Reporting and Analysis Plan Amendment 1.

Study ID: 216149

Official Title of Study: A Randomized, 2-Cohort, 2-Period, Single Dose, Crossover Clinical Study to Assess the Effect of Food on the Pediatric Dispersible Tablet Formulations of TRIUMEQ (Dolutegravir/Abacavir/Lamivudine) and DOVATO (Dolutegravir/Lamivudine) in Healthy Adult Participants

Date of Document: 07-JUN-2021

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

Title	:	Reporting and Analysis Plan for Randomized, 2-Cohort, 2-Period, Single Dose, Crossover Clinical Study to Assess the Effect of Food on the Pediatric Dispersible Tablet Formulations of TRIUMEQ (Dolutegravir/Abacavir/Lamivudine) and DOVATO (Dolutegravir/Lamivudine) in Healthy Adult Participants
Compound Number	:	GSK2619619 (Dolutegravir/Abacavir/Lamivudine) and GSK3515864 (Dolutegravir/Lamivudine)
Clinical Study Identifier	:	GSK216149
Effective Date	:	Refer to Document Date

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 216149.
- 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.
- This version of the RAP is amendment 1 to the original RAP dated 20-MAY-2021 and approved 07-JUN-2021.

The main changes included in RAP Amendment 1 are as follows:

1. Planned changes to deliveries due to need to report Cohort 1 separately following recruitment issues (Section 3.2).
2. Removal of reference to analysis of human leukocyte antigen (HLA) B*5701 which is only collected at the screening visit (Section 8.3).

TABLE OF CONTENTS

PAGE

1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Study Report (CSR) for Protocol: 216149, sponsored by ViiV Healthcare group of companies.

Revision Chronology:		
Original Protocol 216149	04-MAR-2021	Original

2. SUMMARY OF KEY PROTOCOL INFORMATION

This is a 2-cohort, single-center, randomized, open-label, single-dose, crossover study to assess the effect of food on the PK of the pediatric formulations of TRIUMEQ (DTG/ABC/3TC) dispersible tablets and DOVATO (DTG/3TC) dispersible tablets in healthy adult participants.

2.1. Changes to the Protocol Defined Statistical Analysis Plan

There are no changes from the originally planned statistical analysis specified in the protocol.

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

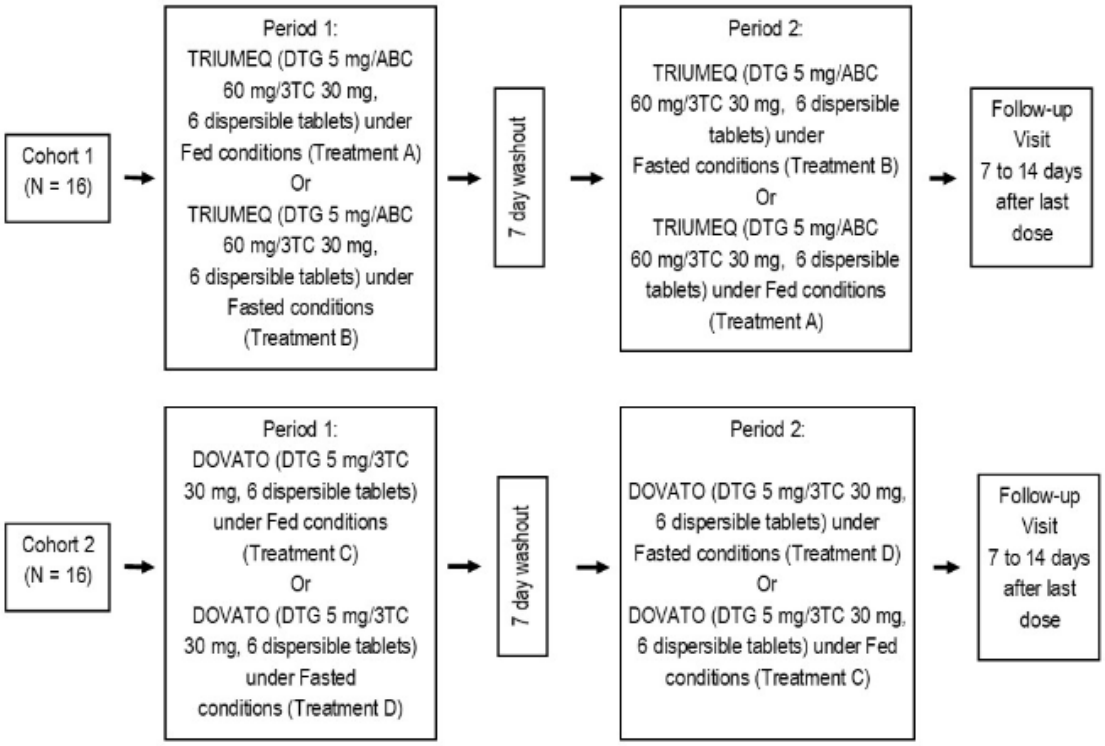
Objectives	Endpoints
Primary	**Primary**
• To assess the effect of food (fasted and high-fat meal) on the PK of TRIUMEQ (DTG/ABC/3TC) dispersible tablets.	• AUC(0-inf), AUC(0-t) and Cmax for TRIUMEQ (DTG/ABC/3TC)
• To assess the effect of food (fasted and high-fat meal) on the PK of DOVATO (DTG/3TC) dispersible tablets	• AUC(0-inf), AUC(0-t) and Cmax for DOVATO (DTG/3TC)
Secondary	**Secondary**
• To assess the effect of food (fasted and high-fat meal) on the secondary PK parameters of TRIUMEQ (DTG/ABC/3TC) dispersible tablets.	• tlag, t1/2, AUC(0-24), Ct, C24, CL/F, Vz/F, and Tmax for TRIUMEQ (DTG/ABC/3TC)
• To assess the effect of food (fasted and high-fat meal) on the secondary PK parameters of DOVATO (DTG/3TC) dispersible tablets.	• tlag, t1/2, AUC(0-24), Ct, C24, CL/F, Vz/F, and Tmax for DOVATO (DTG/3TC)
• To assess the safety and tolerability of TRIUMEQ (DTG/ABC/3TC) dispersible tablets under fasted or fed (high-fat) conditions.	• Safety and tolerability endpoints include incidence of AEs and SAEs, observed and change from baseline in clinical laboratory assessments, ECGs, and vital sign measurements (blood pressure and pulse rate)
• To assess the safety and tolerability of DOVATO (DTG/3TC) dispersible tablets under fasted or fed (high-fat) conditions	
Exploratory	**Exploratory**
• To evaluate the palatability of the dispersible tablets	• Palatability questionnaire scores

3TC = lamivudine; ABC = abacavir; AE = adverse event; AUC(0-24) = area under the plasma concentration-time curve from time zero to 24 hours; AUC(0-inf) = area under the plasma

concentration-time curve from time zero extrapolated to infinity; AUC0-t = area under the plasma concentration-time curve from time zero to time of last quantifiable concentration; C24 = concentration at 24 hours postdose; Cmax = maximum observed plasma concentration; Ct = last quantifiable concentration; DTG = dolutegravir; ECG = electrocardiogram; PK = pharmacokinetics; SAE = serious adverse event; t1/2 = terminal elimination phase half-life; tlag = lag time for absorption; Tmax = time of maximum observed concentration

2.3. Study Design

Overview of Study Design and Key Features



3TC = lamivudine; ABC = abacavir; DTG = dolutegravir,
Washout will be at least 7 days minus 4 hours.

