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

Title	:	Reporting and Analysis Plan for a Phase 3b, multi-center, open label, single arm, 52-week, pilot study, evaluating the feasibility, efficacy and safety of a rapid Test and Treat intervention in newly diagnosed HIV-1 infected adults using a fixed dose combination of dolutegravir plus lamivudine (DOVATO) as a first line regimen
Compound Number	:	GSK1349572+GR109714 (GSK3515864)
Effective Date	:	20-JUN-2019

Description:

- The purpose of this Critical Components RAP is to describe the crucial constituents of the planned analyses and outputs to be included in Clinical Study Reports for Protocol 212355.
- Planned analyses include the primary Week 24 analysis and the End of Study Week 48 analysis.
- This Critical Components RAP will be provided to the study team members to convey the content of the 212355 Statistical Analysis Complete (SAC) deliverable.

RAP Author(s):

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1. INTRODUCTION

The purpose of this Critical Components Reporting and Analysis Plan (RAP) is to describe the key analyses to be included in the Clinical Study Report for Protocol:

Revision Chronology:		
212355	25-MAR-2019	Original Protocol
212355	06-JUN-2019	Protocol Amendment 01

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

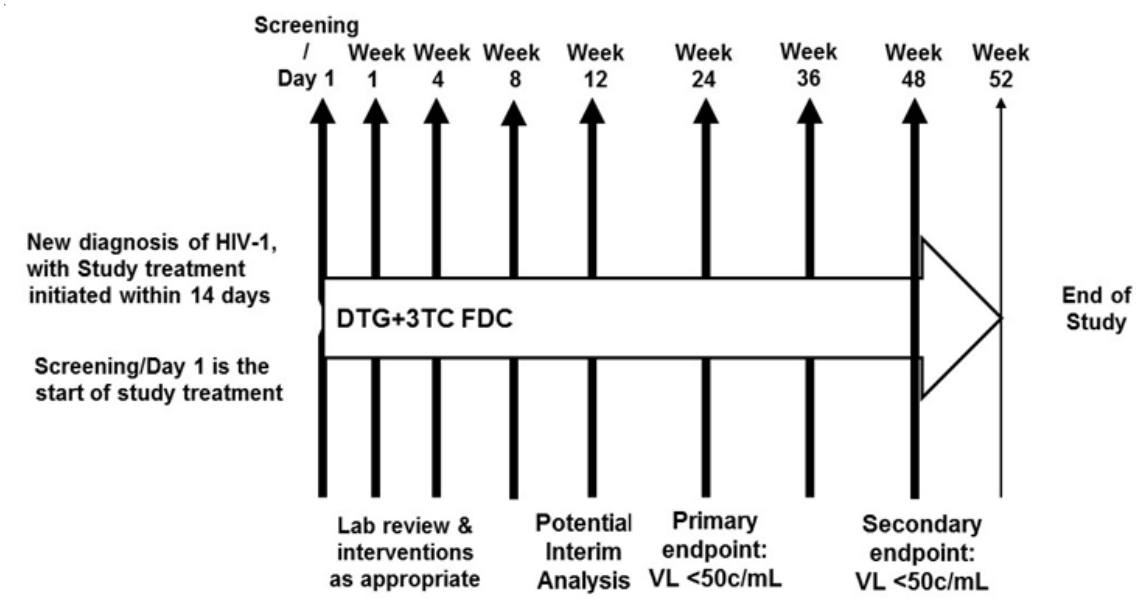
There were no changes or deviations to the planned statistical analysis specified in protocol amendment 01 [(Dated: 06/JUN/2019)].

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

Objectives	**Endpoints**
Primary Objectives	**Primary Endpoints**
To evaluate the feasibility and efficacy of a rapid Test and Treat model of care in participants with a new diagnosis of HIV-1 initiating treatment with DTG + 3TC FDC immediately (or, for those participants referred from another site, within 14 days of initial diagnosis at the external clinic/testing center)	Percentage of all participants who have plasma HIV-1 RNA <50 c/mL at Week 24, regardless of ART regimen (observed analysis)
Secondary Objectives	**Secondary Endpoints**
To demonstrate the antiviral activity of DTG + 3TC FDC over 48 weeks	• Proportion of participants: o with plasma HIV-1 RNA <50 c/mL at Week 48, regardless of ART regimen (observed analysis) o with plasma HIV-1 RNA <50 c/mL at Week 24 and 48 using the FDA Snapshot algorithm • Time to suppression of HIV-1 RNA <50 c/mL
To evaluate the barriers (e.g., HIV-1 resistance mutation results) to initiate and maintain DTG + 3TC FDC treatment in a Test and Treat Model of Care	Proportion of participants who change first line regimen of DTG + 3TC FDC due to Baseline labs or HIV-1 resistance mutation results.
To assess viral resistance in participants meeting confirmed virologic failure criteria	Incidence of treatment-emergent genotypic and phenotypic resistance to DTG and/or 3TC, or any other ART if treatment is modified, in participants meeting confirmed virologic failure criteria
To evaluate the safety and tolerability of a rapid test and treat model of care using	• Incidence and severity of adverse events (AEs) and

Objectives	Endpoints
DTG + 3TC FDC as first line regimen	laboratory abnormalities • Proportion of participants who discontinue treatment due to AEs and drug-related AEs over 48 weeks of treatment
To evaluate the immune effects of a rapid test and treat model of care using DTG + 3TC FDC as first line regimen	• Change from Baseline in CD4+ cell counts and CD4+/CD8+ ratio at Weeks 24 and 48 • Incidence of disease progression (stage 3 HIV-associated conditions, AIDS, and death) through Week 48
To evaluate retention in care	Proportion of participants o who completed their Week 24 and Week 48 Visit o who complete their Week 24 and Week 48 Visit and have an HIV-1 RNA <200 c/mL
Exploratory Objectives	**Exploratory Endpoints**
To evaluate the effect of participant demographics and Baseline characteristics on the feasibility and efficacy of a test and treat model of care using DTG + 3TC FDC as first line regimen	Proportion of participants with plasma HIV-1 RNA <50 c/mL at Weeks 24 and 48 by participant subgroup(s) by Observed Analysis
To assess change in treatment symptom index for participants under a rapid test and treat model of care using DTG + 3TC FDC as a first line regimen	Change from Baseline in overall symptom bother score from the HIV Symptom Distress Module at Weeks 4, 8, 12, 24, 36, and 48
To assess change in specific symptoms for participants treated with DTG + 3TC FDC	Change from Baseline in 20 item-specific symptoms from the HIV Symptom Distress Module at Weeks 4, 8, 12, 24, 36, and 48
To assess adherence to study treatment	Adherence will be assessed by participant recall on number of doses missed over the 7 days prior to the visit

2.3. Study Design

Overview of Study Design and Key Features	
	
Design Features	This is a 52-week, Phase 3b, multi-center, open label, single arm, pilot study. The study will include a Screening/Day 1 (Baseline) Visit. Screening and Day 1 will be the same day. Screening/Day 1 visit should be within 14 days of initial HIV-1 diagnosis. Baseline lab results will be reviewed as they become available and sites will schedule a visit with the participant to review (Week 1 Visit). Baseline resistance mutation results will be reviewed as they are made available (~ Week 4). Subjects may have their first line DTG + 3TC FDC regimen modified based on the Baseline labs or Baseline resistance mutation results or for any other reason during the study. Subjects needing an ART modification will switch from DTG + 3TC FDC to another ART and will remain in the study. All subjects will complete the study by completing the Week 52 Visit.
Dosing	Study intervention, 50 mg DTG + 300 mg 3TC will be provided to all participants as a fixed dose combination (FDC) as first line therapy.
Time & Events	[Refer to Appendix 2]
Treatment Assignment	• Approximately 120 subjects will be recruited to start ART immediately with DTG + 3TC FDC to be taken orally, once daily, with or without food. • Subjects may have their first line DTG + 3TC FDC regimen modified based on the Baseline labs or Baseline resistance mutation results or for any other reason during the study. More than one modification to ART is possible. Subjects whose ART is modified will remain in the study until final Week 52 visit. Any ART modification will be performed in an open-label manner and in consultation with medical monitor.
Primary	The primary analysis will be conducted to evaluate the primary objective of the protocol

Overview of Study Design and Key Features	
Analysis	when all subjects have completed their Week 24 visit, including viral load re-test, if needed.
Interim Analysis	A Week 12 interim analysis may be performed after the last participant completes the Week 12 Visit. The main purpose of this potential analysis will be to assess the proportion of participants that required a modification in the first line ART regimen, following the evaluation of Baseline laboratory and Baseline genotypic resistance mutation results. A Week 48 analysis will be conducted when all participants have had their Week 52 Visit and follow-up visit (if required). The Week 48 analysis will be the last (End of Study) analysis and the only one planned after the primary Week 24 analysis.

See study protocol for further details.

2.4. Statistical Hypotheses / Statistical Analyses

This is a single arm study. No formal statistical hypothesis will be tested.

3. PLANNED ANALYSES

3.1. Interim Analyses

A Week 12 interim analysis might be performed after the last participant completes the Week 12 Visit. It is not required for participants to have completed a Week 12 viral load re-test, if needed, for this analysis. The main purpose of this potential analysis will be to assess the proportion of participants that required a modification in the first line ART regimen, following the evaluation of Baseline laboratory and Baseline genotypic resistance mutation results. Results of Week 12 analysis may be publicly presented before the publication of primary Week 24 results. There are no planned modifications to the study based on the interim analysis results.

3.2. Final Analyses

The primary analysis will be conducted to evaluate the primary objective of the protocol when all subjects have completed their Week 24 visit, including viral load re-test, if needed.

An additional final analysis (Week 48 analysis) will be performed when all participants complete their Week 52 Visit and follow-up visit (if required). This includes any visits for viral load re-test following the Week 48 Visit. All participants who remain in the study should complete the Week 52 Visit (which can occur anytime within 2-4 week of the Week 48 Visit), where in addition to viral load re-test, if needed, study intervention stop date will be captured, and collect and follow-up on AEs and SAEs. The Week 48 analysis will be the last (End of Study) analysis and the only one planned analysis after the primary Week 24 analysis. Results from Week 24 and 48 analyses will be publicly presented.

The planned analyses at Weeks 24 and 48 will be performed after the completion of the following sequential steps:

1. All participants have completed their relevant visit (i.e. Week 24, Week 52 Visits) as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All subjects screened	• Comprise of all participants screened for inclusion in the study, including screen-failures. • Participants are not allowed to re-screen for this study.	• Study Population
Enrolled	All participants who signed ICF, passed screening and are administered DTG + 3TC FDC	• Study Population
Intent-To-Treat Exposed (ITT-E)	• All enrolled participants who received at least one dose of study treatment (i.e. DTG + 3TC FDC).	• Efficacy
Safety	• All enrolled participants who received at least one dose of study treatment (i.e. DTG + 3TC FDC). • Since this is a single arm study Safety population will be the same as ITT-E	• Safety
CVF	• Comprise of all subjects in the ITT-E population who have met Confirmed Virologic Failure (CVF) criteria either under DTG + 3TC FDC or any other ART • The date of SVF will be used to determine if CVF occurred while on-treatment with DTG + 3TC FDC or another ART.	• Efficacy
Viral Genotypic	• Comprise of all subjects in the ITT-E population who have available genotypic resistance data either under DTG + 3TC FDC or any other ART. • The date of collection of blood sample will be used to determine if resistance data are while on-treatment with DTG + 3TC FDC or another ART.	• Virology
	Additional populations may be included in the main RAP	

Refer to Appendix 12: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

Term	Definition
Study Deviation Rules Document	The document describing study deviations (and associated coding/naming conventions) that may be identified during a study and the frequency of study deviation reviews.
Protocol Deviation (PD)	Any departure from study-specific requirements specified in a protocol. Subsets of protocol deviations are categorized as important or significant.

