Signs	X	X	X	Day 1 (Pre-Dose) [1] for each period
12-Lead ECG	X	X	X	Day 1 (Pre-Dose) [1] for each period
Hematology	X	X		Day -1 for each period[2]
Clinical Chemistry	X	X		Day -1 for each period[2]
Urinalysis	X	X		Day -1 for each period[2]

ECG = electrocardiogram.
[1] The average (for quantitative assessments) or the worst case (for interpretation) of the pre-dose triplicate assessments will be used as the baseline.
[2] Day -1 in periods 2 and 3 refers to the Day 7 of the previous period.

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

5.3. Other Considerations for Data Analyses and Data Handling Conventions

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

Section	Component
11.1	Appendix 1: Schedule of Activities
11.2	Appendix 2: Study Phases and Treatment Emergent Adverse Events
11.3	Appendix 3: Data Display Standards & Handling Conventions
11.3.3	Appendix 4: Derived and Transformed Data
11.5	Appendix 5: Reporting Standards for Missing Data
11.6	Appendix 6: Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events
11.7	Appendix 7: Values of Potential Clinical Importance
11.8	Appendix 8: Abbreviations & Trade Marks
11.9	Appendix 9: List of Data Displays

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the Screened, Randomized, or Safety population, unless otherwise specified.

Study population analyses including analyses of participant's disposition, protocol deviations (including inclusion/exclusion criteria deviations), demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on VH/GSK's Integrated Data Standards Library standards. Details of the planned displays are presented in Appendix 9: List of Data Displays.

7. PHARMACOKINETIC ANALYSES

7.1. Primary Pharmacokinetic Analyses

7.1.1. Endpoint / Variables

7.1.1.1. Drug Concentration Measures

Refer to Appendix 3: Data Display Standards & Handling Conventions (Section 11.3.3 Reporting Standards for PK). Plasma concentrations of GSK3640254 and DTG will be measured and presented in tabular form and will be summarized descriptively. Plasma GSK3640254 and DTG concentration-time data will be listed by participant, treatment group, and sampling time for each study part and summarized by treatment group and sampling time for each study part.

7.1.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters will be calculated by standard non-compartmental analysis according to current working practices and using the currently supported version of WinNonlin (8.0 or higher). All calculations of non-compartmental parameters will be based on actual sampling times. Pharmacokinetic parameters listed will be determined from the plasma concentration-time data, as data permit. Participants who experience emesis at or before 2 times median Tmax or participants whose pre-dose concentrations are >5% of their Cmax value for the given treatment will be excluded from the calculation of summary statistics and statistical analysis for the respective treatment.

Parameter	Parameter Description
AUC(0-∞)	Area under the plasma concentration-time curve from time 0 extrapolated to infinity, to be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
AUC(0-t)	Area under the plasma concentration-time curve from time 0 to the last quantifiable concentration, to be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
Cmax	Maximum observed concentration, determined directly from the concentration-time data.

NOTES:

- Additional parameters may be included as required.

7.1.2. Summary Measure

Pharmacokinetic parameters AUC(0-∞), AUC(0-t), and Cmax of GSK3640254 and DTG following single dose administration of GSK3640254 and DTG administered together as single agents and following single dose administration of FDC tablet formulations of GSK3640254 / DTG to healthy participants.

7.1.3. Population of Interest

The primary PK analyses will be based on the PK concentration population for plasma PK concentrations and the PK parameter population for plasma PK parameters and statistical analysis.

7.1.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 9: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.1.1 will be summarized using descriptive statistics and listed.

Primary plasma PK parameters (AUC[0-∞], AUC[0-t], and Cmax) will be estimated for GSK3640254 and DTG. Summary statistics (arithmetic mean, geometric mean, median, standard deviation [SD], coefficient of variation [CV], minimum, maximum, between-subject coefficient of variation [CVb], and 95% confidence interval [CI]) for plasma GSK3640254 and DTG PK parameter values will be summarized by treatment for each study part.

Summary statistics (arithmetic mean, 95% CI, SD, median, minimum, and maximum) for plasma GSK3640254 and DTG PK concentrations will be summarized by treatment using the PK Concentration Population.

7.1.4.1. Statistical Methodology Specification

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

Endpoint / Variables
• Plasma primary PK endpoints include AUC(0-∞), AUC(0-t), and Cmax for GSK3640254 and DTG as data permit.
Model Specification
Part 1 • Analysis will be performed to compare the relative BA of 2 FDCs of GSK3640254 and DTG with GSK3640254 and DTG administered together as single agents. Analyses will be performed on the natural logarithms of AUC(0-∞), AUC(0-t), and Cmax using linear -mixed effect models with treatment, period, and sequence as fixed effects and participant nested within a sequence as a random effect. Effects will be estimated, and CIs will be constructed for the following treatment comparisons: o Treatment B (test) versus Treatment A (reference) o Treatment C (test) versus Treatment A (reference) o Point estimates, 90% CIs, and intra-subject CV% for treatment differences on the log scale derived from the model will be exponentiated to obtain estimates for geometric mean ratios and CIs on the original scale. Part 2 • Analysis will be performed to compare the effect of food (-high fat and calorie meal) on the PK of GSK3640254 and DTG following administration of the selected FDC tablet formulation from Part 1. Analyses will be performed on the natural logarithms of AUC(0-∞), AUC(0-t), and Cmax using linear mixed-effect models with treatment, period, and sequence as fixed

effects and participant nested within a sequence as a random effect. Effects will be estimated, and CIs will be constructed for the following treatment comparisons: o Treatment D (test) versus Treatment E (reference) o Point estimates, 90% CIs, and intra-subject CV% for treatment differences on the log scale derived from the model will be exponentiated to obtain estimates for geometric mean ratios and CIs on the original scale
Model Checking & Diagnostics
• Model assumptions will be applied, but appropriate adjustments may be made based on the data.
Model Results Presentation
Part 1 • Statistical analysis for comparison of GSK3640254 and DTG relative BA by analysis of variance (ANOVA) will be presented in tabular format with geometric mean ratios for the following treatment comparison: o Treatment B (test) versus Treatment A (reference) o Treatment C (test) versus Treatment A (reference) Part 2 • Statistical analysis for the effect of food (high fat high calorie meal) by ANOVA will be presented in tabular format with geometric mean ratios for the following treatment comparisons: o Treatment D (test) versus Treatment E (reference)

7.2. Secondary Pharmacokinetic Analyses

7.2.1. Endpoint / Variables

7.2.1.1. Drug Concentration Measures

Refer to Appendix 3: Data Display Standards & Handling Conventions (Section 11.3.3 Reporting Standards for Pharmacokinetic).

7.2.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters will be calculated by standard non-compartmental analysis according to current working practices and using the currently supported version of WinNonlin (8.0 or higher). All calculations of non-compartmental parameters will be based on actual sampling times. Participants who experience emesis at or before 2 times median Tmax or participants whose pre-dose concentrations are >5% of their Cmax value for the given treatment will be excluded from the calculation of summary statistics for the respective treatment.

