Statistical Analysis Plan

Study ID: 207966

Official Title of Study: A Phase IIIb, Randomized, Multicenter, Parallel-group, Non-inferiority, Open-label Study Evaluating the Efficacy, Safety, and Tolerability of Long-acting Cabotegravir Plus Long-acting Rilpivirine Administered Every 8 Weeks or Every 4 Weeks in HIV-1-infected Adults who are Virologically Suppressed (ATLAS-2M), further referred to as A2M.

NCTID: NCT03299049

Sub-study Protocol Amendment Title: Sub-sudy to the A2M study to Evaluate the Pharmacokinetics, Tolerability and Efficacy of Cabotegravir and Rilpivirine Long-Acting Injections Following Intramuscular Administration in the Vastus Lateralis Muscle (thigh) in HIV-infected Adult Participants who have Received at Least Three Years of Gluteal Injections in the A2M Study.

NCTID: NCT05896761

Date of Document: 23 September 2022

The sub-study was added to the protocol of the main study via an amendment. Details of the sub-study can be found in the protocol section *11.13 Appendix 13: Vastus Lateralis Muscle (Thigh) PK sub-study Amendment*. A separate record has been created on ClinicalTrials.gov for the sub-study.

Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)
Title	:	Reporting and Analysis Plan for Protocol 207966: Study Evaluating the Efficacy, Safety, and Tolerability of Long-acting Cabotegravir Plus Long-acting Rilpivirine administered every 8 weeks in Virologically Suppressed HIV-1-infected Adults
Compound Number	:	GSK1265744
Effective Date	:	08-Sep-2022

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Thigh PK Sub-study Clinical Study Report for Protocol 207966. Reporting details pertaining to the primary Week 48 and the earlier analyses (Week 24 IDMC, Week 24, Week 96 and Week 152) have been retained for completeness.
- This version of the RAP includes amendments to the originally approved RAP.

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Reviewer	Date
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1. INTRODUCTION

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

Revision Chronology:		
2017N326521_00	17-JUL-2017	Original
2017N326521_01	14-SEP-2017	The primary purpose of protocol amendment # 1 is to revise the study sample size to randomize approximately 1020 participants including 510 participants per arm based on a non-inferiority margin of 4% between the CAB LA + RPV LA Q8W and Q4W arms.
2017N326521_02	03-Jul-2018	The primary reasons for amendment #2 are to: • Add the additional interim analysis of data when all subjects have completed the Week 24 visit, with the intent of expediting the submission of study results to Health Authorities; • Change the objective for assessing the preference for CAB LA + RPV LA every 8 weeks or CAB LA + RPV LA every 4 weeks LA compared to oral antiretroviral (ARV) and the preference for CAB LA+ RPV LA every 8 weeks compared to CAB LA + RPV LA every 4 weeks from an exploratory objective to a secondary objective. A change to the supporting version of the Preference questionnaire administered to participants at Week 48 (or withdrawal) is also acknowledged; • Add revisions and clarifications for the administration of health outcomes questionnaires; • Extend exclusion criterion #28 to also exclude hereditary coagulation and platelet disorders such as haemophilia or Von Willebrand Disease; • Update exclusion criterion #11 to indicate that CD4+ counts <200 cells/µL are not exclusionary; • Offer clarification that withdrawal assessments will be performed for any participant who withdraws prematurely from the Maintenance or Extension Phase. Additional guidance for participants withdrawing at Week 52 or Week 100 has been added; • Offer guidance to monitor medications that are dependent on OAT1 and OAT3 transport upon concomitant exposure with CAB; • Specify that 2-hour post-dose ECG should be performed at Day 1 and Week 48 only for participants receiving CAB LA + RPV LA as it is not required to perform 2-hour post-dose ECG for those receiving oral CAB + RPV at Day 1;

Revision Chronology:		
		• Exclude language that previously indicated hormonal contraception may be susceptible to interaction with the study drugs. The lack of a demonstrated interaction with a representative contraceptive supports use of CAB and RPV across a broad range of estrogen and progestin or progestin only hormonal contraceptives; • Add minor clarifications and corrections to typographical errors/formatting to protocol text.
2017N326521_03	21-May-2020	The primary reason for protocol amendment 03 is to include information on Covid-19 specific guidance for clinical trial continuity (participant and study management) during the pandemic. This information is included within Appendix 10: COVID-19 Pandemic and Clinical Trial Continuity.
2017N326521_04	05-Aug-2020	The primary reasons for protocol amendment 04 are to add a formal efficacy and safety secondary analysis at Week 152, allowing participants to continue treatment with randomized study medication through at minimum the Week 152 timepoint. The study endpoints and additional assessments in support of the planned secondary analyses have been updated for Week 152. Health outcomes assessments including the HIV-TSQs, Accept, and PIN questionnaires are included at Week 152 to gain further insight into participant's long-term treatment experience with Long-acting Cabotegravir Plus Long-acting Rilpivirine. The Preference questionnaire will also be administered at Week 152 only to participants who received oral bridging during the Maintenance and/or Extension Phases. Additional minor clarifications to protocol language have also been incorporated.
TMF-11797977	16-Apr-2021	The primary purposes of this amendment are: • To allow participants who become pregnant to remain in the study and not be withdrawn due to pregnancy. Allowing pregnant participants to continue in the study will negate any additional and subsequent fetal exposures to new antiretrovirals agents that would occur if the pregnant participant was withdrawn from the study and placed on an oral SOC regimen. An Appendix, "Information and Guidance for Managing Pregnant Participants" was inserted as Appendix 11, and all subsequent appendices were renumbered accordingly. • Contraceptive methods have been updated to permit the use of progestogen-only implantable and injectable contraceptives without the requirement of a second highly effective method. • Removal of the optional collection of cord blood and/or breast milk after delivery.

Revision Chronology:		
		• Removal of the option for study treatment rechallenge following suspected druginduced liver injury (DILI) • Clarification of which participants enter the LTFU phase when CAB+RPV LA marketed product is locally available. • Clarification added: The Reason for Oral Bridgingand Preference questionnaire will also be administered at Withdrawal if it occurred at or before Week 152 only to participants who received oral bridging during the Maintenance and/or Extension Phases. • Medical Device reporting requirement added • Co-enrolment (Only applicable for South African participants) • Clinical and safety references updated • Removal of the reference to "randomized study treatment" in Overall design sections for alignment with CAB program studies and transition to marketed product plan.
TMF-13901227	11-Aug-2021	The primary purposes of this amendment are: • Included Thigh Injection Sub-study appendix • Added safety and PK laboratory assessments during pregnancy for subjects who become pregnant during the study and decide to continue receiving IM treatment in the study. • Medical device deficiencies reporting requirements updated to be aligned with GSK reporting processes. • Updated safety information • Other minor clarifications added

1.1. RAP Amendments

Revision Chronology:

RAP Section	Amendment Details
Reporting and Analysis Plan_Study207966_Final_V1 [17-JAN-2019]	
Reporting and Analysis Plan_Study207966_Amendment_Final_V1 [23-JUN-2020]	
Reporting and Analysis Plan_Study207966_Amendment_2_Final_V1 [28-JUN-2020]	
Reporting and Analysis Plan_Study207966_Amendment_3_Final_V1	
Data Handling and Data Displays for Sub-study	• Updated visit/phase slotting algorithms to handle the newly added assessments and time points in the protocol. • Added new analysis populations for sub-study analysis.

	• Defined a separate list of displays for sub-study analysis.
Safety Analysis	• Added calculation methods for extent of exposure in sub-study. • Extended lipid LOCF approach to include both Thigh Injection and Return to Gluteal Injection phases in sub-study. • Updated the display shells for summaries of COVID-19 assessments to accommodate possible scenarios of multiple COVID-19 case diagnosis per participant.
PK Analysis	• Added analysis methods for PK parameters derived from sub-study concentration-time data. • Extended evaluability criteria to include sub-study PK concentration data.
Study Population Analysis	• Added windows for evaluating concomitant ART/non-ART medications in sub-study. • Added a listing for data collected from the Transition to CAB + RPV LA Marketed Product Status eCRF form.
Health Outcomes Analysis	• Added analysis for the newly added Preference Thigh Injection vs Gluteal Injection questionnaire.
General Updates	• Added sub-study Schedule of Activities per new protocol. • Added additional minor clarifications and corrections to typographical errors/formatting to RAP text.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

There were no changes or deviations to the originally planned statistical analysis specified in the protocol amendment 6 [(Dated: 11/AUG/2021)].

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

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To demonstrate the non-inferior antiviral activity of CAB LA + RPV LA every 8 weeks (every two months) compared to CAB LA + RPV LA every 4 weeks (monthly) over 48 weeks in suppressed HIV-1 infected antiretroviral therapy (ART)-experienced participants	• Proportion of participants with plasma HIV-RNA greater than or equal to 50 copies/mL as per Food and Drug Administration (FDA) Snapshot algorithm at Week 48 (Intent-to-Treat Exposed [ITT-E] population)
Secondary Objectives	**Secondary Endpoints**
• To demonstrate the antiviral and immunologic activity of CAB LA + RPV LA every 8 weeks compared to CAB LA + RPV LA every 4 weeks	• Proportion of participants with plasma HIV-1 RNA <50 c/mL (c/mL) at Week 24, Week 48, Week 96 and Week 152 using the FDA Snapshot algorithm (Intent-to-Treat Exposed [ITT-E] population) • Proportion of participants with protocol-defined confirmed virologic failure (CVF) through Week 24, Week 48, Week 96 and Week 152 • Proportion of participants with HIV-RNA greater than or equal to 50 c/mL as per FDA Snapshot algorithm at Week 24, Week 96 and Week 152 • Absolute values and changes from Baseline in viral load and CD4+ cell counts over time including Week 48 and Week 96 and Week 152
• To evaluate the safety and tolerability of CAB LA + RPV LA every 8 weeks compared to CAB LA + RPV LA every 4 weeks	• Incidence and severity of AEs and laboratory abnormalities over time including Week 24, Week 48, Week 96 and Week 152 • Proportion of participants who discontinue treatment due to AEs over time including Week 24, Week 48, Week 96 and Week 152 • Change from Baseline in laboratory parameters over time including Week 48, Week 96 and Week 152
• To assess viral resistance in participants experiencing protocol-defined confirmed virologic failure	• Incidence of treatment emergent genotypic and phenotypic resistance to CAB, RPV through Week 24, Week 48, Week 96 and Week 152
• To characterize CAB and RPV concentrations and population pharmacokinetics and identify important determinants of variability	• Plasma PK parameters for CAB LA and RPV LA (when evaluable, Ctrough, concentrations post dose [~Cmax], and area under the curve [AUC]) • Demographic parameters including, but not limited to, age, sex, race, body weight, body mass index, and relevant laboratory parameters will be evaluated as

Objectives	Endpoints
	potential predictors of inter- and intra-participant variability for pharmacokinetic parameters
• To assess preference for CAB LA + RPV LA every 8 weeks or CAB LA + RPV LA every 4 weeks LA compared to oral antiretroviral (ARV) • To assess preference for CAB LA+ RPV LA every 8 weeks compared to CAB LA + RPV LA every 4 weeks	• Preference for CAB LA + RPV LA every 8 weeks and CAB LA + RPV LA every 4 weeks compared to oral ARV and preference for CAB LA + RPV LA every 8 weeks compared to CAB LA + RPV LA every 4 weeks will be assessed using a preference questionnaire at week 48 (or Withdrawal).
• To assess patient reported health-related quality of life, treatment satisfaction, injection tolerability, and treatment acceptance.	• Change from Baseline (Day 1) in HRQoL at Week 24, and Week 48 (or Withdrawal) • Change from baseline (Day 1) in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Status Questionnaire (HIVTSQs) at Week 24, 48 and 152 (or Withdrawal) • Change in treatment satisfaction over time using the HIV Treatment Satisfaction Change Questionnaire HIVTSQc at Week 48 (or Withdrawal). • Change from Week 8 in Dimension scores ("Bother of ISRs", "Leg movement", "Sleep", and "Injection Acceptance") and individual item scores assessing pain during injection, anxiety before and after injection, willingness to be injected in the future and overall satisfaction with mode of administration over time will be assessed using the Perception of Injection questionnaire (PIN) at Weeks 24, 48 and 152 (or Withdrawal) • Change from Baseline (Day 1) in treatment acceptance at Week 24, Week 48 and 152 (or Withdrawal) will be assessed using the "General acceptance" dimension of the Chronic Treatment Acceptance (ACCEPT) questionnaire
Exploratory Objectives	**Exploratory Endpoints**
• To evaluate the antiviral and immunologic effects, safety and tolerability, and viral resistance of CAB LA + RPV LA for all participants in the Extension Phase.	• Proportion of participants with plasma HIV-1 RNA <50 c/mL over time • Proportion of participants with confirmed virologic failure over time • Incidence of treatment emergent genotypic and phenotypic resistance to CAB and RPV over time • Incidence and severity of AEs and laboratory abnormalities over time • Proportion of participants who discontinue treatment due to AEs over time • Absolute values and changes in laboratory parameters over time • Incidence of disease progression (HIV-associated conditions, acquired immunodeficiency syndrome [AIDS] and death)
• To explore the effect of patient characteristics on virologic and immunologic responses to CAB LA+	• Proportion of participants by patient subgroup(s) (e.g., by age, gender, BMI, race, HIV-1 subtype, Baseline CD4+, type of oral treatment [NNRTI, PI, or INSTI], duration prior

Objectives	Endpoints
RPV LA every 8 weeks compared to CAB LA + RPV LA every 4 weeks	CAB LA and RPV LA exposure [0 weeks, 1-24 weeks, > 24 weeks]) with HIV-RNA greater than or equal to 50 c/mL, and with protocol-defined confirmed virologic failure over time including Week 48, Week 96 and Week 152 using the Snapshot algorithm for the ITT-E population • Change from Baseline in CD4+ cell counts by subgroups at Week 48, Week 96 and Week 152
• To explore relationship(s) between plasma concentrations of CAB and RPV and pharmacodynamic endpoints.	• Relationship between plasma CAB and RPV concentrations and virologic, immunologic responses, and/or occurrence of adverse events [AEs] over time.
• To assess reason for switching using a single question. • To assess reason for continuation using a single question	• For patients randomized from oral SOC, the reasons for willingness to switch ART at baseline (Day 1) will be assessed • For patients randomized from CAB LA + RPV LA every 4 weeks in ATLAS, the reasons for willingness to continue long-acting ART at baseline (Day 1) will be assessed
• To assess preference for CAB LA + RPV LA every 8 weeks or every 4 weeks compared to daily oral for participants receiving oral bridging during the Maintenance and/or Extension phases	• Preference for CAB LA + RPV LA every 8 weeks or every 4 weeks compared to daily oral for participants receiving oral bridging during the Maintenance and/or Extension phases will be assessed using a preference questionnaire at week 152

2.2.1. Thigh PK Sub-study Objectives and Endpoints

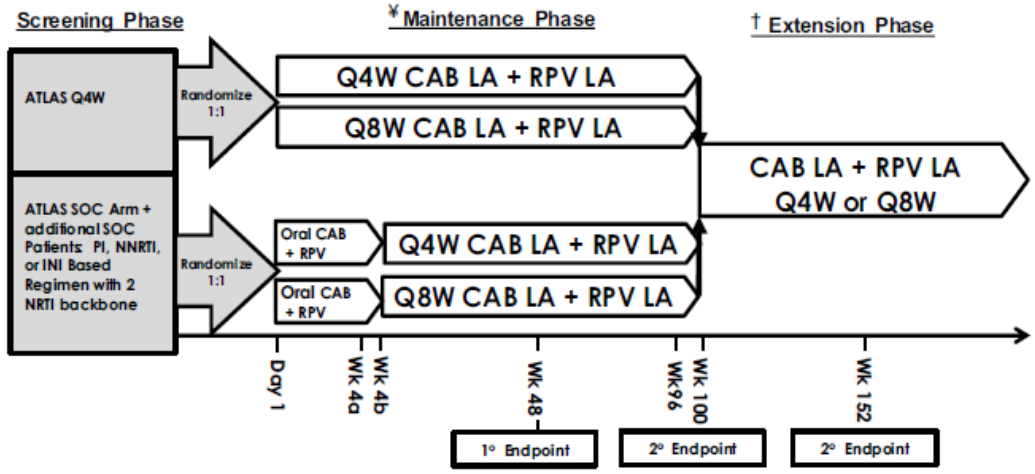
Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To evaluate the PK of monthly and every two months dosing of CAB LA and RPV LA injections following intramuscular administration in the vastus lateralis (thigh) muscle (compared to gluteal injections) in HIV-1 infected participants currently enrolled in the A2M sub-study	• Plasma PK parameters for CAB LA and RPV LA (Ctau, concentrations post dose [~Cmax], and area under the curve [AUC (0-tau)]) for thigh injections during the thigh injection phase compared with similar PK parameters for gluteal injections.
Secondary Objectives	**Secondary Endpoints**
• To assess safety and tolerability of monthly and every two months dosing of CAB LA and RPV LA following intramuscular injections in the vastus lateral (thigh) muscle in HIV-1 infected participants currently enrolled in the A2M sub-study.	• Incidence and severity of ISRs and AEs of special interest during the thigh injection phase. • Proportion of participants who discontinue treatment due to ISRs and AEs of special interest during the thigh injection phase.
• To assess the ability to maintain virologic suppression (HIV-RNA < 50 copies/mL) in subjects who transition to thigh administrations of CAB and	• Proportion of participants with plasma HIV-1 RNA <50 c/mL over time (including at Week 16) during the thigh injection phase using the FDA Snapshot algorithm. • Proportion of participants with plasma HIV-RNA ≥50 c/mL over time (including at Week 16) as per Food and Drug

Objectives	Endpoints
RPV after receiving at least 3 years of gluteal injections.	Administration (FDA) Snapshot algorithm during the thigh injection phase. • Proportion of participants with protocol-defined confirmed virologic failure (CVF) during the thigh injection phase.
• To assess viral resistance in participants experiencing protocol-defined confirmed virologic failure.	• Incidence of treatment emergent genotypic and phenotypic resistance to CAB, RPV during the thigh injection phase.
• To assess patient reported outcomes during the thigh injection phase by administering the following health outcome measurements: Numerical Rating Scale (NRS) and HIVTSQ.	• **Numerical Rating Scale (NRS):** To assess the tolerability of injections during both the Thigh and Gluteal Injection Phase • **HIVTSQ (both s and c versions):** To measure levels of satisfaction and detect change in satisfaction when switching from gluteal to thigh injections in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Questionnaire (HIVTSQ) during the Thigh Injection Phase as well as the change from thigh during the Return to Gluteal Phase.
• To assess participant's preference of thigh injections during the thigh injection phase compared to gluteal injections.	• **Preference Questionnaire:** To assess patient's preference, and reasons for preference, for injections received during the Thigh Injection Phase compared with prior gluteal injections as well as for injections received during the Return to Gluteal phase compared with prior thigh injections.
Exploratory Objectives	**Exploratory Endpoints**
• To assess additional safety events including other AEs, SAEs, and safety labs of monthly and every two months dosing of CAB LA and RPV LA following intramuscular injections in the vastus lateral (thigh) muscle in HIV-1 infected participants currently enrolled in the A2M sub-study.	• Incidence of other AEs not of special interest, SAEs and change in laboratory and change in laboratory parameters from the last gluteal injection (prior to the Thigh Injection Phase).

2.3. Study Design

Overview of Study Design and Key Features

Main Study:



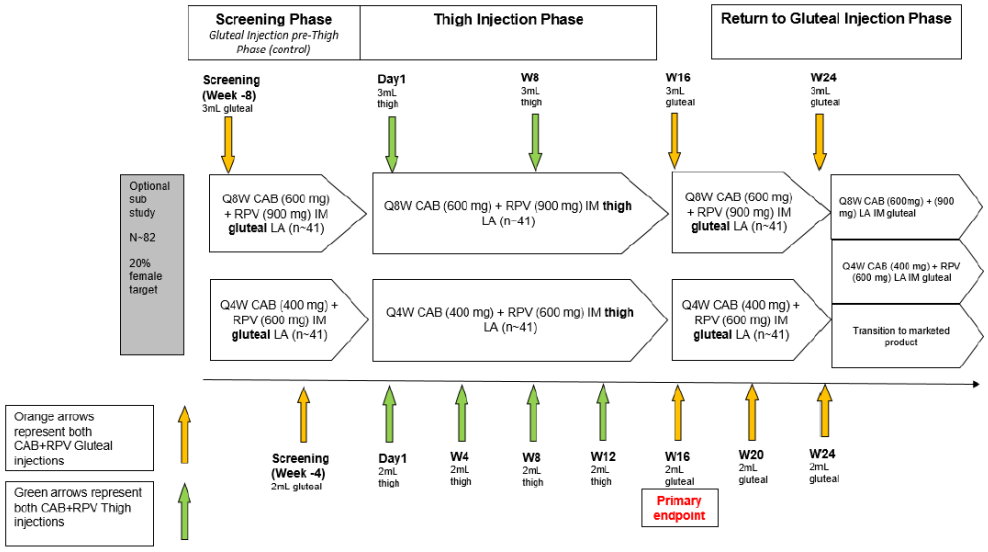
N=1020, randomized 1:1 to each arm and stratified by prior CAB+RPV Exposure

SOC Patients not transitioning from the ATLAS study must be on uninterrupted current regimen (either the initial or second cART regimen) for at least 6 months prior to Screening. Documented evidence of at least two plasma HIV-1 RNA measurements <50 c/mL in the 12 months prior to Screening: one within the 6 to 12 month window, and one within 6 months prior to Screening. No history of virologic failure. No evidence of viral resistance based on the presence of any resistance-associated major INI, or NNRTI mutation (except K103N) from prior genotype assay results. No current or prior history of etravirine use.

†Optional Extension Phase to continue randomized CAB LA + RPV LA Q4W or Q8W at Wk 100

¥Participants who withdraw from IM arm must go into 52 week long term follow up phase if randomized regimen is not yet locally approved and commercially available.

Sub-study:



Note: All injection visits during the sub-study should be kept to the same projected visit schedule as in the main study.

Overview of Study Design and Key Features	

Design Features	• Study 207966 (Antiretroviral Therapy as Long Acting Suppression every 2 Months-ATLAS-2M) is a Phase IIIb, randomized, open-label, active-controlled, multicenter, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of CAB LA + RPV LA administered every 4 weeks compared CAB LA + RPV LA administered every 8 weeks in approximately 1020 adult HIV-1 infected patients.
	• The ATLAS-2M main study comprises a Screening Phase (up to 35 days), and a Maintenance Phase (Day 1 to Week 100), followed by an Extension Phase (post Week 96). Additionally, any participant who receives at least a single dose of CAB LA and/or RPV LA and discontinues the CAB LA + RPV LA regimen will enter the Long-term Follow-up Phase and will initiate highly active antiretroviral therapy (HAART) for 52 weeks after the last dose of CAB LA and/or RPV LA, or until the assigned CAB LA + RPV LA regimen is locally approved and commercially available.
	• Two groups of patients who fulfill eligibility requirements will be randomized (1:1) at Day 1 in the main study to receive CAB LA + RPV LA Q4W, or CAB LA + RPV LA Q8W regimen for at least 100 weeks:
	  • Group 1: Patients randomized from current ART Standard of Care (SOC) therapy
	  • Group 2: Patients currently receiving CAB LA + RPV LA Q4W
	• After a minimum of 152 weeks on the ATLAS-2M main study, approximately 82 (41 per treatment arm) eligible participants will be enrolled in the sub-study. The enrolled sub-study participants will receive the study treatment on the same frequency as their randomized treatment, for example, participants randomized to the Q8W treatment in the main study will continue receiving the study treatment in every 8 weeks in the sub-study.
	• The ATLAS-2M sub-study will consist of three phases including a Screening Phase (1 injection interval: 4 weeks for Q4W participants and 8 weeks for Q8W participants), a Thigh Injection Phase with 16 weeks of thigh injections (4 injection intervals for Q4W participants and 2 injection intervals for Q8W participants) and a Return to Gluteal Injection Phase with 8 weeks of gluteal injections for both Q4W and Q8W participants. At the conclusion of the sub-study, participants will have the option to continue on the A2M main study or if commercial access treatment is available, the participants can transition off the sub-study and withdraw from ATLAS-2M and proceed directly to CAB/RPV LA.