Term	Definition
Important Protocol Deviations	A subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being. All important deviations have a Violation Flag in CTMS and are associated with a Rule Number.
Significant Protocol Deviations	Considered a subset of important protocol deviations, typically impacting efficacy assessments, which lead to the exclusion from the per-protocol population. All significant deviations identified as such during the study are captured in CTMS and are associated with a Rule Number. No per protocol population analysis will be performed in this study, thus no subjects will be excluded from any analysis due to Significant PDs. No Significant PDs will be identified programmatically (e.g. treatment interruption for >10% of total time on-treatment). Significant PDs will not be reported in listings or summarised in Tables.

Important protocol deviations will be summarised and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with PPD's Study Deviation Rules Document which will be reviewed and agreed. All decisions made by study team will be documented.

- Data will be reviewed prior to freezing the database to ensure all important deviations are captured and categorised on the protocol deviations dataset.
- This dataset will be the basis for the summaries and listings of protocol deviations.

A separate listing of all inclusion/exclusion criteria deviations will also be provided. This will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions		
[RandAll NG / FSO Randomization System]		Data Displays for Reporting
Code	Description	Description
A	GSK3515864 50mg DTG, 300mg 3TC	DTG + 3TC

5.2. Baseline Definitions

For all endpoints the Baseline value will be the latest pre-dose assessment with a non-missing value. In this study, Screening and Day 1 assessments will be completed on the same day, i.e. Screening/Day 1 Visit, so it is expected assessments from this Visit to form the Baseline values. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as Baseline.

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

Unless otherwise specified, the definitions specified in the table below will be used for derivations for endpoints/parameters and indicated on summaries and listings.

Definition	Reporting Details
Change from Baseline	= Post-Dose Visit Value – Baseline
% Change from Baseline	= 100 x [(Post-Dose Visit Value – Baseline) / Baseline]

5.3. Multicentre Studies

Data will be summarised for all centres combined. Examination of Covariates, Other Strata and Subgroups

5.3.1. Covariates

The following is a list of covariates that may be used for descriptive summaries (e.g. Baseline Demographics and other Baseline characteristics). Additional covariates of clinical interest may also be considered.

Category	Details

Covariates	• Age (years):
	  o <35, 35 to < 50, ≥ 50
	• Gender:
	  o Male, Female
	• Race:

Category	Details
	○ White, Non-White, ○ White, Black or African American, Other • Ethnicity: ○ Hispanic or Latino, not Hispanic nor Latino • BMI (Kg/m^2): ○ <25, ≥25 • Baseline CD4+ cell count (cells/mm^3): ○ <200, 200 to <350, ≥350 • HBV Co-infection: ○ Yes, No • HCV Co-infection: ○ Yes, No • Further details may be provided in the main RAP

5.3.2. Examination of Subgroups

The below list of subgroups may be used in descriptive summaries and in potential subgroup statistical analyses. Additional subgroups of clinical interest may also be considered.

If the percentage of subjects is small within a particular subgroup, then the subgroup categories may be redefined prior to Database Freeze for a reporting effort (e.g. Week 24, 48 analysis).

Category	Subgroups
Demographic and Baseline Characteristics	• Age (years): ○ < 50, ≥ 50 • Gender: ○ Male, Female • Race: ○ White, Non-White • Baseline CD4+ cell count: ○ <200, ≥200 cells/mm^3 • Baseline plasma HIV-1 RNA (copies/mL): ○ <100,000, ≥100,000 • Baseline CDC HIV-1 classification • Further subgroups may be provided in the main RAP

Further details will be provided in the main RAP

5.4. Multiple Comparisons and Multiplicity

This is a single arm study; no formal statistical hypothesis will be tested, and no comparisons will be performed. Therefore, no adjustment for multiplicity is necessary.

5.5. 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
11.2	Appendix 3: Assessment Windows
11.3	Appendix 4: Study Phases and Treatment Emergent Flags
11.4	Appendix 5: Data Display Standards & Handling Conventions
11.5	Appendix 6: Derived and Transformed Data
11.6	Appendix 7: Reporting Standards for Missing Data
11.7	Appendix 8: Values of Potential Clinical Importance
11.8	Appendix 9: Time to Event Details
11.9	Appendix 10: Observed and Snapshot Algorithms

6. STUDY POPULATION ANALYSES

The study population analyses will be based on the Intent-To-Treat Exposed (ITT-E) population, unless otherwise specified.

Study population analyses including analyses of subject's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 12: List of Data Displays.

Details of Study Population analyses will be provided in the main RAP.

7. EFFICACY ANALYSES

7.1. Primary Efficacy Analyses

The primary analysis will be conducted after LSLV for Week 24 visit, including any re-tests.

7.1.1. Endpoint / Variables

Subjects with HIV-1 RNA < 50 copies/mL (Virologic Success) at Week 24.

7.1.2. Summary Measure

Proportion of subjects with plasma HIV-1 RNA < 50 copies/mL at Week 24, regardless of ART regimen (Observed Analysis)

7.1.3. Population of Interest

The primary efficacy analysis will be based on the Intent-To-Treat Exposed population, unless otherwise specified.

7.1.4. Strategy for Intercurrent (Post-Randomization) Events

Study discontinuations/deaths prior to Week 24 visit will be penalised in the Observed Analysis. Change in ART because of any reason will not be penalised; for a subject any number of ART changes is allowed and won't be penalised by the Observed Analysis. Other intercurrent events (e.g. patient's unavailability to attend the Week 24 visit) that may result in subjects missing the Week 24 viral load assessment will not be penalised as such but will lead subjects to be classified as Virologic Failures due to absence of viral load assessment within the Week 24 visit window. See Section 11.9.1 for more details.

7.1.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Table 1 provides an overview of the planned efficacy analyses, with full details of data displays being presented in Appendix 12.

Table 1 Overview of Planned Primary Efficacy Analyses

Endpoint	Absolute						
	Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L
Proportion of Subjects with plasma HIV-1 RNA <50 c/mL – Observed Analysis							
Study Outcomes[1] at Week 24 based on an Observed Analysis				Y			Y[2]
Percentage of Virologic Success based on an Observed Analysis by visit				Y[3]	Y[4]		

NOTES :

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

[1] Study outcomes i.e., HIV-1 RNA < 50 c/mL (Virologic Success) or HIV-1 RNA ≥ 50 c/mL (Virologic Failure) based on an Observed Analysis.
[2] Listing of Study Outcomes based on Observed Analysis and Listing of Quantitative and Qualitative Plasma HIV-1 RNA Data.
[3] Report percentage of Virologic Success and 95% CI by visit (numbers to be used in the line plot; see [4]).
[4] Line plots with 95% confidence intervals, for the proportion of subjects with HIV-1 RNA < 50 c/mL (Virologic Success) by visit.

7.1.5.1. Statistical Methodology Specification

Endpoint

- Proportion of subjects with plasma HIV-1 RNA < 50 copies c/mL (Virologic Success) at Week 24 using an Observed Analysis for the ITT-E population

Model Specification

Observed Analysis

- Observed Analysis will classify subjects into two categories
  - HIV-1 RNA < 50 c/ml (Virologic Success)
  - HIV-1 RNA ≥ 50 c/ml (Virologic Failure)

- HIV-1 RNA < 50 c/ml (Virologic Success)
  - Subjects will be classified as "HIV-1 RNA < 50 c/ml (Virologic Success)" if the last viral load assessment within the Week 24 visit window is < 50 c/ml, regardless of the ART regimen they are on at the time of viral load assessment (i.e. re-tests are considered).
  - Any switch from DTG + 3TC FDC or subsequent ART switches will not be penalised.
  - Only viral load assessments performed while a subject is under treatment with an ART regimen (i.e. DTG + 3TC FDC or any other ART combination) will be considered (that

is viral loads with study phase "On-D3-Treatment" or "On-Modified-Treatment"; see Section 11.3.1). Any off treatment viral loads will be ignored.

- Subjects classified as Virologic Success will be further classified as being under DTG + 3TC treatment or modified ART at the time of viral load assessment (see Section 11.9.1.)
- All other cases will be classified as "HIV-1 RNA ≥ 50 c/ml (Virologic Failure)" (a detailed description of 'other cases' is given below)

- HIV-1 RNA ≥ 50 c/ml (Virologic Failure)

  Subjects will be classified as "HIV-1 RNA ≥ 50 c/ml (Virologic Failure)" if:

  - The last viral load assessment within the Week 24 visit window is ≥ 50 c/ml (i.e. re-tests are considered). Only viral load assessments performed while a subject is under treatment with an ART regimen (i.e. DTG + 3TC FDC or any other ART combination) will be considered (that is viral loads with study phase "On-D3-Treatment" or "On-Modified-Treatment"; see Section 11.3.1) Any off treatment viral loads will be ignored.
  - Subjects are on study but have no viral load assessment under treatment with any ART regimen within the Week 24 Visit window (missing on treatment viral load data)
  - Subjects have withdrawn from study for any reason before the Week 24 visit

Model Results Presentation

- Number and percentage of subjects in "HIV-1 RNA < 50 c/ml (Virologic Success)" and "HIV-1 RNA ≥ 50 c/ml (Virologic Failure)" categories will be reported in a Table.
- For subjects on "HIV-1 RNA < 50 c/ml (Virologic Success)" the Table will further report whether subjects were still on DTG + 3TC FDC or on modified treatment.
- For subjects on "HIV-1 RNA ≥ 50 c/ml (Virologic Failure)" the Table will further report sub-reasons of Virologic Failure as "Data in window not below threshold", "Missing data during window but on study", "Disc. study due to LFU/withdrew consent", "Disc. study for other reasons"
- A line plot with 95% confidence intervals for the proportion of subjects with HIV-1 RNA < 50 c/mL from each visit will be created.

Subgroup Analyses

- Observed Analysis Outcomes at Week 24 by subgroup will be presented in the main RAP

Sensitivity and Supportive Analyses

- For the proportion of subjects with HIV-1 RNA < 50 c/mL, 95% confidence intervals (CI) will be calculated based on the exact Clopper-Pearson method. CIs based on the same method will also be calculated for the proportion of subjects with HIV-1 RNA < 50 c/mL at Week 24 who are still on DTG + 3TC FDC at Week 24, and for those with HIV-1 RNA < 50 c/mL at Week 24 who switched to another ART before Week 24 visit.

7.2. Secondary Efficacy Analyses

7.2.1. Endpoint / Variables

- Subjects with plasma HIV-1 RNA < 50 copies c/mL at week 24 and 48.
- Subjects with ART change from the first line DTG + 3TC FDC regimen due to abnormal Baseline laboratory or Baseline genotypic resistance data or any other reason at Weeks 24 and 48.
- Details for remaining endpoints will be included in the full RAP

7.2.2. Summary Measure

- Proportion of subjects with plasma HIV-1 RNA < 50 copies c/mL at week 48, regardless of ART regimen (Observed Analysis).
- Proportion of subjects with plasma HIV-1 RNA < 50 copies c/mL at weeks 24 and 48, using the FDA's Snapshot Algorithm.
- Proportion of participants with ART change from Study Treatment DTG + 3TC FDC due to abnormal Baseline laboratory or Baseline genotypic resistance data or any other reason at Weeks 24, and 48.
- Details for remaining summary measures will be included in the full RAP

7.2.3. Population of Interest

The secondary efficacy analyses will be based on the Intent-To-Treat Exposed population, unless otherwise specified.