Design Features	• Phase I, 2-cohort, single-center, randomized, open-label, single-dose, crossover study. • The study will consist of a screening period, 2 treatment periods with a single dose of study intervention per treatment period in each cohort, a washout period, and a follow-up visit. Participants will have a screening visit within 28 days before the first dose of study intervention.
Dosing	**Cohort 1:** • Treatment A: Pediatric TRIUMEQ (DTG 5 mg/ABC 60 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fed conditions. • Treatment B: Pediatric TRIUMEQ (DTG 5 mg/ABC 60 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fasted conditions. **Cohort 2:** • Treatment C: Pediatric DOVATO (DTG 5 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fed conditions. • Treatment D: Pediatric DOVATO (DTG 5 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fasted conditions.

Overview of Study Design and Key Features	
Treatment Assignment	• In each cohort, prior to dosing on Day 1 of Period 1, participants will be randomly assigned to 1 of 2 treatment sequences (AB or BA in Cohort 1 and CD or DC in Cohort 2). Cohorts are independent of one another and may run in parallel.
Interim Analysis	• There will be no interim analysis.

2.4. Statistical Hypotheses

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

2.5. Sample Size

2.5.1. Sample Size Assumption

A maximum of 16 participants per cohort will be enrolled to study intervention such that approximately 14 evaluable participants per cohort complete the study.

Note: "Enrolled" means a participant's, or his or her legally acceptable representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.

Based on the results from a previous PK study of DTG granules administered to healthy participants [GSK Document Number 2017N330422_00], the within participant variability (CVw%) of DTG/ABC/3TC and DTG/3TC area under the plasma concentration-time curve (AUC) from time zero extrapolated to infinity (AUC[0-inf]), AUC from time zero to time of last observed quantifiable concentration calculated using the linear trapezoidal method when concentrations are increasing and the logarithmic trapezoidal method when concentrations are decreasing AUC(0-t), and maximum observed plasma concentration (Cmax) ranged from 4.8% and 21.4%. Therefore, it was decided that 21.4% would be a conservative estimate on which the sample size calculation is based.

For each study cohort, with a sample size of 14 evaluable participants, it is estimated that the precision [i.e., half-width of the 90% confidence interval (CI) on the ratio scale] for the test:reference comparison will be within 15.3% of the point estimate for AUC(0-inf), AUC(0-t), and Cmax. Hence, if the point estimate of the ratio of geometric means is 1, then the 90% CI will be approximately (0.87, 1.15).

2.5.2. Sample Size Sensitivity

For the sensitivity analysis, assuming a higher %CVw (30%) and a sample size of 14 evaluable participants in each study cohort, it was estimated that the half-width of the 90% CI for the ratio of treatment comparison (test:reference) would be within 21.7% of

the point estimate for AUC(0-inf), AUC(0-t), and Cmax. Hence, if the point estimate of the ratio of geometric means is 1, then the 90% CI will be approximately (0.82, 1.22).

2.6. Study Blinding

While this is an open label study, the following measures will be taken to restrict information that may lead to unblinding, where feasible. PPD will work with ADaM datasets and TLFs based on the surrogate randomization schedule, and not have access to the actual randomization schedule. While the source data can still reveal the actual treatment, this data will be concealed to the Biostatistics and Programming teams for GSK during the course of the study.

Once RAVE Database 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. At this point the entire GSK study team is officially unblinded.

The PPD Clinical Pharmacology and GSK CPMS team will be unblinded throughout the study.

3. PLANNED ANALYSES

3.1. Interim Analyses

There is no formal interim analysis planned.

3.2. Final Analyses

Due to the recruitment challenges with Cohort 2, Cohort 1 will be reported separately prior to full study reporting with the corresponding TLFs included in the CSR. At study completion, the CSR will be amended to include all study TLFs, fully covering both Cohort 1 and Cohort 2 reporting. For this reporting at study completion, all TLFs for both Cohort 1 and Cohort 2 will be produced based on the final database.

Prior to the initial reporting of Cohort 1 and full reporting at study completion, the following sequential steps will be followed:

1. All participants have completed Cohort 1 / the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database released (DBR).
3. All criteria for unblinding the randomization codes have been met.
4. Randomization codes have been distributed by PPD Randomization Team to PPD Biostatistics and Programming team.
5. Database freeze (DBF) 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.
7. For the initial reporting of Cohort 1, PPD Randomization Team will only release the randomization codes for Cohort 1 to PPD Biostatistics and Programming team upon all criteria for unblinding Cohort 1 are met, while PPD Biostatistics and Programming team remain blinded for Cohort 2.
8. For the full reporting at study completion, PPD Randomization Team will release the randomization codes for Cohort 2 to PPD Biostatistics and Programming team upon all criteria for unblinding Cohort 2 are met.

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 receive at least one dose of study intervention. • This population will be used for the safety displays and baseline/demographic characteristics.	• Study Population • Safety
Pharmacokinetic (PK) Concentration	• All participants who underwent plasma PK sampling and had evaluable (nonmissing) 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 (nonmissing) 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 summarised and listed.
- Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Study Deviation 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 summary and listing of all inclusion/exclusion criteria deviations will also be provided. This summary will be based on data as recorded on the inclusion/exclusion page of the 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			
Description	**Code**	**Order in TLF**	**Cohort Used**
Pediatric TRIUMEQ (DTG 5 mg/ABC 60 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fed conditions.	Treatment A	1	Cohort 1
Pediatric TRIUMEQ (DTG 5 mg/ABC 60 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fasted conditions.	Treatment B	2	Cohort 1
Pediatric DOVATO (DTG 5 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fed conditions.	Treatment C	3	Cohort 2
Pediatric DOVATO (DTG 5 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fasted conditions.	Treatment D	4	Cohort 2

5.2. Baseline Definitions

Baseline is defined as the latest pre-dose assessment with a non-missing value for each period, including those from unscheduled visits.

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
11.4	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 (All participants) population, unless otherwise specified.

Study population analyses including analyses of participants' disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 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 Pharmacokinetics). Plasma concentrations of DTG, ABC, and 3TC will be measured and presented in tabular form and will be summarized descriptively by treatment. Plasma DTG, ABC, and 3TC concentration-time data will be listed by participant, treatment group, and sampling time and summarized by treatment group and sampling time.

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 predose 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-inf)	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

Primary pharmacokinetic parameters are AUC(0-inf), AUC(0-t), and Cmax of DTG, ABC, and 3TC following single dose administration of pediatric TRIUMEQ dispersible tablet formulation and AUC(0-inf), AUC(0-t), and Cmax of DTG and 3TC following single dose administration of pediatric DOVATO dispersible tablet formulations under fed or fasted conditions to healthy participants.

7.1.3. Population of Interest

The primary PK analyses will be based on 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-inf], AUC[0-t], and Cmax) will be estimated for DTG, ABC, and 3TC. Summary statistics [arithmetic mean, geometric mean, median, standard deviation (SD), percent coefficient of variation (CV%), minimum, maximum, between-subject percent coefficient of variation (CVb%), and 95% confidence interval (CI)] for plasma DTG, ABC, and 3TC PK parameter values will be summarized by treatment using PK Parameter Population.