Plasma PK parameters listed below will be determined from the plasma concentration-time data, as data permits:

Parameter	Parameter Description
Tmax	Time of maximum observed concentration
Tlag	Lag time for absorption
t1/2	Apparent terminal phase half-life
CL/F	Apparent clearance following extravascular administration

NOTES:

- Additional parameters may be included as required.

7.2.2. Summary Measure

Pharmacokinetic parameters Tmax, Tlag, t1/2, and CL/F following single dose administration of GSK3640254 and DTG administered together as single agents and following single dose administration of FDC tablet formulations of GSK3640254 / DTG to healthy participants.

7.2.3. Population of Interest

The secondary PK analyses will be based on the PK parameter population for plasma PK parameters, unless otherwise specified.

7.2.4. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 9: List of Data Displays and statistical principles.

Unless otherwise specified, endpoints/variables defined in Section 7.2.1 will be summarized using descriptive statistics and listed.

Secondary plasma PK parameters Tmax, Tlag, t1/2, and CL/F will be estimated for GSK3640254 and DTG. Summary statistics (arithmetic mean, geometric mean, median, CV, SD, minimum, maximum, CVb, and 95% CI) for secondary plasma PK parameters of GSK3640254 and DTG will be summarized by treatment.

8. SAFETY ANALYSES

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

8.1. Adverse Events Analyses

Adverse events (AEs) analyses including the analysis of AEs, serious (SAEs), and other significant AEs will be based on VH/GSK's Integrated Data Standards Library standards. The details of the planned displays are provided in Appendix 9: List of Data Displays.

Adverse events will be assigned to the last treatment received prior to start date/time of the AE. If no time was reported for an AE and the date is the same as date of dosing, the AE will be assigned to the treatment dosed on that day. Adverse events occurring after the last dose date and time + 5 days (Day 6 and beyond for each treatment period) and before the dose date and time of the next treatment will not be summarized but will be listed.

8.2. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of chemistry laboratory tests, hematology laboratory tests, urinalysis, pregnancy tests, and other screening tests will be based on VH/GSK's Integrated Data Standards Library standards and will be graded using the Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events (Version 2.1, July 2017). The details of the planned displays are in Appendix 9: List of Data Displays.

8.3. Adverse Events of Special Interest

-At the end of the study, QT prolongation, gastrointestinal intolerability, gastric toxicity, psychiatric events, nervous system disorders, and skin and subcutaneous tissue disorders will be summarized by treatment. A listing will also be provided accordingly.

The AESI of QT prolongation will be defined as cardiac disorders system organ class (SOC) plus preferred terms (PTs) using the Medical Dictionary for Regulatory Activities (MedDRA) Standardized MedDRA Query (SMQ) "Torsade de pointes/QT Prolongation" (narrow and broad terms) plus seizure.

Gastrointestinal intolerability and gastric toxicity AESIs will be defined within three narrow sub-SMQs [Gastrointestinal nonspecific symptoms and therapeutic procedures SMQ; Gastrointestinal nonspecific dysfunction SMQ; Gastrointestinal nonspecific inflammation (SMQ)] plus a selection of relevant broad PTs from the Gastrointestinal non-specific symptoms and therapeutic procedures SMQ.

Psychiatric AESI will be defined within the following:

- Sub-SMQ "Suicide/self-injury" (SMQ) from parent SMQ of "Depression and Suicide/Self Injury". Only narrow terms from the sub-SMQ will be selected.

- Sub-SMQ “Depression (excluding suicide and self-injury)” (SMQ) from parent SMQ of “Depression and Suicide/Self Injury”. Only narrow terms from the sub-SMQ will be selected.
- All PTs from high level group term (HLGT) “Manic and Bipolar Mood Disorders and Disturbances” under SOC “Psychiatric Disorders”.
- Narrow terms from SMQ “Psychosis and Psychotic Disorders” selected.
- All PTs from HLGT “Anxiety Disorders and Symptoms”, under SOC “Psychiatric disorders”.
- All PTs from HLGT “Sleep Disorders and Disturbances” and HLGT “Sleep disturbances (include subtypes)”.

Nervous system disorders AESIs will be defined within the following:

- Four HLGTs under Nervous System Disorders SOC: “Headaches”; “Mental impairment disorders (excluding dementia)”; “Disturbance in consciousness” and “Seizures and seizure disorder”

Skin and subcutaneous tissue disorder AESIs will be defined with the following PTs:

Skin and subcutaneous tissue disorders term to be provided when the final analyis is carried out(term will include rash, maculopapular rash, urticaria etc).

8.4. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs, vital signs, pregnancy, and Columbia-Suicide Severity Rating Scale (CSSR-S) questionnaire will be based on VH/GSK’s Integrated Data Standards Library standards, unless otherwise specified. A figure of mean change from baseline in QTc using the Fridericia formula (QTcF) interval along with the 2-sided 95% CI using Student’s t distribution will be presented by treatment and visit. The details of the planned displays are presented in Appendix 9: List of Data Displays.

9. ADDITIONAL ANALYSES DUE TO THE COVID-19 PANDEMIC

9.1. Study Population

9.1.1. Additional Displays for Participants with a COVID-19 Infection

A participant is defined as having a suspected, probable, or confirmed COVID-19 infection during the study if the answer is “Confirmed”, “Probable”, or “Suspected” to the case diagnosis question from the COVID-19 coronavirus infection assessment eCRF.

Summaries and listings of the numbers of participants with a suspected, probable, or confirmed COVID-19 infection, and of COVID-19 test results will be based on VH/GSK’s Integrated Data Standards Library standards. The details of the planned displays are provided in Appendix 9: List of Data Displays.

9.2. Safety

9.2.1. Assessment of COVID-19 AEs

A Standardised MedDRA Query (SMQ) will be used to identify all COVID-19 AEs.

The incidence of AEs and SAEs (Fatal and Non-Fatal) of COVID-19, COVID-19 AEs leading to study drug discontinuation, COVID-19 AEs leading to study withdrawal, and COVID-19 AEs by severity, will be obtained from standard AE and SAE summaries.

10. REFERENCES

- Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse. Version 2.1. July 2017. Division of AIDS National Institute of Allergy and Infectious Diseases National Institutes of Health US Department of Health and Human Services Events. Retrieved on 28/04/2021 at : https://rsc.niaid.nih.gov/sites/default/files/daidsgradingcorrectedv21.pdf
- ViiV Healthcare Study number 213055. A Relative Bioavailability and Food-Effect Study of the Fixed Dose Combination of GSK3640254 and Dolutegravir in Healthy Participants. ClinicalTrials.gov Identifier: IND139,838. 25 March 2021.