7.2.4. Strategy for Intercurrent (Post-Randomization) Events

Study discontinuations/deaths prior to an analysis visit (e.g. Week 24, 48) will be penalised in the Observed Analysis. Intercurrent events will be accounted for as per FDA's Snapshot Algorithm for the analysis of plasma HIV-1 RNA <50 copies c/mL. Details for other endpoints will be included in the full RAP.

7.2.5. Statistical Analyses / Methods

Table 2 provides an overview of the planned secondary efficacy analyses, with full details of data displays being presented in Appendix 12: List of Data Displays and will be based on GSK data standards and statistical principles.

Table 2 Overview of Planned Secondary Efficacy Analyses

Endpoints	Absolute							Change from Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L	T	F	L	T	F	F	L
Proportion of Subjects with plasma HIV-1 RNA <50 c/mL – Observed Analysis														
Study Outcomes[1] at Week 48 based on an Observed Analysis				Y			Y[2]							
Percentage of Virologic Success based on an Observed Analysis by visit				Y[3]	Y[4]									
Proportion of Subjects with plasma HIV-1 RNA <50 copies c/mL – Snapshot Algorithm														
Study Outcomes[5] at Week 24 based on Snapshot Algorithm				Y			Y							
Study Outcomes[5] at Week 48 based on Snapshot Algorithm				Y			Y							
Percentage of Virologic Success based on Snapshot Algorithm				Y[3]	Y[4]									
Proportion of Subjects with ART switch														
Switch from Study Treatment due to abnormal Baseline lab or Baseline resistance data or any other reason				Y			Y							
Switch from second (or higher) ART due to any reason							Y							

NOTES :

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

[1] Study outcomes i.e., HIV-1 RNA < 50 c/mL (Virologic Success) or HIV-1 RNA ≥ 50 c/mL (Virologic Failure) based on an Observed Analysis.
[2] Listing of Study Outcomes based on Observed Analysis and Listing of Quantitative and Qualitative Plasma HIV-1 RNA Data.
[3] Report percentage of Virologic Success and 95% CI by visit (numbers to be used in the line plot; see [4]).
[4] Line plots with 95% confidence intervals, for the proportion of subjects with HIV-1 RNA < 50 c/mL (Virologic Success) by visit.
[5] Study outcomes (i.e., HIV-1 RNA < 50 c/mL, HIV-1 RNA ≥ 50 c/mL, No Virologic Data) based on Snapshot algorithm.

Additional details for remaining secondary analyses will be included in the main RAP.

7.2.5.1. Statistical Methodology Specification

Endpoint / Variables

- Proportion of subjects with plasma HIV-1 RNA <50 copies c/mL at Week 48, using an Observed Analysis
- Proportion of subjects with plasma HIV-1 RNA <50 copies c/mL at Weeks 24 and 48, using the Snapshot Algorithm
- Proportion of subjects with change from Study Treatment (i.e. DTG + 3TC FDC) due to abnormal Baseline laboratory or Baseline genotypic resistance data or any other reason at Weeks 24, and 48.
-

Model Specification

- For the proportion of subjects with plasma HIV-1 RNA <50 c/mL at Week 48 using an Observed Analysis, the methodology described in Section 7.1.5.1 will be used.

- **FDA Snapshot Algorithm**
  - Snapshot Algorithm is intended to be primarily a virologic assessment of the endpoint, and as such follows a “virology first” hierarchy.
  - Snapshot algorithm uses the last on-treatment available HIV-1 RNA assessment within the visit of interest analysis window to classify subjects as HIV-1 RNA < 50 c/mL (Virologic Success) or HIV-1 RNA ≥ 50 c/mL (Virologic Failure).
  - All subjects without HIV-1 RNA assessment at the visit of interest (due to missing HIV-1 RNA assessment but on study, or permanent discontinuation of Study Treatment prior to the visit window) are classified as non-successes. The nature of non-success is further classified in Snapshot summaries as either ‘HIV-1 RNA ≥ 50 c/mL’ (Virologic Failure) or ‘No Virologic Data at Week X’ with further sub-classification depending on certain scenarios (see Section 11.1.2 for details).
  - Typically, a subject withdrawn due to Safety reasons (i.e. AE, death, liver chemistry stopping criteria, renal toxicity withdrawal criteria etc.) or for another reason but being suppressed at the time of withdrawal is classified as ‘No Virologic Data at Week X’. Should a subject withdraw for non-Safety related reasons and was not suppressed at the time,

he/she is classified as 'HIV-1 RNA ≥ 50 c/mL' (Virologic Failure).

- Subjects who switch from their Study Treatment prior to the visit of interest window under certain scenarios are classified as 'HIV-1 RNA ≥ 50 c/mL' (Virologic Failure). In this study, given that Study Treatment is a 2-drug regimen (i.e. DTG + 3TC FDC) and there is no background ART, any subject switching from Study Treatment for any reason prior to the visit of interest window will be penalised and will be considered 'HIV-1 RNA ≥ 50 c/mL' (Virologic Failure).
- In general, HIV-1 RNA ≥ 50 c/mL (Virologic Failure) includes subjects who:
  - have HIV-1 RNA ≥ 50 c/mL at the visit of interest window (re-test is considered),
  - discontinued from study for lack of efficacy before the visit of interest window,
  - discontinued from study for other reasons while not < 50 c/mL before the visit of interest window,
  - changed ART

See Section 11.5.3 for further details. Full details of the Snapshot algorithm are given in Section 11.9.

- For the proportion of subjects with change from Study Treatment due to abnormal Baseline laboratory or Baseline genotypic resistance data or due to any other reason, simple raw proportions will be calculated. A list of subjects who switched from Study Treatment to another ART will be created.

Model Results Presentation

Presentation of Observed Analysis results will be similar to that described in Section 7.1.5.1.

For Snapshot Analysis number and percentage of subjects in each outcome category (i.e. HIV-1 RNA < 50 c/mL, HIV-1 RNA ≥ 50 c/mL, No Virologic Data) and in sub-categories (see Section 11.9.) will be reported along with the 95% Confidence Intervals for HIV-1 RNA < 50 c/mL and HIV-1 RNA ≥ 50 c/mL categories.

Subgroup Analyses

Subgroups analyses of Observed and Snapshot Analysis Outcomes will be presented in the main RAP

7.3. Exploratory Efficacy Analyses

Exploratory Efficacy analyses will be described in the main RAP.

8. SAFETY ANALYSES

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

All Safety analyses will be based on period under treatment with DTG + 3TC FDC. In addition, selected safety endpoints will also be analysed including data after participants have ART modifications from DTG + 3TC FDC.

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of Adverse Events (AEs), Serious (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 12: List of Data Displays.

The proportion of participants reporting AEs will be tabulated. The following summaries of AEs will be provided for AEs with onset under treatment with DTG + 3TC FDC (i.e. AEs occurred after DTG + 3TC FDC modification will be excluded) at the analysis time period:

- Incidence and severity of all AEs;
- Incidence and severity of treatment related AEs;
- Incidence and severity of AEs leading to withdrawal; and
- Incidence of SAEs.

In addition, the following summaries of AEs will be provided including those occurring after treatment modification from DTG + 3TC FDC:

- Incidence and severity of all AES;
- Incidence and severity of treatment related AEs;
- Incidence and severity of AEs leading to withdrawal; and
- Incidence of SAEs

Further details for the analyses of AEs will be provided in the main RAP.

8.2. Adverse Events of Special Interest Analyses

A comprehensive list of MedDRA terms based on clinical review will be used to identify each type of event. Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional adverse events of special interest, therefore the list of terms to be used for each event of interest and the specific events of interest will be based on the safety review team (SRT) agreements in place at the time of reporting. The details of the planned displays are provided in Appendix 12: List of Data Displays.

Details of analyses of Adverse Events of Special Interest will be provided in the main RAP.

8.3. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 12: List of Data Displays.

Further details will be provided in the main RAP.

8.4. Other Safety Analyses

The analyses of non-laboratory safety test results including vital signs will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 12: List of Data Displays.

Further details will be provided in the main RAP.

9. OTHER STATISTICAL ANALYSES

9.1. Virology

Details will be provided in the main RAP.

9.2. Health Outcomes

Details will be provided in the main RAP.

10. REFERENCES

- Clopper, C. Pearson, E. S. (1934). The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika. 26: 404–413.

11. APPENDICES

Section	Appendix
RAP Section 5 : Considerations for Data analyses and Data Handling Conventions	
Section 11.1	Appendix 2: Schedule of Activities
Section 11.2	Appendix 3: Assessment Windows
Section 11.3	Appendix 4: Study Phases and Treatment Emergent Flags
Section 11.4	Appendix 5: Data Display Standards & Handling Conventions • Reporting Process • Reporting Standards
Section 11.5	Appendix 6: Derived and Transformed Data
Section 11.6	Appendix 7: Reporting Standards for Missing Data • Premature Withdrawals • Handling of Missing Data and Outliers • Handling of Missing and Partial Dates
Section 11.7	Appendix 8: Values of Potential Clinical Importance
Section 11.8	Appendix 9: Time to Event Details
Section 11.9	Appendix 10: Observed and Snapshot Algorithms
Other RAP Appendices	
Section 11.10	Appendix 11: Abbreviations & Trade Marks
Section 11.11	Appendix 12: List of Data Displays
Section 11.12	Appendix 13: Example Mock Shells for Data Displays

11.1. Appendix 2: Schedule of Activities

11.1.1. Protocol Defined Schedule of Events

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48 [g,h]	52 [h]			

a. The Screening/Day 1 Visit is to assess the participant's appropriateness for the study, confirm the participant has a new diagnosis of HIV-1 infection and is willing to initiate ART on the same day. For those participants referred from another site, Screening/Day 1 must be 14 days or less from the initial diagnosis at the external clinic/testing center.
b. If the participant meets all study inclusion and exclusion criteria, participant will start study treatment (DTG + 3TC FDC) at the end of Screening/Day 1 Visit after all other assessments have been completed.
c. Participants will attend a Week 1 Visit after notification from the sites once the Screening/Day 1 laboratory results become available. Investigators should review the safety labs and assess whether any additional interventions are required (see Section 7.2 Discontinuation and Additional Intervention Criteria in protocol amendment 01).
d. Participants will attend a Week 4 Visit after notification from the sites once the HIV-1 Resistance mutation results become available. Investigators should review the resistance data and assess whether additional interventions are required (see Section 7.2. Discontinuation and Additional Intervention Criteria in protocol amendment 01).
e. At Week 8, if the decrease HIV-1 RNA is less than 2.0 log10 c/mL, a retest should be scheduled 2-4 weeks later, unless plasma HIV-1 RNA is <200 c/mL.
f. At Week 12, participants will require a virologic retest if HIV-1 RNA ≥1000 c/mL.
g. At Week 24 and Week 48 participants will require a virologic retest if HIV-1 RNA ≥50 c/mL. At Week 36, participants will require a virologic retest if HIV-1 RNA ≥200 c/mL.
h. Participants who require a virologic retest at Week 48, must have HIV-1 RNA level re-assessed by a second measurement performed 2-4 weeks later, which will be captured under the Week 52 Visit.
i. An in-clinic Follow-up Visit will be conducted 4 weeks after the last dose of study medication only for participants with the following conditions at the last on-study visit: All ongoing SAEs and non-serious AEs of special interest (as defined in Section 2.3.1 in protocol amendment 01), regardless of attributability. However, the investigator, in consultation with the medical monitor, should follow-up with the participant until the event is resolved, stabilized, otherwise explained, or the participant is lost to follow-up.