Dosing	• Group 1: oral therapy with CAB 30 mg + RPV 25 mg once daily at main study Day 1 for 28 days (±3 days) to determine individual safety and tolerability, followed by CAB LA + RPV LA Q4W or CAB LA + RPV LA Q8W (as randomized at main study Day 1) • Group 2: CAB LA + RPV LA Q4W or CAB LA + RPV LA Q8W (as randomized at main study Day 1)
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• Randomized (1:1) at Day 1 to receive CAB LA + RPV LA Q4W or CAB LA + RPV LA Q8W • GSK RandAll NG used to generate randomization schedules • Stratified Randomization by prior CAB+RPV exposure (0 weeks, 1 to 24 weeks, >24 weeks)
Interim Analysis	• Futility analysis at (approx.) 50% of subjects completing Week 24 • Continuous time monitoring of confirmed virologic failure (CVF) in the Q8W randomized arm until all participants complete Week 24 visit

Overview of Study Design and Key Features	
	• The main analysis will be conducted to evaluate the primary objective of the protocol at Week 48. • Preliminary analyses at Week 24 and analyses at Week 96 and Week 152 • Sub-study analysis • Further data cuts and analyses may be conducted as necessary in order to support regulatory submissions and publications.

2.4. Statistical Hypotheses / Statistical Analyses

The study is designed to demonstrate that the antiviral effect of Q8W dosing with CAB LA + RPV LA is non-inferior to Q4W dosing CAB LA + RPV LA in subjects stably suppressed on an oral SOC regimen or Q4W CAB LA + RPV LA regimen prior to randomization. Non-inferiority in the proportion of participants with HIV-1 RNA ≥50 c/mL at Week 48 (defined by the US FDA snapshot algorithm) can be concluded if the upper bound of a two-sided 95% confidence interval for the difference between the two treatment arms (Q8W – Q4W) is less than 4%.

If f_{Q8W} is the snapshot failure rate for Q8W CAB LA + RPV LA, and f_{Q4W} is the snapshot failure rate for Q4W CAB LA + RPV LA then the null (H_0) and alternative (Ha) hypotheses can be written as follows:

$$H_o: f_{Q8W} - f_{Q4W} \geq 4\% \textit{ vs } H_a: f_{Q8W} - f_{Q4W} < 4\%$$

3. PLANNED ANALYSES

Analyses will be conducted to support Independent Data Monitoring Committee (IDMC) review of study data. At least four analyses in main study will be conducted to evaluate the objectives of the protocol after all subjects have completed their visits at Week 24, Week 48, Week 96 and Week 152, respectively. Prior to Week 48 analysis complete, the Week 24 results will be restricted to only those study team members and GSK/ViiV Healthcare senior management who need to be involved in the analysis and interpretation of the results for reporting to regulatory authorities. Details on protection against operation bias for Week 48 analysis are documented in the Blinded Team Operating Principles for this study. There is no planned hypothesis testing on the treatment difference at Week 24 and no decisions will be made based on the Week 24 results. Details of the planned displays for Week 24 analyses are provided in Section 15.15.4. Further data cuts and analyses may be conducted as necessary in order to support regulatory submissions and publications (first publication at Week 48). The Week 48 analysis will be primary and no results will be shared publicly until Week 48 analysis is complete. Additional analysis will be conducted to evaluate the objectives of the sub-study after all subjects have completed their visits at Sub-study Week 24. A final End-of-Study analysis will be conducted when all subjects have completed the study.

3.1. IDMC Analyses

An IDMC will be instituted to ensure external objective medical and/or statistical review of efficacy and safety to protect the ethical interests and well-being of subjects and to protect the scientific validity of this study.

The IDMC will evaluate accumulating efficacy, tolerability, safety and PK of CAB LA + RPV LA Q8W during the study. An interim futility analysis will be performed for the IDMC to evaluate the efficacy of CAB LA + RPV LA Q8W prior to the final analyses.

The interim futility analysis will be performed with the intent of having approximately 50% of participants reaching Week 24 and providing sufficient lead time to allow the IDMC to review the data prior to any participants reaching the Week 48 visit. A futility rule based on Bayesian posterior predictive probability approach will be applied to assess the probability that the CAB LA + RPV LA Q8W injectable regimen demonstrates non-inferiority to the CAB LA + RPV LA Q4W regimen at Week 24, given the partial data set. The sponsor will remain blinded to this analysis.

In addition, the IDMC may also monitor the incidence of participants meeting Confirmed Virologic Failure (CVF) criteria before all subjects have completed Week 24 to ensure that subjects are not being sub-optimally treated in the CAB LA + RPV LA Q8W arm.

Full details of the analyses, estimated timing, and the decision criteria that will be used to determine regimen performance will be pre-specified in the IDMC Charter.

A list of outputs required for each IDMC analysis will be provided in the IDMC Charter. Data handing methods and derived data definitions will be the same as detailed in this RAP, unless otherwise stated.

3.2. Final Analyses

The primary analysis will be conducted to evaluate the primary objective of the protocol at Week 48. These analyses will be performed after the completion of the following sequential steps:

1. All subjects have completed Week 48 and had a re-test for HIV-1 RNA if necessary.
2. All required database cleaning activities have been completed and database release (DBR) and database freeze (DBF) or database lock (DBL) has been declared by Data Management.
3. All criteria for unblinding the randomization codes have been met.
4. Randomization codes have been distributed according to Ramos NG procedures.

Three secondary analyses in main study will be conducted at Week 24, Week 96 and Week 152, sub-study analysis, and a final End-of-Study analysis will be conducted when all subjects have completed the study as defined in the protocol.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• Comprised of all subjects screened for inclusion in the study. • Subjects may be re-screened once, for which they will receive a new subject number. • For disposition displays, except for the listing of subjects who were rescreened, only the latest re-screening data will be included. All screening data will be summarized or listed for other displays.	• Study Population
Randomized	• All subjects who were randomly assigned to treatment in the study. • In this study, the randomized population includes all enrolled participants, i.e. the randomized population is equivalent to the enrolled population. • This population will be based on the treatment the participant was randomized to.	• Study Population
Safety	• All randomized subjects who received at least one dose of study treatment. • Participants will be assessed according to actual treatment received.	• Safety
Intent-to-Treat Exposed (ITT-E)	• All randomized subjects who received at least one dose of study treatment. • Subjects will be assessed according to their randomized treatment, regardless of the treatment they received.	• Study Population • Efficacy • Health Outcomes
Per-Protocol (PP)	• All subjects in the ITT-E population with the exception of major protocol violators. • Protocol deviations that would exclude participants from the PP population are defined in Section 4.1 (Protocol Deviations) and Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population).	• Efficacy (Sensitivity Analysis)
Pharmacokinetic (PK)	• All subjects who received CAB and / or RPV and underwent PK sampling during the study and provide at least 1 non-missing CAB and / or RPV plasma concentration value (Non-quantifiable [NQ] values will be considered as non-missing values).	• PK
Confirmed Virologic Failure (CVF)	• All subjects in the ITT-E population who met Confirmed Virologic Failure (CVF) criteria.	• Virology • Efficacy
Long-term Follow-up (LTFU)	• All subjects receiving at least one dose of CAB LA and/or RPV LA who have discontinued the CAB LA + RPV LA regimen and have either at least one Long-term Follow-up phase clinic visit (i.e. have at least one long-term follow-up visit shown in the study database, LTFU month 1, LTFU month 3, etc) or have filled out the LTFU phase conclusion form or have indicated the continuation to LTFU phase in the subject continuation form.	• Safety • Study Population

Population	Definition / Criteria	Analyses Evaluated
Week 24 Futility	• All subjects in the ITT-E population who started study treatment at least 168 days prior to the IDMC cut-off date (in order to account for subjects who withdrew early but would have reached Week 24) • The IDMC cut-off date is the predicted Week 24 visit date (Last Subject Last Visit) corresponding to the time at which approximately 50% of subjects have completed Week 24.	• IDMC Futility Analysis (i.e. IDMC Week 24 Analyses)
Oral Lead-in	• All subjects who received at least one dose of study treatment during the oral lead-in period in ATLAS-2M study.	• Safety • Study Population • Efficacy
Q4W ATLAS	• All subjects in the ITT-E population who were randomized to Q4W arm in ATLAS.	• Health Outcomes
SOC	• All subjects in the ITT-E population who either were randomized to SOC arm in ATLAS or did not participate in ATLAS.	• Health Outcomes
Oral Bridging	• All subjects in the ITT-E population who received the oral bridging during the Maintenance and/or Extension phases.	• Health Outcomes
Sub-study Screened	• Comprised of all subjects screened for inclusion in the sub-study. • All screened subjects will continue using their subject numbers received in the main study.	• Study Population
Sub-study Safety	• All randomized subjects who received at least one CAB and/or RPV thigh injection. • Subjects will be assessed according to actual treatment received.	• Safety • Virology
Sub-study ITT-E	• All randomized subjects who received at least one CAB and/or RPV thigh injection. • Subjects will be assessed according to their randomized treatment, regardless of the treatment they received.	• Study Population • Efficacy • Health Outcomes
Sub-study PK Concentration	• All subjects who received at least one CAB and/or RPV thigh injection and provided at least one non-missing CAB and/or RPV plasma concentration value (non-quantifiable values will be considered as non-missing values) during the sub-study.	• PK
Sub-study PK Parameter	• All subjects who received at least one CAB and/or RPV thigh injection and had at least one evaluable PK parameter estimate during the sub-study.	• PK
Sub-study CVF	• All subjects receiving at least one CAB and/or RPV thigh injection who met Confirmed Virologic Failure (CVF) criteria in the sub-study.	• Virology • Efficacy

Population	Definition / Criteria	Analyses Evaluated
Sub-study LTFU	• All subjects receiving at least one CAB and/or RPV thigh injection who have discontinued the CAB LA + RPV LA regimen and have either at least one Long-term Follow-up phase clinic visit (i.e. have at least one long-term follow-up visit shown in the study database, LTFU month 1, LTFU month 3, etc) or have filled out the LTFU phase conclusion form or have indicated the continuation to LTFU phase in the subject continuation form.	• Study Population

Refer to Section 15.15: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

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

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

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

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

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

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions			
RandAll NG Randomization System		Data Displays for Reporting	
Code	Description	Description	Order in TLF
A	Q8W	Q8W	1
B	Q4W	Q4W	2
C/A	Oral followed by Q8W	Q8W	1
C/B	Oral followed by Q4W	Q4W	2

Notes:

- Unless stated otherwise, data displays will present two treatment group columns (Q8W and Q4W), where treatment sequence C/A is pooled with sequence A and treatment sequence C/B is pooled with sequence B. The detailed treatment sequence descriptors (i.e. C/A and C/B) may be used in selected data listings. Treatment C refers to oral CAB + oral RPV, used for oral lead-in for subjects entering the study with no prior CAB+RPV exposure.

Treatment comparisons will be displayed as follows using the descriptors as specified:

1. Q8W vs Q4W

5.2. Baseline Definitions

For all endpoints (except as noted in baseline definitions) the baseline value will be the latest pre-treatment (see Table 8) assessment with a non-missing value, including those from unscheduled visits. 'Pre-treatment' in main study refers to prior to the study treatment (i.e. CAB and/or RPV) in this study, and 'pre-treatment' in sub-study refers to prior to the first CAB and/or RPV thigh injection.

Electrocardiograms (ECGs) are to be performed in triplicate on main study Day 1 visit. The baseline value for an ECG parameter will be the mean of the last pre-treatment set of assessments from the same date, so long as at least one of the triplicate assessments is available.

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

5.3. Multicentre Studies

Data will be summarized for all centres combined. Country will be treated as an exploratory subgroup for analyses of the primary efficacy endpoint as described in Section 7.1.5.1 and secondary efficacy endpoint (HIV-1 RNA <50 c/mL) as described in Section 7.2.5.1. Some countries may be combined for exploratory subgroup analyses with consideration due to the number of participants enrolled.

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
Strata	Randomization Strata: For the proportion of participants with plasma HIV-1 RNA ≥ 50 c/mL per FDA Snapshot algorithm at Week 48 (primary endpoint), a stratified analysis with Cochran-Mantel Haenszel weights will be used to adjust the primary treatment comparison for the randomization strata corresponding to prior exposure to CAB+RPV (0 weeks, 1-24 weeks, >24 weeks). A similar approach will be used to adjust the analysis of the proportion of participants with HIV-1 RNA <50 c/mL (per the FDA's Snapshot algorithm) at Week 48 (key secondary endpoint) and repeat analyses of these endpoints at Week 96 and Week 152. See Section 7.1.5.1 for additional details on the statistical analysis methodology.
Other Subgroups / Covariates	See details in Section 5.4.2

5.4.2. Examination of Subgroups

The following is a list of subgroups that may be used in descriptive summaries 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 prior to un-blinding the trial.
- If the category cannot be refined further, then descriptive rather than statistical comparisons may be performed for the particular subgroup.
- For subgroup analysis, per European Medicines Agency Guideline on the investigation of subgroups in confirmatory clinical trials (EMA, 2014), factors defining a subgroup population may be put in three categories:

EMA Subgroup Category 1: Factors with strong reason to expect a heterogeneous response to treatment. In this case separate trials should usually be planned. There are no factors falling into this category in this study.

EMA Subgroup Category 2: Factors with at least some biological plausibility or external evidence such that a heterogeneous response might be hypothesized. In this study, stratified randomization strata, key demographic factors, Baseline CD4, CDC stage will be fall into this category. For these factors, subgroup analyses will be performed but

likely underpowered so that a formal proof of efficacy will not be available individually in all subgroups. If consistent findings across multiple comparisons were observed then these analyses would still be suggestive of a generalizable finding from the overall population.

EMA Subgroup Guideline Category 3: Factor with good argumentation why homogeneity of response to treatment is plausible. The impact of factors falling into this category will be explored.

- Additional covariates of clinical interest may also be considered.

Category	Covariates and / or Subgroups
EMA Subgroup Category 2:	
Randomization Strata	• Prior exposure to CAB+RPV (0 weeks, 1-24 weeks, >24 weeks) For analysis purposes, randomization strata will be rederived using eCRF data, even if this differs from the strata captured in RAMOS NG. All statistical analyses will adjust for the above randomization strata, unless stated otherwise. Treatment-by-Strata interactions will be assessed as specified in the analysis sections.
Demographic and Baseline Characteristic Subgroups	• Age: o < 35, 35 - < 50, ≥ 50 For the statistical modelling, '< 35' and '35 - < 50' will be consolidated i.e. the following age group will be used: o < 50, ≥ 50 For the summary of demographic characteristics, the following age groups will also be presented: o ≤ 18, 19 - 64, ≥ 65 (FDAAA requirement) o 18 - 64, 65 - 84, ≥ 85 (EMA requirement) • Race: o White, Non-White o Black/African American, Non-Black/African American For the statistical modelling, only White vs Non-White is considered. • Sex at birth: o Female o Male • Country (not used for statistical modelling) o Argentina o Australia o Canada o France o Germany o Italy o Korea, Republic of o Mexico

Category	Covariates and / or Subgroups
	○ Russian Federation ○ South Africa ○ Spain ○ Sweden ○ United States • Baseline CD4+ cell count (cells/mm^3): ○ <350 ○ 350 - < 500 ○ ≥ 500 • Baseline HIV-1 RNA (c/mL): ○ <50 ○ ≥ 50 • Derived Baseline Centers for Disease Control and Prevention (CDC) category: ○ Stage I ○ Stage II ○ Stage III • Prior Exposure to CAB+RPV: ○ 0 weeks ○ ≥ 1 weeks This subgroup will be used in efficacy analysis, in addition to the redrived randomization strata (prior exposure to CAB+RPV: 0, 1-24, and >24 weeks). It will also be used in health outcomes analysis. In other types of analysis, only the rederived randomization strata will be used. • Baseline BMI (kg/m^2) ○ <30 ○ ≥30 • Baseline Third Agent Class: ○ CAB+RPV (for subjects with prior exposure to CAB+RPV in ATLAS, i.e. subjects transitioning from ATLAS who received CAB+RPV in ATLAS before entering ATLAS-2M) ○ NNRTI ○ INI ○ PI • Baseline Genotypic Subgroup Variables: The Baseline genotypic data became available for most of the subjects after the Week 48 analysis data cut, the following subgroups will be used in post-Week 48 analyses as appropriate. The baseline genotypic data for subjects transitioning from ATLAS comes from ATLAS PBMC samples collected at Baseline and the baseline genotypic data for new subjects comes from ATLAS-2M PBMC samples collected at Baseline. Different types of mutation are defined in Section 15.6.7. ○ Baseline HIV-1 Subtype: ▪ A, A1, AG Combined ▪ B

Category	Covariates and / or Subgroups
	▪ C ▪ Other o Baseline L74I (Non-mixture) INSTI Mutation: ▪ Present ▪ Not Present o Baseline Pre-specified INSTI Mutation (Excluding L74I Non-mixture): ▪ Present ▪ Not Present o Baseline RPV RAM: ▪ Present ▪ Not Present o Baseline NNRTI RAM (Excluding RPV RAM): ▪ Present ▪ Not Present
EMA Subgroup Category 3:	
Additional subgroup/covariates for PK/PD efficacy analysis	PK/PD efficacy analysis will be performed for participants without prior exposure to CAB + RPV. • Week 8 CAB/RPV Trough PK concentration (i.e. pre-dose PK concentration at nominal visit of Week 8) The above covariate will be dichotomized into two subgroup factors as follows: o ≤ first Quartile vs > first quartile, o ≤ Median vs > Median The concentration will also be treated as continuous variable in logistic regression modelling analysis (i.e. the concentration data will be $\log_2$ transformed in this analysis so that, for assessing the effect, one unit increase of the point estimate of log2 PK concentration is equivalent to 'doubling the concentration' in the original value). • Length of First CAB/RPV Injection Needle (<2, ≥2 inches)
Additional subgroup/covariates for PK/PD safety analysis	Last CAB/RPV trough PK concentration For the plot of Maximum Change from Baseline (CFB) in ALT/Total Bilirubin versus Last Trough CAB/RPV PK Concentrations, Last CAB/RPV Trough PK Concentration is the most recent trough PK concentration prior or equal to the date of the lab assessment with maximum CFB during the maintenance phase. For the Plot of Maximum Toxicity Grades of Most Frequently Reported Study Drug ISR adverse events (AEs) versus Last Trough CAB/RPV PK Concentrations, Last CAB/RPV Trough PK Concentration is the most recent trough PK concentration prior or equal to the earliest onset date of the most frequently reported Study Drug ISR AE with maximum toxicity grade, during the maintenance phase. If a participant has no Study Drug ISR AE most commonly

Category	Covariates and / or Subgroups
	reported, then the last trough value during the maintenance phase will be used for the plot.
Additional subgroup for common drug-related study drug injection site reaction (ISR) with maximum toxicity grade	For each preferred term of the common drug-related study drug ISR with maximum toxicity grade (pain, induration, nodules and any other study drug ISR with >=5% subjects in either treatment arm) during the maintenance phase: • Needle Length for Last CAB Injection prior to and including the onset date of the earliest corresponding drug-related CAB ISR with maximum toxicity grade during the maintenance phase: ≤1.5, >1.5 to <2, ≥2 inches • Needle Length for Last RPV Injection prior to and including the onset date of the earliest corresponding drug-related RPV ISR with maximum toxicity grade during the Maintenance Phase: ≤1.5, >1.5 to <2, ≥2 inches Note: If there is no ISR of interest reported during the period of interest for a subject, the needle length of last injection during that period will be used in the summary.

5.5. Multiple Comparisons and Multiplicity

5.5.1. Primary Comparison of Interest

The primary analysis will be based on the ITT-E population. The primary comparison will be made at a one-sided 2.5% level of significance. Treatment with Q8W will be declared non-inferior to Q4W if the upper end of a two-sided 95% confidence interval for the difference between the two groups (Q8W – Q4W) in the proportion of participants with HIV-1 RNA ≥50 c/mL at Week 48 (defined by the US FDA snapshot algorithm) lies below 4%.

The primary comparison of interest is the comparison between Q8W (CAB LA + RPV LA Q8W) and Q4W (CAB LA + RPV LA Q4W) for the primary endpoint in the ITT-E population. This analysis will be adjusted for by the re-derived randomization strata based on eCRF data.

5.5.2. Other Comparisons of Interest

If the primary comparison of interest (Section 5.5.1) using the ITT-E population demonstrates non-inferiority of Q8W compared to Q4W then the following key secondary comparisons will be tested:

- Treatment with Q8W will be declared non-inferior to Q4W with respect to the proportion of participants with HIV-1 RNA < 50 c/mL at Week 48 (defined by the US FDA snapshot algorithm) if the lower end of a two-sided 95% confidence interval for the difference between in rates (Q8W – Q4W) lies above -10% using the ITT-E population

- Superiority of Q8W compared to Q4Wwith respect to change from baseline HIVTSQs total score at Week 48 using the ITT-E population and a two-sided 5% level of significance. Refer to Section 12.5.1 for details.

For the primary endpoint treatment comparison at Week 48, no multiple comparison adjustment is necessary for testing non-inferiority followed by superiority (conditional on achieving a significant test for non-inferiority) since testing follows a pre-specified sequence of hypothesis such that if the first hypothesis tested is not significant, all subsequent tests will not be performed. This fixed sequence procedure controls the type I error rate at the nominal level. The primary endpoint treatment comparison at Week 48 will also be performed using the PP population and the results will be compared for consistency with the results from the ITT-E population.

In addition to the primary and the key secondary comparisons, the comparisons between two treatment arms for ACCEPT (general acceptance score), PIN (Domain scores (Bother of ISRs, Leg movement, Sleep, and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety After, Willingness)), HAT-QoL (Life satisfaction, HIV medications, disclosure worries) and HIVTSQc (Treatment Satisfaction score) at timepoints through Week 48 will also be performed as supportive analyses.

Lastly, for the IDMC interim analyses, since the statistical stopping guidelines will not result in early stopping for positive efficacy findings, these interim treatment comparisons will not inflate the Type I error rate for the primary treatment comparison.

5.6. Other Considerations for Data Analyses and Data Handling Conventions

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

Section	Component
15.2.3	**Error! Not a valid result for table.**: Assessment Windows
15.4	Appendix 4: Study Phases and Treatment State
15.5	Appendix 5: Data Display Standards & Handling Conventions
15.6	Appendix 6: Derived and Transformed Data
15.7	Appendix 7: Reporting Standards for Missing Data
15.8	Appendix 8: Values of Potential Clinical Importance
15.9	Appendix 9: Snapshot Algorithm Details
15.10	Appendix 10: Variables Defined for Time to Event Analysis
15.11	Appendix 11: Identification of Adverse Events of Special Interest
15.12	Appendix 12: Identification of COVID-19 Adverse Events
15.13	Appendix 13: IDMC

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the Intent-to-Treat Exposed population, unless otherwise specified.

Study population analyses including analyses of subject's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and oral study treatment accountability will be based on GSK Core Data Standards.

Table 1 provides an overview of the planned study population analyses, with details of the planned displays are presented in Appendix 15: List of Data Displays.