11. APPENDICES

11.1. Appendix 1: Schedule of Activities

11.1.1. Protocol Defined Schedule of Events

Screening Visit (Part 1 and Part 2)

Visit Window (relative to Day 1)	Screening (up to 35 days before Day 1)
Outpatient Visit	X
Informed Consent	X
Inclusion and exclusion criteria	X
Demography	X
Full physical examination including height and weight[1]	X
Laboratory assessments (hematology, clinical chemistry, urinalysis)	X
12-lead electrocardiogram	X
Vital sign measurements	X
Medication/drug/alcohol history	X
Past and current medical conditions	X
Columbia-Suicide Severity Rating Scale	X
Serum pregnancy test	X
Follicle-stimulating hormone (as needed, to confirm postmenopausal status)	X
Drug, alcohol, and cotinine screen	X
Human immunodeficiency virus, hepatitis B and C screening	X
Molecular test for SARS-CoV-2[2]	X
1. A full physical examination will include at a minimum, assessments of the skin, cardiovascular, respiratory, gastrointestinal, and neurological systems. 2. Two consecutive approved molecular tests (polymerase chain reaction or antigen test). The first test should be performed ≥7 days prior to admission.	

Time and Events (Part 1)

Procedure	Check-in	Baseline[1]	Period 1 & 2				Period 3				Notes
	Day -2	Day –1	Day 1	Washout			Day 1	Day 2	Days 3-4	Day 5[2]	
				Day 2	Days 3-5	Days 6-7					
Admit to clinic	X										
Discharge from clinic										X	Discharge from clinic following completion of the last study procedure on Day 5 of Period 3.
Brief physical examination		X				D7				X	Interim or symptom-targeted physical examination will be performed at the discretion of the investigator. See Section 8.2.1 of the protocol for description of brief physical examination.
Vital signs		X	X	X	D3	D7	X	X	X	X	Blood pressure and pulse will be measured in triplicate at predose on Day 1 in all periods. Single blood pressure and pulse will be measured on other study days.
Temperature check	X	X	X	X	X	X	X	X	X	X	
12-lead ECG		X	X				X			X	The ECGs on Day 1 in all periods will be taken at predose, and post-dose at 2, 4, and 6 hours. The predose ECGs will be taken in triplicate to establish a baseline QTcF. The post-dose ECGs are single ECGs.
Drug, alcohol, and cotinine screen	X										See Appendix 2 of the protocol for specific tests to be performed.
Molecular test for SARS-CoV-2	X*				D5					X	* The second test will be performed on Day -2 after admission to the clinic. Participants will be quarantined within the clinic until the second test result is negative. Once the second test result is confirmed negative, participants can be released into the study unit and will follow infection control practices.
Laboratory assessments (hematology, chemistry, urinalysis)		X[3]		X		D7		X		X	See Appendix 2 of the protocol for specific tests to be performed. Day 2 samples in each period to be collected 24 hours after dosing.
Pregnancy test	X									X	Serum testing on Day –2
Columbia-Suicide Severity Rating Scale		X				D7				X	
Study intervention: GSK3640254 25 mg, 100 mg or GSK3640254 / DTG 150 mg / 50 mg fixed-dose combination Or DTG 50 mg			X				X				See Section 4.1. of the protocol
GSK3640254 PK sampling			X	X	D3, D4, D5		X	X	X	X	Blood for PK analysis of GSK3640254 will be collected within 40 minutes prior to dosing and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 24, 48, 72, and 96 hours post-dose in all periods.

Procedure	Check-in	Baseline[1]	Period 1 & 2				Period 3				Notes
	Day -2	Day –1	Day 1	Washout			Day 1	Day 2	Days 3-4	Day 5[2]	
				Day 2	Days 3-5	Days 6-7					
Dolutegravir PK sampling			X	X	D3, D4, D5		X	X	X	X	Blood for PK analysis of dolutegravir will be collected within 40 minutes prior to dosing and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 24, 48, 72, and 96 hours post-dose in all periods.
AE review			←==========X==========→								
SAE review	←==========X==========→										
Concomitant medications	←==========X==========→										

AE = adverse event; D = day; ECG = electrocardiogram; PK = pharmacokinetic; QTcF = QT interval corrected using Fridericia's formula; SAE = serious adverse event.

1 Baseline assessments will be collected on Day -1 before Period 1.

2 Evaluations scheduled for Day 5 in Period 3 will also be performed for participants who discontinue early.

3 Review and approval prior to dosing on Day 1 in Periods 1, 2 and 3..

Time and Events (Part 2)

Procedure	Check-in	Baseline[1]	Period 1				Period 2				Notes
	Day -2	Day –1	Day 1	Washout			Day 1	Day 2	Days 3-4	Day 5[2]	
				Day 2	Days 3-5	Days 6-7					
Admit to clinic	X										
Discharge from clinic										X	Discharge from clinic following completion of the last study procedure on Day 5 of Period 2.
Brief physical examination		X				D7				X	Interim or symptom-targeted physical examination will be performed at the discretion of the investigator. See Section 8.2.1 of the protocol for description of brief physical examination.
Vital signs		X	X	X	D3	D7	X	X	X	X	Blood pressure and pulse will be measured in triplicate at predose on Day 1 in both periods. Single blood pressure and pulse will be measured on other study days.
Temperature check	X	X	X	X	X	X	X	X	X	X	
12-lead ECG		X	X			D7	X			X	The ECGs on Day 1 in all periods will be taken at predose, and post-dose at 2, 4, and 6 hours. The predose ECGs will be taken in triplicate to establish a baseline QTcF. The post-dose ECGs are single ECGs.
Drug, alcohol, and cotinine screen	X										See Appendix 2 of the protocol for specific tests to be performed.
Molecular test for SARS-CoV-2	X*				D5					X	* The second test will be performed on Day -2 after admission to the clinic. Participants will be quarantined within the clinic until the second test result is negative. Once the second test result is confirmed negative, participants can be released into the study unit and will follow infection control practices.
Laboratory assessments (hematology, chemistry, urinalysis)		X[3]		X		D7		X		X	See Appendix 2 of the protocol for specific tests to be performed. Day 2 samples in each period to be collected 24 hours after dosing.
Pregnancy test	X									X	Serum testing on Day –2
Columbia-Suicide Severity Rating Scale		X				D7				X	
Study intervention: GSK3640254 25 mg, 100 mg or GSK3640254 / DTG 150 mg / 50 mg fixed-dose combination Or DTG 50 mg			X				X				See Section 4.1. of the protocol

Procedure	Check-in	Baseline[1]	Period 1				Period 2				Notes
	Day -2	Day –1	Day 1	Washout			Day 1	Day 2	Days 3-4	Day 5[2]	
				Day 2	Days 3-5	Days 6-7					
GSK3640254 PK sampling			X	X	D3, D4, D5		X	X	X	X	Blood for PK analysis of GSK3640254 will be collected within 40 minutes prior to dosing and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 24, 48, 72, and 96 hours post-dose in both periods.
Dolutegravir PK sampling			X	X	D3, D4, D5		X	X	X	X	Blood for PK analysis of dolutegravir will be collected within 40 minutes prior to dosing and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 24, 48, 72, and 96 hours post-dose in both periods.
AE review			←==========X==========→								
SAE review	←==========X==========→										
Concomitant medications	←==========X==========→										

AE = adverse event; D = day; ECG = electrocardiogram; PK = pharmacokinetic; QTcF = QT interval corrected using Fridericia's formula; SAE = serious adverse event.
1 Baseline assessments will be collected on Day -1 before Period 1.
2 Evaluations scheduled for Day 5 in Period 2 will also be performed for participants who discontinue early.
3 Review and approval prior to dosing on Day 1 of Periods 1, 2 and 3.