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48 [g,h]	52 [h]			
Clinical and Other Assessments												
Informed consent	X											
Inclusion and exclusion criteria	X											Inclusion/exclusion criteria will be fully assessed at the Screening/Day 1 Visit.
Demography	X											Sex at birth and current gender by subject will be collected.
Medical history (includes active substance usage)	X											Full medical history will be conducted prior to initiating study intervention and include assessments of cardiovascular, metabolic (e.g., Type I or II diabetes mellitus), psychiatric (e.g., depression), renal (e.g., nephrolithiasis, nephropathy, renal failure), hepatobiliary disorders (e.g., history of jaundice, icterus, ascites) and bone disorders.
Current Medical Conditions	X											
Symptom Directed Physical Exam	X											Limited physical examination to include blood pressure (recorded in eCRF) for Framingham score assessment. Physical exams should be conducted as part of normal routine clinical care but will not be collected systematically in the eCRF. Abnormalities noted during any exam must be recorded in the eCRF (e.g. in the current medical conditions or AE logs).

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48 [g,h]	52 [h]			
Cardiovascular risk assessment	X											At Diagnosis Visit, assessment for cardiovascular risk will include height, weight, blood pressure, smoking status and history, pertinent medical conditions (e.g., hypertension, diabetes mellitus), and family history of premature cardiovascular disease. Body mass index (BMI) will be calculated within the eCRF.
Vital signs	X	X	X	X	X	X	X	X		X	X	Blood pressure to be measured after resting in a semi-supine position for at least 5 minutes.
Body Weight	X	X	X	X	X	X	X	X		X	X	BMI will be calculated within the eCRF. The same scale should be used at each study visit.
Prior PEP/PREP Therapy	X											Participants who received HIV post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP) in the past are allowed as long as the last PEP/PrEP dose was >6 months from HIV diagnosis or there is documented HIV sero-negativity at least 2 months after the last prophylactic dose and before the date of HIV diagnosis.
HIV risk factors and mode of transmission	X											
CDC Classification for HIV-1 Infection	X											Review the Baseline laboratory results as they become available and record in the eCRF (see Section 10.9 in protocol amendment 01).
HIV associated conditions	X	X	X	X	X	X	X	X		X		

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48 [g,h]	52 [h]			
Suicidality Assessment	X	X	X	X	X	X	X	X	X	X	X	Investigator must assess participant suicidality using their usual clinical practice.
HIV Symptom Distress Module	X		X	X	X	X	X	X		X		Questionnaire/Surveys are recommended to be administered at the beginning of the visit before any other assessments are conducted. See Section 8.9 in protocol amendment 01 for additional information on how this questionnaire should be completed.
Laboratory assessments												
HIV Diagnostic Test	X*											*Participants must have a new and confirmed diagnosis of HIV-1 infection based on the criterion outlined in Section 5.1 (Inclusion Criteria) in protocol amendment 01. HIV Diagnostic test results should be stored in the participant source documents.
Quantitative plasma HIV-1 RNA	X	X	X	X	X	X	X	X	X	X		See Section 7.3 Virologic Failure Criteria in protocol amendment 01 for more information on how to manage suspected and confirmed viral failures. If a subject requires a regimen modification (e.g., based on Baseline labs, a Confirmed Virologic Failure, or an AE), see SoA ART Regimen Modification Section 11.1.2 in protocol amendment 01.
Whole Blood	X					X		X		X*		*Collect sample only if Withdrawal Visit is replacing the Week 24 or Week 48 Visit.
Lymphocyte subset	X		X		X	X	X	X		X		

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48[g,h]	52 [h]			
Plasma for HIV genotyping	X											An additional plasma for HIV genotyping will be included at the time of regimen change in case of Baseline HIV-1 resistance mutations (see Section 11.1.2 in protocol amendment 01).
Plasma for storage	X	X	X	X	X	X	X	X	X	X		Plasma samples for storage will be collected at each visit, including unscheduled visits (e.g. for HIV-1 RNA levels and immunological parameters). Additionally, these samples will be used when needed such as when samples are lost or arrive at the laboratory unevaluable or as a priority need for genotypic and/or phenotypic analyses when participants meet Confirmed Virologic Failure criteria.
Clinical Chemistry	X		X	X	X	X	X	X		X	X	
Hematology	X		X	X	X	X	X	X		X	X	
Lipid Panel	X					X		X				
HBsAg, anti-HBc, anti-HBs, and HBV DNA	X											HBV DNA testing will be performed for participants with positive anti-HBc and negative HBsAg and negative anti-HBs.

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48 [g,h]	52 [h]			
HBV 3TC Resistance and HBV DNA (only for participants with chronic HBV infection)	X	X*	X*									*Testing for HBV 3TC resistance will be performed using samples from Week 1 or Week 4 (depending on when ART modification occurs) as well as Baseline samples. For these participants, HBV DNA will also be obtained at the Week 1 and/or Week 4 visit.
HCV antibody	X											
Rapid plasma reagin (RPR)	X											
Urinalysis	X		X		X	X	X	X		X		A morning specimen is preferred. Reflex microscopic.
Pregnancy test (POCBP only)	S/U	S	S	S	S	S	S	S	S	S		Pregnancy testing will be conducted (participants of childbearing potential only) on serum (S) samples. At Screening/Day 1 Visit (before start of study treatment), a urine (U) test must be used to confirm pregnancy status prior to administration of study treatment. Remind participants of childbearing potential at each study visit of the need to avoid pregnancy and to adhere to the study's contraception requirements.

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48 [g,h]	52 [h]			
FSH	X											A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a postmenopausal state in females at birth not using hormonal contraception or hormonal replacement therapy (HRT).
HLA B5701*												*Testing for HLA B5701 may be required before adding or modifying ART therapy and should be discussed with the Medical Monitor. Please schedule this test using the Unscheduled Q2 requisition.
Study treatment												
IWRS	X				X	X	X					Screening/Day 1 is the day the participant initiates study treatment. At Week 36, an extra bottle of study intervention should be provided so that all participants will have treatment until Week 52 in case a virologic retest is required.
Dispense DTG + 3TC FDC study treatment	X				X	X	X					Participants must return their pill container. Site should remind participants of the importance of adherence. ART may be modified as described in Section 7.Required ART modification assessments are outlined in Section 11.1.2 in protocol amendment 01.
Treatment Adherence		X	X	X	X	X	X	X	X	X		7-day participant recall. All study treatment stop and start dates must be recorded.

Procedures	Screening / Day 1 (Baseline) [a, b]	Intervention Period Weeks								Withdrawal	Follow-up [i]	Comments
		1 [c]	4 [d]	8 [e]	12 [f]	24 [g]	36	48[g,h]	52 [h]			
Adverse Event (AE) review	X	←==========X==========→							X	X	X	Only AEs related to study related events will be collected between obtaining informed consent and initiation of study treatment on Screening/Day 1. After Day 1, all AEs and SAEs will be collected through the Follow-up Visit. See additional information in the SAE Review on Follow-up assessments.
Serious Adverse Event (SAE) review	X	←==========X==========→							X	X	X	Only SAEs related to study participation or to a concomitantly administered ViiV Healthcare/GSK product will be collected between obtaining informed consent and administration of study drug at the Screening/Day 1 Visit. Only Participants with ongoing SAEs and non-serious AEs of special interest (as defined in Section 2.3.1 in protocol amendment 01), regardless of attributability, will attend a Follow-up Visit approximately four weeks after their last dose of study treatment. Assessments at the Follow-up Visit should reflect any ongoing complaints (e.g. blood draws to follow a laboratory abnormality). The investigator, in consultation with the medical monitor, should follow-up with the participant until the event is resolved, stabilized, otherwise explained, or the participant is lost to follow-up
Prior and Concomitant medication review	X	←==========X==========→							X	X	X	Prior medications over the last 4 weeks will be collected at the Screening/Day 1 Visit.

11.1.2. SoA for ART Regimen Modifications

Procedures	ART Regimen Modification [a]	Post-ART Regimen Modification [b]	**Note:** If the ART Regimen Modification Visit or the Post-ART Regimen Modification Visit occurs at a scheduled visit (Section 1.3 in protocol amendment 01), assessments should be completed at the scheduled visit and only the additional assessments in this table should be completed.
a. The ART Regimen Modification visit is used when modifying a participants ART regimen (e.g., based on Baseline labs, a Confirmed Virologic Failure, or an AE) between scheduled visits. b. Four weeks after the ART modification, the participant must return for the Post ART regimen Modification Visit; participants will resume the regular study visit schedule after this visit.			
Clinical and Other Assessments			
Vital signs	X	X	Blood pressure to be measured after resting in a semi-supine position for at least 5 minutes.
Body Weight	X	X	BMI will be calculated within the eCRF. The same scale should be used at each study visit.
Suicidality Assessment	X	X	Investigator must assess participant suicidality using their usual clinical standards.
HIV associated conditions	X	X	
HIV Symptom Distress Module	X	X	Questionnaire/Surveys are recommended to be administered at the beginning of the visit before any other assessments are conducted. See Section 8.9 in protocol amendment 01 for additional information on how this questionnaire should be completed.
Laboratory assessments			
Quantitative plasma HIV-1 RNA	X*	X	*If the ART modification is based on Baseline laboratory results, a HIV-1 RNA sample is not required at the ART Regimen Modification Visit. If the ART Modification Visit is not aligned with a regular study visit and an HIV-1 RNA assessment in the last 4 weeks is not available, a HIV-1 RNA sample should be collected at this visit.
Whole Blood		X	
Lymphocyte subset		X	

Procedures	ART Regimen Modification [a]	Post-ART Regimen Modification [b]	**Note:** If the ART Regimen Modification Visit or the Post-ART Regimen Modification Visit occurs at a scheduled visit (Section 1.3 in protocol amendment 01), assessments should be completed at the scheduled visit and only the additional assessments in this table should be completed.
Plasma for storage	X	X	Plasma samples for storage will be collected (e.g. for HIV-1 RNA levels and immunological parameters). These samples will be used when needed such as when samples are lost or arrive at the laboratory unevaluable or as a priority need for genotypic and/or phenotypic analyses when participants meet Confirmed Virologic Failure criteria.
Clinical Chemistry		X	
Hematology		X	
HBV 3TC Resistance and HBV DNA (only for participants with chronic HBV infection)	X*		* A sample should be taken for HBV 3TC resistance and HBV DNA if the ART modification visit is not at the Week 1 or at the Week 4 study visit, or if a chronic HBV infection is acquired during the study after Baseline.
Urinalysis		X	A morning specimen is preferred. Reflex microscopic.
Pregnancy test (POCBP only)	S	S	Pregnancy testing will be conducted (participants of childbearing potential only) on serum (S) samples. Remind participants of childbearing potential at each study visit of the need to avoid pregnancy and to adhere to the study's contraception requirements.
Study treatment			
Treatment Adherence	X	X	7-day participant recall. All study treatment stop and start dates must be recorded.
Adverse Event (AE) review	X	X	
Serious Adverse Event (SAE) review	X	X	
Concomitant medication review	X	X	

11.2. Appendix 3: Assessment Windows

Laboratory data, health outcomes, vital signs, treatment adherence and genotypic and phenotypic data will be assigned to assessment windows according to actual dates rather than the nominal visit labels as recorded on the eCRF or in the laboratory database. This applies also to data collected during the ART Regimen Modification and Post-ART Regimen Modification Visits for subjects switching from their first line DTG + 3TC FDC regimen.

A window around a target Study Day will typically include all days from the midpoints between it and the target Study Days of the previous and the proceeding visits. In general, the nominal target study day for week w is (7*w)+1.