Summary statistics (arithmetic mean, median, standard deviation, minimum, maximum, and coefficient of variation) for plasma DTG, ABC, and 3TC 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-inf), AUC(0-t), and Cmax, for DTG, ABC, and 3TC as data permit.
Model Specification
Cohort 1 • Analysis will be performed to compare the effect of food (high-fat meal) on the PK of DTG, ABC, and 3TC following administration of TRIUMEQ dispersible tablets compared to the PK of DTG, ABC, and 3TC following administration of TRIUMEQ dispersible tablets under fasted conditions. Analyses will be performed on the natural logarithms of AUC(0-inf), AUC(0-t), and Cmax using linear mixed-effect models with treatment, period, and sequence as fixed effects and participant nested within a sequence (participant(sequence)) as a random effect. Effects will be estimated, and CIs will be constructed for the following treatment comparisons: o Treatment A (test) versus Treatment B (reference) o Point estimates, 90% CIs [estimate ± SE*tinv(0.95, df)], and intra-subject CV% [sqrt (exp (variance for ln-transformed data)-1)*100]. 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. Cohort 2 • Analysis will be performed to compare the effect of food (high-fat meal) on the PK of DTG and 3TC following administration of DOVATO dispersible tablets compared to the PK of DTG and 3TC following administration of DOVATO dispersible tablets under fasted conditions. Analyses will be performed on the natural logarithms of AUC(0-inf), AUC(0-t),

and Cmax using linear mixed-effect models with treatment, period, and sequence as fixed effects and participant nested within a sequence [participant(sequence)] as a random effect. Effects will be estimated, and CIs will be constructed for the following treatment comparisons: o Treatment C (test) versus Treatment D (reference) o Point estimates, 90% CIs [estimate ± SE*tinv(0.95, df)], and intra-subject CV% [sqrt (exp (variance for ln-transformed data)-1)*100] 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
• 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 A (test) versus Treatment B (reference) o Treatment C (test) versus Treatment D (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. 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 T_{max} or participants whose predose 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.

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

Parameter	Parameter Description
AUC(0-24)	Area under the plasma concentration-time curve from time 0 to 24 hours postdose, to be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.

Parameter	Parameter Description
Tmax	Time of maximum observed concentration
Tlag	Lag time for absorption
t1/2	Apparent terminal phase half-life
C24	Plasma concentration at 24 hours postdose
Ct	Last quantifiable plasma concentration

NOTES:

- Additional parameters including CL/F and Vz/F may be included as required.

7.2.2. Summary Measure

Secondary pharmacokinetic parameters: AUC(0-24), Tmax, tlag, t1/2, C24, and Ct of DTG, ABC, and 3TC following single dose administration of pediatric TRIUMEQ and AUC(0-24), Tmax, tlag, t1/2, C24, and Ct of DTG and 3TC following single dose administration of pediatric DOVATO formulations under fed or fasted conditions to healthy participants.

7.2.3. Population of Interest

The secondary PK analyses will be based on the PK concentration population for plasma PK concentrations, and 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 will be based on GSK Data Standard 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 [AUC(0-24), Tmax, tlag, t1/2, C24, and Ct] will be estimated for DTG, ABC, and 3TC. Summary statistics (arithmetic mean, geometric mean, median, SD, CV%, minimum, maximum, CVb%, and 95% CI) for secondary plasma PK parameters of DTG, ABC, and 3TC will be summarized by treatment using PK Parameter Population.

Summary statistics (arithmetic mean, median, SD, minimum, maximum, and CV%) for plasma DTG, ABC, and 3TC PK concentrations will be summarized by treatment using the PK Concentration Population.

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 AEs (SAEs), and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 9: List of Data Displays.

For studies with greater than one treatment period (e.g., crossover study), if AE onset is during one period and worsens in severity during a later period, it will be counted in both periods. For the later period the onset date of AE with the elevated grade will be the first dose date of the later treatment period.

8.2. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of chemistry laboratory tests, hematology laboratory tests, urinalysis, and pregnancy test will be based on GSK Core Data 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. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs, vital signs, liver events, and pregnancy will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 9: List of Data Displays.

8.4. COVID 19 Related Analyses

Based on GSK's "Impact of COVID-19 on Assessment of Safety in Clinical Trials Points to Consider", it is GSK's recommendation that study teams should capture COVID-19 cases based on the WHO criteria using the categories of: suspected, probable, and confirmed cases. COVID-19 eCRF pages are used in the study for data collection and analysis purposes. After a discussion with the study team, the following analyses will be included:

- Number of subjects with suspected, probable, or confirmed COVID-19 infection
- Number of subjects who had a COVID-19 diagnosis test performed and the number of subjects with positive, negative, or indeterminate results.

Further display details are provided in Appendix 9: List of Data Displays.

9. OTHER ANALYSES

Palatability Assessment results will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 9: List of Data Displays.

10. REFERENCES

- Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events. 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 12/3/2021 at : https://rsc.niaid.nih.gov/sites/default/files/daidsgradingcorrectedv21.pdf

11. APPENDICES

11.1. Appendix 1: Schedule of Activities

11.1.1. Protocol Defined Schedule of Events

Screening Visit

Procedure	Screening (Day -28 to -2)
Informed consent	X
Inclusion and exclusion criteria	X
Demographics	X
Full physical examination including height, weight, and body mass index[1]	X
Laboratory assessments (hematology, chemistry, urinalysis)	X
Human leukocyte antigen (HLA)-B*5701	X
12-lead electrocardiogram	X
Vital sign measurements	X
Medication/drug/alcohol history	X
Past and current medical conditions	X
Pregnancy test	X
Follicle-stimulating hormone (as needed, to confirm postmenopausal status)	X
Molecular test for SARS-CoV-2[2]	X
Drug, alcohol, and cotinine screen	X
Human immunodeficiency virus, hepatitis B and hepatitis C screening	X

1. A full physical examination will include at a minimum, assessments of the skin, lungs, cardiovascular system, respiratory, gastrointestinal, abdomen (liver and spleen), 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.

Treatment Period Assessment – Cohort 1 and Cohort 2

Procedure	All Study Periods					Follow-up/Early Discontinuation[3]	Notes
Assessments	Day –2 or Day –1[2]	Day 1	Washout[1]				
			Day 2	Day 3	Day 4		
Admit to clinic	X						Day -1 of Period 2 may be the same day as Day 6 of Period 1.
Discharge from clinic					X		Discharge from the study site following completion of the last study procedure on Day 4 of each period.
Outpatient visit[4]						X	
Brief physical examination	X						Brief physical examinations may be completed as a full physical examinations at the discretion of the investigator. See Protocol Section 8.2.1 for description of brief physical examination.
Vital signs	X				X	X	Single vital sign measurements at all time points (Protocol Section 8.2.2).
12-lead ECG	X				X		Single ECG measurements. Additional ECGs may be performed at the discretion of the investigator.
Urine drug, alcohol, and cotinine screen	X						See Protocol Appendix 2 for specific tests to be performed.
Clinical laboratory assessments[5]	X				X	X	See Protocol Section 8.2.4 for additional information and Protocol Appendix 2 for specific tests to be performed.
Molecular test for SARs-CoV-2[6]	X						Polymerase Chain Reaction (PCR) or Antigen test.
Pregnancy test	X					X	Pregnancy test will be performed as per the standard practice of the study site.
Dosing with study intervention[7]		X					
Palatability assessment		X					To be completed within 10 minutes following dosing (see Protocol Section 8.2.6)
Meals		Standard for the study site					See Protocol Section 4.1 for specific information on meals.
Serial PK sampling[8]		X	X	X	X		
AE and SAE review[9]	←==========X==========→						

Procedure	All Study Periods					Follow-up/Early Discontinuation[3]	Notes
Assessments	Day –2 or Day –1[2]	Day 1	Washout[1]				
			Day 2	Day 3	Day 4		
Concomitant medications	←==========X==========→						

3TC = lamivudine; ABC = abacavir; AE = adverse event; DTG = dolutegravir; ECG = electrocardiogram; PK = pharmacokinetic; SAE = serious adverse event.