The timing of planned study assessments may change during the course of the study based on emerging data/in-stream data review (e.g., to obtain data closer to the time of peak plasma concentrations) to ensure appropriate monitoring. Any changes in the timing of time points for any planned study assessments as the result of emerging PK data from this study must be documented and approved by the relevant study team member and then archived in the sponsor and site study files but will not constitute a protocol amendment. The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) will be informed of any safety issues that constitute a substantial amendment and require alteration of the safety monitoring scheme or amendment of the informed consent form (ICF). The changes will be approved by the healthy authority and the ethics committee before implementation.

11.2. Appendix 2: Study Phases and Treatment Emergent Adverse Events

11.2.1. Study Phases

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

Study Phase	Definition
Pre-Treatment	Date and Time ≤ Study Treatment Start Date and Time
On-Treatment	Study Treatment Start Date and Time < Date and Time ≤ Study Treatment Stop Date and Time + 5 days the Date and Time of Early Withdrawal Visit whichever is later.
Post-Treatment	Date and Time > Study Treatment Stop Date and Time + 5 days or the Date and Time of Early Withdrawal Visit whichever is later

11.2.1.1. Study Phases for Concomitant Medication

Study Phase	Definition
Prior	If medication end date is not missing and is before Day -1
Concomitant	Any medication that is not a prior

NOTES:

- Please refer to Appendix 5: Reporting Standards for Missing Data for handling of missing and partial dates for concomitant medication. Use the rules in this table if concomitant medication date is completely missing.

11.2.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	• If AE onset date and time is on or after treatment start date and time & on or before treatment stop date and time + 5 days within each treatment period. • Study Treatment Start Date and Time ≤ AE Start Date and Time ≤ Study Treatment Stop Date and Time + 5 days within each treatment period. • If the AE onset date is completely missing, the AE is considered as treatment emergent.

NOTES:

- If the study treatment stop date is missing, then the AE will be considered to be On-Treatment.
- Please refer to Appendix 5: Reporting Standards for Missing Data for handling of missing and partial dates for AEs. Use the rules in this table if the AE onset date is completely missing.

11.3. Appendix 3: Data Display Standards & Handling Conventions

11.3.1. Reporting Process

Software	
• The currently supported versions of SAS software (9.4) will be used.	
Reporting Area	
HARP Server	\\us1salx00259.corpnet2.com
HARP Compound	GSK3640254
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.1). • For creation of ADaM datasets (ADC1/ADCM/ADAE), the same version of dictionary datasets will be implemented as those being used for conversion from SI to SDTM.	
Generation of RTF Files	
• RTF files will be generated for all reporting efforts described in the RAP.	

11.3.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics
• Do not include participant level listings in the main body of the GSK CSR. All participant level listings should be located in the modular appendices as ICH or non-ICH listings.
• MedDRA version 24.0 will be applied for reporting, unless otherwise stated.

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

• Reporting for tables, figures, and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated. For procedures without predose assessment within period, the baseline planned time will be the Day 7 of the previous period.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.

• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the participant's listings.
  • Visits outside the protocol defined time-windows (i.e. recorded as protocol deviations) will be included in listings but omitted from figures (mean figures only for PK concentrations), summaries, and statistical analyses (excluding statistical analyses of PK parameters).

Unscheduled Visits
• Unscheduled visits will not be included in summary tables except for determining baseline and the worst-case values. • 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, %
Graphical Displays
• Refer to IDSL Statistical Principals 7.01 to 7.13.

11.3.3. Reporting Standards for Pharmacokinetics

Pharmacokinetic Concentration Data	

Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards.
	Refer to IDSL Statistical Principle 6.06.1.
	For continuous data:
	• NQs at the beginning of a participant profile (i.e., before the first incidence of a measurable concentration) are deemed to be 0 as it is assumed that in this circumstance no drug is yet measurable in the blood.
	• For NQs at the end of the participant profile (i.e., after the last incidence of a measurable concentration):
	  • For individual plots and PK analyses these are dropped (set to missing) as they do not provide any useful information (and can erroneously indicate that absolutely no drug is present)
	  • For summary statistics, these are set to 0 (to avoid skewing of the summary statistics)
	• Individual NQs which fall between two measurable concentrations are set to missing (individual values of this nature are assumed to be an anomaly).
	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 participant plots, these NQs will be set to 0, and the subsequent measurable concentrations will be retained. For the derivation of PK parameters, these NQs and any subsequent measurable concentrations will be omitted (set to missing).
	Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.

Pharmacokinetic Parameter Data	
Descriptive Summary Statistics, Graphical Displays, and Listings	N, n, arithmetic mean, 95% CI of arithmetic mean, geometric mean, 95% CI of geometric mean, SD, SD of logged data CV (%), and between-subject geometric CVb (%) will be reported. CV_b (%) = $\sqrt{}$ (exp(SD^2) - 1) * 100 (SD = SD of Ln-Transformed data)
Parameters Not Being Ln-Transformed	Tmax, λz, λz lower, λz upper, and λz no. of points.
Parameters Not Being Summarized	λz, λz lower, λz upper, and λz no. of points.
Listings	Include the first point, last point and number of points used in the determination of λz and Rsq_adjusted for listings.

11.4. Appendix 4: Derived and Transformed Data

11.4.1. General

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

• Calculated as the number of days from Dose Date on Period 1 Day 1:
  • Assessment Date = Missing
  → Study Day = Missing
  • Assessment Date < Dose Date on Period 1 Day 1
  → Study Day = Assessment Date –Dose Date on Period 1 Day 1
  • Assessment Date >= Dose Date on Period 1 Day 1
  → Study Day = Assessment Date – Dose Date on Period 1 Day 1 + 1

Period Day

• Calculated as the number of days from First Dose Date for the respective period:
  • Assessment Date = Missing
  → Period Day = Missing
  • Assessment Date < Dose Date on Period 1 Day 1
  → Period Day = Assessment Date – Dose Date on Period 1 Day 1
  • Dose Date on Period 1 Day 1 <= Assessment Date < Dose Date on Period 2 Day 1
  → Period Day = Assessment Date – Dose Date on Period 1 Day 1 + 1
  • Dose Date on Period 2 Day 1 <= Assessment Date < Dose Date on Period 3 Day 1
  → Period Day = Assessment Date – Dose Date on Period 2 Day 1 + 1
  • Assessment Date >= Dose Date on Period 3 Day 1
  → Period Day = Assessment Date – Dose Date on Period 3 Day 1 + 1

11.4.2. Study Population

Age

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

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

11.5. Appendix 5: Reporting Standards for Missing Data

11.5.1. Premature Withdrawals

Element	Reporting Detail
General	• Participant study completion (i.e., as specified in the protocol) was defined as the participant had completed all phases of the study including the final date on which data were or are expected to be collected. • Withdrawn participants were not replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

11.5.2. Handling of Missing Data

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

11.5.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in participant listing displays.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 2: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.
Concomitant Medications/Medical History	• Partial dates for any concomitant medications recorded in the eCRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. • The recorded partial date will be displayed in listings.