11.2.1. Definitions of Assessment Windows for Analyses

11.2.1.1. Assessment Windows for all parameters except for treatment adherence

Analysis Set / Domain	Parameter (if applicable)	Target	Analysis Window		Analysis Timepoint
			Beginning Timepoint	Ending Timepoint	
All apart from Treatment Adherence	All apart from Treatment Adherence	-4	≤-14	≤-4	Screening
		1	-3	1	Day 1
		8	2	18	Week 1
		29	19	42	Week 4
		57	43	70	Week 8
		85	71	126	Week 12
		169	127	210	Week 24
		253	211	294	Week 36
		337	295	378	Week 48
		Study Day of last dose[1] + 28	Min(Study Day of last dose +1, 379)	Study day of last assessment in the database (not necessarily a visit)	Follow-up

NOTES:

- For parameters which are not scheduled to be assessed at particular visits, the all-inclusive windows defined will still be used.

[1] Last dose is defined as the last dose of the ART that the subject is on at the Withdrawal Visit or if the subject is not on any ART at the Withdrawal Visit then the last dose of the last ART prior to the Withdrawal Visit (this is not necessarily last dose of DTG + 3TC FDC). It is possible a subject to withdraw from study without having permanently stopped the ART that is currently on (e.g. a female subject who has switched from DTG + 3TC FDC to another ART, then gets pregnant and decides to withdraw from study but, there is no reason to stop the modified ART). In such a case, if there is no last dose then in the definition of Beginning Timepoint for Follow-Up, Study Day of last dose should be considered Infinite for programming purposes.

11.2.1.2. Assessment Windows for treatment adherence

Analysis Set / Domain	Parameter (if applicable)	Target	Analysis Window		Analysis Timepoint
			Beginning Timepoint	Ending Timepoint	
Treatment Adherence	Treatment Adherence	8	2	18	Week 1
		29	19	42	Week 4
		57	43	70	Week 8
		85	71	126	Week 12
		169	127	210	Week 24
		253	211	294	Week 36
		337	295	350	Week 48
		365	351	406	Week 52
		Study Day of last dose[1] + 28	Min(Study Day of last dose +1, 407)	Study day of last assessment in the database (not necessarily a visit)	Follow-up

NOTES:

- For parameters which are not scheduled to be assessed at particular visits, the all-inclusive windows defined will still be used.

[1] Last dose is defined as the last dose of the ART that the subject is on at the Withdrawal Visit or if the subject is not on any ART at the Withdrawal Visit then the last dose of the last ART prior to the Withdrawal Visit (this is not necessarily last dose of DTG + 3TC FDC). It is possible a subject to withdraw from study without having permanently stopped the ART that is currently on (e.g. a female subject who has switched from DTG + 3TC FDC to another ART, then gets pregnant and decides to withdraw from study but, there is no reason to stop the modified ART). In such a case, if there is no last dose then in the definition of Beginning Timepoint for Follow-Up, Study Day of last dose should be considered Infinite for programming purposes.

11.3. Appendix 4: Study Phases and Treatment Emergent Flags

There is only one Period in this study (i.e. Intervention Period) which extends from study treatment (i.e. DTG + 3TC FDC) start date up to Week 52 visit or Withdrawal/Follow-Up. Participants begin on DTG + 3TC FDC on Day 1 and may switch to another ART regimen during the study but will remain on study under different ART until Week 52 visit or Withdrawal/Follow-Up visit. Participants can have their ART modified more than once but are expected to remain on study until Week 52 visit.

For the Tables below the following definitions apply:

- Study Treatment is DTG + 3TC FDC.
- Modified Treatment is any ART other than DTG + 3TC FDC to which participants switch before they complete the study or withdraw (in case a subject withdraws from study). For participants switching more than once, the start date of the first modified ART should be used to define the start of the "On-Modified-Treatment" Phase and the stop date of the last modified ART which started before completing the study or withdrawal (in case the subject withdrew from study), should be used to define the end of the "On-Modified-Treatment" Phase.

11.3.1. Study Phases for Laboratory, HIV Associated Conditions, Vital Signs, Health Outcomes, Treatment Adherence and Genotypic and Phenotypic Data

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date
On-D3-Treatment	Study Treatment Start Date < Date ≤ Study Treatment Stop Date + 1
On-Modified-Treatment	If (Study Treatment Stop Date < Modified Treatment Start Date) then Modified Treatment Start Date < Date ≤ Modified Treatment Stop Date + 1 else if (Study Treatment Stop Date = Modified Treatment Start Date) then Modified Treatment Start Date + 1 < Date ≤ Modified Treatment Stop Date + 1
Post-D3-Treatment	If (Study Treatment Stop Date ≤ Modified Treatment Start Date) then Study Treatment Stop Date + 1 < Date ≤ Modified Treatment Start Date else if (Modified Treatment Start Date does not exist) then Study Treatment Stop Date + 1 < Date
Post-Modified Treatment	Modified Treatment Stop Date + 1 < Date

NOTES:

- See Section 11.5.1 for definition of Modified Treatment Start/Stop Dates.
- Cases where Modified Treatment Start Date < Study Treatment Stop Date will be queried and corrected in the database

11.3.2. Study Phases for Adverse Events

Treatment State	Definition
Pre-Treatment	AE Onset Date < Study Treatment Start Date
On-D3-Treatment	Study Treatment Start Date ≤ AE Onset Date ≤ Study Treatment Stop Date
On-Modified-Treatment	If (Study Treatment Stop Date < Modified Treatment Start Date) then Modified Treatment Start Date ≤ AE Onset Date ≤ Modified Treatment Stop Date else if (Study Treatment Stop Date = Modified Treatment Start Date) then Modified Treatment Start Date < AE Onset Date ≤ Modified Treatment Stop Date
Post-D3-Treatment	If (Study Treatment Stop Date < Modified Treatment Start Date) then Study Treatment Stop Date < AE Onset Date < Modified Treatment Start Date else if (Modified Treatment Start Date does not exist) then Study Treatment Stop Date < AE Onset Date
Post-Modified Treatment	Modified Treatment Stop Date < AE Onset Date
Onset Time Since 1st DTG + 3TC FDC Dose (Days)	If Study Treatment Start Date > AE Onset Date: AE Onset Date – Study Treatment Start Date If Study Treatment Start Date ≤ AE Onset Date: AE Onset Date – Study Treatment Start Date + 1
Onset Time Since 1st Dose of Modified ART	If Start Date of Modified Treatment > AE Onset Date: AE Onset Date – Modified Treatment Start Date If Start Date of Modified Treatment ≤ AE Onset Date: AE Onset Date - Modified Treatment Start Date + 1
Duration (Days)	AE Resolution Date – AE Onset Date + 1
Drug-related	If relationship is marked 'YES' on eCRF

NOTES:

- See Section 11.5.1 for definition of Modified Treatment Start/Stop Dates.
- Cases of missing relationship to Study Treatment or Modified ART in eCRF will be queried and completed.
- Cases where Modified Treatment Start Date < Study Treatment Stop Date will be queried and corrected in the database
- Partial AE Onset and Stop Dates will be imputed as described in Section 11.6.2.1.
- In case of a completely missing AE Onset Date, the AE will be considered to have started "On-D3-Treatment", unless an end date for the AE is provided. If the AE end date is before the Study Treatment Start Date, the AE will be assigned as Pre-treatment, in all other cases (i.e. the AE end date is on "Post-D3-Treatment" or on "On-Modified-Treatment" or on "Post-Modified-Treatment") it will be assigned as "On-D3-Treatment".
- If the Study Treatment Stop Date is missing then any AE with an Onset Date on or after Study Treatment Start Date will be considered to be "On-D3-Treatment", unless there is a Modified Treatment Start Date which is before the AE Onset Date, in which case the AE will be considered to be "On-Modified-Treatment".
- If the AE Onset Date is after Study Treatment Stop Date and before the Modified Treatment Start Date or there is no Modified Treatment Start Date (i.e. no switch), and the AE has been recorded as potentially related to Study Treatment, then it will be classified as "On-D3-Treatment".
- If the AE Onset Date is after Modified Treatment Stop Date (in case switch from DTG + 3TC FDC has occurred) and the AE has been recorded as potentially related to Modified Treatment, then it will be classified as "On-Modified-Treatment".

11.3.2.1. Study Phases for Concomitant Medication

Study Phases for Concomitant Medications will be classified with regards to DTG + 3TC FDC treatment only. Only summaries for medications concomitant to DTG + 3TC FDC treatment will be provided (e.g. no summaries for medications concomitant to modified ART will be provided).

Non-ART Medications

- Prior medications: Those taken i.e., started and stopped before the start date of Study Treatment. Such medications will be flagged as 'Pre D3 Treatment'.

- Concomitant medications: Those taken (i.e., started or continued) at any time between the start date and stop date of Study Treatment, inclusive. Prior medications that were continued during this period are also considered as Concomitant medications. Such medications will be flagged as 'Pre and On D3 Treatment' or 'On D3 Treatment' or 'Pre and On and Post D3 Treatment' or 'On and Post D3 Treatment', according to the scenario which applies (see Table below).

- Post treatment medications: Those started after the stop date of Study Treatment. Concomitant medications that were continued during this period are also considered as post-treatment medications. Such medications will be flagged as 'Post D3 Treatment'.

It will be assumed that medication has been taken on the date in which it is reported as started or stopped. For any medication starting on the same date as Study Treatment, it will be assumed that the medication was taken after the subject started taking Study Treatment.

Duration of episodes of concomitant medication will be calculated as medication stop date – medication start date, so long as the medication is defined as concomitant according to the rules above (and presented below in the scenario matrix). Durations will be left blank if stop date is missing.

ART Medications

ART medications (i.e. ART medications recorded on conART eCRF page) will also be classified as prior, concomitant or post-treatment as described above and in the Table below for non-ART medications, with the following modifications:

- ART starting on study treatment stop date will be considered as only post-treatment and not concomitant. It is possible that after discontinuation of Study Treatment, a subject may immediately (i.e. same day) begin taking another ART. Note, this is different to non-ART medications which are considered concomitant and post-treatment if they start on the Study Treatment stop date.

- ART stopping on Study Treatment start date will only be considered as prior and not concomitant. Note, this is different to non-ART medications which are considered concomitant if they stop on the Study Treatment start date. For this

treatment naïve population, prior ART (for pre/post exposure prophylaxis) is captured in the PEP/PREP history CRF page and no cases of ART stopping on the Study Treatment start date are expected, as such cases violate Inclusion criterion #3 and constitute Important Protocol Deviation. Any prior ART (i.e. ART with start date prior to Study Treatment Start Date) with partial stop date will be considered to have stopped prior to Study Treatment start date.

	Pre-D3-treatment	On-D3-Treatment			Post-D3-Treatment		Prior	Conco-mitant	Post
		Study Treatment Start Date		Study Treatment Stop Date	Study Treatment Stop Date+1				
(a)	x————x						Y	N	N
(b)	x————		————x				Y†	Y	N
(c)	x————		————			————x	Y	Y†	Y
(d)			x————x				N	Y	N
(e)			x————			————x	N	Y	Y
(f)						x————x	N	N	Y
(g)	?————x						Y	N	N
(h)	?————		————x				Y*	Y	N
(i)	?————		————			————x	Y*	Y*	Y
(j)	x————		————			————?	Y	Y**	Y**
(k)			x————			————?	N	Y	Y**
(l)						x————?	N	N	Y
(m)	?————		————			————?	Y***	Y***	Y***
(n)	x————	x					Y	Y	N
(o)	?————	x					Y*	Y	N
(p)		x	————x				N	Y	N
(q)		x	————	x			N	Y	N
(r)				x	—	————x	N	Y	Y
(s)				x	—	————?	N	Y	Y**
(t)					x	————x	N	N	Y
(u)					x	————?	N	N	Y
(v)			x————	—	x		N	Y	Y

x = start/stop date of medication
? = missing start/stop date of medication
* If a medication is stopped during On-D3-treatment or during Post-D3-Treatment and no start date is recorded it will be assumed that the medication was ongoing from the Pre-treatment phase
** If a medication is started Pre-treatment or On-D3-Treatment and no stop date is recorded then usage will be assumed to be ongoing for the remainder of the study
*** If a medication has no start or stop date it will be assumed that the medication was ongoing from the Pre-treatment phase to the Post-D3-Treatment phase
† A medication which started before Study Treatment Start Date and stopped during On-D3-Treatment it will be classified as 'Pre and On D3 Treatment'. A medication which started before Study Treatment Start Date and stopped after Study Treatment Stop Date it will be classified as 'Pre and On and Post D3 Treatment'. Similarly, for other cases.

