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

Title	:	Reporting and Analysis Plan for A Phase IIb, Multicenter, Open-label, Rollover Study Evaluating the Efficacy, Safety and Tolerability of Long-acting Cabotegravir Plus Long-acting Rilpivirine Administered Every Two Months in HIV-1 infected Adults who are Virologically Suppressed and Participated in Study LAI116482
Compound Number	:	GSK1265744
Effective Date	:	31-JAN-2020

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 209035.
- This RAP is intended to describe the efficacy, safety and tolerability analyses required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

RAP Author(s):

Approver	Date	Approval Method
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1. INTRODUCTION

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

Revision Chronology:		
2018N356280_00	16-MAY-2018	Original
2018N356280_01	22-JUN-2018	This amendment was completed to clarify procedures, adjust exclusion criteria, add missing risk assessment language and to clean up minor grammatical errors.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

The following are changes or deviations to the originally planned statistical analysis specified in the 209035 protocol amendment 1 [(Dated: 22/JUN/2018)]:

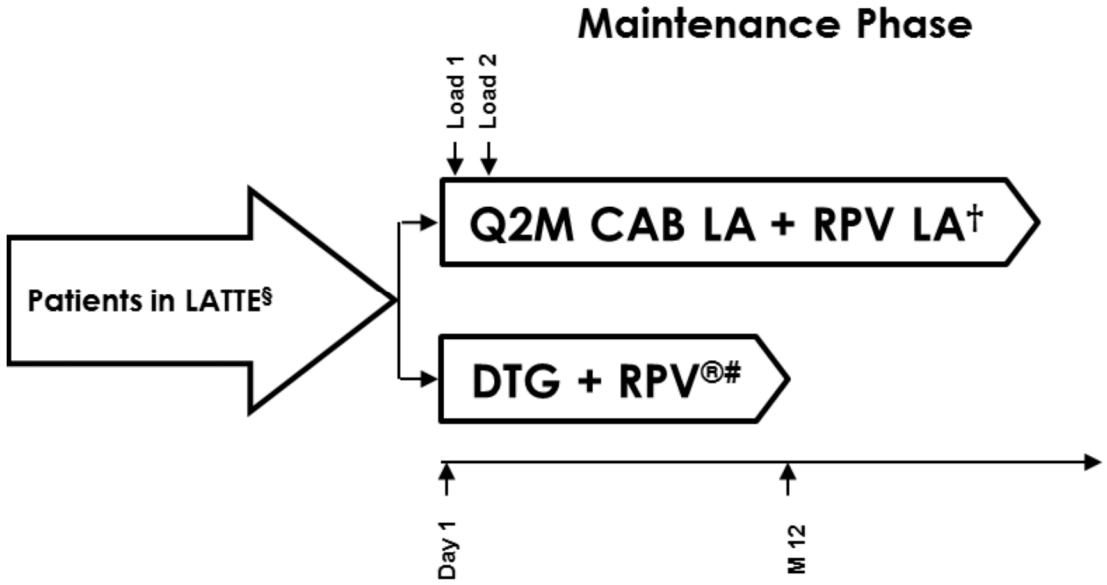
- PK samples would not be analysed and no PK outputs would be produced. Due to the vast amount of PK data available from other studies examining CAB LA + RPV LA PK data, CPMS decided not to evaluate PK data from this study. Additionally, the time points of PK sample collection correspond to peak, rather than trough, concentrations.
- Data from the digital assistance program was not collected due to cost concerns of using Ensemble and will not be analysed.

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

Objectives	**Endpoints**
Primary Objectives	**Primary Endpoints**
• To demonstrate the antiviral activity of CAB LA + RPV LA every 2 months in suppressed HIV-1 infected antiretroviral therapy ART-experienced participants	• Proportion of participants with HIV-RNA ≥ 50 c/mL as per FDA Snapshot algorithm at Month 12
Secondary Objectives	**Secondary Endpoints**
• To demonstrate the antiviral and immunologic activity of CAB LA + RPV LA every 2 months and oral DTG +RPV once daily	• Proportion of participants with plasma HIV-1 RNA <50 c/mL (c/mL) at Month 12 using the FDA Snapshot algorithm • Proportion of participants with protocol-defined confirmed virologic failure (CVF) over time • Proportion of participants with HIV-RNA greater than or equal to 50 c/mL as per FDA Snapshot algorithm over time • Absolute values and changes from Baseline in viral load and CD4+ cell counts over time
• To demonstrate the safety and	• Incidence and severity of AEs and laboratory

Objectives	Endpoints
tolerability of CAB LA + RPV LA every 2 months and oral DTG + RPV once daily	abnormalities over time • Proportion of participants who discontinue treatment due to AEs over time • Change from Baseline in laboratory parameters over time
• To assess viral resistance in participants experiencing protocol-defined confirmed virologic failure	• Incidence of treatment emergent genotypic and phenotypic resistance to CAB, RPV, and DTG + RPV
• To assess participant reported health-related quality of life, treatment satisfaction, injection tolerability, and treatment acceptance.	• Change from Baseline (Day 1) in HIVDQoL at Months 6 and 12 (or Withdrawal) • Change from baseline (Day 1) in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Status Questionnaire (HIVTSQs) at Months 6 and 12 (or Withdrawal) • Change in treatment satisfaction over time using the HIV Treatment Satisfaction Change Questionnaire HIVTSQc at Month 12 (or Withdrawal).
Exploratory Objectives	**Exploratory Endpoints**
• To assess reason for switching using a single question • To assess preference using a single question	• The 'Preference" question will be used to assess preference for CAB LA + RPV LA every 2 months compared to prior oral CAB + RPV regimen, at Month 12 using a single dichotomous preference question. • The "Reason for Switch" question will be administered at Day 1 (Baseline) to assess the reasons for willingness to switch to LA injectable ART or to another oral regimen.

2.3. Study Design

Overview of Study Design and Key Features	
 § All participants in LATTE administered oral CAB 30 mg + RPV 25 mg † Access commercially once Q8W is approved # Access longer term via commercial route. Participants will continue to receive DTG + RPV if located in a region where not commercially available.	
Design Features	The study is a Phase IIb, open-label, 2 arms, multicenter rollover study designed to assess the antiviral activity and safety of CAB LA + RPV LA administered every 2 months in approximately 100 adult HIV-1 infected participants from the LATTE study. Participants who fulfill eligibility requirements will be entered into the study to receive CAB LA + RPV LA Q2M or the oral DTG + RPV regimen for at least 12 months, until commercially available. Any participant who receives at least one dose of CAB LA and/or RPV LA and discontinues the CAB LA + RPV LA regimen for any reason will enter a 52-week LTFU Phase. Those participants must remain on suppressive HAART for at least 52 weeks after the last dose of CAB LA and/or RPV LA.
Dosing	Group 1: First Injections (Loading Doses) – Day 1 and Month 2 Day 1: • Receive last dose of oral CAB + RPV regimen • Receive CAB LA 600 mg given as 1 X 3 mL IM injection • Receive RPV LA 900 mg given as 1 X 3 mL IM injection Month 2: • Receive CAB LA 600 mg given as 1 X 3 mL IM injection • Receive RPV LA 900 mg given as 1 X 3 mL IM injection Maintenance Injections – every 2 months (Q2M) following Month 2 Month 4 to End of Study (two 3 mL injections every 2 months): • Receive CAB LA 600 mg given as 1 X 3 mL IM injection • Receive RPV LA 900 mg given as 1 X 3 mL IM injection

Overview of Study Design and Key Features	
	Group 2: Day 1 to Month 12 (once daily FDC tablet taken with food): • Take one tablet of DTG 50 mg + RPV 25 mg once daily See the protocol Table 2.
Time & Events	Refer to Appendix 2: Schedule of Activities
Treatment Assignment	Participants transitioning from the LATTE study on oral CAB + RPV treatment will transition to their elected treatment regimen, either Q2M administration of CAB LA + RPV LA or oral DTG + RPV single tablet regimen.
Interim Analysis	No Interim Analysis will be conducted.

2.4. Statistical Hypotheses / Statistical Analyses

No statistical hypotheses of treatment comparisons will be conducted within this study.

3. PLANNED ANALYSES

At least one analyses will be conducted to evaluate primary and secondary objectives of the protocol after all subjects have completed their visits at Month 12. Further data cuts and analyses may be conducted as necessary after Month 12 to support regulatory publications. The Month 12 analysis will be primary. Further analyses may be conducted when all subjects on CAB LA + RPV LA have completed their Month 26 visit or when all subjects have completed the study (final End-of-Study analysis).

3.1. Interim Analyses

No Interim Analysis will be conducted.

3.2. Final Analyses

The primary analysis will be conducted to evaluate the primary objective of the study at Month 12. These analyses will be performed after the completion of the following sequential steps:

1. All participants have completed Month 12 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.

A final End-of-Study analysis will be conducted when all subjects have completed the study as defined in the protocol. Additional analysis may be conducted when all subjects on CAB LA + RPV LA have completed their Month 26 visit.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Participants Screened	All participants screened for inclusion in the study. For disposition displays, except for the listing of subjects who were rescreened, only the latest re-screening data will be included. All screening data will be summarized or listed for other displays.	• Study Population
All Participants Enrolled	All participants transitioning from the LATTE study and signed the informed consent form (ICF).	• Study Population
Safety Population	All participants who receive at least one dose of IP on or after Day 1 visit. Participants will be assessed according to actual treatment received.	• Safety
Intent-to-Treat Exposed Population (ITT-E)	All participants who receive at least one dose of IP during on or after Day 1 visit. Participants will be analyzed according to the selected treatment regardless of what treatment was actually received. This population will be used for all summaries unless otherwise specified.	• Study Population • Efficacy

Population	Definition / Criteria	Analyses Evaluated
Per-Protocol Exposed (PP-E)	All participants in the ITT-E Population who comply with the protocol except for major protocol violators. Protocol deviations that would exclude subjects from the PP-E population are defined in Section 4.1 (Protocol Deviations) and Appendix 1 (Protocol Deviation Management and Definition for Per-Protocol Population).	• PP
Confirmed Virologic Failure (CVF)	All participants in the ITT-E population who met Confirmed Virologic Failure (CVF) criteria.	• Virology • Efficacy
Long-tem Follow-up	All subjects receiving at least one dose of CAB LA and/or RPV LA who have discontinued the CAB LA + RPV LA regimen and have at least one Long-term Follow-up phase clinic visit (i.e. have at least one long-term follow-up visit shown in the study database, LTFU month 1, LTFU month 3, etc).	• Safety

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

4.1. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarised and listed.

Important deviations which result in exclusion from the analysis population will also be summarised and listed. (Please refer to Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population).

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan.

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

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

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions			
RandAll NG		Data Displays for Reporting	
Code	Description	Description	Order in TLF
A	CAB LA (600 mg) + RPV LA (900 mg) Q2M	Q2M	1
B	Oral DTG (50mg) + RPV (25mg) daily	DTG + RPV	2

5.2. Baseline Definitions

Baseline information to be collected at Day 1 includes general medical history and current medical conditions. Laboratory and health outcomes assessments will also be assessed. Questionnaire/surveys are recommended to be administered at the beginning of the visit before any other assessments are conducted, in the order specified. For participants who agree to the optional assessment, a whole blood sample for genetic research should be collected at Day 1 (if not already collected during participation in the LATTE study). For all endpoints (except as noted in baseline definitions) the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as baseline. See the protocol Section 8.2 for more details.

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

5.3. Multicentre Studies

Data will be summarized for all centres combined. The primary efficacy endpoint will be summarized by Country. Countries will be combined if the number of participants enrolled is low.

5.4. Examination of Covariates, Other Strata and Subgroups

5.4.1. Covariates and Other Strata

The list of covariates may be used in descriptive summaries. Additional covariates of clinical interest may also be considered.

Category	Details
Strata	None
Covariates	See details in Section 5.4.2

5.4.2. Examination of Subgroups

The following is a list of subgroups that may be used in descriptive summaries. 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 combined.
- Additional covariates of clinical interest may also be considered.

Category	Covariates and / or Subgroups
Demographic and Baseline Characteristic Subgroups	• Age (years): o <35, 35 - <50,≥50 o ≤18, 19 - 64, ≥65 (FDAAA requirement) o 18 - 64, 65 - 84, ≥85 (EMA requirement) • Race: o White, Non-White o Black/African American, Non-Black/African American • Sex at birth: o Female o Male • Country: o Canada o United States • Derived Baseline Centers for Disease Control and Prevention (CDC) category: o Stage I o Stage II o Stage III • Baseline BMI (kg/m^2) o <30 o ≥30
Additional subgroup for common drug-related study drug injection site reaction (ISR) with maximum toxicity grade	For each preferred term of the common drug-related study drug ISR with maximum toxicity grade (pain, induration, nodules and any other study drug ISR with ≥5% subjects in either treatment arm) during the maintenance phase: • Needle Length for Last CAB Injection prior to and including the onset date of the earliest corresponding drug-related CAB ISR with maximum toxicity grade during the maintenance phase: ≤1.5, >1.5 to <2, ≥2 inches • Needle Length for Last RPV Injection prior to and including the onset date of the earliest corresponding drug-related RPV ISR with maximum toxicity grade during the maintenance phase: ≤1.5, >1.5 to <2, ≥2 inches Note: If there is no ISR of interest reported during maintenance

Category	Covariates and / or Subgroups
	phase for a subject, the needle length of last injection during maintenance phase will be used in the summary.

5.5. Multiple Comparisons and Multiplicity

5.5.1. Primary Comparison of Interest

No formal statistical analysis will be performed for this study. The primary endpoint will be summarized based on the ITT-E population.

5.6. 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
12.3	Appendix 3: Assessment Windows
12.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
12.5	Appendix 5: Data Display Standards & Handling Conventions
12.6	Appendix 6: Derived and Transformed Data
12.7	Appendix 7: Reporting Standards for Missing Data
12.8	Appendix 8: Values of Potential Clinical Importance
12.9	Appendix 9: Snapshot Algorithm Details
12.10	Appendix 10: Identification of Adverse Events of Special Interest

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population will be based on the Intent-to-Treat Exposed 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.

Table 1 provides an overview of the planned study population analyses, with details of the planned displays presented in Appendix 12: List of Data Displays.

Table 1 Overview of Planned Study Population Analyses

Display Type	Data Displays Generated	
	Table	Listing
Randomization		
Randomization [1]		Y[2]
Subject Disposition		
Study Populations [3]	Y	
Study Recruitment [3]	Y	Y
Reasons for Screening Failures [3]	Y	Y
Rescreened Subjects [3]		Y
Age Ranges	Y	
Subject Disposition	Y[4][5]	
Reasons for Withdrawal by Visit	Y[4][5]	Y
IP Discontinuation	Y	Y
Important Protocol Deviations	Y	Y
Deviations leading to exclusion from PP	Y	Y
Inclusion and Exclusion Criteria Deviations	Y	Y
Demography and Baseline		
Demographics Characteristics	Y	Y
Race & Racial Combinations [6]	Y	Y
Hepatitis Status	Y	
CDC Classification of HIV infection (2014)	Y	
Distribution of CD4+ Cell Counts at Baseline	Y	
HIV-1 Risk Factors	Y	

Display Type	Data Displays Generated	
	Table	Listing
Medical Conditions, Concomitant Medications & Antiretroviral Therapy		
Medical Conditions (Current/Past) [7]	Y	
Medical Conditions: Sub-conditions (Current/Past) [7,8]	Y	
Concomitant Medications (non-ART)	Y[9]	
Concomitant Antiretroviral Medications During Maintenance Phase		Y
ART Medications Received During LTFU Phase		Y
Lipid Modifying Agents (Baseline and During Maintenance Phase)	Y	
Substance use	Y	
Medical History of Seizure		Y
Other		
Extent of Exposure to IP[10]	Y	
Adherence to Injection Dosing Schedule for CAB/RPV[10]	Y	

NOTES :

- T = Tables, L = Listings, Y = Display Generated,

1. All Participants Enrolled population
2. Listing of planned and actual treatment.
3. All Participants Screened population.
4. Subjects who have not been recorded as either completing or withdrawing from the study will be categorized as "Ongoing at time of the analysis" for summary purposes.
5. Analysis of subject disposition will be performed for each study phase separately, as well as for overall study conclusion.
6. The five high level FDA race categories and designated Asian subcategories will be summarised along with all combinations of high level categories which exist in the data. The nine race categories collected will be summarised along with categories for mixed race. A by-subject listing of race will also be produced.
7. Medical conditions will be coded using the Medical Dictionary for Regulatory Activities (MedDRA).
8. Sub conditions are Cardiovascular, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions and Hepatobiliary
9. Summarised by Ingredient ATC Level 1, Ingredient combinations and Combination term ATC Level 1 (EG Includes single-ingredient medications with multi-ingredient medications labeled according to the sum of their ingredients, e.g., "TYLENOL Cold and Flu" would appear as "CHLORPHENAMINE MALEATE + DEXTROMETHORPHAN HYDROBROMIDE + PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE" under the ATC headings for "Nervous System" and "Respiratory System" (the combination's ATC classifications).)
10. Safety Population

6.2. Prior and Concomitant Medications

Non-ART and/or ART Medications will be classified by categories shown in Table 2. The same medication may be classified by more than one category. For example, if the Non-ART medication was started prior to the Maintenance treatment start date and was stopped at Month 6 while subject was still receiving study treatment, this medication would be considered both 'prior' and 'concomitant during maintenance'.

Table 2 Derived Data for Non-ART Medications/ART Medications

	Definition
Prior	ART Medication Taken ≤ Maintenance Treatment Start Date Non-ART Medication Taken < Maintenance Treatment Start Date
Concomitant during Maintenance	Maintenance Treatment Start Date ≤ Non-ART Medication Taken < LTFU ART Start Date Maintenance Treatment Start Date < ART Medication Taken < LTFU ART Start Date
Received during Long-term Follow-up	For subjects Who received at least one CAB and/or RPV injection and have started LTFU ART: Non-ART/ART Medication Taken ≥ LTFU ART Start Date

NOTES:

- Please refer to Appendix 7: Reporting Standards for Missing Data for handling of missing and partial dates for medications. Use the rules in this table if medication date is completely missing.
- If subjects have missing LFTU ART start date, only the lower bound will be considered in the derivation.

7. EFFICACY ANALYSES

7.1. Primary Efficacy Analyses

No formal statistical analysis will be performed for the primary endpoint of the study.

7.1.1. Endpoint / Variables

Proportion of participants with plasma HIV-1 RNA ≥ 50 copies/mL as per Food and Drug Administration (FDA) Snapshot algorithm at Month 12.

7.1.2. Summary Measure

Number of subjects and percentage of participants with HIV-1 RNA ≥50 c/mL at Month 12 (defined by the US FDA snapshot algorithm) will be provided by treatment group.

7.1.3. Population of Interest

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

7.1.4. Strategy for Intercurrent (Post-treatment selection) Events

As defined by the Snapshot algorithm, HIV-1 RNA ≥ 50 c/mL is determined by the last available HIV-1 RNA measurement while the participant is on treatment within the analysis visit window of interest.

Participants without on-treatment HIV-1 RNA data for the visit of interest and who discontinue treatment for reasons not related to adverse event while having HIV-1 RNA ≥ 50 c/mL at time of discontinuation or who change study treatment not permitted per protocol before the analysis window are classified as having HIV-1 RNA ≥ 50 c/mL.

Full details of the snapshot algorithm are defined in Appendix 9: Snapshot Algorithm 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.

Unless otherwise specified, endpoints / variables defined in Section 7.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.2. Secondary Efficacy Analyses

7.2.1. Endpoint / Variables

The secondary efficacy endpoints for the study are listed below:

- Proportion of participants with plasma HIV-1 RNA <50 c/mL (c/mL) at Month 12 using the FDA Snapshot algorithm
- Proportion of participants with protocol-defined confirmed virologic failure (CVF) over time
- Proportion of participants with HIV-1 RNA ≥ 50 c/mL as per FDA Snapshot algorithm over time
- Absolute values and changes from Baseline in viral load and cluster of differentiation 4 (CD4+) cell counts over time

7.2.2. Summary Measure

Number of subjects and percentage of participants with HIV-1 RNA < 50 c/mL at Month 12 (defined by the US FDA snapshot algorithm) will be presented by treatment group.