1. To ensure adequate washout, there will be at least 7 days between each dose of study intervention, with an allowance window of 4 hours (i.e., 7 days minus 4 hours).
2. Participants will be admitted to the study site up to 48 hours prior to dosing.
3. Follow-up visit will occur 7 to 14 days after the last dose of study intervention.
   At follow-up, male participants with no ongoing AEs or vital sign/clinical laboratory results of clinical concern may be followed up virtually by the site via telephone contact. Female participants must return for a pregnancy test.
4. Follow-up assessments should be completed in the event of an early participant discontinuation.
5. Clinical laboratory assessment at follow-up is only necessary if a participant had a previous abnormal clinical laboratory value.
6. The first test should be performed ≥7 days prior to admission. The second test should be performed 24 hours prior to admission to the unit. Participants should be quarantined within the unit until the second test result is negative. Once the test result is confirmed to be negative, participants can be released into the unit and will follow infection control practices.
7. Dosing will occur at Hour 0 on Day 1 of each period.
   Treatment A: Pediatric TRIUMEQ (DTG 5 mg/ABC 60 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fed conditions.
   Treatment B: Pediatric TRIUMEQ (DTG 5 mg/ABC 60 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fasted conditions.
   Treatment C: Pediatric DOVATO (DTG 5 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fed conditions.
   Treatment D: Pediatric DOVATO (DTG 5 mg/3TC 30 mg, 6 dispersible tablets) administered as a dispersion and taken immediately under fasted conditions.
8. Blood collection for PK analysis of DTG, ABC, and/or 3TC will be collected within 60 minutes prior to dosing (0 hour) and 0.25, 0.50, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4 (prior to provision of food), 5, 6, 8, 12, 24, 48, and 72 hours post dose in each period.
9. See Protocol Section 8.3 for details for AE and SAE time periods and reporting.

- The timing and number of planned study assessments, including safety, PK, or other assessments may be altered during the course of the study based on newly available data (e.g., to obtain data closer to the time of peak plasma concentrations) to ensure appropriate monitoring.
- Any changes in the timing or addition 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/Independent Ethics Committee 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. The changes will be approved by the competent authorities 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).

11.2.2. Study Phases for Lab, Electrocardiograms, and Vital Signs

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 + 6 days
Post-Treatment	Date and Time >Study Treatment Stop Date and Time + 6 days

11.2.3. Study Phases for Concomitant Medication

Study Phase	Study Phase
Prior	End Date and Time < Study First Dosing Start Date and Time
Concomitant	End Date and Time > = Study First Dosing Start Date and Time and Start Date <= Study Treatment Stop Date and Time + 6 days

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.

11.2.4. 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 + 6 days. • Study Treatment Start Date and Time ≤AE Start Date and Time ≤Study Treatment Stop Date and Time + 6 days. • 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	gsk1349572
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 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 Clinical Study Report. All participant level listings should be located in the modular appendices as ICH or non-ICH listings.

Formats
• All data will be reported according to the actual treatment the participant received unless otherwise stated. • GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DPs) will be rounded to integer, unless otherwise specified. • 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 DPs.

Planned and Actual Time	

• Reporting for tables, figures, and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses, and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the 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 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 zero 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 pharmacokinetic 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 pharmacokinetic 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 coefficient of variation (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 Day 1:
  • Assessment Date = Missing
  → Study Day = Missing
  • Assessment Date <Dose Date on Day 1
  → Study Day = Assessment Date –Dose Date on Day 1
  • Assessment Date >= Dose Date on Day 1
  → Study Day = Assessment Date – Dose Date on 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
  • Assessment Date >= Dose Date on Period 2 Day 1
  → Period Day = Assessment Date – Dose Date on Period 2 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:
  o Any participant with a missing day will have this imputed as day '15'.
  o 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 $(m)^2$]

11.4.3. Safety

12-Lead Electrocardiograms
QTcB Interval
• QTcB interval in msec will be calculated using QT interval (msec) and RR interval (msec) as $QTcB = \frac{QT}{\sqrt{\frac{RR}{1000}}}$ where RR interval in msec is calculated using QT interval (msec) and QTcF interval (msec) as $RR = (\frac{QT}{QTcF})^3 \times 1000$

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) is defined as the participant has completed all phases of the study including the final date on which data were or are expected to be collected. • Withdrawn participants will not be replaced in the study. • All available data from participants who are 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 are 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 are 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	• 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

Laboratory abnormalities will be graded according to the DAIDS grading table Version 2.1, July 2017. 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.

Hematology				
	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
Absolute Lymphocyte Count, Low (cell/mm^3; cells/L) >5 years of age (not HIV infected)	600 to <650 0.600 × 10^9 to <0.650 × 10^9	500 to <600 0.500 × 10^9 to <0.600 × 10^9	350 to <500 0.350 × 10^9 to <0.500 × 10^9	<350 <0.350 × 10^9
Absolute Neutrophil Count, Low (cells/mm^3; cells/L) >7 days of age	800 to 1,000 0.800 × 10^9 to 1.000 × 10^9	600 to 799 0.600 × 10^9 to 0.799 × 10^9	400 to 599 0.400 × 10^9 to 0.599 × 10^9	<400 <0.400 × 10^9
Hemoglobin, Low (g/dL; mmol/L) ≥13 years of age (male only)	10.0 to 10.9 6.19 to 6.76	9.0 to <10.0 5.57 to <6.19	7.0 to <9.0 4.34 to <5.57	<7.0 <4.34
Hemoglobin, Low (g/dL; mmol/L) ≥13 years of age (female only)	9.5 to 10.4 5.88 to 6.48	8.5 to <9.5 5.25 to <5.88	6.5 to <8.5 4.03 to <5.25	<6.5 <4.03
Platelets, Decreased (cells/mm^3; cells/L)	100,000 to <125,000 100.000 × 10^9 to <125.000 × 10^9	50,000 to <100,000 50.000 × 10^9 to <100.000 × 10^9	25,000 to <50,000 25.000 × 10^9 to <50.000 × 10^9	<25,000 <25.000 × 10^9
White Blood Cell, Decreased (cells/mm^3; cells/L) >7 days of age	2,000 to 2,499 2.000 × 10^9 to 2.499 × 10^9	1,500 to 1,999 1.500 × 10^9 to 1.999 × 10^9	1,000 to 1,499 1.000 × 10^9 to 1.499 × 10^9	<1,000 <1.000 × 10^9