11.3.3. Treatment Emergent Flag for Laboratory Toxicities

Flag	Definition
Emergent	Emergent refers to graded Laboratory toxicity (based on DAIDS categories; see protocol Section 10.8) developed or increased in intensity post-Baseline

NOTES:

- Graded laboratory toxicities occurring post-Baseline will be compared against Baseline to define whether they are emergent, irrespective of whether they occurred under treatment with DTG + 3TC FDC or any other modified ART. In other words, for subjects switching from DTG + 3TC FDC to another ART no Baseline will be re-defined.
- For laboratory data, there will be no imputation of dates, which are expected to be fully complete and available in SDTM transfers. Any laboratory dates that are partially missing will be queried.

11.4. Appendix 5: Data Display Standards & Handling Conventions

11.4.1. Reporting Process

Software	
The currently supported versions of SAS software and any other statistical reporting software required for the analysis and reporting will be used.	
Reporting Area	
HARP Server	: uk1salx00175
HARP Compound	: arenv/arprod/gsk3515864/mid212355/reporting_effort_number
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 (ADCM/ADAE), the same version of dictionary datasets will be implemented as SDTM.	
Generation of RTF Files	
• RTF files will be generated for all reporting efforts.	

11.4.2. 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
• All data displays (Tables, Figures & Listings) will use the term “Subject” which reflects CDISC and GSK Data Display Standards terminology.
• Subject level listings will not be included in the main body of the GSK Clinical Study Report. All subject level listings will be located in the modular appendices as ICH or non-ICH listings.

Formats
• GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DP’s) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF. • The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP’s.
Planned and Actual Time
• Reporting for tables, figures and formal statistical analyses: • Actual time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.

- The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.

- Reporting for Data Listings:
  - Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  - Unscheduled or unplanned readings will be presented within the subject's listings.

Unscheduled Visits

- Unscheduled visits will be assigned to a study visit using the all-inclusive analysis windows defined in Section 11.2.1
- However, data summaries will only report visits that are planned assessment time points for each parameter (according to the Time and Events table).
- All unscheduled visits will be reported in listings.

Data inclusion in Data Summaries

- Summary Tables and Figures on Study population, Efficacy, Virology, Health Outcomes and Treatment Adherence:
  - will present data up to and within the visit window of interest (i.e. Week 24 for the primary Week 24 analysis and Week 52 for the EOS Week 48 analysis).
  - will not include Post-D3-Treatment or Post-Modified-Treatment data, unless otherwise stated.
- Summary Tables and Figures on Safety AE, lab toxicity and exposure:
  - will present all data available in Database at the time of reporting (e.g. AEs or emergent toxicities occurred after Week 24 visit and included in the Week 24 database will be included in Tables/Figures in Week 24 analysis).
  - will include Post-D3-Treatment and/or Post-Modified-Treatment data, unless otherwise stated
- Summary Tables and Figures on Safety non-AE/lab toxicity/exposure:
  - will present data up to and within the visit window of interest (i.e. Week 24 for the primary Week 24 analysis and Week 52 for the EOS Week 48 analysis)
  - will not include Post-D3-Treatment or Post-Modified-Treatment data, unless otherwise stated
- Listings will report all data, irrespective of planned/unscheduled visits or treatment phase.

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.

11.5. Appendix 6: Derived and Transformed Data

11.5.1. General

Multiple Measurements at One Analysis Time Point

- In case of multiple assessments prior to Study Treatment start the latest pre-dose assessment will be used as Baseline.
- With the exception of Virologic Observed and Snapshot Analyses endpoints, if after window assignment (see Section 11.2.1), there are multiple valid assessments of a parameter within an analysis visit window, then the following hierarchy will be used to determine the value to be used for summary statistics of observed values:
    - the assessment closest to the window target Study Day;
    - if there are multiple assessments equidistant from the target Study Day, then:
        - for continuous parameters the mean of these values will be used; for HIV-1 RNA, the geometric mean will be used as opposed to the arithmetic mean.
        - for categorical parameters the worse assessment will be used.
- Assessments not chosen for use in summary statistics by this algorithm will still appear in the associated listings. Also, such valid assessments will be used when determining values of potential clinical concern, and for any algorithm that has specific rules for which observation to use (e.g., SNAPSHOT or LOCF).
- 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, if any.

Study Treatment, Modified Treatment and Treatment Start/Stop Dates

- Study Treatment refers to DTG + 3TC FDC (i.e. Fixed Dose Combination; single pill).
- Study Treatment start/stop dates are the dates entered onto the IP exposure CRF for when study Treatment started/stopped.
- It is possible for some participants to switch from DTG + 3TC FDC to another ART during study, prior to study completion or withdrawal (i.e. Modified Treatment); the participants will remain on study. The start/stop dates of the Modified Treatment are the dates entered onto the conART CRF for when the modified treatment started/stopped.
- Anything other than DTG + 3TC FDC constitutes Modified Treatment (e.g. an addition of a third drug to DTG + 3TC FDC; initiation of any of DTG, 3TC as single entities etc.)
- For participants switching from DTG + 3TC FDC to another ART, the reason of Study Treatment stop (and hence reason for ART switch) is recorded in the IP exposure and IP discontinuation eCRF pages.
- For the needs of calculating "On-Modified-Treatment" Phase the Modified Treatment Start Date will be the earliest Start Date of any drug other than DTG + 3TC FDC that started before study completion or withdrawal and the Modified Treatment Stop Date will be the maximum Stop Date of any drug other than DTG + 3TC FDC that started before study completion or withdrawal.

Study Day
• Calculated as the number of days from Study Treatment start date: o Ref Date = Missing → Study Day = Missing o Ref Date < Treatment Start Date → Study Day = Ref Date – Study Treatment Start Date o Ref Data ≥ Treatment Start Date → Study Day = Ref Date – Study Treatment Start Date + 1
Baseline
For all endpoints the Baseline value will be the latest pre-study treatment start dose assessment, unless otherwise stated. This is expected to be from the Screening/Day 1 visit. Unless otherwise stated, if Baseline data is missing no imputation will be performed and will be set to missing
Post-Baseline
Post-baseline refers to the combined time periods of "On-D3-Treatment", "Post-D3-Treatment", "On-Modified-Treatment" and "Post-Modified Treatment".

11.5.2. Study Population

Age
• Age, in whole years, will be calculated with respect to the subject's Screening visit where year of birth is collected. • GSK standard IDSL algorithms will be used for calculating age where birth date will be imputed as follows: o Any subject with a missing day and month will have this imputed as '30th June'. o For analysis purposes, if a subject did not fail to meet inclusion criteria #1 (aged 18 years or older), then set any age imputed as <18 by the standard IDSL algorithm to 18. If the subject failed to meet inclusion criteria #1 then the imputed age will not be reset. • Birth date will be presented in listings as 'YYYY'. • Completely missing dates of birth will remain as missing, with no imputation applied. Consequently, the age of the subject will not be calculated and will remain missing.
Framingham Risk Equation
Details will be provided in the Main RAP
Treatment Compliance
Details will be provided in the Main RAP
Cut-off Date for Protocol Deviations
Details will be provided in the Main RAP

Extent of Exposure
• Exposure to DTG + 3TC FDC will be calculated from the IP eCRF pages. Number of days of exposure to study treatment will be calculated based on the formula: *Duration of Exposure in Days = Study Treatment Stop Date – (Study Treatment Start Date) + 1* • For participants having switched from DTG + 3TC FDC to another ART, no total exposure (i.e. exposure to DTG + 3TC FDC plus the regimen they switched to) will be calculated. • Subjects who enrolled in the study but do not have Study Treatment Start Date will be categorised as having zero days of exposure. • For purposes of calculating exposure, missing Study Treatment Stop Date will be imputed as described in Section 11.6.2.1.
Study Accountability
A participant is considered to have completed the study if he/she has completed all study visits up to Week 52 including an HIV-1 RNA retest visit, if needed.

11.5.3. Efficacy

Observed Analysis
• A description of the Observed Analysis has been provided in Section 7.1.5.1 and detailed steps are given in Section 11.9.1 • For each scheduled assessment time, the Observed HIV-1 RNA < 50 c/mL (Observed Virologic Success rate) is defined as: Observed Success Rate = $\frac{\text{Number of participants with HIV-1 RNA <50 c/mL}}{\text{Total number of participants in the analysis population}}$
Snapshot Algorithm
• A description of key aspects of Snapshot Algorithm has been provided in Section 7.2.5.1. • For each scheduled assessment time, the Snapshot HIV-1 RNA < 50 c/mL (Snapshot Virologic Success rate) is defined as: Snapshot Success Rate = $\frac{\text{Number of participants with HIV-1 RNA <50 c/mL}}{\text{Total number of participants in the analysis population}}$ Snapshot Algorithm in this study is used as a secondary analysis for the proportion of participants with HIV-1 RNA < 50 c/mL. Full details of Snapshot Algorithm are provided in Section 11.9.2.
Plasma HIV-1 RNA
• For summaries and analyses which use HIV-1 RNA level as a continuous measure, the logarithm to base 10 of the value will be used. • HIV-1 RNA results may be provided as censored values, such as <40 or >9,999,999 c/mL. For the purposes of summary statistics, such values will be replaced by the next value beyond the limit of detection, e.g., 39 or 10,000,000 c/mL, respectively, for the given examples. Data listings will show the censored values as provided. • Qualitive measures (i.e. “target detected” and “target non-detected”) may also be provided by the

laboratory vendor for values <40 c/ml. When a measurement of plasma HIV-1 RNA is below the limit of quantification (i.e. 40 c/mL) and is qualitatively observable that will be denoted as a "Target Detected" (TD) measure, whereas if it is not qualitatively observable that will be denoted as "Target Not Detected" (TND). Any measurements <40 c/mL characterised as "Target Non-Detected" or "Target Detected" will be captured in the database. A flag to hold TD/TND info should be created in the Snapshot Analysis dataset (i.e. ADSNAP). • Any HIV-1 RNA measurements above 40 c/mL having TD or TND status captured in the Database will be queried.
Suspected Virologic Failure and Confirmed Virologic Failure
Details will be provided in the main RAP
CDC HIV-1 Classification and HIV-associated conditions
Details will be provided in the main RAP

11.5.4. Safety

AE Severity – DAIDS Grading
• The DAIDS grading (VERSION 2.1, March 2017) for severity of clinical adverse events will be performed. • See protocol for DAIDS grading criteria.
[AE'S OF Special Interest]
Details will be provided in the main RAP
Lab Toxicities – DAIDS Grading
Details will be provided in the main RAP
Glomerular Filtration Rate (GFR)
Details will be provided in the main RAP
Hepatitis Status
Details will be provided in the main RAP
BMI
Details will be provided in the main RAP

11.5.5. Viral Genotypic and Phenotypic

Genotype
[Insert as Required]
Details will be provided in the main RAP

Phenotype
[Insert as Required]
Details will be provided in the main RAP

11.5.6. Health Outcomes

Treatment Satisfaction
[Insert as Required]
Details will be provided in the main RAP