11.6. Appendix 6: Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events

11.6.1. Laboratory Values

The Division of AIDS (DAIDS) grading for severity of laboratory toxicities and clinical AEs, version 2.1, July 2017 (2) will be used to assign grades to laboratory values. Laboratory results are converted to use SI units; only the numeric part of the criteria will be used. If for a laboratory parameter there are multiple grades sharing the same criteria, the maximum grade will be used. The table below outlines the planned laboratory assessments to be done in the study.

Laboratory Assessments	**Parameters**		
Hematology	Platelet Count RBC Count Hemoglobin Hematocrit	RBC Indices: Mean corpuscular volume Mean corpuscular hemoglobin	WBC count with Differential: Neutrophils Lymphocytes Monocytes Eosinophils Basophils Absolute neutrophil count
Clinical Chemistry	BUN Glucose (fasting) Creatinine Potassium Sodium Calcium Chloride Phosphorus	Carbon dioxide Aspartate Aminotransferase Alanine Aminotransferase Gamma-glutamyl transferase Total and direct bilirubin Lactate dehydrogenase Total cholesterol Triglycerides Alkaline phosphatase[2]	Total Protein Albumin Globulin Anion gap Uric acid Creatine phosphokinase Serum lipase Serum amylase
Routine Urinalysis	• Specific gravity • pH, glucose, protein, blood, ketones, bilirubin, urobilinogen, nitrite, leukocyte esterase by dipstick • Microscopic examination (if blood, leukocyte esterase, or protein is abnormal)		
Pregnancy testing	• Highly sensitive human chorionic gonadotropin (hCG) pregnancy test (as needed for women of childbearing potential)[3]		
Other Screening Tests	• Molecular test for SARS-CoV-2 (Two consecutive approved molecular tests [polymerase chain reaction or antigen test]. The first test should be performed ≥7 days prior to admission and the second test will be performed on Day -2 after admission to the clinic. • Follicle-stimulating hormone (as needed in women of non-childbearing potential only) • Serology: HIV-1 and -2 antigen/antibody immunoassay, hepatitis B surface antigen, hepatitis C antibody • Alcohol, cotinine, and drug screen (to include at minimum amphetamines, barbiturates, cannabinoids, cocaine, or phencyclidine, or nonprescribed opiates, oxycodone, benzodiazepines, methadone, or tricyclic antidepressants)		

1. Details of liver chemistry stopping criteria and required actions and follow-up assessments after liver stopping or monitoring event are given in Section 7.1 and Appendix 5. All events of ALT >=3 × ULN and bilirubin >=2 × ULN (>35% direct bilirubin) or ALT >=3 × ULN and INR >1.5, if INR measured, which may indicate severe liver injury (possible Hy's Law), must be reported as an SAE (excluding studies of hepatic impairment or cirrhosis).
2. If alkaline phosphatase is elevated, consider fractionating.
3. Local urine pregnancy testing will be standard for the protocol unless serum testing is required by local regulation or IRB/IEC.

11.7. Appendix 7: Values of Potential Clinical Importance

11.7.1. ECG

ECG Parameter	Units	Potential Clinically Important Range	
		Lower	Upper
Absolute			
Absolute QTc Interval	msec	< 320	> 450*
Absolute PR Interval	msec	< 110	> 220
Absolute QRS Interval	msec	< 75	> 110
Change from Baseline			
Increase from Baseline QTc	msec		> 60

* Exclusion criteria: Confirmed QTcF value >450 msec at screening or Day 1.

11.7.2. Vital Signs

Vital Sign Parameter (Absolute)	Units	Potential Clinically Important Range	
		Lower	Upper
Systolic Blood Pressure	mmHg	< 85	> 160
Diastolic Blood Pressure	mmHg	< 45	> 100
Heart Rate	bpm	< 40	> 110

11.8. Appendix 8: Abbreviations & Trademarks

11.8.1. Abbreviations

Abbreviation	Description
AE	Adverse Event
ANOVA	Analysis of Variance
AUC	Area under the plasma concentration-time curve
AUC(0-∞)	AUC from time 0 extrapolated to infinity
AUC(0-t)	AUC from Time 0 to Time t
BA	Bioavailability
BMI	Body Mass Index
bpm	Beats per minute
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence interval
CL/F	Apparent oral clearance
Cmax	Maximum observed concentration
COVID-19	Coronavirus disease
CRF	Case report form
CSR	Clinical Study Report
C-SSRS	Columbia-Suicide Severity Rating Scale
CV	Coefficient of variation
CVb	Coefficient of variation (Between)
DAIDS	Division of AIDS
DBF	Database Freeze
DBR	Database Release
DP	Decimal Places
ECG	Electrocardiogram
FDA	Food and Drug Administration
GSK	GlaxoSmithKline
hCG	Human Chorionic Gonadotropin
HIV	Human Immunodeficiency Virus
ICH	International Council On Harmonisation
IDSL	Integrated Data Standards Library
IRB	Institutional Review Board
LLN	Lower Limit of Normal
MedDRA	Medical Dictionary for Regulatory Activities
PI	Principal Investigator
PK	Pharmacokinetic
PT	Preferred Term
QTcF	QTc using the Fridericia formula
RAP	Reporting & Analysis Plan
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event
SARS-CoV2	Severe Acute Respiratory Syndrome Coronavirus 2
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SMQ	Standardized MedDRA Query
SOC	System Organ Class
t1/2	Apparent Terminal Phase Half-life

Abbreviation	Description
Tmax	Time of Maximum Observed Concentration
TLF	Tables, listings, figures
ULN	Upper Limit of Normal
VH	ViiV Healthcare

11.8.2. Trademarks

Trademarks of ViiV Healthcare
Tivicay

Trademarks not owned by ViiV Healthcare
DAIDS
SAS
WinNonlin

11.9. Appendix 9: List of Data Displays

11.9.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.14	
Safety	2.1 to 2.56	2.1 to 2.2
Pharmacokinetic	3.1 to 3.14	3.1 to 3.18
Section	**Listings**	
ICH Listings	1 to 72	
Other Listings	73 to 80	

11.9.2. Mock Example Shell Referencing

Non-IDSL specifications will be referenced as indicated and if required example mock-up displays provided in the Table/Listing/Figure Shells.