Clinical Chemistry				
	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
Albumin, Low (g/dL; g/L)	3.0 to <LLN 30 to <LLN	≥2.0 to <3.0 ≥20 to <30	<2.0 <20	NA
Alkaline Phosphatase, High	1.25 to <2.5 × ULN	2.5 to <5.0 × ULN	5.0 to <10.0 × ULN	≥10.0 × ULN
Alanine Aminotransferase, High	1.25 to <2.5 × ULN	2.5 to <5.0 × ULN	5.0 to <10.0 × ULN	≥10.0 ULN
Amylase (Total), High	1.1 to <1.5 × ULN	1.5 to <3.0 × ULN	3.0 to <5.0 × ULN	≥5.0 × ULN
Aspartate Aminotransferase, High	1.25 to <2.5 × ULN	2.5 to <5.0 × ULN	5.0 to <10.0 × ULN	≥10.0 × ULN
Bicarbonate, Low (mEq/L; mmol/L)	16.0 to <LLN 16.0 to <LLN	11.0 to <16.0 11.0 to <16.0	8.0 to <11.0 8.0 to <110.	<8.0 <8.0
Direct Bilirubin, High >28 days of age	NA	NA	>ULN with other signs and symptoms of hepatotoxicity	>ULN with life-threatening consequences (e.g., signs and symptoms of liver failure)
Total Bilirubin, High >28 days of age	1.1 to <1.6 × ULN	1.6 to <2.6 × ULN	2.6 to <5.0 × ULN	≥5.0 × ULN
Calcium, High (mg/dL; mmol/L) ≥7 days of age	10.6 to <11.5 2.65 to <2.88	11.5 to <12.5 2.88 to <3.13	12.5 to <13.5 3.13 to <3.38	≥13.5 ≥3.38
Calcium, Low (mg/dL; mmol/L) ≥7 days of age	7.8 to <8.4 1.95 to <2.10	7.0 to <7.8 1.75 to <1.95	6.1 to <7.0 1.53 to <1.75	<6.1 <1.53
Creatine Kinase, High	3 to <6 × ULN	6 to <10 × ULN	10 to <20 × ULN	≥20 × ULN
Creatinine, High *Choose the method that selects for the higher grade*	1.1 to 1.3 × ULN	>1.3 to 1.8 × ULN OR Increase to 1.3 to <1.5 × participant's baseline	>1.8 to <3.5 ULN OR Increase to 1.5 to <2.0 × participant's baseline	≥3.5 × ULN OR Increase of ≥2.0 × participant's baseline
Glucose Fasting, High (mg/dL; mmol/L)	110 to 125 6.11 to <6.95	>125 to 250 6.95 to <13.89	>250 to 500 13.89 to <27.75	≥500 ≥27.75
Glucose, Low (mg/dL; mmol/L) ≥1 month of age	55 to 64 3.05 to <3.55	40 to <55 2.22 to <3.05	30 to <40 1.67 to <2.22	<30 <1.67
Lipase, High	1.1 to <1.5 × ULN	1.5 to <3.0 × ULN	3.0 to <5.0 × ULN	≥5.0 × ULN

Cholesterol, Fasting, High (mg/dL; mmol/L) ≥18 years of age	200 to <240 5.18 to <6.19	240 to <300 6.19 to <7.77	≥300 ≥7.77	NA
Triglycerides, Fasting, High (mg/dL; mmol/L)	150 to 300 1.71 to 3.42	>300 to 500 >3.42 to 5.7	>500 to <1.000 >5.7 to 11.4	>1,000 >11.4
Phosphate, Low (mg/dL; mmol/L) >14 years of age	2.0 to <LLN 0.65 to <LLN	1.4 to <2.0 0.45 to <0.65	1.0 to <1.4 0.32 to <0.45	<1.0 <0.32
Potassium, High (mEq/L; mmol/L)	5.6 to <6.0 5.6 to <6.0	6.0 to <6.5 6.0 to <6.5	6.5 to <7.0 6.5 to <7.0	≥7.0 ≥7.0
Potassium, Low (mEq/L; mmol/L)	3.0 to <3.4 3.0 to <3.4	2.5 to <3.0 2.5 to <3.0	2.0 to <2.5 2.0 to <2.5	<2.0 <2.0
Sodium, High (mEq/L; mmol/L)	146 to <150 146 to <150	150 to <154 150 to <154	154 to <160 154 to <160	≥160 ≥160
Sodium, Low (mEq/L; mmol/L)	130 to <135 130 to <135	125 to <130 125 to <130	121 to <125 121 to <125	≤ 120 ≤ 120
Uric Acid, High (mEq/L; mmol/L)	7.5 to <10.0 0.45 to <0.59	10.0 to <12.0 0.59 to <0.71	12.0 to <15.0 0.71 to <0.89	≥15.0 ≥0.89

NA=not applicable; LLN = lower limit of normal; ULN=upper limit of normal.

Urinalysis				
	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
Glucose/Glycosuria (random collection tested by dipstick)	Trace to 1+ or ≤ 250 mg	2+ or >250 to ≤ 500 mg	>2+ or >500 mg	NA
Protein/Proteinuria (random collection tested by dipstick)	1+	2+	3+ or higher	NA
Red Blood Cells (RBCs)/Hematuria (not to be reported based on dipstick findings or on blood believed to be of menstrual origin)	6 to <10 RBCs per high power field	≥10 RBCs per high power field	Gross, with or without clots OR with RBC casts OR intervention indicated	Life-threatening consequences

NA=not applicable

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	<120	>200
Absolute QRS Complex	msec	<75	>110
Change from Baseline			
Increase from Baseline QTc	msec		>60

11.7.2. Vital Signs

Vital Sign Parameter (Absolute)	Units	Potential Clinically Important Range	
		Lower	Upper
Systolic Blood Pressure	mmHg	<85	>140
Diastolic Blood Pressure	mmHg	<45	>90
Heart Rate	Beats per minute	<40	>100

11.8. Appendix 8: Abbreviations & Trademarks

11.8.1. Abbreviations

Abbreviation	Description
3TC	Lamivudine
ABC	Abacavir
AE	Adverse Event
ANOVA	Analysis of Variance
ARV	Antiretroviral therapy
AUC	Area under the Plasma Concentration-Time Curve
AUC(0-inf)	AUC from Time 0 Extrapolated to Infinity
AUC(0-t)	AUC from Time 0 to Time t
BMI	Body Mass Index
C24	Plasma Concentration at 24 hours postdose
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CIOMS	Council for International Organizations of Medical Sciences
CL/F	Apparent Oral Clearance
Cmax	Cmax Maximum Observed Plasma Concentration
CRF	Case Report Form
CSR	Clinical Study Report
Ct	Last quantifiable concentration
CV	Coefficient of Variation
CVb	Coefficient of Variation (Between)
CVw	Within participant variability
DAIDS	Division of AIDS
DBF	Database Freeze
DBR	Database Release
DP	Decimal Places
DTG	Dolutegravir
ECG	Electrocardiogram
ER	Extended Release
EU	European Union
FDA	Food and Drug Administration
FSH	Follicle Stimulating Hormone
GSK	GlaxoSmithKline
hCG	Human Chorionic Gonadotropin
HLGT	High Level Group Term
HIV	Human Immunodeficiency Virus
ICH	International Council On Harmonisation
IDSL	Integrated Data Standards Library
LLN	Lower Limit of Normal
MedDRA	Medical Dictionary for Regulatory Activities
NQ	Not quantifiable
PK	Pharmacokinetic

Abbreviation	Description
PT	Preferred Term
QTcF	QTc using the Fridericia formula
RAP	Reporting & Analysis Plan
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SMQ	Standardized MedDRA Query
SOC	System Organ Class
t1/2	Apparent Terminal Phase Half-life
Tlag	lag time for absorption
Tmax	Time of Maximum Observed Concentration
TLF	Tables, listings, figures
ULN	Upper Limit of Normal
Vz/F	Apparent Oral Volume of Distribution

11.8.2. Trademarks

Trademarks of the ViiV Healthcare Group of Companies
DOVATO
TRIUMEQ

Trademarks not owned by the GlaxoSmithKline Group of Companies
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 2.48	2.1 to 2.2
Pharmacokinetic	3.1 to 3.17	3.1 to 3.22
Other	4.1 to 4.2	
Section	**Listings**	
ICH Listings	1 to 67	
Other Listings	68 to 83	