Table 1 Overview of Planned Study Population Analyses

Display Type	Data Displays Generated	
	Table	Listing
Randomization		
Randomization [1]		Y[2]
Subject Disposition		
Study Populations [3]	Y	
Study Recruitment [3]	Y	
Reasons for Screening Failures [3]	Y	Y
Rescreened Subjects [3]		Y
Age Ranges	Y	
Subject Disposition	Y[4][5]	
Reasons for Withdrawal	Y[4][5]	Y
IP Discontinuation	Y	Y
Important Protocol Deviations	Y	Y
Deviations leading to exclusion from PP	Y	Y
Inclusion and Exclusion Criteria Deviations	Y	Y
Demography and Baseline		
Demographics Characteristics [6]	Y	Y
Race & Racial Combinations [7]	Y	Y
Hepatitis Status at Entry	Y	
Baseline CDC Classification of HIV infection (2014)	Y	
Baseline Cardiovascular Risk Assessments	Y	
Distribution of CD4+ Cell Counts at Screening and Baseline	Y	
Prior Exposure to CAB+RPV	Y	
HIV-1 Risk Factors	Y	

Display Type	Data Displays Generated	
	Table	Listing
Medical Conditions, Concomitant Medications & Antiretroviral Therapy		
Medical Conditions (Current/Past) [8]	Y	
Medical Conditions: Sub-conditions (Current/Past) [9, 10]	Y	
Concomitant Medications (non-ART)	Y[10]	
Prior ART Medications	Y	Y
Concomitant ART Medications during Maintenance Phase		Y
ART Medications Received during LTFU Phase		Y
Lipid Modifying Agents (Baseline and during Maintenance Phase)	Y	
Substance use at Entry	Y	
Medical History of Seizure		Y
Other		
Oral Study Treatment Accountability [11]		Y
Transition to CAB+RPV LA Marketed Product		Y

NOTES:

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

1. Base on Randomized population.
2. One listing of participants randomized but not treated, and one listing of randomized and actual strata and treatment assignment.
3. All Subjects screened population.
4. Participants who have not been recorded as either completing or withdrawing from the study will be categorized as “Ongoing at time of the analysis” for summary purposes.
5. Analysis of subject disposition will be performed for each Study Phase separately, as well as for overall study conclusion.
6. Age and ethnicity collected at Screening; weight and height collected at Baseline.
7. The five high level FDA race categories and designated Asian subcategories will be summarised along with all combinations of high level categories which exist in the data. The nine race categories collected will be summarised along with categories for mixed race. A by-subject listing of race will also be produced.
8. Medical conditions will be coded using the Medical Dictionary for Regulatory Activities (MedDRA).
9. Sub conditions are Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, and Nervous System Conditions.
10. summarised by, Ingredient combinations.
11. Dispensation information (dates and number of tablets dispensed and returned).

6.2. Prior and Concomitant Medications

Non-ART and/or ART Medications will be classified by categories shown in Table 2. The same medication may be classified by more than one category. For example, if the medication was started after the maintenance treatment start date and was stopped at nominal Week 104 visit while subject was still receiving study treatment, this medication would be considered both ‘concomitant during maintenance’ and ‘concomitant during extension’.

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

	Definition
Prior	Medication Taken < Maintenance Treatment Start Date
Concomitant during Maintenance	**For subjects continuing into Extension Phase:** Maintenance Treatment Start Date[a] ≤ Medication Taken < Date of Nominal Week 100 Visit **For subjects not continuing into Extension Phase:** **For participants continuing into LTFU Phase:** Maintenance Treatment Start Date[a] ≤ Medication Taken < LTFU ART Start Date[b]
Concomitant during Extension	**For subjects continuing into Extension Phase and not entering the sub-study:** If subjects continued into LTFU Phase after the Extension phase: Date of Nominal Week 100 Visit[c] ≤ Medication Taken < LTFU ART Start Date If subjects transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then Date of Nominal Week 100 Visit[c] ≤ Medication Taken < Date of end of study +35 days (Q4W) or + 63 days (Q8W) **For subjects continuing into Extension Phase, entering the sub-study but not returning to Extension Phase:** Date of Nominal Week 100 Visit[c] ≤ Medication Taken < Date of First Sub-study Record **For subjects continuing into Extension Phase, entering the sub-study and returning to Extension Phase:** Before the sub-study: Date of Nominal Week 100 Visit[c] ≤ Medication Taken < Date of First Sub-study Record After the sub-study: **For participants continuing into LTFU Phase after return to extension phase:** End of Sub-study Date[c] < Medication Taken < LTFU ART Start Date[b] **For participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason:** End of Sub-study Date[c] < Medication Taken < Date of end of study +35 days (Q4W) or + 63 days (Q8W)

Concomitant during Sub-study Screening	**For subjects entering the sub-study and not receiving any thigh injection:**
	If participants continued into LTFU Phase after the sub-study, then
	Date of First sub-study record ≤ Medication Taken < LTFU ART Start Date[b]
	If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then
	Date of First sub-study record ≤ Medication Taken < Date of end of study +35 days (Q4W) or + 63 days (Q8W)
	If participants continued into Extension Phase after the sub-study, then
	Date of First sub-study record ≤ Medication Taken ≤ End of Sub-study Date[c]
	For participants entering the sub-study and receiving thigh injection(s):
	Date of First sub-study record ≤ Medication Taken < Date of First Thigh Injection

Concomitant during Thigh Injection	**For participants continuing into Return to Gluteal Injection Phase:**
	Date of First Thigh Injection[d] ≤ Medication Taken < Date of Nominal Sub-study Week 16 Visit[c]
	For participants not continuing into Return to Gluteal Injection Phase:
	If participants continued into LTFU Phase after the sub-study, then
	Date of First Thigh Injection ≤ Medication Taken < LTFU ART Start Date[b]
	If participants continued into Extension Phase after the sub-study, then
	Date of First Thigh Injection ≤ Medication Taken ≤ End of Sub-study Date[c]
	If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then
	Date of First Thigh Injection ≤ Medication Taken ≤ Date of end of study +35 days (Q4W) or + 63 days (Q8W)

Concomitant during Return to Gluteal Injection	**For participants continuing into Extension Phase after the sub-study:** Date of Nominal Sub-study Week 16 Visit[c] ≤ Medication Taken ≤ End of Sub-study Date[c] **For participants continuing into LTFU Phase after the sub-study:** Date of Nominal Sub-study Week 16 Visit[c] ≤ Medication Taken < LTFU ART Start Date[b] **For participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason:** Date of Nominal Sub-study Week 16 Visit[c] ≤ Medication Taken ≤ Date of end of study +35 days (Q4W) or + 63 days (Q8W)
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 7: Reporting Standards for Missing Data for handling of missing and partial dates for medications. Use the rules in this table if medication date is completely missing.
- [a] The ART medication stopped on start date of Maintenance treatment will be considered a prior medication and will not be considered concomitant during the Maintenance phase. If the stop date of ART medication is completely missing and this medication is recorded in eCRF as prior (e.g. prior ART or prior ATLAS ART forms), it will be considered a prior medication and will not be considered concomitant during the Maintenance phase.
- [b] If subjects have missing LFTU ART start date, only the lower bound will be considered in the derivation.
- [c] Refer to Section 15.6.1 for the definition.

7. EFFICACY ANALYSES

7.1. Primary Efficacy Analyses

7.1.1. Endpoint / Variables

Proportion of participants with plasma HIV-1 RNA ≥50 c/mL as per Food and Drug Administration (FDA) Snapshot algorithm at Week 48 (Intent-to-Treat Exposed [ITT-E] population); see Section 15.9 for additional details.

7.1.2. Summary Measure

Difference in the proportion of participants with HIV-1 RNA ≥50 c/mL at Week 48 (defined by the US FDA snapshot algorithm) between each treatment group (Q8W – Q4W).

7.1.3. Population of Interest

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

7.1.4. Strategy for Intercurrent (Post-Randomization) Events

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

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

7.1.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 15: 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.

7.1.5.1. Statistical Methodology Specification

Endpoint
• Proportion of Participants with plasma HIV-1 RNA ≥ 50 c/mL at Week 48 using the Snapshot algorithm for the ITT-E population. Subjects with 'HIV-1 RNA ≥ 50 c/mL' per Snapshot algorithm include those who had plasma HIV-1 RNA ≥ 50 c/mL at Week 48, who discontinued for lack of efficacy, who discontinued for other reasons while not <50 c/mL, or who changed ART.

Snapshot Dataset

- Virologic outcome ('HIV-1 RNA <50 c/mL' or 'HIV-1 RNA ≥ 50 c/mL') per Snapshot algorithm is determined by the last available on-treatment HIV-1 RNA measurement within the analysis visit window of interest (please refer to analysis window defined in Table 10). In addition, subjects who discontinue for reasons not related to adverse event with on-treatment HIV-1 RNA result at the time of discontinuation ≥ 50 c/mL or who change study treatment not permitted per protocol during maintenance phase before the analysis visit are classified as 'HIV-1 RNA ≥ 50 c/mL'.
- Full details of the Snapshot algorithm are provided in Section 15.9.

Model Specification

- The primary efficacy endpoint will be analysed using a stratified analysis with Cochran-Mantel-Haenszel (CMH) weights, adjusting for the rederived randomization strata corresponding to prior exposure to CAB+RPV (0 weeks, 1-24 weeks, >24 weeks)
- The CMH estimate of the adjusted treatment difference will be calculated as a weighted average of strata-specific estimates of the treatment difference calculated within each stratum as follows:
    - If n_k is the number of Q8W treated participants, m_k is the number of Q4W arm treated participants, and $N_k = n_k + m_k$ is the total number of participants in the kth stratum, then the CMH estimate is given by

$$\hat{d}_{cmh} = \frac{\sum W_k \hat{d}_k}{\sum W_k}$$

where

$$W_k = \frac{n_k m_k}{N_k}$$

are CMH weights and $\hat{d}_k$ are estimates of the differences in proportions between the two treatment arms, f_{Q8W}-f_{Q4W}, for the *kth* stratum.

- The corresponding two-sided 95% CI will be calculated as

$$\hat{d}_{cmh} \pm 1.96 \times \sqrt{\hat{var}(\hat{d}_{cmh})}$$

where the variance estimator [Sato, 1989] is consistent in both sparse data and large strata and is given below:

$$\hat{\text{var}}\left(\hat{d}_{cmh}\right) = \frac{\hat{d}_{cmh}\left(\sum P_k\right) + \sum Q_k}{\left(\sum n_k m_k / N_k\right)^2} = \frac{\hat{d}_{cmh}\left(\sum P_k\right) + \sum Q_k}{\left(\sum W_k\right)^2}$$

where

$$P_k = \frac{n_k^2 y_k - m_k^2 x_k + n_k m_k (m_k - n_k)/2}{N_k^2}$$

$$Q_k = \frac{x_k (m_k - y_k)/N_k + y_k (n_k - x_k)/N_k}{2}$$

with x_k and y_k corresponding to the number of participants with Plasma HIV-1 RNA ≥ 50 c/mL at Week 48 per FDA Snapshot for Q8W and Q4W, respectively, for the *kth* stratum.

Model Results Presentation

- Adjusted CMH estimate of the difference in the proportion of subjects with Plasma HIV-1 ≥ 50 c/mL between each treatment group (Q8W – Q4W) and corresponding 95% confidence interval.
- Non-inferiority will be concluded if the upper bound of the two-sided 95% confidence interval for the CMH adjusted treatment difference (Q8W – Q4W) is less than 4%.
- If this analysis shows non-inferiority, then a superiority hypothesis will be tested at the two-sided 5% level of significance. Superiority favoring Q8W will be declared if the upper bound of the confidence interval is below 0% for the ITT-E population analysis. If superiority is declared, the p-value for superiority will also be calculated.

Subgroup Analyses

1. Treatment Heterogeneity across rederived randomization strata [prior exposure to CAB+RPV (0 weeks, 1-24 weeks, >24 weeks)]:
   - The weighted least squares chi-squared statistic [Fleiss, 1981] will be used to test for one-way homogeneity across the levels of each categorical variable, with each categorical variable considered separately.
   - Following Lui and Kelly [Lui, 2000] ½ will be added to each cell in any strata for which the stratum-specific rate estimates of either f_{Q8W} or f_{Q4W} are zero or one, and tests will be one-sided.
   - Any heterogeneity found to be statistically significant will be explored and if necessary results will be reported for each level of the categorical variable. Investigation of heterogeneity will be confined to the primary endpoint. Tests of homogeneity will be assessed at the one-sided 10% level of significance.

2. Stratum-specific analyses for two groups of participants: (Group 1) those currently receiving Standard of Care antiretroviral therapy at Baseline (i.e. no prior exposure to CAB+RPV), (Group 2) those receiving Q4W CAB LA + RPV LA therapy in the ongoing ATLAS study (i.e. have prior exposure to CAB+RPV). For each stratum (Group 1 and Group 2), the following will be presented:
   - Proportion of subjects with plasma HIV-1 RNA ≥ 50 c/mL at Week 48 by treatment group.
   - Unadjusted difference in proportions between treatment groups and corresponding two-sided 95% CI.
   - Summary of study outcomes (i.e. HIV-1 RNA < 50 c/mL, HIV-1 RNA ≥50 c/mL and reason for no data in the window)

For Group 2, a stratum-adjusted analysis will also be provided, with adjustment for prior CAB+RPV exposure (1 to 24 weeks vs. >24 weeks) using Cochran-Mantel Haenszel (CMH) weights, as described in the model specification above for the overall primary analysis.

3. Exploration of Subgroups
   - An analysis for subgroups listed in Section 5.4.2 will be performed. This will show the proportion of subjects with plasma HIV-1 RNA ≥50 c/mL at the time of analysis (Week 48) based on the Snapshot algorithm and will be presented by treatment group.
   - Unadjusted difference in proportions between treatment groups and corresponding two-sided 95% CI will also be presented by subgroups. The confidence interval will be calculated using an unconditional exact method [Chan, 1999] with two inverted one-sided tests based on the score statistic. These results will also be presented graphically.
   - Summary of study outcomes (i.e. HIV-1 RNA < 50 c/mL, HIV-1 RNA ≥50 c/mL or reason for no data in the window) by subgroup will be produced.

   Note: These subgroup analyses will be exploratory and likely underpowered so that interpretation may therefore focus on point estimates as well as the upper bounds of 95% CIs for the treatment differences and response rates. Additionally, multiple comparisons are being made which inflates the risk of false positive findings. Therefore, if consistent findings across the multiple comparisons were observed then these analyses would still be suggestive of a generalizable finding of non-inferiority.

Sensitivity and Supportive Analyses

1. Per-protocol population analysis:
   - To assess the impact of important protocol deviations, statistical analysis will be repeated using the Per-protocol population and compared for consistency with the results from the primary ITT-E population analysis.

7.2. Secondary Efficacy Analyses

7.2.1. Endpoints

The key secondary efficacy endpoint is the proportion of participants with plasma HIV-1 RNA < 50 c/mL at Week 48 using the FDA Snapshot algorithm (Intent-to-Treat Exposed [ITT-E] population).

Other secondary efficacy endpoints for the study are listed below:

- Proportion of participants with plasma HIV-1 RNA < 50 c/mL at Week 24, Week 96 and Week 152 using the FDA Snapshot algorithm (ITT-E population)
- Proportion of participants with plasma HIV-1 RNA < 50 c/mL over time (including at Sub-study Week 16) using the FDA Snapshot algorithm during the Sub-study Thigh Injection phase (Sub-study ITT-E population)
- Proportion of participants with protocol-defined confirmed virologic failure (CVF) through Week 24, Week 48, Week 96 and Week 152
- Proportion of participants with protocol-defined confirmed virologic failure (CVF) through the Sub-study Thigh Injection phase

- Proportion of participants with HIV-1 RNA ≥50 c/mL as per FDA Snapshot algorithm at Week 24, Week 96 and Week 152
- Proportion of participants with plasma HIV-1 RNA ≥ 50 c/mL over time (including at Sub-study Week 16) using the FDA Snapshot algorithm during the Sub-study Thigh Injection phase
- Absolute values and changes from Baseline in viral load and CD4+ cell counts over time including Week 48, Week 96 and Week 152

7.2.2. Summary Measure

Difference in the proportion of participants with HIV-1 RNA < 50 c/mL at Week 24, Week 48, Week 96 and Week 152 (defined by the US FDA snapshot algorithm) between each treatment group (Q8W – Q4W).

Difference in the proportion of participants with HIV-1 RNA ≥ 50 c/mL at Week 24, Week 96 and Week 152 (defined by the US FDA snapshot algorithm) between each treatment group (Q8W – Q4W).

7.2.3. Population of Interest

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

7.2.4. Strategy for Intercurrent (Post-Randomization) Events

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

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

7.2.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 15: List of Data Displays and will be based on GSK data standards and statistical principles.

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

7.2.5.1. Statistical Methodology Specification

Key Secondary Statistical Analysis
Endpoint
• Proportion of participants with plasma HIV-1 RNA <50 c/mL at Week 48 using the FDA Snapshot algorithm (Intent-to-Treat Exposed [ITT-E] population)

Key Secondary Statistical Analysis
Snapshot Dataset
• As Section 7.1.5.1 and Section 15.9
Model Specification
• As specified in Section 7.1.5.1 but with 'HIV-1 RNA <50 c/mL' replacing HIV-1 ≥ 50 c/mL

Key Secondary Statistical Analysis
Model Results Presentation
• Adjusted CMH estimate of the difference in the proportion of participants with HIV-1 RNA < 50 c/mL at Week 48 between each treatment group (Q8W – Q4W) and corresponding 95% confidence interval. • Non-inferiority will be concluded if the lower bound of the two-sided 95% confidence interval for the CMH adjusted treatment difference (Q8W – Q4W) is greater than -10%.
Subgroup Analyses
• As specified in Section 7.1.5.1 but with HIV-1 RNA < 50 c/mL replacing 'HIV-1 RNA ≥ 50 c/mL.
Sensitivity and Supportive Analyses
1. Per-protocol population analysis: • To assess the impact of important protocol deviations, statistical analysis will be repeated using the Per-protocol population and compared for consistency with the results from the primary ITT-E population analysis.

7.3. Exploratory Efficacy Analyses

Table 3 provides an overview of the planned exploratory efficacy analyses. Details of the planned displays are provided in Appendix 15: List of Data Displays and will be based on GSK data standards and statistical principles. The exploratory efficacy analyses will be based on the Intent-to-Treat Exposed population, unless otherwise specified.

Table 3 Overview of Exploratory Efficacy Analyses

Endpoints	Absolute							Change from Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L	T	F	L	T	F	F	L
Proportion of participants without efficacy-related discontinuation (ERDF) or treatment-related discontinuation (TRDF) failure at Week 24/Week 48/Week 96/Week 152														
Kaplan-Meier estimate				Y										
Proportion of participants with plasma HIV-1 RNA ≥50 c/mL over time (Maintenance Phase) - Snapshot														
by visit				Y	Y[1]									
By visit and subgroup				Y	Y[2]									
Proportion of participants with plasma HIV-1 RNA <50 c/mL over time (Maintenance Phase) - Snapshot														
by visit				Y	Y[3]									
By visit and subgroup				Y	Y[2]									
Proportion of participants with plasma HIV-1 RNA ≥200 c/mL over time (Maintenance Phase) - Snapshot														
by visit				Y[4]	Y[5]									
Proportion of participants with plasma HIV-1 RNA <200 c/mL over time (Maintenance Phase) - Snapshot														
by visit				Y[4]	Y[5]									
Proportion of participants with plasma HIV-1 RNA ≥50 c/mL at Week 48/Week 96/Week 152 by delay in IP injection - Snapshot														
by delay in IP injection [6]				Y										
Proportion of participants with plasma HIV-1 RNA <2 c/mL over time (Maintenance Phase)														
by visit				Y										
Plasma HIV-1 RNA over time														
by visit				Y[7]		Y[8]	Y[9]							Y[9]
Target Detected vs Target Not Detected by visit [10]				Y			Y[11]							
Confirmed Virologic Failure (CVF)														
CVF overall				Y										
CVF by visit				Y			Y							

Endpoints	Absolute							Change from Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L	T	F	L	T	F	F	L
Plasma HIV-1 RNA at time of suspected and confirmed virologic failure				Y										
CD4+ & CD8+ Cell Counts Over Time														
CD4+ observed [12]				Y							Y			
CD8+ observed [12]				Y							Y			
CD4+/CD8+ ratio observed [12]				Y										
HIV-1 Conditions and Disease Progression														
HIV Conditions including/excluding Recurrences as recorded in eCRF				Y			Y							
HIV Disease Progressions [13]				Y										

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TF related to any summaries (i.e. descriptive statistics) of data.
- Individual = Represents FL related to any displays of individual participant's data.

1. Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥50 c/mL by treatment group at each visit. The 95% CIs will be calculated using Exact (Clopper-Pearson) confidence interval if the proportion is 0%; otherwise, they are derived using the normal approximation.
2. Plot of the unadjusted treatment difference and its 95% confidence intervals (Snapshot algorithm) overall and by subgroup at Week 48/Week 96/Week 152.
3. Line plots, with 95% confidence intervals, for the proportion of participants with HIV-1 RNA<50 c/mL by treatment group at each visit. The 95% CIs will be calculated using Exact (Clopper-Pearson) confidence interval if the proportion is 100%; otherwise, they are derived using the normal approximation.
4. Study outcomes (i.e., HIV-1 RNA <200 c/mL, HIV-1 RNA ≥200 c/mL, or reason for no data in the window) based on the snapshot algorithm at Week 48 will also be produced.
5. Line plots, with 95% confidence intervals, for the proportion of participants with HIV-1 RNA <200 c/mL and ≥200 c/mL by treatment group at each visit. The 95% CIs will be calculated using Exact (Clopper-Pearson) confidence interval if the proportion is 0% or 100%; otherwise, they are derived using the normal approximation.
6. Delay in IP injection (days) is defined in Section 15.6.3.
7. Using log10 transformed values.
8. Individual plasma HIV-1 RNA only for participants who are in the category of 'viral load ≥50 c/mL' at Week 48 per Snapshot algorithm or who are CVF participants. The figures will display all HIV-1 RNA values collected.
9. For CVF participants, participants with viral load ≥ 50 c/mL during the Maintenance Phase, and participants with viral load ≥ 50 c/mL during the Maintenance oral lead-in period.
10. See Section 15.6.3 for definition of "Target Detected" and "Target Not Detected", and for the specification of corresponding summary table.
11. Target Detected" and "Target Not Detected" are included in the listing for plasma HIV-1 RNA by visit.
12. Using available data without imputation for missing values.
13. See Section 15.6.3 for HIV disease progressions.

8. SAFETY ANALYSES

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

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs), COVID-19 AEs and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Section 15.15: List of Data Displays.

8.1.1. Analyses for Injection Site Reaction Adverse Events from Study Drug Injection

Injection Site Reaction (ISR) adverse events of interest are those from study drug injections. For the summary of study drug ISR adverse events by visit and maximum severity (overall and by common ISRs): ISRs will be assigned based on onset date to the most recent planned IM injection visit prior or equal to the AE onset date.

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

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

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

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

8.2. Adverse Events of Special Interest Analyses

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

emerging data from on-going studies may highlight additional adverse events of special interest, therefore the list of AESIs may change at the time of reporting.

A summary by system organ class and preferred term will be provided for each of AESI. The characteristics of event occurrences will be summarized in main study for common AESI which have at least 20 participants in either treatment arm, and will be summarized in sub-study for common AESI which have at least five participants in either treatment arm. For Depression, anxiety and suicidal ideation/behaviour AESI, a summary by system organ class, maximum DAVIDS toxicity grade and prior history of suicidal ideation will be provided. The details of the planned grouping and planned displays are provided in Section 15.11 and Appendix 15: List of Data Displays.

Table 4 Adverse Events of Special Interest

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

Adverse Events of Special Interest	Drug(s) of Interest	Reason for Inclusion
Injection Site Reactions (ISR) from Study Drug Injections [1]	CAB+RPV	Clinical
Seizures and Seizure-like Events	CAB	Clinical, Regulatory Interest
Weight Gain	CAB	Clinical, Class
Rhabdomyolysis	CAB	Clinical, Class
Pancreatitis	CAB	Clinical, Therapeutic Area, More prevalent in HIV population
Impact on Creatinine	CAB+RPV	Regulatory Interest, Therapeutic Area, More prevalent in HIV population
Safety in Pregnancy	CAB	Regulatory Interest, Class
Hyperglycaemia	CAB	Class, Regulatory Interest
NOTE: [1] A separate analysis will be performed for ISRs from study drug injections as described in Section 8.1.1.		

8.3. Clinical Laboratory Analyses

Laboratory evaluations including the analysis of results of Chemistry laboratory tests, Haematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 15: List of Data Displays.