Number of subjects and percentage of participants with protocol-defined confirmed virologic failure (CVF) will be presented by treatment group and by visit.

Number of subjects and percentage of participants with HIV-1 RNA ≥ 50 c/mL (defined by the US FDA snapshot algorithm) will be presented by treatment group and by visit.

Descriptive statistics of the absolute values and changes from Baseline in viral load and cluster of differentiation 4 (CD4+) cell counts will be presented by treatment group and by visit.

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-treatment selection) Events

As defined by the snapshot algorithm, participants with last available HIV-1 RNA measurement < 50 c/mL while the participant is on treatment within the analysis visit window of interest are classified as HIV-1 RNA < 50 c/mL.

Participants without on-treatment HIV-1 RNA data for the visit of interest and who discontinue treatment for reasons not related to adverse event while having HIV-1 RNA ≥ 50 c/mL at time of discontinuation or who change study treatment not permitted per protocol before the analysis window are classified as having HIV-1 RNA ≥ 50 c/mL.

7.2.5. 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.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.3. Exploratory Efficacy Analyses

Table 3 provides an overview of the planned exploratory efficacy analyses. 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. The exploratory efficacy analyses will be based on the Intent-to-Treat Exposed population, unless otherwise specified.

Table 3 Overview of Exploratory Efficacy Analyses

Endpoints	Absolute				Change from Baseline			
	Summary		Individual		Summary		Individual	
	T	F	F	L	T	F	F	L
Plasma HIV-1 RNA over time								
By visit	Y[1]		Y[2]	Y[3]	Y[1]			Y[3]
Target Detected vs Target Not Detected by visit [4]	Y			Y[5]				
Confirmed Virologic Failure (CVF)								
CVF overall	Y							
Plasma HIV-1 RNA at time of suspected and confirmed virologic failure	Y							
CD4+ cell counts over time								
Observed[6]	Y				Y			
HIV-1 conditions and disease progression								
HIV Conditions including/excluding Recurrences as recorded in eCRF	Y			Y				
HIV Disease Progressions[7]	Y							

NOTES:

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Summary = Represents TF related to any summaries (i.e. descriptive statistics) of data.
- Individual = Represents FL related to any displays of individual participant's data.

1. Using log10 transformed values.
2. Individual plasma HIV-1 RNA only for participants who are in the category of 'viral load ≥50 c/mL' at Month 12 per Snapshot algorithm or who are CVF participants. The figures will display all HIV-1 RNA values collected.
3. For CVF participant and, participants with viral load ≥ 50 c/mL during the Maintenance Phase.
4. See Section 12.6.3 for definition of "Target Detected" and "Target Not Detected", and for the specification of corresponding summary table.
5. Target Detected" and "Target Not Detected" are included in the listing for plasma HIV-1 RNA by visit.
6. Using available data without imputation for missing values.
7. See Section 12.6.3 for HIV disease progressions.

8. SAFETY ANALYSES

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

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.

8.1.1. Injection Site Reactions

For the summary of Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and by Common ISRs): ISRs will be assigned based on onset date to the most recent planned IM injection visit prior or equal to the AE onset date.

Maximum grade at each visit will be derived as the maximum grade among ISRs assigned to the particular visit, with consideration for whether the summary applies to a particular preferred term (vs. across preferred terms), or drug-related associated to CAB and/or RPV, or stratification by needle length (refer to Section 5.4.2).

Drug-related ISRs (based on investigator discretion) will be attributed to the causal agent (CAB vs. RPV) when this can be determined specifically based the side of injection administration and the side of the reported ISR (as collected in the eCRF). If we are unable to determine the causal agent in those cases where both drugs are given on one side and the ISR is reported non-specifically, then the attribution to a specific causal agent will remain unknown.

Common study drug ISR adverse events are defined by MedDRA preferred terms including injection site pain, injection site induration, injection site nodules and preferred terms of any other ISR with ≥5% participants in the CAB LA + RPV LA arm, coming from study drug injections. The same set of common terms will be applied to 'overall' (CAB and/or RPV), CAB alone, RPV alone.

ISRs will be attributed to the needle length (≤1.5, >1.5 to <2, ≥2 inches) when this can be determined specifically based on the side of injection administration and the side of the reported ISR (as collected in the eCRF). If we are unable to determine the needle length in those events where both drugs are given on one side and their needle lengths are different, then the attribution to a needle length will remain unknown.

8.2. Clinical Laboratory Analyses

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

8.3. Adverse Events of Special Interest Analyses

Adverse events of special interest (AESI) are determined for CAB and/or RPV based on pre-clinical and clinical experience, along with information for the Integrase Inhibitor class of HIV medications and RPV safety profile. Table 4 shows the currently identified AESI, drug(s) of Interest and the reasons for inclusion. 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 AESIs may change at the time of reporting.

A summary by system organ class and preferred term will be provided for each of AESI. For Depression, anxiety and suicidal ideation/behaviour AESI, a summary by system organ class, maximum DAIDS toxicity grade and prior history will be provided. The details of the planned grouping and planned displays are provided in Section 12.10 and Appendix 12: List of Data Displays.

Table 4 Adverse Events of Special Interest

Adverse Events of Special Interest	Drug(s) of Interest	Reason for Inclusion
Hepatic Safety Profile: Assessment of Risk of hepatoxicity	CAB+RPV	Clinical, Class, Regulatory Interest, More prevalent in HIV population
Hypersensitivity Reactions (HSR)	CAB	Class, Regulatory Interest, Occurs in HIV population
Rash	RPV	Class, Regulatory Interest, Occurs in HIV population
Prolongation of the Corrected QT Interval of the ECG in Supratherapeutic Doses	RPV	Non-clinical, Clinical, Regulatory Interest
Suicidal Ideation/Behaviour	CAB+RPV	Clinical, Class, Regulatory Interest, More prevalent in HIV population
Depression	CAB+RPV	Clinical, Class, Regulatory Interest, More prevalent in HIV population
Bipolar Disorder	CAB+RPV	Clinical, Class, Regulatory Interest, More prevalent in HIV population
Psychosis	CAB+RPV	Clinical, Class, Regulatory Interest, More prevalent in HIV population

Adverse Events of Special Interest	Drug(s) of Interest	Reason for Inclusion
Mood Disorders	CAB+RPV	Clinical, Class, Regulatory Interest
Anxiety	CAB+RPV	Clinical, Class, Regulatory Interest
Sleep Disorders	CAB+RPV	Clinical, Class, Regulatory Interest, More prevalent in HIV population
Injection Site Reactions (ISR) from Study Drug Injections [1]	CAB+RPV	Clinical
Seizures and Seizure-like Events	CAB	Clinical, Regulatory Interest
Weight Gain	CAB	Clinical, Class
Rhabdomyolysis	CAB	Clinical, Class
Pancreatitis	CAB	More prevalent in HIV population
Impact on Creatinine	CAB+RPV	Regulatory Interest, Therapeutic Area, More prevalent in HIV population
Safety in Pregnancy	CAB	Regulatory Interest, Class

NOTE:
1. A separate analysis will be performed for ISRs from study drug injections as described in Section 8.1.1.

8.4. Other Safety Analyses

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

ECG values of potential clinical importance are defined as a QTc of > 500 msec or increase from baseline in QTc ≥ 60 msec.

9. HEALTH OUTCOMES ANALYSES

9.1. Endpoint / Variables

- Change from Baseline (Day 1) in HIVDQoL at Months 6 and 12 (or Withdrawal)
- Change from baseline (Day 1) in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Status Questionnaire (HIVTSQs) at Months 6 and 12 (or Withdrawal)

- Change in treatment satisfaction over time using the HIV Treatment Satisfaction Change Questionnaire HIVTSQc at Month 12 (or Withdrawal).
- Preference between injections of LA HIV treatment and daily oral HIV treatment at Month 12. This is an exploratory endpoint.
- Reasons for switching to injectable HIV treatment at Baseline (Day 1). This is an exploratory endpoint.

9.2. Summary Measure

Summary statistics of the above endpoints will be presented by treatment group.

9.3. Population of Interest

The health outcomes outputs will be based on the Intent-to-Treat Exposed population, unless otherwise specified.

9.4. Strategy for Intercurrent (Post-treatment selection) Events

No imputations would be performed for any missing data.

9.5. 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.
Unless otherwise specified, endpoints / variables defined in Section 9.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

10. VIROLOGY

The virology analyses will mainly use genotype and phenotype data based on plasma sample for CVF population, unless otherwise specified. Additional analyses for HIV-1 resistance may be carried out on peripheral blood mononuclear (PBMC) samples collected at Day 1 or Withdrawal.

If pre-treatment genotypic/phenotypic results are available from both the central laboratory and Monogram Biosciences, then Baseline genotype/phenotype will be determined based only upon the data provided by Monogram assays.

Table 5 Overview of Planned Virology Analyses

Endpoints	Absolute			
	Summary		Individual	
	T	F	F	L
Genotypic resistance at time of CVF[1]				
Prevalence of Resistance Mutations	Y[2]			Y
Prevalence of Genotypic Susceptibility	Y			
Phenotypic resistance at time of CVF[1]				
Prevalence of Phenotype	Y[3]			Y

Endpoints	Absolute			
	Summary		Individual	
	T	F	F	L
Fold Change to CAB and RPV	Y			Y[4]
IN, PR/RT Replication Capacity				Y
Other				
Viral load, Genotypic and Phenotypic data for Participants with genotype and/or phenotype data for CVF participants				Y[4]
Net Assessment	Y			

NOTES:

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Summary = Represents TF related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual participant observed raw data.

1. For the CVF as indicated by two consecutive plasma HIV-1 RNA levels ≥200 c/mL after prior suppression to <200 c/mL, the first visit of these two consecutive visits is defined as 'the suspected visit', and the 2nd one is the confirmed visit. Sample used for resistance testing is taken at the suspected visit, and only tested once a participant confirms virological failure at a subsequent visit. If the test fails with the sample at the suspected visit, we will just report it as 'no data'. The sample from the confirmed visit may be used for exploratory analyses.
2. No. and percentage of participants with IN resistance mutations or major mutations in the classes of NNRTI, NRTI, PI, respectively, as defined in Section 12.6.6.
3. Separate outputs by phenotypic susceptibility and by number of drugs to which participants are phenotypic resistant or partial sensitive or sensitive.
4. Fold change to CAB and RPV will be included in the listing for viral load, genotypic and phenotypic data for participants with genotype and/or phenotype data for CVF and non-CVF participants.

11. REFERENCES

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12. APPENDICES

12.1. Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population

12.1.1. Exclusions from Per Protocol Population

Important protocol deviations leading to exclusion from the Per Protocol population are those deviations which may

i. directly impact the efficacy endpoint of HIV-1 RNA; or

ii. lead to permanent discontinuation of IP/withdrawal and hence indirectly impact the efficacy endpoint by causing data to be missing.

The following criteria define the protocol deviations which, if they occur prior to an analysis timepoint of interest (e.g. Month 12), will lead to exclusion of a subject from the Per-Protocol population for that analysis. Potential protocol deviations leading to exclusion from PP population will be reviewed by the study team to confirm that they meet these criteria. A final review will occur before the clinical database has been frozen for analysis.

A subject meeting any of the following criteria will be excluded from the Per Protocol population based on case-by-case clinical determination:

Number	Exclusion Description
01	Participant deviates from any inclusion or exclusion criteria that may significantly affect exposure, response to therapy or participant safety or that are fundamentally inconsistent with the intended study population, as recorded in the Protocol Deviation form in the eCRF based on study team review (where indicated in the PDMP as case-by-case determination).
02	Participant has maintenance phase non-compliance (including IM dosing errors) with investigational product up to an analysis timepoint of interest, meeting one of the following conditions: 1. Month 12 analysis only: • Q2M arm: two or more injection intervals affected by over dosage deviations (e.g. extra injection or excessive volume administered, length of time between injections less than 7 weeks, excluding split doses). 2. ≥10% of total time on-treatment with under dosing deviations. The percentage of total time on-treatment with under dosing deviations will be calculated by (the total number of non-compliant dosing days / the total number of intended exposure days) * 100%. Number of Intended Exposure Days = Date of Last Viral Load – Start Date of Study Treatment + 1, where the last viral load refers to the last on-treatment viral load up to Study Day 360 for Q2M arm and study day of last nominal Month 12 visit for DTG + RPV arm during maintenance phase for Month 12 analysis.

Number	Exclusion Description
	The total number of non-compliant dosing days up to the analysis timepoint visit (or date of IP discontinuation/withdrawal, whichever is earlier), is derived as follows (summing across all instances): • Q2M arm: o Length of time (in days) until next injection from date of dosage deviation (e.g. 2 mL administered instead of 3 mL). o Length of time (in days) in excess beyond 67 days between injections. o Length of time (in days) in excess beyond 67 days from last injection until start of oral bridging post Month 4. o Interrupted days in oral bridging if the oral dose has been interrupted for 3 or more consecutive days and the primary interruption reason is not adverse event or laboratory abnormality (based on the eCRF Exposure forms). 3 days will be assumed if such interrupted days are not available in the database. • DTG + RPV arm: Durations of interruptions for reasons other than treatment-related adverse events or laboratory abnormalities (based on Exposure eCRF forms).
03	Prohibited medications: receiving ART medication other than that prescribed/allowed by the study (excluding permanent changes in ART regimen; such cases will be retained as 'HIV1-RNA ≥50 c/mL' in the per protocol snapshot analysis) or receiving prohibited concomitant medication that would impact exposure or response to therapy with duration and route of administration taken into consideration, as recorded in the Protocol Deviation form in the eCRF based on study team review (where indicated in the PDMP as case-by-case determination).
04	Permanent discontinuation of IP/withdrawal due to a reason of "Protocol Deviation" (as recorded in the eCRF).
05	Other important protocol deviations that exclude Participant from Per protocol population as recorded in the Protocol Deviation form in the eCRF based on study team review (where indicated in the PDMP as case-by-case determination).

12.2. Appendix 2: Schedule of Activities

12.2.1. Protocol Defined Schedule of Events for CAB LA + RPV LA Q2M Administration

Procedures Q2M	Day 1 [a]	Month													WD [l, m]
		2 [o]	4	6	8	10	12	14	16	18	20[b]	22[b]	24	26	
Written Informed Consent	X														
Demography	X														
Eligibility Verification	X														
Physical Exam	X														
Medical History	X														
Center for Disease Control and Prevention (CDC) Classification	X														
Rapid Plasma Reagin (RPR)	X														
Symptom Directed Physical Exam, injection site reaction (ISR) and Medical Assessment [c]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Vital Signs (blood pressure [BP], heart rate [HR]) [d]	X	X	X		X		X		X		X		X		X

Procedures Q2M	Day 1 [a]	Month													WD [l, m]
		2 [o]	4	6	8	10	12	14	16	18	20[b]	22[b]	24	26	
Weight, Height & body mass index (BMI)[e]	X	X	X		X		X		X		X		X		X
HIV Associated Conditions, AE and serious adverse event (SAE) Assessments, Con Meds	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
12-Lead electrocardiogram (ECG) [f]	X						X								X
Clinical Chemistry and Hematology	X	X	X		X		X		X		X		X		X
Pregnancy Testing (U)rine or (S)erum [g]	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U
HIV-1 RNA and sample for storage [h]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CD4+	X	X	X		X		X		X		X		X		X
Urinalysis	X														X

Procedures Q2M	Day 1 [a]	Month													WD [l, m]
		2 [o]	4	6	8	10	12	14	16	18	20[b]	22[b]	24	26	
Fasting Glucose, Cholesterol (Total, high density lipoprotein [HDL] and low density lipoprotein [LDL]) and Triglycerides [i]	X						X						X		X
Prothrombin time (PT)/ partial thromboplastin time (PTT)/international normalized ratio (INR)	X														X
PK Diary (D)ispensation and (R)eview	R														
PK Sample (S)torage [j]	S						S								S
LA Study Intervention Administration [k]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
HIVTSQc							X								X
HIVTSQs	X			X			X								X
HIVDQoL	X			X			X								X
Preference							X								
Reason for Switch	X														

Procedures Q2M	Day 1 [a]	Month												WD [l, m]
		2 [o]	4	6	8	10	12	14	16	18	20[b]	22[b]	24	26	
Participant Visit Reminder Contact	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Participant Contact Detail Confirmation	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

See footnote "b" for continuation of visit schedule after Month 26. Continue until either locally approved and commercially available, the participant no longer derives clinical benefit or meets a protocol-defined reason for discontinuation or until development is terminated.

a. The Day 1 visit will take place during Week 312 (or Week 324 in the event of unavoidable delays) of the LATTE study, the participant's last week on study. LATTE participants eligible for POLAR study dosing will take final dose of CAB 30 mg + RPV 25 mg in the clinic within 2 hours of the Q2M IM regimen. For IM dosing administration loading doses are required. (Day 1=1st loading dose; Month 2=2nd loading dose)
b. Continue this pattern for visits for the remainder of the study. For example, Month 28 will be conducted just like Month 20, Month 30 will be conducted just like Month 22 and so on.
c. Physical exams should be conducted as part of normal routine clinical care but data will not be collected in the electronic case report form (eCRF). Medical assessments include any decisions the study staff must make for participant management.
d. Measure vital signs after about 5 minutes of rest in a semi-supine position.
e. Height collected at Day 1 only.
f. On Day 1, ECGs should be performed in triplicate at least 5 minutes apart and following 5 minutes of rest in a semi-supine position within 1 hour prior to first dose. Also on Day 1, a 2-hour post dose ECG will be performed for all participants. The 2-hour post dose ECG on Day 1 can also be used for the LATTE Week 312 (or Week 324, if needed) visit. ECG evaluations at other visits should be obtained after dosing, preferably 2-4 hours post dosing.
g. A (-) urine pregnancy test is required prior to any injection and as required by medical monitor after a treatment interruption. A (+) urine test should be confirmed with a stat serum test. If (+), participant will need to be withdrawn.
h. Plasma for storage samples are collected for possible future analyses, back-up in cases of loss/damage in transit and geno/pheno analyses for virologic failures.
i. Fast overnight; however, a minimum of a 6 hour fast is acceptable.
j. Take PK samples pre-dose.
k. Q2M Injections are 1 x CAB LA 600 mg IM + 1 x RPV LA 900 mg IM. If possible, injections should be spaced approximately 2 cm from one another and from the site of any previous injection and or any injection site reaction. Bring RPV LA to approximately room temperature prior to injecting. Time and location of injection (right or left) as well as needle length used will be collected in the eCRF. **IM dosing is expected to occur during the month in which the participant's projected visit falls (as according to the Day 1 visit). An additional (+ or -) 7day window from date of projected visit is stipulated for IM dosing. All decisions regarding dose interruption/ resumption must be discussed with the medical monitor in advance.**

l. Or Long-Term Follow Up
m. Follow Up Visit - Conduct ~4 weeks after the last dose of investigational product (IP) if not entering Long-Term Follow Up and only if the participant has ongoing AEs or lab abnormalities at the last on-study visit. May be conducted by telephone.