11.6. Appendix 7: Reporting Standards for Missing Data

11.6.1. Premature Withdrawals

Element	Reporting Detail
General	• Participant study completion (i.e. as specified in the protocol) was defined as having completed all study visits up to Week 52 including an HIV-1 RNA retest visit, if needed. • Participants will remain on study even if they have their first line DTG + 3TC FDC regimen modified for any reason or have Important Protocol Deviations (e.g. take prohibited medication), or meet CVF criteria, or have AEs/SAEs. • Participants can discontinue from study because of o Participant or Investigator non-compliance o at the discretion of the investigator for safety, behavioural, compliance or administrative reasons o withdrawal consent o lost to follow-up o AEs/SAEs • Withdrawn subjects will not be replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

11.6.2. Handling of Missing Data and Outliers

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o These data will be indicated by the use of a "blank" in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such. • No imputation for missing data or premature discontinuation will be performed and the observed values will be used unless otherwise stated (e.g. see below for LOCF, and Treatment Satisfaction).
Outliers	No participants will be excluded from summaries and/or statistical analyses due to outliers. If needed, a post-hoc sensitivity analysis will be performed having outliers excluded and details of analyses will be described in the Clinical Study Report.
LOCF	In any LOCF dataset, missing values under treatment with DTG + 3TC FDC (i.e. during phase "On-D3-Treatment") will be carried forward from the previous, non-missing available "On-D3-Treatment" assessment. If the Baseline value is missing any missing values until

Element	Reporting Detail
	the first non-missing value will remain missing. For subjects switching from DTG + 3TC FDC to another ART, data from the "On-D3-Treatment" phase will not be carried forward to the "On-Modified-Treatment" phase. Missing values under Modified ART treatment (i.e. during phase "On-Modified-Treatment") will be carried forward from the previous, non-missing available "On-Modified-Treatment" assessment.
Treatment Satisfaction [HIV TSQ]	Details will be provided in the main RAP
Observed Case (OC)	This dataset uses only the data that is available at a particular timepoint, with no imputation for missing values.

11.6.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	Partial dates will be displayed as captured in subject listing displays.
Exposure	• If study treatment stop date is missing, then for the purposes of calculating exposure, it will be imputed using the date of last visit or the recorded date of withdrawal/completion whichever is earlier. • If day is missing in study treatment stop date then the last day of the month will be used, unless this is after the withdrawal/completion date; in this case the earliest of the two dates will be used. • If month is missing in study treatment stop date then the last month of the year will be used, unless this is after the withdrawal/completion date; in this case the earliest of the two dates will be used. • If both day and month are missing then the last day of last month of the year will be used, unless this date is after the withdrawal/completion date; in this case the earliest of the two dates will be used. • Note, Study Treatment (i.e. DTG + 3TC FDC) is recorded on the Study Treatment CRF page.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only year) to be recorded for AE start and end dates; that is, the day or the month may be missing. • Any partial dates will be raised to data management prior to DBF. If the full date cannot be ascertained prior to DBF the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Partial Start Day: First day of the month or first month of the year will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used. ○ Partial Stop Day: Last day of the month or last month of the year will be used, unless this is after the stop date of study treatment or last modified treatment (if such exist), whichever is the latest; in this case the latest of study treatment,

Element	Reporting Detail
	modified treatment stop dates will be used. • Completely missing dates (i.e. no year specified) will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing. • The recorded partial date will be displayed in listings.
Concomitant Medications/ Medical History	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: o If the partial date is a start date, the first day of the month will be used for the day and 'Jan' will be used for the month o If the partial date is a stop date, last day of the month will be used for the day and 'Dec' will be used for the month. o For medications recorded in the eCRF as prior ART, the earlier of this imputed date or the day before Study Treatment start date will be used. • The recorded partial date will be displayed in listings.
Protocol Deviations	• Partial dates for protocol deviations will be imputed using the following rule o the first day of the month will be used for a missing day o if month is missing then it will remain missing • The recorded partial date will be displayed in the PD listings.

11.7. Appendix 8: Values of Potential Clinical Importance

11.7.1. Laboratory Values and Adverse Events

- The DAIDS grading for severity of laboratory toxicities and clinical adverse events is included in the protocol.
- The central laboratory will flag lab parameter toxicities directly in the provided datasets.

11.8. Appendix 9: Time to Event Details

Details will be provided in the main RAP.

11.9. Appendix 10: Observed and Snapshot Algorithms

11.9.1. Observed Analysis

Detailed Observed Analysis Steps

Condition In Conditions below, 'Week X' indicates Week X window, and X stands for 24 (primary analysis) or 48 (secondary analysis) or any other visit of interest (in case of any exploratory analysis)	Response	Reasons
1. If On-D3-Treatment or On-Modified-Treatment VL available during Week X (i.e. Post-D3-Treatment and Post-Modified-Treatment VLs are ignored)		
1.1 Last VL during Week X < 50 c/mL and subjects are On-D3-Treatment	HIV1-RNA < 50	On DTG + 3TC
1.2 Last VL during Week X < 50 c/mL and subjects are On-Modified-Treatment	HIV1-RNA < 50	On Modified ART
1.3 Last VL during Week X ≥ 50 c/mL	HIV1-RNA ≥ 50	Data in window not below threshold
2: If no On-D3-Treatment or On-Modified-Treatment VL available during Week X		
• If subjects still on study (i.e. VL assessment at Week X was missed or only Post-D3-Treatment/Post-Modified-Treatment VL is available at Week X)	HIV1-RNA ≥ 50	Missing data during window but on study
• If subjects withdraw from study before/during Week X due to LFU or withdrawal consent	HIV1-RNA ≥ 50	Disc. study due to LFU/withdrew consent
• If subjects withdraw from study for any other reason	HIV1-RNA ≥ 50	Disc. study for other reasons

11.9.2. Snapshot Algorithm

Detailed Snapshot Algorithm Steps

As the Study Treatment is a 2-drug regimen (i.e. DTG + 3TC FDC), no change in Study Treatment is permitted. In other words, any change from DTG + 3TC FDC, for any reason, will be penalised.

Condition In Conditions below, 'Week X' indicates Week X window, and X stands for 24 (primary analysis) or 48 (secondary analysis) or any other visit of interest (in case of any exploratory analysis)	**Response**	**Reasons**
1: If change in Study Treatment ***prior to*** Week X	HIV1-RNA ≥ 50	Change in ART
2: If change in Study Treatment ***during*** Week X		
• Last On-D3-Treatment VL during Week X prior to/on the date of change ≥ 50 c/mL	HIV1-RNA ≥ 50	Data in window not below threshold
• Last On-D3-Treatment VL during Week X prior to/on the date of change <50 c/mL	HIV1-RNA < 50	
• No VL during Week X prior to/on the date of change	HIV1-RNA ≥ 50	Change in ART
3: If none of the above conditions met		
3.1 VL available during Week X		
• Last On-D3-Treatment VL during Week X ≥ 50 c/mL	HIV1-RNA ≥ 50	Data in window not below threshold
• Last On-D3-Treatment VL during Week X <50 c/mL	HIV1-RNA < 50	
3.2 No VL during Week X		
3.2.1 if subjects still on study (i.e. Study Treatment has not been permanently stopped up to Week X or Study Treatment has been permanently stopped but no Modified Treatment has started)	No virologic data at Week X Window	On study but missing data in window
3.2.2 If subjects withdraw from study before/during Week X due to		
3.2.2.1 Safety reasons (e.g. AE/death, liver chemistry stopping criteria, renal toxicity withdrawal criteria, QTc withdrawal criteria et al, as recorded	No virologic data at Week X Window	Disc due to AE/death

in eCRF Study Conclusion form)		
3.2.2.2 Non-safety related reasons (e.g. Lack of efficacy, protocol deviation, withdrew consent, loss to follow-up, study closed/terminated, investigator discretion et al, as recorded in eCRF Study Conclusion Form)		
• Last On-D3-Treatment VL <50 c/mL OR no On-D3-Treatment available during study	No virologic Data at Week X Window	Disc for other reasons
• Last On-D3-Treatment VL ≥ 50 c/mL AND withdrawal due to Lack of efficacy	HIV1-RNA ≥ 50	Disc. for lack of efficacy
• Last On-D3-Treatment VL ≥ 50 c/mL AND withdrawal due to any other non-safety related reasons	HIV1-RNA ≥ 50	Dis. for other reason while not below threshold

11.10. Appendix 11: Abbreviations & Trade Marks

11.10.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
AIC	Akaike's Information Criteria
A&R	Analysis and Reporting
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DOV	Date of Visit
DP	Decimal Places
eCRF	Electronic Case Record Form
EMA	European Medicines Agency
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
GSK	GlaxoSmithKline
IA	Interim Analysis
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
ITT	Intent-To-Treat
MMRM	Mixed Model Repeated Measures
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
PP	Per Protocol
PopPK	Population PK
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
SAC	Statistical Analysis Complete
SDSP	Study Data Standardization Plan
SDTM	Study Data Tabulation Model
SOP	Standard Operation Procedure
TA	Therapeutic Area

Abbreviation	Description
TFL	Tables, Figures & Listings

11.10.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
Dolutegravir
Lamivudine

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS

11.11. Appendix 12: List of Data Displays

11.11.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.n	1.1 to 1.n
Efficacy	2.1 to 2.n	2.1 to 2.n
Safety	3.1 to 3.n	3.1 to 3.n
Virology	4.1 to 4.n	4.1 to 4.n
Health Outcomes	5.1 to 5.n	5.1 to 5.n
Section	**Listings**	
ICH Listings	1 to x	
Other Listings	y to z	

11.11.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 13: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Virology	VIR_Fn	VIR_Tn	VIT_Ln
Health Outcomes	HO_Fn	HO_Tn	HO_Ln

NOTES:

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

11.11.3. Deliverables

Delivery[1]	Description
Wk24	Week 24 Primary Analysis
WK48	End of Study Week 48 Analysis

NOTES:

1. Indicates reporting effort (i.e. SAC deliverable) for which displays will be generated.

In the following sections where the Delivery column states 'All', this refers to all reporting efforts i.e. Weeks 24 and 48.

11.11.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Delivery**
Subject Disposition					
1.1.	ITT-E	ES1	Summary of Subject Disposition for the Subject Conclusion Record	ICH E3, FDAAA, EudraCT	IA [1], SAC [1]
1.2.	ITT-E	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment	ICH E3	IA [1], SAC [1]
1.3.	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure	Journal Requirements	IA [1], SAC [1]
1.4.	Enrolled	NS1	Summary of Number of Participant by Country and Site ID	EudraCT/Clinical Operations	IA [1], SAC [1]
Protocol Deviation					
1.5.	[Insert]	DV1	Summary of Important Protocol Deviations	ICH E3	IA [1], SAC [1]
Population Analysed					
1.6.	[Insert]	SP1 / SP1A	Summary of Study Populations	IDSL	IA [1], SAC [1]
1.7.	[Insert]	SP2 / SP2A	Summary of Exclusions from the [Per Protocol/Safety/etc] Population	IDSL	IA [1], SAC [1]
Demographic and Baseline Characteristics					
1.8.	[Insert]	DM1 / DM3	Summary of Demographic Characteristics	ICH E3, FDAAA, EudraCT	IA [1], SAC [1]
1.9.	Enrolled	DM11	Summary of Age Ranges	EudraCT	IA [1], SAC [1]
1.10.	[Insert]	DM5	Summary of Race and Racial Combinations	ICH E3, FDA, FDAAA, EudraCT	IA [1], SAC [1]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Delivery**
Prior and Concomitant Medications					
1.11.	[Insert]	MH1 / MH4	Summary of [Current/Past] Medical Conditions	ICH E3	IA [1], SAC [1]
1.12.	[Insert]	CM1	Summary of Concomitant Medications	ICH E3	IA [1], SAC [1]
Exposure and Treatment Compliance					
1.13.	[Insert]	EX1 / EX5	Summary of Exposure to Study Treatment	ICH E3	IA [1], SAC [1]

11.11.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
[Insert Endpoint Category]					
2.1.	ITT-E	EFF_T1	Summary of Study Outcomes (<50 c/mL) at Week 24 – Observed Analysis		WK24
2.2.					
2.3.					
[Insert Endpoint Category]					
2.4.	ITT-E	EFF_T2	Summary of Study Outcomes (<50 c/mL) at Week 24 – Snapshot Analysis		WK24
2.5.					WK24
2.6.					WK48
[Insert Endpoint Category]					
2.7.					
2.8.					
2.9.					

