Statistical Analysis Plan Amendment 1

Study ID: 213199

Official Title of Study: A Phase IIIb, Open-label, Hybrid Type III Trial Evaluating Implementation Strategies for Long-acting Cabotegravir Plus Long-acting Rilpivirine Every Two Months in HIV-1 Infected, Virologically Suppressed Adults in Select European Healthcare Settings

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Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)
Title	:	**Reporting and Analysis Plan for A Phase IIIb, open-label, hybrid type III trial evaluating implementation strategies for long-acting cabotegravir plus long-acting rilpivirine every two months in HIV-1 infected, virologically suppressed adults in select European healthcare settings.**
Compound Number	:	GSK1265744
Clinical Study Identifier	:	213199
Effective Date	:	30 Nov 2022

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 213199, specifically for clinical efficacy and safety data. Any implementation science/health outcome analysis non-clinical data will be detailed in the Evidera SAP.
- This RAP will be provided to the study team members to convey the content of pertaining to clinical data for the interim, Month 12, and End of Study (EOS) analyses.

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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 213199. This RAP is based on the original protocol (Dated 06-MAY-2020) of study GSK1265744/213199 (GSK Document Number 2019N420690_01) and its protocol amendments 01 (Dated 02-DEC-2020, GSK Document Number 2019N420690_02) and 02 (Dated 24-MAY-2021, GSK Document No. TMF-13794092).

GlaxoSmithKline Document Number	**Date**	**Version**
TMF-11899418	12-MAR-2021	Original
TMF-15213711	30 Nov 2022	Amendment No. 1
The reasons for this amendment were to: plan specific outputs related to participant pregnancy in line with protocol amendment 02; add clarity on the Covid PD impact on exposure formula; Adjust on treatment definition to add 63 days post injection instead of 35; Additional categories added to summarize oral exposure to Oral Bridging (Covid and Non-Covid related); if SOC ART started immediately after missed injection, then injection would not be count as missed. Clarity added around entry into LTFU and transition to commercial product. List of displays for EOS updated to account for pregnancy and RAPIDO Data Viewer.		

1.1. RAP Amendments

Revision chronology:

RAP Section	**Amendment Details**
Reporting and Analysis Plan (RAP) CARISEL_213199_Final [12-MAR-2021]	
Reporting and Analysis Plan (RAP) CARISEL_213199_Amendment_1 [30 Nov 2022]	
Inclusion of additional pregnancy based output	• Protocol amendment 02 allows pregnant participants to continue on study. Listings have been added to address pregnancy specific events.
Data Handling	• Pregnancy data accommodations have been added. • Exposure formulas were adjusted to account for Q8W dosing, protocol deviation impact, transition to commercial product, and various scenarios related to Oral Bridging or missed injections.
Data Displays	• Display status for EOS was updated to consider use of the RAPIDO Data Viewer. The following displays were added for pregnancy summarization: Listings 49-57

2. SUMMARY OF KEY PROTOCOL INFORMATION

Cabotegravir long-acting + rilpivirine long-acting (CAB LA + RPV LA) is an HIV-1 treatment regimen administered as two individual intramuscular injections monthly or every two months (following an optional oral lead-in [OLI] period). The overall objective of the CAB LA + RPV LA clinical development program was to develop a highly effective, well-tolerated, two-drug, long-acting injectable regimen which has the potential to offer improved treatment convenience, compliance and improved quality of life for people living with HIV (PLHIV) compared to current standard of care.

This new HIV treatment will require changes to the current standard of prescribing oral antiretroviral therapies to prescribing and delivering a complete antiretroviral long acting injectable regimen. As this is a new treatment modality, it is important to understand how to optimize the delivery of CAB LA + RPV LA from a patient, healthcare provider and healthcare system perspective in order to implement into routine care with fewer obstacles. Each country's healthcare system has its own challenges and nuanced differences in the delivery of HIV care. Strategies to support the unique and dynamic contexts for CAB LA + RPV LA implementation is key. As a result, this research study will examine different implementation strategies in different clinics settings across European countries to identify which strategies best meet the needs in each local context. The research in this study will involve both patients receiving the study treatment CAB LA + RPV LA (patient study participants, PSP) as well as the healthcare providers at the investigator site level (staff study participants, SSP).

For PSPs, the study is single-arm, unblinded and interventional, where all patients who fulfil eligibility requirements will be assigned to receive CAB LA + RPV LA and complete assessments as per the study protocol.

For SSPs, the study is two-arm, unblinded, non-interventional and cluster-randomized at the country level. Sites within a given country will be randomized to either the Standard (Arm-s) or the Enhanced (Arm-e) implementation arm. The two arms will involve the provision of overlapping but distinct types of implementation components that are designed to assist in the local implementation of the study drug at each site. Arm-s represents the traditional provider support by a medical science lead and product materials. Arm-e models a higher level of provider support with added face to face meeting, trainings, and additional touchpoints for administration of CAB LA + RPV LA. The study will evaluate both qualitative and quantitative measures across arm, clinic type, provider type, and country to determine the most effective implementation strategies and to identify barriers and facilitators (including solutions). Clinical data will be collected to monitor safety and efficacy.

2.1. Changes to the Protocol Defined Statistical Analysis Plan

A change to the originally planned statistical analysis specified in the 213199 protocol [Dated: 06MAY2020] consists of dropping the ITT-E population and introducing the Enrolled population. This is being done as the ITT-E carries the same definition as the Safety population so both populations are not needed. Efficacy is also a secondary endpoint so it would add unnecessary programming work to include an identical

population. The Safety population will serve as the primary population for both safety and efficacy analyses. The Enrolled population is being added in order to adhere to EudraCT standards.

2.1.1. Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan	Rationale
• An ITT-E population is listed to be used in statistical analysis.	• This population is being dropped and the Safety population will be used for efficacy analysis. An Enrolled population is also being added.	• The ITT-E and Safety populations carry the same definition so only one is needed for analysis. The Enrolled population is added to adhere to EudraCT standards.

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

Objectives	Endpoints/Estimands
Primary	
Staff Study Participants (SSP): To evaluate • acceptability • appropriateness • feasibility	Quantitative Change of Acceptability of Implementation Measure (AIM) Score, Implementation Appropriateness Measure (IAM) Score, Feasibility of Implementation Measure (FIM) Score over time assessed quantitatively via questionnaires through Month 12.[a] Qualitative Semi-structured interviews (SSI) assessed qualitatively through Month 12.
Secondary	
Staff Study Participants: To evaluate • Facilitators to implementation • Barriers to implementation • Adaptations/Modifications to address barriers and facilitators	Quantitative: Change of Implementation Leadership Scale (ILS), Change and Implementation Climate Scale (ICS) over time assessed quantitatively via questionnaires through Month 12.[a] Summarize components from Enhanced Implementation & Standard Implementation: • FRAME-IS outcome Months 2 – 12 (monthly) Summarize components from Enhanced Implementation: • CQI 1-hour calls/PDSAs minimum of Months 2-7 (monthly)

Objectives	Endpoints/Estimands
	Qualitative SSIs assessed qualitatively through Month 12.
Patient Study Participants (PSP) To evaluate • Facilitators to implementation • Barriers to Implementation	Quantitative: Questionnaires assessed quantitatively through Dose 7.[b] Length of patient study participant visit from arrival until departure from clinic assessed at Dose 1, Dose 2, Dose 4, and Dose 5. Qualitative SSIs assessed qualitatively through Dose 7.
To evaluate **Patient Study Participants** experience for delivering CAB LA + RPV LA, including • Acceptability • Appropriateness • Feasibility	Quantitative Change in Acceptability of Intervention Measure (AIM) Score, Intervention Appropriateness Measure (IAM) Score, and Feasibility of Intervention Measure (FIM) Score over time. Assessed via questionnaires at Dose 7.[b] Qualitative SSIs assessed qualitatively through Dose 7.
To evaluate sustainability of CAB LA + RPV LA with **Study Staff Participants** each clinic	Total score of the Clinical Sustainability Assessment Tool (CSAT) at Month 12.
To assess fidelity to CAB LA + RPV LA injection dosing windows	Percentage of injections occurring within target window from the target date.
Evaluate efficacy and safety measures of CAB LA + RPV LA	Proportion of participants with plasma HIV-1 RNA <50 c/mL over time. Proportion of participants with confirmed virologic failure (CVF) over time Incidence of treatment-emergent genotypic and phenotypic resistance to CAB and RPV in patient study participants with CVF

Objectives	Endpoints/Estimands
	Incidence and severity of AEs, SAEs and proportion of participants who discontinue treatment due to AEs over time
To assess preference between CAB LA + RPV LA and oral ART medication received prior to entering the study	Preference between CAB + RPV LA and daily oral ART medication (received prior to entering the study) at quantitatively assessed via preference questionnaire at Dose 7

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[redacted]

2.3. Study Design

Study 213199 (Cabotegravir And Rilpivirine Implementation Study in European Locations -CARISEL) is a cluster randomized, two-arm, open-label, hybrid effectiveness-implementation study designed to evaluate two implementation strategy conditions (Enhanced [Arm-e] vs Standard [Arm-s]) in various clinical settings across five European countries.

This study is an evaluation of implementation strategies on the degree of acceptability, appropriateness, feasibility, fidelity, and sustainability of clinic practices to deliver the CAB LA + RPV LA regimen. The study will use an implementation science approach to understand the barriers and facilitators for both patients and providers, including best practices for delivering CAB LA + RPV LA within an interventional clinical trial where the CAB LA + RPV LA regimen is delivered to HIV-1-infected, virologically-suppressed adult patients. This design allows for a simultaneous focus on both implementation and effectiveness, which allows for maximizing our understanding of how-to best support translation of CAB LA + RPV LA into routine care while continuing to collect effectiveness and safety data. The hybrid type III focuses primarily on the impact of the implementation to get the intervention (CAB LA + RPV LA) into routine care. As a result, the primary focus of this study is implementation. The secondary focus is on the clinical effectiveness.

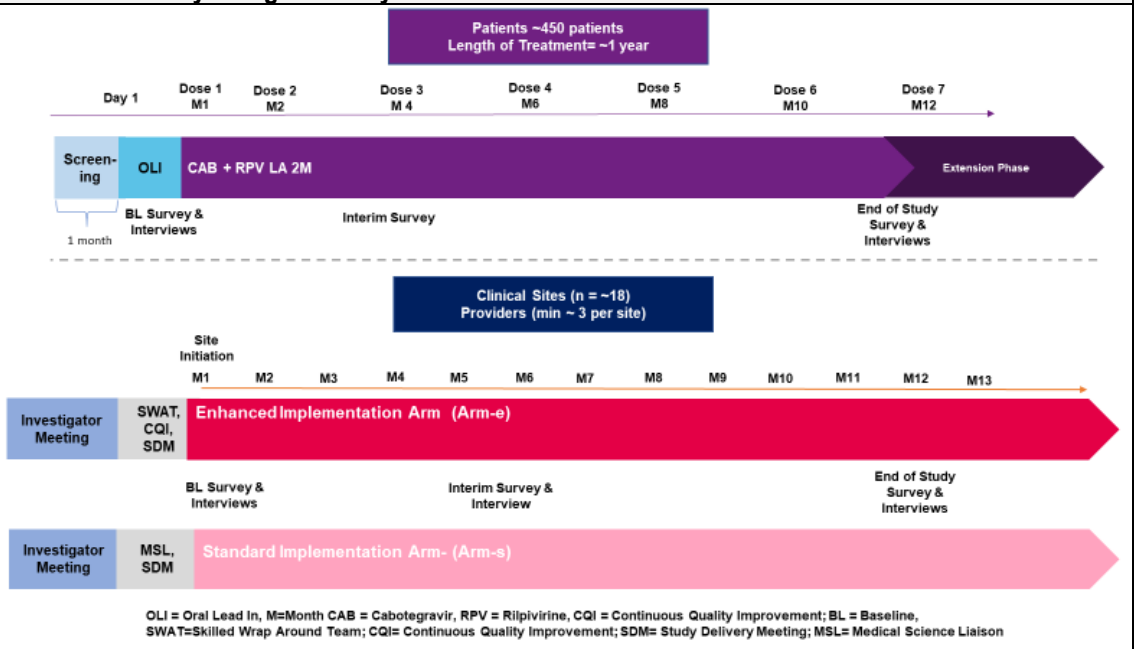
All patients who fulfill eligibility requirements will receive the study treatment of CAB LA + RPV LA and will begin oral therapy with CAB 30 mg + RPV 25 mg once daily for approximately one month to determine individual safety and tolerability prior to receiving CAB LA + RPV LA for an additional 11 months. Total patient study participant duration in the study is approximately 13 months including screening.

Patient participants in CARISEL who successfully complete the study (Dose 7), without meeting study-defined withdrawal criteria, will be given the option to continue to receive CAB LA + RPV LA, administered Q2M in the Extension Phase until the study treatment is either locally approved and commercially available (including through local public/government health sectors), the participant no longer derives clinical benefit, the participant meets a protocol-defined reason for discontinuation or until development of either CAB LA + RPV LA Q2M is terminated. Alternatively, participants can choose to complete study participation and enter the 52-week LTFU Phase of the study.

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 highly active antiretroviral therapy (HAART) for at least 52 weeks after the last dose of CAB LA and/or RPV LA.

There are two arms for the providers (arm-e and arm-s) which contain different levels and type of support for the implementation of the HIV Regimen. Cluster randomization will be used to randomize sites in each country to either arm-e or arm-s.

Overview of Study Design and Key Features



- N=450 patients; Open-label in respect to treatment; patients selected to CAB LA+RPV LA Interview or CAB LA + RPV LA Non-Interview based on stratification factors of gender, age, and race.
- 18 sites randomized to each of the implementation strategy arms, ARM-E or ARM-S

Design Features	• The proposed study is a cluster-randomized, implementation-effectiveness hybrid type III study to identify and evaluate strategies for successful implementation of the cabotegravir + rilpivirine long-acting injectable regimen in Europe. • The CARISEL study comprises of screening phase (up to 35 days prior to enrolment), Maintenance Phase from Day 1 to Month 12, including Oral Lead-in, long term follow-up (LTFU) phase, and extension phase. During screening phase all clinical and laboratory assessments of eligibility must be performed and reviewed. Participants may be re-screened once
Dosing	• Intervention Phase" Open-label in respect to treatment; • Site Randomization: Intervention Phase: Site Randomization 1:1 to ARM-E: ARM-S
Time & Events	• Refer to Appendix 1: Schedule of Activities
Treatment Assignment	• CAB LA+RPV LA (N=450)
Interim Analysis	• Interim analyses will be conducted at two timepoints: 1) when 50% of subjects have received their 3rd injection and 2) when 100% of subjects have received their 3rd injection. • The primary analysis will be conducted at Month 12

2.4. Statistical Hypotheses / Statistical Analyses

The hypotheses on the quantitative aspects of this study is that enhanced implementation strategy is superior than the standard implementation strategy in terms of mean staff study participant (SSP) AIM/IAM/FIM scores. i.e.,

- H_0: μ(enhanced) = μ(standard) vs. H_1: μ(enhanced) > μ(standard)

Further analysis details for this hypothesis will be covered in the Evidera SAP.

2.4.1. Sample Size Determination

The study size is based on practical considerations in terms of feasibility of enrolling an adequate number of sites on each implementation strategy balanced with the desire to have interventions tested across several types of investigative sites; as well as enrolling an adequate number of patient study participants in each site.

Approximately 24 sites (from feasibility process) will be selected from the feasibility process to achieve 18 sites randomly assigned to study implementation strategies and approximately 54 evaluable staff study participants for an estimated total of 27 evaluable study staff participants per implementation strategy group.

Assuming 10% screen failures, it is estimated that with 18 sites approximately 527 patient study participants will be screened to achieve 474 subjects enrolled and 450 evaluable patient study participants completing the study (assumes 5% of patient study participants would be non-evaluable) for an estimated total of 225 evaluable patient study participants per implementation strategy group.

2.4.1.1. Power to Show Superiority in mean SSP AIM/IAM/FIM scores

Table A shows preliminary AIM/IAM/FIM data from the ongoing U.S. implementation study CUSTOMIZE (209493).

Table A Staff Study Participants Scores at Month 4 in CUSTOMIZE (209493)

	N	Mean	SD	Median	Observed Range (min-max)	Floor n (%)	Ceiling n (%)	Skewness	Kurtosis
AIM Scale (Total Sample)	24	4.39	0.61	4.13	3.25-5.00	0 (0.0%)	11 (45.8%)	-0.16	-1.58
IAM Scale (Total Sample)	24	4.45	0.59	4.50	3.25-5.00	0 (0.0%)	12 (50.0%)	-0.34	-1.39
FIM Scale (Total Sample)	24	4.32	0.71	4.25	3.00-5.00	0 (0.0%)	11 (45.8%)	-0.47	-1.09

Based on these preliminary data from CUSTOMIZE study, and the given sample size (the number of study participants), the power to detect a difference of 0.5 between the implementation arms in terms of AIM, IAM and FIM in line with our primary hypothesis are shown in Table B.

Table B Power to Detect a 0.5 Difference in AIM/IAM/FIM

Endpoint	ARM-S	ARM-E	Delta	SD	Alpha	N(S)	N(E)	Power*
AIM	4.39	4.89	0.5	0.61	0.05	27	27	84%
						36	36	93%
IAM	4.45	4.95	0.5	0.59	0.05	27	27	86%
						36	36	94%
FIM	4.32	4.82	0.5	0.71	0.05	27	27	72%
						36	36	84%

*Power calculation using two-sided T-test assuming equal variance.

As shown in Table B, with 27 study staff participants (3 per site) surveyed on each arm, the study would have 72%-86% power to detect a 0.5 difference in FIM, AIM and IAM endpoints between ARM-E (Enhanced implementation strategy arm) and ARM-S (Standard implementation arm) assuming data from Table A (CUSTOMIZE study) for ARM-S.

And with 36 study staff participants (4 per site) surveyed on each arm, the study would have 84% - 94% power to detect a 0.5 difference in FIM, AIM and IAM endpoints between ARM-E and ARM-S.

2.4.1.2. Sample Size for Provider Population

An overall average number of 9 sites, per arm (18 sites), would produces a two-sided 95% confidence interval with a distance from the mean paired difference (e.g. site level mean change from baseline in AIM, IAM or FIM score) to the limits (half-width) that is equal to 0.497 when the estimated standard deviation of the paired differences is 1.0, across sites.