12.2.2. Protocol Defined Schedule of Events for DTG + RPV Administration

Procedures for DTG+RPV	Day 1 [a]	Month 3	Month 6	Month 9	Month 12	WD [j]	Notes
Written Informed Consent	X						a. The Day 1 visit will take place during Week 312 (or Week 324 in the event of unavoidable delays) of the LATTE study, the participant's last week on study. LATTE participants eligible for POLAR study dosing will take final dose of CAB 30 mg + RPV 25 mg in the clinic. See Section 6.2 of the protocol for dosing administration. b. Physical exams should be conducted as part of normal routine clinical care but data will not be collected in the eCRF. Medical assessments include any decisions the study staff must make for participant management. c. Measure vital signs after about 5 minutes of rest in a semi-supine position. d. Height collected at Day 1 only. e. On Day 1, ECGs should be performed in triplicate at least 5 minutes apart and following 5 minutes of rest in a semi-supine position within 1 hour prior to first dose. Also on Day 1, a 2-hour post dose ECG will be performed for all participants. The 2-hour post dose ECG on Day 1 can also be used for the LATTE Week 312 (or Week 324, if needed) visit. ECG evaluations at other visits should be obtained after dosing, preferably 2-4 hours post dosing. f. Plasma for storage samples are collected for possible future analyses, back-up in cases of loss/damage in transit and geno/pheno analyses for virologic failures. g. A (-) urine pregnancy test is required prior to any administration of drug and as required by medical monitor after a treatment interruption. A (+) urine test should be confirmed with a stat
Demography	X						
Eligibility Verification	X						
Physical Exam	X						
Medical History	X						
CDC Classification	X						
RPR	X						
Symptom Directed Physical Exam and Medical Assessment [b]		X	X	X	X	X	
Vital Signs(BP, HR) [c]	X	X	X	X	X	X	
Weight, Height & BMI [d]	X	X	X	X	X	X	
HIV Associated Conditions, AE and SAE Assessments, Con Meds	X	X	X	X	X	X	

Procedures for DTG+RPV	Day 1 [a]	Month 3	Month 6	Month 9	Month 12	WD [j]	Notes
12-Lead ECG [e]	X				X	X	serum test. If (+), participant will need to be WD. h. Fast overnight; however, a minimum of a 6 hour fast is acceptable. i. DTG 50 mg + RPV 25 mg. Administer daily with food j. Follow Up Visit - Conduct ~4 weeks after the last dose of IP and only if the participant has ongoing AEs or lab abnormalities at the last on-study visit. May be conducted by telephone.
HIV-1 RNA	X	X	X	X	X	X	
CD4+	X	X	X	X	X	X	
Plasma for Storage [f]	X	X	X	X	X	X	
PK Sample for Storage						S	
Clinical Chemistry and Hematology	X	X	X	X	X	X	
Pregnancy Testing [g]	U	U	U	U	U	U	
Urinalysis	X					X	
Fasting: Glucose, Cholesterol (Total, HDL and LDL) and Triglycerides [h]	X					X	
PT/PTT/INR	X					X	
HIVTSQc					X	X	
HIVTSQs	X		X		X	X	
HIVDQoL	X		X		X	X	
Participant Visit Reminder Contact	X	X	X	X	X		
Participant Contact Detail Confirmation	X	X	X	X	X		

Procedures for DTG+RPV	Day 1 [a]	Month 3	Month 6	Month 9	Month 12	WD [j]	Notes
Study Treatment Dispensation [i]	X	X	X	X	X		

12.2.3. Protocol Defined Schedule of Events for Long Term Follow Up

Procedures for Long-Term Follow Up	Month 1 [a]	Month 3	Month 6	Month 9	Month 12	WD	Notes
HIV Associated Conditions, AE and SAE Assessments, Con Meds	X	X	X	X	X	X	Every effort should be made to enter participants into the Long-Term Follow Up if they withdraw from or discontinue the study after receiving at least one dose of CAB LA and / or RPV LA. a. The start of the 52-week follow up period begins the day of the last CAB LA and/or RPV LA dose. b. Women of childbearing potential only. S = Serum c. Fast overnight; however, a minimum of a 6 hour fast is acceptable. d. Women of childbearing potential should continue to receive counselling on the need to use adequate contraception for the entirety of the Long-Term Follow-Up Period. e. Investigators must discuss choice of HAART regimen and timing of initiation with the medical monitor before initiating. This regimen may be supplied regionally by GlaxoSmithKline (GSK) or reimbursement will be provided.
HIV-1 RNA	X	X	X	X	X	X	
CD4+	X	X	X	X	X	X	
Plasma for Storage	X	X	X	X	X	X	
PK Sample for Storage	S	S	S	S	S	S	
Clinical Chemistry and Hematology	X	X	X	X	X	X	
Pregnancy Testing [b]	S	S	S	S	S	S	
Urinalysis	X				X	X	
Fasting: Glucose, Cholesterol (Total, HDL and LDL) and Triglycerides [c]					X	X	
PT/PTT/INR					X	X	

Procedures for Long-Term Follow Up	Month 1 [a]	Month 3	Month 6	Month 9	Month 12	WD	Notes
Contraception Counselling [d]	X	X	X	X	X	X	
HAART Dispensation [e]	X	X	X	X	X	X	

12.3. Appendix 3: Assessment Windows

12.3.1. Definitions of Assessment Windows for Analyses

Laboratory data, vital signs, ECGs, health outcomes assessments, and genotypic/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.

In most cases the window around an assessment will include all dates from the midpoints between the target day and that of the previous and the proceeding visits. In general, the nominal target study day for Month *m* is ((*m*-1)*30)+1 for Q2M and (*m**30)+1 for DTG + RPV.

For parameters which are not scheduled to be assessed at particular visits, the all-inclusive assessment windows will still be used; however, data summaries will only report scheduled visits. Assessments at unscheduled visits will be included for 'any time On-treatment' time points and in data listings, as well any algorithms that make use of additional data (e.g., Snapshot).

Prior to visit slotting, assessments are first assigned to a study phase (maintenance, and Long Term Follow Up) based on the Tables in Section 12.4.1 and treatment state based on Section 12.4.2.

Maintenance phase assessments other than health outcomes are assigned based on Maintenance Phase Study Day, as shown in Table 6, Table 7, Table 8 and Table 9. The analysis visits from Month 2 to Month 12 and so on should be only applied to the assessments that are already assigned to Maintenance phase (on-treatment).

Long-term Follow-up phase assessments are assigned based on the LTFU study day as shown in Table 10. The analysis visits in LTFU should be only applied to the assessments that are already assigned to LTFU phase regardless of treatment state. See Section 12.6.1 for derivation of Maintenance and LTFU Study Day.

12.3.2. Definitions of Assessment Windows for Data Other than Health Outcomes

Table 6 Assessment Windows for Screening and Maintenance Phase Data for CAB LA + RPV LA arm

All Parameters (except for where noted)	Target Study Day	Analysis Window	Analysis Timepoint
	1	Baseline information to be collected at nominal visit Day 1 which is the last available recorded value up to and including the Maintenance treatment start	Baseline

All Parameters (except for where noted)	Target Study Day	Analysis Window	Analysis Timepoint
		date, excluding 2-hour post-dose ECG taken on the Maintenance treatment start date	
	1	Date of first maintenance dose of IP+	Day 1
	31	2 ≤ Study Day ≤ 60	Month 2*
	91	61 ≤ Study Day ≤ 120	Month 4
	151	121 ≤ Study Day ≤ 180	Month 6
	211	181 ≤ Study Day ≤ 240	Month 8
	271	241 ≤ Study Day ≤ 300	Month 10
	331	301 ≤ Study Day ≤ 360	Month 12
	391	361 ≤ Study Day ≤ 420	Month 14
	451	421 ≤ Study Day ≤ 480	Month 16
	511	481 ≤ Study Day ≤ 540	Month 18
	571	541 ≤ Study Day ≤ 600	Month 20
	631	601 ≤ Study Day ≤ 660	Month 22
	691	661 ≤ Study Day ≤ 720	Month 24
	751	721 ≤ Study Day ≤ 780	Month 26
	((*m*-1)*30)+1	(((*m*-1)*30)-29) ≤ Study Day ≤ (((*m*-1)*30)+30)	Month *m*, *m*=28, 30,…
If a participant permanently discontinued study treatment:			
		Date > max (Date of Last Oral Dose of CAB+RPV + 1, Date of Last Injection + 67)	Follow-up#

NOTES:

+ Only non-baseline records from the mentioned assessment window will be assigned to Day 1.

* The second loading injections will be administered 1 month (Month 2 visit, start of the second month of the study) after initial loading dose (CAB LA 600 mg + RPV LA 900 mg), with subsequent injections (CAB LA 600 mg + RPV LA 900 mg) occurring every 2 months thereafter.

Follow-up will be derived only for participants who permanently discontinued study treatment.

Table 7 Assessment Windows for Screening and Maintenance Phase Data for DTG + RPV arm

All Parameters (except for where noted)	Target Study Day	Analysis Window	Analysis Timepoint
	1	Baseline information to be collected at nominal visit Day 1 which is the last available recorded value upto and including the Maintenance treatment start date, excluding 2-hour post-dose	Baseline

All Parameters (except for where noted)	Target Study Day	Analysis Window	Analysis Timepoint
		ECG taken on the Maintenance treatment start date	
	1	Date of first maintenance dose of IP+	Day 1
	91	2 ≤ Study Day ≤ 135	Month 3
	181	136 ≤ Study Day ≤ 225	Month 6
	271	226 ≤ Study Day ≤ 315	Month 9
	361	316 ≤ Study Day ≤ (Study Day of Nominal Month 12 visit)	Month 12
If a participant permanently discontinued study treatment:			
		Date > Date of Last Oral Dose of DTG + 1	Follow-up#

NOTES:
+ Only non-baseline records from the mentioned assessment window will be assigned to Day 1.
# Follow-up will be derived only for participants who permanently discontinued study treatment.

Table 8 Assessment Windows for Summary of Snapshot Data for CAB LA + RPV LA arm— Data assigned to Maintenance Phase Only

Snapshot Analysis Windows (If no on-treatment viral load data in default window, use expanded window)		Analysis Timepoint
Default	**Expanded +45 Day Upper Window[a]**	
Last available recorded value up to and including the date of first Maintenance Phase dose of IP	Last available recorded value up to and including the date of first Maintenance Phase dose of IP	Baseline
2 ≤ Study Day ≤ 60	2 ≤ Study Day ≤ 75	Month 2
61 ≤ Study Day ≤ 120	61 ≤ Study Day ≤ 135	Month 4
121 ≤ Study Day ≤ 180	121 ≤ Study Day ≤ 195	Month 6
181 ≤ Study Day ≤ 240	181 ≤ Study Day ≤ 255	Month 8
241 ≤ Study Day ≤ 300	241 ≤ Study Day ≤ 315	Month 10
285 ≤ Study Day ≤ 375	285 ≤ Study Day ≤ 375	Month 12
361 ≤ Study Day ≤ 420	301 ≤ Study Day ≤ 435	Month 14
421 ≤ Study Day ≤ 480	421 ≤ Study Day ≤ 495	Month 16
421 ≤ Study Day ≤ 540	421 ≤ Study Day ≤ 555	Month 18
541 ≤ Study Day ≤ 600	421 ≤ Study Day ≤ 615	Month 20
601 ≤ Study Day ≤ 660	601 ≤ Study Day ≤ 675	Month 22
661 ≤ Study Day ≤ 720	601 ≤ Study Day ≤ 735	Month 24
721 ≤ Study Day ≤ 780	601 ≤ Study Day ≤ 795	Month 26
(((*m*-1)*30)-29) ≤ Study Day ≤ (((*m*-1)*30)+30)	(((*m*-1)*30)-29) ≤ Study Day ≤ (((*m*-1)*30)+45)	Month *m*, *m*=28, 30,…

NOTES:

- For post-baseline visits (i.e. Month 2 and afterwards), apply Snapshot analysis windows only to viral load data that is on-treatment (per Table 15) within the Maintenance Phase (per Table 13).
- An on-treatment viral load assessment may be assigned to more than one snapshot analysis window, e.g. on-treatment assessment taken on Study Day 300 will be in both Month 10 and Month 12.

a.± 45 Day window is always used at key analysis timepoint of Month 12.

Table 9 Assessment Windows for Summary of Snapshot Data for DTG + RPV arm— Data assigned to Maintenance Phase Only

Snapshot Analysis Windows (If no on-treatment viral load data in default window, use expanded window)		Analysis Timepoint
Default	**Expanded +67 Day Upper Window[a]**	
Last available recorded value up to and including the date of first Maintenance Phase dose of IP	Last available recorded value up to and including the date of first Maintenance Phase dose of IP	Baseline
2 ≤ Study Day ≤ 135	2 ≤ Study Day ≤ 157	Month 3
136 ≤ Study Day ≤ 225	136 ≤ Study Day ≤ 247	Month 6
226 ≤ Study Day ≤ 315	226 ≤ Study Day ≤ 337	Month 9
293 ≤ Study Day ≤ (Study Day of Nominal Month 12 Visit)	293 ≤ Study Day ≤ (Study Day of Nominal Month 12 Visit)	Month 12

NOTES:

- For post-baseline visits (i.e. Month 3 and afterwards), apply Snapshot analysis windows only to viral load data that is on-treatment (per Table 15) within the Maintenance Phase (per Table 13).
- An on-treatment viral load assessment may be assigned to more than one snapshot analysis window, e.g. on-treatment assessment taken on Study Day 300 will be in both Month 9 and Month 12.

a.- 67 Day window is always used at key analysis timepoint of Month 12.

Table 10 Assessment Windows for Summaries of Long-Term Follow Up Phase Data for Subjects Who Received At least One Injection of CAB+RPV and Permanently Discontinued from Study Treatment

Analysis Window	Analysis Timepoint	Target Study Day of Window
1 ≤ LTFU Study Day ≤ 67	LTFU Month 1	30
68 ≤ LTFU Study Day ≤ 135	LTFU Month 3	90
136 ≤ LTFU Study Day ≤ 225	LTFU Month 6	180
226 ≤ LTFU Study Day ≤ 315	LTFU Month 9	270
316 ≤ LTFU Study Day ≤ 405	LTFU Month 12	360
(30*m - 44) ≤ LTFU Study Day≤ (30*m + 45)	LTFU Month *m*, *m* = 15, 18,,…	7*m

NOTES:

An assessment may be slotted to both LTFU and Maintenance Phase

12.3.3. Assessment Window for Study Conclusion

The study conclusion and phase conclusion records in disposition data will be slotted based on Table 6 and Table 7 However, if the discontinuation date is post-treatment (based on Table 15), the record will be slotted to the last on-treatment visit within the same phase rather than follow up.

12.3.4. Assessment Window for Health Outcome Data

12.3.4.1. HIVTSQs, HIVTSQc, HIVDQoL, Preference

HIVTSQs, HIVTSQc, HIVDQoL, and Preference questionnaire assessments will be assigned to analysis visits as follows:

1. Baseline: Like other data, Baseline will be defined as last available recorded value up to and including the date of first Maintenance phase dose of study treatment. Baseline is not applicable for HIVTSQc and Preference assessments
2. Post-Baseline:
    a. if the nominal visit identifier as captured in the source dataset corresponds to a scheduled collection per the Time and Events Schedule (see Section 12.2 and Table 11) and the assessment is collected in the Maintenance Phase (per Table 13), then the nominal visit identifier will be kept as the analysis visit.
    b. if the nominal visit identifier is unscheduled or withdrawal, then the following procedure will be used:
        i. Assign the assessment to a study phase according to Table 13. Proceed to step ii if the assessment is assigned to the Maintenance Phase.
        ii. Identify the 'last nominal visit' with the HO assessment performed prior to the unscheduled/withdrawal visit to be slotted.
        iii. The unscheduled/withdrawal visit will be slotted to the planned nominal visit subsequent to the 'last nominal visit'. If the 'last nominal visits' does not exist (e.g. no records originate from a planned nominal visit), then the unscheduled/withdrawal visit will be slot to the first planned nominal visit after Day 1.

Example 1, for HIVDQoL, the planned nominal visits are Day 1, Month 6 and Month 12. If a participant has the 'last nominal visit' (with HIVDQoL assessment) at Month 6 prior to withdrawal at Month 8, the withdrawal assessment will be slotted to the subsequent planned nominal visit of Month 12.

Example 2, for HIVDQoL, if there is unscheduled visit between Month 6 and Month 12. This unscheduled visit will be slotted to Month 12 per the rule. In this case, there are two assessments with analysis visit equal to Month 12 (i.e. the slotted value and the value at original nominal Month 12 visit). The original nominal value will be selected for summary per the rule below for multiple records—see Section 12.3.5.

Table 11 Planned Nominal Visit of Health Outcome Data

Endpoints	Day 1	Month 6	Month 12
HIVTSQc			X
HIVTSQs	X	X	X
HIVDQoL	X	X	X
Preference *			X

NOTE:
* not collected for DTG+RPV.

12.3.4.2. Reasons for Switch

Reasons for Switch assessments are planned to be taken at nominal Day 1 visit only. The assessments taken within ± 2 weeks window from Maintenance phase treatment start date will be regarded as evaluable. The assessments taken outside this window will be excluded from the summary.

12.3.5. Multiple assessments within an Analysis Window

If after window assignment there are multiple valid assessments of a parameter within the same window, then the following hierarchy will be used to determine the value to be used for summary statistics of observed values:

For data other than health outcome

1. The assessment closest to the window target Study Day;
2. If there are multiple assessments equidistant from the target Study Day, then the mean of these values will be used. For HIV-1 RNA, the geometric mean of the number of copies will be used as opposed to the arithmetic mean.

For Health outcome data,

1. If there are multiple on-treatment assessments assigned to the same analysis visit, the assessment from the planned nominal visit will be used for summary statistics.
2. If there are multiple on-treatment assessments assigned to the same analysis visit and none originates from a planned nominal visit (e.g. two unscheduled/withdrawal nominal visits), then
   a. the assessment closest to the window target Study Day will be used;
   b. if there are multiple assessments equidistant from the target Study Day, then the earliest assessment will be used.

Assessments not chosen for use in summary statistics by this algorithm will still appear in the associated listings. Also, all applicable valid assessments, irrespective of proximity to study day, will be used when categorizing values across visits, such as ‘maximum grade’ or ‘at any time’, and for any algorithm that has specific rules for which observation to use (e.g. snapshot algorithm or CVF identification).

12.4. Appendix 4: Study Phases and Treatment State

12.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to the Treatment Start Date defined in Section 12.6.1.

AEs will be assigned to study phases as defined in Table 12. For example, adverse events on/after start of Maintenance phase IP and prior to start of LTFU ART will be assigned to the Maintenance Phase.

Laboratory data (efficacy, safety and virology), HIV associated Conditions, health outcomes assessments, vital signs, and ECGs will be assigned to study phases as defined as in Table 13. For example, assessments/events occurring after start of Maintenance Phase IP and up to and including start of LTFU ART will be assigned to the Maintenance Phase.

Assessments/events are assigned to study phases sequentially, starting from the top of each table. No study phases will be assigned to medications.

Table 12 Assignment of Study Phases for AEs

Study Phase	Date range
Screening	Date < Maintenance Treatment Start Date
Maintenance	CAB LA + RPV LA:Maintenance Treatment Start Date ≤ Date < LTFU ART Start Date For AEs leading to withdrawal and started on the same date as LTFU ART Start Date, Maintenance Phase, instead of Long-term Follow-up phase, will be assigned. DTG + RPV: Maintenance Treatment Start Date ≤ Date < Date of nominal Month 12 visit

NOTES:

- Date = AE Start date
- If participants have the missing LTFU ART start date, only the lower bound will be considered.
- Maintenance Treatment Start Date: refer to Treatment Start Date in Section 12.6.1

Table 13 Assignment of Study Phases for Lab Assessments (including Virology), ECG, Vital Sign, Health Outcomes, and HIV associated conditions

Study Phase	Date range
Screening	Date ≤ Maintenance Treatment Start Date Note: 2-hour post-dose ECG taken on the Maintenance Treatment Start Date will be excluded.
Maintenance	CAB LA + RPV LA: Maintenance Treatment Start Date < Date ≤ LTFU ART Start Date DTG + RPV: Maintenance Treatment Start Date < Date ≤ Date of nominal Month 12 visit Note: 2-hour post-dose ECG taken on the Maintenance Treatment Start Date will be included.

NOTES:

- Date = start or assessment date
- If participants have the missing LTFU ART start date, only the lower bound will be considered.
- Maintenance Treatment Start Date: refer to Treatment Start Date in Section 12.6.1

Table 14 Assignment to Long-Term Follow-Up Phase

Study Phase	Date range
Long-Term Follow-Up	Date > max(Last IM Injection Date, Last Oral Dose End Date)

NOTES:

- Date = start or assessment date
- For AEs leading to withdrawal and started on the same date as LTFU HAART Start Date, maintenance phase instead of long-term follow-up phase, will be assigned. Refer to Table 12 for details.

Only participants who received at least one CAB and/or RPV injection will enter the long-term follow-up.

Note that the long-term follow-up phase and maintenance phase are not necessarily mutually exclusive and are to be defined with separate phase variables in the datasets. For example, CAB LA + RPV LA subject who has Month 10 injection and withdrawal at Month 12 without receiving Month 12 injection, the "Month 12 withdrawal visit" belongs to both the maintenance phase and long-term follow-up phase.