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
Other	OTHER_Fn	OTHER_Tn	OTHER_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 by Country and Site ID		SAC
1.2.	Safety	ES1xo	Summary of Subject Disposition for the Subject Conclusion Record – TRIUMEQ		SAC
1.3.	Safety	ES1xo	Summary of Subject Disposition for the Subject Conclusion Record – DOVATO		SAC
1.4.	Screened	ES6	Summary of Screening Status and Reasons for Screen Failures		SAC
1.5.	Screened	SP1	Summary of Study Populations – TRIUMEQ		SAC
1.6.	Screened	SP1	Summary of Study Populations – DOVATO		SAC
Protocol Deviations					
1.7.	Safety	DV1	Summary of Important Protocol Deviations – TRIUMEQ		SAC
1.8.	Safety	DV1	Summary of Important Protocol Deviations – DOVATO		SAC
Demographic and Baseline Characteristics					
1.9.	Safety	DM1xo	Summary of Demographic Characteristics – TRIUMEQ		SAC
1.10.	Safety	DM1xo	Summary of Demographic Characteristics – DOVATO		SAC
1.11.	Safety	DM6xo	Summary of Race and Racial Combinations – TRIUMEQ		SAC
1.12.	Safety	DM6xo	Summary of Race and Racial Combinations – DOVATO		SAC
1.13.	Safety	DM11xo	Summary of Age Ranges – TRIUMEQ		SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.14.	Safety	DM11xo	Summary of Age Ranges – DOVATO		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 – TRIUMEQ		SAC
2.2.	Safety	AE1xo	Summary of Adverse Events by System Organ Class and Preferred Term – DOVATO		SAC
2.3.	Safety	AE1xo	Summary of Drug-Related Adverse Events by System Organ Class and Preferred Term – TRIUMEQ		SAC
2.4.	Safety	AE1xo	Summary of Drug-Related Adverse Events by System Organ Class and Preferred Term – DOVATO		SAC
2.5.	Safety	AE3	Summary of Common (>=2 subjects) Adverse Events by Overall Frequency – TRIUMEQ		SAC
2.6.	Safety	AE3	Summary of Common (>=2 subjects) Adverse Events by Overall Frequency – DOVATO		SAC
2.7.	Safety	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term – TRIUMEQ (Number of Subjects and Occurrences)		SAC
2.8.	Safety	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term – DOVATO (Number of Subjects and Occurrences)		SAC
2.9.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term – TRIUMEQ (Number of Subjects and Occurrences)		SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.10.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term – DOVATO (Number of Subjects and Occurrences)		SAC
2.11.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Preferred Term and Maximum Intensity – TRIUMEQ		SAC
2.12.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Preferred Term and Maximum Intensity – DOVATO		SAC
Laboratory: Chemistry					
2.13.	Safety	LB1	Summary of Clinical Chemistry Data – TRIUMEQ		SAC
2.14.	Safety	LB1	Summary of Clinical Chemistry Data – DOVATO		SAC
2.15.	Safety	LB1	Summary of Clinical Chemistry Changes from Baseline – TRIUMEQ		SAC
2.16.	Safety	LB1	Summary of Clinical Chemistry Changes from Baseline – DOVATO		SAC
2.17.	Safety	LB16	Summary of Clinical Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline – TRIUMEQ		SAC
2.18.	Safety	LB16	Summary of Clinical Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline – DOVATO		SAC
Laboratory: Hematology					
2.19.	Safety	LB1	Summary of Hematology Data – TRIUMEQ		SAC
2.20.	Safety	LB1	Summary of Hematology Data – DOVATO		SAC
2.21.	Safety	LB1	Summary of Hematology Changes from Baseline – TRIUMEQ		SAC
2.22.	Safety	LB1	Summary of Hematology Changes from Baseline – DOVATO		SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.23.	Safety	LB16	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline – TRIUMEQ		SAC
2.24.	Safety	LB16	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline – DOVATO		SAC
Laboratory: Urinalysis					
2.25.	Safety	LB1	Summary of Urine Concentration – TRIUMEQ		SAC
2.26.	Safety	LB1	Summary of Urine Concentration – DOVATO		SAC
2.27.	Safety	LB1	Summary of Urine Concentration Changes from Baseline – TRIUMEQ		SAC
2.28.	Safety	LB1	Summary of Urine Concentration Changes from Baseline – DOVATO		SAC
2.29.	Safety	SAFE_T1	Summary of Urinalysis Dipstick Results – TRIUMEQ		SAC
2.30.	Safety	SAFE_T1	Summary of Urinalysis Dipstick Results – DOVATO		SAC
2.31.	Safety	LB16	Summary of Urinalysis by Maximum Grade Increase Post-Baseline Relative to Baseline – TRIUMEQ		SAC
2.32.	Safety	LB16	Summary of Urinalysis by Maximum Grade Increase Post-Baseline Relative to Baseline – DOVATO		SAC
ECG					
2.33.	Safety	EG1	Summary of ECG Findings – TRIUMEQ		SAC
2.34.	Safety	EG1	Summary of ECG Findings – DOVATO		SAC
2.35.	Safety	EG2	Summary of ECG Values – TRIUMEQ		SAC
2.36.	Safety	EG2	Summary of ECG Values – DOVATO		SAC
2.37.	Safety	EG2	Summary of ECG Changes from Baseline – TRIUMEQ		SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.38.	Safety	EG2	Summary of ECG Changes from Baseline – DOVATO		SAC
2.39.	Safety	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category – TRIUMEQ		SAC
2.40.	Safety	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category – DOVATO		SAC
2.41.	Safety	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category – TRIUMEQ		SAC
2.42.	Safety	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category – DOVATO		SAC
Vital Signs					
2.43.	Safety	VS1	Summary of Vital Signs – TRIUMEQ		SAC
2.44.	Safety	VS1	Summary of Vital Signs – DOVATO		SAC
2.45.	Safety	VS1	Summary of Vital Sign Changes from Baseline – TRIUMEQ		SAC
2.46.	Safety	VS1	Summary of Vital Sign Changes from Baseline – DOVATO		SAC
COVID-19					
2.47.	Safety	PAN1	Summary of COVID-19 Assessment – TRIUMEQ		SAC
2.48.	Safety	PAN1	Summary of COVID-19 Assessment – DOVATO		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 – TRIUMEQ		SAC
2.2.	Safety	EG9	Mean (95% CI) Change from Baseline in QTcF Interval by Timepoint and Treatment – DOVATO		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 Dolutegravir Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – TRIUMEQ	DTG for TRIUMEQ	SAC
3.2.	PK Concentration	PK01	Summary of Abacavir Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – TRIUMEQ	ABC for TRIUMEQ	SAC
3.3.	PK Concentration	PK01	Summary of Lamivudine Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – TRIUMEQ	3TC for TRIUMEQ	SAC
3.4.	PK Concentration	PK01	Summary of Dolutegravir Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – DOVATO	DTG for DOVATO	SAC
3.5.	PK Concentration	PK01	Summary of Lamivudine Plasma Pharmacokinetic Concentration-Time Data (units) by Treatment – DOVATO	3TC for DOVATO	SAC
PK Derived Parameters					
3.6.	PK Parameter	PK06	Summary Statistics of Derived Dolutegravir Plasma Pharmacokinetic Parameters (Non-Transformed and Ln-Transformed) Based on Actual Time by Treatment – TRIUMEQ	Parameters with units for TRIUMEQ	SAC
3.7.	PK Parameter	PK06	Summary Statistics of Derived Abacavir Plasma Pharmacokinetic Parameters (Non-Transformed and Ln-Transformed) Based on Actual Time by Treatment – TRIUMEQ	Parameters with units for TRIUMEQ	SAC
3.8.	PK Parameter	PK06	Summary Statistics of Derived Lamivudine Plasma Pharmacokinetic Parameters (Non-Transformed and Ln-Transformed) Based on Actual Time by Treatment – TRIUMEQ	Parameters with units for TRIUMEQ	SAC
3.9.	PK Parameter	PK06	Summary Statistics of Derived Dolutegravir Plasma Pharmacokinetic Parameters (Non-Transformed and Ln-Transformed) Based on Actual Time by Treatment – DOVATO	Parameters with units DOVATO	SAC