Table C Sensitivity Analysis for Sample Size versus Half-Width (Precision)- Two-Sided 95% Confidence Interval (For Number of Sites)

Sample Size	Actual Distance from Mean Difference to Limits (Precision)	
	SD=0.5	SD=1.0
10	0.358	0.715
11	0.336	0.672
12	0.318	0.635
13	0.302	0.604
14	0.289	0.577
15	0.277	0.554
16	0.266	0.533
17	0.257	0.514
18	0.249	0.497
19	0.241	0.482
20	0.234	0.468

A sample size of 27 providers, per arm, produces a two-sided 95% confidence interval with a distance from the mean paired difference to the limits (half-width) that is equal to 0.396 when the estimated standard deviation of the paired differences is 1.0.

Table D Sensitivity Analysis for Sample Size versus Half-Width (Precision)- Two-Sided 95% Confidence Interval (for Number of Providers)

Sample Size	Actual Distance from Mean Difference to Limits (Precision)	
	SD=0.5	SD=1.0
21	0.228	0.455
22	0.222	0.443
23	0.216	0.432
24	0.211	0.422
25	0.206	0.413
26	0.202	0.404
27	0.198	0.396
28	0.194	0.388
29	0.190	0.380
30	0.187	0.373

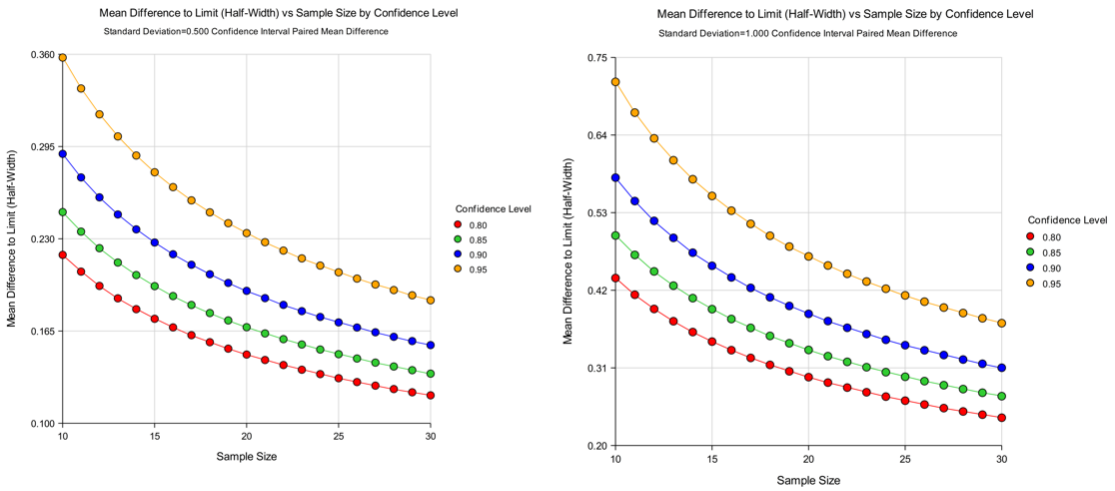


Figure A **Sensitivity Analysis for Sample Size versus Half-Width (Precision)- Two-Sided 95% Confidence Interval (for Sites and Providers)**

2.4.1.3. Sample Size for Patient Population

A sample size of 225 patient subjects per implementation strategy group produces a two-sided 95% confidence interval with a distance from the mean paired difference to the limits that is equal to 0.131 when the estimated standard deviation of the paired difference is 1.

Table E **Sensitivity Analysis for Sample Size versus Half-Width (Precision)- Two-Sided 95% Confidence Interval (for Patients)**

Sample Size	Actual Distance from Mean Difference to Limits (Precision)	
	SD=0.5	SD=1.0
100	0.099	0.198
125	0.089	0.177
150	0.081	0.161
175	0.075	0.149
200	0.070	0.139
225	0.066	0.131
250	0.062	0.125

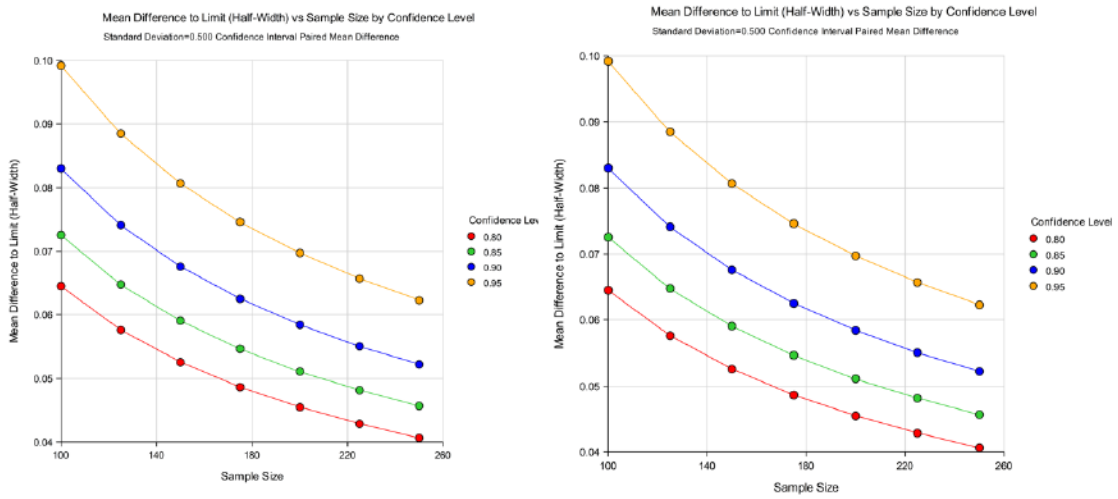


Figure B **Sensitivity Analysis for Sample Size versus Half-Width (Mean Diff to Limit) versus Sample Size - Patients (Multiple Confidence Levels)**

As explained in the protocol, launching CAB LA + RPV LA in the real world may present challenges that were not observed in a clinical trial setting. Therefore, in addition to the primary analyses which focuses on study staff participants data, statistical analyses of patient outcome endpoints will be performed to evaluate changes in study patients' satisfaction score results, to allow an informal comparison between the two implementation strategies.

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3. PLANNED ANALYSES

This RAP describes standard analyses that will be applied to descriptively summarize clinical adverse events, laboratory evaluations, virologic parameters and other clinical safety and efficacy outcomes.

Details pertaining to reporting of survey/interview data and health outcomes/effectiveness analyses will be described in a separate analysis plan provided by Evidera or other CRO partner under GSK's oversight.

At least three analyses will be conducted to evaluate primary and secondary objectives of the protocol; an interim analysis after 50% of subjects have received their 3rd injection, and interim analysis after 100% of subjects have received their 3rd injection, and finally the primary analysis at Month 12. Further data cuts and analyses may be conducted as necessary, in order to support for internal use and publications.

A final end-of-study (EOS) analysis will be conducted when all subjects have completed the study.

3.1. Interim Analyses

As mentioned previously, interim analyses will be performed when 50% and 100% of subjects have received their 3rd injection. No formal criteria for stopping or amending the study based on the interim analysis are envisioned. Further interim analyses may be planned for publication data.

3.2. Final Analyses

The planned Month 12 primary analysis will be performed after the completion of the following sequential steps:

- All participants have completed Month 12 of the study as defined in the protocol, including any required re-tests.
- All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.

4. ANALYSIS POPULATIONS

This RAP defines patient study participants in detail. Analysis populations that pertain to implementation science deliverables are documented in the Evidera SAP.

Population	Definition / Criteria	Analyses Evaluated
All Subjects Screened Population	• All participants who were screened for eligibility and inclusion in the study	• Patient Study Population
Enrolled Population	• All patient study participants who passed screening and entered the study.	• Patient Study Population
Safety	• All enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.	• Patient Study Population, Safety, Efficacy, Virology, Other Assessments
Long Term Follow-up Population	• All subjects receiving at least one dose of CAB LA and/or RPV LA who have discontinued CAB LA +RPV LA regimen and have at least one Long Term Follow-up phase clinic visit	• Efficacy, 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.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan [25NOV2020 v2.0].

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

A separate 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.

Protocol deviations related to the implementation process, and not the clinical conduct of the study will be reported separately. The identification and categorization of PDs as important may be different for implementation PDs vs those associated with the clinical conduct of the study.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions		
Data Displays for Reporting		
Description	**Order in TLF**	**Analysis**
CAB Oral +RPV Oral	1	OLI Safety
CAB LA +RPV LA (includes both QM and Q2M dosing)	1	Study Population, Efficacy, Safety

5.2. Baseline Definitions

For all endpoints 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.

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

5.3. Multicentre Studies

In this multicentre, European-based study, enrolment and demographics will be presented by investigator site.

Exploratory analyses will be considered only if applicable.

5.4. Examination of Covariates, Other Strata and Subgroups

5.4.1. Covariates and Other Strata

The list of covariates and other strata may be used in descriptive summaries and statistical analyses, some of which may also be used for subgroup analyses. Additional covariates and other strata of clinical interest may also be considered.

Category	Details
Covariates	Implementation strategy, Site, Country, Gender, Age Group, Race, CD4 Count

5.4.2. Examination of Subgroups

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

If the percentage of subjects is small within a particular subgroup, then the subgroup categories may be combined.

Subgroup	Categories
Implementation Strategy	• Standard • Enhanced
Site	18 European sites
Country	As collected
Gender	• Male • Female
Age	• ≥50 • <50
Race	• White • African Heritage • Asian • Other
CD4 Count	• <350 • ≥350

5.5. Other Considerations for Data Analyses and Data Handling Conventions

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

Section	Component
13.1	Appendix 1: Schedule of Activities
13.2	Appendix 2: Assessment Windows
13.3	Appendix 3: Study Phases
13.4	Appendix 4: Data Display Standards & Handling Conventions
13.5	Appendix 5: Derived and Transformed Data
13.6	Appendix 6: Reporting Standards for Missing Data
13.7	Appendix 7: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

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

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

For the two interim analyses based on subjects' 3rd injection data, study population tables and listings will be produced by GSK. Details of these Interim Analysis deliverables can be found in Appendix 12: List of Data Displays.

7. EFFICACY ANALYSES

Implementation Science/Health Outcomes endpoints will form the basis for the overall primary analysis of the study, and details of implementation science/health outcomes analyses are documented in a separate Evidera SAP. Clinical efficacy endpoints are evaluated as secondary objectives for this study.

Efficacy analyses will be performed at Month 12 and EOS. There will be no efficacy reported at the interim analyses.

7.1. Secondary Efficacy Analyses

7.1.1. Endpoint / Variables

- Proportion of participants with Plasma HIV-RNA < 50 copies/mL and plasma HIV-1 RNA ≥ 50 copies/mL as per Food and Drug Administration (FDA) Snapshot algorithm at Month 12 (Safety Population). See Appendix 8 for Snapshot Algorithm details.
- Participants with protocol-defined confirmed virologic failure (CVF) over time (Safety population)
- Incidence of treatment-emergent genotypic and phenotypic resistance to CAB and RPV in patient study participants with CVF (Safety population)

7.1.2. Population of Interest

The primary efficacy analyses will be based on the Safety population, unless otherwise specified. HIV-1 RNA summaries will also be reported for the Long-Term Follow-up Population.

7.1.3. Strategy for Intercurrent (Post-Randomization) Events

Participants with last available HIV-1 RNA measurement less than 50 copies/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 evaluable HIV-RNA data for the visit of interest or who change treatment not permitted per protocol before the analysis window are considered non-responders.

Participants with last available HIV-1 RNA measurement greater or equal to 50 copies/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 evaluable HIV-RNA data for the visit of interest and who discontinue treatment for reasons not related to adverse event while having HIV-1 RNA ≥50 copies/mL at time of discontinuation or who change study treatment not permitted per protocol before the analysis window are also classified as having HIV-RNA ≥50 copies/mL.

Missing viral load values for reasons related to COVID-19 issues (e.g. participant is unable to have viral load assessed due to barriers in attending the clinic during the pandemic or COVID-19 related adverse events leading to treatment discontinuation) will

be considered as random missingness and classified the same as all other missingness for the primary efficacy Snapshot analysis. A sensitivity analysis using a modified Snapshot which includes subcategories for Covid-19 related and Non-Covid-19 related missingness will also be performed to display the impact of Covid-19 intercurrent events on the study. See Appendix 8 for Modified Snapshot Algorithm details.

7.1.4. 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.

7.1.4.1. Statistical Methodology Specification

Endpoint / Variables
• Proportion of participants with plasma HIV-1 RNA < 50 c/mL at Month 12 using the FDA Snapshot algorithm (Safety population) • Proportion of participants with plasma HIV-1 RNA ≥50 c/mL at Month 12 using the FDA Snapshot algorithm (Safety population) • Proportion of participants with protocol-defined confirmed virologic failure (CVF) over time (Safety population) • Incidence of treatment-emergent genotypic and phenotypic resistance to CAB and RPV in patient study participants with CVF (Safety population)
Results Presentation
• The proportion of participants with HIV-1 RNA <50 c/mL, HIV-1 RNA ≥ 50c/mL, and with recorded CVF at each planned visit with corresponding 95% confidence intervals calculated using the Clopper-Pearson exact method. • Proportion of subjects with incidence of treatment-emergent genotypic and phenotypic resistance to CAB and RPV in patient study participants with CVF at each visit with corresponding 95% confidence intervals calculated using the Clopper-Pearson exact method. • Descriptive statistics for the nominal values and change from baseline values in CD4+ cell counts and the CD4/CD8 ratio.
Subgroup Analyses
• Summary of study outcomes will be repeated for subgroups of interest as specified in Section 5.4.2: Implementation strategy, Participant sex, age group (<50 vs ≥50), race (White, African Heritage, Asian, Other), and CD4 count (<350, ≥350). • The proportion of participants in each Snapshot study outcome category and sub-category will be summarized in which default sub-categories have been expanded to present Covid-19 vs. Non-Covid-19 related impact (as described in Appendix 8).

8. SAFETY ANALYSES

The safety analyses will be based on the Safety and Long Term Follow-up (LTFU) populations, unless otherwise specified.

For the interim analyses, adherence to dosing will be reported for the Safety population. For the Month 12 primary analysis, outputs will be presented for the Safety population in the Intervention Phase unless otherwise specified. For the EOS analysis, outputs will be presented for the Safety population in the Intervention and Extension phases as well as for the LTFU population in the LTFU phase.

For the Month 12 analysis, a set of separate outputs will also be presented for the oral lead-in period, including a summary of adverse events, SAEs, AEs leading to withdrawal, post-baseline emergent chemistry/haematology abnormalities, and subjects with hepatobiliary abnormality criteria.

8.1. Safety Endpoints

Secondary and tertiary safety endpoints for this study include:

- Percentage of injections occurring within target window from the target date.
- Incidence and severity of AEs and SAEs over time

r time

CCI [redacted]

8.2. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs), Drug-related AEs, AEs leading to withdrawal, AEs by maximum severity, COVID-19 AEs, 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.

CCI [redacted]

CCI

[redacted]

8.3. Adverse Events of Special Interest Analyses

A comprehensive list of MedDRA terms based on clinical review will be used to identify Adverse Events of Special Interest (AESI). Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional adverse events of special interest, therefore the list of terms to be used for each event of interest and the specific events of interest will be based on the safety review team (SRT) agreements in place at the time of reporting. The details of the current planned grouping, including Standardized MedDRA Query (SMQ) values (as applicable), and planned displays are provided in Appendix 9: AESI identification and Appendix 12: List of Data Displays.

8.4. Clinical Laboratory Analyses

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

8.5. Other Safety Analyses

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

9. PHARMACOKINETIC ANALYSES

9.1. Endpoint / Variables

9.1.1. Drug Concentration Measures

Available concentration-time data for CAB and RPV will be presented in listings as specified in Appendix 12: List of Data Displays and will be based on GSK Data Standards and statistical principles

10. VIROLOGY

10.1. Genotypic and Phenotypic Data

Available genotypic and phenotypic data at all collection timepoints will be presented by subject (separately for CVF and Non-CVF subjects), as specified in Appendix 12: List of Data Displays.

11. OTHER ANALYSES

11.1. Endpoint / Variables

11.1.1. Study Visit length

Study Visit Length will be reported for all analyses including interim analyses, Month 12, and EOS. Details of the planned displays for study visit length data are provided in Appendix 12 List of Data Displays and will be based on GSK Data Standard and statistical principle.

11.1.2. Pregnancy

Protocol amendment 02 allows for pregnant participants to remain on study and continue the use of study drug. Should any participants become pregnant while on study drug, pregnancy specific listings will be produced. Listings will include any adverse events, clinical lab results including HIV-1 RNA and plasma CAB & RPV concentrations, exposure to study drug during pregnancy, and pregnancy details including duration and outcomes reported by the participants including birth outcomes. Details of the planned displays are provided in Appendix 12

12. REFERENCES

GSK document number 2019N420690_01. A Phase IIIb, open-label, hybrid type III trial evaluating implementation strategies for long-acting cabotegravir plus long-acting rilpivirine every two months in HIV-1 infected, virologically suppressed adults in select European healthcare settings.

GSK document number 2019N420690_02. A Phase IIIb, open-label, hybrid type III trial evaluating implementation strategies for long-acting cabotegravir plus long-acting rilpivirine every two months in HIV-1 infected, virologically suppressed adults in select European healthcare settings.

Wensing AM, et al. 2019 update of the drug resistance mutations in HIV-1. *Topics in antiviral medicine.* 2019;27:111-121.