12.4.2. Treatment State

Within each treatment study phase (i.e. Maintenance and LTFU—based on assignment of study phase described in Section 12.4.1), only those assessments which occur within the ranges shown in Table 15 will be considered 'on-treatment' for the given phase. No treatment states will be assigned to medications.

Table 15 Treatment State within Study Phases

Study Phase[a]	Treatment State	Date Range
Screening	Pre-treatment	All assessments/events within the phase
Maintenance	On-treatment	CAB LA + RPV LA: Date ≤ max (Date of Last Oral Dose of CAB+RPV + 1, Date of Last Injection + 67)
		DTG + RPV: Date ≤ Last Oral Dose Date + 1
	Post-treatment	CAB LA + RPV LA: Date > max (Date of Last Oral Dose of CAB+RPV + 1, Date of Last Injection + 67)
		DTG + RPV: Date > Last Oral Dose Date + 1
Long-Term Follow-up	On-treatment	Date ≤ min(LTFU ART start date, max(Last Injection Date + 67, Last Oral dose Date + 1))
	Post-treatment	Date > min(LTFU ART start date, max(Last Injection Date + 67, Last Oral dose Date + 1))

NOTES:
a. Treatment State is determined after data has been assigned to the study phases as defined in Section 12.4.1
b. Last injection and/or last oral dose of CAB+RPV are only applied to subjects who permanently discontinue from study treatment. The assessments for participants who did not permanently discontinue the study treatment will be considered 'On-treatment'
c. Date = Assessment/Start Date.

12.4.2.1. Treatment States for AE Data

For adverse events, partial AE start date will use imputation as described in Section 12.7.2.1. In the case of a completely missing start date, the event will be considered to have started On-treatment at Maintenance phase unless an end date for the AE is provided which is before start of study treatment at Maintenance phase; in such a case the AE is assigned as Pre-treatment.

Within each treatment study phase, only those AE with onset date within the ranges shown in Table 15 will be considered 'on-treatment' for the given phase. The onset date will be derived based on Table 16.

Table 16 Days since First Dose of Each Study Phase, Days since Phase Start, AE Duration and Relation to Study Treatment

	Definition
Days since First Dose (Days)[a]	AE Start Date – Maintenance Treatment Start Date + 1
Days since Last Dose (Days)[a]	AE Start Date – Date of Last Dose of Study Treatment prior to/on the Start Date of AE + 1
Days since Phase Start	**For AEs in Maintenance Phase:** AE Start Date - Maintenance Treatment Start Date + 1 **For AEs in Long-term Follow-up Phase:** AE Start Date – Date of Last Dose of Study Treatment[b]
Duration (Days)	AE Resolution Date – AE Start Date + 1
Drug-related	If relationship is marked 'YES' on Inform/CRF OR value is missing.

NOTES:

a. Days since First/Last Dose will only be derived for AEs assigned to maintenance phase and long-term follow-up phase.

b. Date of Last Dose of Study Treatment = max (Last IM Injection Date, Last Oral Bridging End Date), only applicable to participants who permanently discontinued study treatment.

12.5. Appendix 5: Data Display Standards & Handling Conventions

12.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: us1salx00259
HARP Compound	: \ARPROD\GSK1265744\mid209035
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 for conversion from SI to SDTM.	
Generation of RTF Files	
• RTF files will be generated for every reporting effort described in the RAP.	

12.5.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics

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:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the subject's listings.

Unscheduled Visits	
Unscheduled visits will be assigned to a study visit using the all-inclusive windows defined in Section 12.3. However, data summaries will only report visits that are planned assessment time points for each parameter (according to the Time and Events table). Assessments at unscheduled visits will be included for 'any time On-treatment' planned assessment time points and in data listings, as well any algorithms that make use of additional data (e.g., Snapshot).	
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.	

12.6. Appendix 6: Derived and Transformed Data

12.6.1. General

Multiple Measurements at One Time Point
• If after window assignment there are multiple valid assessments of a parameter within the same window, refer to Section 12.3.5 for determination of the value to be used for summary statistics of observed values. Assessments not chosen for use in summary statistics will still appear in the associated listings. Also, all applicable valid assessments irrespective of proximity to the target study day, will be used when categorizing values across visits, such as 'maximum grade' or 'at any time', and for any algorithm that has specific rules for which observation to use (e.g. snapshot algorithm or CVF identification).
Treatment Start Date
Treatment start date is defined for the Maintenance Phase as follows: • For subjects who were on CAB LA + RPV LA, this is the date of the first injection dose entered onto the IP exposure eCRF form. • For subjects who were on oral DTG + RPV, this is the date of the first oral dose entered onto the IP exposure eCRF form. For the long-term follow-up phase (only for CAB LA + RPV LA arm): • If a participant is still on study treatment, or permanently discontinued the study treatment and did not have any previous injections, treatment start date is missing. • If a participant permanently discontinued the study treatment and had at least one injection, treatment start date is the date of first HAART treatment after the last dose of study treatment (oral or injection).
Study Day

The Study Day of an event (e.g., lab assessment, vital sign, ECG, start date of AE or HIV associated condition) will be derived as the number of days between the date of the event and the start date of study treatment on Maintenance phase as follows:
 	
if date of event ≥ start date of study treatment, then
 	
• Study Day = Date of Event – Start Date of Maintenance Phase IP + 1
 	
if date of event < start date of study treatment, then
 	
• Study Day = Date of Event – Start Date of Maintenance Phase IP
 	
Note that the start date of study treatment on Maintenance phase is considered to be on Study Day 1 and the day before this is Study Day -1; i.e., there is no Study Day 0.

Long-Term Follow Up Study Day
The Long-Term Follow Up (LTFU) Study Day of an event (e.g., lab assessment, start date of AE or HIV associated condition) will be derived as the number of days between the date of the event and the end of IP treatment [i.e max (Last IM Injection Date, Last Oral Bridging End Date)]as follows: If the onset of event falls in Long-term Follow up phase, then • LTFU Study Day = date of event – end date of IP
Change from Baseline
Post-Dose Visit Value – Baseline • Unless otherwise specified, the baseline definitions specified in Section 5.2 will be used for derivations for endpoints / parameters.

12.6.2. Study Population

Demographics and Baseline Characteristics
Age
• Age, in whole years, will be calculated with respect to the subject's Baseline visit. • GSK standard IDSL algorithms will be used for calculating age where birth date will be imputed as follows: ○ Any subject with a missing date and month will have this imputed as '30th June'. • 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.
Body Mass Index (BMI)
• Calculated as Weight (kg) / Height $(m)^2$
Hepatitis Status
• Hepatitis C status will be determined using antibody and/or hepatitis C virus (HCV) RNA assessments performed during screening or during the conduct of the study. • If both antibody and virus RNA assessments are available, then the latter will take precedence and positive/negative status will be based on whether HCV RNA is detectable (i.e., ≥ limit of quantification) or not. • A participant will be considered positive for hepatitis B virus (HBV) if they have a positive surface antigen or detectable HBV DNA result. "HBV DNA DETECTED" in the lab comment takes precedence over HBV DNA test result for positive hepatitis B status, for example, if a participant has HBV test result below level of detection, however, the lab comment shows that HBV DNA detected, this participant will be considered positive for hepatitis B. If HBV DNA result is available, it will be used to qualify hepatitis B status as positive or negative (positive if ≥ limit of quantification); otherwise Hepatitis B status will be determined using the surface antigen result. • Hepatitis status at entry will be based on the assessments prior to/on the start of the study treatment.

Demographics and Baseline Characteristics

Lipid-modifying Agents

- The following ATC codes correspond to lipid-modifying agents:
  - ATC Level 2: C10
  - ATC Level 3: C10A, C10B (if Level 2 is not available)
  - ATC Level 4: C10AA, C10AB, C10AC, C10AD, C10AX, C10BA, C10BX (if level 2, 3 are not available)
- Participants are considered to have used a lipid-modifying agent at baseline if they are taking the medication at the time of their baseline fasting lipid testing date.
- Participants are also considered to have used a lipid-modifying agent at baseline if they stopped their lipid modifying medication within 12 weeks prior to their baseline fasting lipid testing date.

Extent of Exposure

Exposure to CAB LA +RPV LA injection and to DTG + RPV oral will be calculated from the IP eCRF pages.

CAB LA + RPV LA:

- Exposure = Number of IP injections received during Maintenance Phase.
- Overall exposure to IP = min(Date of Latest Maintenance Phase visit, max(Date of Last Injection + 67, Date of Last Dose of Oral CAB+RPV)) – Date of First Study Injection + 1
  Note: Last Injection and/or Last Dose of Oral CAB+RPV are only applicable to those who permanently discontinued study treatment.

DTG + RPV:

- Exposure = IP Stop Date – IP Start Date + 1
- Overall exposure to IP = min(Date of Latest Maintenance Phase visit, Date of Last Dose of DTG + RPV) – Date of First Dose + 1
- There will be no adjustments to the exposure duration for any missed doses.

Duration of dosing in subject years will be calculated as the sum of subject duration of dosing in days (across all subjects)/365.25.

Subjects who were enrolled but did not report an IP start date will be categorised as having zero days of exposure.

For DTG + RPV arm, missing IP discontinuation date will be imputed, for purposes of calculating exposure, as the date of last visit or the recorded date of withdrawal/completion, whichever is earlier.

Adherence to CAB LA + RPV LA Injection Schedule

Timeliness of Injections relative to Date of Projected Dosing Visits is assessed by using "actual injection visit date - projected visit date from first injection". The injections of interest in adherence analysis are those after first injection. Each injection visit is counted only once. Individual CAB and RPV injections administered at the same visit are not counted twice. "Extra" unscheduled injections are excluded from all derivations. For example, if during a scheduled visit a participant receives 1 ml

of injection instead of 3 ml due to a dosing error, but this participant returns one week later for the remaining 2 ml injection, then the additional visit is excluded. If a participant receives an extra injection at an unscheduled visit by mistake, this visit will also be excluded.
The planned interval is 60 days for the CAB LA + RPV LA arm. Relative days between two planned consecutive visits for injections relative to the planned interval will be calculated as below:

Relative Days=Actual number of days between adjacent injections – 60.

For example, if the time interval between two scheduled consecutive visits for injections is 55 days then relative days = 55 – 60 = -5; if the interval is 60 days then relative days = 65 – 60 = 5
The relative days will be grouped as below:

< -14 days
-14 to - 8 days
-7 to - 4 days
-3 to -2 days
-1 day
0 days
1 day
2 to 3 days
4 to 7 days
8 to 14 days
>14 days
Missed Injection without Oral Bridging
Missed Injection with Oral Bridging

In the case that a scheduled injection visit is missed, the time interval between the preceding and the subsequent scheduled injection will be calculated. For example, if Month 8 injection is missed, then the number of days between the actual Month 6 and Month 10 injections will be calculated.
To calculate the proportion of injection intervals for each of the above category of relative days, the denominator is the total count of time intervals between adjacent injection visits for CAB LA + RPV LA arm.

12.6.3. Efficacy

Snapshot

- The Snapshot algorithm is intended to be primarily a virologic assessment of the endpoint, and as such follows a “virology first” hierarchy.
- ‘HIV-1 RNA <50 c/mL’ or ‘HIV-1 RNA ≥50 c/mL’ within an analysis window (see Table 8 and Table 9) is typically determined by the last available HIV-1 RNA measurement in that window while the subject is On-treatment in the Maintenance Phase (as assigned based on Section 12.4.1).
- When no HIV-1 RNA data is available within a window, a subject cannot be assigned to the

category of 'HIV-1 RNA < 50 c/mL'. Depending on the reason for lack of data, the subject will be classified as a 'HIV-1 RNA≥50' or reported as 'No Virologic Data at Month X'; in the latter case, the algorithm further classifies the nature of the missing data. Typically, a subject withdrawn (i) due to AE or, (ii) for another reason yet was suppressed at the time, will be counted as 'No Virologic Data at Month X'. Should a subject withdraw for reasons other than AE and was not suppressed at the time, they will be categorized as 'HIV-1 RNA≥50'.

- Full details of the algorithm, including the handling of special cases, are included in Section 12.9
- For each scheduled assessment time, the Snapshot response rate for a given threshold (e.g., <50 c/mL) is defined as:

$$\text{Snapshot Response Rate} = \frac{\text{Number of responders in that analysis window}}{\text{Number of subjects in the analysis population}}$$

- For each scheduled assessment time, the Snapshot 'HIV-1 RNA≥50'rate for a given threshold (e.g., ≥50 c/mL) is defined as:

$$\text{Snapshot VF Rate} = \frac{\text{Number of VFs in that analysis window}}{\text{Number of subjects in the analysis population}}$$

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.

Target Detected / Target Non Detected/Super low viral load testing

- 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" measure, while HIV-1 RNA below the limit of quantification that is not qualitatively observable that will be denoted as "Target Not Detected". Any measurements <40 c/mL characterised as "Target Non Detected" or "Target Detected" will be captured in the database.
- Super low viral load will also be tested by BioMNTR lab for Viral loads below the limit of quantification at some visits (e.g. Month 12)

Confirmed Virologic Failure (CVF)

- The definition of CVF is provided in the Protocol, Section 7.1.4 – Definition of Protocol-Defined Confirmed Virologic Failure
- In case there are multiple plasma HIV-1 RNA results on the same day, the worst result (i.e. the largest value) will be used in determination of CVF.

Summary for Participants per Viral Load Category by Visit

- Summary will be based on observed available data, with no imputation for missing values. The proportion of participants in each viral load category will be calculated using the denominator and numerator specified below:
    - Denominator: Number of participants with on-treatment viral load within the snapshot visit window.
    - Numerator: Number of participants with plasma HIV-1 RNA in the specified category based on the last on-treatment viral load assessment collected within the snapshot visit window.

HIV-1 Disease progression Stage

- Categories:
    - CDC Stage I at Maintenance Baseline to CDC Stage III;
    - CDC Stage II at Maintenance Baseline to CDC Stage III;
    - CDC Stage III at Maintenance Baseline to new CDC Stage III event and
    - CDC Stage I, II, III at Maintenance Baseline to death.

Please refer to Protocol (Appendix 8: CDC Classification for HIV-1 Infection (2014)) for defining Stage.

- For the purpose of analysis, the CDC at Baseline and at post-baseline during Maintenance phase will be derived as below:
    - At Baseline, the 'Baseline CDC stage' for each subject was assessed by the investigator and recorded in the eCRF. However, for the analysis, Maintenance Baseline CDC stage will be re-derived based on Maintenance Baseline CD4+ values as well as whether any HIV-associated conditions present at Baseline per the Criteria's thresholds (Appendix 8 in Protocol).
    - To analyse disease progression, the most advanced post-baseline CDC stage within the period of interest (e.g. Maintenance Phase) will be derived based on the occurrences of new AIDS-defining conditions (please refer to Appendix 8 in Protocol for the list of AIDs-defining Conditions) as well as the nadir value of Maintenance CD4+. For example,
        - If a subject with CDC 'Stage I' at Maintenance Baseline had the lowest Maintenance Phase $CD4^+$ =120 cell/mm^3 without new AIDs-defining conditions, then HIV disease progression for this subject during the Maintenance phase would be considered as 'CDC stage I at Baseline to CDC stage III'.
        - If a subject with CDC 'Stage II' at Baseline had the lowest Maintenance Phase $CD4^+$ =220 cell/mm^3 AND had at least one new AIDs-defining condition, then HIV disease progression for this subject during the Maintenance Phase would be considered as 'CDC stage II at Baseline to CDC stage III'.

12.6.4. Safety

Adverse Events

DAIDS Grading

- Clinical adverse events will be graded based on the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.1, March 2017, as specified in the protocol Appendix 2.

Potential QTc Interval Prolonging Events of Interest

Potential QTc Interval Prolonging Events of Interest cases will be identified based on Standardised MedDRA Query (SMQ) for Torsade de pointes/QT prolongation, broad (MedDRA). The terms per this reference are listed below.

AE preferred term

Adverse Events	
Electrocardiogram QT interval abnormal	
Electrocardiogram QT prolonged	
Long QT syndrome	
Long QT syndrome congenital	
Torsade de pointes	
Ventricular tachycardia	
Cardiac arrest	
Cardiac death	
Cardiac fibrillation	
Cardio-respiratory arrest	
Electrocardiogram repolarisation abnormality	
Electrocardiogram U wave inversion	
Electrocardiogram U wave present	
Electrocardiogram U-wave abnormality	
Loss of consciousness	
Sudden cardiac death	
Sudden death	
Syncope	
Ventricular arrhythmia	
Ventricular fibrillation	
Ventricular flutter	
Ventricular tachyarrhythmia	

Laboratory Parameters

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

Estimate of Glomerular Filtration Rate (GFR) (Levey, 2012)

- Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [Levey, 2012].will be used by the central laboratory to provide an estimate of GFR, in mL/min per 1.73 m^2, as follows:

Laboratory Parameters

$$GFR = 141 \times \min\left(\frac{CRT_{mg/dL}}{\kappa}, 1\right)^{\alpha} \times \max\left(\frac{CRT_{mg/dL}}{\kappa}, 1\right)^{-1.209} \times 0.993^{Age} \times [1.018 \text{ if Female}] \times [1.159 \text{ if Black}]$$

where age (in years) is at time of assessment, κ = 0.7 if female or 0.9 if male, α = -0.329 if female and -0.411 if male, min() indicates the minimum of CRT/κ or 1, max() indicates the maximum of CRT/κ or 1, and CRTmg/dL is serum creatinine concentration in mg/dL. The serum creatinine concentration in mg/dL is obtained from GSK standard units of μmol/L as CRTmg/dL =0.0113x CRTμmol/L.

- The CKD-EPI GFR will also be calculated using Cystatin C, as follows

133 X min(Scys/0.8, 1) $^{-0.499}$ X max (Scys/0.8, 1)$^{-1.328}$ X 0.996 ^{Age} X[0.932 if female]

Where Scys is serum cystatin C mg/Liter, min indicates the minimum of Scr/0.8 or 1, and max indicates the maximum of Scys/0.8 or 1

Lab Toxicities – DAIDS Grading based on Version 2.1, March 2017, as specified in the protocol of Appendix 2

- Toxicities will be based on the Division of AIDS (DAIDS) grading system, Version 2.1, March 2017, as specified in the protocol of Appendix 2.
- Toxicity grades provided by the central laboratory do not distinguish between abnormally high or low criteria, when both are relevant for a particular parameter.
- When summarising toxicity grades for such parameters, they will be categorised as to whether they are above or below the midpoint of normal range.

Parameter	Below Midpoint for those ≥Grade 1	Above Midpoint for those ≥Grade 1
Fasted glucose	Hypoglycemia	Hyperglycemia
Sodium	Hyponatremia	Hypernatremia
Potassium	Hypokalemia	Hyperkalemia

National Cholesterol Education Program (NCEP) Lipid Categories

- In addition to DAIDS toxicity grades (see protocol), lipid values will be categorized according to the 2001 NCEP Adult Lipid Guidelines [Grundy, 2001]

Parameter	Value Range (mmol/L)	Value Range (mg/dL)	Category
Triglycerides	<1.70	<150	Normal
	1.70 to <2.26	150 to <200	Borderline High
	2.26 to <5.65	200 to <500	High
	≥5.65	≥500	Very High
Total Cholesterol	<5.18	<200	Desirable
	5.18 to <6.21	200 to <240	Borderline High
	≥6.21	≥240	High
HDL Cholesterol	<1.04	<40	Low

Laboratory Parameters			
	1.04 to <1.56	40 to <60	Normal
	≥1.56	≥60	High
LDL Cholesterol	<2.59	<100	Optimal
	2.59 to <3.37	100 to <130	Near/Above Optimal
	3.37 to <4.14	130 to <160	Borderline High
	4.14 to <4.92	160 to <190	High
	≥4.92	≥190	Very High

Other Safety Endpoints

Corrected QTC

When not entered directly in the eCRF, corrected QT intervals by Bazett's (QTcB) and Fridericia's (QTcF) formulas will be calculated, in msec, depending on the availability of other measurements.

If RR interval (in msec) is provided then missing QTcB and/or QTcF will be derived as

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

where uncorrected QT interval is also measured in msec.