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

NOTES:

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

11.9.3. Deliverables

Delivery	Description
SAC	Final Statistical Analysis Complete

11.9.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	Enrolled	NS1	Summary of Number of Subjects Enrolled		SAC
1.2.	Safety	ES1	Summary of Subject Disposition for the Subject Conclusion Record – Part 1		SAC
1.3.	Safety	ES1	Summary of Subject Disposition for the Subject Conclusion Record – Part 2		SAC
1.4.	Screened	SD1	Summary of Screening Status and Reasons for Screen Failures		SAC
1.5.	Randomized	SP1	Summary of Study Populations – Part 1		SAC
1.6.	Randomized	SP1	Summary of Study Populations – Part 2		SAC
Protocol Deviations					
1.7.	Safety	DV1	Summary of Important Protocol Deviations – Part 1		SAC
1.8.	Safety	DV1	Summary of Important Protocol Deviations – Part 2		SAC
Demographic and Baseline Characteristics					
1.9.	Safety	DM1	Summary of Demographic Characteristics – Part 1		SAC
1.10.	Safety	DM1	Summary of Demographic Characteristics – Part 2		SAC
1.11.	Safety	DM5	Summary of Race and Racial Combinations – Part 1		SAC
1.12.	Safety	DM5	Summary of Race and Racial Combinations – Part 2		SAC
1.13.	Safety	DM11	Summary of Age Ranges – Part 1		SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.14.	Safety	DM11	Summary of Age Ranges – Part 2		SAC

11.9.5. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
2.1.	Safety	AE1xo	Summary of Adverse Events by System Organ Class and Preferred Term – Part 1		SAC
2.2.	Safety	AE1xo	Summary of Adverse Events by System Organ Class and Preferred Term – Part 2		SAC
2.3.	Safety	AE1xo	Summary of Drug-Related Adverse Events by System Organ Class and Preferred Term – Part 1		SAC
2.4.	Safety	AE1xo	Summary of Drug-Related Adverse Events by System Organ Class and Preferred Term – Part 2		SAC
2.5.	Safety	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency – Part 1		SAC
2.6.	Safety	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency – Part 2		SAC
2.7.	Safety	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term – Part 1 (Number of Subjects and Occurrences)		SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.8.	Safety	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term – Part 2 (Number of Subjects and Occurrences)		SAC
2.9.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term – Part 1 (Number of Subjects and Occurrences)		SAC
2.10.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term – Part 2 (Number of Subjects and Occurrences)		SAC
2.11.	Safety	AE5A	Summary of Adverse Events by System Organ Class and Preferred Term and Maximum Intensity – Part 1		SAC
2.12.	Safety	AE5A	Summary of Adverse Events by System Organ Class and Preferred Term and Maximum Intensity – Part 2		SAC
2.13.	Safety	AE1xo	Summary of Adverse Events of Special Interest by System Organ Class and Preferred Term – Part 1		SAC
2.14.	Safety	AE1xo	Summary of Adverse Events of Special Interest by System Organ Class and Preferred Term – Part 2		SAC
Laboratory: Chemistry					
2.15.	Safety	LB1	Summary of Clinical Chemistry Data – Part 1		SAC
2.16.	Safety	LB1	Summary of Clinical Chemistry Data – Part 2		SAC
2.17.	Safety	LB1	Summary of Clinical Chemistry Changes from Baseline – Part 1		SAC
2.18.	Safety	LB1	Summary of Clinical Chemistry Changes from Baseline – Part 2		SAC
2.19.	Safety	LB16	Summary of Clinical Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline – Part 1		SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.20.	Safety	LB16	Summary of Clinical Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline – Part 2		SAC
Laboratory: Hematology					
2.21.	Safety	LB1	Summary of Hematology Data – Part 1		SAC
2.22.	Safety	LB1	Summary of Hematology Data – Part 2		SAC
2.23.	Safety	LB1	Summary of Hematology Changes from Baseline – Part 1		SAC
2.24.	Safety	LB1	Summary of Hematology Changes from Baseline – Part 2		SAC
2.25.	Safety	LB16	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline – Part 1		SAC
2.26.	Safety	LB16	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline – Part 2		SAC
Laboratory: Urinalysis					
2.27.	Safety	LB1	Summary of Urine Concentration – Part 1		SAC
2.28.	Safety	LB1	Summary of Urine Concentration – Part 2		SAC
2.29.	Safety	LB1	Summary of Urine Concentration Changes from Baseline – Part 1		SAC
2.30.	Safety	LB1	Summary of Urine Concentration Changes from Baseline – Part 2		SAC
2.31.	Safety	UR3	Summary of Urinalysis Dipstick Results – Part 1		SAC
2.32.	Safety	UR3	Summary of Urinalysis Dipstick Results – Part 2		SAC
2.33.	Safety	LB16	Summary of Urinalysis by Maximum Grade Increase Post-Baseline Relative to Baseline – Part 1		SAC
2.34.	Safety	LB16	Summary of Urinalysis by Maximum Grade Increase Post-Baseline Relative to Baseline – Part 2		SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
2.35.	Safety	SAFE_T1	Summary of ECG Findings – Part 1		SAC
2.36.	Safety	SAFE_T1	Summary of ECG Findings – Part 2		SAC
2.37.	Safety	EG2	Summary of ECG Values – Part 1		SAC
2.38.	Safety	EG2	Summary of ECG Values – Part 2		SAC
2.39.	Safety	EG2	Summary of ECG Changes from Baseline – Part 1		SAC
2.40.	Safety	EG2	Summary of ECG Changes from Baseline – Part 2		SAC
2.41.	Safety	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category – Part 1		SAC
2.42.	Safety	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category – Part 2		SAC
2.43.	Safety	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category – Part 1		SAC
2.44.	Safety	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category – Part 2		SAC
Vital Signs					
2.45.	Safety	VS1	Summary of Vital Signs – Part 1		SAC
2.46.	Safety	VS1	Summary of Vital Signs – Part 2		SAC
2.47.	Safety	VS1	Summary of Vital Sign Changes from Baseline – Part 1		SAC
2.48.	Safety	VS1	Summary of Vital Sign Changes from Baseline – Part 2		SAC
C-SSRS					

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.49	Safety	CSSRS4	Listing of C-SSRS Suicidal Ideation and Behavior Data – Part 1		SAC
2.50	Safety	CSSRS4	Listing of C-SSRS Suicidal Ideation and Behavior Data – Part 2		SAC
SARS-CoV-2					
2.51	Safety	PAN1	Summary of COVID-19 Assessments – Part 1		SAC
2.52	Safety	PAN1	Summary of COVID-19 Assessments – Part 2		SAC
2.53	Safety	SAFE_T2	Summary of COVID-19 Adverse Event Summary – Part 1		SAC
2.54	Safety	SAFE_T2	Summary of COVID-19 Adverse Event Summary – Part 2		SAC
2.55	Safety	PAN3	Summary of COVID-19 Symptoms for Subjects with Adverse Event – Part 1		SAC
2.56	Safety	PAN3	Summary of COVID-19 Symptoms for Subjects with Adverse Event – Part 2		SAC

11.9.6. Safety Figures

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG					
2.1.	Safety	EG9	Mean (95% CI) Change from Baseline in QTcF Interval by Timepoint and Treatment – Part 1		SAC
2.2.	Safety	EG9	Mean (95% CI) Change from Baseline in QTcF Interval by Timepoint and Treatment – Part 2		SAC