13. APPENDICES

13.1. Appendix 1: Schedule of Activities

The protocol also lists a schedule of activities for staff study participants (not listed here)

13.1.1. Protocol Defined Schedule of Events: Schedule of Activities for Patient Study Participants

Procedure	Screening[a] up to 35d	Intervention Period (Month)								Withdrawal[m]	Long Term Follow-up[n]
		Day 1	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10 [b]	Month 12 [b]		
		Oral Lead-in	Dose 1 (D1)	Dose 2 (D2)	Dose 3 (D3)	Dose 4 (D4)	Dose 5 (D5)	Dose 6 (D6)	Dose 7 (D7)		
Written Informed consent	X										
Eligibility Verification	X										
Demography	X										
Physical Exam	X										
Medical history	X										
Current medical conditions	X										
Center for Disease Control and Prevention (CDC) HIV-1 Classification	X										

Procedure	Screening[a] up to 35d	Intervention Period (Month)								Withdrawal[m]	Long Term Follow-up[n]
		Day 1	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10 [b]	Month 12 [b]		
		Oral Lead-in	Dose 1 (D1)	Dose 2 (D2)	Dose 3 (D3)	Dose 4 (D4)	Dose 5 (D5)	Dose 6 (D6)	Dose 7 (D7)		
Syphilis serology + reflex Rapid Plasma Reagin (RPR)	X										
CCI [redacted]											
Symptom Directed Physical Exam and Medical Assessment[c]		X	X		X		X		X	X	X
HIV-associated Conditions, AE and serious adverse event (SAE) Assessments[d], Con Meds	X	X	X		X		X		X	X	X
Vital Signs (blood pressure [BP], heart rate [HR])[e]	X	X	X		X		X		X	X	
Weight, Height & body mass index (BMI)[f]	X	X	X		X		X		X	X	
Clinical Chemistry, Hematology and other Tests[o]	X	X	X	X	X		X		X	X	X

Procedure	Screening[a] up to 35d	Intervention Period (Month)								Withdrawal[m]	Long Term Follow-up[n]
		Day 1	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10[b]	Month 12[b]		
		Oral Lead-in	Dose 1 (D1)	Dose 2 (D2)	Dose 3 (D3)	Dose 4 (D4)	Dose 5 (D5)	Dose 6 (D6)	Dose 7 (D7)		
HIV-1 RNA and plasma sample for storage[h]	X	X	X	X	X		X		X	X	X
CD4+ count	X	X	X	X	X		X		X	X	X
CD8+ cell count (will be reported at Baseline and Month 12)		X							X		
Urinalysis	X									X	X
Hepatitis Serology[q]	X										
Whole Blood PBMC[p]		X								X	
Prothrombin time (PT)/ partial thromboplastin time (PTT)/international normalized ratio (INR)	X									X	X
Pregnancy Testing Urine (U) or Serum[g]	U	U	U	U	U	U	U	U	U	U	U
Notification of Interview[t]		X									

Procedure	Screening[a] up to 35d	Intervention Period (Month)								Withdrawal[m]	Long Term Follow-up[n]
		Day 1	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10 [b]	Month 12 [b]		
		Oral Lead-in	Dose 1 (D1)	Dose 2 (D2)	Dose 3 (D3)	Dose 4 (D4)	Dose 5 (D5)	Dose 6 (D6)	Dose 7 (D7)		
Oral CAB + RPV Medication Dispensation		X									
CAB LA + RPV LA IM Treatment Administration[i]			X	X	X	X	X	X	X		
Participant Visit Reminder Contact	X	X	X	X	X	X	X	X			
Participant Contact Detail Confirmation	X	X	X	X	X	X	X	X			
Patient Toolkit[s]		X	X	X	X	X					
Record Visit Length[j]			X	X		X	X				
Contraception Counseling[u]										X	X
HAART dispensation[v]										X	X
Patient Questionnaires[k]			X		X				X		
Selected Patient Interviews[l]		X							X		

Procedure	Screening[a] up to 35d	Intervention Period (Month)								Withdrawal[m]	Long Term Follow-up[n]
		Day 1	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10 [b]	Month 12 [b]		
		Oral Lead-in	Dose 1 (D1)	Dose 2 (D2)	Dose 3 (D3)	Dose 4 (D4)	Dose 5 (D5)	Dose 6 (D6)	Dose 7 (D7)		
HIV and patient satisfaction (HIVTSQs)		X_r	X		X				X		
HIVTSQc									X		
Preference Question									X		

a) A screening visit will be conducted within 35 days of Day 1. However, it is preferred for Day 1 to be conducted as soon as practical after all screening results are available.

b) Continue this pattern for visits for the remainder of the study if needed, until CAB LA + RPV LA is locally approved and available. For example, Dose 8 will be conducted as per Dose 6, Dose 9 will be conducted as per Dose 7, Dose 10 will be conducted as per Dose 6 and so on. The exception to this pattern is that no questionnaires, study visit length collection, or patient interviews will be conducted after Dose 7 visit. See protocol Section 6.8.

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) unless abnormalities are observed. Medical assessments include any decisions the study staff must make for participant management.

d) AE and SAEs will not be proactively assessed at M 2, M 6 and M 10. However, all AEs and SAEs reported by study participants **must** be recorded in eCRF at all visits and reported within required timelines as per protocol Section 8.5.1 .

e) Measure vital signs after about 5 minutes of rest in a semi-supine position.

f) Height is collected at screening only.

g) A (-) urine pregnancy test is required prior to oral lead-in at day 1 and 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. A Serum pregnancy test should be performed at any time pregnancy is suspected by the Investigator. Pregnant participants who remain in the study do not need pregnancy testing for the duration of the pregnancy See Protocol Appendix 15: Information and Guidance for Managing Pregnant Participants.

h) Plasma for storage samples are collected for possible future analyses. Can be used for back-up in cases of loss/damage in transit, geno/pheno analyses for virologic failures. Only for women becoming pregnant and continuing on CAB LA+RPV LA as if pregnant a plasma HIV-1 RNA test and plasma for storage samples at Month 6 and Month 10 visits are required.

i) All injections are 1 x CAB LA 600 mg IM + 1 x RPV LA 900 mg IM. Doses 1 and 2 are one month apart. Subsequent injections beginning at Dose 3 are every two months. The 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 on the same date of the month as determined by IM Dose 1 visit date, this is the Target Date; where possible, this first injection should be performed within 2 hours of taking the last oral regimen dose. For Dose 2, a dosing window of +0 / -7 days from the target visit date is stipulated. A (+ or -) 7-day window from the target date visit is stipulated for IM dosing beginning at Dose 3. All decisions regarding dose interruption/ resumption must be discussed with the Medical Monitor in advance.**

j) Length of study visit from arrival until departure from clinic will be evaluated. Participant's time of arrival, actual start time of the appointment, and actual end time of the appointment will be collected in the eCRF.

k) Questionnaires should be completed before receiving the injections.

l) Interviews should be conducted before the PSP receives Dose 1 and within 4 weeks of receiving Dose 7. Interviews may be done in person, virtually, or by phone. A minimum of 6 patients per site will be selected for interviews.

m) Withdrawal 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.

n) Participants receiving one or more injections with CAB LA and/or RPV LA will be assessed with clinic visits at months 3, 6, 9 and 12 during the Long-Term Follow-Up phase. The start of the 52-week follow-up period begins the day of the last CAB LA and/or RPV LA dose.

o) See protocol Section 8.4.4 for list of tests

p) Whole blood/PBMC collection samples may be used for virologic analyses. PBMCs will be collected at baseline Day1 and at Withdrawal.

q) Hepatitis B (HBsAg), Anti-HBc, Anti-HBsAg, Hepatitis C (anti-HCVAb). A (+) anti-HCVAb will be followed by a confirmatory nucleic acid test for HCV RNA. HBV DNA will only be performed for participants with a (+) anti-HBc and (-) HBsAg and (-) anti-HBs (past and/or current evidence).

r) Administer HIVTSQs in Day 1 before OLI initiation.

s) At a minimum the study toolkit will be offered at the time pointed noted in the protocol Table 6. However, the toolkit items are intended to be used throughout the study.

t) Notification of interviews may occur between Day 1 or during the 7 days after Day 1.

u) 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.

v) Investigators must discuss choice of HAART regimen and timing of initiation with the Medical Monitor before initiating.

13.2. Appendix 2: Assessment Windows

13.2.1. Definitions of Assessment Windows for Analyses

Laboratory data, vital signs, adverse events, 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.

Prior to visit slotting, assessments are first assigned to a study phase (Screening, Intervention Phase, Extension, or Long Term Follow Up) as defined in Appendix 3.

According to the protocol, the nominal target study visit date will be based on the first injection, the Month 1 date. For instance, if Month 1 occurred on July 7th, all subsequent visits are expected to occur on the 7th of each month such that subsequent visits will be August 7th, September 7th, October 7th, etc. Since there are not >28 days in every month of the year, if the Month 1 injection occurred on the 29th, 30th, or 31st of the month, then the target study visit date for the remainder of the visits will be the 28th of the month.

The nominal target study visit day is derived as

- **M1 Target Day** = Date of Actual M1 Injection Visit Date – Date of First Oral lead-in Dose + 1, if subject receives M1 injection; else M1 Target Day = 30.
- **Mx Target Day** = Mx Nominal Target Study Visit Date – Date of First Oral lead-in Dose + 1, for x=2,3, …

Assessment windows will be derived based on the midpoint between two consecutive planned target study visit dates. For the Snapshot efficacy data, the same approach will be used, except for Month 12, which will use a +/- 6-week window around the projected target study visit date at Month 12.

For parameters which are not scheduled to be assessed at 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 in summaries of worst-case values across visit (e.g. during the intervention phase) and in data listings, as well any algorithms that make use of additional data (e.g., Snapshot).

For participants transitioning to commercial product at EOS, the safety follow-up visit date will be the last date referenced and serve as the ending timepoint for the final visit window.

Table 1 Assessment Windows for Screening, Intervention and Extension Phase Data (Excluding HIV-1 RNA)

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	Ending Timepoint	
Day of earliest record	Assessment Study Day ≤1		Screening
For subjects discontinuing prior to receiving first injection:			
30	Assessment Study Day = 2	Study Day of Last CAB/RPV Oral Dose+1	Month 1
	Assessment Study Day > (Study Day of Last CAB/RPV Oral Lead-in Dose +1)		Follow-up
For subjects receiving first injection:			
Day of First Injection	Study Day = 2	M1 target day + *floor* [(M2 target day – M1 target day)/2]	Month 1
M2 Target Day	M1 target day + *floor* [(M2 target day – M1 target day)/2] + 1	M2 target day + *floor* [(M4 target day – M2 target day)/2]	Month 2
M4 Target Day	M2 target day + *floor* [(M4 target day – M2 target day)/2] + 1	M4 target day + *floor* [(M6 target day – M4 target day)/2]	Month 4
M6 Target Day	M4 target day + *floor* [(M6 target day – M4 target day)/2] + 1	M6 target day + *floor* [(M8 target day – M6 target day)/2]	Month 6
M8 Target Day	M6 target day + *floor* [(M8 target day – M6 target day)/2] + 1	M8 target day + *floor* [(M12 target day – M8 target day)/2]	Month 8
M10 Target Day	M8 target day + *floor* [(M10 target day – M8 target day)/2] + 1	M10 target day + *floor* [(M12 target day – M10 target day)/2]	Month 10
M12 Target Day	M10 target day + *floor* [(M12 target day – M10 target day)/2] + 1	M12 target day + *floor* [(M14 target day – M12 target day)/2]	Month 12
M***x*** Target Day	M(***x-2)*** target day - *floor* [(M***x*** target day – M(***x-2***) target day)/2] + 1	M***x*** target day + *floor* [(M(***x+2***) target day – M***x*** target day)/2]	Month ***x*** For ***x*** = 14, 16, etc.
For subjects who permanently discontinue study treatment:			
	Assessment Study Day > Min (LTFU ART Start Date, Max (Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Study Day of Last CAB + RPV Injection + 63))		Follow-up

Table 2 Assessment Windows for Screening and Intervention Phase HIV-1 RNA Data

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	Ending Timepoint	
Day of earliest record	Assessment Study Day ≤1		Screening
	For subjects discontinuing prior to receiving first injection:		
28	Assessment Study Day = 2	Study Day of Last Oral Lead-in Dose +1	Month 1
	Assessment Study Day > (Study Day of Last CAB/RPV Oral Lead-in Dose +1)		Follow-up
	For subjects receiving first injection:		
Date of First Injection	Study Day = 2	M1 target day + *floor* [(M2 target day – M1 target day)/2]	Month 1
M2 Target Day	M1 target day + *floor* [(M2 target day – M1 target day)/2] +1	M2 target day + *floor* [(M4 target day – M2 target day)/2]	Month 2
M4 Target Day	M2 target day + *floor* [(M4 target day – M2 target day)/2] + 1	M4 target day + *floor* [(M6 target day – M4 target day)/2]	Month 4
M6 Target Day	M4 target day + *floor* [(M6 target day – M4 target day + 1	M6 target day + *floor* [(M8 target day – M6 target day)/2]	Month 6
M8 Target Day	M6 target day + *floor* [(M8 target day – M6 target day)/2] + 1	M8 target day + *floor* [(M10 target day – M8 target day)/2]	Month 8
M10 Target Day	M8 target day + *floor* [(M10 target day – M8 target day)/2] + 1	M12 target day – 43	Month 10
M12 Target Day	M12 target day - 42	M12 target day + 42	Month 12
M14 Target Day	Assessment Study Day > M12 target day + 42		Month 14
For subjects who permanently discontinue study treatment during the Intervention Phase:			
	Assessment Study Day > Min (LTFU ART Start Date, Max (Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1, Study Day of Last CAB + RPV Injection + 63))		Follow-up

Table 3 Assessment Windows for Extension Phase HIV-1 RNA Data

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	Ending Timepoint	
M14 Target Day	Study Day of Nominal Week 14 Visit	M14 target day - *floor* [(M16 target day – M14 target day)/2]	Month 14
M16 Target Day	M14 target day - *floor* [(M16 target day – M14 target day)/2] + 1	M16 target day + *floor* [(M18 target day – M16 target day)/2]	Month 16
M***x*** Target Day	M(***x-2***) target day - *floor* [(M***x*** target day – M(***x-2***) target day)/2] + 1	M***x*** target day + *floor* [(M(***x+2***) target day – M***x*** target day)/2]	Month ***x*** For ***x*** =18, 20 etc.
For subjects who permanently discontinue study treatment during the Extension Phase:			
	Assessment Study Day > Min (LTFU ART Start Date, Max (Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1, Study Day of Last CAB + RPV Injection + 63))		Follow-up

Table 4 Assessment Windows for Study Visit Length Data (Intervention and Extension Phase)

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	Ending Timepoint	
Study Day of Actual M1 Injection	Study Day of Actual M1 Injection		Month 1
Study Day of Actual M2 Injection	Study Day of Actual M2 Injection		Month 2
Study Day of Actual M6 Injection	Study Day of Actual M6 Injection		Month 6
Study Day of Actual M8 Injection	Study Day of Actual M8 Injection		Month 8
Study Day of Actual M***x*** Injection	Study Day of Actual M***x*** Injection		Month ***x*** For ***x***=17, 20, etc.
	If none of the above, then Analysis Timepoint = Other		

Table 5 Assessment Windows for Summaries of Long-Term Follow-up Phase Data from Subjects who Received at Least One Injection of CAB+RPV and Permanently Discontinued from the Study

Day of Assessment	Assessment Window	Target LTFU Study Day of Window
1 ≤ 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, 21	30*m

- LTFU Study Day is defined in 13.5.1

13.2.2. Assessment Windows for PK Concentration Data

PK data will be presented in data listings according to planned nominal visits (i.e. as collected in the eCRF), without additional assignment to assessment windows.

13.2.3. Assessment Windows for Pregnancy Data

Pregnancy visits will be assigned in accordance with the derivations listed in Table 1 to Table 5 as appropriate for the relevant data. Post-partum visit data will be labelled based on the nominal timepoint

13.3. Appendix 3: Study Phases

13.3.1. Study Phases

Participants are considered to have entered the Extension phase if they have a Month 14 visit. They are considered to enter the LTFU period if they have a post-treatment, non-bridging ART start date or LTFU visit entered in the CRF, including LTFU withdrawal.

Participants are considered to have completed the Intervention Phase upon successful completion of the Month 12 visit without discontinuing from study treatment. Extension Phase completion is defined as successful transition to commercial product whenever it becomes available by attending a Safety Follow-up visit and not discontinuing treatment.

Table 6 Participant Phase Entry and Conclusion Windows

Phase	Qualifying Entry Timepoint	Qualifying Conclusion Timepoint
Intervention Phase	First CAB + RPV dose date	Month 14 visit date; or Safety Follow-up visit date (if transitioned to commercial product); or LTFU ART start date (if discontinued from treatment after receiving at least one dose of CAB/RPV LA)
Extension Phase	Month 14 visit date	Safety Follow-up visit date (if transitioned to commercial product); or LTFU ART start date (if discontinued from treatment after receiving at least one dose of CAB/RPV LA)
LTFU Phase	LTFU ART start date or LTFU Visit date existence	LTFU Month 12 visit date

AEs will be assigned to study phases as defined in Table 7. Laboratory data (efficacy, safety, and virology), HIV associated Conditions, health outcomes assessments, and vital signs will be assigned to study phases as defined in Table 8.

Assessments/events are assigned to study phases sequentially, starting from the top of each table.

Table 7 Study Phases for AEs

Study Phase	Definition
Screen	Date < Intervention Phase Treatment Start Date
Intervention Phase	**For subjects continuing into the Extension Phase:** Intervention Phase Treatment Start Date ≤ Date < Date of Nominal Month 14 Visit **For subjects not continuing into the Extension Phase:** Intervention Phase Treatment Start Date ≤ Date < LTFU ART Start Date[a]

Study Phase	Definition
	For subjects transitioning to commercial product without discontinuing or entering Extension: Intervention Phase Treatment Start Date ≤ Date ≤ Safety Follow-up visit date For AEs leading to treatment withdrawal with start date equal to the LTFU ART Start Date, Intervention Phase instead of Long-term Follow-up Phase will be assigned.
Extension Phase	**For subjects transitioning to commercial product:** Date of Nominal Month 14 Injection ≤ Date ≤ Safety Follow-up visit date **For subjects not transitioning to commercial product:** Date of Nominal Month 14 Injection ≤ Date < LTFU ART Start Date [a] For AEs leading to treatment withdrawal with start date equal to the LTFU ART Start Date, Extension Phase instead of Long-Term Follow-up Phase will be assigned.
Long Term Follow-Up	**For subjects who receive at least one CAB/RPV injection and permanently discontinue study treatment:** AE Start Date ≥ LTFU ART Start Date
AEs with completely missing start date: • If AE end date is ≤ Intervention Phase Treatment Start Date, then assign to Screening Phase; • Else if AE end date is completely missing or Intervention Phase Treatment Start Date < AE end date ≤ Date of Nominal Month 14 Injection, then assign to Intervention Phase; • Else if AE end date > Date of Nominal Month 14 Injection, then assign to Extension Phase.	

- Date=AE Start Date
- [a] If participants have missing LFTU ART start date, only the lower bound will be considered in the derivation.

Table 8 Study Phases for Laboratory, Vital Signs, HIV-1 Associated Conditions, and Protocol Deviation Data

Study Phase	Definition
Screen	Date ≤ Study Treatment Start Date
Intervention Phase	**For subjects continuing into the Extension Phase:** Intervention Phase Treatment Start Date < Date < Date of Nominal Month 14 Visit **For subjects not continuing into the Extension Phase:** Intervention Phase Treatment Start Date < Date ≤ LTFU ART Start Date [a] **For subjects transitioning to commercial product without discontinuing or entering Extension:** Intervention Phase Treatment Start Date < Date ≤ Safety Follow-up visit date
Extension Phase	**For subjects continuing into Extension Phase:** Date of Nominal Month 14 Visit ≤ Date ≤ LTFU ART Start Date [a] or Safety Follow-up visit date
Long Term Follow-Up	**For subjects who receive at least one CAB/RPV injection and permanently discontinue study treatment:** Assessment Date > LTFU ART Start Date

- Date = start or assessment date
- [a] If participants have missing LFTU ART start date, only the lower bound will be considered in the derivation.