If RR interval is not provided directly and one of QTcB or QTcF has been entered, then RR interval can be obtained from the above formulas and used to calculate the other correction method value; i.e.,

$$QTcB = \sqrt{\frac{QTcF^3}{QT}} \qquad QTcF = \sqrt[3]{QT \cdot QTcB^2}$$

12.6.5. Health Outcomes

HIVTSQs

Questionnaire (Questions 1-12 are scored 0-6)

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

Treatment Satisfaction Score

- Total Treatment Satisfaction Score is computed with items CCI CCI .
- Item 12 will not be included in Total Treatment Satisfaction Score. Instead, it will be treated as a stand-alone item only.
- Higher scores represent greater treatment satisfaction as compared to the past few weeks.
- A maximum of 5 items can be missing, which can be imputed to reflect the mean of the completed item scores. If 6 or more items are missing, then the treatment satisfaction scale score should not be computed and would remain missing.

Individual Item Scores

- Items are rated as CCI (CCI , etc.) to CCI (CCI CCI , etc.).
- Higher scores represent greater satisfaction with each aspect of treatment
- For individual item scores outputs, missing scores will not be computed (according to Page 7 of the [HIVDQoL User Guidelines, 2018]) and would remain missing.

HIVTSQc

Questionnaire (Questions 1-12 are scored -3 to 3)

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

Treatment Satisfaction Score (change)

- Total Treatment Satisfaction Score is computed with items CCI CCI
- Item 12 will be computed as an individual item only.
- The higher the score, the greater the improvement in satisfaction with treatment; the lower the score, the greater the deterioration in satisfaction with treatment. A score of 0 represents no change.
- A maximum of 5 items can be missing, the missing scores will be imputed with the mean of the completed item scores. If 6 or more items are missing, then the overall treatment satisfaction scale score should not be computed and will remain missing.

Individual Treatment Change Item Scores

- Items are rated as CCI , etc.) to CCI , etc.).
- The higher the score, the greater the improvement in satisfaction with each aspect of treatment and the lower the score, the greater the deterioration in satisfaction with each aspect of treatment.

HIVDQoL

Questionnaire (Questions I and II are overview items and 1-26 are domain-specific items)

This questionnaire has been provided in three different languages: English (US and Canadian), French (Canadian), Spanish (US). Below is an example of the questionnaire.

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

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Individual Domain Items [HIVDQoL User Guidelines, 2018]

- There are two overview items which are rated as:
  - I: CCI
  - II: CCI
- CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.
- The 26 domain-specific items include two rating scales, one measuring impact, part a, and the other measuring the importance of the domain for QoL, part b.
- The impact scores are rated as CCI to CCI CCI and the importance scores are rated as CCI to CCI

Weighted Impact Scores [HIVDQoL User Guidelines, 2018]

- The impact ratings are multiplied by the corresponding importance rating to provide a weighted-impact score for each applicable domain from CCI to CCI

CCI [redacted].

- If one part of a domain response (i.e. either part a or part b) is missing, a weighted impact score cannot be imputed for that question.
- If more than one option has been selected for a question, then if the options are consecutive (e.g. 2 and 3), then take the mid-point (i.e. 2.5) to be the final score for that question. However, if the two answers are not immediately next to each other (e.g., 0 and 3), treat the score as missing.

Average Weighted Impact (AWI) Score [HIVDQoL User Guidelines, 2018]

- Weighted impact scores are summed and divided by the number of applicable domains (excluding domains with missing data), to give an overall AWI score. The non-applicable domains are hence ignored.
- If there are more than three items with missing scores out of the 14 core domain-specific items which do not have the N/A option, then the AWI score will not be computed.
- Item 23 and item 25 are not included when calculating AWI scores along with the two overview items I and II.

Reason for Switch

Questionnaire

You have chosen to continue participating in a clinical study where your daily oral HIV medication will be switched to a Long-Acting injectable HIV medication. CCI [redacted]

CCI [redacted]

CCI [redacted] [select all that apply]:

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

Data handling

- If the questionnaire is taken beyond ± 2 weeks window from maintenance phase treatment start date (i.e. Study Day < -14 or Study Day > 14) it will be considered not evaluable and will not be included in the summary.
- Any missing values will remain missing (i.e. no imputation).

Preference question

Questionnaire

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

Data handling

- Any missing values will remain missing (i.e. no imputation)

12.6.6. Virology

Genotype

Amino Acid Changes

- A mutation is considered present whenever the encoded amino acid residue differs from the amino acid that would have been encoded by the wild-type (e.g., HXB2, NL43) comparator gene; e.g., Q148K.
- If the encoded amino acid is seen as a mixture of wild-type and mutant amino acid, e.g., Q148Q/K, the mutated amino acid is considered present at the codon of interest.
- If the encoded amino acid is seen as a mixture of two or more amino acids, which may or may not include wild type, e.g., Q184K/H or Q184K/H/Q, etc., for the purposes of calculating the number of mutated amino acids, only one mutation is considered to be present at the codon of interest.

Representation of Amino Acid Changes

Mutations	Amino acid change
T69S	Single mutation from amino acid 'T' (vendor reference) to 'S' (sample) at codon '69'
Q148H/K/R	Mixture of amino acid mutations 'H', 'K' and 'R' (sample) from amino acid 'Q' (vendor reference) at codon '148'
_69_1T	First insertion of amino acid 'T' (sample) at codon '69'
_69_2S	Second insertion of amino acid 'S' (sample) at codon '69'
_69_3S/A	Third insertion of a mixture of amino acids 'S' and 'A' (sample) at codon '69'
L74L/-	Mixture of amino acid 'L' (sample) and a deletion at codon '74'
V75-	Single deletion of amino acid (sample) at codon '75'

Resistance Associated Mutations

- Known INI mutations associated with the development of resistance to BIC, RAL, EVG or DTG:

Amino Acids in HIV Integrase for Analysis	H51Y, **T66A/I/K**, **E92Q/V**/G, Q95K, T97A, G118R, **F121Y**, E138A/K/T, G140A/C/R/S**, **Y143C/H/R/K/S/G/A, P145S**, **Q146P**, **S147G**, **Q148H/K/R/N**, **V151**A/I/**L**, S153F/Y, **N155H**/S/T, E157Q, G163R/K, S230R, D232N, R263K, L68V/I*, L74I/M*, E138D*, V151I*, G193E*

NOTES:
Draft listing; may be modified in case of additional substantive data availability.
INI mutations listed taken from Stanford HIV Resistance Database (http://hivdb.stanford.edu/DR/cgi-bin/rules_scores_hivdb.cgi?class=INI cited 25Oct2019) and accessed on 28Jan2020.
INI substitutions listed above in bold had a score of =60.
* Denotes additional INI mutations added as they were identified during in vitro passage of DTG or seen in a previous DTG study in INI-experienced subjects (ING112574).
**G140R is potentially associated with CAB based on in-stream data monitoring of CVF participants

- Major resistance mutations to other classes (i.e., NRTI, NNRTI, PI) as defined by the International Antiviral Society-USA (IAS-USA). The most up to date IAS-USA guidelines available at the time of DBF will be used in the analysis [Wensing, 2019].

Class	Mutations
NRTIs	M41L, A62V, K65R/E/N, D67N, 69 insert, K70E/R, L74V, V75I, F77L, Y115F, F116Y, Q151M, M184V/I, L210W, T215Y/F, K219Q/E
NNRTIs	L100I, K101E/P, K103N/S, V106A/M, V108I, E138/A/G/K/Q/R, V179L,Y181C/I/V, Y188C/L/H, G190S/A, H221Y, P225H, F227C, M230I/L,
PIs	D30N, V32I , M46I/L, I47A/V, G48V, I50V/L, I54M/L/V, Q58E, T74P, L76V, V82A/T/F/L/S, N83D, I84V, N88S, L90M

Note: List generated from IAS_USA Guideline, [Wensing, 2019]

Phenotype

Phenotypic Susceptibility

Phenotypic susceptibility to all licensed antiretroviral drugs and CAB will be determined using PhenoSense HIV assays from Monogram Inc. and will be reported as fold change (FC) in IC50 relative to wild-type control virus NL4-3, i.e., FC of sample virus = IC50 of sample virus/IC50 of control virus.

Phenotypic susceptibilities will be categorised according to FC as shown in the tables below (based on Monogram PhenoSense assay). Clinical cutoffs (where available) or biological cutoffs by PhenoSense will be used to define the phenotypic susceptibility of background treatment by Monogram.

Replication capacity is generated as part of standard phenotypic assays

PhenoSense Algorithm

Drug	Abbreviation	Class	PhenoSense cutoff
Abacavir	ABC	NRTI	(4.5 – 6.5)[a]
Lamivudine	3TC	NRTI	3.5[a]
Didanosine	ddI	NRTI	(1.3 – 2.2)[a]
Stavudine	d4T	NRTI	1.7[a]
Zidovudine	AZT (ZDV)	NRTI	1.9
Emtricitabine	FTC	NRTI	3.5
Tenofovir	TDF (TAF)	NRTI	(1.4 – 4)[a]
Delavirdine	DLV	NNRTI	6.2
Efavirenz	EFV	NNRTI	3
Nevirapine	NVP	NNRTI	4.5
Etravirine	ETR	NNRTI	(2.9-10)[a]
Rilpivirine	RPV	NNRTI	2.0
Fosamprenavir/r	FPV/r	PI	(4-11)[a]
Atazanavir	ATV	PI	2.2a
Atazanavir/r	ATV/r	PI	5.2[a]
Indinavir/r	IDV/r	PI	10[a]
Lopinavir/r	LPV/r	PI	(9 – 55)[a]
Nelfinavir	NFV	PI	3.6
Saquinavir/r	SQV/r	PI	(2.3 – 12)[a]
Tipranavir/r	TPV/r	PI	(2 – 8)[a]
Darunavir/r	DRV/r	PI	(10 – 90)[a]
Ritonavir	RTV	PI	2.5
Enfuvirtide	T20	FI	6.48
Cabotegravir	CAB	INI	2.5
Raltegravir	RAL	INI	1.5
Elvitegravir	EVG	INI	2.5
Dolutegravir	DTG	INI	(4-13)[a]
Bictegravir	BIC	INI	(2.5 - 10)

clinical cutoff (lower cutoff – higher cutoff).

Phenotypic susceptibility to each drug in a subject's background regimen is determined by applying drug-associated cutoffs as defined by the PhenoSense algorithm to the phenotypic fold resistance as below:

Full Sensitivity

Fold Change	Interpretation
> clinical lower cutoff or biologic cutoff	resistance
≤ clinical lower cutoff or biologic cutoff	sensitive

Partial Sensitivity

Fold Change	Interpretation
> clinical higher cutoff	resistance
≤ clinical higher cutoff and > clinical lower cutoff	partially sensitive
≤ clinical lower cutoff	sensitive

PHENOTYP dataset from Monogram contains the phenotypic susceptibility for each drug derived from the cutoff listed above. Thus, phenotypic susceptibility (i.e. full sensitivity and partial sensitivity) will not be re-derived for our analysis.

Genotypic and Net Assessment Susceptibility
Genotypic and Net assessment susceptibility to all licensed antiretroviral drugs and CAB will be determined from Monogram Inc. Net assessment susceptibility will be reported with the categories of 'resistance', 'partially sensitive', and 'sensitive' as what will be performed for phenotypic susceptibility. Genotypic and Net assessment susceptibility will be assessed at time of CVF using plasma sample, Genotypic susceptibility may be assessed at baseline using PBMC.

12.7. Appendix 7: Reporting Standards for Missing Data

12.7.1. Premature Withdrawals

Element	Reporting Detail
General	Subject study completion (i.e. as specified in the protocol) was defined as: Participants are considered to have completed the study if they remain on therapy (i.e., have not permanently discontinued study intervention) and satisfy one of the following: • Assigned to either treatment group, completed the Maintenance Phase (Month 12 for DTG +RPV participants only), remaining on study until commercial supplies of CAB LA + RPV LA Q2M or DTG + RPV regimens become locally available or development of CAB LA + RPV LA is terminated; Additionally, participants will continue this study until: • the participant no longer derives clinical benefit, • the participant meets a protocol-defined reason for discontinuation Participants who withdraw from CAB LA + RPV LA and go into the LTFU Phase will be considered to have prematurely withdrawn from the study intervention. • In addition to the 52-week Follow-Up phase required for participants who receive one or more injections with CAB LA or RPV LA, an in-clinic Follow-Up visit will be conducted approximately 4 weeks after the last dose of study medication for participants who withdraw from the DTG + RPV regimen with ongoing AEs, and serious adverse events (SAEs) and also any laboratory abnormalities that are considered to be AEs or potentially harmful to the participant, at the last on-study visit. Assessments at the Follow-up visit should reflect any ongoing complaints (e.g., blood draws to follow a laboratory abnormality). Follow-Up visits are not required for successful completion of the study. • Withdrawn participants will not be replaced • 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. • Withdrawal visits will be slotted as per Appendix 3: Assessment Windows or will be summarised as withdrawal visits.

12.7.2. Handling of Missing Data

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

Element	Reporting Detail
	○ Answers such as “Not applicable” and “Not evaluable” are not considered to be missing data and should be displayed as such.
Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.

12.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in subject listing displays.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.
ART/Non-ART Medications /Medical History	• Partial dates recorded in the CRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. If medications recorded in the eCRF as prior (e.g. recorded in prior ART or prior ATLAS ART forms, taken prior to study), the earlier date of the imputed and the day prior to the maintenance phase treatment start date will be used, i.e. min (imputed stop date, maintenance phase treatment start date - 1). • For medications with completely missing start date, they will be considered started prior to the maintenance phase treatment start date. • For medications with completely missing stop date, they will be considered ongoing unless recorded in eCRF as prior (e.g. recorded in prior ART form, taken prior to study). • For ART booster medications, the start and stop dates are not recorded in the database (i.e. missing), the dates will be imputed to be the same as the dates of their parent medications. • The recorded partial date will be displayed in listings.
Health outcomes	• For the summary of individual item scores outputs, missing scores will not be computed.

12.8. Appendix 8: Values of Potential Clinical Importance

12.8.1. Laboratory Values

Element	Reporting Detail
Laboratory Values and Adverse Events	• The central laboratory will flag lab parameter toxicities directly in the provided datasets based on Division of AIDS Table for Grading the Severity of Adult and Paediatric Adverse Events Version 2.1, March 2017

12.8.2. ECG

ECG values of potential clinical importance are defined as QTc > 500 msec or increase from baseline in QTc ≥ 60 msec.

12.9. Appendix 9: Snapshot Algorithm Details

Detailed Algorithm Steps

- Consider an analysis visit window for Month X as defined in Table 8 and Table 9.
- The HIV1-RNA threshold of 50, copies/mL will be analysed, in this study

- The analysis window 'Month 12' and HIV1-RNA threshold of '50 copies/mL' are used for the purpose of illustration. A subject's Snapshot response and reason at Month 12 are categorized as below.

    - HIV1-RNA < **50** copies/mL
    - HIV1-RNA ≥ **50** copies/mL
        - Data in window not below 50
        - Discontinued for lack of efficacy
        - Discontinued for other reason while not below 50
        - Change in background therapy*

    - No Virologic Data at Month 12 Window
        - Discontinued study due to AE or death
        - Discontinued study for other reasons
        - On study but missing data in window

* Note: since changes in ART are not permitted in this protocol, all such subjects who change ART during the maintenance phase and prior to an analysis timepoint will be considered 'HIV1-RNA ≥ **50** copies/mL'. Participants with protocol permitted oral bridging treatment will not be considered 'HIV-1 RNA ≥ 50 c/mL' due to 'change in ART'.

- The steps in determining response and reasons are indicated in Table below, in the order stated.

Detailed steps

Please note that the following scenarios will NOT be penalized Per Snapshot algorithm (i.e. please exclude these scenarios from **Condition** 1-4).

- Dose reduction, dropping a component, or change in formulation (e.g. 'Tivicay + Kivexa' to 'Triumeq' with the identical ingredients)

Condition ('Month 12' indicates Month 12 window)	**Response**	**Reasons**
1. If ***non-permitted*** change in background therapy ***prior to*** Month 12	HIV1-RNA ≥ 50	Change in background therapy
2. If ***permitted*** change[a] in background therapy ***prior to*** Month 12 AND the latest on-treatment VL prior to/on the date of change is ≥ 50 c/m (NA to this study)	HIV1-RNA ≥ 50	Change in background therapy
3: If ***non-permitted*** change in background therapy		

during Month 12		
• Last on-treatment VL during Month 12 prior to/on the date of change ≥ 50 c/mL	HIV1-RNA ≥ 50	Data in window not below 50
• Last on-treatment VL during Month 12 prior to/on the date of change <50 c/mL	HIV1-RNA < 50	
• No VL during Month 12 prior to/on the date of change	HIV1-RNA ≥ 50	Change in background therapy
4: If ***permitted*** change[a] in background therapy ***during*** Month 12 AND the last on-treatment VL prior to/on the date of change is ≥ 50 c/mL (NA to this study)		
4.1 this last on-treatment VL occurs prior to Month 12	HIV1-RNA ≥ 50	Change in background therapy
4. 2 this last on-treatment VL occurs during Month 12 but prior to/on the date of change	HIV1-RNA ≥ 50	Data in window not below 50
5: If none of the above conditions met		
5.1 VL available during Month 12		
• Last on-treatment VL during Month 12 ≥ 50 c/mL	HIV1-RNA ≥ 50	Data in window not below 50
• Last on-treatment VL during Month 12 <50 c/mL	HIV1-RNA < 50	
5.2 No VL during Month 12		
5.2. 1 if subjects still on study i.e. a participant has not permanently discontinued the study treatment yet, or if a participant permanently discontinued the study treatment and the upper bound of analysis snapshot window is prior to the following date: <u>CAB LA + RPV LA arm:</u> Min (max(Date of last CAB LA + RPV LA injection + 67, Date of last Dose of Oral CAB + RPV + 1), withdrawal date) <u>DTG + RPV arm:</u> Min (Date of Last oral dose of DTG + RPV + 1, withdrawal date) where 'Withdrawal Date' refers to the date the participant	No virologic data at Month 12 Window	On study but missing data in window

failed to complete per corresponding conclusion form.		
5.2.2 If subjects withdraw before/during Month 12 due to		
5.2.2.1 Safety reasons (e.g. AE/death, liver chemistry stopping criteria, renal toxicity withdrawal criteria, QTc withdrawal criteria etc, as recorded in eCRF Conclusion form)	No virologic data at Month 12 Window	Disc due to AE/death
5.2.2.2 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 Conclusion Form)		
• Last on-treatment VL <50 c/mL OR no on-treatment VL available during study	No virologic Data at Month 12 Window	Disc for other reasons
• Last on-treatment VL ≥ 50 c/mL AND withdrawal due to Lack of efficacy	HIV1-RNA ≥ 50	Disc. for lack of efficacy
• Last on-treatment VL ≥ 50 c/mL AND withdrawal due to all other non-safety related reasons	HIV1-RNA ≥ 50	Disc. for other reason while not below 50

a: Excluding permitted change in background therapy where change or decision to change is made prior to/on the first on-treatment viral result

Examples from FDA guidance

Data in Window

Virologic outcome should be determined by the last available measurement while the patient is on treatment and continued on trial within the time window:

- HIV-RNA = 580 copies/mL at Day 336, HIV-RNA below 50 copies/mL on Day 350. This should be categorized as HIV-RNA below 50 copies/mL.

No Data in Window

Discontinued study due to Adverse Event or Death:

- Any patient who discontinues because of an AE or death before the window should be classified as *Discontinued due to AE or Death* (as appropriate), regardless of the HIV-RNA result, even if the HIV-RNA is below 50 copies/mL at the time of discontinuation.
- However, if a patient has an HIV-RNA value in the time window and also discontinues in the time window, the viral load data should be used to classify the patient's response. This is the Virology First hierarchy:
    a. HIV-RNA below 50 copies/mL at Day 336 and discontinues because of AE or even dies on Day 360 — this person is categorized as having HIV-RNA below 50 copies/mL.
    b. HIV-RNA is 552 copies/mL on Day 336 and the patient discontinues on Day 360, the patient is categorized as having HIV-RNA greater than or equal to 50

copies/mL.