8.4. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs and vital signs will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 15: List of Data Displays.

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

9. PHARMACOKINETIC ANALYSES

The GSK Division of Clinical Pharmacology Modelling and Simulation (CPMS) will be responsible for the PK analysis of CAB. The Division of Clinical Pharmacology and Pharmacometrics at Janssen Research and Development will be responsible for conduct or oversight of the PK analysis for RPV.

9.1. Endpoint / Variables

9.1.1. Drug Concentration Measures

Refer to Appendix 5 Data Display Standards & Handling Conventions (Section 15.5.3 Reporting Standards for Pharmacokinetic)

9.2. Overview of Planned Analyses

Table 5 provides an overview of the planned analyses with full details being presented in Appendix 15: List of Data Displays. All PK displays will be based on the PK Population, unless otherwise specified.

Table 5 Overview of Planned Pharmacokinetic Analyses

	Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L
Pharmacokinetic [5]							
Plasma CAB concentration by visit				Y[1][2]	Y[1][3][4]	Y[3]	Y
Plasma RPV concentration by visit				Y[1][2]	Y[1][3][4]	Y[3]	Y
Steady state concentration	Y						
Plasma CAB parameters by dosing interval	Y	Y		Y			Y
Plasma RPV parameters by dosing interval	Y	Y		Y			Y

NOTES:

- T = Table, F = Figure, L = Listings, Y = Display generated.
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TF related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual participant observed raw data.
- Unless otherwise specified, all displays for evaluable concentrations except for individual displays will be presented by both overall and the rederived randomization strata.

1. For both 'all' concentration and the 'evaluable' concentration. The evaluable concentration is derived from samples collected within pre-specified Time window (Section 15.6.5)
2. For both 'untransformed' and 'log–transformed' statistics.
3. The plots will be produced for the untransformed scale (i.e., a linear plot) and the log transformed scale (i.e., log-linear plot), separately.
4. Separate plots will be produced for Mean (SD) and Median concentration.
5. Standard summary statistics for concentration data will be calculated (i.e., mean, standard deviation, coefficient of variation, median, minimum and maximum). For Logarithmically transformed data, the summary statistics (i.e. geometric mean, between subject coefficient of variation, 95% confidence interval for the geometric mean and standard deviation) will also be calculated.

9.3. Statistical Analyses / Methods

Planned PK statistical analysis
Steady State Concentration
Endpoints
• log_e-transformation of the Trough/Pre-dose evaluable plasma concentrations (CAB/RPV) on Week 16-48 (i.e. Weeks 16, 24, 32, 40 and 48) for participants receiving Q8W study treatment
Covariates
• Study Week
Data Handling
• All data remains as is (observed).
Model Specification
• A mixed effects ANOVA model will be fitted for each rederived randomization stratum [prior exposure to CAB+RPV (0 weeks, 1-24 weeks, >24 weeks)] with Study Week (continuous variable) as a fixed effect and subject as a random effect for each analysis separately. The Kenward & Roger (KR) degrees of freedom approach will be used. The coefficient for the slope of the week effect on the loge-scale will be used to evaluate steady state for each drug (CAB/RPV). The 90% confidence intervals for the slope for each treatment will be calculated. If it does not appear that steady-state has been demonstrated, early weeks (e.g. Week 16, 24, etc...) results will be dropped and the analysis repeated.
Model Checking & Diagnostics
• The steady state will be claimed (the coefficient for the slope of the week effect on the (natural) log scale was close to 0 or the 90% CI for the slope estimate included zero. If steady-state is not demonstrated, concentrations from early weeks (e.g. Week 16, 20, 24, etc...) dropped in sequence and the analysis repeated until either steady state is shown or only two timepoints remain.
Model Results Presentation
• The coefficient for the slope of the week effect on the log_e-scale, its standard error and 90% interval will be presented for each rederived randomization stratum.
PK Parameters
Endpoints
• As data permit, Log_e-transformation of the PK parameters (Ctau, Cmax and AUC(0-tau) for each sub-study dosing interval (refer to Section 15.6.5 for definition of the dosing interval) for participants enrolled in the sub-study
Model Specification
• Following Log_e-transformation, PK parameters will be separately analyzed by treatment arm and analyte using a mixed effects model with dosing interval (gluteal injection, first thigh injection and last thigh injection) as fixed effects and subject as random effects. In each model, only subjects with evaluable PK parameter estimates in both dosing intervals are included. For example, in the model for comparing Cmax estimated from the first CAB thigh

injection interval with Cmax estimated from the gluteal injection interval among Q8W subjects, only the Q8W subjects with evaluable Cmax estimates from both first CAB thigh injection interval and gluteal injection interval are included.
Model Checking & Diagnostics
• Model assumptions will be applied, but appropriate adjustments may be made based on the data.
Model Results Presentation
• The estimated difference and 90% CI obtained on the $\log_e$ scale will be exponentiated to provide an estimate of geometric mean ratio and its associated 90% CI. The estimate of within-subject variability (%CVw) will also be provided.

10. POPULATION PHARMACOKINETIC ANALYSES

The Population PK analyses will be described under a separate Population-PK Reporting and Analysis Plans for CAB LA and RPV LA

11. PHARMACOKINETIC / PHARMACODYNAMIC ANALYSES

The primary goal of this analysis is to characterize the pharmacokinetic / pharmacodynamic relationship of CAB/RPV administered in participants with HIV-1-infection who are virologically suppressed. The influence of subject demographics and baseline characteristics and additional subgroups/covariates in this population will be investigated.

11.1. Overview of Planned Analyses

Table 6 provides an overview of the planned analyses with full details being presented in Appendix 15: List of Data Displays. All PK displays will be based on the PK Population, unless otherwise specified.

Table 6 Overview of Planned Pharmacokinetic / Pharmacodynamic Analyses

	Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L
CAB/RPV Week 8 concentrations by snapshot 'HIV-1 RNA ≥50 c/mL' (Yes vs. No) at Week 48 for participants without prior exposure to CAB+RPV				Y	Y		
Analysis of snapshot 'HIV-1 RNA ≥50 c/mL' at Week 48 by Week 8 trough concentration, and subgroup [1] – univariable analysis /multivariable analysis for participants without prior exposure to CAB+RPV	Y						
Individual CAB/RPV concentration-time profiles for participants with snapshot 'HIV-1 RNA ≥50 c/mL' at Week 48 or 96 or 152					Y		
Maximum change from baseline in ALT/Total Bilirubin versus last trough CAB/RPV concentrations for Week 48 and Week 152 analyses[2]					Y		
Change from baseline in pre-dose QTcF versus CAB/RPV concentrations at Week 48 or 152					Y		
Maximum toxicity grades of most frequently reported study drug ISR AEs [3] versus last trough CAB/RPV PK concentrations for Week 48 analysis[2]					Y		

NOTES:

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- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TF related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual participant observed raw data.

1. Refer to Section 11.2.
2. Display by rederived randomization strata, i.e. prior exposure to CAB+RPV (0, 1-24, >24 weeks) derived based on eCRF.
3. Most frequently reported study drug ISR AEs are those top 5 in incidence in either treatment arm (i.e. Q8W or Q4W arm).

11.2. Statistical Analyses / Methods

PK/PD Efficacy Analysis for Participants without Prior Exposure to CAB+RPV
Endpoints
• Snapshot 'HIV-1 RNA≥50 c/mL' at Week 48
Covariates
• Treatment, demographic and baseline characteristics except for country and Prior Exposure to CAB+RPV (0, ≥1 weeks), and additional subgroup/covariates for PK/PD efficacy analysis - see derivation details in Section 5.4.2.
Data Handling
• All data remains as is (observed).
Model Specification
• Logistic regression will be used to exam the correlation between the endpoint (Snapshot 'HIV-1 RNA≥50 c/mL') at Week 48 and the covariates/subgroups. This logistic regression analysis will be performed for each covariate or subgroup, separately (univariable analysis), and will also be performed with one multivariable analysis using Backward stepwise selection approach to identify the covariates/subgroups potentially affecting virologic response.
Model Checking & Diagnostics
• For the multivariable analysis, a logistic regression model that best predicts the dependent variable (i.e. snapshot 'HIV-1 RNA≥50 c/mL') from the independent variables (i.e. covariates/factors with P <0.15 from univariable analysis) will be determined using the backward stepwise selecting approach. Week 8 trough PK concentration will be logarithmically transformed with base of 2 (i.e. one-unit increase of the point estimate of log2 PK concentration is equivalent to 'doubling the concentration' in the original value). The analysis will start with all covariates in the model and remove a covariate with the largest p-value (i.e. the least statistically significant) each time and continue until the stopping rule is reached when all remaining covariates have p-value <15%. • If problems with model convergence occur due to zero event counts or complete/quasi-complete separation, then alternative methods such as exact logistic regression may be used.
Model Results Presentation
• The odds ratio, 95% confidence interval, and p-value will be presented.

12. HEALTH OUTCOMES ANALYSES

12.1. Endpoint / Variables

12.1.1. Main Study

- Preference between injections of LA HIV treatment and daily oral HIV treatment at Week 48
- Preference between LA injection every 8 weeks and LA injection every 4 weeks at Week 48 (Q8W arm only)
- Change from baseline in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Status Questionnaire (HIVTSQs) at Weeks 24, 48 and 152
- Change from baseline in life satisfaction, HIV medication, and disclosure worries using HIV/AIDS Targeted Quality of Life (HAT-QoL) at Weeks 24 and 48
- Change in treatment satisfaction over time using the HIV Treatment Satisfaction Change (HIVTSQc) questionnaire at Week 48
- Change from Week 8 in Dimension Scores and individual item scores assessing pain during injection, anxiety before and after injection, willingness to be injected in the future and overall satisfaction with mode of administration over time using Perception of Injection (PIN) questionnaire at Weeks 24, 48 and 152
- Change from baseline in treatment acceptance using ACCEPT at Weeks 24, 48 and 152
- Reasons for continuation of receiving injectable HIV treatment at Baseline (Day 1) visit. This is an exploratory endpoint.
- Reasons for switching to injectable HIV treatment at Baseline (Day 1) visit. This is an exploratory endpoint.
- Preference for CAB LA + RPV LA injection compared to daily oral for participants receiving oral bridging during the Maintenance and/or Extension phases at Week 152. This is an exploratory endpoint.

12.1.2. Sub-study

- Change from gluteal to thigh in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Status Questionnaire (HIVTSQs) during the Thigh Injection phase as well as the change from thigh to gluteal during the Return to Gluteal Injection phase
- Change from gluteal to thigh using the HIV Treatment Satisfaction Change (HIVTSQc) questionnaire at Sub-study Week 16
- Changes in the tolerability of injections (NRS) over time during the sub-study
- Preference for thigh injections compared with prior gluteal injections and the injections received during the Return to Gluteal Injection phase respectively.

12.2. Summary Measure

For main study, mean treatment difference (Q8W – Q4W) at visits of interest, except for Preference between LA injection every 8 weeks and LA injection every 4 weeks at Week 48.

For sub-study, mean difference between thigh injections and gluteal injections from visits of interest, except for the Preference between thigh injections and gluteal injections.

12.3. Population of Interest

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

Analysis of Reason for continuation will be based on a subset of the Intent-to-Treat Exposed population who were randomized to Q4W arm in ATLAS (i.e. ATLAS Q4W population).

12.4. Analysis of Reason for switch will be based on a subset of Intent-to-Treat Exposed population who either were randomized to SOC arm in ATLAS or did not participate in ATLAS study (i.e. SOC population).Strategy for Intercurrent (Post-Randomization) Events

If a participant discontinues treatment prior to the timepoint of interest such that there is no evaluable assessment for the timepoint of interest, the data will be computed or imputed (see Section 15.6.6).

12.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 15: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 12.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

12.5.1. Statistical Methodology Specification

Statistical Analyses
Endpoints

• Change from Baseline in
  ○ HIVTSQs total treatment satisfaction score at Weeks 24,48 and 152
  ○ ACCEPT general acceptance score at Weeks 24, 48 and 152
  ○ HAT-QoL (Life satisfaction, HIV medications, disclosure worries) at Weeks 24 and 48
• Change from Week 8 in PIN Domain Scores (Bother of ISRs, Leg movement, Sleep, and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety After, Willingness) at Weeks 24, 48 and 152

Statistical Analyses
Model Specification

• The analysis for HIVTSQs, ACCEPT and HAT-QoL will be performed for subjects with and without prior exposure to CAB+RPV separately.
  ○ For subjects without prior exposure to CAB+RPV, an analysis of covariance (ANCOVA) model will be used at each visit during the maintenance phase with covariates: treatment, age (<50, ≥ 50 years old), sex at birth, race (i.e. white, non-white) and baseline score value for other endpoints (as a continuous variable).
  ○ For subjects with prior exposure to CAB+RPV, an analysis of covariance (ANCOVA) model will be used at each visit during the maintenance phase with covariates: treatment, age (<50, ≥ 50 years old), prior exposure to CAB+RPV (i.e. 1 to 24 weeks, >24 weeks), sex at birth, race (i.e. white, non-white) and baseline score value (as a continuous variable).
• For PIN, an analysis of covariance (ANCOVA) model will be used at each visit during the maintenance phase with covariates: treatment, age (<50, ≥ 50 years old), prior exposure to CAB+RPV (i.e. 0 weeks, 1 to 24 weeks, >24 weeks), sex at birth, race (i.e. white, non-white), and Week 8 score value (as a continuous variable).
• Adjusted point estimates will be derived as LSMEANS using the observed margins (OM) option within PROC MIXED in SAS.
• The superiority testing of Q8W compared to Q4W with respect to change from baseline in HIVTSQs total score at Week 48 will be performed using the fixed sequence procedure to control for the type I error rate at the nominal level of 5%. If the superiority testing within subjects without prior exposure to CAB+RPV demonstrates Q8W is superior to Q4W in change from baseline in HIVTSQs total score at Week 48 at two-sided 5% level of significance, the superiority testing at the same level of significance (i.e. two-sided 5%) within subjects with prior exposure to CAB+RPV will be followed. No adjustment for multiplicity will be applied for other tests as they will be considered supportive.
• Interactions between treatment and each of the covariates will not be assessed unless the exploratory subgroup analyses on the primary endpoint highlights significant interactions. In this situation, the interaction(s) of interest will be assessed and, if necessary, results will be reported in the clinical study report. Interactions between treatment and the baseline score will be investigated but not included in the model. If interactions are found to be significant (p<0.10), results may be presented separately by subgroup.

Dataset
• LOCF dataset will be used.
Model Results Presentation
• Adjusted treatment difference (Q8W – Q4W), its 95% CI and the associated p-value. The interaction between treatment and the baseline score will be included in a footnote. • Plots of adjusted mean change from baseline (95% CI) for each treatment group, and the adjusted mean difference (95%CI) between the two treatment arms from the model will be generated across visit.

Statistical Analyses
HIVTSQc
• Total Treatment Satisfaction Score (Change) at Week 48

Model Specification
• An analysis of variance (ANOVA) model will be used with covariates: treatment, age (<50, ≥ 50 years old), prior exposure to CAB+RPV (i.e. 0 weeks, 1 to 24 weeks, >24 weeks), sex at birth and race (i.e. white, non-white). • Adjusted point estimates will be derived as LSMEANS using the observed margins (OM) option within PROC MIXED in SAS. • Interactions between treatment and each of the covariates will not be assessed unless the exploratory subgroup analyses on the primary endpoint highlights significant interactions. In this situation, the interaction(s) of interest will be assessed and, if necessary, results will be reported in the clinical study report. If interactions are found to be significant (p<0.10), results may be presented separately by subgroup. • No adjustment for multiplicity will be applied as these analyses will be considered supportive.
Dataset
The observed case (OC) dataset uses only the data that is available at Week 48, with no imputation for missing values.
Model Results Presentation
Adjusted means, 95% CI, and associated p-value will be presented for the treatment difference (Q8W – Q4W).

Statistical Analyses
PIN/HIVTSQs
• Change from Week 8 in the PIN acceptance score at Week 24, Week 48 and Week 152 • Change from Sub-study Baseline in the HIVTSQs total treatment satisfaction score at Sub-study Week 16, Sub-study Week 24 (for Q8W arm) or Sub-study Week 20 (for Q4W arm).
Statistical Test
• The Wilcoxon Signed-Rank Test will be used to evaluate: For PIN, whether the change from Week 8 to each post Week 8 main study visit, is statistically different from zero based on a two-sided p<0.05. For HIVTSQs, whether the change from Sub-study Baseline to each post-baseline sub-study visit is statistically different from zero based on a two-sided p<0.05.
Dataset
• For PIN, LOCF dataset will be used. • For HIVTSQs, observed dataset will be used.
Results Presentation
• For PIN, summary statistics at each timepoint (Week 8, Week 24, Week 48 and Week 152) and p-value for each comparison between scores at Week 24/48/152 with scores at Week 8. • For HIVTSQs, summary statistics at Sub-study Baseline, Sub-study Week 16, Sub-study Week 24 (for Q8W arm) or Sub-study Week 20 (for Q4W arm), and p-value for the comparison between scores at each post-baseline sub-study visit with scores at Sub-study Baseline.

13. VIROLOGY

The virology analyses will mainly use genotype and phenotype data based on plasma sample for CVF population, unless otherwise specified. Additional analyses for HIV-1 resistance may be carried out on peripheral blood mononuclear (PBMC) samples collected at Day 1, Week 48, Week 96, Week 152 or Withdrawal if prior to Week 152, Sub-study Day 1.

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

Table 7 provides an overview of the planned analyses, with further details of data displays being presented in Appendix 15: List of Data Displays.

Table 7 Overview of Planned Virology Analyses

Endpoint	Absolute			
	Summary		Individual	
	T	F	F	L
Genotypic resistance at time of CVF[1]				
Prevalence of Resistance Mutations	Y [2]			Y
Prevalence of Genotypic Susceptibility	Y			
Phenotypic resistance at time of CVF[1]				
Prevalence of Phenotype	Y [3]			Y
Fold Change to CAB and RPV	Y			Y[4]
IN, PR/RT Replication Capacity				Y
Other				
Viral load, Genotypic and Phenotypic data for Participants with genotype and/or phenotype data for CVF and non-CVF participants				Y[4]
Net Assessment	Y			

NOTES:

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

1. For the CVF as indicated by two consecutive plasma HIV-1 RNA levels ≥200 c/mL after prior suppression to <200 c/mL, the first visit of these two consecutive visits is defined as 'the suspected visit', and the 2nd one is the confirmed visit. Sample used for resistance testing is taken at the suspected visit, and only tested once a participant confirms virological failure at a subsequent visit. If the test fails with the sample at the suspected visit, we will just report it as 'no data'. The sample from the confirmed visit may be used for exploratory analyses.
2. No. and percentage of participants with IN resistance mutations or major mutations in the classes of NNRTI, NRTI, PI, respectively, as defined in Section 15.6.7.
3. Separate outputs by phenotypic susceptibility and by number of drugs to which participants are phenotypic resistant or partial sensitive or sensitive.

Endpoint	Absolute			
	Summary		Individual	
	T	F	F	L

4. Fold change to CAB and RPV will be included in the listing for viral load, genotypic and phenotypic data for participants with genotype and/or phenotype data for CVF and non-CVF participants.

14. REFERENCES

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15. APPENDICES

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

15.1.1. Exclusions from Per Protocol Population

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

- directly impact the efficacy endpoint of HIV-1 RNA; or
- lead to permanent discontinuation of IP/withdrawal and hence indirectly impact the efficacy endpoint by causing data to be missing.

The following criteria define the important protocol deviations which, if they occur prior to an analysis timepoint of interest (e.g. Week 48/96/152), will lead to exclusion of a participant from the Per-Protocol population for that analysis. Potential protocol deviations leading to exclusion from PP population will be reviewed by the study team to confirm that they meet these criteria. A final review will occur before the clinical database has been frozen for analysis.

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

Number	Exclusion Description
01	Participant deviates from any inclusion or exclusion criteria that may significantly affect exposure, response to therapy or participant safety or that are fundamentally inconsistent with the intended study population, as recorded in the Protocol Deviation form in the eCRF based on study team review (where indicated in the PDMP as case-by-case determination).
02	Participant has maintenance phase non-compliance (including IM dosing errors) with investigational product up to an analysis timepoint of interest, meeting one of the following 3 conditions. For Week 48 analysis, the analysis timepoint of interest is the date of last on-treatment viral load up to Study Day 378 during maintenance phase, where Study Day 378 is the upper bound of snapshot window for Week 48 visit. For Week 96 analysis, the analysis timepoint of interest is the date of last on-treatment viral load up to Study Day 714 during the maintenance phase, where Study Day 714 is the upper bound of snapshot window for Week 96 visit. For Week 152 analysis, the analysis timepoint of interest is the date of last on-treatment viral load up to Study Day 1106 during the maintenance and extension phase, where Study Day 1106 is the upper bound of snapshot window for Week 152 visit. 1. Week 48 analysis only: • Two or more injection intervals affected by over dosage deviations, for example o Extra injection or excessive volume administered. o For Q8W participants requiring oral lead-in: length of time between Week 4B injection and Week 8 injection less than 3 weeks, or between injections post Week 8 less than 7 weeks, excluding split doses. o For Q8W participants not requiring oral lead-in: length of time between injections less than 7 weeks, excluding split doses.

Number	Exclusion Description
	○ For Q8W participants requiring reloading injections: length of time between the reloading injection and the injection after reloading less than 3 weeks, excluding split doses. ○ For Q4W participants: length of time between injections less than 3 weeks, excluding split doses. 2. Week 96 analysis only: • For participants who permanently discontinued study treatment on/before the analysis timepoint of interest for Week 48 analysis (i.e. the date of last on-treatment viral load up to Study Day 378): two or more injection intervals affected by over dosage deviations. • For participants who received injections beyond the analysis timepoint of interest for Week 48 analysis (i.e. the date of last on-treatment viral load up to Study Day 378): three or more injection intervals affected by over dosage deviations. 3. Week 152 analysis only: • For participants who permanently discontinued study treatment on/before the analysis timepoint of interest for Week 48 analysis (i.e. the date of last on-treatment viral load up to Study Day 378): two or more injection intervals affected by over dosage deviations. • For participants who received injections beyond the analysis timepoint of interest for Week 48 analysis (i.e. the date of last on-treatment viral load up to Study Day 378): five or more injection intervals affected by over dosage deviations. 4. ≥ 10% of total time on-treatment with under dosing deviations. The percentage of total time on-treatment with under dosing deviations will be calculated by (the total number of non-compliant dosing days / the total number of intended exposure days) * 100%. Number of Intended Exposure Days = Date of Last Viral Load – Start Date of Study Treatment + 1, where the last viral load refers to the last on-treatment viral load up to Study Day 378 during maintenance phase for Week 48 analysis, the last on-treatment viral load up to Study Day 714 during maintenance phase for Week 96 analysis, the last on-treatment viral load up to Study Day 1106 during maintenance and extension phase for Week 152 analysis . The total number of non-compliant dosing days up to the analysis timepoint visit (or date of IP discontinuation/ withdrawal, whichever is earlier), is derived as follows (<u>summing across all instances</u>): • For Q4W arm participants requiring oral lead-in: ○ Length of time (in days) until next injection from date of dosage deviation (e.g. 2 mL administered instead of 3mL for Week 4B injection, 1ml administered instead of 2 mL for post Week 4B injections). ○ Length of time (in days) in excess beyond 35 days between injections post Week 12 and in excess beyond 28 days for Week 8 and Week 12 (e.g. missed or late injection visit). ○ Length of time (in days) in excess beyond 35 days from last injection until start of oral bridging post Week 12 and in excess beyond 28 days for Week 8 and Week 12. • For Q4W arm participants not requiring oral lead-in:

Number	Exclusion Description
	○ Length of time (in days) until next injection from date of dosage deviation (e.g. 1 mL administered instead of 2 mL). ○ Length of time (in days) in excess beyond 35 days between injections. ○ Length of time (in days) in excess beyond 35 days from last injection until start of oral bridging. • For Q8W arm participants requiring oral lead-in: ○ Length of time (in days) until next injection from date of dosage deviation (e.g. 2 mL administered instead of 3mL). ○ Length of time (in days) in excess beyond 63 days between injections post Week 16 and in excess beyond 28 days for Week 8 and 56 days for Week 16 (e.g. missed or late injection visit). The similar calculation of the length of time in excess will be used for the period after the reloading dose injection visit. ○ Length of time (in days) in excess beyond 63 days from last injection until start of oral bridging post Week 16 and in excess beyond 28 days for Week 8 and 56 days for Week 16. • For Q8W arm participants not requiring oral lead-in: ○ Length of time (in days) until next injection from date of dosage deviation (e.g. 2 mL administered instead of 3 mL). ○ Length of time (in days) in excess beyond 63 days between injections. ○ Length of time (in days) in excess beyond 63 days from last injection until start of oral bridging. • For subjects requiring reloading injections, the number of non-compliant days for the first and second injection visits after the reloading will be calculated similarly to that for Week 8 and Week 12 for subjects on the same treatment arm requiring oral lead-in. • Interrupted days in oral study treatment (oral lead-in or oral bridging) if the oral dose has been interrupted for 3 or more consecutive days and the primary interruption reason is not adverse event or laboratory abnormality (based on the eCRF Exposure forms). 3 days will be assumed if such interrupted days are not available in the database.
03	Prohibited medications: receiving ART medication other than that prescribed/allowed by the study (excluding permanent changes in ART regimen; such cases will be retained as 'HIV1-RNA ≥50 c/mL' in the per protocol snapshot analysis) or receiving prohibited concomitant medication that would impact exposure or response to therapy with duration and route of administration taken into consideration, as recorded in the Protocol Deviation form in the eCRF based on study team review (where indicated in the PDMP as case-by-case determination).
04	Permanent discontinuation of IP/withdrawal due to a reason of "Protocol Deviation" (as recorded in the eCRF).
05	Other important protocol deviations that exclude Participant from per protocol population as recorded in the Protocol Deviation form in the eCRF based on study team review (where indicated in the PDMP as case-by-case determination). The participants who has taken SOC oral bridging at/prior to the analysis timepoint due to COVID-19 may be excluded from per protocol population for the analysis and will be evaluated based on case-by-case clinical determination.