11.9.7. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK Concentration Data					
3.1.	PK Concentration	PK01	Summary of GSK3640254 Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – Part 1	Part 1	SAC
3.2.	PK Concentration	PK01	Summary of Dolutegravir Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – Part 1	Part 1	SAC
3.3.	PK Concentration	PK01	Summary of GSK3640254 Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – Part 2	Part 2	SAC
3.4.	PK Concentration	PK01	Summary of Dolutegravir Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – Part 2	Part 2	SAC
PK Derived Parameters					
3.5.	PK Parameter	PK04	Summary Statistics of Derived GSK3640254 Plasma Pharmacokinetic Parameters (Non-Transformed) Based on Actual Time by Treatment – Part 1	Part 1 Parameters with units	SAC
3.6.	PK Parameter	PK04	Summary Statistics of Derived GSK3640254 Plasma Pharmacokinetic Parameters (Ln-Transformed) Based on Actual Time by Treatment – Part 1	Part 1 Parameters with units	SAC
3.7.	PK Parameter	PK04	Summary Statistics of Derived Dolutegravir Plasma Pharmacokinetic Parameters (Non-Transformed) Based on Actual Time by Treatment – Part 1	Part 1 Parameters with units	SAC
3.8.	PK Parameter	PK04	Summary Statistics of Derived Dolutegravir Plasma Pharmacokinetic Parameters (Ln-Transformed) Based on Actual Time by Treatment – Part 1	Part 1 Parameters with units	SAC
3.9.	PK Parameter	PK04	Summary Statistics of Derived GSK3640254 Plasma Pharmacokinetic Parameters (Non-Transformed) Based on Actual Time by Treatment – Part 2	Part 2 Parameters with units	SAC

3.10.	PK Parameter	PK04	Summary Statistics of Derived GSK3640254 Plasma Pharmacokinetic Parameters (Ln-Transformed) Based on Actual Time by Treatment – Part 2	Part 2 Parameters with units	SAC
3.11.	PK Parameter	PK04	Summary Statistics of Derived Dolutegravir Plasma Pharmacokinetic Parameters (Non-Transformed) Based on Actual Time by Treatment – Part 2	Part 2 Parameters with units	SAC
3.12.	PK Parameter	PK04	Summary Statistics of Derived Dolutegravir Plasma Pharmacokinetic Parameters (Ln-Transformed) Based on Actual Time by Treatment – Part 2	Part 2 Parameters with units	SAC
PK Analysis Tables					
3.13.	PK Parameter	PK05	Statistical Analysis of Plasma Pharmacokinetic Parameters: Analysis of Variance (ANOVA) – Part 1	Part 1 AUC(0-∞), AUC(0-t) and Cmax for GSK3640254 and Dolutegravir	SAC
3.14.	PK Parameter	PK05	Statistical Analysis of Plasma Pharmacokinetic Parameters: Analysis of Variance (ANOVA) – Part 2	Part 2 AUC(0-∞), AUC(0-t) and Cmax for GSK3640254 and Dolutegravir	SAC

11.9.8. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Individual Concentration Plots					
3.1.	PK Concentration	PK16A	Individual GSK3640254 Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – Part 1	Part 1, Paginate by Participant Dashed line represents the LLQ Treatments Overlaid	SAC
3.2.	PK Concentration	PK16A	Individual Dolutegravir Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – Part 1	Part 1, Paginate by Participant Dashed line represents the LLQ Treatments Overlaid	SAC
3.3.	PK Concentration	PK16A	Individual GSK3640254 Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – Part 2	Part 2, Paginate by Participant Dashed line represents the LLQ Treatments Overlaid	SAC
3.4.	PK Concentration	PK16A	Individual Dolutegravir Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – Part 2	Part 2 Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
3.5.	PK Concentration	PK16A	Individual GSK3640254 Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – Part 1	Part 1 Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
3.6.	PK Concentration	PK16A	Individual Dolutegravir Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – Part 1	Part 1 Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
3.7.	PK Concentration	PK16A	Individual GSK3640254 Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – Part 2	Part 2 Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC

3.8.	PK Concentration	PK16A	Individual Dolutegravir Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – Part 2	Part 2 Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
Mean / Median Concentration Plots					
3.9.	PK Concentration	PK17	Mean (Standard Deviation) GSK3640254 Plasma Concentration-Time Plots by Treatment - Part 1 (Linear and Semi-Logarithmic)	Treatments (A, B, and C) Overlaid	SAC
3.10.	PK Concentration	PK17	Mean (Standard Deviation) Dolutegravir Plasma Concentration-Time Plots by Treatment - Part 1 (Linear and Semi-Logarithmic)	Treatments (A, B, and C) Overlaid	SAC
3.11.	PK Concentration	PK17	Mean (Standard Deviation) GSK3640254 Plasma Concentration-Time Plots by Treatment - Part 2 (Linear and Semi-Logarithmic)	Treatments (D and E) Overlaid	SAC
3.12.	PK Concentration	PK17	Mean (Standard Deviation) Dolutegravir Plasma Concentration-Time Plots by Treatment - Part 2 (Linear and Semi-Logarithmic)	Treatments (D and E) Overlaid	SAC
3.13.	PK Concentration	PK18	Median (Range) GSK3640254 Plasma Concentration-Time Plots by Treatment - Part 1 (Linear and Semi-Logarithmic)	Treatments (A, B, and C) Overlaid	SAC
3.14.	PK Concentration	PK18	Median (Range) Dolutegravir Plasma Concentration-Time Plots by Treatment - Part 1 (Linear and Semi-Logarithmic)	Treatments (A, B, and C) Overlaid	SAC
3.15.	PK Concentration	PK18	Median (Range) GSK3640254 Plasma Concentration-Time Plots by Treatment - Part 2 (Linear and Semi-Logarithmic)	Treatments (D and E) Overlaid	SAC
3.16.	PK Concentration	PK18	Median (Range) Dolutegravir Plasma Concentration-Time Plots by Treatment - Part 2 (Linear and Semi-Logarithmic)	Treatments (D and E) Overlaid	SAC
3.17.	PK Parameter	EFF_F3	Forest Plot for Plasma Pharmacokinetic Parameters - Part 1	ANOVA for GSK3640254 and Dolutegravir; AUC0-inf, AUC0-t, Cmax	SAC
3.18.	PK Parameter	EFF_F3	Forest Plot for Plasma Pharmacokinetic Parameters - Part 2	ANOVA for GSK3640254 and Dolutegravir; AUC0-inf, AUC0-t, Cmax	SAC