Study phase of discontinuation will be determined according to Table 9.

Table 9 Study Phases for Study Conclusion/IP Discontinuation

Study Phase	Definition
Intervention Phase	Discontinuation Date is not missing, and no assessments collected at any extension phase nominal visits (i.e. Month 14, Month 16, Month 18 etc.).
Extension Phase	Discontinuation Date is not missing, and assessments collected at any extension phase nominal visits (i.e. Month 14, Month 16, Month 18 etc.).

- Discontinuation Date = date of failure to complete study/date of IP discontinuation

Medication use will be classified as prior and concomitant with study treatment according to Table 10, noting that a medication can be assigned as "taken" during more than one study phase.

Table 10 Study Phases for Non-ART Medications/ART Medications

	Definition
Prior	Medication Taken < Intervention Treatment Start Date
Concomitant during Intervention Phase	**For subjects continuing into Extension Phase:** Intervention Treatment Start Date[a] ≤ Medication Taken < Date of Nominal Month 14 Visit **For subjects not continuing into Extension Phase[b]:** Intervention Treatment Start Date[a] ≤ Medication Taken < LTFU ART Start Date **For subjects transitioning to commercial product without discontinuing or entering Extension:** Intervention Phase Treatment Start Date ≤ Medication Taken ≤ Safety Follow-up visit date
Concomitant during Extension Phase	**For subjects transitioning to commercial product:** Date of Nominal Month 14 Injection ≤ Medication Taken ≤ Safety Follow-up visit date **For subjects not transitioning to commercial product:** Date of Nominal Month 14 Injection ≤ 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:** Medication Taken ≥ LTFU ART Start Date

NOTES:

- Please refer to Appendix 6: 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.

a. The ART medication stopped on start date of Intervention treatment will be considered a prior medication and will not be considered concomitant during the Intervention phase. If the stop date of ART medication is completely missing and this medication is recorded in eCRF as prior, it will be considered a prior medication and will not be considered concomitant during the intervention phase.

b. If subjects have missing LFTU ART start date, only the lower bound will be considered in the derivation.

13.3.2. Treatment State

Within each study phase (based on assignment of study phase described in Section 13.3.1), only those events/assessments which occur within the ranges shown in Table 11 will be considered 'on-treatment' for the given phase. No treatment states will be assigned to medications.

For adverse events, partial AE start date will use imputation as described in 13.6.2.1.

Table 11 Treatment State within Study Phases

Study Phase	State	Definition
Screen	Pre-Treatment	All assessments/events within phase
Intervention/Extension	On-treatment	Date ≤ max (Date of Last CAB LA +RPV LA IM Dose + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1)
	Post-Treatment	Date > max (Date of Last CAB LA +RPV LA IM Dose + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1)
Long Term Follow-Up	Post-Treatment	All assessments/events within phase

NOTES:

- Date = Assessment/Start Date

a. Treatment State is determined after data has been assigned to the study phases as defined in Section 13.3.1.

b. Last injection and/or last dose of oral study treatment (CAB+RPV or SOC bridging) are only applied to participants who permanently discontinued the study treatment. The assessments for participants who did not permanently discontinue the study treatment will be considered 'On-treatment'. For participants continuing into extension phase, all data assigned to intervention phase per Section 13.3.1 will be considered 'On-treatment'.

13.3.3. Oral Lead-in Period

Certain displays will be produced for data collected or events occurring during the oral-lead-in period as defined in Table 12 and Table 13.

Table 12 Oral Lead-in Period for AEs

Study Period	Date Range
Oral Lead-in	**For participants receiving at least one Injection:** Intervention Treatment Start Date ≤ Date [a] < Date of First IM Injection **For participants withdrawing prior to first Injection:** Date ≥ Intervention Treatment Start Date Note that the oral lead-in period is only applicable to the participants who received at least one dose of study treatment during the oral lead-in period in the study. Oral lead-in period is within the intervention phase.

[a] AEs with completely missing start date which have been assigned to the Intervention Phase based on Table 7 will not be assigned to the Oral Lead-in Period.

NOTES:

- Date = AE Start date

Table 13 Oral Lead-in Period for Laboratory Data

Period	Date Range
Oral Lead-in	**For participants receiving at least one Injection:** Intervention Treatment Start Date < Date ≤ Date of First IM Injection **For participants withdrawing prior to first Injection:** Date > Intervention Treatment Start Date Note that the oral lead-in period is only applicable to the participants who received at least one dose of study treatment during the oral lead-in period in the study. Oral lead-in period is within the intervention phase.

NOTES:

- Date = Date of assessment

13.4. Appendix 4: Data Display Standards & Handling Conventions

13.4.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	us1salx00259
HARP Compound	\ARPROD\GSK1265744\mid213199\interim_01 \ARPROD\GSK1265744\mid213199\interim_02 \ARPROD\GSK1265744\mid213199\primary_01
Analysis Datasets	
• Analysis datasets will be created for the interim analyses according to SI data standards. • Analysis datasets will be created for the Month 12 reporting effort according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.1).	
Generation of RTF Files	
• RTF files will be generated for all reporting efforts described in the RAP.	

13.4.2. Reporting Standards

General

• The current GSK Statistical Display Standards in the GSK Standards Library (IDSL) will be applied for reporting, unless otherwise stated (Library 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 Statistical Display 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 GSK Standard Statistical Display 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 GSK Standard Statistical Display Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the participant's listings.

Unscheduled Visits	
• Unscheduled visits will be assigned to an analysis visit using the all-inclusive windows defined in Section 13.2. • However, data summaries will only report visits that are planned assessment time points for each parameter (according to the Schedule of Activities in Section 13.1.1). • Evaluable assessments at unscheduled visits will be used when categorizing values across visits, such as 'maximum grade during the intervention phase' or 'at any time post-baseline', and for any algorithm that has specific rules for which observation to use (e.g. snapshot algorithm or CVF identification).	
Descriptive Summary Statistics	
Continuous Data	Refer to GSK Standard Statistical Display Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to GSK Standard Statistical Display Principals 7.01 to 7.13.	

13.4.3. Reporting Standards for Pharmacokinetic Data

Pharmacokinetic Concentration Data	
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to the GSK Standard PK Display Standard. Refer to the GSK Standard Statistical Display Principle 6.06.1. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.

13.5. Appendix 5: Derived and Transformed Data

13.5.1. General

Multiple Measurements at One Analysis Time Point
• If there are two values within a time window (as per Section 13.2.1) the value closest to the target day for that window will be used. If values are the same distance from the target, then the mean (geometric mean for HIV-1 RNA, arithmetic mean for all other measurement) will be taken. • Assessments not chosen for use in summary statistics by this algorithm will still appear in the associated listings. • All applicable valid assessments, irrespective of proximity to the target study day, will be used when categorizing values across visits, such as 'maximum grade during the intervention phase' or 'at any time post-baseline', and for any algorithm that has specific rules for which observation to use (e.g. snapshot algorithm, LOCF or CVF identification). • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of "Any visit post-baseline" row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Treatment Start Date
• Intervention Phase Treatment Start Date = Earliest date of CAB + RPV oral lead-in entered in the IP exposure eCRF form
Nominal Month 14 Visit Date
• For participants who received Month 14 injection, the nominal Month 14 visit date is defined by the Month 14 injection date. • Otherwise, nominal Month 14 visit date is defined by the date of latest Month 14 assessment. • For participants who continued into Extension Phase but missed the Month 14 visit, the nominal Month 14 visit date is defined by the last contact date prior to the date of the first nominal extension phase visit (i.e. Month 16, Month 18, etc.).
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 Intervention Phase treatment start date as follows:
  ○ If date of event ≥ start date of study treatment, then
  ▪ Study Day = Date of Event - Intervention Phase Treatment Start Date +1
  ○ If date of event < start date of study treatment, then
  ▪ Study Day = Date of Event - Intervention Phase Treatment Start Date
• Note that the start date of intervention phase study treatment is 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
• Participants are considered to have entered LTFU if they have a post-treatment, non-bridging ART medication start date or a LTFU visit entered in the CRF. • 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. min(LTFU ART Start Date, max(Last IM Injection Date, Last Oral Bridging End Date)] as follows: o If the date of event falls in Long-term Follow up phase, then ▪ LTFU Study Day = Date of event - min(LTFU ART Start Date, max(Last IM Injection Date, Last Oral Bridging End Date)) + 1
Study Treatment
• Refers to CAB+RPV oral lead-in, CAB + RPV oral bridging, SOC bridging, CAB LA + RPV LA
Change from Baseline
• Post-Dose Visit Value – Baseline o Unless otherwise specified, the baseline definitions specified in Section 5.2 will be used for derivations for endpoints / parameters.

13.5.2. Study Population

Demographics
Age
• Age, in whole years, will be calculated with respect to the subject's Screening 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
• 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 DNA test result below level of detection and 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.
Adherence to CAB/RPV Injection Schedule
• Timeliness of Injections relative to Date of Projected Dosing Visits are assessed by using "actual injection visit date - projected visit date from first injection". The injections of interest in adherence

Demographics

analysis are those after first injection at Month 1. (. 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 2 ml due to a dosing error, but this participant returns one week later for the remaining 1 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 categories of Timeliness of Injections relative to Date of Projected Dosing Visits are listed below:
  - < -14 days
  - -14 to - 8 days
  - -7 to 1
  - 0
  - 1 to 7 days
  - 8 to 14 days
  - >14 days
  - Missed Injection without Oral Bridging (COVID-19 related)
  - Missed Injection without Oral Bridging (Non COVID-19 related)
  - Missed Injection with Oral Bridging (COVID-19 related)
  - Missed Injection with Oral Bridging (non COVID-19 related)
  - Missed Injection with subsequent SOC ART Initiation
- The following categories surrounding out of window (OOW) visits will also be calculated separately for participants at each visit.
  - Oral Bridging without a Missed Injection
  - OOW Injection with Oral Bridging (non-Covid-19 related)
  - OOW Injection with Oral Bridging (Covid-19 related)
  - OOW Injection without Oral Bridging (Covid-19 related)
- Injection visits are expected bi-monthly after an initial Month 1 Q4W injection from Month 2 until the nominal month of a participant's last injection visit during the phase(s) of interest. For example:
  - If a participant discontinues study treatment with last injection visit occurring at nominal visit Month 6, then injection visits are expected at Month 1, Month 2, Month 4, and Month 6.
- Expected injection visits will include all treatment visits (not LTFU) where an assessment was recorded regardless of whether the injection took place, including visits where treatment was discontinued.
- Missed injections with subsequent LTFU SOC ART Initiation are not counted in 'Missed Injection without Oral Bridging' categories. Missed injections will be slotted to this category if LTFU SOC ART is initiated within 30 days of the missed injection.
- Out of Window injections are determined based on criteria listed in protocol Section 4.3.3.
- Covid-19 relatedness is determined as follows:
  - As labelled in concomitant medication or exposure as Oral Bridging due to Covid-19
  - As indicated by Covid-19 protocol deviations that occur on the impacted visit date

13.5.3. Efficacy

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 2 and Table 3) is typically determined by the last available HIV-1 RNA measurement in that window while the participant is On-treatment in the Intervention Phase (as assigned based on Section 13.3). • When no HIV-1 RNA data is available within a window, a participant cannot be assigned to the category of 'HIV-1 RNA < 50 c/mL'. Depending on the reason for lack of data, the participant will be classified as 'HIV-1 RNA ≥ 50 c/mL' or reported as 'No Virologic Data at Week X'; in the latter case, the algorithm further classifies the nature of the missing data. Typically, a participant withdrawn (i) due to AE or, (ii) for another reason yet was suppressed at the time, will be counted as 'No Virologic Data at Week X'. Should a participant withdraw for reasons other than AE and was not suppressed at the time, they will be categorized as 'HIV-1 RNA ≥ 50 c/mL'. • Full details of the algorithm, including the handling of special cases, are included in Appendix 8: Snapshot Algorithm Details.
Plasma HIV-1 RNA
• 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.
Confirmed Virologic Failure (CVF)
• For the purposes of clinical management in this study, CVF is defined as: ○ Rebound as indicated by two consecutive plasma HIV-1 RNA levels ≥ 200 c/mL. • The CVF definition is provided in the protocol Section 7.1.7 • Only plasma HIV-1 RNA values determined by the central laboratory will be used to assess virologic failure.
CDC Classification for HIV-1 Infection (2014)
• CDC HIV-1 Classification at Baseline is collected in eCRF and no derivation with be performed programmatically for analysis purposes. Please refer to study protocol for detail description of CDC HIV-1 Classification.

13.5.4. 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 10.2. • If a grade value is expected per DAIDS but is missing in the eCRF, then the missing grade will be given an ordinal grade value of -1 for determining the maximum grade within and across preferred terms. For example:

Adverse Events
• if a participant has two separate instances of the same preferred term, one with grade 2 and one with missing grade, then the maximum grade for the preferred term will be set to grade 2. • if a participant reports two different AE preferred terms overall, one with grade 1 and one with missing grade (where a DAIDS grade is expected), then the maximum grade across preferred terms (i.e. in the ANY EVENT row) will be set to grade 1. • If a participant reports only one AE overall and this has a missing grade (where a DAIDS grade is expected), then this will be presented under a grade = missing category
Days since First Dose (Days)
• AE Start Date – Intervention Phase Treatment Start Date + 1
Days since Last Dose (Days)
• AE Start Date – Date of Last Dose of Study Treatment (Oral CAB+RPV, SOC bridging, CAB/RPV IM Injection) prior to/on the Start Date of AE + 1
Days since Phase Start

• For AEs in Intervention/Extension Phase:
  o AE Start Date - Intervention Treatment Start Date + 1
• For AEs in Long-term Follow-up Phase:
  o AE Start Date – LTFU ART Start Date

Duration (Days)
• AE Resolution Date – AE Start Date + 1
Drug-related
• If relationship is marked 'YES' on Inform/eCRF • Injection site reactions will be considered as drug-related if the relationship to study drug value is missing in the eCRF.
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.
  o Example 1: 2 Significant Digits = '< x 'becomes x – 0.01
  o Example 2: 1 Significant Digit = '> x' or '>=x' becomes x + 0.1
  o Example 3: 0 Significant Digits = '< x' becomes x – 1

Lab Toxicities – DAIDS Grading
• Toxicities will be based on the Division of AIDS (DAIDS) grading system, Version 2.1, March 2017, as specified in the protocol of Appendix 10.2 • Toxicity grades provided by the central laboratory do not distinguish between abnormally high or low criteria, when both are relevant for a particular parameter.

Other Safety Endpoints
Extent of Exposure
• Exposure to CAB+RPV (oral lead-in or oral bridging) and CAB LA+RPV LA will be calculated from the IP eCRF pages. For Intervention Phase: • **Exposure to CAB+RPV Oral Lead-in** = IP (oral lead-in) stop date - IP (oral lead-in) start date +1 • **Exposure to CAB LA + RPV LA** = Number of IP injection visits received during the Intervention Phase (up to but not including injections administered at Month 14) • **Exposure to SOC oral bridging**: Duration of the SOC ART medication taken as oral bridging during the Intervention Phase. If the SOC oral bridging is taken in different periods during the Intervention Phase, the duration will be calculated by the sum of non-overlapped periods. • **Exposure to CAB+RPV Oral Bridging (COVID-19 Related)**: Duration of the CAB+RPV taken as oral bridging for reasons related to COVID-19 during the Intervention Phase. If COVID-19 related CAB+RPV oral bridging is taken in different periods during the Intervention Phase, the duration will be calculated by the sum of the non-overlapped periods. • **Exposure to CAB+RPV Oral Bridging (Non COVID-19 Related)**: Duration of the CAB+RPV taken as oral bridging for reasons not related to COVID-19 during the Intervention Phase. If non COVID-19 related CAB+RPV oral bridging is taken in different periods during the Intervention Phase, the duration will be calculated by the sum of the non-overlapped periods. • **Overall Exposure to Study Treatment**: min [Date of Latest Intervention Phase Visit up to and including Month 12, max (Date of Last Injection + 63, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – min (Start Date for Oral lead-in CAB+RPV, Date of First CAB/RPV Injection) + 1 • **Overall Exposure to CAB + RPV** = Overall Exposure to Study Treatment – Exposure to SOC Oral Bridging For Intervention + Extension Phase: • **Exposure to CAB LA + RPV LA** = Number of IP injection visits received during Intervention Phase and Extension Phase • Exposure to SOC or CAB+RPV Oral Bridging during the Intervention and Extension Phase will be calculated similarly to that during the Intervention Phase except that the exposure includes both Intervention and Extension Phase. • **Overall Exposure to Study Treatment**: min [LTFU ART start date, Commercial product Safety Follow-up Visit date, max (Date of Last Injection + 63, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – min (Start Date for Oral lead-in CAB+RPV, Date of First Study Injection) + 1 • **Overall Exposure to IP** = Overall Exposure to Study Treatment – Exposure to SOC Oral Bridging • Duration of dosing in participant years will be calculated as the sum of participant duration of dosing in days (across all participants)/365.25

13.5.5. 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 Integrase Strand Transfer Inhibitors:

Amino Acids in HIV Integrase for Analysis	H51Y, **T66**A/**I**/K, L68V/I, L74I/M, **E92Q**/V/G, Q95K, T97A, **G118R**, **F121Y**, E138A/D/K/T, **G140**A/C/**R**/S, **Y143C**/**H**/**R**/K/S/G/A, P145S, Q146P, **S147G**, **Q148H/K/R**/N, V151/IL/A, S153F/Y, **N155H**/S/T, E157Q, G163R/K, G193E, S230R, **R263K**

- Draft listing; may be modified in case of additional substantive data availability.
- Based on the IAS-USA list of mutations associated with resistance to Bictegravir, Cabotegravir, Dolutegravir, Elvitegravir, or Raltegravir (IAS-USA 2019 resistance mutations update volume 27 issue 3, 2019): T66A/I/K, L74M, E92Q/G, T97A, G118R, F121Y, E138A/K/T, G140A/C/R/S, Y143C/H/R, S147G, Q148H/K/R, S153F/Y, N155H, R263K) and observed mutations during in vitro passage of DTG or seen in a previous DTG study in INI-experienced subjects (study ING112574): H51Y, L74I, L68V/I, E92V, Q95K, E138D, Y143K/S/G/A, P145S, Q146P, V151I/L/A, N155S/T, E157Q, G163R/K, G193E, S230R.
- Major USA-IAS mutations associated with resistance to INSTI are bolded.