15.2. Appendix 2: Schedule of Activities

While some assessments included in the Time and Events Table are conducted less frequently following the primary endpoint (Week 48), IM injections for participants during the Extension Phase will continue to be administered Q4W or Q8W based on original study randomization assignment.

All patients will be randomized at Day 1 to initiate either Q4 weekly or Q8 weekly administration of IM CAB LA + RPV LA. Only participants randomized from oral SOC treatment will participate in the Day 1 to Week 4 Oral CAB + Oral RPV lead-in treatment.

15.2.1. Protocol Defined Schedule of Events for Q4W Arm in Main Study

Procedure	Screening Visit [a]	Maintenance Phase																		Extension Phase			Withdrawal Assessments.[y]	Long-Term Follow-up [z]
		Week																						
		Day 1	Week 4A (Oral Lead-in Only)[b]	Week 4B	8	12	16	20	24	28	32	36	40	44	48	52	Q4W 56-92	Q8W 56-92	96	100	Q4W After Week 100	Q8W After Week 96	152		
Written informed consent	X																								
Eligibility Verification (Inclusion/Exclusion Criteria)	X		X [c]																X[c]						
Randomization		X																							
Demography	X																								
Medical History[d]	X																								
Cardiovascular risk assessment[d]	X	X																							
Medication History/ Prior ART history	X																								
Syphilis serology + Reflex Rapid Plasma Reagin (RPR)	X	X																							

Procedure	Screening Visit [a]	Maintenance Phase																			Extension Phase			Withdrawal Assessments.[y]	Long-Term Follow-up [z]
		Week																							
		Day 1	Week 4A (Oral Lead-in Only)[b]	Week 4B	8	12	16	20	24	28	32	36	40	44	48	52	Q4W 56-92	Q8W 56-92	96	100	Q4W After Week 100	Q8W After Week 96	152		
Symptom Directed Physical Exam and Medical Assessment[e]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Weight, Height and BMI[f]		X													X				X					X	X	
Vital Signs: BP, HR, Temperature)[g]	X	X													X				X					X	X	
12-lead ECG [h] (triplicate at Day 1 pre-dose)	X	X													X				X					X	X	
CDC HIV-1 stage	X	X																								
HIV Associated Conditions		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
AEs, SAEs, Concomitant Medications[i]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Procedure	Screening Visit [a]	Maintenance Phase																			Extension Phase			Withdrawal Assessments,[y]	Long-Term Follow-up [z]
		Week																							
		Day 1	Week 4A (Oral Lead-in Only)[b]	Week 4B	8	12	16	20	24	28	32	36	40	44	48	52	Q4W 56-92	Q8W 56-92	96	100	Q4W After Week 100	Q8W After Week 96	152		
ISR Assessment for IM injections		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Columbia Suicide Severity Rating Scale (eC-SSRS) [j]	X	X		X	X		X		X		X		X		X			X	X					X	
Clinical chemistry and Hematology	X	X	X	X	X		X		X		X		X		X			X	X	X		X	X	X	X
Pregnancy Testing [k]	S	U	S	U	S	U	S	U	S	U	S	U	S	U	S	S	U	S	S	S	U	S	S	S	S
HIV-1 RNA and sample for storage (S) [l]	X	X	X	X	X		X		X		X		X		X	S		X	X	S		X	X	X	X
CD4+ cell count	X	X		X	X		X		X		X		X		X			X	X			X	X	X	X
CD8+ cell count		X							X						X				X				X	X	
Urinalysis [m]		X	X						X						X				X				X	X	

Procedure	Screening Visit [a]	Maintenance Phase																		Extension Phase			Withdrawal Assessments.[y]	Long-Term Follow-up [z]
		Week																						
		Day 1	Week 4A (Oral Lead-in Only)[b]	Week 4B	8	12	16	20	24	28	32	36	40	44	48	52	Q4W 56-92	Q8W 56-92	96	100	Q4W After Week 100	Q8W After Week 96	152		
Fasting Lab Assessment: Glucose, Cholesterol (Total, HDL and LDL) and Triglycerides[n]		X													X				X				X	X o	
Hepatitis B (HBsAg), Anti-HBc, and Anti-HBsAG, Hepatitis C (anti-HCV Ab)	X																								
PT/PTT/INR	X	X																							
PBMCs[p]		X													X				X				X	X	
Genetics sample[q]		X																							
PK sampling[r] (S)=Storage only				X	X	S	X	S	X	S	X	S	X	S	X	S	S	S	X	S			X	X	S

Procedure	Screening Visit [a]	Maintenance Phase																			Extension Phase			Withdrawal Assessments.[y]	Long-Term Follow-up [z]
		Week																							
		Day 1	Week 4A (Oral Lead-in Only)[b]	Week 4B	8	12	16	20	24	28	32	36	40	44	48	52	Q4W 56-92	Q8W 56-92	96	100	Q4W After Week 100	Q8W After Week 96	152		
Oral CAB and Oral RPV Dispensation[s]		X	X																						
IP accountability (Pill Counts)[s]			X	X																					
IM treatment administration when transitioning from SOC[t]				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
IM treatment administration when transitioning from CAB + RPV LA Q4W		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Patient Reported Outcomes[u]																									
HAT-QoL (short-form)		X							X						X									X	
HIV TSQs		X							X						X								X	X	
HIV TSQc [v]															X									X	
ACCEPT		X							X						X								X	X	

Procedure	Screening Visit [a]	Maintenance Phase																				Extension Phase			Withdrawal Assessments,[y]	Long-Term Follow-up [z]
		Week																								
		Day 1	Week 4A (Oral Lead-in Only)[b]	Week 4B	8	12	16	20	24	28	32	36	40	44	48	52	Q4W 56-92	Q8W 56-92	96	100	Q4W After Week 100	Q8W After Week 96	152		
Reason for Switch or Reason for continuation [w]		X																								
Preference Questionnaires															X[x]								X[aa]	X	
PIN					X				X						X								X	X	
	Safety Follow Up Visit: Conduct approximately 4 weeks after the last dose of IP. Required only if the participant has ongoing AEs or lab abnormalities at the last on-study visit. This visit may be conducted by telephone.																									

a. Complete all Screening assessments within 35 days. Participants may begin the Maintenance Phase as soon as all Screening assessments are complete. Participants may be rescreened once and will be assigned a new participant number. Participants transitioning from the 201585 (ATLAS) study must reach ATLAS Week 48 (at minimum) prior to initiating Screening procedures for ATLAS-2M and must reach ATLAS Week 52 (at minimum) prior to randomization in ATLAS-2M.

b. Visits Week 4a is part of the CAB + RPV Oral Lead-in period and is required only for participants transitioning from current SOC to CAB LA + RPV LA.

c. Confirmation of eligibility to continue the Maintenance Phase and eligibility to enter the Extension Phase.

d. Collect full routine medical history plus (report at Baseline visit): HIV risk factors (may be collected at a later study visit), cardiovascular risk factors (assessments include smoking status and history, family history of cardiac events), recent [≤6 months] illicit drug use, intravenous drug use, gastrointestinal disease, metabolic, psychiatric, renal, bone, and neurologic disorders.

e. Physical exams should be conducted as part of normal routine clinical care. Medical assessments include any decisions the study staff must make for participants management and/or care of participant.

f. Height collected at Baseline Day 1 only.

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

h. A 12-lead ECG will be performed after resting in a semi-supine position for at least 5 minutes. ECGs will be performed pre-dose. For participants transitioning from ATLAS, the pre-dose Week 48 ECG can also serve as the ATLAS-2M Screening ECG. ECG pre-dose will be performed in triplicate at

Day 1. A 2-hour post-dose ECG will also be performed at Days 1 and Week 48 for participants receiving CAB LA + RPV LA with an allowable window of ±30 minutes.

i. Only SAEs related to study participation or to a concomitantly administered ViiV/GSK product will be collected between obtaining informed consent and administration of study drug at Day 1.

j. On Day 1, the eC-SSRS is to be administered prior to randomization. The eC-SSRS will preferably be completed at the beginning of the visit following administration of other PROs required prior to injections. The eC-SSRS is not required during the Withdrawal visit if withdrawal occurs during the Extension Phase.

k. Women of childbearing potential only. SR=serum, UR=urine. Pregnancy events will be captured starting at Day 1 following initial exposure to study drug. Urine pregnancy test performed at Day 1 prior to administration of study drug, at Week 4B, and at study visits when other blood draws are not required in order to limit needle sticks. Serum pregnancy test can substitute for urine pregnancy test if locally required but must be appropriately timed to confirm pregnancy status prior to randomization and first IM administration.

l. Week 48, Week 96 and Week 152 HIV-1 RNA retest (within 4 weeks) for results > 50 c/mL will be captured as unscheduled visit. Plasma for storage samples will be used for possible future analyses.

m. A morning specimen is preferred. To assess biomarkers: urine albumin/creatinine ratio; urine protein/creatinine ratio; and urine phosphate. Urine phosphate results from visit 4a are not required by protocol to inform the safety review at visit 4b prior to receipt of initial CAB LA + RPV LA injections.

n. An overnight fast is preferred; however, a minimum of a 6-hour fast is acceptable.

o. Only collect if the Withdrawal visit occurs at Week 48, Week 96 or Week 152.

p. Whole blood/PBMC collection samples may be used for virologic analyses. PBMCs will be collected at baseline Day 1, Week 48, Week 96, Week 152 or Withdrawal if prior to Week 152.

q. Genetics sample should be collected only for patients who did not participate in the 201585(ATLAS) study (sample was previously collected and stored). Informed consent for genetic research must be obtained before sample collection. Sample may be collected at any visit after signing informed consent, but preferably at the Day 1 visit.

r. One blood sample for CAB and RPV each to be collected at each PK timepoint. At Day 1, for participants from the ATLAS Q4W arm, PK samples are to be collected pre-dose relative to IM administration. At Week 4B, for participants randomized from SOC, Pre dose PK samples are to be collected: AFTER review of the PK diary to ensure that the samples are taken 20/28 hours after previous oral dose (diaries to be given at *Day 1 or W4a*); PRIOR to the final oral dose of CAB + RPV; PRIOR to the first IM injection.

s. Only for Participants entering CAB + RPV Oral Treatment

t. Participants switching to CAB LA + RPV LA will take final dose of oral lead-in regimen in the clinic at the Week 4B visit and begin injections. If possible, injections should be spaced approximately 2 cm from one another and from the site of any previous injection and or any injection site reaction. Bring RPV LA to approximately room temperature prior to injecting. Time and location of injection (right or left) as well as needle length used will be collected in the eCRF. The first injection can be performed as soon as central lab results become available and safety parameters are reviewed.

u. All Patient Report Questionnaires/Surveys will be administered via paper instrument at the beginning of the visit before any other assessments are conducted and prior to administration of the eC-CSSRS. Conduct questionnaires/surveys at Withdrawal only if occurring at or prior to Week 152.

v. The HIV-TSQc is to be administered to all participants transitioning from ATLAS and new participants transitioning from oral SOC. For participants transitioning from ATLAS, the version of the HIV-TSQc instrument to be administered will be based on the initial randomization arm at ATLAS Day 1.

w. For patients randomized to oral SOC at Day 1 in ATLAS or new patients on SOC, the reasons for willingness to switch ART will be assessed at Day 1. For patients randomized to CAB LA + RPV LA Q4W in ATLAS, the reasons for willingness to continue long-acting ART in ATLAS-2M will be assessed at Day 1.

x. Preference Questionnaire will be administered to all participants.

y. Refer to Section 5.5 of the protocol for additional information on performing withdrawal assessments. HIV-1 RNA will be collected as Storage sample only if withdrawal assessments coincide with Week 52 or Week 100 or Week 156 (as per Section 5.5)

z. 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

aa. Preference at Week 152 will be administered only to participants who received oral bridging during the Maintenance and/or Extension Phases

Note: BP – Blood pressure, HR – Heart Rate, HDL – High Density Lipoprotein, LDL – Low Density Lipoprotein, PT Prothrombin Time, PTT Partial Thromboplastin Time, INR International normalized ratio

15.2.2. Protocol Defined Schedule of Events for Q8W Arm in Main Study

Procedure	Screening Visit [a]	Maintenance Phase																		Extension Phase		Withdrawal Assessments[y]	Long-Term Follow-up [z]
		Week																					
		Day 1	Week 4A (Oral lead-in	Week 4B (Oral lead-in ONLY) b	8	9	16	24	32	40	41	48	56	64	72	80	88	96	100	Q8W After Week 96	152		
Written informed consent	X																						
Eligibility Verification (Inclusion/ Exclusion Criteria)	X		X[c]															X[c]					
Randomization		X																					
Demography	X																						
Medical History[d]	X																						
Cardiovascular risk assessment[d]	X	X																					
Medication History/ Prior ART history	X																						
Syphilis serology + reflex Rapid Plasma Reagin (RPR)	X	X																					
Symptom Directed Physical Exam and Medical Assessment[e]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Procedure	Screening Visit [a]	Maintenance Phase																		Extension Phase		Withdrawal Assessments[y]	Long-Term Follow-up [z]
		Week																					
		Day 1	Week 4A (Oral lead-in	Week 4B (Oral lead-in ONLY) b	8	9	16	24	32	40	41	48	56	64	72	80	88	96	100	Q8W After Week 96	152		
Weight, Height and BMI[f]		X										X						X			X	X	
Vital Signs (BP, HR, Temperature)[g]	X	X										X						X			X	X	
12-lead ECG [h] (triplicate at Day 1 pre-dose)	X	X										X						X			X	X	
CDC HIV-1 stage	X	X																					
HIV Associated Conditions		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
AEs, SAEs, Concomitant Medications	X[i]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ISR Assessment for IM injection		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Columbia Suicide Severity Rating Scale (eC-SSRS)[j]	X	X		X	X		X	X	X	X		X	X	X	X	X	X	X				X	
Clinical chemistry and Hematology	X	X	X	X	X		X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy Testing[k]	S	U	S	U	S		S	S	S	S		S	S	S	S	S	S	S	S	S	S	S	S

Procedure	Screening Visit [a]	Maintenance Phase																		Extension Phase		Withdrawal Assessments[y]	Long-Term Follow-up [z]
		Week																					
		Day 1	Week 4A (Oral lead-in)	Week 4B (Oral lead-in ONLY) b	8	9	16	24	32	40	41	48	56	64	72	80	88	96	100	Q8W After Week 96	152		
HIV-1 RNA and sample for storage (S)[l]	X	X		X	X		X	X	X	X		X	X	X	X	X	X	X	S	X	X	X	X
CD4+ cell count	X	X		X	X		X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X
CD8+ cell count		X						X				X						X			X	X	
Urinalysis[m]		X	X					X				X						X			X	X	
Fasting Labs Glucose, Cholesterol (Total, HDL and LDL) and Triglycerides[n]		X										X						X			X	X[o]	
Hepatitis B (HBsAg), Anti-HBc, and Anti-HBsAG, Hepatitis C (anti-HCV Ab)	X																						
PT/PTT/INR	X	X																					
PBMCs [p]		X										X						X			X	X	
Genetics sample q		X																					

Procedure	Screening Visit [a]	Maintenance Phase																	Extension Phase		Withdrawal Assessments [y]	Long-Term Follow-up [z]
		Week																				
		Day 1	Week 4A (Oral lead-in	Week 4B (Oral lead-in ONLY) [b]	8	9	16	24	32	40	41	48	56	64	72	80	88	96	100	Q8W After Week 96	152		
PK sampling when transitioning from SOC [r] (S)=Storage only				X	X	X	X	X	X	X	X	X	S	S	S	S	S	X	S		X	X	S
PK sampling when transitioning from CAB + RPV Q4W [r] (S)=Storage only		X			X	X	X	X	X	X	X	X	S	S	S	S	S	X	S		X	X	S
Oral CAB and Oral RPV Dispensation [s]		X	X																				
IP accountability (Pill Counts)			X	X																			
IM treatment administration when transitioning from SOC [t]				X	X		X	X	X	X		X	X	X	X	X	X	X		X	X		

Procedure	Screening Visit [a]	Maintenance Phase																		Extension Phase		Withdrawal Assessments [y]	Long-Term Follow-up [z]
		Week																					
		Day 1	Week 4A (Oral lead-in)	Week 4B (Oral lead-in ONLY) [b]	8	9	16	24	32	40	41	48	56	64	72	80	88	96	100	Q8W After Week 96	152		
IM treatment administration when transitioning from CAB + RPV Q4W		X			X		X	X	X	X		X	X	X	X	X	X	X		X	X		
Patient Reported Outcomes [u]																							
HAT-QoL (short-form)		X						X				X										X	
HIV TSQs		X						X				X									X	X	
HIV TSQc [v]												X										X	
ACCEPT		X						X				X									X	X	
Reason for Switch or Reason for continuation [w]		X																					
Preference Questionnaires												X[x]									X[aa]	X	
PIN					X			X				X									X	X	
Safety Follow Up Visit: Conduct approximately 4 weeks after the last dose of IP. Required only if the participant has ongoing AEs or lab abnormalities at the last on-study visit. This visit may be conducted by telephone.																							

a. Participants may be rescreened once and will be assigned a new participant number. Participants transitioning from the 201585 (ATLAS) study must reach ATLAS Week 48 (at minimum) prior to initiating Screening procedures for ATLAS-2M and must reach ATLAS Week 52 (at minimum) prior to randomization in ATLAS-2M.

b. Visits Weeks 4A and 4B are part of the CAB + RPV Oral Lead-in period and are required only for participants transitioning from current SOC to CAB LA + RPV LA.

c. Confirmation of eligibility to continue the Maintenance Phase, and eligibility to enter the Extension Phase.

d. Collect full routine medical history plus (report at Baseline visit): HIV risk factors (may be collected at a later study visit), cardiovascular risk factors (assessments include smoking status and history, family history of cardiac events), recent [≤6 months] illicit drug use, intravenous drug use, gastrointestinal disease, metabolic, psychiatric, renal, bone, and neurologic disorders.

e. Physical exams should be conducted as part of normal routine clinical care. Medical assessments include any decisions the study staff must make for participants management and/or care of participant.

f. Height collected at Baseline Day 1 only.

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

h. A 12-lead ECG will be performed after resting in a semi-supine position for at least 5 minutes. ECGs will be performed pre-dose. For participants transitioning from ATLAS, the pre-dose Week 48 ECG can also serve as the ATLAS-2M Screening ECG. ECG pre-dose will be performed in triplicate at Day 1. A 2-hour post-dose ECG will also be performed at Days 1 and Week 48 for participants receiving CAB LA + RPV LA with an allowable window of ± 30 minutes.

i. Only SAEs related to study participation or to a concomitantly administered ViiV/GSK product will be collected between obtaining informed consent and administration of study drug at Day 1.

j. On Day 1, the eC-SSRS is to be administered prior to randomization. The eC-SSRS will preferably be completed at the beginning of the visit following administration of other PROs required prior to injections. The eC-SSRS is not required during the Withdrawal visit if withdrawal occurs during the Extension Phase.

k. Women of childbearing potential only. SR=serum, UR=urine. Pregnancy events will be captured starting at Day 1 following initial exposure to study drug. Serum pregnancy test can substitute for urine pregnancy test if locally required but must be appropriately timed to confirm pregnancy status prior to randomization and first IM administration.

l. Week 48, Week 96 and Week 152 HIV-1 RNA retest (within 4 weeks) for results > 50 c/mL will be captured as unscheduled visit. Plasma for storage samples will be used for possible future analyses.

m. A morning specimen is preferred. To assess biomarkers: urine albumin/creatinine ratio; urine protein/creatinine ratio; and urine phosphate. Urine phosphate results from visit 4a are not required by protocol to inform the safety review at visit 4b prior to receipt of initial CAB LA + RPV LA injections.

n. An overnight fast is preferred; however, a minimum of a 6-hour fast is acceptable.

o. Only collect if the Withdrawal visit occurs at Week 48, Week 96 or Week 152.

p. Whole blood/PBMC collection samples may be used for virologic analyses. PBMCs will be collected at baseline Day 1, Week 48, Week 96, Week 152 or Withdrawal if prior to Week 152.

q. Genetics sample should be collected only for patients who did not participate in the 201585(ATLAS) study (sample was previously collected and stored). Informed consent for genetic research must be obtained before sample collection. Sample may be collected at any visit after signing informed consent, but preferably at the Day 1 visit.

r. One blood sample for CAB and RPV each to be collected at each PK timepoint. At Day 1, for participant from the ATLAS Q4W arm, PK samples are to be collected pre-dose relative to IM administration. injection. At Week 4B, for participants randomized from SOC, Pre dose PK samples are to be collected: AFTER review of the PK diary to ensure that the samples are taken 20/28 hours after previous oral dose (diaries to be given at Day 1 or W4a); PRIOR to the final oral dose of CAB + RPV; and PRIOR to the first IM injection. At Week 9 and 41, the PK samples should be collected 3 to 10 days after the Week 8 and Week 40 visits, respectively.

s. Only for Participants entering CAB + RPV Oral Treatment

t. Participants switching to CAB LA + RPV LA will take final dose of oral lead-in regimen in the clinic at the Week 4B visit and begin injections. If possible, injections should be spaced approximately 2 cm from one another and from the site of any previous injection and or any injection site reaction. Bring RPV LA to approximately room temperature prior to injecting. Time and location of injection (right or left) as well as needle length used will be collected in the eCRF. The first injection can be performed as soon as central lab results become available and safety parameters are reviewed.

u. All Patient Report Questionnaires/Surveys will be administered via paper instrument at the beginning of the visit before any other assessments are conducted and prior to administration of the eC-CSSRS. Conduct questionnaires/surveys upon Withdrawal only if occurring at or prior to Week 48

v. The HIVTSQc is to be administered to all participants transitioning from ATLAS and new participants transitioning from oral SOC. For participants transitioning from ATLAS, the version of the HIV-TSQc instrument to be administered will be based on the initial randomization arm at ATLAS Day 1

w. For patients randomized to oral SOC at Day 1 in ATLAS or new patients on SOC, the reasons for willingness to switch ART will be assessed at Day 1. For patients randomized to CAB LA + RPV LA Q4W in ATLAS, the reasons for willingness to continue long-acting ART in ATLAS-2M will be assessed at Day 1.