Discontinued for Other Reasons:

- Only patients who have achieved virologic suppression can be counted as *Discontinued for Other Reasons.*
- If a patient discontinues the study before the time window because of *lack of efficacy* then the patient should be included in the HIV-RNA greater than or equal to 50 row and not in the Discontinued for Other Reasons row.
- If a patient discontinues because of *subject withdrew consent* and his or her HIV-1 RNA result at the time of discontinuation was equal to or above 50 copies/mL, then he or she should be categorized as HIV-RNA greater than or equal to 50 and NOT as Discontinued for Other Reasons.
- If a patient discontinued because of *Lost to Follow-Up* and the last HIV-RNA result was 49 copies/mL, then the patient can be categorized as Discontinued for Other Reasons.
- If patients changed background treatment — *not permitted by protocol*— they should be captured in the HIV-RNA greater than or equal to 50 copies/mL row.

On study but missing data in window:

- If there are no data during Days 294 to 377, but there is an HIV-RNA below 50 copies/mL on Day 380, this patient should be considered *On Study but Missing Data in Window.*
- If there are no data during Days 294 to 377, but there is an HIV-RNA equal to or above 50 copies/mL on Day 280, this patient also should be classified as *On Study but Missing Data in Window.*

12.10. Appendix 10: Identification of Adverse Events of Special Interest

The adverse events of special interest are identified based on MedDRA coded values and/or AE data available in the study database. The system organ classes (SOCs), preferred terms (PTs) or codes, Standardised MedDRA Queries (SMQs), High Level Group Terms (HLGTs), and High Level Terms (HLTs) below are from MedDRA 22.0. In case there is a change to the version of MedDRA at time of reporting, the coded values based on the MedDRA version at the time of reporting will be used. The additional events may also be added based on the blinded review of AE data collected on study prior to the database freeze.

1. **Hepatic Safety Profile**

Medical concept of hepatic failure and hepatitis. Sub- SMQs (1) 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions' and (2) 'Hepatitis, non-infectious', both of parent SMQ 'Hepatic Disorders'; only narrow terms selected from sub-SMQs. Some preferred terms e.g. PT 'hepatitis fulminant' are duplicated.

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 **Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions'** **Category: A** **Scope: Narrow**	
Preferred Term	**PT Code**
Acquired hepatocerebral degeneration	10080860
Acute hepatic failure	10000804
Acute on chronic liver failure	10077305
Acute yellow liver atrophy	10070815
Ascites	10003445
Asterixis	10003547
Bacterascites	10068547
Biliary cirrhosis	10004659
Biliary fibrosis	10004664
Cardiohepatic syndrome	10082480
Cholestatic liver injury	10067969
Chronic hepatic failure	10057573
Coma hepatic	10010075
Cryptogenic cirrhosis	10063075

Diabetic hepatopathy	10071265
Drug-induced liver injury	10072268
Duodenal varices	10051010
Gallbladder varices	10072319
Gastric variceal injection	10076237
Gastric variceal ligation	10076238
Gastric varices	10051012
Gastric varices haemorrhage	10057572
Hepatectomy	10061997
Hepatic atrophy	10019637
Hepatic calcification	10065274
Hepatic cirrhosis	10019641
Hepatic encephalopathy	10019660
Hepatic encephalopathy prophylaxis	10066599
Hepatic failure	10019663
Hepatic fibrosis	10019668
Hepatic hydrothorax	10067365
Hepatic infiltration eosinophilic	10064668
Hepatic lesion	10061998
Hepatic necrosis	10019692
Hepatic steato-fibrosis	10077215
Hepatic steatosis	10019708
Hepatitis fulminant	10019772
Hepatobiliary disease	10062000
Hepatocellular foamy cell syndrome	10053244
Hepatocellular injury	10019837
Hepatopulmonary syndrome	10052274
Hepatorenal failure	10019845
Hepatorenal syndrome	10019846

Hepatotoxicity	10019851
Intestinal varices	10071502
Intestinal varices haemorrhage	10078058
Liver dialysis	10076640
Liver disorder	10024670
Liver injury	10067125
Liver operation	10062040
Liver transplant	10024714
Lupoid hepatic cirrhosis	10025129
Minimal hepatic encephalopathy	10076204
Mixed liver injury	10066758
Nodular regenerative hyperplasia	10051081
Nonalcoholic fatty liver disease	10082249
Non-alcoholic steatohepatitis	10053219
Non-cirrhotic portal hypertension	10077259
Oedema due to hepatic disease	10049631
Oesophageal varices haemorrhage	10030210
Peripancreatic varices	10073215
Portal fibrosis	10074726
Portal hypertension	10036200
Portal hypertensive colopathy	10079446
Portal hypertensive enteropathy	10068923
Portal hypertensive gastropathy	10050897
Portal vein cavernous transformation	10073979
Portal vein dilatation	10073209
Portopulmonary hypertension	10067281
Primary biliary cholangitis	10080429
Regenerative siderotic hepatic nodule	10080679
Renal and liver transplant	10052279

Retrograde portal vein flow	10067338
Reye's syndrome	10039012
Reynold's syndrome	10070953
Splenic varices	10067823
Splenic varices haemorrhage	10068662
Steatohepatitis	10076331
Subacute hepatic failure	10056956
Varices oesophageal	10056091
Varicose veins of abdominal wall	10072284
White nipple sign	10078438
SMQ: 'Hepatic Disorders'; SMQ Code: 20000005	
Sub-SMQ: 'Hepatitis, non-infectious' Category: A Scope: Narrow	
Preferred Term	**PT Code**
Acute graft versus host disease in liver	10066263
Allergic hepatitis	10071198
Alloimmune hepatitis	10080576
Autoimmune hepatitis	10003827
Chronic graft versus host disease in liver	10072160
Chronic hepatitis	10008909
Graft versus host disease in liver	10064676
Hepatitis	10019717
Hepatitis acute	10019727
Hepatitis cholestatic	10019754
Hepatitis chronic active	10019755
Hepatitis chronic persistent	10019759
Hepatitis fulminant	10019772
Hepatitis toxic	10019795
Immune-mediated hepatitis	10078962

Ischaemic hepatitis	10023025
Lupus hepatitis	10067737
Non-alcoholic steatohepatitis	10053219
Radiation hepatitis	10051015
Steatohepatitis	10076331

2. Hypersensitivity Reactions (HSR)

Medical concept of hypersensitivity reactions/DRESS. Only narrow terms selected from Category A of SMQ 'Drug reaction with eosinophilia and systemic symptoms syndrome'. Algorithmic approach for this SMQ not used due to complexity in applying and poor specificity of remaining categories. Category A selected as PTs because more specific for concept (only narrow terms) and a pre-requisite for any combination in algorithmic search. Overlap of some preferred terms with SMQ 'Severe Cutaneous Adverse Reactions'. Plus, additional preferred terms selected from HGLT 'Allergic conditions' under SOC 'Immune system disorders.

SMQ: Drug reaction with eosinophilia and systemic symptoms syndrome SMQ Code: 20000225 Category: A Scope: Narrow	
Preferred Term	**PT Code**
Drug reaction with eosinophilia and systemic symptoms	10073508
Pseudolymphoma	10037127
Additional preferred terms selected from HLGT 'Allergic conditions' under SOC 'Immune system disorders'	
Preferred Term	**PT Code**
Drug hypersensitivity	10013700
Hypersensitivity	10020751
Type IV Hypersensitivity reaction	10053613
Eosinophillia	10014950
Eye swelling	10015967
Eyelid oedema	10015993
Lip swelling	10024570
Angioedema	10002424

Circumoral oedema	10052250
Face oedema	10016029
Idiopathic angioedema	10073257
Lip oedema	10024558
Mouth swelling	10075203
Oedema mouth	10030110
Periorbital oedema	10034545
Swelling face	10042682
Periorbital swelling	10056647
Swelling of eyelid	10042690

3. Rash including severe cutaneous adverse reactions

Medical concept of rash including severe cutaneous adverse reactions. Only narrow terms from SMQ 'Severe cutaneous adverse reactions' selected. Plus several additional preferred terms selected from HLTs 'Rashes, eruptions and exanthems NEC', 'Pruritus NEC', 'Pustular conditions', 'Dermatitis ascribed to specific agent' all under SOC 'Skin and subcutaneous tissue disorders'.

SMQ: Severe Cutaneous Adverse Reactions **SMQ Code: 20000020** **Category: A** **Scope: Narrow**	
SMQ	**PT Code**
Acute generalised exanthematous pustulosis	10048799
Cutaneous vasculitis	10011686
Dermatitis bullous	10012441
Dermatitis exfoliative	10012455
Dermatitis exfoliative generalised	10012456
Drug reaction with eosinophilia and systemic symptoms	10073508
Epidermal necrosis	10059284
Erythema multiforme	10015218
Exfoliative rash	10064579

Oculomucocutaneous syndrome	10030081
Skin necrosis	10040893
Stevens-Johnson syndrome	10042033
Target skin lesion	10081998
Toxic epidermal necrolysis	10044223
Toxic skin eruption	10057970
Additional preferred terms selected from HLTs 'Rashes, eruptions and exanthems NEC', 'Pruritus NEC', 'Pustular conditions', 'Dermatitis ascribed to specific agent' all under SOC 'Skin and subcutaneous tissue disorders'.	
Preferred Term	**PT Code**
Eyelid rash	10074620
Genital rash	10018175
Mucocutaneous rash	10056671
Nodular rash	10075807
Perineal rash	10075364
Rash	10037844
Rash erythematous	10037855
Rash generalised	10037858
Rash macular	10037867
Rash maculo-papular	10037868
Rash maculovesicular	10050004
Rash morbilliform	10037870
Rash papular	10037876
Rash rubelliform	10057984
Rash scarlatiniform	10037890
Rash vesicular	10037898
Rash pruritic	10037884
Rash follicular	10037857
Rash pustular	10037888

Drug eruption	10013687

4. Prolongation of the Corrected QT Interval of the ECG in Supratherapeutic Doses

Notes: Medical concept of QT prolongation and complications. Only narrow terms from SMQ 'Torsade de pointes/QT prolongation' selected plus one additional PT under HLT 'ECG investigations'.

SMQ: Torsade de pointes/QT prolongation SMQ Code: 20000001 Category: A Scope: Narrow	
Preferred Term	**PT Code**
Electrocardiogram QT interval abnormal	10063748
Electrocardiogram QT prolonged	10014387
Long QT syndrome	10024803
Long QT syndrome congenital	10057926
Torsade de pointes	10044066
Ventricular tachycardia	10047302
Additional preferred terms selected from HGLT ' ECG investigations' under SOC 'Investigations'.	
Preferred Term	**PT Code**
Electrocardiogram repolarisation abnormality	10052464

5. Suicidal Ideation/Behaviour

Medical concept of suicidal ideation and behaviour. Sub-SMQ 'Suicide/self-injury' (SMQ) from parent SMQ of 'Depression and Suicide/Self Injury'. Only narrow terms from the sub-SMQ selected.

SMQ: 'Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Suicide/self-injury' Category: A Scope: Narrow	
Preferred Term	**PT Code**
Assisted suicide	10079105
Columbia suicide severity rating scale abnormal	10075616

Completed suicide	10010144
Depression suicidal	10012397
Intentional overdose	10022523
Intentional self-injury	10022524
Poisoning deliberate	10036000
Self-injurious ideation	10051154
Suicidal behaviour	10065604
Suicidal ideation	10042458
Suicide attempt	10042464
Suicide threat	10077417
Suspected suicide	10082458
Suspected suicide attempt	10081704

6. Depression

Medical concept of Depression. Sub-SMQ 'Depression (excl suicide and self injury)' (SMQ) from parent SMQ of 'Depression and Suicide/Self Injury'. Only narrow terms from the sub-SMQ selected.

SMQ: ‘'Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Depression (excl suicide and self injury)' Category: A Scope: Narrow	
Preferred Term	**PT Code**
Activation syndrome	10066817
Adjustment disorder with depressed mood	10001297
Adjustment disorder with mixed anxiety and depressed mood	10001299
Agitated depression	10001496
Anhedonia	10002511
Antidepressant therapy	10054976
Childhood depression	10068631
Decreased interest	10011971

Depressed mood	10012374
Depression	10012378
Depression postoperative	10012390
Depressive symptom	10054089
Dysphoria	10013954
Electroconvulsive therapy	10014404
Feeling guilty	10049708
Feeling of despair	10016344
Feelings of worthlessness	10016374
Helplessness	10077169
Major depression	10057840
Menopausal depression	10067371
Mixed anxiety and depressive disorder	10080836
Perinatal depression	10078366
Persistent depressive disorder	10077804
Post stroke depression	10070606
Postictal depression	10071324

7. Bipolar Disorder

Medical concept of bipolar disorder. All preferred terms from HLGT 'Manic and Bipolar mood disorders and disturbances' under SOC 'Psychiatric disorders'.

Preferred Term	PT Code
Bipolar I disorder	10004939
Bipolar II disorder	10004940
Bipolar disorder	10057667
Cyclothymic disorder	10011724
Hypomania	10021030
Mania	10026749

8. Psychosis

Medical concept of psychosis. Only narrow terms from SMQ 'Psychosis and psychotic disorders' selected.

SMQ: 'Psychosis and psychotic disorders' SMQ Code: 20000117 Category: A Scope: Narrow	
Preferred Term	**PT Code**
Acute psychosis	10001022
Alcoholic psychosis	10001632
Alice in wonderland syndrome	10001666
Brief psychotic disorder with marked stressors	10048549
Brief psychotic disorder without marked stressors	10056395
Brief psychotic disorder, with postpartum onset	10006362
Charles Bonnet syndrome	10063354
Childhood psychosis	10061040
Clang associations	10009232
Cotard’s syndrome	10059591
Delusion	10012239
Delusion of grandeur	10012241
Delusion of reference	10012244
Delusion of replacement	10012245
Delusional disorder, erotomanic type	10012249
Delusional disorder, grandiose type	10012250
Delusional disorder, jealous type	10012251
Delusional disorder, mixed type	10012252
Delusional disorder, persecutory type	10053195
Delusional disorder, somatic type	10012254
Delusional disorder, unspecified type	10012255
Delusional perception	10012258

Dementia of the Alzheimer's type, with delusions	10012295
Depressive delusion	10063033
Derailment	10012411
Epileptic psychosis	10059232
Erotomanic delusion	10015134
Flight of ideas	10016777
Hallucination	10019063
Hallucination, auditory	10019070
Hallucination, gustatory	10019071
Hallucination, olfactory	10019072
Hallucination, synaesthetic	10062824
Hallucination, tactile	10019074
Hallucination, visual	10019075
Hallucinations, mixed	10019079
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Hysterical psychosis	10062645
Ideas of reference	10021212
Illusion	10021403
Jealous delusion	10023164
Loose associations	10024825
Mixed delusion	10076429
Neologism	10028916
Neuroleptic-induced deficit syndrome	10075295
Paranoia	10033864
Paranoid personality disorder	10033869
Parkinson's disease psychosis	10074835
Paroxysmal perceptual alteration	10063117
Persecutory delusion	10034702

Postictal psychosis	10070669
Post-injection delirium sedation syndrome	10072851
Posturing	10036437
Psychosis postoperative	10065617
Psychotic behaviour	10037249
Psychotic disorder	10061920
Psychotic disorder due to a general medical condition	10061921
Reactive psychosis	10053632
Rebound psychosis	10074833
Schizoaffective disorder	10039621
Schizoaffective disorder bipolar type	10068889
Schizoaffective disorder depressive type	10068890
Schizophrenia	10039626
Schizophreniform disorder	10039647
Schizotypal personality disorder	10039651
Senile psychosis	10039987
Shared psychotic disorder	10040535
Somatic delusion	10041317
Somatic hallucination	10062684
Substance-induced psychotic disorder	10072388
Tangentiality	10043114
Thought blocking	10043495
Thought broadcasting	10052214
Thought insertion	10043496
Thought withdrawal	10043497
Transient psychosis	10056326
Waxy flexibility	10047853

9. Mood Disorders

Medical concept of mood disorders. All preferred terms from HLGT 'Mood disorders and disturbances NEC', under SOC 'Psychiatric disorders'.

Preferred Term	PT Code
Affect lability	10054196
Affective ambivalence	10077173
Affective disorder	10001443
Alexithymia	10077719
Anger	10002368
Apathy	10002942
Blunted affect	10005885
Boredom	10048909
Constricted affect	10010778
Crying	10011469
Diencephalic syndrome of infancy	10012774
Dysphoria	10013954
Emotional disorder	10014551
Emotional distress	10049119
Emotional poverty	10014557
Euphoric mood	10015535
Flat affect	10016759
Frustration tolerance decreased	10077753
Inappropriate affect	10021588
Irritability	10022998
Laziness	10051602
Lethargy	10024264
Listless	10024642
Moaning	10027783
Mood altered	10027940

Mood disorder due to a general medical condition	10027944
Mood swings	10027951
Morose	10027977
Neuroleptic-induced deficit syndrome	10075295
Premenstrual dysphoric disorder	10051537
Premenstrual syndrome	10036618
Screaming	10039740
Seasonal affective disorder	10039775
Steroid withdrawal syndrome	10042028
Substance-induced mood disorder	10072387

10. Anxiety

Notes: Medical concept of anxiety disorders. All preferred terms from HLGT "Anxiety disorders and symptoms", under SOC "Psychiatric disorders".

Preferred Terms	PT Code
Acrophobia	10000605
Activation syndrome	10066817
Acute stress disorder	10001084
Aerophobia	10080300
Agitation	10001497
Agitation postoperative	10049989
Agoraphobia	10001502
Akathisia	10001540
Algophobia	10078056
Animal phobia	10002518
Anniversary reaction	10074066
Anticipatory anxiety	10002758
Anxiety	10002855
Anxiety disorder	10057666

Anxiety disorder due to a general medical condition	10002859
Arachnophobia	10051408
Astraphobia	10078372
Autophobia	10071070
Body dysmorphic disorder	10052793
Burnout syndrome	10065369
Catastrophic reaction	10082329
Cibophobia	10082413
Claustrophobia	10009244
Compulsions	10010219
Compulsive cheek biting	10076510
Compulsive handwashing	10071263
Compulsive hoarding	10068007
Compulsive lip biting	10066241
Compulsive shopping	10067948
Dermatillomania	10065701
Dysmorphophobia	10049096
Emetophobia	10070637
Fear	10016275
Fear of animals	10016276
Fear of closed spaces	10016277
Fear of crowded places	10050365
Fear of death	10066392
Fear of disease	10016278
Fear of eating	10050366
Fear of falling	10048744
Fear of injection	10073753
Fear of open spaces	10016279
Fear of pregnancy	10067035

Fear of weight gain	10016280
Fear-related avoidance of activities	10080136
Generalised anxiety disorder	10018075
Glossophobia	10080077
Haemophobia	10073458
Haphephobia	10067580
Herpetophobia	10081809
Hydrophobia	10053317
Hyperarousal	10080831
Immunisation anxiety related reaction	10075205
Kinesiophobia	10078430
Limited symptom panic attack	10024511
Mysophobia	10078769
Nail picking	10066779
Nervousness	10029216
Neurosis	10029333
Noctiphobia	10057946
Nocturnal fear	10057948
Nosophobia	10063546
Obsessive need for symmetry	10077179
Obsessive rumination	10056264
Obsessive thoughts	10029897
Obsessive-compulsive disorder	10029898
Obsessive-compulsive symptom	10077894
Ochlophobia	10050095
Osmophobia	10060765
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	10072147
Panic attack	10033664

Panic disorder	10033666
Panic reaction	10033670
Paruresis	10069024
Performance fear	10034432
Phagophobia	10050096
Pharmacophobia	10069423
Phobia	10034912
Phobia of driving	10056676
Phobia of exams	10034913
Phobic avoidance	10034918
Phonophobia	10054956
Photaugiaphobia	10064420
Postpartum anxiety	10082233
Postpartum neurosis	10036419
Postpartum stress disorder	10056394
Post-traumatic stress disorder	10036316
Procedural anxiety	10075204
Pseudoangina	10056610
Selective mutism	10039917
Separation anxiety disorder	10040045
Sitophobia	10080170
Social anxiety disorder	10041242
Social fear	10041247
Stress	10042209
Tension	10043268
Terminal agitation	10077416
Thanatophobia	10064723
Thermophobia	10075147
Trichotemnomania	10072752

Trichotillomania	10044629

11. Sleep Disorders

Medical concept of sleep disorders. All preferred terms from (1) HLGT 'Sleep Disorders and Disturbances', 'Psychiatric disorders' SOC plus (2) HLGT 'Sleep disturbances (including subtypes)', 'Nervous system' SOC. Numerous duplicated preferred terms e.g. middle insomnia.