- 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

Genotype	
PIs	D30N, V32I, M46I/L, I47A/V, G48V, I50V/L, I54V/M/L, Q58E, T74P, L76V, V82A/T/F/L/S, N83D, I84V, N88S, L90M

- Draft listing; may be modified in case of additional substantive data availability.

13.5.6. Other Assessments

Study Visit Length
• Lead Time = Actual Start Time of Appointment – Arrival Time • Process Time = Actual End Time of Appointment – Actual Start Time of Appointment • Total Time = Actual End Time of Appointment – Arrival Time

13.6. Appendix 6: Reporting Standards for Missing Data

13.6.1. Premature Withdrawals

Element	Reporting Detail
General	• Withdrawn participants were not replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified. • Withdrawal visits will be slotted according to Appendix 2: Assessment Windows (excluding PK data)

13.6.2. Handling of Missing Data

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

13.6.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in participant listing displays. • Where necessary, display macros may impute dates as temporary variables for sorting data in listings only. In addition, partial dates may be imputed for 'slotting' data to study phases or for specific analysis purposes as outlined below. • Imputed partial dates will not be used to derive study day, time to onset or duration (e.g., time to onset or duration of adverse events), or elapsed time variables (e.g., time since diagnosis). In addition, imputed dates are not used for deriving the last contact date in overall survival analysis dataset.
Adverse Events	• Imputations in the adverse events dataset are used for slotting events to the appropriate study time periods and for sorting in data listings. • Partial dates for AEs recorded in the CRF will be imputed using the following conventions: Missing start day: • If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = 1st of month. • Else if study treatment start date is not missing: ○ If month and year of start date = month and year of study treatment start date, then

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td></td><td>
<table>
<tr><td></td><td>

If stop date contains a full date and stop date is earlier than study treatment start date, then set start date= 1st of month.
Else set start date = study treatment start date.

Else

For Non-ISR AEs: set start date = 1st of month
For ISR AEs: if oral bridging taken during the month and year, set start date = min(last day of the month, day of AE stop date if available, day of study treatment discontinuation if occurring during the month and year); else set start date = 1st of month.

</td></tr>
<tr><td>Missing start day and month</td><td>

If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = January 1.
Else if study treatment start date is not missing:

If year of start date = year of study treatment start date, then

If stop date contains a full date and stop date is earlier than study treatment start date, then set start date = January 1.
Else set start date = study treatment start date.

Else set start date = January 1.

</td></tr>
<tr><td>Missing stop day</td><td>Last day of the month will be used.</td></tr>
<tr><td>Missing stop day and month</td><td>No Imputation</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>

Completely missing start or end dates will remain missing, with no imputation applied.

</td></tr>
<tr><td>Non-ART Medications (including Oral Bridging CAB + RPV)</td><td>

Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention:

<table>
<tr><td>Missing start day</td><td>

If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = 1st of month.
Else if study treatment start date is not missing:

If month and year of start date = month and year of study treatment start date, then

If stop date contains a full date and stop date is earlier than study treatment start date, then set start date= 1st of month.
Else set start date = study treatment start date.

Else set start date = 1st of month.

</td></tr>
<tr><td>Missing start day and month</td><td>

If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = January 1.
Else if study treatment start date is not missing:

If year of start date = year of study treatment start date, then

If stop date contains a full date and stop date is earlier than study treatment start date, then set start date = January 1.
Else set start date = study treatment start date.

Else set start date = January 1.

</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td></td><td>
<table>
<tr><td>Missing end day</td><td>A '28/29/30/31' will be used for the day (dependent on the month and year)</td></tr>
<tr><td>Missing end day and month</td><td>A '31' will be used for the day and 'Dec' will be used for the month.</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>
The recorded partial date will be displayed in listings.
</td></tr>
<tr><td>ART Medications</td><td>

Partial dates recorded in the eCRF will be imputed using the following convention:

If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month.
If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. If medications recorded in the PRIOR ART form of the eCRF, then 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, Intervention phase treatment start date - 1).

For medications with completely missing start date, they will be considered started prior to the Intervention phase treatment start date.
For medications with completely missing stop date, they will be considered ongoing unless recorded in the PRIOR ART form of the eCRF.
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 or missing date will be displayed in listings.

</td></tr>
</table>

13.6.2.2. Handling of Missing Data for Statistical Analysis

Element	Reporting Detail
Snapshot	• In the Snapshot dataset, subjects without HIV – 1 RNA data in the assessment window for the visit of interest (due to missing data or discontinuation of IP prior to the visit window) do not belong to 'HIV-1< 50 c/mL (or 200 c/mL) The nature of this missing data will be further classified in Snapshot summaries as either 'HIV-1 RNA≥50' or 'No Virologic Data at Week X'; • See Appendix 8: Snapshot Algorithm Details • Note: The primary snapshot analysis will not impute any missing data due to Covid-19 and will consider Covid-19 related missing data in accordance with all other missing data.

13.7. Appendix 7: Values of Potential Clinical Importance

Values of clinical importance will be summarized for hepatobiliary abnormalities. Abnormal laboratory value grades will be assigned as specified by protocol Section 10.2. Liver chemistry stopping criteria can be found in the protocol Section 10.3.1.

13.7.1. Hepatobiliary Abnormality Criteria

Element	Reporting Detail
General	• To include ALT, ALP, Bilirubin, & INR parameters
ALT >=3xULN and BIL >=2xULN	• If direct bilirubin is available (on the same date as Total Bilirubin), then direct bilirubin as a portion of total bilirubin must be >=35% when total bilirubin is >=2xULN, in order to satisfy the criteria. • Bilirubin value is on or up to 28 days after ALT value.
ALT >=3xULN and INR >1.5	• INR value is on or up to 28 days after ALT value.
ALT >=3xULN and BIL >=2xULN and ALP 2 (<1%) <2xULN	• If direct bilirubin is available (on the same date as Total Bilirubin), then direct bilirubin as a portion of total bilirubin must be >=35% when total bilirubin is >=2xULN, in order to satisfy the criteria. • Bilirubin value is on or up to 28 days after ALT value. • The ALP value must occur on or up to 28 days after the ALT value.
Hepatocellular injury	• Hepatocellular injury is defined as ((ALT/ALT ULN)/(ALP/ALP ULN)) >=5 and ALT >=3xULN. ALT and ALP values must occur on the same day.
Hepatocellular injury and BIL >=2xULN	• Hepatocellular injury is defined as ((ALT/ALT ULN)/(ALP/ALP ULN)) >=5 and ALT >=3xULN. ALT and ALP values must occur on the same day. • If direct bilirubin is available (on the same date as Total Bilirubin), then direct bilirubin as a portion of total bilirubin must be >=35% when total bilirubin is >=2xULN, in order to satisfy the criteria. • Bilirubin value is on or up to 28 days after ALT value.
BIL >=2xULN	• If direct bilirubin is available (on the same date as Total Bilirubin), then direct bilirubin as a portion of total bilirubin must be >=35% when total bilirubin is >=2xULN, in order to satisfy the criteria.
AST >3xULN and ALP <2xULN and BIL >=2xULN	• ALP and BIL values must occur on or up to 28 days after AST value. • If direct bilirubin is available (on the same date as Total Bilirubin), then direct bilirubin as a portion of total bilirubin must be >=35% when total bilirubin is >=2xULN, in order to satisfy the criteria.
ALT>=X ULN and AST>=X ULN	• AST and ALT values must occur on the same day

13.8. Appendix 8: Snapshot Algorithm Details

Detailed Algorithm Steps

- Consider an analysis visit window for Month X as defined in Table 2.
- The HIV-1 RNA threshold of 50 will be analysed in this study
- The COVID-19 pandemic presents significant logistical challenges for many clinical sites around the world, with variable restrictions being placed on site resources and operations, and on an individual participants ability to attend clinic visits. The snapshot algorithm is modified to allow for the presentation of full scope of COVID-19 relatedness. The analysis window for 'Month 12' and HIV-1 RNA threshold of '50 c/mL' are used for the purpose of illustration. A participant's Snapshot response and reason at Month 12 are categorized as below.

```
o  HIV-1 RNA < 50 c/mL
o  HIV-1 RNA ≥ 50 c/mL
   Data in window not below 50
     Non-COVID-19 related
          Discontinued for lack of efficacy
          Discontinued for other reason while not below 50
     COVID-19 related
          Discontinued for lack of efficacy
          Discontinued for other reason while not below 50

o  No Virologic Data at Month 12 Window
     Non-COVID-19 related
          Discontinued study due to AE or death
          Discontinued study for other reasons
          On study but missing data in window
   COVID-19 related
          Discontinued study due to AE or death
          Discontinued study for other reasons
          On study but missing data in window
 Change in background therapy*
```

* Note: Use of CAB + RPV oral bridging and SOC oral bridging medication, where the latter is due to unavailability of CAB/RPV IM injections or oral CAB+RPV during the pandemic, will not be considered a "Change in background therapy" in the Snapshot algorithm. All other permanent changes in ART are not permitted in this protocol.

- The steps in determining response and reasons are indicated in the table below, in the order stated.
- Background therapy is not given to participants while on study. The "change in background therapy" in detailed steps below refers to the "change in ART" in this study.

Detailed steps

- Please note that the following scenarios will NOT be penalized in the Snapshot algorithm Oral bridging (CAB+RPV or SOC, where SOC oral bridging medication is permitted during COVID-19 pandemic due to the unavailability of the CAB/RPV IM injections and oral CAB+RPV)

Detailed Algorithm Steps

Condition ('Month 12' indicates Month 12 window)	**Response**	**Reasons**
1. If non-permitted change in background therapy prior to Month 12	HIV-1 RNA ≥ 50	Change in background therapy
2. 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	HIV-1 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	HIV-1 RNA < 50	
• No VL during Month 12 prior to/on the date of change	HIV-1 RNA ≥ 50	Change in background therapy
3. If none of the above conditions met		
3.1. On-treatment VL available during Month 12		
• Last on-treatment VL during Month 12 ≥ 50 c/mL	HIV-1 RNA ≥ 50	Data in window not below 50
• Last on-treatment VL during Month 12 < 50 c/mL	HIV-1 RNA < 50	
3.2. No on-treatment VL during Month 12		
3.2.1. If participants are 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: • Min[max(Date of last injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV, SOC Bridging) + 1), LTFU ART Start Date]		
3.2.1.1. If no on-treatment VL during Month 12 is not due to COVID-19	No virologic data at Month 12 Window	On study but missing data in window (Non-COVID-19 related)
3.2.1.2. If no on-treatment VL during Month 12 is due to COVID-19	No virologic data at Month 12 Window	On study but missing data in window (COVID-19 related)
3.2.2. If participants withdraw before/during Month 12 due to		
3.2.2.1. Non-COVID-19 related 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 (Non-COVID-19 related)

Detailed Algorithm Steps

3.2.2.2. COVID-19 related 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 (COVID-19 related)
3.2.2.3. Non-safety and Non-COVID-19 related reasons (e.g. Lack of efficacy, protocol deviation, withdrew consent, loss to follow-up, study closed/terminated, investigator discretion etc., as recorded in eCRF Treatment Discontinuation 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 (Non-COVID-19 related)
○ Last on-treatment VL ≥ 50 c/mL AND withdrawal due to Lack of efficacy	HIV-1 RNA ≥ 50	Disc. for lack of efficacy (Non-COVID-19 related)
○ Last on-treatment VL ≥ 50 c/mL AND withdrawal due to all other non-safety related reasons	HIV-1 RNA ≥ 50	Disc. for other reason while not below 50 (Non-COVID-19 related)
3.2.2.4. Non-safety and COVID-19 related reasons (e.g. protocol deviation, withdrew consent, loss to follow-up, study closed/terminated, investigator discretion etc., 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 (COVID-19 related)
○ Last on-treatment VL ≥ 50 c/mL AND withdrawal due to Lack of efficacy	HIV-1 RNA ≥ 50	Disc. for lack of efficacy (COVID-19 related)
○ Last on-treatment VL ≥ 50 c/mL AND withdrawal due to all other non-safety related reasons	HIV-1 RNA ≥ 50	Disc. for other reason while not below 50 (COVID-19 related)

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-1 RNA = 580 c/mL at Day 336, HIV-1 RNA below 50 c/mL on Day 350. This should be categorized as HIV-1 RNA below 50 c/mL.

No Data in Window

Detailed Algorithm Steps

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-1 RNA result, even if the HIV-1 RNA is below 50 c/mL at the time of discontinuation.
- However, if a patient has an HIV-1 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-1 RNA below 50 c/mL at Day 336 and discontinues because of AE or even dies on Day 360 — this person is categorized as having HIV-1 RNA below 50 c/mL.
    b. HIV-1 RNA is 552 c/mL on Day 336 and the patient discontinues on Day 360, the patient is categorized as having HIV-1 RNA ≥ 50 c/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-1 RNA ≥ 50 row and not in the Discontinued for Other Reasons row.
- If a patient discontinues because *participant withdrew consent* and his or her HIV-1 RNA result at the time of discontinuation was equal to or above 50 c/mL, then he or she should be categorized as HIV-1 RNA ≥ 50 and NOT as Discontinued for Other Reasons.
- If a patient discontinued because of *Lost to Follow-Up* and the last HIV-1 RNA result was 49 c/mL, then the patient can be categorized as Discontinued for Other Reasons.
- If patients changed background treatment — *not permitted by protocol*— they should be considered an efficacy failure and captured in the HIV-1 RNA ≥ 50 c/mL row.

On study but missing data in window:

- If there are no data during Days 294 to 377, but there is an HIV-1 RNA below 50 c/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-1 RNA equal to or above 50 c/mL on Day 280, this patient also should be classified as *On Study but Missing Data in Window.*

13.9. Appendix 9: Identification of Adverse Events of Special Interest

SMQ and PT codes based on MedDRA dictionary version 23.1 for the Month 12 analysis.

13.9.1. 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 (SMQ code 20000005)'; 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

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005	
Duodenal varices	10051010
Gallbladder varices	10072319
Gastric variceal injection	10076237
Gastric variceal ligation	10076238
Gastric varices	10051012
Gastric varices haemorrhage	10057572
Gastrooesophageal variceal haemorrhage prophylaxis	10066597
Flood Syndrome	10084797
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

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005	
Hepatorenal syndrome	10019846
Hepatotoxicity	10019851
Immune-mediated cholangitis	10083406
Immune-mediated hepatic disorder	10083521
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

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005	
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
Sugiura procedure	10083010
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

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005	
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

13.9.2. Hyperglycaemia

Medical concept of Hyperglycaemia/new onset diabetes mellitus - SMQs (1) 'Hyperglycaemia/new onset diabetes mellitus (SMQ) Narrow SMQ code 20000041.

SMQ: 'Hyperglycaemia/new onset diabetes mellitus '; SMQ Code: 20000041 Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related Category: A Scope: Narrow	
Preferred Term	PT Code
Acquired lipoatrophic diabetes	10073667
Blood 1,5-anhydroglucitol decreased	10065367
Blood glucose increased	10005557
Diabetes complicating pregnancy	10012596
Diabetes mellitus	10012601
Diabetes mellitus inadequate control	10012607
Diabetes with hyperosmolarity	10012631
Diabetic arteritis	10077357
Diabetic coma	10012650
Diabetic coronary microangiopathy	10080788
Diabetic hepatopathy	10071265

SMQ: 'Hyperglycaemia/new onset diabetes mellitus '; SMQ Code: 20000041	
Diabetic hyperglycaemic coma	10012668
Diabetic hyperosmolar coma	10012669
Diabetic ketoacidosis	10012671
Diabetic ketoacidotic hyperglycaemic coma	10012672
Diabetic ketosis	10012673
Diabetic metabolic decompensation	10074309
Diabetic wound	10081558
Euglycaemic diabetic ketoacidosis	10080061
Fructosamine increased	10017395
Fulminant type 1 diabetes mellitus	10072628
Gestational diabetes	10018209
Glucose tolerance impaired	10018429
Glucose tolerance impaired in pregnancy	10018430
Glucose urine present	10018478
Glycated albumin increased	10082836
Glycosuria	10018473
Glycosuria during pregnancy	10018475
Glycosylated haemoglobin abnormal	10018481
Glycosylated haemoglobin increased	10018484
Hyperglycaemia	10020635
Hyperglycaemic hyperosmolar nonketotic syndrome	10063554
Hyperglycaemic seizure	10071394
Hyperglycaemic unconsciousness	10071286
Impaired fasting glucose	10056997
Insulin resistance	10022489
Insulin resistant diabetes	10022491
Insulin-requiring type 2 diabetes mellitus	10053247
Ketoacidosis	10023379

SMQ: 'Hyperglycaemia/new onset diabetes mellitus '; SMQ Code: 20000041	
Ketonuria	10023388
Ketosis	10023391
Ketosis-prone diabetes mellitus	10023392
Latent autoimmune diabetes in adults	10066389
Monogenic diabetes	10075980
Neonatal diabetes mellitus	10028933
New onset diabetes after transplantation	10082630
Pancreatogenous diabetes	10033660
Steroid diabetes	10081755
Type 1 diabetes mellitus	10067584
Type 2 diabetes mellitus	10067585
Type 3 diabetes mellitus	10072659
Urine ketone body present	10057597

13.9.3. Hypersensitivity Reactions

Notes: 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'; HLGT code 10001708	
Preferred Term	PT Code

SMQ: Drug reaction with eosinophilia and systemic symptoms syndrome SMQ Code: 20000225 Category: A Scope: Narrow	
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
Granulomatous T-cell pseudolymphoma	10084214

13.9.4. 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
Bullous haemorrhagic dermatosis	10083809
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
Erythrodermic atopic dermatitis	10082985
Exfoliative rash	10064579
Oculomucocutaneous syndrome	10030081
SJS-TEN overlap	10083164
Skin necrosis	10040893
Stevens-Johnson syndrome	10042033
Target skin lesion	10081998
Toxic epidermal necrolysis	10044223
Toxic skin eruption	10057970
Addition selected preferred terms from HLTs 'Rashes, eruptions and exanthems NEC', HLT Code 1005266; 'Pruritus NEC', HLT Code 10049293, 'Pustular conditions', HLT Code 10037573; 'Dermatitis ascribed to specific agent', HLT Code 10012437.	
Preferred Term	PT Code
Eyelid rash	10074620
Genital rash	10018175
Mucocutaneous rash	10056671

SMQ: Severe Cutaneous Adverse Reactions SMQ Code: 20000020 Category: A Scope: Narrow	
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

13.9.5. Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses

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

SMQ: Torsade de pointes/QT prolongation SMQ Code: 20000001 Category: A Scope: Narrow	
Electrocardiogram QT prolonged	10014387
Long QT syndrome	10024803
Long QT syndrome congenital	10057926
Torsade de pointes	10044066
Ventricular tachycardia	10047302
Additional selected preferred terms from HLT 'ECG investigations', HLT Code 10053104.	
Preferred Term	PT Code
Electrocardiogram repolarisation abnormality	10052464

13.9.6. 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 (SMQ Code 20000035)'. 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

SMQ: 'Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Suicide/self-injury' Category: A Scope: Narrow	
Suicidal ideation	10042458
Suicide attempt	10042464
Suicide threat	10077417
Suspected suicide	10082458
Suspected suicide attempt	10081704

13.9.7. 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 rating scale score increased	10084390
Discouragement	10084257
Depression postoperative	10012390
Depressive symptom	10054089
Dysphoria	10013954
Electroconvulsive therapy	10014404
Feeling guilty	10049708
Feeling of despair	10016344
Feelings of worthlessness	10016374
Helplessness	10077169

SMQ: ‘'Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Depression (excl suicide and self-injury)' Category: A Scope: Narrow	
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

13.9.8. Bipolar Disorder

Medical concept of bipolar disorder. All preferred terms from HLGT ‘Manic and Bipolar mood disorders and disturbances’ under SOC “Psychiatric disorders”; HLGT Code 10026753.