x. Preference Questionnaire will be administered to all participants

y. Refer to Section 5.5 of the protocol for additional information on performing withdrawal assessments. HIV-1 RNA will be collected as Storage sample only if withdrawal assessments coincide with Week 52 or Week 100 (as per Section 5.5)

z. 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

aa. Preference at Week 152 will be administered only to participants who received oral bridging during the Maintenance and/or Extension Phases

Note: BP – Blood pressure, HR – Heart Rate, HDL – High Density Lipoprotein, LDL – Low Density Lipoprotein, PT Prothrombin Time, PTT Partial Thromboplastin Time, INR International normalized ratio

15.2.3. Protocol Defined Schedule of Events for Q4W Arm in Sub-study

Procedure	Screening Phase[d] Gluteal administration		Thigh Injection Phase[d] Q4 Weekly thigh administration						Return to Gluteal Injection Phase[d] Q4 Weekly gluteal admin.			
	Screening (Week -4)	Week -3	Day1	Week 1	Week 4	Week 8	Week 12	Week 13	Week 16	Week 17	Week 20	Week 24
IM treatment administration[i]	X		X		X	X	X		X		X	
Written Inform consent	X											
Eligibility Verification (Inclusion/Exclusion criteria)	X											
Symptom directed physical exam and Medical assessment[a]	X		X		X	X	X		X		X	X
Weight and BMI			X						X			

Procedure	Screening Phase[d] Gluteal administration		Thigh Injection Phase[d] Q4 Weekly thigh administration						Return to Gluteal Injection Phase[d] Q4 Weekly gluteal admin.			
	Screening (Week -4)	Week -3	Day1	Week 1	Week 4	Week 8	Week 12	Week 13	Week 16	Week 17	Week 20	Week 24
Vital Signs, BP, HR, temp[b]	X		X						X			
Smoking status	X											
12-lead ECG[c]	X		X						X			
HIV associated conditions	X	X	X	X	X	X	X	X	X	X	X	X
AEs, SAEs, concomitant medications	X	X	X	X	X	X	X	X	X	X	X	X
ISR assessments for IM injections	X	X	X	X	X	X	X	X	X	X	X	X
Clinical Chemistry and Hematology	X		X		X	X	X		X			X
Pregnancy Testing, SERUM[e]	S		S		S	S	S		S		U	S

Procedure	Screening Phase[d] Gluteal administration		Thigh Injection Phase[d] Q4 Weekly thigh administration						Return to Gluteal Injection Phase[d] Q4 Weekly gluteal admin.			
	Screening (Week -4)	Week -3	Day1	Week 1	Week 4	Week 8	Week 12	Week 13	Week 16	Week 17	Week 20	Week 24
HIV-1 RNA and sample for storage (S)	X		X		X	X	X		X			X
CD4+ cell count	X		X		X	X	X		X			X
CD8+ cell count			X						X			
Urinalysis[f]			X						X			
Fasting lab assessments: Glucose, Cholesterol (Total, HDL and LDL) and triglycerides[g]			X						X			
PBMC for storage			X									

Procedure	Screening Phase[d] Gluteal administration		Thigh Injection Phase[d] Q4 Weekly thigh administration						Return to Gluteal Injection Phase[d] Q4 Weekly gluteal admin.			
	Screening (Week -4)	Week -3	Day1	Week 1	Week 4	Week 8	Week 12	Week 13	Week 16	Week 17	Week 20	Week 24
PK sample collection[j]												
Pre dose PK sampling	X		X		X	X	X		X			
2h Post dose PK sampling			X		X	X	X					
Post dose PK sampling (~Cmax)		X		X				X		X		
PROs[l]												
HIVTSQc									X[k]			
HIVTSQs			X						X[k]		X	
NRS[h]	X	X	X	X			X	X	X	X		
Preference Thigh inj. vs Gluteal inj.							X				X	

a. Physical exams should be conducted as part of normal routine clinical care. Medical assessments include any decisions the study staff must make for participants management and/or care of participant.

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

c. A 12-lead ECG will be performed after resting in a semi-supine position for at least 5 minutes. ECGs will be performed pre-dose. A 2-hour post dose ECG will also be performed at sub-study Day1 visit.

d. All injection visits during the sub-study should kept to the same projected visit schedule as in the parent study.

e. Women of childbearing potential only. SR=serum, UR=urine. Urine pregnancy test can be performed at study visits when other blood draws are not required in order to limit needle sticks.

f. A morning specimen is preferred.

g. An overnight fast is preferred; however, a minimum of a 6-hour fast is acceptable.

h. Should be collected 30 to 60 minutes post injection

i. Week 24 IM administration will not be considered part of the sub-study assessments. The IM administration at W24 and any assessments completed after IM administration at this visit will be considered part of the parent study.

j. PK window allowed for sample collection: For 1-week post dose sample (3 to 10 days post dose), for 4-week post dose sample (+-7 days) and for 2-hours post dose samples (±1 hour)

k. At Week 16, HIVTSQs should be administered before HIVTSQc.

l. All Patient Report Questionnaires/Surveys - except NRS - will be administered via paper instrument (in exceptional circumstances the questionnaires could be completed via telephonic interview, please refer to COVID19 appendix for additional details) at the beginning of the visit before any other assessments are conducted.

Note: There is a typo in the schedule of events table where weight and BMI will be collected at Week -4 visit instead of Day 1 visit.

15.2.4. Protocol Defined Schedule of Events for Q8W Arm in Sub-study

Procedure	Screening Phase[d] Gluteal administration			Thigh injection phase[d] Q8 Weekly thigh administration						Return to Gluteal Injection Phase[d] Q8 Weekly gluteal admin.		
	Screening (Week -8)	Week -7	Week -4	Day1	Week 1	Week 4	Week 8	Week 9	Week 12	Week 16	Week 17	Week 24
IM treatment administration[i]	X			X			X			X		
Written Inform consent	X											
Eligibility Verification (Inclusion/Exclusion criteria)	X											
Symptom directed physical exam and Medical assessment[a]	X			X			X			X		X
Weight and BMI	X									X		
Vital Signs, BP, HR, temp[b]	X			X						X		
Smoking status	X											
12-lead ECG[c]	X			X						X		

Procedure	Screening Phase[d] Gluteal administration			Thigh injection phase[d] Q8 Weekly thigh administration						Return to Gluteal Injection Phase[d] Q8 Weekly gluteal admin.		
	Screening (Week -8)	Week -7	Week -4	Day1	Week 1	Week 4	Week 8	Week 9	Week 12	Week 16	Week 17	Week 24
HIV associated conditions	X	X	X	X	X	X	X	X	X	X	X	X
AEs, SAEs, concomitant medications	X	X	X	X	X	X	X	X	X	X	X	X
ISR assessments for IM injections	X	X	X	X	X	X	X	X	X	X	X	X
Clinical Chemistry and Hematology	X			X			X			X		X
Pregnancy Testing, SERUM[e]	S			S			S			S		S
HIV-1 RNA and sample for storage (S)	X			X		X	X		X	X		X
CD4+ cell count	X			X			X			X		X
CD8+ cell count	X			X						X		
Urinalysis[f]	X			X						X		
Fasting lab assessments: Glucose, Cholesterol (Total,	X			X						X		

Procedure	Screening Phase[d] Gluteal administration			Thigh injection phase[d] Q8 Weekly thigh administration					Return to Gluteal Injection Phase[d] Q8 Weekly gluteal admin.		
	Screening (Week -8)	Week -7	Week -4	Day1	Week 1	Week 4	Week 8	Week 9	Week 12	Week 16	Week 17	Week 24
HDL and LDL) and triglycerides[g]												
PBMC for storage				X								
PK samples[j]												
Pre dose PK sampling	X			X			X			X		
2h Post dose PK sampling				X			X					
Post dose PK sampling (~Cmax)		X	X		X	X		X	X		X	
PROs[l]												
HIVTSQc										X[k]		
HIVTSQs				X						X[k]		X
NRS[h]	X	X		X	X		X	X		X	X	
Preference Thigh inj. vs Gluteal inj.							X					X

a. Physical exams should be conducted as part of normal routine clinical care. Medical assessments include any decisions the study staff must make for participants management and/or care of participant.

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

c. A 12-lead ECG will be performed after resting in a semi-supine position for at least 5 minutes. ECGs will be performed pre-dose. A 2-hour post dose ECG will also be performed at sub-study Day1 visit.

d. All injection visits during the sub-study should kept to the same projected visit schedule as in the parent study.

e. Women of childbearing potential only. SR=serum, UR=urine. Urine pregnancy test can be performed at study visits when other blood draws are not required in order to limit needle sticks.

f. A morning specimen is preferred.

g. An overnight fast is preferred; however, a minimum of a 6-hour fast is acceptable.

h. Should be collected 30 to 60 minutes post injection

i. Week 24 IM administration will not be considered part of the sub-study assessments. The IM administration at W24 and any assessments completed after IM administration at this visit will be considered part of the parent study.

j. PK window allowed for sample collection: For 1-week post dose sample (3 to 10 days post dose), for 4-week post dose sample (+-7 days) and for 2-hours post dose samples (±1 hour)

k. At Week 16, HIVTSQs should be administered before HIVTSQc.

l. All Patient Report Questionnaires/Surveys - except NRS - will be administered via paper instrument (in exceptional circumstances the questionnaires could be completed via telephonic interview, please refer to COVID19 appendix for additional details) at the beginning of the visit before any other assessments are conducted.

15.3. Appendix 3: Assessment Windows

15.3.1. Definitions of Assessment Windows for Analyses

Laboratory data, vital signs, ECGs, health outcomes assessments, and genotypic/phenotypic data will be assigned to assessment windows according to actual dates rather than the nominal visit labels as recorded on the eCRF or in the laboratory database.

In most cases the window around an assessment will include all dates from the midpoints between the target day and that of the previous and the proceeding visits. In general, the nominal target study day for week *w* is (7**w*)+1.

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

Prior to visit slotting, assessments are first assigned to a study phase (screening, maintenance, extension, sub-study screening, thigh injection, return to gluteal injection or long-term follow-up) based on the Tables in Section 15.4.1 and treatment state based on Section 15.4.2.

Maintenance phase assessments other than health outcome and PK are assigned based on the Study Day as shown in Table 8. Table 8 also includes visiting slotting for screening assessments. The analysis visits from Week 4 to Week 100 should be only applied to the assessments that are already assigned to Maintenance phase (on-treatment). Extension phase assessments other than health outcome and PK are assigned based on the Study Day as shown in Table 9. The analysis visits from Week 104 (except for Follow-up) in the Extension phase should be only applied to the assessments that are already assigned to Extension phase (on-treatment). The snapshot visits up to Week 152 during the Maintenance or Extension phase are assigned based on Study Day as shown in Table 10.

The sub-study assessments other than health outcome, PK and HIV-1 RNA are assigned analysis visits based on Study Day as shown in Table 11. The assessment visit windows for HIV-1 RNA data are defined in Table 12, and the snapshot windows for visits up to Sub-study Week 16 are defined in Table 13.

Long-term Follow-up phase assessments are assigned based on the LTFU study day as shown in **Error! Reference source not found.** The analysis visits in LTFU should be only applied to the assessments that are already assigned to LTFU phase regardless of treatment state. See Section 15.6.1, for derivation of Study Day and LTFU Study Day.

15.3.2. Definitions of Assessment Windows for Analyses other than Health Outcome and PK

Table 8 Assessment Windows for Screening and Maintenance Phase Data

All Parameters except for where noted[c]	Target Study Day	Analysis Window	Analysis Timepoint
	The study day of first record	Study Day ≤ 1	Screening
	1	Last available recorded value up to and including the Maintenance treatment start date, excluding post-dose ECG taken on the Maintenance treatment start date	Baseline
ECG	1	Value taken post-dose on the Maintenance treatment start date	Day 1 (Post Dose)
Urinalysis[a]	29	2 ≤ Study Day ≤ 70	Week 4
		2 ≤ Study Day ≤ 42	
	57	43 ≤ Study Day ≤ 84	Week 8
	113	85 ≤ Study Day ≤ 140	Week 16
Urinalysis[a], CD8, CD4/CD8 ratio	169	141 ≤ Study Day ≤ 210	Week 24
		141 ≤ Study Day ≤ 196	
	225	197 ≤ Study Day ≤ 252	Week 32
	281	253 ≤ Study Day ≤ 308	Week 40
Urinalysis[a], fasting glucose, lipids[b], CD8, CD4/CD8 ratio, weight, vital signs, ECG	337	309 ≤ Study Day ≤ 378	Week 48
		309 ≤ Study Day ≤ 364	
	393	365 ≤ Study Day ≤ 420	Week 56
	449	421 ≤ Study Day ≤ 476	Week 64
	505	477 ≤ Study Day ≤ 532	Week 72
	561	533 ≤ Study Day ≤ 588	Week 80
	617	589 ≤ Study Day ≤ 644	Week 88
Urinalysis[a], fasting glucose, lipids[b], CD8, CD4/CD8 ratio, weight, vital signs, ECG	673	645 ≤ Study Day ≤ 714	Week 96
		645 ≤ Study Day ≤ min (Study Day of Nominal Week100 Visit -1, 700)	

All Parameters except for where noted[c]	Target Study Day	Analysis Window	Analysis Timepoint
	701	min (Study Day of Nominal Week 100 Visit, 701) ≤ Study Day ≤ (Study Day of Nominal Week 100 Visit)	Week 100
If a participant permanently discontinued study treatment:			
		For Participants on Q8W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 63)	Follow-up
		For Participants on Q4W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 35)	

NOTES:

- The nominal Week 100 visit refers to the Week 100 visit per eCRF.
- Follow-up will be derived only for participants who permanently discontinued study treatment.

[a] **Urinalysis:** All parameters provided by the central laboratory under the category of urinalysis, including Urine Albumin/Creatinine, Urine Creatinine, Urine pH, Urine Protein/Creatinine, Urine Erythrocytes, Urine Specific Gravity, Urine Leukocytes, Urine Retinol Binding Protein, Urine Phosphate, Urine Creatinine.
[b] **Lipids**: Cholesterol, HDL Cholesterol Direct, LDL Cholesterol Calculation, LDL Cholesterol Direct, Total Cholesterol/HDL Cholesterol Ratio, Triglycerides
[c] Analysis windows for parameters with sparse collection are noted.

Table 9 Assessment Windows for Extension Phase Data

All Parameters except for where noted[d]	Target Study Day	Analysis Window	Analysis Timepoint
	729	(Study Day of Nominal Week 100 Visit + 1) ≤ Study Day ≤ 756	Week 104[a]
	785	757 ≤ Study Day ≤ 812	Week 112
	841	813 ≤ Study Day ≤ 868	Week 120
	897	869 ≤ Study Day ≤ 924	Week 128
	953	925 ≤ Study Day ≤ 980	Week 136
	1009	981 ≤ Study Day ≤ 1036	Week 144
Urinalysis[b], fasting glucose, lipids[c], CD8, CD4/CD8 ratio, weight, vital signs, ECG	1065	1037 ≤ Study Day ≤ 1106	Week 152
		1037 ≤ Study Day ≤ 1092	

All Parameters except for where noted[d]	Target Study Day	Analysis Window	Analysis Timepoint
	7*w + 1	(7*w - 27) ≤ Study Day ≤ (7*w + 28)	Week w w = 160, 168,…
If a participant permanently discontinued study treatment:			
		For participants on Q8W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 63)	Follow-up
		For participants on Q4W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 35)	

NOTES:

- The nominal Week 100 visit refers to the Week 100 visit per eCRF.
- Follow-up will be derived only for participants who permanently discontinued study treatment.

[a] Assessments taken after Week 100 injection at the nominal Week 100 visit will be assigned to Week 104. Adverse events started on the same day as nominal Week 100 visit date will also be assigned to Week 104.
[b] **Urinalysis:** All parameters provided by the central laboratory under the category of urinalysis, including Urine Albumin/Creatinine, Urine Creatinine, Urine pH, Urine Protein/Creatinine, Urine Erythrocytes, Urine Specific Gravity, Urine Leukocytes, Urine Retinol Binding Protein, Urine Phosphate, Urine Creatinine.
[c] **Lipids**: Cholesterol, HDL Cholesterol Direct, LDL Cholesterol Calculation, LDL Cholesterol Direct, Total Cholesterol/HDL Cholesterol Ratio, Triglycerides
[d] Analysis windows for parameters with sparse collection are noted.

Table 10 Assessment Windows for Summary of Snapshot Data Up to Week 152— Data Assigned to Maintenance or Extension Phase

Snapshot Analysis Windows (If no on-treatment viral load data in default window, use expanded window)		Analysis Timepoint
Default	**Expanded +6 Week Upper Window[a]**	
Last available recorded value up to and including the date of first Maintenance Phase dose of IP	Last available recorded value up to and including the date of first Maintenance Phase dose of IP	Baseline
2 ≤ Study Day ≤ 42	2 ≤ Study Day ≤ 70	Week 4
43 ≤ Study Day ≤ 84	43 ≤ Study Day ≤ 98	Week 8
85 ≤ Study Day ≤ 140	85 ≤ Study Day ≤ 154	Week 16
141 ≤ Study Day ≤ 196	141 ≤ Study Day ≤ 210	Week 24
197 ≤ Study Day ≤ 252	197 ≤ Study Day ≤ 266	Week 32
253 ≤ Study Day ≤ 308	253 ≤ Study Day ≤ 322	Week 40
295 ≤ Study Day ≤ 378	295 ≤ Study Day ≤ 378	Week 48
365 ≤ Study Day ≤ 420	365 ≤ Study Day ≤ 434	Week 56
421 ≤ Study Day ≤ 476	421 ≤ Study Day ≤ 490	Week 64
477 ≤ Study Day ≤ 532	477 ≤ Study Day ≤ 546	Week 72
533 ≤ Study Day ≤ 588	533 ≤ Study Day ≤ 602	Week 80
589 ≤ Study Day ≤ 644	589 ≤ Study Day ≤ 658	Week 88
631 ≤ Study Day ≤ 714	631 ≤ Study Day ≤ 714	Week 96
(Study Day of Nominal Week 100 Visit + 1) ≤ Study Day ≤ 756	(Study Day of Nominal Week 100 Visit + 1) ≤ Study Day ≤ 770	Week 104
757 ≤ Study Day ≤ 812	757 ≤ Study Day ≤ 826	Week 112
813 ≤ Study Day ≤ 868	813 ≤ Study Day ≤ 882	Week 120
869 ≤ Study Day ≤ 924	869 ≤ Study Day ≤ 938	Week 128
925 ≤ Study Day ≤ 980	925 ≤ Study Day ≤ 994	Week 136
981 ≤ Study Day ≤ 1036	981 ≤ Study Day ≤ 1050	Week 144
1023 ≤ Study Day ≤ 1106	1023 ≤ Study Day ≤ 1106	Week 152

NOTES:

- For post-baseline visits (i.e. Week 4 and afterwards), apply Snapshot analysis windows only to viral load data that is on-treatment (per Table 20) within the Maintenance Phase (per Table 18).
- An on-treatment viral load assessment may be assigned to more than one snapshot analysis window, e.g. on-treatment assessment taken on Study Day 300 will be in both Week 40 and Week 48.

a. ± 6 Week window is always used at key analysis timepoints (Week 48, Week 96 and Week 152). For analysis timepoint of Week 24, if no viral load data in default window, expand to ± 6 Week window, i.e. (127 ≤ Study Day ≤ 210) in Week 24 IDMC and Week 24 Analyses, and expand upper bound to +6 weeks in all other analyses.

Table 11 Assessment Windows for Sub-study Baseline, Thigh Injection Phase and Return to Gluteal Injection Phase Data (Excluding HIV-1 RNA Data)

All Parameters except for where noted[c]	Target Study Day	Analysis Window	Analysis Timepoint
	7*w + 1	Last available recorded value up to and including the date of first thigh injection, excluding post-dose ECG taken on the date of first thigh injection	Sub-study Baseline[d]

All Parameters except for where noted[c]	Target Study Day	Analysis Window	Analysis Timepoint
ECG	7*w + 1	Value taken post-dose on the date of first thigh injection	Sub-study Day 1 (Post Dose)
Injection Site Reaction	7*w + 1	First thigh injection date≤Study Day≤ max (7*w + 1, First thigh injection date +1)	Sub-study Day 1
	7*(w+8) + 1	Min (7*w + 2, first thigh injection date+1) ≤ Study Day ≤ 7*(w+12)	Sub-study Week 8
Urinalysis[a], fasting glucose, lipids[b], CD8, CD4/CD8 ratio, weight, vital signs, ECG	7*(w+16) + 1	7*(w+12) + 1 ≤ Study Day ≤ 7*(w+22)	Sub-study Week 16
		7*(w+12) + 1 ≤ Study Day ≤ 7*(w+20)	
	7*(w+24) + 1	7*(w+20) + 1 ≤ Study Day ≤ 7*(w+28)	Sub-study Week 24
If a participant permanently discontinued study treatment:			
		For Participants on Q8W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 63)	Follow-up
		For Participants on Q4W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 35)	

NOTES:

- The "w" in the target study day calculation refers to the corresponding week number in Extension for the planned Sub-study Day 1 visit. For example, if a participant's last planned Extension phase visit before entering the Sub-study is Week 192, the "w" would be 200 if the participant is on Q4W arm and would be 208 if the participant is on Q8W arm.
- Follow-up will be derived only for participants who permanently discontinued study treatment.
- Sub-study Day 1 (Post Dose), Sub-study Week 8 and Sub-study Week 16 visits are Thigh Injection phase visits, Sub-study Week 24 is Return to Gluteal Injection phase visit.

[a] **Urinalysis:** All parameters provided by the central laboratory under the category of urinalysis, including Urine Albumin/Creatinine, Urine Creatinine, Urine pH, Urine Protein/Creatinine, Urine Erythrocytes, Urine Specific Gravity, Urine Leukocytes, Urine Retinol Binding Protein, Urine Phosphate, Urine Creatinine.
[b] **Lipids**: Cholesterol, HDL Cholesterol Direct, LDL Cholesterol Calculation, LDL Cholesterol Direct, Total Cholesterol/HDL Cholesterol Ratio, Triglycerides
[c] Analysis windows for parameters with sparse collection are noted.
[d] The values considered for deriving Sub-study Baseline value include both Extension phase and sub-study data.

Table 12 Assessment Windows for Sub-study Baseline, Thigh Injection Phase and Return to Gluteal Injection Phase HIV-1 RNA Data

Phase	Target Study Day	Analysis Window	Analysis Timepoint
Sub-study Screening	7*w + 1	Last available recorded value up to and including the date of first thigh injection	Sub-study Baseline[a]
Thigh Injection	7*(w+4) + 1	Min (7*w + 2, first thigh injection date +1) ≤ Study Day ≤ 7*(w+6)	Sub-study Week 4
	7*(w+8) + 1	7*(w+6) + 1 ≤ Study Day ≤ 7*(w+10)	Sub-study Week 8
	7*(w+12) + 1	7*(w+10) + 1 ≤ Study Day ≤ 7*(w+14)	Sub-study Week 12
	7*(w+16) + 1	7*(w+14) + 1 ≤ Study Day ≤ 7*(w+20)	Sub-study Week 16
Return to Gluteal Injection	7*(w+24) + 1	7*(w+20) + 1 ≤ Study Day ≤ 7*(w+28)	Sub-study Week 24
If a participant permanently discontinued study treatment:			
		For Participants on Q8W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 63)	Follow-up
		For Participants on Q4W Arm: Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 35)	

NOTES:

- The "w" in the target study day calculation refers to the corresponding week number in Extension for the planned Sub-study Day 1 visit. For example, if a participant's last planned Extension phase visit before entering the Sub-study is Week 192, the "w" would be 200 if the participant is on Q4W arm and would be 208 if the participant is on Q8W arm.
- Follow-up will be derived only for participants who permanently discontinued study treatment.