3.10.	PK Parameter	PK06	Summary Statistics of Derived Lamivudine Plasma Pharmacokinetic Parameters (Non-Transformed and Ln-Transformed) Based on Actual Time by Treatment – DOVATO	Parameters with units DOVATO	SAC
PK Analysis Tables					
3.11.	PK Parameter	PK05	Statistical Analysis of Plasma Pharmacokinetic Parameters: Analysis of Variance (ANOVA) – TRIUMEQ	TRIUMEQ AUC(0-inf), AUC(0-t) and Cmax for each analyte	SAC
3.12.	PK Parameter	PK05	Statistical Analysis of Plasma Pharmacokinetic Parameters: Analysis of Variance (ANOVA) – DOVATO	DOVATO AUC(0-inf), AUC(0-t) and Cmax for each analyte	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 Dolutegravir Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – TRIUMEQ	TRIUMEQ, Paginate by Participant Dashed line represents the LLQ Treatments Overlaid	SAC
3.2.	PK Concentration	PK16A	Individual Abacavir Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – TRIUMEQ	TRIUMEQ, Paginate by Participant Dashed line represents the LLQ Treatments Overlaid	SAC
3.3.	PK Concentration	PK16A	Individual Lamivudine Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – TRIUMEQ	TRIUMEQ, 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) – DOVATO	DOVATO, Paginate by Participant Dashed line represents the LLQ Treatments Overlaid	SAC
3.5.	PK Concentration	PK16A	Individual Lamivudine Plasma Concentration-Time Plots by Participant (Linear and Semi-Logarithmic) – DOVATO	DOVATO, Paginate by Participant Dashed line represents the LLQ Treatments Overlaid	SAC
3.6.	PK Concentration	PK16A	Individual Dolutegravir Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – TRIUMEQ	TRIUMEQ Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
3.7.	PK Concentration	PK16A	Individual Abacavir Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – TRIUMEQ	TRIUMEQ Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.8.	PK Concentration	PK16A	Individual Lamivudine Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – TRIUMEQ	TRIUMEQ Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
3.9.	PK Concentration	PK16A	Individual Dolutegravir Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – DOVATO	DOVATO Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
3.10.	PK Concentration	PK16A	Individual Lamivudine Plasma Concentration-Time Plots by Treatment (Linear and Semi-Logarithmic) – DOVATO	DOVATO Paginate by Treatment Dashed line represents the LLQ Individuals Overlaid	SAC
Mean / Median Concentration Plots					
3.11.	PK Concentration	PK17	Mean (Standard Deviation) Dolutegravir Plasma Concentration-Time Plots by Treatment - TRIUMEQ (Linear and Semi-Logarithmic)	Treatments (A and B) Overlaid	SAC
3.12.	PK Concentration	PK17	Mean (Standard Deviation) Abacavir Plasma Concentration-Time Plots by Treatment - TRIUMEQ (Linear and Semi-Logarithmic)	Treatments (A and B) Overlaid	SAC
3.13.	PK Concentration	PK17	Mean (Standard Deviation) Lamivudine Plasma Concentration-Time Plots by Treatment - TRIUMEQ (Linear and Semi-Logarithmic)	Treatments (A and B) Overlaid	SAC
3.14.	PK Concentration	PK18	Median (Range) Dolutegravir Plasma Concentration-Time Plots by Treatment - TRIUMEQ (Linear and Semi-Logarithmic)	Treatments (A and B) Overlaid	SAC
3.15.	PK Concentration	PK18	Median (Range) Abacavir Plasma Concentration-Time Plots by Treatment - TRIUMEQ (Linear and Semi-Logarithmic)	Treatments (A and B) Overlaid	SAC
3.16.	PK Concentration	PK18	Median (Range) Lamivudine Plasma Concentration-Time Plots by Treatment - TRIUMEQ (Linear and Semi-Logarithmic)	Treatments (A and B) Overlaid	SAC

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.17.	PK Concentration	PK17	Mean (Standard Deviation) Dolutegravir Plasma Concentration-Time Plots by Treatment - DOVATO (Linear and Semi-Logarithmic)	Treatments (C and D) Overlaid	SAC
3.18.	PK Concentration	PK17	Mean (Standard Deviation) Lamivudine Plasma Concentration-Time Plots by Treatment - DOVATO (Linear and Semi-Logarithmic)	Treatments (C and D) Overlaid	SAC
3.19.	PK Concentration	PK18	Median (Range) Dolutegravir Plasma Concentration-Time Plots by Treatment - DOVATO (Linear and Semi-Logarithmic)	Treatments (C and D) Overlaid	SAC
3.20.	PK Concentration	PK18	Median (Range) Lamivudine Plasma Concentration-Time Plots by Treatment - DOVATO (Linear and Semi-Logarithmic)	Treatments (C and D) Overlaid	SAC
3.21.	PK Parameter	PK_F1	Forest Plot for Plasma Pharmacokinetic Parameters – TRIUMEQ	TRIUMEQ ANOVA AUC(0-inf), AUC(0-t) and Cmax for each analyte	SAC
3.22.	PK Parameter	PK_F1	Forest Plot for Plasma Pharmacokinetic Parameters - DOVATO	DOVATO ANOVA AUC(0-inf), AUC(0-t) and Cmax for each analyte	SAC

11.9.9. Other Tables

Palatability Assessment					
4.1.	Safety	OTHER_T1	Summary of Palatability Assessment – TRIUMEQ		SAC
4.2.	Safety	OTHER_T1	Summary of Palatability Assessment – DOVATO		SAC