Preferred Term	PT Code
Bipolar I disorder	10004939
Bipolar II disorder	10004940
Bipolar disorder	10057667
Cyclothymic disorder	10011724
Hypomania	10021030
Mania	10026749
Manic symptom	10084119

13.9.9. 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 parasitosis	10012242
Delusion of reference	10012244
Delusion of replacement	10012245
Delusion of theft	10084030
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

SMQ: 'Psychosis and psychotic disorders' SMQ Code: 20000117 Category: A Scope: Narrow	
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

SMQ: 'Psychosis and psychotic disorders' SMQ Code: 20000117 Category: A Scope: Narrow	
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

SMQ: 'Psychosis and psychotic disorders' SMQ Code: 20000117 Category: A Scope: Narrow	
Thought withdrawal	10043497
Transient psychosis	10056326
Waxy flexibility	10047853

13.9.10. Mood Disorders

Medical concept of mood disorders. All preferred terms from HLGT 'Mood disorders and disturbances NEC', under SOC 'Psychiatric disorders'; HLGT Code 10027946.

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
Discouragement	10084257
Dysphoria	10013954
Emotional disorder	10014551
Emotional distress	10049119
Emotional poverty	10014557
Euphoric mood	10015535
Flat affect	10016759

Preferred Term	PT Code
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

13.9.11. Anxiety

Notes: Medical concept of anxiety disorders. All preferred terms from HLGT “Anxiety disorders and symptoms”, under SOC “Psychiatric disorders”; HLGT Code 10002861.

Preferred Terms	PT Code
Acrophobia	10000605
Activation syndrome	10066817
Acute stress disorder	10001084
Aerophobia	10080300
Agitation	10001497

Preferred Terms	PT Code
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
Cryophobia	10082662
Dermatillomania	10065701
Dysmorphophobia	10049096
Emetophobia	10070637

Preferred Terms	PT Code
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 surgery	10084519
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

Preferred Terms	PT Code
Noctiphobia	10057946
Nocturnal fear	10057948
Nosocomephobia	10083993
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

Preferred Terms	PT Code
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

13.9.12. 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 (incl 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

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Loss of dreaming	10065085
Middle insomnia	10027590
Narcolepsy	10028713
Nightmare	10029412
Non-24-hour sleep-wake disorder	10078086
Parasomnia	10061910
Paradoxical insomnia	10083337
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

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
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

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
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

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13.9.14. 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
Alpers disease	10083857
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
CEC syndrome	10083749
CDKL5 deficiency disorder	10083005
Change in seizure presentation	10075606
Clonic convulsion	10053398
Congenital bilateral perisylvian syndrome	10082716
Convulsion in childhood	10052391
Convulsions local	10010920
Convulsive threshold lowered	10010927
CSWS syndrome	10078827
Deja vu	10012177

SMQ: 'Convulsions' SMQ Code: 20000079 Category: A Scope: Narrow	
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
Faciobrachial dystonic seizure	10084187
Febrile convulsion	10016284
Febrile infection-related epilepsy syndrome	10079438
Focal dyscognitive seizures	10079424
Frontal lobe epilepsy	10049424
Gelastic seizure	10082918
Generalised onset non-motor seizure	10083376
Generalised tonic-clonic seizure	10018100
Glucose transporter type 1 deficiency syndrome	10078727
GM2 gangliosidosis	10083933
Grey matter heterotopia	10082084
Hemimegalencephaly	10078100
Hyperglycaemic seizure	10071394
Hypocalcaemic seizure	10072456
Hypoglycaemic seizure	10048803
Hyponatraemic seizure	10073183

SMQ: ‘Convulsions’ SMQ Code: 20000079 Category: A Scope: Narrow	
Idiopathic generalised epilepsy	10071081
Infantile spasms	10021750
Jeavons syndrome	10084303
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

SMQ: 'Convulsions' SMQ Code: 20000079 Category: A Scope: Narrow	
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, HLT code 10013509 and HLT Confusion and disorientation, HLT code 10010301.	
Preferred Term	PT Code
Confusional state	10010305
Loss of consciousness	10024855
Syncope	10042772
Sopor	10058709
Stupor	10042264
Altered state of consciousness	10050093
Depressed level of consciousness	10012373
Consciousness fluctuating	10050093

13.9.15. 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'.

PTs (Select) from HLT General nutritional disorders NEC, HLT code 10018067	
Preferred Term	PT Code
Abdominal fat apron	10077983
Overweight	10033307
Abnormal weight gain	10000188
Central obesity	10065941
Obesity	10029883
Abdominal fat apron	10077983
Overweight	10033307
Abnormal weight gain	10000188
Central obesity	10065941
Obesity	10029883
PTs (Select) from HLT Physical examination procedures and organ system status, HLT Code 10071941	
Preferred Term	PT Code
Weight abnormal	10056814
Weight increased	10047899
Waist circumference increased	10064863
Body mass index abnormal	10074506
Body mass index increased	10005897
PTs (Select) from HLT General signs and symptoms NEC, HLT Code 10018072	
Preferred Term	PT Code
Fat tissue increased	10016251
Sarcopenic obesity	10083992

13.9.16. 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
PTs (Select) from HGLT muscle disorders, HLGT Code 10028302	
Preferred Term	PT Code
Myalgia	10028411
Myositis	10028653

13.9.17. 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
Immune-mediated pancreatitis	10083072
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
Pancreatic pseudocyst haemorrhage	10083813
Pancreatic pseudocyst rupture	10083811
Pancreatitis	10033645
Pancreatitis acute	10033647
Pancreatitis haemorrhagic	10033650
Pancreatitis necrotising	10033654
Pancreatitis relapsing	10033657
Pancreatorenal syndrome	10056277
Subacute pancreatitis	10084554

13.9.18. 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
Subacute kidney injury	10081980

Renal Failure and Impairment HLT, HLT Code 10038443	
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

13.9.19. Safety During Pregnancy

Use AE terms co-reported in pregnancy exposures to CAB.

13.10. Appendix 10: Identification of COVID-19 Adverse Events

COVID-19 adverse events are identified based on MedDRA coded values and/or AE referenced in the COVID-19 Coronavirus Infection assessment. The Lowest Level Terms (LLTs) and codes, Preferred Terms (PTs), High Level Terms (HLTs), High Level Group Terms (HLGTs), and System Organ Classes (SOCs), below are from MedDRA 23.0. 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.

SOC: Infections and infestations

LLT code	LLT	PT	HLT	HLGT
10084459	Asymptomatic COVID-19	Asymptomatic COVID-19	Coronavirus infections	Viral infectious disorders
10084467	Asymptomatic SARS-CoV-2 infection	Asymptomatic COVID-19	Coronavirus infections	Viral infectious disorders
10053983	Corona virus infection	Coronavirus infection	Coronavirus infections	Viral infectious disorders
10051905	Coronavirus infection	Coronavirus infection	Coronavirus infections	Viral infectious disorders
10084382	Coronavirus disease 2019	COVID-19	Coronavirus infections	Viral infectious disorders
10070255	Coronavirus test positive	Coronavirus test positive	Virus identification and serology	Microbiology and serology investigations
10084460	COVID-19 treatment	COVID-19 treatment	Antiinfective therapies	Therapeutic procedures and supportive care NEC
10084639	SARS-CoV-2 sepsis	SARS-CoV-2 sepsis	Coronavirus infections	Viral infectious disorders
10084271	SARS-CoV-2 test positive	SARS-CoV-2 test positive	Virus identification and serology	Microbiology and serology investigations

LLT code	LLT	PT	HLT	HLGT
10084640	SARS CoV-2 viraemia	SARS CoV-2 viraemia	Coronavirus infections	Viral infectious disorders
10084268	COVID-19	COVID-19	Coronavirus infections	Viral infectious disorders
10084401	COVID-19 respiratory infection	COVID-19	Coronavirus infections	Viral infectious disorders
10084270	SARS-CoV-2 acute respiratory disease	COVID-19	Coronavirus infections	Viral infectious disorders
10084272	SARS-CoV-2 infection	COVID-19	Coronavirus infections	Viral infectious disorders
10084381	Coronavirus pneumonia	COVID-19 pneumonia	Coronavirus infections	Viral infectious disorders
10084380	COVID-19 pneumonia	COVID-19 pneumonia	Coronavirus infections	Viral infectious disorders
10084383	Novel COVID-19-infected pneumonia	COVID-19 pneumonia	Coronavirus infections	Viral infectious disorders
10084451	Suspected COVID-19	Suspected COVID-19	Coronavirus infections	Viral infectious disorders
10084452	Suspected SARS-CoV-2 infection	Suspected COVID-19	Coronavirus infections	Viral infectious disorders
10084461	SARS-CoV-2 carrier	SARS-CoV-2 carrier	Infectious disorders carrier	Ancillary infectious topics

13.11. Appendix 11: Abbreviations & Trade Marks

13.11.1. Abbreviations

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

Abbreviation	Description
SDSP	Study Data Standardization Plan
SDTM	Study Data Tabulation Model
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings

13.11.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
Cabotegravir

Trademarks not owned by the GlaxoSmithKline Group of Companies
Rilpivirine
SAS

13.12. Appendix 12: List of Data Displays

All data displays will use the term "subject" rather than "participant" in accordance with CDSIC and GSK Statistical Display Standards.

Where applicable, all summary displays will present data across both the Intervention and Extension phases unless explicitly stated otherwise in the display title.

At EOS, the RAPIDO Data Viewer will be produced to allow for the clinical team to review ADaM data directly related to adverse events, exposure, HIV-1 RNA, and labs. This will take the place of some, previously standard generic listings from these categories. Listings including results of pregnancy details will only be included if a pregnancy occurs.

13.12.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.27	
Efficacy	2.1 to 2.16	2.1 to 2.4
Safety	3.1 to 3.75	3.1 to 3.4
Other	4.1 to 4.4	
Section	**Listings**	
ICH Listings	1 to 24	
Other Listings	25 to 57	

13.12.2. Mock Example Shell Referencing

Nonstandard specifications will be referenced as indicated below (where a study specific mock shell is available) or the location of a similar display produced for a different study in the HARP reporting environment will be provided as reference. If required example mock-up displays provided in Appendix 13: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAF_Fn	SAF_Tn	SAF_Ln
Other	OTR_Tn	OTR_Fn	OTR_Ln

13.12.3. Deliverables

Delivery	Description
IA1	Interim Analysis Statistical Analysis Complete at IA (Month 4) when 50% of subjects have received their 3rd injection.
IA2	Interim Analysis Statistical Analysis Complete at IA (Month 4) when 100% of subjects have received their 3rd injection.

Delivery	Description
HL	Headline at Month 12
M12	Statistical Analysis Complete at Month 12
EOS	End of Study

13.12.4. Study Population Tables

Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.1.	Safety	ES1	Summary of Subject Disposition for the Subject Conclusion Record	ICH E3, FDAAA, EudraCT	HL, M12, EOS
1.2.	Safety	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment	ICH E3	M12, EOS
1.3.	Safety	DISP_T1	Summary of Subject Disposition at Each Study Phase	ICH E3 Intervention/Extension phase: status and reason for withdrawal based on date and reason collected in the study treatment discontinuation form. Long term Follow-up: completion/withdrawal based on data collected in the Study Conclusion form. For the Intervention Phase, columns should report OLI results, LA results, & Total results; All other phases only list total results Under withdrawals, add subcategory for Covid-19	M12, EOS

Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.4.	Safety	DISP_T2	Summary of Reason for Withdrawal at Each Study Phase	FDAAA, EudraCT For Intervention Phase, columns should report OLI results, LA results, & Total results; All other phases only list total results See mockup for relevant Covid-19 Subcategories	IA2, HL, M12, EOS
1.5.	Safety	ES11	Summary of Outcome of Adverse Events Which Led to Study Withdrawal/Treatment Discontinuation at Each Study Phase	EudraCT	M12, EOS
1.6.	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure	Journal Requirements	M12
1.7.	Enrolled	NS1	Summary of Number of Subjects by Country and Site ID	EudraCT/Clinical Operations	IA1, HL, M12
Protocol Deviation					
1.8.	Enrolled	DV1	Summary of Important Protocol Deviations	ICH E3	M12, EOS
1.9.	Enrolled	DV1	Summary of Important COVID-19 Related Protocol Deviations	Update the label for the first row to be “ANY IMPORTANT COVID-19 RELATED PROTOCOL DEVIATIONS”	M12, EOS
1.10.	Enrolled	DV1	Summary of Important Non-COVID-19 Protocol Deviations	Update the label for the first row to be “ANY IMPORTANT NON-COVID-19 RELATED PROTOCOL DEVIATIONS”	M12, EOS
1.11.	Enrolled	DV1	Summary of COVID-19 Protocol Deviations by Site	Update the label for the first row to be “ANY COVID-19 RELATED PROTOCOL DEVIATIONS”. Summary for each site and ‘Total’ across sites.	IA2, HL, M12, EOS

Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.12.	Enrolled	DV1	Summary of All Implementation Protocol Deviations by Site	Update the label for the first row to be "ANY IMPLEMENTATION RELATED PROTOCOL DEVIATIONS" Summary for each site and 'Total' across sites.	HL, M12, EOS
Population Analysed					
1.13.	Screened	SP1	Summary of Study Populations	GSK Statistical Display Standard	M12, EOS
1.14.	Enrolled	SP2	Summary of Exclusions from the Safety Population	GSK Statistical Display Standard	M12
Demographic and Baseline Characteristics					
1.15.	Safety	DM1	Summary of Demographic Characteristics	ICH E3, FDAAA, EudraCT Include Baseline CD4+ Cell Count Results and CDC HIV-1 Infection Classification.	IA1, HL, M12
1.16.	Enrolled	DM11	Summary of Age Ranges	EudraCT	M12
1.17.	Safety	DM6	Summary of Race and Racial Combinations	ICH E3, FDA, FDAAA, EudraCT	M12
Prior and Concomitant Medications					
1.18.	Safety	MH1	Summary of Past Medical Conditions	ICH E3	M12
1.19.	Safety	MH4	Summary of Past Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders	ICH E3	M12
1.20.	Safety	MH1	Summary of Current Medical Conditions	ICH E3	M12
1.21.	Safety	MH4	Summary of Current Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders	ICH E3	M12

Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.22.	Safety	CM9	Summary of Concomitant Medications by Ingredient Combinations	ICH E3 See GSK Statistical Display Standard Multi-ingredient medications will be labelled according to the sum of their ingredients, i.e., Generic Term.	M12, EOS
1.23.	Safety	207966/primary_15/T1.30	Summary of Prior Antiretroviral Therapy Taken during Screening	Remove the footnote. Follow definitions in Section 13.3.1 to determine the prior ART medications.	M12
1.24.	Safety	RF1	Summary of HIV Risk Factors		M12
1.25.	Safety	201585/primary_02/T1.31	Time Since First Antiretroviral Therapy Until Intervention Phase Start	Add footnote "Note: Duration is calculated as the day prior to first dose of CAB+RPV – the first recorded date of prior ART usage +1."	M12
1.26.	Safety	DM1	Summary of Categorical Baseline BMI		M12
1.27.	Safety	DM1	Summary of Baseline BMI Based on Day 1 Weight Values	Repeat the descriptive BMI statistics from Table 1.15 and the categorical statistics from Table 1.26 using a newly calculated Baseline BMI based on Day 1 weight values instead of CRF reported BMI values.	EOS

13.12.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Snapshot					
2.1.	Safety	EFF_T1	Summary of Study Outcomes (50 c/mL cutoff) at Month 12 (Intervention Phase) –Snapshot Analysis		HL, M12
2.2.	Safety	EFF_T2	Summary of Study Outcomes (50 c/mL cutoff) at Month 12 (Intervention Phase) –Snapshot Analysis Considering Covid-19 Based Events	With expanded COVID-19 related/Non-related categories	HL, M12
2.3.	Safety	SNAPSHOT4	Proportion of Subjects with Plasma HIV-1 RNA ≥ 50 c/mL Over Time (Intervention Phase) –Snapshot Analysis	Use Exact (Clopper-Pearson) method for 95% confidence Intervals. Expand to all visits, drop 'n' row, replace x (%) column data with x/n (%), drop '(Intervention Phase)' and use Observed Case instead of Snapshot for EOS	M12, EOS
2.4.	Safety	SNAPSHOT4	Proportion of Subjects with Plasma HIV-1 RNA < 50 c/mL Over Time (Intervention Phase) –Snapshot Analysis	Use Exact (Clopper-Pearson) method for 95% confidence Intervals. Expand to all visits, drop 'n' row, replace x (%) column data with x/n (%), drop '(Intervention Phase)' and use Observed Case instead of Snapshot for EOS	M12, EOS
2.5.	Safety	SNAPSHOT4	Proportion of Subjects with Plasma HIV-1 RNA ≥ 50 c/mL Over Time by Subgroup (Intervention Phase) –Snapshot Analysis	Include the following subgroups: country, implementation arm, sex, age group, race group, and CD4 group as mentioned in Section 5.4.2.	M12