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Preferred Term	**PT Code**
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Advanced sleep phase	10001423
Behavioural induced insufficient sleep syndrome	10081938
Behavioural insomnia of childhood	10072072
Breathing-related sleep disorder	10006344
Cataplexy	10007737
Circadian rhythm sleep disorder	10009191
Confusional arousal	10067494
Delayed sleep phase	10012209
Dyssomnia	10061827
Exploding head syndrome	10080684
Hypersomnia	10020765
Hypersomnia related to another mental condition	10020767
Hypersomnia-bulimia syndrome	10053712
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Insomnia related to another mental condition	10022443

Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Loss of dreaming	10065085
Middle insomnia	10027590
Narcolepsy	10028713
Nightmare	10029412
Non-24-hour sleep-wake disorder	10078086
Parasomnia	10061910
Periodic limb movement disorder	10064600
Pickwickian syndrome	10035004
Poor quality sleep	10062519
Rapid eye movement sleep behaviour disorder	10077299
Rapid eye movements sleep abnormal	10037841
Shift work disorder	10078088
Sleep apnoea syndrome	10040979
Sleep attacks	10040981
Sleep disorder	10040984
Sleep disorder due to a general medical condition	10063910
Sleep disorder due to general medical condition, hypersomnia type	10040985
Sleep disorder due to general medical condition, insomnia type	10040986
Sleep disorder due to general medical condition, mixed type	10040987
Sleep disorder due to general medical condition, parasomnia type	10040988
Sleep inertia	10067493
Sleep paralysis	10041002
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347

Somnolence	10041349
Somnolence neonatal	10041350
Sopor	10058709
Stupor	10042264
Terminal insomnia	10068932
Upper airway resistance syndrome	10063968
HLGT Sleep disturbances (incl subtypes), HLGT code 10040998	
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Advanced sleep phase	10001423
Behavioural induced insufficient sleep syndrome	10081938
Behavioural insomnia of childhood	10072072
Breathing-related sleep disorder	10006344
Cataplexy	10007737
Central-alveolar hypoventilation	10007982
Circadian rhythm sleep disorder	10009191
Confusional arousal	10067494
Delayed sleep phase	10012209
Dyssomnia	10061827
Fatal familial insomnia	10072077
Hypersomnia	10020765
Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Loss of dreaming	10065085
Microsleep	10076954
Middle insomnia	10027590

Narcolepsy	10028713
Non-24-hour sleep-wake disorder	10078086
Periodic limb movement disorder	10064600
Pickwickian syndrome	10035004
Poor quality sleep	10062519
Rapid eye movement sleep behaviour disorder	10077299
Rapid eye movements sleep abnormal	10037841
Shift work disorder	10078088
Sleep apnoea syndrome	10040979
Sleep deficit	10080881
Sleep inertia	10067493
Sleep paralysis	10041002
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347
Sudden onset of sleep	10050014
Terminal insomnia	10068932
Upper airway resistance syndrome	10063968

12. Injection Site Reactions (ISR) from Study Drug Injections

Study drug ISR data available in the database, i.e. data collected from non-serious ISR AE eCRF form and collected serious adverse events with ‘STUDY DRUG INJECTION SITE’ included in the AE term.

13. Seizures

Medical concept of seizures. Only narrow terms from SMQ 'Convulsions' selected plus selected PTs of possible seizure events from HLT 'Disturbances in consciousness NEC' under SOC 'Nervous systems disorders' and HLT 'Confusion and disorientation' under SOC 'Psychiatric disorders'.

SMQ: 'Convulsions' **SMQ Code: 20000079** **Category: A** **Scope: Narrow**	
Preferred Term	**PT Code**
1p36 deletion syndrome	10082398
2-Hydroxyglutaric aciduria	10078971
Acquired epileptic aphasia	10052075
Acute encephalitis with refractory, repetitive partial seizures	10076948
Alcoholic seizure	10056347
Aspartate-glutamate-transporter deficiency	10079140
Atonic seizures	10003628
Atypical benign partial epilepsy	10056699
Automatism epileptic	10003831
Autonomic seizure	10049612
Baltic myoclonic epilepsy	10054895
Benign familial neonatal convulsions	10067866
Benign rolandic epilepsy	10070530
Biotinidase deficiency	10071434
Change in seizure presentation	10075606
Clonic convulsion	10053398
Convulsion in childhood	10052391
Convulsions local	10010920
Convulsive threshold lowered	10010927
CSWS syndrome	10078827
Deja vu	10012177
Double cortex syndrome	10073490
Dreamy state	10013634
Drug withdrawal convulsions	10013752
Early infantile epileptic encephalopathy with burst-suppression	10071545

Eclampsia	10014129
Epilepsy	10015037
Epilepsy surgery	10079824
Epilepsy with myoclonic-atonic seizures	10081179
Epileptic aura	10015049
Epileptic psychosis	10059232
Febrile convulsion	10016284
Febrile infection-related epilepsy syndrome	10079438
Focal dyscognitive seizures	10079424
Frontal lobe epilepsy	10049424
Generalised non-convulsive epilepsy	10018090
Generalised tonic-clonic seizure	10018100
Glucose transporter type 1 deficiency syndrome	10078727
Grey matter heterotopia	10082084
Hemimegalencephaly	10078100
Hyperglycaemic seizure	10071394
Hypocalcaemic seizure	10072456
Hypoglycaemic seizure	10048803
Hyponatraemic seizure	10073183
Idiopathic generalised epilepsy	10071081
Infantile spasms	10021750
Juvenile myoclonic epilepsy	10071082
Lafora’s myoclonic epilepsy	10054030
Lennox-Gastaut syndrome	10048816
Migraine-triggered seizure	10076676
Molybdenum cofactor deficiency	10069687
Multiple subpial transection	10079825
Myoclonic epilepsy	10054859
Myoclonic epilepsy and ragged-red fibres	10069825

Neonatal epileptic seizure	10082068
Neonatal seizure	10082067
Partial seizures	10061334
Partial seizures with secondary generalisation	10056209
Petit mal epilepsy	10034759
Polymicrogyria	10073489
Post stroke epilepsy	10076982
Post stroke seizure	10076981
Postictal headache	10052470
Postictal paralysis	10052469
Postictal psychosis	10070669
Postictal state	10048727
Post-traumatic epilepsy	10036312
Schizencephaly	10073487
Seizure	10039906
Seizure anoxic	10039907
Seizure cluster	10071350
Seizure like phenomena	10071048
Severe myoclonic epilepsy of infancy	10073677
Simple partial seizures	10040703
Status epilepticus	10041962
Sudden unexplained death in epilepsy	10063894
Temporal lobe epilepsy	10043209
Tonic clonic movements	10051171
Tonic convulsion	10043994
Tonic posturing	10075125
Topectomy	10073488
Transient epileptic amnesia	10081728
Tuberous sclerosis complex	10080584

Uncinate fits	10045476
Additional selected preferred terms from HLT 'Disturbances in consciousness NEC' under SOC 'Nervous systems disorders' and HLT 'Confusion and disorientation' under SOC 'Psychiatric disorders'.	
Preferred Term	**PT Code**
Confusional state	10010305
Loss of consciousness	10024855
Syncope	10042772
Sopor	10058709
Stupor	10042264
Altered state of consciousness	10001854
Depressed level of consciousness	10012373
Consciousness fluctuating	10050093

14. Weight Gain

Medical concept of weight gain. Selected PTs from HLT 'General nutritional disorders NEC', under SOC 'Metabolism and nutrition disorders', and HLT 'Physical examination procedures and organ system status', under SOC 'Investigations' and HLT 'General signs and symptoms NEC', under SOC 'General disorders and administration site conditions'.

Preferred Term	PT Code
Abdominal fat apron	10077983
Overweight	10033307
Abnormal weight gain	10000188
Central obesity	10065941
Obesity	10029883
Weight abnormal	10056814
Weight increased	10047899
Waist circumference increased	10064863
Body mass index abnormal	10074506
Body mass index increased	10005897
Fat tissue increased	10016251

15. Rhabdomyolysis

Medical concept of rhabdomyolysis. Only narrow terms only for SMQ 'Rhabdomyolysis/myopathy' plus 2 additional preferred terms selected from HGLT 'muscle disorders' under SOC 'Musculoskeletal and connective tissue disorders'.

SMQ: 'Rhabdomyolysis/myopathy' SMQ Code: 20000002 Category: A Scope: Narrow	
Preferred Term	**PT Code**
Muscle necrosis	10028320
Myoglobin blood increased	10028625
Myoglobin blood present	10059888
Myoglobin urine present	10028631
Myoglobinaemia	10058735
Myoglobinuria	10028629
Myopathy	10028641
Myopathy toxic	10028648
Necrotising myositis	10074769
Rhabdomyolysis	10039020
Thyrotoxic myopathy	10081524
Additional selected preferred terms from HLGT 'muscle disorders' under SOC 'Musculoskeletal and connective tissue disorders'	
Preferred Term	**PT Code**
Myalgia	10028411
Myositis	10028653

16. Pancreatitis

Medical concept of acute pancreatitis. Only narrow terms of SMQ 'Acute pancreatitis' selected. Algorithmic approach for this SMQ not used due to complexity in applying and poor specificity of remaining categories. Category A selected as PTs because more specific for concept (only narrow terms).

SMQ: 'Acute pancreatitis' SMQ Code: 20000022 Category: A Scope: Narrow	
Preferred Term	**PT Code**
Cullen’s sign	10059029
Grey Turner’s sign	10075426
Haemorrhagic necrotic pancreatitis	10076058
Hereditary pancreatitis	10056976
Ischaemic pancreatitis	10066127
Oedematous pancreatitis	10052400
Pancreatic abscess	10048984
Pancreatic cyst drainage	10082531
Pancreatic haemorrhage	10033625
Pancreatic necrosis	10058096
Pancreatic phlegmon	10056975
Pancreatic pseudoaneurysm	10081762
Pancreatic pseudocyst	10033635
Pancreatic pseudocyst drainage	10033636
Pancreatitis	10033645
Pancreatitis acute	10033647
Pancreatitis haemorrhagic	10033650
Pancreatitis necrotising	10033654
Pancreatitis relapsing	10033657
Pancreatorenal syndrome	10056277

17. Impact on Creatinine

Medical concept of worsening renal function/renal failure in the context of impact on creatinine. Only narrow terms from SMQ 'Acute renal failure' plus all PTs from HLT 'Renal failure and impairment', under SOC 'Renal and urinary disorders'. Numerous duplicated preferred terms e.g. renal failure.

SMQ: 'Acute renal failure' SMQ Code: 20000003 Category: A Scope: Narrow	
Preferred Term	**PT Code**
Acute kidney injury	10069339
Acute phosphate nephropathy	10069688
Anuria	10002847
Azotaemia	10003885
Continuous haemodiafiltration	10066338
Dialysis	10061105
Foetal renal impairment	10078987
Haemodialysis	10018875
Haemofiltration	10053090
Neonatal anuria	10049778
Nephropathy toxic	10029155
Oliguria	10030302
Peritoneal dialysis	10034660
Prerenal failure	10072370
Renal failure	10038435
Renal failure neonatal	10038447
Renal impairment	10062237
Renal impairment neonatal	10049776
Subactute kidney injury	10081980
Plus, all PTs from HLT 'Renal failure and impairment' under SOC 'Renal and urinary disorders'	
Preferred Term	**PT Code**
Acute Kidney injury	10069339
Anuria	10002847
Atypical haemolytic uraemic syndrome	10079840

Cardiorenal syndrome	10068230
Chronic kidney disease	10064848
Crush syndrome	10050702
Diabetic end stage renal disease	10012660
End stage renal disease	10077512
Foetal renal impairment	10078987
Haemolytic uraemic syndrome	10018932
Hepatorenal failure	10019845
Hepatorenal syndrome	10019846
Nail-patella syndrome	10063431
Neonatal anuria	10049778
Oliguria	10030302
Pancreatorenal syndrome	10056277
Postoperative renal failure	10056675
Postrenal failure	10059345
Prerenal failure	10072370
Propofol infusion syndrome	10063181
Renal failure	10038435
Renal failure neonatal	10038447
Renal impairment	10062237
Renal impairment neonatal	10049776
Renal injury	10061481
Scleroderma renal crisis	10062553
Traumatic anuria	10044501

18. Safety in Pregnancy

Use AE terms co-reported in pregnancy exposures to CAB and/or RPV.

12.11. Appendix 11: Abbreviations & Trade Marks

12.11.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
AESI	Adverse Events of Special Interest
ART	Antiretroviral Therapy
A&R	Analysis and Reporting
BMI	Body Mass index
CAB	Cabotegravir
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
DTG	Dolutegravir
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
HIVDQoL	HIV Dependent Quality of Life
HIV	Human Immunodeficiency Virus
HIVTSQc	Change Version of HIV Treatment Satisfaction Questionnaire
HIVTSQs	Status Version of HIV Treatment Satisfaction Questionnaire
HLGT	High Level Group Term
HLT	High Level Term
HSR	Hypersensitivity Reaction
IA	Interim Analysis
ICH	International Conference on Harmonization
IDSL	Integrated Data Standards Library
INI	Integrase Inhibitors
IP	Investigational Product
ITT	Intent-To-Treat
ITT-E	Intent-To-Treat Exposed
NA	Not Applicable
NCEP	National Cholesterol Education Program
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTI	Nucleoside Reverse Transcriptase Inhibitors
PCI	Potential Clinical Importance
PDMP	Protocol Deviation Management Plan
PI	Protease Inhibitors
PK	Pharmacokinetic

Abbreviation	Description
PP	Per Protocol
PT	Preferred Term
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
RPV	Rilpivirine
SAE	Serious Adverse Event
SAC	Statistical Analysis Complete
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SMQ	Standardised MedDRA Query
SOC	System Organ Class
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings

12.11.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
Dolutegravir
Triumeq

Trademarks not owned by the GlaxoSmithKline Group of Companies
Rilpivirine
SAS

12.12. Appendix 12: List of Data Displays

12.12.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.01 to 1.n	1.01 to 1.n
Efficacy	2.01 to 2.n	2.01 to 2.n
Safety	3.01 to 3.n	3.01 to 3.n
Health Outcomes	6.01 to 6.n	6.01 to 6.n
Virology	7.01 to 7.n	7.01 to 7.n
Section	**Listings**	
ICH Listings	1 to x	
Other Listings	y to z	

12.12.2. 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.

The example mock-up displays from other reporting efforts will be named in the format: Study Number/HARP Reporting Effort/Output Type (T/ F/L)/Display Number, where T stands for Table, F stands for Figure and L stands for Listing. For example, the Table 1.1 from primary_02 reporting effort for Study 201585 will be named by 201585/primary_02/T1.1.
Other example mock-up displays will be named using the following format.

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
Health Outcomes	HO_Fn	HO_Tn	HO_Ln
Virology	VIR_Fn	VIR_Tn	VIR_Ln

NOTES:
Non-Standard displays are indicated in the 'IDSL / Example Shell' or 'Programming Notes' column.'

12.12.3. Deliverables

Delivery [1]	Description
HL	Headline
M12	All participants complete Month 12
M26	All participants on CAB LA + RPV LA complete Month 26 *
EOS	End of Study

NOTES:
*M26 and EOS analyses might not be produced
1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort

12.12.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.01.	ITT-E	ES5	Summary of Reasons for Withdrawal at Each Study Phase	Replace 'Epoch' with 'Phase' in column header. Screening Phase will not be included. Add a footnote "Note: Entry into Long-Term Follow-up is based on presence of a long-term follow-up visit in the eCRF (i.e. LTFU Month 1, LTFU Month 3, etc.)"	M12, M26, EOS
1.02.	ITT-E	ES4	Summary of Subject Disposition at Each Study Phase		M12, M26, EOS
1.03.	Screened	ES6	Summary of Screening Status and Reasons for Screening Failures		M12, M26, EOS
1.04.	Enrolled	NS1	Summary of Number of Subjects Enrolled by Country and Site ID		M12, M26, EOS
1.05.	ITT-E	DV1	Summary of Important Protocol Deviations		M12, M26, EOS
1.06.	Screened	207966/primary_02/T1.12	Summary of Study Populations		M12, M26, EOS

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.07.	ITT-E	207966/primary_02/T1.13	Summary of Protocol Deviations Leading to Exclusion from the Per-Protocol Population		M12, M26, EOS
1.08.	ITT-E	ES1	Summary of Subject Accountability: Study Conclusion Record		HL, M12, M26, EOS
1.09.	ITT-E	207966/primary_02/T1.8	Summary of Subject Accountability: Withdrawals by Visit		M12, M26, EOS
1.10.	ITT-E	207966/primary_02/T1.9	Summary of Study Drug Discontinuation		M12, M26, EOS
1.11.	ITT-E	207966/primary_02/T1.11	Summary of Inclusion/Exclusion Criteria Deviations		M12, M26, EOS
Demographic and Baseline Characteristics					
1.12.	ITT-E	207966/primary_02/T1.14	Summary of Demographic Characteristics		HL, M12, M26, EOS
1.13.	Enrolled	207966/primary_02/T1.15	Summary of Age Ranges		M12, M26, EOS
1.14.	ITT-E	DM5	Summary of Race and Racial Combinations		M12, M26, EOS

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.15.	ITT-E	DM6	Summary of Race and Racial Combinations Details		M12, M26, EOS
1.16.	ITT-E	207966/primary_02/T1.18	Summary of Hepatitis Status at Entry		M12, M26, EOS
1.17.	ITT-E	207966/primary_02/T1.19	Summary of Derived Baseline CDC Stages of HIV Infection		M12, M26, EOS
1.18.	ITT-E	207966/primary_02/T1.21	Distribution of CD4+ Cell Count Results at Baseline	Do not include 'Screening'	M12, M26, EOS
1.19.	ITT-E	207966/primary_02/T1.23	Summary of HIV Risk Factors		M12, M26, EOS
Medical Conditions and Medications					
1.20.	ITT-E	MH1	Summary of Current Medical Conditions		M12, M26, EOS
1.21.	ITT-E	MH1	Summary of Past Medical Conditions		M12, M26, EOS
1.22.	ITT-E	MH4	Summary of Current Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders		M12, M26, EOS

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.23.	ITT-E	MH4	Summary of Past Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders		M12, M26, EOS
1.24.	ITT_E	CM8	Summary of Concomitant Non-ART Medication Ingredient Combinations		M12, M26, EOS
1.25.	ITT-E	207966/primary_02/T 1.30	Summary of Lipid Modifying Agent Use at Baseline		M12, M26, EOS
1.26.	ITT-E	207966/primary_02/T 1.31	Summary of Lipid Modifying Agent Use Started during the Maintenance Phase		M12, M26, EOS
1.27.	ITT-E	207966/primary_02/T 1.32	Summary of Substance Use at Entry		M12, M26, EOS
Exposure and Treatment Compliance					
1.28.	Safety	207966/primary_02/T 3.1	Summary of Extent of Exposure to Investigational Product		M12, M26, EOS
1.29.	Safety	207966/primary_02/T 3.4	Summary of Adherence to CAB/RPV Injection Dosing Schedule	Only display for Q2M	M12, M26, EOS

12.12.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Primary Efficacy Analyses					
2.01.	ITT-E	207966/primary_02/T2.3	Summary of Study Outcomes (50 c/mL Threshold) at Month 12 – Snapshot Analysis – ITT-E	For M26, replace the 'Month 12' in the title with 'Month 26'	HL, M12, M26, EOS
2.02.	PP	207966/primary_02/T2.3	Summary of Study Outcomes (50 c/mL Threshold) at Month 12 – Snapshot Analysis – Per-Protocol	For M26, replace the 'Month 12' in the title with 'Month 26'	M12, M26, EOS
Secondary and Exploratory Efficacy Analyses					
2.03.	ITT-E	207966/primary_02/T2.13	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Visit – Snapshot Analysis		M12, M26, EOS
2.04.	ITT-E	207966/primary_02/T2.14	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Subgroup and Visit – Snapshot Analysis		M12, M26, EOS
2.05.	ITT-E	207966/primary_02/T2.15	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit – Snapshot Analysis		M12, M26, EOS
2.06.	ITT-E	207966/primary_02/T2.16	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Subgroup and Visit – Snapshot Analysis		M12, M26, EOS
2.07.	ITT-E	207966/primary_02/T2.22	Summary of Plasma HIV-1 RNA (log10 c/mL) by Visit		M12, M26, EOS
2.08.	ITT-E	207966/primary_02/T2.23	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria by Visit during the Maintenance Phase (Up to Month 12)	For M26, replace the 'Month 12' in the title with 'Month 26'	M12, M26, EOS
2.09.	ITT-E	207966/primary_02/T2.24	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria		M12, M26, EOS