11.9.10. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	Randomized	POP_L1	Listing of Randomization Schedule – TRIUMEQ		SAC
2.	Randomized	POP_L1	Listing of Randomization Schedule – DOVATO		SAC
3.	Safety	ES2xo	Listing of Reasons for Study Withdrawal – TRIUMEQ		SAC
4.	Safety	ES2xo	Listing of Reasons for Study Withdrawal – DOVATO		SAC
5.	Screened	ES7	Listing of Reasons for Screen Failure		SAC
Protocol Deviations					
6.	Safety	DV2xo	Listing of Important Protocol Deviations – TRIUMEQ		SAC
7.	Safety	DV2xo	Listing of Important Protocol Deviations – DOVATO		SAC
8.	Safety	IE3xo	Listing of Subjects with Inclusion/Exclusion Criteria Deviations – TRIUMEQ		SAC
9.	Safety	IE3xo	Listing of Subjects with Inclusion/Exclusion Criteria Deviations – DOVATO		SAC
Populations Analyzed					
10.	Safety	SP3xo	Listing of Subjects Excluded from Any Population – TRIUMEQ		SAC
11.	Safety	SP3xo	Listing of Subjects Excluded from Any Population – DOVATO		SAC
Demographic and Baseline Characteristics					
12.	Safety	DM2xo	Listing of Demographic Characteristics – TRIUMEQ		SAC
13.	Safety	DM2xo	Listing of Demographic Characteristics – DOVATO		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.	Safety	DM9xo	Listing of Race – TRIUMEQ		SAC
15.	Safety	DM9xo	Listing of Race – DOVATO		SAC
Prior and Concomitant Medications					
16.	Safety	CM3xo	Listing of Concomitant Medications – TRIUMEQ	Based on GSK Drug Dictionary	SAC
17.	Safety	CM3xo	Listing of Concomitant Medications – DOVATO	Based on GSK Drug Dictionary	SAC
Exposure and Treatment Compliance					
18.	Safety	EX3xo	Listing of Exposure Data – TRIUMEQ		SAC
19.	Safety	EX3xo	Listing of Exposure Data – DOVATO		SAC
20.	Safety	SAFE_L1	Listing of Meal Data – TRIUMEQ		SAC
21.	Safety	SAFE_L1	Listing of Meal Data – DOVATO		SAC
Adverse Events					
22.	Safety	AE2	Listing of Relationship Between System Organ Class and Verbatim Text – TRIUMEQ		SAC
23.	Safety	AE2	Listing of Relationship Between System Organ Class and Verbatim Text – DOVATO		SAC
24.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events – TRIUMEQ		SAC
25.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events – DOVATO		SAC
26.	Safety	AE8CPxo	Listing of All Adverse Events – TRIUMEQ		SAC
27.	Safety	AE8CPxo	Listing of All Adverse Events – DOVATO		SAC
Serious and Other Significant Adverse Events					
28.	Safety	AE8CPxo	Listing of Study Drug Related Adverse Events – TRIUMEQ		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
29.	Safety	AE8CPxo	Listing of Study Drug Related Adverse Events – DOVATO		SAC
30.	Safety	AE8CPxo	Listing of Serious Adverse Events (Fatal & Non-Fatal) – TRIUMEQ		SAC
31.	Safety	AE8CPxo	Listing of Serious Adverse Events (Fatal & Non-Fatal) – DOVATO		SAC
32.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event – TRIUMEQ		SAC
33.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event – DOVATO		SAC
34.	Safety	AE8CPxo	Listing of Adverse Events Leading to Withdrawal from Study – TRIUMEQ		SAC
35.	Safety	AE8CPxo	Listing of Adverse Events Leading to Withdrawal from Study – DOVATO		SAC
36.	Safety	AE8CPxo	Listing of Adverse Events With Grade 3 or Higher – TRIUMEQ		SAC
37.	Safety	AE8CPxo	Listing of Adverse Events With Grade 3 or Higher – DOVATO		SAC
Hepatobiliary (Liver)					
38.	Safety	MH2xo	Listing of Medical Conditions for Subjects with Liver Stopping Events – TRIUMEQ		SAC
39.	Safety	MH2xo	Listing of Medical Conditions for Subjects with Liver Stopping Events – DOVATO		SAC
40.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events – TRIUMEQ		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
41.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events – DOVATO		SAC
All Laboratory					
42.	Safety	LB5Axo	Listing of Clinical Chemistry with any Toxicities – TRIUMEQ		SAC
43.	Safety	LB5Axo	Listing of Clinical Chemistry with any Toxicities – DOVATO		SAC
44.	Safety	LB5Axo	Listing of All Clinical Chemistry Data for Subjects with any Toxicities – TRIUMEQ		SAC
45.	Safety	LB5Axo	Listing of All Clinical Chemistry Data for Subjects with any Toxicities – DOVATO		SAC
46.	Safety	LB5Axo	Listing of Hematology with any Toxicities – TRIUMEQ		SAC
47.	Safety	LB5Axo	Listing of Hematology with any Toxicities – DOVATO		SAC
48.	Safety	LB5Axo	Listing of All Hematology Data for Subjects with any Toxicities – TRIUMEQ		SAC
49.	Safety	LB5Axo	Listing of All Hematology Data for Subjects with any Toxicities – DOVATO		SAC
50.	Safety	LB5Axo	Listing of Urinalysis with any Toxicities – TRIUMEQ		SAC
51.	Safety	LB5Axo	Listing of Urinalysis with any Toxicities – DOVATO		SAC
52.	Safety	LB5Axo	Listing of All Urinalysis Data for Subjects with any Toxicities – TRIUMEQ		SAC
53.	Safety	LB5Axo	Listing of All Urinalysis Data for Subjects with any Toxicities – DOVATO		SAC
ECG					
54.	Safety	EG5xo	Listing of All ECG Findings – TRIUMEQ		SAC
55.	Safety	EG5xo	Listing of All ECG Findings – DOVATO		SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
56.	Safety	EG5xo	Listing of All Abnormal ECG Findings – TRIUMEQ		SAC
57.	Safety	EG5xo	Listing of All Abnormal ECG Findings – DOVATO		SAC
58.	Safety	EG3xo	Listing of All ECG Values – TRIUMEQ		SAC
59.	Safety	EG3xo	Listing of All ECG Values – DOVATO		SAC
Vital Signs					
60.	Safety	VS4xo	Listing of All Vital Signs of Potential Clinical Importance – TRIUMEQ		SAC
61.	Safety	VS4xo	Listing of All Vital Signs of Potential Clinical Importance – DOVATO		SAC
62.	Safety	VS4xo	Listing of All Vital Signs for Subjects with any Value of Potential Clinical Importance – TRIUMEQ		SAC
63.	Safety	VS4xo	Listing of All Vital Signs for Subjects with any Value of Potential Clinical Importance – DOVATO		SAC
Human Leukocyte Antigen – B					
64.	Safety	SAFE_L2	Listing of Human leukocyte antigen B*5701– TRIUMEQ		SAC
65.	Safety	SAFE_L2	Listing of Human leukocyte antigen B*5701– DOVATO		SAC
COVID-19					
66.	Safety	PAN12	Listing of COVID-19 Assessments and Symptom Assessment – TRIUMEQ		SAC
67.	Safety	PAN12	Listing of COVID-19 Assessments and Symptom Assessment – DOVATO		SAC

11.9.11. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Palatability Assessment					
68.	Safety	OTHER_L1	Listing of Palatability Assessment – TRIUMEQ		SAC
69.	Safety	OTHER_L1	Listing of Palatability Assessment – DOVATO		SAC
Pharmacokinetics					
70.	PK Concentration	PK07xo	Listing of Dolutegravir Plasma Concentration-Time Data by Treatment – TRIUMEQ	DTG for TRIUMEQ	SAC
71.	PK Concentration	PK07xo	Listing of Abacavir Plasma Concentration-Time Data by Treatment – TRIUMEQ	ABC for TRIUMEQ	SAC
72.	PK Concentration	PK07xo	Listing of Lamivudine Plasma Concentration-Time Data by Treatment – TRIUMEQ	3TC for TRIUMEQ	SAC
73.	PK Concentration	PK07xo	Listing of Dolutegravir Plasma Concentration-Time Data by Treatment – DOVATO	DTG for DOVATO	SAC
74.	PK Concentration	PK07xo	Listing of Lamivudine Plasma Concentration-Time Data by Treatment – DOVATO	3TC for DOVATO	SAC
75.	PK Parameter	PK13xo	Listing of Dolutegravir Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – TRIUMEQ	DTG for TRIUMEQ	SAC
76.	PK Parameter	PK13xo	Listing of Abacavir Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – TRIUMEQ	ABC for TRIUMEQ	SAC
77.	PK Parameter	PK13xo	Listing of Lamivudine Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – TRIUMEQ	3TC for TRIUMEQ	SAC
78.	PK Parameter	PK13xo	Listing of Dolutegravir Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – DOVATO	DTG for DOVATO	SAC

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
79.	PK Parameter	PK13xo	Listing of Lamivudine Plasma Pharmacokinetic Parameters Based on Actual Time by Treatment – DOVATO	3TC for DOVATO	SAC
Pregnancy					
82.	Safety	SAFE_L3	Listing of Pregnancy – TRIUMEQ		
83.	Safety	SAFE_L3	Listing of Pregnancy – DOVATO		