Efficacy: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.6.	Safety	SNAPSHOT4	Proportion of Subjects with Plasma HIV-1 RNA < 50 c/mL Over Time by Subgroup (Intervention Phase) –Snapshot Analysis	Include the following subgroups: country, implementation arm, sex, age group, race group, and CD4 group as mentioned in Section 5.4.2.	M12
CVF					
2.7.	Safety	VF1	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria Over Time (Intervention Phase)		HL, M12
2.8.	Safety	VF2	Proportion of Subjects Meeting Confirmed Virologic Failure Criteria Over Time		M12, EOS
Genotype & Phenotype					
2.9.	Safety	201584/primary_17/T7.1	Summary of the Prevalence of Treatment-Emergent Major Resistance Mutations of INI, NRTI, NNRTI and PI Class at time of CVF - Plasma Sample	Known resistance mutations per Section 13.5.5. Include 95% confidence Intervals using Exact (Clopper-Pearson) method.	HL, M12, EOS
2.10.	Safety	201584/primary_17/T7.2	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria		M12, EOS
2.11.	Safety	201584/primary_17/T7.4	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Did Not Meet Confirmed Virologic Failure Criteria	Only include subjects with available genotypic or phenotypic data.	M12, EOS
CD4					
2.12.	Safety	LB1	Summary of CD4+ Cell Count (cells/mm^3) by Visit		M12, EOS
2.13.	Safety	LB1	Summary of Change from Baseline in CD4+ Cell Count (cells/mm^3) by Visit		M12, EOS

Efficacy: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.14.	Safety	LB1	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) at Baseline & Month 12		M12
HIV Associated Conditions					
2.15.	Safety	CDC2	Summary of Post-Baseline CDC Stage 3 HIV-1 Associated Conditions Including Recurrences		M12, EOS
2.16.	Safety	CDC2	Summary of Post-Baseline CDC Stage 3 HIV-1 Associated Conditions Excluding Recurrences		M12, EOS

13.12.6. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Snapshot					
2.1.	Safety	SNAPSHOT8	Percent (95% CI) of Subjects with Plasma HIV-1 RNA ≥ 50 copies/mL Over Time (Intervention Phase) –Snapshot Analysis	Use Exact (Clopper-Pearson) method for 95% confidence Intervals. Drop '(Intervention Phase)', Observed cases to be used at EOS instead of Snapshot	M12, EOS
2.2.	Safety	SNAPSHOT8	Percent (95% CI) of Subjects with Plasma HIV-1 RNA < 50 copies/mL Over Time (Intervention Phase) –Snapshot Analysis	Use Exact (Clopper-Pearson) method for 95% confidence Intervals. Drop '(Intervention Phase)', Observed cases to be used at EOS instead of Snapshot	M12, EOS

Efficacy: Figures					
2.3.	Safety	SNAPSHOT10	Individual HIV-1 RNA Plasma Profiles by Visit for Subjects with HIV-1 RNA >= 50 copies/mL at Month 12 per Snapshot Algorithm	The 1st vertical line indicates start of study treatment at Intervention Phase. The second vertical reference line indicates last IP on-treatment study day. i.e. min (last IP injection dose+35 days, LTFU HAART start date, date of last oral CAB+RPV+1). This vertical line is only for subjects who withdraw from Intervention Phase/Extension phase.	M12
2.4.	Safety	SNAPSHOT10	Individual HIV-1 RNA Plasma Profiles by Visit for Subjects with Confirmed Virologic Failure	Same as Figure 2.3.	M12, EOS

13.12.7. Safety Tables

Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Exposure					
3.1.	Safety	207966/primary_15/T3.1	Summary of Exposure to Study Treatment by Implementation Arm (Intervention Phase)	Includes Oral Bridging	IA2, M12
3.2.	Safety	207966/primary_15/T3.1	Summary of Exposure to Study Treatment by Implementation Arm	Includes Oral Bridging	M12, EOS
3.3.	Safety	SAF_T1	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Country, and Site (Intervention Phase)	See Section 13.5.2 for Covid Impact Remove Covid-19 impact results from IA1.	IA1, IA2, HL, M12
3.4.	Safety	SAF_T2	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit and Subgroup (Intervention Phase)	See Section 13.5.2 for Covid Impact Include all subgroups listed in Section 5.4.2 except for Site & Country	HL, M12
3.5.	Safety	SAF_T1	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Country, and Site	See Section 13.5.2 for Covid Impact	EOS
3.6.	Safety	SAF_T2	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit and Subgroup	See Section 13.5.2 for Covid Impact Include all subgroups listed in Section 5.4.2 except for Site & Country	EOS

Safety: Tables					
3.7.	Safety	Study 201584 (primary_02): Table 3.114	Summary of Categorized Needle Length and Gauge for CAB Injection		M12, EOS
3.8.	Safety	Study 201584 (primary_02): Table 3.115	Summary of Categorized Needle Length and Gauge for RPV Injection		M12, EOS
Adverse Events (AEs)					
3.9.	Safety	AE99	Adverse Event Overview by Study Phase and Overall	High level summary to include counts of overall AEs, Serious AEs, AEs leading to withdrawal, related AEs, AEs related to Covid-19, AEs related to Covid-19 leading to withdrawal, fatal AEs Overall breakdown to be condensed to Int + Ext phases.	HL, M12, EOS
3.10.	Safety	AE3	Summary of Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.11.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Maximum Grade	ICH E3	HL, M12, EOS
3.12.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Maximum Grade — Excluding Study Drug Injection Site Reactions		M12, EOS
3.13.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Maximum Grade (Oral Lead-in Period)		M12
3.14.	LTFU	AE5B	Summary of Adverse Events by System Organ Class and Maximum Grade (Long Term Follow-up Period)		M12, EOS
3.15.	Safety	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.16.	Safety	AE3	Summary of Common (>=1%) Grade 2-5 Adverse Events by Overall Frequency	ICH E3	M12, EOS

Safety: Tables					
3.17.	Safety	201584/primary_7/T3.46	Summary of Adverse Events by Visit and Maximum Severity – Overall and Common		HL, M12, EOS
3.18.	Safety	AE3	Summary Drug-Related Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.19.	Safety	AE5B	Summary of Drug-Related Adverse Events by System Organ Class and Maximum Grade	ICH E3	HL, M12, EOS
3.20.	Safety	AE5B	Summary of Drug-Related Adverse Events by System Organ Class and Maximum Grade (Oral Lead-in Period)	ICH E3	M12
3.21.	LTFU	AE5B	Summary of Drug-Related Adverse Events by System Organ Class and Maximum Grade (Long Term Follow-up Period)	ICH E3	M12, EOS
3.22.	Safety	AE5B	Summary of Drug-Related Adverse Events by System Organ Class and Maximum Grade — Excluding Study Drug Injection Site Reactions		M12, EOS
3.23.	Safety	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT	M12, EOS
3.24.	Safety	AE3	Summary of Common (>=1%) Drug-Related Grade 2-5 Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.25.	Safety	AE3	Summary of Non-Serious Drug-Related Adverse Events by Overall Frequency	Plain Language Summary requirements.	M12, EOS
3.26.	Safety	201584/primary_7/T3.46	Summary of Drug-Related Adverse Events by Visit and Maximum Severity – Overall and Common		M12, EOS
Serious and Other Significant Adverse Events					
3.27.	Safety	AE5B	Summary of Serious Adverse Events by System Organ Class and Maximum Grade	ICH E3	HL, M12, EOS

Safety: Tables					
3.28.	Safety	AE5B	Summary of Serious Adverse Events by System Organ Class and Maximum Grade (Oral Lead-in Period)	ICH E3	M12
3.29.	LTFU	AE5B	Summary of Serious Adverse Events by System Organ Class and Maximum Grade (Long Term Follow-up Period)	ICH E3	M12, EOS
3.30.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT	M12, EOS
3.31.	Safety	201584/primary_7/T3.46	Summary of Serious Adverse Events by Visit and Maximum Severity – Overall and Common		M12, EOS
3.32.	Safety	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term	GSK Statistical Display Standard	HL, M12, EOS
3.33.	Safety	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Oral Lead-in Period)	GSK Statistical Display Standard	M12
3.34.	LTFU	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term (Long Term Follow-up Period)	GSK Statistical Display Standard	M12, EOS
3.35.	Safety	201584/primary_7/T3.46	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by Visit and Maximum Severity – Overall and Common		M12, EOS

Safety: Tables					
3.36.	Safety	AE1	Summary of Serious Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term	GSK Statistical Display Standard	M12, EOS
CCI [redacted]					
Laboratory: Chemistry					
3.40.	Safety	LB1	Summary of Chemistry Changes from Baseline	ICH E3	M12, EOS
3.41.	LTFU	LB1	Summary of Chemistry Changes from Baseline (Long Term Follow-up Population)	ICH E3	M12, EOS
3.42.	Safety	LB16	Summary of Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3	HL, M12, EOS
Laboratory: Hematology					
3.43.	Safety	LB1	Summary of Hematology Changes from Baseline	Includes pre-specified parameters repeated in conventional units.	M12, EOS
3.44.	LTFU	LB1	Summary of Hematology Changes from Baseline (Long Term Follow-up Population)	Includes pre-specified parameters repeated in conventional units.	M12, EOS
3.45.	Safety	LB16	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3	HL, M12, EOS
Laboratory: Hepatobiliary (Liver)					

Safety: Tables					
3.46.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting	GSK Statistical Display Standard	M12, EOS
3.47.	Safety	LIVER10	Summary of Post Baseline Hepatobiliary Laboratory Abnormalities	GSK Statistical Display Standard See hepatobiliary abnormality criteria Section 13.7.1	HL, M12, EOS
3.48.	Safety	LIVER11	Summary of Liver Restart/Re-Challenges	GSK Statistical Display Standard	M12, EOS
Vital Signs					
3.49.	Safety	VS1	Summary of Change from Baseline in Vital Signs	ICH E3 Include Baseline values, weight, and BMI	M12, EOS
Cardiovascular Risk Factors					
3.50.	Safety	FH1	Summary of Family History of Cardiovascular Risk Factors	GSK Statistical Display Standard	M12
3.51.	Safety	SU1	Summary of Substance Use	GSK Statistical Display Standard	M12
COVID-19 Adverse Events					
3.52.	Safety	PAN1	Summary of COVID-19 Assessments for Subjects with COVID-19 Adverse Events	GSK Statistical Display Standard Includes events across all phases	IA2, M12, EOS
3.53.	Safety	PAN2	Summary of COVID-19 Additional Assessments for Subjects with COVID-19 Adverse Events	GSK Statistical Display Standard Includes events across all phases	M12, EOS
3.54.	Safety	PAN3	Summary of COVID-19 Symptoms for Subjects with COVID-19 Adverse Events	GSK Statistical Display Standard Includes events across all phases	M12, EOS
3.55.	Safety	PAN10	Incidence of Covid-19 Adverse Events Overall and by Subgroup	Subgroups include Sex, Implementation Arm Includes events across all phases	M12, EOS

Safety: Tables					
Adverse Events of Special Interest					
3.56.	Safety	201584/primary_27/T3.140	Summary of Depression, Anxiety and Suicidal or Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety or Suicidal Ideation/Behaviour at Screening		M12, EOS
3.57.	Safety	201584/primary_07/T3.122	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.58.	Safety	201584/primary_07/T3.125	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.59.	Safety	201584/primary_07/T3.128	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.60.	Safety	201584/primary_07/T3.134	Summary of Seizures Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.61.	Safety	201584/primary_07/T3.137	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, EOS
3.62.	Safety	201584/primary_07/T3.140	Summary of Hypersensitivity Reactions (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.63.	Safety	201584/primary_07/T3.143	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS

Safety: Tables					
3.64.	Safety	201584/primary_07/T3.149	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.65.	Safety	201584/primary_07/T3.152	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.66.	Safety	201584/primary_07/T3.155	Summary of Mood Disorders Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.67.	Safety	201584/primary_07/T3.158	Summary of Sleep Disorders Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.68.	Safety	201584/primary_07/T3.161	Summary of Hyperglycaemia Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.69.	Safety	201584/primary_07/T3.161	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.70.	Safety	201584/primary_07/T3.164	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.71.	Safety	201584/primary_07/T3.167	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.72.	Safety	201584/primary_07/T3.170	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS

Safety: Tables					
3.73.	Safety	201584/primary_07/T3.173	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.74.	Safety	207966/primary_15/T3.109	Summary of Characteristics of Adverse Events of Special Interest		M12, EOS
3.75.	Safety	AE99	Adverse Event Overview by Study Phase and Subgroup	Repeat Table 3.9 for all relevant subgroups including country, sex, age group, race group, and CD4 group as mentioned in Section 5.4.2. Do not include LTFU data. Include BMI >=30/<30 as a subgroup	M12

CCI [redacted]

Safety: Tables

CCI

[redacted]

3.88.	Safety	VS1	Summary of Change from Day 1 Weight Values	Repeat of Table 3.49 using Day 1 values as Baseline.	EOS

13.12.8. Safety Figures

Safety: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Adverse Events					
3.1.	Safety	201584/primary_07/F3.14	Plot of Incidence of Study Drug Injection Site Reaction Adverse Events by Implementation Arm and Visit (Overall and Common) – CAB and/or RPV	Sort by CAB+RPV, CAB, then RPV ISR onset assigned to most recent IM injection Visit	M12, EOS
CCI [redacted]					
Laboratory					
3.3.	Safety	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT	GSK Statistical Display Standard	M12, EOS
3.4.	Safety	LIVER9	Scatter Plot of Maximum Total Bilirubin vs Maximum ALT – eDISH Plot	GSK Statistical Display Standard	M12, EOS

13.12.9. Other Tables

Study Visit Length					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	Safety	OTR_T1	Summary of Study Visit Length (minutes) by Visit, Country, and Site (Intervention Phase)	Include overall summary for each visit and country.	IA1, IA2, HL, M12
4.2	Safety	OTR_T2	Summary of Study Visit Length (minutes) by Visit and Subgroup (Intervention Phase)	Include all subgroups listed in Section 5.4.2 except for Site & Country	M12
4.3	Safety	NS1	Summary of Remote & Nursing Visits by Visit, Country, and Site	Include overall summary for each visit and country. Add footnote: "All remote visits were recorded in response to missed visits due to Covid-19."	IA2, M12, EOS
4.4	Safety	NS1	Summary of Remote & Nursing Visits by Visit and Subgroup	Include all subgroups listed in Section 5.4.2 except for Site & Country Add footnote: "All remote visits were recorded in response to missed visits due to Covid-19."	M12, EOS

13.12.10. ICH Listings

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.	Enrolled	ES2	Listing of Reasons for Study Withdrawal	ICH E3 Add column for Phase, Visit, and Implementation arm	M12, EOS
2.	Enrolled	SD2	Listing of Reasons for Study Treatment Discontinuation	ICH E3 Add column for Phase, Visit, and Implementation arm	HL, M12, EOS
Protocol Deviations					
3.	Enrolled	DV2	Listing of Important Protocol Deviations	ICH E3 Add column for Phase, Visit, and Implementation arm Add a column on the right for "COVID-19 Related". The possible values in this column are Y and N, where Y indicates the deviation is COVID-19 related and N indicates the deviation is non-COVID-19 related.	IA1, IA2, M12, EOS
4.	Enrolled	DV2	Listing of Protocol Deviations Related to COVID-19	Add column for Phase, Visit, and Implementation arm	HL, M12, EOS
5.	Enrolled	DV2	Listing of Implementation Science Protocol Deviations	Add column for Phase, Visit, and Implementation arm	HL, M12, EOS
6.	Safety	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	ICH E3	M12
Populations Analysed					
7.	Enrolled	SP3	Listing of Subjects Excluded from Safety Population	ICH E3	M12

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Demographic and Baseline Characteristics					
8.	Safety	DM2	Listing of Demographic Characteristics	ICH E3	M12
9.	Safety	DM9	Listing of Race	ICH E3	M12
Efficacy					
10.	Safety	SNAPSHOT11	Listing of Qualitative and Quantitative Plasma HIV-1 RNA Data		HL, M12
11.	Safety	SNAPSHOT12	Listing of Study Outcome (50 copies/mL cutoff) at Month 12 – Snapshot Analysis		HL, M12
12.	Safety	VF4	Listing of Plasma HIV-1 RNA and CD4+ Cell Count for subjects with Confirmed Virologic Failure		M12, EOS
Exposure and Treatment Compliance					
13.	Safety	207966/primary_15/L12	Listing of Exposure Data	ICH E3 Remove Phase Day	M12
Adverse Events					
14.	Safety	AE8	Listing of All Adverse Events	ICH E3 Add column for Phase, Visit, and Implementation arm; see gsk1265744/mid207966/primary_15/L19	HL, M12
15.	Safety	AE8	Listing of Grade 3-5 Adverse Events	Add column for Phase, Visit, and Implementation arm; see gsk1265744/mid207966/primary_15/L19	M12
16.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3	M12
17.	Safety	201584/primary_07/L22	Listing of Changes in Intensity/Grades of Study Drug Injection Site Adverse Events	Remove phase treatment, add visit	M12, EOS

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
18.	Safety	AE8	Listing of COVID-19 Adverse Events	Add column for Phase, Visit, and Implementation arm; see gsk1265744/mid207966/primary_15/L19 Include Y/N column checked if the AE lead to discontinuation	HL, M12
19.	Safety	PAN12	Listing of COVID-19 Assessments and Symptom Assessments	Add column for Phase and Visit	M12
20.	Safety	PAN5	Country Level Listing of Start Dates of COVID-19 Pandemic Measures		M12, EOS
Serious and Other Significant Adverse Events					
21.	Safety	AE8	Listing of Fatal Serious Adverse Events	ICH E3 Add column for Phase, Visit, and Implementation arm	M12
22.	Safety	AE8	Listing of Non-Fatal Serious Adverse Events	ICH E3 Add column for Phase, Visit, and Implementation arm	M12, EOS
23.	Safety	AE8	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment	ICH E3 Add column for Phase, Visit, and Implementation arm	M12, EOS
Laboratory					
24.	Safety	LB14	Listing of Laboratory Data with Character Results	ICH E3 Add Category, Phase/Period, Visit	M12