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.10.	CVF	207966/primary_02/T2.25	Distribution of Quantitative Plasma HIV-1 RNA Results at Suspected and Confirmation of Confirmed Virologic Failure		M12, M26, EOS
2.11.	ITT-E	207966/primary_02/T2.28	Summary of Subjects per Viral Load Category by Visit		M12, M26, EOS
2.12.	ITT-E	207966/primary_02/T2.29	Summary of Change from Baseline in CD4+ Cell Count (cells/mm^3) by Visit		M12, M26, EOS
2.13.	ITT-E	207966/primary_02/T2.31	Summary of CD4+ Cell Count (cells/mm^3) by Visit		M12, M26, EOS
2.14.	ITT-E	207966/primary_02/T2.35	Summary of HIV-1 Associated Conditions Including Recurrences		M12, M26, EOS
2.15.	ITT-E	207966/primary_02/T2.36	Summary of HIV-1 Associated Conditions Excluding Recurrences		M12, M26, EOS
2.16.	ITT-E	207966/primary_02/T2.37	Summary of HIV-1 Disease Progression and/or Deaths		M12, M26, EOS
2.17.	ITT-E	207966/primary_02/T2.22	Summary of Change from Baseline in Plasma HIV-1 RNA (log10 c/mL) by Visit	Add footnote: “Note: Baseline values are actual plasma HIV-1 RNA (log10 c/mL) values.’ Display actual values at Baseline and change from baseline for post-baseline visits	M12, M26, EOS

12.12.6. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Primary Efficacy Analyses					
2.01.	ITT-E	207966/primary_02/F2.1	Proportion (95% CI) of Subjects with HIV-1 RNA >=50 c/mL by Visit - Snapshot Analysis		M12, M26, EOS
Secondary and Exploratory Efficacy Analyses					
2.02.	ITT-E	207966/primary_02/F2.3	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit - Snapshot Analysis		M12, M26, EOS
2.03.	ITT-E	207966/primary_02/F2.7	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit – for CVF Subjects		M12, M26, EOS
2.04.	ITT-E	207966/primary_02/F2.8	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit for Subjects Who are in the Category of 'HIV-1 RNA >=50 c/mL' at Month 12 per Snapshot Algorithm	For M26, replace the ‘Month 12’ in the title with ‘Month 26’	M12, M26, EOS

12.12.7. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Adverse Events (AEs)					
3.01.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term		M12, M26, EOS
3.02.	Safety	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency		M12, M26, EOS
3.03.	Safety	AE3	Summary of Common (>=1%) Grade 2-4 Adverse Events by Overall Frequency		M12, M26, EOS
3.04.	Safety	AE1	Summary All Drug-Related Adverse Events by System Organ Class		M12, M26, EOS
3.05.	Safety	207966/primary_02/T3.25	Summary of Subjects and Number of Occurrences of Common (>=5%) Non-Serious Adverse Events by System Organ Class	Add footnote: 'Note: Common adverse events are those with >=5% incidence in either treatment group.	M12, M26, EOS
3.06.	Safety	AE3	Summary of Common (>=1%) Drug-Related Grade 2-4 Adverse Events by Overall Frequency	Add footnote: 'Note: Common adverse events are those with >=1% incidence in either treatment group.	M12, M26, EOS
3.07.	Safety	207966/primayr_02/T3.26	Summary of Subjects and Number of Occurrences of SAEs, Fatal SAEs, and Drug-related SAEs		HL, M12, M26, EOS

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Other Significant Adverse Events					
3.08.	Safety	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class		HL, M12, M26, EOS
Laboratory: Chemistry and Hematology					
3.09.	Safety	207966/primary_02/T3.39	Summary of Chemistry Changes from Baseline by Visit		M12, M26, EOS
3.10.	Safety	207966/primary_02/T3.41	Summary of Hematology Changes from Baseline by Visit		M12, M26, EOS
Laboratory: Urinalysis					
3.11.	Safety	207966/primary_02/T3.48	Summary of Urine Concentration Changes from Baseline by Visit		M12, M26, EOS
Laboratory: Hepatobiliary (Liver)					
3.12.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting		M12, M26, EOS
3.13.	Safety	207966/primary_02/T3.57	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria		M12, M26, EOS

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
ECG					
3.14.	Safety	EG1	Summary of ECG Findings		M12, M26, EOS
3.15.	Safety	207966/primary_02/T3.61	Summary of QTc Values by Category		M12, M26, EOS
3.16.	Safety	207966/primary_02/T3.62	Summary of Change from Baseline QTc Values by Category		M12, M26, EOS
Vital Signs					
3.17.	Safety	VS1	Summary of Change from Baseline in Vital Signs by Visit		M12, M26, EOS
Study Drug Injection Site Reaction Adverse Events (display for Q2M arm only)					
3.18.	Safety	207966/primary_02/T3.28	Summary of Study Drug Injection Site Reaction Adverse Events (Event-level Summary)		HL, M12, M26, EOS
3.19.	Safety	207966/primary_02/T3.29	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common		M12, M26, EOS
3.20.	Safety	207966/primary_02/T3.30	Summary of Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity – Overall and Common	Replace definition of common in the footnote with 'Note: Common ISR includes pain, induration, nodules and any other ISR with >=5% subjects in Q2M treatment arm'	M12, M26, EOS

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.21.	Safety	207966/primary_02/T3.31	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) – CAB		M12, M26, EOS
3.22.	Safety	207966/primary_02/T3.32	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common (CAB)		M12, M26, EOS
3.23.	Safety	207966/primary_02/T3.33	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity – CAB		M12, M26, EOS
3.24.	Safety	207966/primary_02/T3.34	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length – Common (CAB)	Replace definition of common in the footnote with 'Note: Common ISR includes pain, induration, nodules and any other ISR with >=5% subjects in Q2M treatment arm'	M12, M26, EOS
3.25.	Safety	207966/primary_02/T3.35	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) – RPV		M12, M26, EOS
3.26.	Safety	207966/primary_02/T3.36	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common (RPV)		M12, M26, EOS
3.27.	Safety	207966/primary_02/T3.37	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity – RPV		M12, M26, EOS

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.28.	Safety	207966/primary_02/T3.38	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length – Common (RPV)	Replace definition of common in the footnote with 'Note: Common ISR includes pain, induration, nodules and any other ISR with >=5% subjects in Q2M treatment arm'	M12, M26, EOS
Adverse Events of Special Interest					
3.29.	Safety	207966/primary_02/T3.72	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.30.	Safety	207966/primary_02/T3.76	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.31.	Safety	207966/primary_02/T3.71	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.32.	Safety	207966/primary_02/T3.66	Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety and Suicidal Ideation/Behaviour at Baseline	For M26 and EOS, include additional stratification by 'any history' vs. 'no history'	M12, M26, EOS
3.33.	Safety	207966/primary_02/T3.78	Summary of Seizure Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.34.	Safety	207966/primary_02/T3.67	Summary of Hepatic Safety Profile: Assessment of Risk of Hepatoxicity Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.35.	Safety	207966/primary_02/T3.68	Summary of Hypersensitivity Reaction (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.36.	Safety	207966/primary_02/T3.69	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.37.	Safety	207966/primary_02/T3.70	Summary of Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.38.	Safety	207966/primary_02/T3.73	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.39.	Safety	207966/primary_02/T3.74	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.40.	Safety	207966/primary_02/T3.75	Summary of Mood Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.41.	Safety	207966/primary_02/T3.77	Summary of Sleep Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.42.	Safety	207966/primary_02/T3.79	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.43.	Safety	207966/primary_02/T3.80	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.44.	Safety	207966/primary_02/T3.81	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.45.	Safety	207966/primary_02/T3.82	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.46.	Safety	207966/primary_02/T3.83	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, M26, EOS
3.47.	Safety	207966/primary_02/T3.6	Summary of All Adverse Events by System Organ Class and Maximum Toxicity		HL, M12, M26, EOS
3.48.	Safety	207966/primary_02/T3.13	Summary of All Drug-related Adverse Events by System Organ Class and Maximum Toxicity		HL, M12, M26, EOS

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.49.	Safety	207966/primary_02/T3.43	Summary of Maximum Post-Baseline Emergent Chemistry Toxicities		M12, M26, EOS
3.50.	Safety	207966/primary_02/T3.45	Summary of Maximum Post-Baseline Emergent Hematology Toxicities		M12, M26, EOS

12.12.8. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Adverse Events					
3.01.	Safety	207966/primary_02/F3.1	Plot of Common Adverse Events and Relative Risk – Q2M vs. DTG + RPV - Excluding Study Drug ISRs		M12, M26, EOS
Study Drug Injection Site Reaction Adverse Events (display for Q2M arm only)					
3.02.	Safety	207966/primary_02/F3.2	Plot of Common Study Drug Injection Site Reaction Adverse Events	Only display first panel	M12, M26, EOS
3.03.	Safety	207966/primary_02/F3.3	Plot of Onset, Duration, and Severity of Overall and Common Study Drug Injection Site Reaction AEs by Maximum Grade - CAB and/or RPV		M12, M26, EOS
3.04.	Safety	207966/primary_02/F3.4	Plot of Onset, Duration, and Severity of Overall and Common Drug-related Study Drug Injection Site Reaction AEs by Maximum Grade - CAB		M12, M26, EOS
3.05.	Safety	207966/primary_02/F3.5	Plot of Onset, Duration, and Severity of Overall and Common Drug-related Study Drug Injection Site Reaction AEs by Maximum Grade - RPV		M12, M26, EOS
3.06.	Safety	207966/primary_02/F3.6	Plot of Incidence of Maintenance Phase Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - CAB and/or RPV		M12, M26, EOS
3.07.	Safety	207966/primary_02/F3.7	Plot of Incidence of Maintenance Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - CAB		M12, M26, EOS

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.08.	Safety	207966/primary_02/F3.8	Plot of Incidence of Maintenance Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - RPV		M12, M26, EOS
3.09.	Safety	207966/primary_02/F3.9	Plot of Incidence of Grade 3-5 Maintenance Phase Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - CAB and/or RPV		M12, M26, EOS
3.10.	Safety	207966/primary_02/F3.10	Plot of Incidence of Grade 3-5 Maintenance Phase Drug-related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - CAB		M12, M26, EOS
3.11.	Safety	207966/primary_02/F3.11	Plot of Incidence of Grade 3-5 Maintenance Phase Drug-related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - RPV		M12, M26, EOS
Laboratory					
3.12.	Safety	207966/primary_02/F3.12	Scatter Plot of Maximum vs. Baseline for ALT	.	M12, M26, EOS
3.13.	Safety	207966/primary_02/F3.13	Scatter Plot of Maximum Total Bilirubin vs. Maximum ALT		M12, M26, EOS
3.14.	Safety	207966/primary_02/F3.14	Matrix Plot of Maximum Liver Chemistries		M12, M26, EOS
3.15.	Safety	207966/primary_02/F3.15	Bar Chart of Lipid NCEP Categories at Month 12 vs. Baseline - Triglycerides, Total Cholesterol, LDL Cholesterol	For M26, replace the 'Month 12' in the title with 'Month 26'	M12, M26, EOS
3.16.	Safety	207966/primary_02/F3.16	Bar Chart of Lipid NCEP Categories at Month 12 vs. Baseline - HDL Cholesterol	For M26, replace the 'Month 12' in the title with 'Month 26'	M12, M26, EOS

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Exposure (display for Q2M arm only)					
3.17.	Safety	207966/primary_02/F3.17	Histogram of Timeliness of Injections		M12, M26, EOS

12.12.9. Health Outcomes Tables

Health Outcomes: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
HIV Dependent Quality of Life (HIVDQoL)					
6.01.	ITT-E	HO_T1	Proportion of Subjects with Each Individual Questionnaire Item Score in HIVDQoL by Visit		M12
6.02.	ITT-E	HO_T2	Summary of HIVDQoL in Overview Items, Domain Weighted Impact Scores and Average Weighted Impact Score by Visit		M12
6.03.	ITT-E	HO_T3	Summary of HIVDQoL Change from Baseline in Overview Items, Domain Weighted Impact Scores and Average Weighted Impact Score by Visit		M12
HIV Treatment Satisfaction Questionnaire Status Version (HIVTSQs)					
6.04.	ITT-E	207966/primary_02/T6.14	Proportion of Subjects with HIVTSQs - Individual Item Scores by Visit	Note: no LOCF	M12
6.05.	ITT-E	207966/primary_02/T6.16	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit		M12
6.06.	ITT-E	207966/primary_02/T6.18	Summary of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Visit	Note: Do not include column for prior exposure	M12
6.07.	ITT-E	207966/primary_02/T6.20	Summary of HIVTSQs - Change from Baseline in Individual Item Score by Visit	Note: no LOCF; do not include column for prior exposure	M12

Health Outcomes: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
HIV Treatment Satisfaction Questionnaire Change Version (HIVTSQc)					
6.08.	ITT-E	207966/primary_02/T6.23	Proportion of Subjects with HIVTSQc - Individual Item Change Score at Month 12		M12
6.09.	ITT-E	207966/primary_02/T6.25	Summary of HIVTSQc - Total Treatment Satisfaction Change Score at Month 12		M12
6.10.	ITT-E	207966/primary_02/T6.27	Summary of HIVTSQc - Individual Item Change Score at Month 12		M12
Preference (display for Q2M arm only)					
6.11.	ITT-E	207966/primary_02/T6.38	Proportion of Subjects with Response to Each Individual Question in Preference Questionnaire at Month 12 for Subjects in Q2M	Display questions and responses per the data. Do not include footnotes [1] and [2]	M12
Reasons for Switch (display for Q2M arm only)					
6.12.	ITT-E	207966/primary_02/T6.41	Reasons for Switch at Baseline for Subjects from Oral CAB + RPV to Q2M	Display responses per the data.	M12

12.12.10. Virology Tables

Virology: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Genotype					
7.01.	CVF	207966/primary_02/T7.1	Summary of the Prevalence of Known INI Resistance Mutations at Time of CVF - Plasma Sample		M12, M26, EOS
7.02.	CVF	207966/primary_02/T7.2	Summary of the Prevalence of Major Resistance Mutations of NRTI, NNRTI and PI Class at Time of CVF - Plasma Sample		M12, M26, EOS
7.03.	CVF	207966/primary_02/T7.3	Summary of Genotypic Susceptibility at Time of CVF - Plasma Sample		M12, M26, EOS
Phenotype					
7.04.	CVF	207966/primary_02/T7.4	Summary of Phenotype Susceptibility at Time of CVF - Plasma Sample		M12, M26, EOS
7.05.	CVF	207966/primary_02/T7.5	Summary of Phenotype: Number of Drugs to Which Subject is Phenotypic Resistant or Partial Sensitive or Sensitive at Time of CVF - Plasma Sample		M12, M26, EOS
7.06.	CVF	207966/primary_02/T7.6	Summary of Fold Change to CAB and RPV at Time of CVF - Plasma Sample	Display for Q2M arm only	M12, M26, EOS
7.07.	CVF	207966/primary_02/T7.7	Summary of Net Assessment at Time of CVF - Plasma Sample		M12, M26, EOS

Virology: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Miscellaneous					
7.08.	CVF	207966/primary_02/T7.8	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria during the Maintenance Phase		M12, M26, EOS

12.12.11. ICH Listings

Strata and Latest Subject Id will not be included in any listings taken from 207966/primary_02.

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
1.	Screened	207966/primary_02/L3	Listing of Reasons for Screen Failure		M12, M26, EOS
2.	ITT-E	207966/primary_03/L4	Listing of Reasons for Study Withdrawal		M12, M26, EOS
3.	Enrolled	207966/primary_02/L2	Listing of Treatment Assignment	Do not include footnotes and columns for randomization number, randomization and actual strata and deviation. Do not display randomized treatment	M12, M26, EOS
4.	ITT-E	207966/primary_02/L6	Listing of Important Protocol Deviations		M12, M26, EOS
5.	ITT-E	207966/primary_02/L8	Listing of Subjects with Inclusion/Exclusion Criteria Deviations		M12, M26, EOS
6.	ITT-E	207966/primary_02/L7	Listing of Protocol Deviations Leading to Exclusion from the Per-Protocol Population		M12, M26, EOS
7.	ITT-E	207966/primary_02/L9	Listing of Demographic Characteristics		M12, M26, EOS

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
8.	ITT-E	207966/primary_02/L10	Listing of Race		M12, M26, EOS
9.	ITT-E	207966/primary_02/L36	Listing of Concomitant ART Medications Received	Do not include final column for phase during which concomitant	M12, M26, EOS
10.	ITT-E	207966/primary_02/L5	Listing of Reasons for Study Drug Discontinuation		M12, M26, EOS
Efficacy					
11.	ITT-E	207966/primary_02/L11	Listing of Study Outcome (50 c/mL Threshold) at Month 12 - Snapshot Analysis	For M26, replace the 'Month 12' in the title with 'Month 26'	M12, M26, EOS
Safety: Exposure					
12.	Safety	207966/primary_02/L12	Listing of Investigational Product Exposure Data		M12, M26, EOS
Adverse Events					
13.	Safety	207966/primary_02/L19	Listing of All Adverse Events		M12, M26, EOS
14.	Safety	207966/primary_02/L13	Listing of Subject Numbers for Individual Adverse Events		M12, M26, EOS
15.	Safety	207966/primary_02/L15	Listing of Fatal Adverse Events		M12, M26, EOS
16.	Safety	207966/primary_02/L16	Listing of Non-Fatal Serious Adverse Events		M12, M26, EOS

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
17.	Safety	207966/primary_02/L14	Listing of Reasons for Considering as a Serious Adverse Event		M12, M26, EOS
18.	Safety	207966/primary_02/L17	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product		M12, M26, EOS
Safety: Hepatobiliary (Liver)					
19.	Safety	207966/primary_02/L21	Listing of Medical Conditions for Subjects with Liver Stopping Events		M12, M26, EOS
20.	Safety	207966/primary_02/L22	Listing of Substance Use for Subjects with Liver Stopping Events		M12, M26, EOS
Safety: ECG					
21.	Safety	207966/primary_02/L23	Listing of ECG Values for Subjects with a Value of Potential Clinical Importance		M12, M26, EOS
22.	Safety	207966/primary_02/L24	Listing of ECG Findings		M12, M26, EOS

12.12.12. Non-ICH Listings

Strata and Latest Subject Id will not be included in any listings taken from 207966/primary_02.

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
23.	ITT-E	207966/primary_02/L34	Listing of Subjects Who were Rescreened	Do not include annotation [1]	M12, M26, EOS
24.	ITT-E	207966/primary_02/L37	Listing of ART Medications Received during Long-term Follow-up Phase		M12, M26, EOS
25.	ITT-E	207966/primary_02/L39	Listing of Medical History of Seizure		M12, M26, EOS
Adverse Events					
26.	LTFU	207966/primary_02/L19	Listing of All Adverse Events (Long-term Follow-up Phase)		M12, M26, EOS
Efficacy					
27.	CVF	207966/primary_02/L40	Listing of All Plasma HIV-1 RNA Data for Subjects with Confirmed Virologic Failure		M12, M26, EOS
28.	ITT-E	207966/primary_02/L41	Listing of All Plasma HIV-1 RNA Data for Subjects with Viral Load >=50 c/mL during the Maintenance Phase		M12, M26, EOS
29.	ITT-E	207966/primary_02/L43	Listing of HIV-1 Associated Conditions		M12, M26, EOS
30.	CVF	207966/primary_02/L62	Listing of Replication Capacity in IN and PR/RT Region		M12, M26, EOS

12.13. Appendix 13: Example Mock Shells for Data Displays

Available upon request.