[a] The values considered for deriving Sub-study Baseline value include both Extension phase and sub-study data.

Table 13 Assessment Windows for Summary of Snapshot Data Up to Week 16 in Sub-study— Data Assigned to Thigh Injection Phase

Snapshot Analysis Windows (If no on-treatment viral load data in default window, use expanded window)		
Default	**Expanded +6 Week Upper Window[a]**	**Analysis Timepoint**
Last available recorded value up to and including the date of first thigh injection	Last available recorded value up to and including the date of first thigh injection	Sub-study Baseline[a]
Min(7*w + 2, first thigh injection date+1) ≤ Study Day ≤ 7*(w+6)	Min (7*w + 2, first thigh injection date+1) ≤ Study Day ≤ 7*(w+10)	Sub-study Week 4
7*(w+6) + 1 ≤ Study Day ≤ 7*(w+10)	7*(w+6) + 1 ≤ Study Day ≤ 7*(w+14)	Sub-study Week 8
7*(w+10) + 1 ≤ Study Day ≤ 7*(w+14)	7*(w+10) + 1 ≤ Study Day ≤ 7*(w+16)	Sub-study Week 12
7*(w+10) + 1 ≤ Study Day ≤ 7*(w+22)	7*(w+10) + 1 ≤ Study Day ≤ 7*(w+22)	Sub-study Week 16

NOTES:

- The "w" in the target study day calculation refers to the corresponding week number in Extension for the planned Sub-study Day 1 visit. For example, if a participant's last planned Extension phase visit before entering

the Sub-study is Week 192, the "w" would be 200 if the participant is on Q4W arm and would be 208 if the participant is on Q8W arm.

- For post-baseline visits (i.e. Week 4 and afterwards), apply Snapshot analysis windows only to viral load data that is on-treatment (per Table 20) within the Thigh Injection Phase (per Table 18).
- An on-treatment viral load assessment may be assigned to more than one snapshot analysis window, e.g. on-treatment assessment taken on 7*(w+14) will be in both Sub-study Week 12 and Sub-study Week 16 visits.
- ± 6 Week window is always used at the key analysis timepoint, Sub-study Week 16 visit.

[a] The values considered for deriving Sub-study Baseline value include both Extension phase and sub-study data.

Table 14 Assessment Windows for Summaries of Long-Term Follow Up Phase Data for Participants Who Received At Least One Injection of CAB+RPV and Permanently Discontinued Study Treatment

Analysis Window	Analysis Timepoint	Target Study Day of Window
1 ≤ LTFU Study Day ≤ 63	LTFU Month 1/WD[a]	30
64 ≤ 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

NOTES:

- An assessment may be assigned to both LTFU and maintenance/extension phases.

a. For participants who receives at least one injection of CAB+RPV and permanently discontinues study treatment, they will not complete withdrawal visit, will instead move directly into the LTFU and have LTFU Month 1 visit as the first planned LTFU visit per protocol amendment 1; however, per protocol amendment 2, they will complete withdrawal visit and then have LTFU Month 3 visit as the first planned LTFU visit. Data have been collected either per protocol amendment 1 or per protocol amendment 2 and are included in the database. The analysis timepoint of LTFU Month 1/WD is intended for slotting data mainly collected from either LTFU Month 1 visit per protocol amendment 1 or withdrawal visit per protocol amendment 2 if the date of assessments or onset date of event falls within the specified analysis window.

15.3.3. Assessment Window for Phase Conclusion

The 'Phase Conclusion' records in disposition data will be slotted based on Table 8 (for Maintenance Phase conclusion records), Table 9 (for Extension Phase conclusion records), and Table 12 (for Thigh Injection Phase and Return to Gluteal Injection Phase conclusion records). However, if the discontinuation date is post-treatment per Table 20, the record will be slotted to the last on-treatment visit within the same phase rather than follow up.

15.3.4. Assessment Window for Health Outcome Data

15.3.4.1. PIN / HAT-QoL / HIVTSQs / HIVTSQc / ACCEPT / Preference in Main Study

PIN, HAT-QoL, HIVTSQs, HIVTSQc, ACCEPT, Preference, reasons for oral bridging and preference questionnaire assessments will be assigned to analysis visits as follows:

1. Baseline will be defined as last available recorded value up to and including the Maintenance treatment start date (expected to be collected at Day 1). Baseline is not applicable for PIN, HIVTSQc and Preference assessments.
2. For post-baseline visits, if the nominal visit identifier as captured in the source dataset corresponds to a scheduled collection per the Time and Events Schedule (see Section 15.2 and Table 15) and the assessment is collected in the Maintenance or Extension Phase (per Table 18), then the nominal visit identifier will be kept as the analysis visit.
3. For post-baseline visits, if the nominal visit identifier is unscheduled or withdrawal, then the following procedure will be used:
    a) Assign the assessment to a study phase according to Table 18. Proceed to step b if the assessment is assigned to the Maintenance or Extension Phase.
    b) Identify the 'last nominal visit' with the HO assessment performed prior to the unscheduled/withdrawal visit to be slotted in the same phase.
    c) The unscheduled/withdrawal visit will be slotted to the planned nominal visit subsequent to the 'last nominal visit' in the same phase. If the 'last nominal visits' does not exist (e.g. no records originate from a planned nominal visit), then the unscheduled/withdrawal visit will be slotted to the first planned nominal visit after Day 1 in the same phase. If the planned nominal visit subsequent to the 'last nominal visit' is not available, then the unscheduled/withdrawal visit will be slotted to the last planned nominal visit after Day 1 in the same phase.

Example 1, for HATQoL, the planned nominal visits are Day 1, Week 24, and 48. If a participant has the 'last nominal visit' (with HATQoL assessment) at Week 24 prior to withdrawal at Week 36, the withdrawal assessment will be slotted to the subsequent planned nominal visit of Week 48.

Example 2, for HATQoL, if there is unscheduled visit between Week 24 and Week 48. This unscheduled visit will be slotted to Week 48 per the rule. In this case, there are two assessments with analysis visit equal to Week 48 (i.e. the slotted value and the value at original nominal week 48 visit). The original nominal value will be selected for summary per the rule below for multiple records—see Section 15.3.5.1.

Table 15 Planned Nominal Visit of Health Outcome Data in Main Study

Questionnaire	Day 1	Week 8	Week 24	Week 48	Week 152
PIN		x	x	x	x
HAT-QoL	x		x	x	
HIVTSQs	x		x	x	x
HIVTSQc				x	
ACCEPT	x		x	x	x
Preference				x	
Reasons for Oral Bridging and Preference					x
NOTES: Day 1 visits are recorded as "Baseline" visits in the database.					

15.3.4.2. Reasons for Continuation/Switch in Main Study

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

15.3.4.3. HIVTSQs/HIVTSQc/Preference in Sub-study

HIVTSQs, HIVTSQc, Preference Thigh Injection vs Gluteal Injection questionnaire assessments will be assigned to analysis visits as follows:

1. Sub-study Baseline will be defined as last available recorded value up to and including the date of first thigh injection. Baseline is not applicable for HIVTSQc and Preference Thigh Injection vs Gluteal Injection assessments as they are not planned to be collected during the Sub-study Baseline. In Sub-study Baseline value derivation for HIVTSQs, the assessments conducted in the main study will also be considered.
2. For post-baseline visits, if the nominal visit identifier as captured in the source dataset corresponds to a scheduled collection per the Time and Events Schedule (see Section 15.2) and the assessment is collected in the planned phase (per Table 18, visits at/before Sub-study Week 16 belong to Thigh Injection phase, and visits after Sub-study Week 16 belong to Return to Gluteal Injection phase), then the nominal visit identifier will be kept as the analysis visit.
3. For post-baseline visits, if the nominal visit identifier is unscheduled or it is scheduled however not conducted in the planned phase (e.g. the sub-study Week 16 HIVTSQs assessment is conducted after the Week 16 gluteal injection and therefore belong to Return to Gluteal Injection phase), then this visit will be assigned to the planned visit in the same phase.

15.3.4.4. Tolerability of Injections (NRS) in Sub-study

After assigning the phases per Table 18, the NRS assessments will be slotted to analysis visits per Table 16.

Table 16 Assessment Window for NRS Data

Phase	Assessment Window	Visit
Sub-study Screening	Q8W: post-dose and on the Week -8 injection date Q4W: post-dose and on the Week -4 injection date	Q8W: Sub-study Week -8 Q4W: Sub-study Week -4
	Q8W: (Week -8 injection date+1, Week -8 injection date+14), inclusive Q4W: (Week -4 injection date+1, Week -4 injection date+14), inclusive	Q8W: Sub-study Week -7 Q4W: Sub-study Week -3
Thigh Injection	Post-dose and on the Day 1 injection date	Sub-study Day 1
	(Day 1 injection date+1, Day 1 injection date+14), inclusive	*Sub-study Week 1*
	Q8W: post-dose and on the Week 8 injection date Q4W: post-dose and on the Week 12 injection date	Q8W: Sub-study Week 8

		Q4W: Sub-study Week 12
	Q8W: (Week 8 injection date+1, Week 8 injection date+14), inclusive Q4W: (Week 12 injection date+1, Week 12 injection date+14), inclusive	Q8W: Sub-study Week 9 Q4W: Sub-study Week 13
Return to Gluteal	Post-dose and on the Week 16 injection date	Sub-study Week 16
	(Week 16 injection date+1, Week 16 injection date+14), inclusive	Sub-study Week 17

15.3.5. Assessment Window for PK Concentration Data

15.3.5.1. Maintenance and Extension Phase Assessments

For PK concentration data at the withdrawal/unscheduled/LTFU Month 1visits during the maintenance and extension phase (after assignment to study phase per Table 18), the visit will be slotted to the analysis visit per the following steps:

- Identify the 'last nominal visit' with the planned PK pre-dose assessment prior to the visit to be slotted during the same study phase
- Identify the nominal visit corresponding to the next planned pre-dose PK assessment visit (excluding visits with storage PK collection), that is subsequent to the 'last nominal visit' with PK pre-dose assessment during the same study phase. If the 'last nominal visit' during the maintenance phase does not exist, the first planned pre-dose PK assessment visit for the participant during the maintenance phase will be considered the nominal visit corresponding to the next planned pre-dose PK assessment. If the 'last nominal visit' during the extension phase does not exist, slot the PK assessment to the nominal visit of the next planned injection occurring on or after the date of the PK assessment during the extension phase.
- If the nominal visit corresponding to next planned pre-dose PK assessment visit is prior to/at Week 48 visit, the PK assessment at the unscheduled/withdrawal/LTFU Month 1 visit will be slotted to this nominal visit corresponding to next planned pre-dose PK assessment visit.
- Otherwise, the PK assessment at the unscheduled/withdrawal/LTFU Month1 visit will be slotted to the earliest nominal visit from the following:
  - Nominal visit corresponding to the next planned pre-dose PK assessment visit
  - The nominal visit of the next planned injection occurring on or after the date of the PK assessment during the same study phase

  If both the next planned pre-dose PK assessment visit and the next planned injection visit during the same study phase are not available, for example, withdrawal PK assessment taken after Week 96 for participants on Q8W arm, the PK assessment will be slotted to Week 100 visit.

During the maintenance and extension phase, the planned nominal visits for PK Pre-dose are Week 4B, 8, 16, 24, 32, 40, 48, 96, 152 for Q4W arm; and are Day 1, Week 4B, 8, 16, 24, 32, 40, 48, 96, 152 for Q8W arm while Day 1 is required only for those transitioning from ATLAS on Q4W injections and Week 4B is required only for participants transitioning from oral SOC and requiring oral CAB+RPV lead-in. In addition, the participants on Q8W arm have planned nominal visits at Week 9 and 41 for 1-week post-dose.

For participants requiring oral CAB+RPV lead-in, the planned injection visits are Week 4B, Week 8, continuing every 4 weeks for Q4W arm and continuing every 8 weeks for Q8W arm. For participants not requiring oral CAB+RPV lead-in, the planned injection visits are every 4 weeks starting from Day 1 for Q4W arm and every 8 weeks starting from Day 1 for Q8W arm.

Example 1: If a participant on Q8W arm has the 'last nominal visit' (with PK pre-dose assessment) at Week 24 and then withdraws around Week 28, with the last injection at Week 24 and a Maintenance Phase PK assessment labelled at 'LTFU Month 1'., This PK assessment labelled as 'LTFU Month 1' will be slotted to the subsequent planned nominal visit of Week 32.

Example 2: If a participant on Q4W arm has the 'last nominal visit' (with PK pre-dose assessment) at Week 48 and then have an unscheduled Maintenance Phase PK assessment around Week 74. This assessment will be slotted to the next planned injection visit, Week 76.

There will be no slotting for planned nominal visits (i.e. analysis visit =visit).

15.3.5.2. Long-term Follow-up Phase Assessments

PK concentration data at nominal visits other than withdrawal/LTFU Month 1/LTFU Month 3/LTFU Month 6/LTFU Month 9/LTFU Month 12/Liver Event which have been assigned to the LTFU phase (according to according to Table 18) will be slotting to analysis visits per the following steps:

- Identify the 'last nominal PK visit' with the PK assessment performed prior to the visit to be slotted during the LTFU phase
- The PK assessments will be slotted to the nominal visit corresponding to the next planned LTFU PK assessment visit that is subsequent to the 'last nominal PK visit' during the LTFU phase. If the 'last nominal visit' does not exist, the PK assessment will be slotted per **Error! Reference source not found.**.

There will be no slotting for planned PK nominal visits (i.e. analysis visit =visit): LTFU Month 1 or withdrawal, LTFU Month 3, LTFU Month 6, LTFU Month 9 and LTFU Month 12.

15.3.5.3. Sub-study Assessments

Unscheduled sub-study assessments will not be slotted to any analysis visit. There will be no slotting for planned nominal visits (i.e. analysis visit=visit).

15.3.6. Multiple Assessments within an Assessment Window

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

For data other than health outcome/PK concentration:

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

For Health outcome and PK concentration data, the following hierarchy will be used to determine the value to be used for summary statistics of observed values:

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

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

15.4. Appendix 4: Study Phases and Treatment State

15.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to the Treatment Start Date defined in Section 15.6.1.

AEs will be assigned to study phases as defined in Table 17. For example, adverse events on/after start of maintenance phase IP and prior to start of Extension phase IP/LTFU ART will be assigned to the Maintenance Phase.

Laboratory data (efficacy, safety, PK and virology), HIV associated Conditions, health outcomes assessments, vital signs, and ECGs will be assigned to study phases as defined as in Table 18. For example, assessments/events occurring after start of maintenance phase IP and up to and including start of extension phase IP/LTFU ART will be assigned to the Maintenance Phase.

Assessments/events are assigned to study phases sequentially, starting from the top of each table, except for the assessments/events occurring after returning to Extension phase from the sub-study participation. No study phases will be assigned to medications.

Table 17 Assignment of Study Phases for AEs

Study Phase	Definition
Screening	Date < Maintenance Treatment Start Date
Maintenance	**For participants continuing into Extension Phase:** Maintenance Treatment Start Date ≤ Date < Date of Nominal Week 100 Visit **For participants <u>not</u> continuing into Extension Phase:** **For participants continuing into LTFU Phase:** Maintenance Treatment Start Date ≤ Date < LTFU ART Start Date[a]

Extension	**For participants continuing into Extension Phase and not entering the sub-study:** If participants continued into LTFU Phase after the Extension phase:Date of Nominal Week 100 Visit ≤ Date < LTFU ART Start Date[a] If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then Date of Nominal Week 100 Visit[a] ≤ Date < Date of end of study +35 days (Q4W) or + 63 days (Q8W) **For participants continuing into Extension Phase, entering the sub-study but not returning to Extension Phase:** Date of Nominal Week 100 Visit ≤ Date < Date of First Sub-study Record **For participants continuing into Extension Phase, entering the sub-study and returning to Extension Phase:** Before the sub-study: Date of Nominal Week 100 Visit ≤ Date < Date of First Sub-study Record After the sub-study: **For participants continuing into LTFU Phase after return to extension phase:** End of Sub-study Date[b] < Date < LTFU ART Start Date[a] **For participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason:** End of Sub-study Date[b] < Date < Date of end of study +35 days (Q4W) or + 63 days (Q8W)

Sub-study Screening	**For participants entering the sub-study and not receiving any thigh injection:**
	If participants continued into LTFU Phase after the sub-study, then
	Date of First sub-study record ≤ Date < LTFU ART Start Date[a]
	If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then
	Date of First sub-study record ≤ Date < Date of end of study +35 days (Q4W) or + 63 days (Q8W)
	If participants continued into Extension Phase after the sub-study, then
	Date of First sub-study record ≤ Date ≤ End of Sub-study Date[b]
	For participants entering the sub-study and receiving thigh injection(s):
	Date of First sub-study record ≤ Date < Date of First Thigh Injection

Thigh Injection	**For participants continuing into Return to Gluteal Injection Phase:**
	Date of First Thigh Injection ≤ Date < Date of Nominal Sub-study Week 16 Visit[c]
	For participants not continuing into Return to Gluteal Injection Phase:
	If participants continued into LTFU Phase after the sub-study, then
	Date of First Thigh Injection ≤ Date < LTFU ART Start Date[a]
	If participants continued into Extension Phase after the sub-study, then
	Date of First Thigh Injection ≤ Date ≤ End of Sub-study Date[b]
	If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then
	Date of First Thigh Injection ≤ Date < Date of end of study +35 days (Q4W) or + 63 days (Q8W)

Return to Gluteal Injection	**For participants continuing into Extension Phase after the sub-study:** Date of Nominal Sub-study Week 16 Visit[c] ≤ Date ≤ End of Sub-study Date[b] **For participants continuing into LTFU Phase after the sub-study:** Date of Nominal Sub-study Week 16 Visit[c] ≤ Date < LTFU ART Start Date[a] **For participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason:** Date of Nominal Sub-study Week 16 Visit[c] ≤ Date < Date of end of study +35 days (Q4W) or + 63 days (Q8W)

NOTES:

- Date = AE Start date
- For AEs started on the End of Sub-study Date, if participants received injection belonging to the Extension Phase on End of Sub-study Date, Extension Phase will be assigned to these AEs.
- [a] If participants have missing LFTU ART start date, only the lower bound will be considered in the derivation. For AEs leading to withdrawal and started on the same date as LTFU ART Start Date, appropriate study treatment associated phase (e.g. Maintenance, Extension, Sub-study Screening, Thigh Injection, Return to Gluteal Injection), instead of Long-term Follow-up phase, will be assigned.
- [b] End of Sub-study Date is defined in Section 15.6.1.
- [c] Nominal Sub-study Week 16 Visit Date is defined in Section 15.6.1.

Table 18 Assignment of Study Phases for Lab Assessments (including PK and Virology), ECG, Protocol Deviations, Vital Sign, Health Outcomes, HIV Associated Conditions

Study Phase	Definition
Screening	Date ≤ Maintenance Treatment Start Date Note: 2-hour post-dose ECG taken on the Maintenance Treatment Start Date will be excluded.
Maintenance	**For participants continuing into Extension Phase**: Maintenance Treatment Start Date < Date ≤Date of Nominal Week 100 Visit[a] Note: 2-hour post-dose ECG taken on the Maintenance Treatment Start Date will be included. **For participants not continuing into Extension Phase:** **For participants continuing into LTFU Phase:** Maintenance Treatment Start Date < Date ≤ LTFU ART Start Date[b] **For participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason**: Maintenance Treatment Start Date < Date ≤ Date of end of study +35 days (Q4W) or + 63 days (Q8W) Note: 2-hour post-dose ECG taken on the Maintenance Treatment Start Date will be included.
Extension	**For participants continuing into Extension Phase and not entering the sub-study:** If participants continued into LTFU Phase after the Extension phase: Date of Nominal Week 100 Visit[a] < Date ≤ LTFU ART Start Date[b] If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then Date of Nominal Week 100 Visit[a] < Date ≤ Date of end of study +35 days (Q4W) or + 63 days (Q8W)**For participants continuing into Extension Phase, entering the sub-study but not returning to Extension Phase:** Date of Nominal Week 100 Visit[a] < Date < Date of First Sub-study Record **For participants continuing into Extension Phase, entering the sub-study and returning to Extension Phase:** Before the sub-study: Date of Nominal Week 100 Visit[a] < Date < Date of First Sub-study Record After the sub-study: **For participants continuing into LTFU Phase after return to extension phase:** End of Sub-study Date[b] < Date ≤ LTFU ART Start Date[a] **For participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason:** End of Sub-study Date[b] < Date ≤ Date of end of study +35 days (Q4W) or + 63 days (Q8W)

Sub-study Screening	**For participants entering the sub-study and not receiving any thigh injection:**
	If participants continued into LTFU Phase after the sub-study, then
	Date of First sub-study record ≤ Date < LTFU ART Start Date[b]
	If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then
	Date of First sub-study record ≤ Date < Date of end of study +35 days (Q4W) or + 63 days (Q8W)
	If participants continued into Extension Phase after the sub-study, then
	Date of First sub-study record ≤ Date ≤ End of Sub-study Date[c]
	For participants entering the sub-study and receiving thigh injection(s):
	Date of First sub-study record ≤ Date ≤ Date of First Thigh Injection[d]

Thigh Injection	**For participants continuing into Return to Gluteal Injection Phase:**
	Date of First Thigh Injection[d] < Date ≤ Date of Nominal Sub-study Week 16 Visit[e]
	For participants not continuing into Return to Gluteal Injection Phase:
	If participants continued into LTFU Phase after the sub-study, then
	Date of First Thigh Injection[d] < Date ≤ LTFU ART Start Date[b]
	If participants continued into Extension Phase after the sub-study, then
	Date of First Thigh Injection[d] < Date ≤ End of Sub-study Date[c]
	If participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason, then
	Date of First Thigh Injection ≤ Date ≤ Date of end of study +35 days (Q4W) or + 63 days (Q8W)

Return to Gluteal Injection	**For participants continuing into Return to Extension Phase after the sub-study:** Date of Nominal Sub-study Week 16 Visit[e] < Date ≤ End of Sub-study Date[c] **For participants continuing into LTFU Phase after the sub-study:** Date of Nominal Sub-study Week 16 Visit[e] < Date ≤ LTFU ART Start Date[b] **For participants transitioned to marketed product/alternative HAART and did not withdraw study due to safety related reason:** Date of Nominal Sub-study Week 16 Visit[c] < Date ≤ Date of end of study +35 days (Q4W) or + 63 days (Q8W)

- Date = start or assessment date
- [a] If the collected time of the assessment is available, the assessment taken on the same day as nominal Week 100 visit date but after the Week 100 injection will be assigned to Extension Phase.
- [b] If participants have missing LFTU ART start date (i.e. the participants have not started ART in LFTU yet), only the lower bound of the window will be considered in the derivation.
- [c] End of Sub-study Date is defined in Section 15.6.1.
- [d] The post-dose assessments (e.g. 2-hour post-dose ECG, 2-hour post-dose PK and NRS) taken on the date of first thigh injection will be assigned Thigh Injection Phase, instead of Sub-study Screening Phase.
- [e] The Date of Nominal Sub-study Week 16 is defined in Section 15.6.1. The post-dose assessment (e.g. NRS) taken on the date of Sub-study Week 16 injection will be assigned Return to Gluteal Injection Phase, instead of Thigh Injection Phase.

Table 19 Assignment to Long-term Follow-up Phase

Study Phase	Definition

Long-term Follow-up	Date > max (Last IM Injection Date, Last Oral Bridging End Date)

- Date = Assessment/Start Date
- For AEs leading to withdrawal and started on the same date as LTFU ART Start Date, appropriate study treatment associated phase, instead of long-term follow-up phase, will be assigned. Refer to Table 17 for details.