13.12.11. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**GSK Standard GSK Statistical Display Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
25.	Screened	ES7	Listing of Reasons for Screen Failure	Journal Guidelines	M12
26.	Screened	ES9	Listing of Subjects Who Were Rescreened		M12
27.	Enrolled	SD2	Listing of Reasons for Study Treatment Discontinuation During the Oral Lead-in Period	Add column for Visit and Implementation arm	M12
28.	Safety	TA1	Listing of Planned and Actual Treatments by Implementation Arm	GSK Statistical Display Standard	M12
29.	Safety	TA1	Listing of Subjects with Missed Visits Due to Covid-19 by Implementation Arm	Add a column indicating whether a remote visit was performed (Y/N)	M12, EOS
Prior and Concomitant Medications					
30.	Safety	207966/primary_15/Listing 36	Listing of Prior ART Medications	Remove the column 'Phase during Which Concomitant'	M12
31.	Safety	207966/primary_15/Listing 37	Listing of Concomitant ART Medications	Add column for Phase, Visit, and Implementation arm Add a column specifying "SOC Oral Bridging?" which has values of "Yes" and "No".	HL, M12, EOS
32.	Safety	207966/primary_15/Listing 38	Listing of ART Medications Received during Long-term Follow-up Phase	Remove the column 'Phase during Which Concomitant'	M12, EOS
Medical History					
33.	Safety	201584/primary_01/L43	Listing of Medical History of Seizure		M12

Efficacy					
34.	Safety	CDC4	Listing of CDC Classification of HIV-1 Infection at Baseline		M12
35.	Safety	CDC5	Listing of CDC Stage 3 HIV-1 Associated Conditions	Add column for Phase, Visit	M12, EOS
Exposure					
36.	Safety	EX3	Listing of Actual Visit Dates and Day Since Last Dose	Add column for implementation arm	IA1, IA2, M12, EOS
37.	Safety	207966/primary_15/L60	Listing of Oral Bridging Exposure Data	Add visit to phase. Add column for implementation arm and to identify COVID relatedness.	HL, M12, EOS
38.	Safety	207966/primary_15/L60	Listing of Exposure Data for Subjects Who Received Oral Bridging	Add visit to phase. Add columns for implementation arm, Total Volume Injected / Duration of Oral Treatment	M12
Hepatobiliary (Liver)					
39.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting	GSK Statistical Display Standard Add column for Phase, Visit	M12, EOS
40.	Safety	LIVER15	Liver Stopping Event Profile	GSK Statistical Display Standard Add column for Phase, Visit	M12, EOS
41.	Safety	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline	GSK Statistical Display Standard Add column for Phase, Visit	HL, M12, EOS
42.	Safety	LB12	Listing of ALT, AST, Bilirubin (including Total and Direct Bilirubin), INR, and ALP for Subjects Meeting Hepatobiliary Lab Abnormality Criteria	Add column for Phase, Visit	M12, EOS

Other					
43.	Safety	EG3	Listing of All ECG Values for Subjects with Recorded ECG Data	GSK Statistical Display Standard Add column for Phase, Visit	M12
44.	Safety	PREG1	Listing of Subjects Who Became Pregnant During the Study	GSK Statistical Display Standard Add column for Phase, Visit	M12, EOS
45.	Safety	201584/primary_17/L54	Listing of Replication Capacity in IN and PR/RT Region	Add column for Phase, Visit	M12, EOS
Vital Signs					
46.	Safety	VS5	Listing of Vital Sign Results	GSK Statistical Display Standard Required for ClinPharm studies only.	M12
Pharmacokinetic					
47.	Safety	PK07	Listing of Plasma CAB Pharmacokinetic Concentration-Time Data		M12, EOS
48.	Safety	PK07	Listing of Plasma RPV Pharmacokinetic Concentration-Time Data		M12, EOS
Pregnancy (conditional on incidence of pregnancy)					
49.	Safety	PREG_01	Listing of Pregnancy Details and Outcomes	Results to be pulled from the Pregnancy Notification Form	EOS
50.	Safety	PREG_02	Listing of Pregnancy Outcomes	Results to be pulled from the Pregnancy Follow-up Form	EOS
51.	Safety	207966/primary_15/Listing 37	Listing of Concomitant Medications for Pregnant Participants During and After Pregnancy	Results should reconcile with the Pregnancy Notification and Follow-up Forms Follow specifications for the current Listing 31	EOS
52.	Safety	SNAPSHOT11	Listing of Qualitative and Quantitative Plasma HIV-1 RNA Data for Pregnant Participants	Follow specifications for the current Listing 10	EOS
53.	Safety	207966/primary_15/L12	Listing of Exposure Data for Pregnant Participants	Follow specifications for the current Listing 13	EOS

54.	Safety	AE8	Listing of Adverse Events for Pregnant Participants During and After Pregnancy	Follow specifications for the current Listing 14	EOS
55.	Safety	LB5A	Listing of All Laboratory Data for Pregnant Participants During and After Pregnancy		EOS
56.	Safety	PK07	Listing of Plasma CAB Pharmacokinetic Concentration-Time Data for Pregnant Participants During and After Pregnancy	Follow specifications for the current Listing 43	EOS
57.	Safety	PK07	Listing of Plasma RPV Pharmacokinetic Concentration-Time Data for Pregnant Participants During and After Pregnancy	Follow specifications for the current Listing 44	EOS

13.13. Appendix 13: Example Mock Shells for Data Displays

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Table DISP_T1
Summary of Subject Disposition at Each Study Phase

Study Phase		CAB Oral + RPV Oral (N=100)	CAB LA + RPV LA (N=100)	Total (N=200)
Intervention Phase	ENTERED	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	COMPLETED	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WITHDRAWN	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	COVID-19 RELATED	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Completed Intervention Phase but Withdrew Prior to Extension Phase	ENTERED			xx (xx.x%)
	COMPLETED			xx (xx.x%)
	WITHDRAWN			xx (xx.x%)
	COVID-19 RELATED			xx (xx.x%)
Extension Phase	ENTERED			xx (xx.x%)
	COMPLETED			xx (xx.x%)
	WITHDRAWN			xx (xx.x%)
	COVID-19 RELATED			xx (xx.x%)
Long-term Follow-up Phase	ENTERED			xx (xx.x%)
	COMPLETED			xx (xx.x%)
	WITHDRAWN			xx (xx.x%)
	COVID-19 RELATED			xx (xx.x%)

Intervention/Extension phase status and reason for withdrawal is based on date and reason collected in the study treatment discontinuation form.
A subject is considered to have entered the Extension phase if the subject received a Month 14 injection or had any assessments collected at any Extension phase nominal visit.
A subject is considered to have entered the Long-term Follow-up phase if they have received at least one CAB and/or RPV injection and have started Long-term Follow-up ART
Long-term Follow-up completion/withdrawal is based on data collected in the Study Conclusion form.
PPD /arenv/arprod/gsk1265744/mid209493/primary_01/drivers/t_sp_sd_phase.sas 02FEB2021 11:58

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Table DISP_T2
Summary of Reasons for Withdrawal at Each Study Phase

Phase	Primary Reason[1]/Subreason[2] for Withdrawal	CAB Oral + RPV Oral (N=100)	CAB LA + RPV LA (N=100)	Total (N=200)
Intervention Phase	ADVERSE EVENT	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	COVID-19 RELATED	x (xx.x%)	x (xx.x%)	x (xx.x%)
	LACK OF EFFICACY	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	PROTOCOL DEVIATION	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	COVID-19 RELATED	x (xx.x%)	x (xx.x%)	x (xx.x%)
	PROHIBITED MEDICATION USE	x (xx.x%)	x (xx.x%)	x (xx.x%)
	NON-COMPLIANCE WITH STUDY TREATMENT	x (xx.x%)	x (xx.x%)	x (xx.x%)
	SUBJECT REACHED PROTOCOL-DEFINED STOPPING CRITERIA	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	STUDY TERMINATED BY SPONSOR	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	LOST TO FOLLOW-UP	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	INVESTIGATOR SITE CLOSED	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	PHYSICIAN DECISION	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WITHDRAWAL BY SUBJECT	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	COVID-19 RELATED	x (xx.x%)	x (xx.x%)	x (xx.x%)
	FREQUENCY OF INJECTIONS	x (xx.x%)	x (xx.x%)	x (xx.x%)
Long-term Follow-up Phase	LOST TO FOLLOW-UP			xx (xx.x%)
	WITHDRAWAL BY SUBJECT			xx (xx.x%)
	SUBJECT RELOCATED			x (xx.x%)

BURDEN OF PROCEDURES x (xx.x%)

[1] Subjects may have only one primary reason.
[2] Percentages for subreasons may sum to more or less than 100%. Subjects may have more than one sub-reason underneath a single primary reason. Subjects are not required to indicate subreasons.
Intervention/Extension phase: status and reason for withdrawal based on date and reason collected in the study treatment discontinuation form. Long term Follow-up: completion/withdrawal based on data collected in the Study Conclusion form.

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Table EFF_T1
Summary of Study Outcomes (50 c/mL cutoff) at Month 12 (Intervention Phase) - Snapshot Analysis

Outcome	Q4W IM (N=xx)
HIV-1 RNA<50 c/mL	xx (xx%)
HIV-1 RNA>=50 c/mL	xx (xx%)
Data in window not below threshold	xx (xx%)
Discontinued for lack of efficacy	xx (xx%)
Discontinued for other reason while not below threshold	xx (xx%)
Change in ART [1]	xx (xx%)
No Virologic Data	xx (xx%)
Discontinued study due to AE or Death	xx (xx%)
Discontinued study for Other Reasons	xx (xx%)
On study but missing data in window	xx (xx%)

[1] Excludes CAB + RPV Oral Bridging and COVID-19 related temporary oral bridging with SOC.

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Table EFF_T2
Summary of Study Outcomes (50 c/mL cutoff) at Month 12 (Intervention Phase)
- Snapshot Analysis

Outcome	Q4W IM (N=xx)
HIV-1 RNA<50 c/mL	xx (xx%)
HIV-1 RNA>=50 c/mL	xx (xx%)
Data in window not below threshold	xx (xx%)
Non-COVID-19 related	xx (xx%)
Discontinued for lack of efficacy	xx (xx%)
Discontinued for other reason while not below threshold	xx (xx%)
COVID-19 related	xx (xx%)
Discontinued for lack of efficacy	xx (xx%)
Discontinued for other reason while not below threshold	xx (xx%)
Change in ART [1]	xx (xx%)
No Virologic Data	xx (xx%)
Non-COVID-19 related	xx (xx%)
Discontinued study due to AE or Death	xx (xx%)
Discontinued study for Other Reasons	xx (xx%)
On study but missing data in window	xx (xx%)
COVID-19 related	xx (xx%)
Discontinued study due to AE or Death	xx (xx%)
Discontinued study for Other Reasons	xx (xx%)
On study but missing data in window	xx (xx%)

[1] Excludes CAB + RPV Oral Bridging and COVID-19 related temporary oral bridging with SOC.

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Table SAF_T1
Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Country, Site, and COVID Impacted/Non-Impacted (Intervention Phase)

Country: xxxxx *{Programmer's Note: repeat for each of 5 countries overall, each individual site, and total}*
Site ID: xxxx
COVID-19: xxx {non-impacted + impacted/non-impacted/impacted}

Timeliness of Injections Relative to Date of Projected Dosing Visits	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12	Total
No. of Expected Injection Visits	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
<-14 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
-14 days to – 8 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
-7 days to – 1 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
0	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
1 days to 7 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
8 days to 14 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
> 14 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection without OB (non-COVID-19 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection without OB (COVID-1 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection with OB (non-COVID-19 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection with OB (COVID-19 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Late Out of Window Injections (days outside +7 day window)							
n	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
Q1	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Q3	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Min	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Timeliness of Injections Relative to Date of Projected Dosing Visits	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12	Total
Max	xxx	xxx	xxx	xxx	xxx	xxx	xxx

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Table SAF_T2
Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Subgroup, and COVID Impacted/Non-Impacted
(Intervention Phase)

Subgroup: xxxx *{Programmer's Note: repeat for each subgroup}*
COVID-19: xxx {*Programmer's Note: repeat for* non-impacted + impacted/non-impacted/impacted}

Timeliness of Injections Relative to Date of Projected Dosing Visits	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12	Total
No. of Expected Injection Visits	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
<-14 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
-14 days to – 8 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
-7 days to – 1 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
0	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
1 days to 7 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
8 days to 14 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
> 14 days	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection without OB (non-COVID-19 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection without OB (COVID-1 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection with OB (non-COVID-19 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Missed Injection with OB (COVID-19 related)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)	xx (%)
Late Out of Window Injections (days outside +7 day window)							
n	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
Q1	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Q3	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Min	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Timeliness of Injections Relative to Date of Projected Dosing Visits	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12	Total
Max	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Population: Safety

Table OTR_T1

Summary of Study Visit Length (minutes) by Visit, Country, and Site

Country Site	N			Month 1	Month 2	Month 6	Month 8	Total
Overall Overall		Lead Time	n	xxx	xxx	xxx	xxx	xxx
			Mean	xx.x	xx.xx	xx.x	xx.x	xx.x
			SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
			Median	xx.x	xx.x	xx.x	xx.x	xx.x
			Q1	xx.x	xx.x	xx.x	xx.x	xx.x
			Q3	xx.x	xx.x	xx.x	xx.x	xx.x
			Min.	xx	xx	xx	xx	xx
			Max.	xx	xx	xx	xx	xx
		Process Time	n	xxx	xxx	xxx	xxx	xxx
			Mean	xx.x	xx.xx	xx.x	xx.x	xx.x
			SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
			Median	xx.x	xx.x	xx.x	xx.x	xx.x
			Q1	xx.x	xx.x	xx.x	xx.x	xx.x
			Q3	xx.x	xx.x	xx.x	xx.x	xx.x
			Min.	xx	xx	xx	xx	xx
			Max.	xx	xx	xx	xx	xx
		Total Time	n	xxx	xxx	xxx	xxx	xxx
			Mean	xx.x	xx.xx	xx.x	xx.x	xx.x
			SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
			Median	xx.x	xx.x	xx.x	xx.x	xx.x
			Etc.	xx.x	xx.x	xx.x	xx.x	xx.x

Lead Time = Actual Start Time of Appointment – Arrival Time.

Process Time = Actual End Time of Appointment – Actual Start Time of Appointment.
[Programmers Note: repeat for each, country site, and total]

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Table OTR_T2
Summary of Study Visit Length (minutes) by Visit and Subgroup

Subgroup Strata	N			Month 1	Month 2	Month 6	Month 8	Total
Sex Male		Lead Time	n	xxx	xxx	xxx	xxx	xxx
			Mean	xx.x	xx.xx	xx.x	xx.x	xx.x
			SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
			Median	xx.x	xx.x	xx.x	xx.x	xx.x
			Q1	xx.x	xx.x	xx.x	xx.x	xx.x
			Q3	xx.x	xx.x	xx.x	xx.x	xx.x
			Min.	xx	xx	xx	xx	xx
			Max.	xx	xx	xx	xx	xx
		Process Time	n	xxx	xxx	xxx	xxx	xxx
			Mean	xx.x	xx.xx	xx.x	xx.x	xx.x
			SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
			Median	xx.x	xx.x	xx.x	xx.x	xx.x
			Q1	xx.x	xx.x	xx.x	xx.x	xx.x
			Q3	xx.x	xx.x	xx.x	xx.x	xx.x
			Min.	xx	xx	xx	xx	xx
			Max.	xx	xx	xx	xx	xx
		Total Time	n	xxx	xxx	xxx	xxx	xxx
			Mean	xx.x	xx.xx	xx.x	xx.x	xx.x
			SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
			Median	xx.x	xx.x	xx.x	xx.x	xx.x
			Etc.	xx.x	xx.x	xx.x	xx.x	xx.x

Lead Time = Actual Start Time of Appointment – Arrival Time.
Process Time = Actual End Time of Appointment – Actual Start Time of Appointment.
[Programmers Note: repeat for each Subgroup and Strata]

Preg_01

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Population: Safety

Listing 49 (Data as of: 30MAY2011)

Listing of Pregnancy Details

Site Id.: PPD

Unique Subject Id./ Subject Id./Implementation Arm	Mother's Year of Birth	Date of Last Menstrual Period/ Study Day	Estimated Date of Delivery/ Study Day	Contraception?/Contraception Type/Conception Type (Normal, IVF)[1]	Relevant Lab Tests and Procedures	No. of Previous Pregnancies: Pre-term	No. of Previous Pregnancies: Full-term	Additional Facrors that May Impact Pregnancy
PPD /CAB LA + RPV LA ARM-e	xxxx	2012-PPD T23:59/ 1	2012-PPD T23:59/ 1	Y/Birth Control/Normal	Amniocentesis performed	Spontaneous Abortion (n): x	Normal Births (n): x	
						Elective Abortion (n): x	Stillbirths (n): x	
						Other (n): x	Born w/Defects (n): x	
PPD /CAB LA + RPV LA ARM-e	xxxx	2012-PPD T23:59/ 1	2012-PPD T23:59/ 1	N/ /Normal		Spontaneous Abortion (n): x	Normal Births (n): x	
						Elective Abortion (n): x	Stillbirths (n): x	
						Other (n): x	Born w/Defects (n): x	

[1] Normal conception includes the use of fertility drugs. IVF = in vitro fertilization.

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Preg_02

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Population: Safety

Listing 50 (Data as of: 30MAY2011)

Listing of Pregnancy Outcomes

Site Id.: PPD

Unique Subject Id./ Subject Id./Implementation Arm	Pregnancy Status [1]	Foetal/Neonatal Status (Normal, Brith Defect, Other)	Origin of Birth Defect Known?	Date of Birth,miscarriage,termination / Study Day / Gestational Weeks	Infant Sex/Length (cm)/Weight (g)	Apgar Score (0-10) 1st / 2nd	Pregnancy Dur-ation (days)[2]	Additional Pregnancy Details
PPD /CAB LA + RPV LA ARM-e	Delivery: Normal	Birth Defect	Yes : xxxx	2012-PPD T23:59/ 1 / 38	M / 50 / 2500	8/8	xx	
PPD CAB LA + RPV LA ARM-e	PPD	NA	NA	2012-PPD T23:59/ 1 / 36	NA	0	xx	SAE delivery complication

[1] Status options include Delivery: method specified, Stillbirth, Foetal death, Spontaneous abortion, Elective abortion, Other: specified.

[2] Pregnancy duration calculated as Date of Birth/Miscarriage/Termination - Date of Last Menstrual Period + 1.

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Signature Page for 213199 TMF-15213711 v1.0

Reason for signing: Approved	Name: PPD Role: A Date of signature: 12-Dec-2022 13:40:23 GMT+0000

Reason for signing: Approved	Name: PPD Role: A Date of signature: 12-Dec-2022 13:44:41 GMT+0000

Reason for signing: Approved	Name: PPD Role: A Date of signature: 12-Dec-2022 15:30:08 GMT+0000

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