11.9.9. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	Randomized	POP_L1	Listing of Randomization Schedule – Part 1		SAC
2.	Randomized	POP_L1	Listing of Randomization Schedule – Part 2		SAC
3.	Safety	ES3	Listing of Reasons for Study Withdrawal – Part 1		SAC
4.	Safety	ES3	Listing of Reasons for Study Withdrawal – Part 2		SAC
5.	Screened	ES7	Listing of Reasons for Screen Failure		SAC
Protocol Deviations					
6.	Safety	DV2	Listing of Important Protocol Deviations – Part 1		SAC
7.	Safety	DV2	Listing of Important Protocol Deviations – Part 2		SAC
8.	Safety	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations – Part 1		SAC
9.	Safety	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations – Part 2		SAC
Populations Analyzed					
10.	Safety	SP3A	Listing of Subjects Excluded from Any Population – Part 1		SAC
11.	Safety	SP3A	Listing of Subjects Excluded from Any Population – Part 2		SAC
Demographic and Baseline Characteristics					
12.	Safety	DM2	Listing of Demographic Characteristics – Part 1		SAC
13.	Safety	DM2	Listing of Demographic Characteristics – Part 2		SAC
14.	Safety	DM9	Listing of Race – Part 1		SAC
15.	Safety	DM9	Listing of Race – Part 2		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Prior and Concomitant Medications					
16.	Safety	CM5	Listing of Concomitant Medications – Part 1	Based on GSK Drug Dictionary	SAC
17.	Safety	CM5	Listing of Concomitant Medications – Part 2	Based on GSK Drug Dictionary	SAC
Exposure and Treatment Compliance					
18.	Safety	EX4	Listing of Exposure Data – Part 1		SAC
19.	Safety	EX4	Listing of Exposure Data – Part 2		SAC
20.	Safety	POP_L2	Listing of Meal Data – Part 1		SAC
21.	Safety	POP_L2	Listing of Meal Data – Part 2		SAC
22.	Safety	SU2	Listing of Substance Use History – Part 1		SAC
23.	Safety	SU2	Listing of Substance Use History – Part 2		SAC
Adverse Events					
24.	Safety	AE2	Listing of Relationship Between System Organ Class and Verbatim Text – Part 1		SAC
25.	Safety	AE2	Listing of Relationship Between System Organ Class and Verbatim Text – Part 2		SAC
26.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events – Part 1		SAC
27.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events – Part 2		SAC
28.	Safety	AE8xo	Listing of All Adverse Events – Part 1		SAC
29.	Safety	AE8xo	Listing of All Adverse Events – Part 2		SAC
Serious and Other Significant Adverse Events					
30.	Safety	AE8xo	Listing of Study Drug Related Adverse Events – Part 1		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
31.	Safety	AE8xo	Listing of Study Drug Related Adverse Events – Part 2		SAC
32.	Safety	AE8xo	Listing of Serious Adverse Events (Fatal & Non-Fatal) – Part 1		SAC
33.	Safety	AE8xo	Listing of Serious Adverse Events (Fatal & Non-Fatal) – Part 2		SAC
34.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event – Part 1		SAC
35.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event – Part 2		SAC
36.	Safety	PSRAE2-5	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description – Part 1		SAC
37.	Safety	PSRAE2-5	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description – Part 2		SAC
38.	Safety	AE8xo	Listing of Adverse Events Leading to Withdrawal from Study – Part 1		SAC
39.	Safety	AE8xo	Listing of Adverse Events Leading to Withdrawal from Study – Part 2		SAC
40.	Safety	AE8xo	Listing of Adverse Events of Special Interest – Part 1		SAC
41.	Safety	AE8xo	Listing of Adverse Events of Special Interest – Part 2		SAC
Hepatobiliary (Liver)					
42.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events – Part 1		SAC
43.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events – Part 2		SAC
44.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events – Part 1		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
45.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events – Part 2		SAC
46.	Safety	LIVER15	Listing of Liver Stopping Event Profile for Subjects with Liver Stopping Criteria Met		SAC
All Laboratory					
47.	Safety	LB5A	Listing of Clinical Chemistry with any Toxicities – Part 1		SAC
48.	Safety	LB5A	Listing of Clinical Chemistry with any Toxicities – Part 2		SAC
49.	Safety	LB5A	Listing of All Clinical Chemistry Data for Subjects with any Toxicities – Part 1		SAC
50.	Safety	LB5A	Listing of All Clinical Chemistry Data for Subjects with any Toxicities – Part 2		SAC
51.	Safety	LB5A	Listing of Hematology with any Toxicities – Part 1		SAC
52.	Safety	LB5A	Listing of Hematology with any Toxicities – Part 2		SAC
53.	Safety	LB5A	Listing of All Hematology Data for Subjects with any Toxicities – Part 1		SAC
54.	Safety	LB5A	Listing of All Hematology Data for Subjects with any Toxicities – Part 2		SAC
55.	Safety	LB5A	Listing of Urinalysis with any Toxicities – Part 1		SAC
56.	Safety	LB5A	Listing of Urinalysis with any Toxicities – Part 2		SAC
57.	Safety	LB5A	Listing of All Urinalysis Data for Subjects with any Toxicities – Part 1		SAC
58.	Safety	LB5A	Listing of All Urinalysis Data for Subjects with any Toxicities – Part 2		SAC
ECG					

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
59.	Safety	EG6	Listing of All ECG Findings – Part 1		SAC
60.	Safety	EG6	Listing of All ECG Findings – Part 2		SAC
61.	Safety	EG6	Listing of All Abnormal ECG Findings – Part 1		SAC
62.	Safety	EG6	Listing of All Abnormal ECG Findings – Part 2		SAC
63.	Safety	EG4	Listing of All ECG Values – Part 1		SAC
64.	Safety	EG4	Listing of All ECG Values – Part 2		SAC
Vital Signs					
65.	Safety	VS5	Listing of All Vital Signs of Potential Clinical Importance – Part 1		SAC
66.	Safety	VS5	Listing of All Vital Signs of Potential Clinical Importance – Part 2		SAC
67.	Safety	VS5	Listing of All Vital Signs for Subjects with any Value of Potential Clinical Importance – Part 1		SAC
68.	Safety	VS5	Listing of All Vital Signs for Subjects with any Value of Potential Clinical Importance – Part 2		SAC
Other Safety					
69.	Safety	PAN12	Listing of COVID-19 Assessments and Symptom Assessments – Part 1		SAC
70.	Safety	PAN12	Listing of COVID-19 Assessments and Symptom Assessments – Part 2		SAC
71.	Safety	AE8xo	Listing of Adverse Events of COVID-19 – Part 1		SAC
72.	Safety	AE8xo	Listing of Adverse Events of COVID-19 – Part 2		SAC

11.9.10. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetics					
73.	PK Concentration	PK07xo	Listing of GSK3640254 Plasma Concentration-Time Data by Treatment – Part 1	Part 1	SAC
74.	PK Concentration	PK07xo	Listing of Dolutegravir Plasma Concentration-Time Data by Treatment – Part 1	Part 1	SAC
75.	PK Concentration	PK07xo	Listing of GSK3640254 Plasma Concentration-Time Data by Treatment – Part 2	Part 2	SAC
76.	PK Concentration	PK07xo	Listing of Dolutegravir Plasma Concentration-Time Data by Treatment – Part 2	Part 2	SAC
77.	PK Parameter	PK13xo	Listing of GSK3640254 Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – Part 1	Part 1	SAC
78.	PK Parameter	PK13xo	Listing of Dolutegravir Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – Part 1	Part 1	SAC
79.	PK Parameter	PK13xo	Listing of GSK3640254 Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – Part 2	Part 2	SAC
80.	PK Parameter	PK13xo	Listing of Dolutegravir Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – Part 2	Part 2	SAC