11.11.6. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
[Insert Endpoint Category]					
2.10.	[ITT]				IA [1], SAC [1]
2.11.					
2.12.					
[Insert Endpoint Category]					
2.13.					
2.14.					
2.15.					
[Insert Endpoint Category]					
2.16.					
2.17.					
2.18.					

11.11.7. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.1.	[Safety]	AE1 / AE1CP / AE5A/B	Summary of All Adverse Events by System Organ Class and Preferred Term OR Summary of All Adverse Events by Maximum Grade / Intensity by System Organ Class and Preferred Term	ICH E3	IA [1], SAC [1]
3.2.	[Safety]	AE3	Summary of Common (>=X%) Adverse Events by Overall Frequency	ICH E3	IA [1], SAC [1]
3.3.	[Safety]	AE3	Summary of Common (>=X%) Grade 2-4 Adverse Events by Overall Frequency	ICH E3	IA [1], SAC [1]
3.4.	[Safety]	AE1 / AE1CP / AE3 / OR AE5A/B	Summary All Drug-Related Adverse Events by System Organ Class and Preferred Term/by Overall Frequency OR Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term and Maximum Grade / Intensity	ICH E3	IA [1], SAC [1]
3.5.	[Safety]	AE15	Summary of Common (>=X%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participant and Occurrences)	FDAAA, EudraCT	IA [1], SAC [1]
3.6.	[Safety]	AE3	Summary of Common (>=X%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency	ICH E3	IA [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious and Other Significant Adverse Events					
3.7.	[Safety]	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences)	FDAAA, EudraCT	IA [1], SAC [1]
3.8.	[Safety]	AE1 / AE3	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term /by Overall Frequency	IDSL	IA [1], SAC [1]
Laboratory: Chemistry					
3.9.	[Safety]	LB1	Summary of Chemistry Changes from Baseline	ICH E3	IA [1], SAC [1]
3.10.	[Safety]	LB15/ LB16/ LB17	Summary of Worst Case Chemistry Results [by Maximum Grade Increase] [Relative to Normal Range] [by PCI Criteria] Post-Baseline Relative to Baseline	ICH E3	IA [1], SAC [1]
Laboratory: Hematology					
3.11.	[Safety]	LB1	Summary of Hematology Changes from Baseline	ICH E3	IA [1], SAC [1]
3.12.	[Safety]	LB15/ LB16/ LB17	Summary of Worst Case Hematology Results [by Maximum Grade Increase] [Relative to Normal Range] [by PCI Criteria] Post-Baseline Relative to Baseline	ICH E3	IA [1], SAC [1]
Laboratory: Urinalysis					
3.13.	[Safety]	LB1	Summary of Urine Concentration Changes from Baseline	ICH E3	IA [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.14.	[Safety]	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline	ICH E3	IA [1], SAC [1]
Laboratory: Hepatobiliary (Liver)					
3.15.	[Safety]	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting	IDSL	IA [1], SAC [1]
3.16.	[Safety]	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities	IDSL	IA [1], SAC [1]
ECG					
3.17.	[Safety]	EG1	Summary of ECG Findings	IDSL	IA [1], SAC [1]
3.18.	[Safety]	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category	IDSL	IA [1], SAC [1]
3.19.	[Safety]	EG2	Summary of Change from Baseline in ECG Values by Visit	IDSL	IA [1], SAC [1]
3.20.	[Safety]	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category	IDSL	IA [1], SAC [1]
Vital Signs					
3.21.	[Safety]	VS1	Summary of Change from Baseline in Vital Signs	ICH E3	IA [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.22.	[Safety]	VS3 / VS6 / VS7	Summary of Worst Case Vital Signs Results [by Maximum Grade Increase][Relative to Normal Range][by PCI Criteria] Post-Baseline Relative to Baseline	IDSL	IA [1], SAC [1]

11.11.8. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
3.1.	[Safety]	AE10	Plot of Common (>=X%) Adverse Events and [Relative Risk / Other Statistics]	IDSL	IA [1], SAC [1]
Laboratory					
3.2.	[Safety]	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT	IDSL	IA [1], SAC [1]
3.3.	[Safety]	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin	IDSL	IA [1], SAC [1]
[Insert Endpoint Category]					
3.4.					
3.5.					
3.6.					

11.11.9. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	Screened	ES7	Listing of Reasons for Screen Failure	Journal Guidelines	IA [1], SAC [1]
2.	[Insert]	ES2 / ES3	Listing of Reasons for Study Withdrawal	ICH E3	IA [1], SAC [1]
3.	[Insert]	SD2/SD3	Listing of Reasons for Study Treatment Discontinuation	ICH E3	IA [1], SAC [1]
4.	[Insert]	BL1 / BL2	Listing of Participants for Whom the Treatment Blind was Broken	ICH E3	IA [1], SAC [1]
5.	[Insert]	TA1 / CP_RD1x	Listing of Planned and Actual Treatments	IDSL	IA [1], SAC [1]
Protocol Deviations					
6.	[Insert]	DV2	Listing of Important Protocol Deviations	ICH E3	IA [1], SAC [1]
7.	[Insert]	IE3 / IE4	Listing of Participants with Inclusion/Exclusion Criteria Deviations	ICH E3	IA [1], SAC [1]
Populations Analysed					
8.	[Insert]	SP3/SP3a	Listing of Participants Excluded from Any Population	ICH E3	IA [1], SAC [1]
Demographic and Baseline Characteristics					
9.	[Insert]	DM2 / DM4	Listing of Demographic Characteristics	ICH E3	IA [1], SAC [1]
10.	[Insert]	DM9 / DM10	Listing of Race	ICH E3	IA [1], SAC [1]
Prior and Concomitant Medications					
11.	[Insert]	CP_CM3 / CP_CM4	Listing of Concomitant Medications	IDSL	IA [1], SAC [1]
Exposure and Treatment Compliance					
12.	[Insert]	EX3 / EX4	Listing of Exposure Data	ICH E3	IA [1], SAC [1]
Adverse Events					

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
13.	[Insert]	AE8 / AE8CP / AE9 / AE9CP	Listing of All Adverse Events	ICH E3	IA [1], SAC [1]
14.	[Insert]	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3	IA [1], SAC [1]
15.	[Insert]	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text	IDSL	IA [1], SAC [1]
Serious and Other Significant Adverse Events					
16.	[Insert]	AE8 / AE8CPa / AE9 / AE9CPa	Listing of Fatal Serious Adverse Events	ICH E3	IA [1], SAC [1]
17.	[Insert]	AE8 / AE8CPa / AE9 / AE9CPa	Listing of Non-Fatal Serious Adverse Events	ICH E3	IA [1], SAC [1]
18.	[Insert]	AE14	Listing of Reasons for Considering as a Serious Adverse Event	ICH E3	IA [1], SAC [1]
19.	[Insert]	AE8 / AECP8 / AE9 / AE9CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment	ICH E3	IA [1], SAC [1]
20.	[Insert]	AE8 / AECP8 / AE9 / AE9CP	Listing of Other Significant Adverse Events	ICH E3	IA [1], SAC [1]
Hepatobiliary (Liver)					
21.	[Insert]	MH2	Listing of Medical Conditions for Participants with Liver Stopping Events	IDSL	IA [1], SAC [1]
22.	[Insert]	SU2	Listing of Substance Use for Participants with Liver Stopping Events	IDSL	IA [1], SAC [1]
All Laboratory					
23.	[Insert]	LB5 / LB6	Listing of All Laboratory Data for Participants with Any Value of Potential Clinical Importance/Outside Normal Range	ICH E3	IA [1], SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
24.	[Insert]	LB5 / LB6	Listing of Laboratory Values of Potential Clinical Importance		IA [1], SAC [1]
25.	[Insert]	LB14	Listing of Laboratory Data with Character Results	ICH E3	IA [1], SAC [1]
26.	[Insert]	UR2A/UR2B	Listing of Urinalysis Data for Participants with Any Value of Potential Clinical Importance	ICH E3	IA [1], SAC [1]
ECG					
27.	[Insert]	EG3 / EG4	Listing of All ECG Values for Participants with Any Value of Potential Clinical Importance	IDSL	IA [1], SAC [1]
28.	[Insert]	EG3 / EG4	Listing of ECG Values of Potential Clinical Importance	IDSL	IA [1], SAC [1]
29.	[Insert]	EG5/EG6	Listing of All ECG Findings for Participants with an Abnormal ECG Finding	IDSL	IA [1], SAC [1]
30.	[Insert]	EG5 / EG6	Listing of Abnormal ECG Findings	IDSL	IA [1], SAC [1]
Vital Signs					
31.	[Insert]	VS4 / VS5	Listing of All Vital Signs Data for Participants with Any Value of Potential Clinical Importance	IDSL	IA [1], SAC [1]
32.	[Insert]	VS4 / VS5	Listing of Vital Signs of Potential Clinical Importance	IDSL	IA [1], SAC [1]

11.11.10. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
[Insert Endpoint Category]					
33.	[Insert]				IA [1], SAC [1]
34.					
35.					
[Insert Endpoint Category]					
36.					
37.					
38.					
[Insert Endpoint Category]					
39.					
40.					
41.					

11.12. Appendix 13: Example Mock Shells for Data Displays

Protocol: 212355
Population: Intent to Treat – Exposed

Table EFF_T1
Summary of Study Outcomes (<50 c/mL) at Week 24 – Observed Analysis

Outcome	**DTG + 3TC (N=120)**	**95% CI**
HIV1-RNA <50 c/mL (Virologic Success)	**xx (xx%)**	**xx%, xx%**
On DTG + 3TC	xx (xx%)	xx%, xx%
On Modified ART	xx (xx%)	xx%, xx%
HIV1-RNA >=50 c/mL (Virologic Failure)	**xx (xx%)**	
Data in window not below threshold	xx (xx%)	
Missing data during window but on study	xx (xx%)	
Disc. study due to LFU/withdrew consent	xx (xx%)	
Disc. study for other reasons	xx (xx%)	

Protocol: 212355
Population: Intent to Treat – Exposed

Table EFF_T2
Summary of Study Outcomes (<50 c/mL) at Week 24 – Snapshot Analysis

Outcome	**DTG + 3TC FDC (N=120)**	**95% CI**
HIV1-RNA <50 c/mL (Virologic Success)	**95 (79%)**	**xx%, xx%**
HIV1-RNA >=50 c/mL (Virologic Failure)	**20 (17%)**	**xx%, xx%**
Data in window not below threshold	4 (3%)	
Disc. for lack of efficacy	0	
Disc. for other reason while not below threshold	1 (<1%)	
Change in ART	15 (13%)	
No Virologic Data	**5 (4%)**	
Disc. study due to AE or Death	3 (3%)	
Disc. study for Other Reasons	1 (<1%)	
Missing data during window but on study	1 (<1%)	