Only participants who received at least one CAB and/or RPV injection will enter the long-term follow-up. Participants transitioning to CAB+RPV LA marketed product or alternative HAART (except due to safety-related reasons) do not need to enter the LTFU Phase. Note that the long-term follow-up phase and maintenance/extension/sub-study screening/thigh injection/return to gluteal injection phases are not necessarily mutually exclusive and are to be defined with separate phase variables in the datasets. For example, an Q4W IM participant who has Week 44 injection and withdrawal at Week 48 without receiving Week 48 injection, the "Week 48 withdrawal visit" belongs to both the maintenance phase and long-term follow-up phase.

15.4.2. Treatment State

Within each treatment study phase (i.e. Maintenance and Extension—based on assignment of study phase described in Section 15.4.1), only those assessments which occur within the ranges shown in Table 20 will be considered 'on-treatment' for the given phase. No treatment states will be assigned to medications.

Table 20 Treatment State within Study Phases[b]

Study Phase[a]	Treatment State	Date Range
Screening	Pre-treatment	All assessments/events within the phase
Maintenance	On-treatment	Q8W arm: Date ≤ max (Date of Last Injection + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)
		Q4W arm: Date ≤ max (Date of Last Injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)
	Post-treatment	Q8W arm: Date > max (Date of Last Injection + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)
		Q4W arm: Date > max (Date of Last Injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)
Extension	On-treatment	Q8W arm: Date ≤ max (Date of Last Injection + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1) Q4W arm:

		Date ≤ max (Date of Last Injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)
	Post-treatment	Q8W arm: Date > max (Date of Last Injection + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1) Q4W arm: Date > max (Date of Last Injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)
Long-term Follow-up	On-treatment	Q8W arm: Date ≤ min (LTFU ART start date, max (Date of Last Injection + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)) Q4W arm: Date ≤ min (LTFU ART start date, max (Date of Last Injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1))
	Post-treatment	Q8W arm: Date > min (LTFU ART start date, max (Date of Last Injection + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)) Q4W: Date > min (LTFU ART start date, max (Date of Last Injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1))

NOTE:

- Date = Assessment/Start Date.
- For Sub-study Screening, Thigh Injection and Return to Gluteal Injection phases, the same on-treatment and post-treatment algorithms as those in Extension Phase will be applied.

a. Treatment State is determined after data has been assigned to the study phases as defined in Section 15.4.1.

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 maintenance phase per Section 15.4.1 will be considered 'On-treatment'.

15.4.2.1. Treatment States for AE Data

For adverse events, partial AE start date will use imputation as described in Section 15.7.2.1. In the case of a completely missing start date, the event will be considered to have started On-treatment in the Maintenance phase unless an end date for the AE is provided which is before start of study treatment at Maintenance phase; in such a case the AE is assigned as Pre-treatment.

Additional variables will be derived as shown in Table 21.

Table 21 Days since First Dose of Each Study Phase, Days since Phase Start, AE Duration and Relation to Study Treatment

	Definition
Days since First Dose (Days)[a]	AE Start Date – Maintenance Treatment Start Date + 1
Days since Last Dose (Days)[a]	AE Start Date – Date of Last Dose of Study Treatment prior to/on the Start Date of AE + 1
Days since Phase Start	**For AEs in Maintenance Phase:** AE Start Date - Maintenance Treatment Start Date + 1 **For AEs in Extension Phase before Sub-study:** AE Start Date – Date of Nominal Week 100 Visit + 1 **For AEs in Extension Phase after Sub-study:** AE Start Date – End of Sub-study Date[c] + 1 **For AEs in Long-term Follow-up Phase:** AE Start Date – Date of Last Dose of Study Treatment[b] **For AEs in Sub-study Screening Phase:** AE Start Date – Date of First Sub-study Record + 1 **For AEs in Sub-study Thigh Injection Phase:** AE Start Date - Date of First Thigh Injection + 1 **For AEs in Return to Gluteal Injection Phase:** AE Start Date - Date of Nominal Sub-study Week 16 Visit + 1
Duration (Days)	AE Resolution Date – AE Start Date + 1
Drug-related	If relationship is marked 'YES' on Inform/eCRF or value is missing.

NOTES:

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

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

c. End of Sub-study Date is defined in Section 15.6.1.

15.4.3. Study Period

Certain displays will be produced for data collected during the oral lead-in. The study period variable is defined in Table 22 and Table 23. Study period is assigned after the study phase is assigned (screening, maintenance, extension, or long-term follow-up) based on the Tables in Section 15.4.1.

Table 22 Assignment of Study Period for AE Data

Study Period	Date range

Oral Lead-in	**For participants receiving at least one Injection:** Maintenance Treatment Start Date ≤ Date < Date of First IM Injection **For participants withdrawing prior to first Injection:** Date ≥ Maintenance 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 maintenance phase.

NOTES:

- Date = AE Start date.

Table 23 Assignment of Study Period for Lab Assessments:

Period	Date range
Oral Lead-in	**For participants receiving at least one Injection:** Maintenance Treatment Start Date < Date ≤ Date of First IM Injection **For participants withdrawing prior to first Injection:** Date > Maintenance 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 maintenance phase.

NOTES:

- Date = Date of assessment.

15.5. Appendix 5: Data Display Standards & Handling Conventions

15.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: us1salx00259
HARP Compound	: \ARPROD\GSK1265744\mid207966
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.1). • For creation of ADaM datasets (ADCM/ADAE), the same version of dictionary datasets will be implemented for conversion from SI to SDTM.	
Generation of RTF Files	
• RTF files will be generated for every reporting effort described in the RAP.	

15.5.2. Reporting Standards

General

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

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

• Reporting for tables, figures and formal statistical analyses:
  ○ Actual time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  ○ The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  ○ If space allows, planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).

○ Unscheduled or unplanned readings will be presented within the participant's listings. ○ When data falls within both maintenance / extension and long-term follow-up phases, it will be presented in maintenance / extension phase, unless otherwise specified. ○ Unless otherwise specified, when data falls within both screening and baseline visits per analysis visit windows, it will be presented at baseline visit.
Unscheduled Visits
• Unscheduled visits will be assigned to a study visit using the all-inclusive windows defined in Section 15.2.3. • However, data summaries will only report visits that are planned assessment time points for each parameter (according to the Time and Events table). • Assessments at unscheduled visits will be included for 'any time On-treatment' time points and in data listings, as well any algorithms that make use of additional data (e.g., Snapshot).

Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1. First and third quartiles will also be included in the summary.
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

15.5.3. Reporting Standards for Pharmacokinetic

Reporting of Pharmacokinetic Concentration Data	
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to IDSL Statistical Principle 6.06.1 Assign the low limit of quantification (CAB 0.025 ug/mL, RPV 1 ng/mL) to NQ values.
Reporting of Pharmacokinetic Parameters	
Descriptive Summary Statistics (Log_e Transformed)	N, n, geometric mean, 95% CI of geometric mean, standard deviation (SD) of log_e transformed data and between participant coefficient of variation (CV_b (%)) will be reported. ○ $CV_b(\%) = \sqrt{\exp(SD^2) - 1} \times 100$ (SD = SD of log_e transformed data)

15.6. Appendix 6: Derived and Transformed Data

15.6.1. General

Multiple Measurements at One Time Point
• If after window assignment there are multiple valid assessments of a parameter within the same window, refer to Section 15.3.5.1 for determination of the value to be used for summary statistics of observed values. Assessments not chosen for use in summary statistics will still appear in the associated listings. Assessments not chosen for use in summary statistics by this algorithm will still appear in the associated listings. Also, all applicable valid assessments, irrespective of proximity to the target study day, will be used when categorizing values across visits, such as 'maximum grade' or 'at any time', and for any algorithm that has specific rules for which observation to use (e.g. snapshot algorithm, LOCF or CVF identification).
Nominal Week 100 Visit Date
• For participants who received Week 100 injection, nominal Week 100 visit date is defined by the Week 100 injection date. • Otherwise, nominal Week 100 visit date is defined by the date of latest Week 100 assessment. • For participants who continued into Extension Phase however missed Week 100 visit, nominal Week 100 visit date is defined by the end of Maintenance Phase date (i.e. date for the Maintenance Phase conclusion record in the SDTM DS domain) for the analysis purpose.
Nominal Sub-study Week 16 Visit Date
• For participants who received Sub-study Week 16 injection, nominal Sub-study Week 16 visit date is defined by the Sub-study Week 16 injection date. • Otherwise, nominal Sub-study Week 16 visit date is defined by the date of latest Sub-study Week 16 assessment. • For participants who continued into Return to Gluteal Injection Phase however missed Sub-study Week 16 visit, nominal Sub-study Week 16 visit date is defined by the end of Thigh Injection Phase date (i.e. date for the Thigh Injection Phase conclusion record in the SDTM DS domain) for the analysis purpose.
End of Sub-study Date
• For sub-study screen failures, the end of sub-study date is defined by the date they failed to meet the inclusion/exclusion criteria in the sub-study. • For other sub-study participants, the end of sub-study date is defined by the date of completion or withdrawal available in the sub-study conclusion eCRF form.

Study Day

The Study Day of an event (e.g., lab assessment, vital sign, ECG, start date of AE or HIV associated condition) will be derived as the number of days between the date of the event and the start date of study treatment during the Maintenance Phase as follows:

if date of event ≥ start date of study treatment, then

- Study Day=date of event - start date of Maintenance Phase treatment +1

if date of event < start date of study treatment, then

- Study Day=date of event - start date of Maintenance Phase treatment

Note that the start date of study treatment during maintenance phase is considered to be on Study Day 1 and the day before this is Study Day -1; i.e., there is no Study Day 0.

Extension Phase 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 date of nominal Week 100 visit as follows:

if date of event ≥ date of nominal Week 100 visit, then

- Study Day=date of event - date of nominal Week 100 visit + 1

if date of event < date of nominal Week 100 visit, then

- Study Day=date of event - date of nominal Week 100 visit

Note that the date of nominal Week 100 visit is considered to be on Extension Phase Study Day 1 and the day before this is Extension Phase Study Day -1; i.e., there is no Extension Phase Study Day 0.

Sub-study Phase Study Day

Each phase 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 reference date for each phase of the sub-study as follows:

if date of event ≥ reference date, then

- Study Day=date of event - reference date + 1

if date of event < reference date, then

- Study Day=date of event - reference date

The reference date for the Screening Phase is the date of first screening visit in the sub-study, for the Thigh Injection Phase is the date of first thigh injection, and for the Return to Gluteal Injection Phase is the nominal sub-study Week 16 visit date as specified in this section.

Long-term Follow-up Study Day

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

15.6.2. Study Population

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

Demographics and Baseline Characteristics

- The predicted probability, $\hat{p}$, of having a cardiovascular disease (CVD) within the next 10-years according to the Framingham formula [D'Agostino, 2008] is

  For females:

$$\hat{p}_F = 1 - S_0(t)^{exp\left\{\begin{array}{c}2.32888\times\log(age)+1.20904\times\log(TC)-0.70833\times\log(HDL)+2.76157\times\log(SBP_u)+\\ 2.82263\times\log(SBP_t)+0.52873\times I_s+0.69154\times I_d-26.1931\end{array}\right\}}$$

  For males:

$$\hat{p}_M = 1 - S_0(t)^{exp\left\{\begin{array}{c}3.06117\times\log(age)+1.12370\times\log(TC)-0.93263\times\log(HDL)+1.93303\times\log(SBP_u)+\\ 1.99881\times\log(SBP_t)+0.65451\times I_s+0.57367\times I_d-23.9802\end{array}\right\}}$$

  where

$$S_0(t) = \begin{cases}0.95012, \text{females}\\ 0.88936, males\end{cases}$$

$$I_s = \begin{cases}1, \text{current smoker}\\ 0, \quad otherwise\end{cases}$$

$$I_d = \begin{cases}1, \quad \text{diabetic}\\ 0, \quad otherwise\end{cases}$$

  TC = total serum cholesterol (mg/dL),
  HDL = serum HDL cholesterol (mg/dL),
  SBPu = systolic blood pressure (mmHg) if participant is not treated for high blood pressure (note that if a participant is treated for high blood pressure then log(SBPu) = 0)
  SBPt = systolic blood pressure (mmHg) if participant is treated for high blood pressure (note that if a participant is not treated for high blood pressure then log(SBPt) = 0)

- A participant will be considered as treated for high blood pressure if during screening it has specified that is suffering from hypertension.
- A participant is classified as diabetic if current or past is indicated in the medical conditions eCRF for Type 1 or Type 2 diabetes mellitus, or if baseline fasting glucose ≥7.00 mmol/L (126 mg/dL).
- Smoking status is collected in the eCRF at Day 1. A current smoker is defined as currently smoking/using tobacco or has smoked/used tobacco within the previous 6 months; a former smoker is defined as previously smoked/used tobacco products and has not smoked/used tobacco products within the previous 6 months.
- This calculation will not be performed for participants who have indicated current or past myocardial infarction conditions on the eCRF. These participants will not be included in summary statistics of risk, but they will be counted in the highest category of risk in the summary by category.

Prior Exposure to CAB+RPV

- For participants transitioning from ATLAS study and having prior exposure to CAB+RPV in ATLAS study: Duration of Prior Exposure to CAB+RPV = Randomization Date – Prior Oral CAB Start Date in ATLAS Study + 1.

Demographics and Baseline Characteristics
• For participants transitioning from ATLAS study and not having prior exposure to CAB+RPV in ATLAS study, or for participants randomized from current SOC, Duration of Prior Exposure to CAB+RPV = 0. • Duration of Prior Exposure to CAB+RPV will be categorized to 0 weeks, 1-24 weeks and >24 weeks.
Lipid-modifying Agents
• The following ATC codes correspond to lipid-modifying agents: o ATC Level 2: C10 o ATC Level 3: C10A, C10B (if Level 2 is not available) o ATC Level 4: C10AA, C10AB, C10AC, C10AD, C10AX, C10BA, C10BX (if level 2, 3 are not available) • Participants are considered to have used a lipid-modifying agent at baseline if they are taking the medication at the time of their baseline fasting lipid testing date. • Participants are also considered to have used a lipid-modifying agent at baseline if they stopped their lipid modifying medication within 12 weeks prior to their baseline fasting lipid testing date.

15.6.3. Efficacy

Snapshot
• The Snapshot algorithm is intended to be primarily a virologic assessment of the endpoint, and as such follows a "virology first" hierarchy. • 'HIV-1 RNA < 50 c/mL' or 'HIV-1 RNA ≥ 50 c/mL' within an analysis window (see Table 10 and Table 13) is typically determined by the last available HIV-1 RNA measurement in that window while the participant is On-treatment in the Maintenance Phase (as assigned based on Section 15.4). • 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 Section 15.9
Plasma HIV-1 RNA
• For summaries and analyses which use HIV-1 RNA level as a continuous measure, the logarithm to base 10 of the value will be used. • HIV-1 RNA results may be provided as censored values, such as <40 or >9,999,999 c/mL. For the purposes of summary statistics, such values will be replaced by the next value beyond the limit of detection, e.g., 39 or 10,000,000 c/mL, respectively, for the given examples. Data listings will show the censored values as provided.
Target Detected / Target Not Detected / Super Low Viral Load Testing
• When a measurement of plasma HIV-1 RNA is below the limit of quantification (i.e. 40 c/mL) and is qualitatively observable that will be denoted as a "Target Detected" measure, while HIV-1 RNA below the limit of quantification that is not qualitatively observable that will be denoted as "Target Not Detected". Any measurements <40 c/mL characterised as "Target Not Detected" or "Target Detected" will be captured in the database. • Super low viral load will also be tested by BioMONTR Labs for viral loads below the limit of quantification at some visits (e.g. Week 48).
Confirmed Virologic Failure (CVF)
• The definition of CVF is provided in the Protocol, Section 5.5.4 – Definition of Confirmed Virologic Failure. • In case there are multiple plasma HIV-1 RNA results on the same day, the worst result (i.e. the largest value) will be used in determination of CVF.
Treatment (TRDF) and Efficacy Related (ERDF) Discontinuation = Failure
• The analysis of time to confirmed virologic failure (CVF) or discontinuation due to treatment related reasons (i.e., drug-related AE, intolerability of injections, protocol defined safety stopping criteria, or lack of efficacy) will censor participants who have not met CVF criteria and are ongoing in the study, or who have discontinued for reasons other than those related to treatment. This will be the Treatment Related Discontinuation = Failure (TRDF) data.

- Participants who have not met CVF criteria and are ongoing in the study, or who have discontinued for reasons other than lack of efficacy, will be censored in the analysis of the Efficacy Related Discontinuation = Failure (ERDF) data.
- Proportion of Participants without virologic (ERDF) or tolerability (TRDF) failure will be estimated using the Kaplan-Meier nonparametric method based on the time to ERDF or TRDF. The estimated proportion at time point of interest will be presented by treatment group, along with estimated difference in proportions between treatment groups and its associated two-sided 95% CI. The estimate of the standard error used to derive confidence intervals will be based on Greenwood's formula [Kalbfleisch,1980].
- See Appendix 10: Variables Defined for Time to Event Analysis for additional details.

Summary for Participants per Viral Load Category by Visit

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

HIV-1 Disease progression Stage

- Categories:
  - CDC Stage 1 at Baseline to CDC Stage II;
  - CDC Stage I at Baseline to CDC Stage III;
  - CDC Stage II at Baseline to CDC Stage III;
  - CDC Stage III at Baseline to new CDC Stage III event;
  - CDC Stage I, II, III at Baseline to Death.

Please refer to Protocol (Appendix 4: CDC Classification for HIV-1 Infection) for defining Stage.

- For the purpose of analysis, the CDC at Baseline and at post-baseline during Maintenance Phase will be derived as below:
  - At Baseline, the 'Baseline CDC stage' for each participant was assessed by investigator and recorded in the eCRF. However, for the analysis, Baseline CDC stage will be rederived based Baseline CD4+ values as well as whether any HIV-associated/AIDS-defining conditions present at baseline per the Criteria's thresholds (Appendix 4 in Protocol).
  - To analyse disease progression, the most advanced post-baseline CDC stage within the period of interest (e.g. Maintenance Phase) will be derived based on the occurrences of new AIDs-defining conditions (please refer to Appendix 4 in Protocol for the list of AIDs-defining Conditions) as well as the nadir value of post-baseline CD4+.
    - For example, if a participant with CDC 'Stage I' at Baseline had the lowest Maintenance Phase CD4+ =120 cell/mm^3 without new AIDs-defining conditions, then HIV disease progression for this participant during the Maintenance Phase would be considered as 'CDC stage I at Baseline to CDC stage III'.
    - If a participant with CDC 'Stage II' at Baseline had the lowest Maintenance Phase CD4+ =220 cell/mm3 AND had at least one new AIDs-defining condition, then HIV

disease progression for this participant during the Maintenance Phase would be considered as 'CDC stage II at Baseline to CDC stage III'.
Delay in IP Injection
• For participants on the Q4W arm, IM dosing is expected to occur every 4 weeks from Week 4B onwards for those transitioning from SOC (i.e. those requiring oral lead-in) and from Day 1 onwards for those transitioning from CAB+RPV Q4W in ATLAS (i.e. those not requiring oral lead-in). The Delay in IP injection (days) will be calculated as: Delay in IP Injection (days) = Injection date - date of preceding injection - 28 days • For participants on the Q8W arm, IM dosing is expected to occur at Week 4B and then every 8 weeks from Week 8 onwards for those transitioning from SOC (i.e. those requiring oral lead-in) and every 8 weeks from Day 1 for those transitioning from CAB+RPV Q4W (i.e. those not requiring oral lead-in) in ATLAS. If participants receive reloading dose injection after oral bridging, the next IM dosing is expected to be 4 weeks from the reloading injection and then every 8 weeks onwards. o For participants transitioning from SOC on the Q8W arm, if the preceding injection occurs at Week 4B, the Delay in IP injection (days) will be calculated as: Delay in IP Injection (days) = Date of Week 8 injection - date of Week 4B injection - 28 days o For participants receiving oral bridging medication and then returning to LA injections, if the preceding injection occurs at a reloading dose visit, the Delay in IP injection (days) will be calculated as: Delay in IP Injection (days) = Injection date - date of preceding injection - 28 days o For participants transitioning from SOC on the Q8W arm, if the preceding injection occurs at a visit later than Week 4B or at non-reloading visit, the Delay in IP injection (days) will be calculated as: Delay in IP Injection (days) = Injection date - date of preceding injection - 56 days o For participants transitioning from CAB+RPV Q4W in ATLAS on the Q8W arm, if the preceding injection occurs at non-reloading visit, the Delay in IP injection (days) will be calculated as: Delay in IP Injection (days) = Injection date - date of preceding injection - 56 days • If the preceding study treatment is oral (e.g. CAB+RPV or SOC oral bridging), the Delay in IP injection (days) will be calculated as: o Delay in IP Injection (days) = Injection date – date of last oral dose on/prior to the injection date • Delay in IP injection will be grouped into: ≤1, 2-3, 4-7, >7 days. • The proportion of participants with HIV-1 RNA ≥50 c/mL at Week 48 (Snapshot) will be summarized by last delay in IP Injection. The last delay in IP injection will be the delay in IP injection at Week 48, or the delay in last IP injection prior to Week 48 if a participant did not receive Week 48 injection (i.e. missing visit or withdrawal). The similar analysis will be done for Week 96 and Week 152 timepoints where the proportion of participants with HIV-1 RNA ≥50 c/mL at Weeks 96 and 152 (Snapshot) and the delay in IP injection at Weeks 96 and 152 are considered respectively.

15.6.4. Safety

Adverse Events

DAIDS Grading

- Clinical adverse events will be graded based on the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.1, March 2017, as specified in the protocol Appendix 11.2.

Potential QTc Interval Prolonging Events of Interest

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

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

Laboratory Parameters

- If a laboratory value which is expected to have a numeric value for summary purposes, has a non-detectable level reported in the database, where the numeric value is missing, but typically a character value starting with '<x' or '>x' (or indicated as less than x or greater than x in the comment field) is present, the number of significant digits in the observed values will be used to

Laboratory Parameters

determine how much to add or subtract in order to impute the corresponding numeric value. If a character value starting with "<=x", then the numeric value will be x.

- Example 1: 2 Significant Digits = '< x ' becomes x – 0.01
- Example 2: 1 Significant Digit = '> x' or '>=x' becomes x + 0.1
- Example 3: 0 Significant Digits = '< x' becomes x – 1

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

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

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

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

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

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

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

Lab Toxicities – DAIDS Grading based on Version 2.1, March 2017, as specified in the protocol of Appendix 11.2.

- Toxicities will be based on the Division of AIDS (DAIDS) grading system, Version 2.1, March 2.17, as specified in the protocol of Appendix 11.2
- Toxicity grades provided by the central laboratory do not distinguish between abnormally high or low criteria, when both are relevant for a parameter.
- When summarising toxicity grades for such parameters, they will be categorised as to whether they are above or below the midpoint of normal range.

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

National Cholesterol Education Program (NCEP) Lipid Categories

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

Laboratory Parameters

Parameter	Value Range (mmol/L)	Value Range (mg/dL)	Category
Triglycerides	<1.70	<150	Normal
	1.70 to <2.26	150 to <200	Borderline High
	2.26 to <5.65	200 to <500	High
	≥5.65	≥500	Very High
Total Cholesterol	<5.18	<200	Desirable
	5.18 to <6.21	200 to <240	Borderline High
	≥6.21	≥240	High
HDL Cholesterol	<1.04	<40	Low
	1.04 to <1.56	40 to <60	Normal
	≥1.56	≥60	High
LDL Cholesterol	<2.59	<100	Optimal
	2.59 to <3.37	100 to <130	Near/Above Optimal
	3.37 to <4.14	130 to <160	Borderline High
	4.14 to <4.92	160 to <190	High
	≥4.92	≥190	Very High

Percentage change for lipids

The percentage change from baseline is calculated as:

$$\% \text{ change from baseline} = \frac{\text{value at Week 48 or 96} - \text{baseline value}}{\text{baseline value}} \times 100\%$$

Total Cholesterol / HDL Cholesterol Ratio

- When both total cholesterol and HDL cholesterol results are available from the same date for a participant, then the ratio will be calculated by dividing the total cholesterol result by the HDL cholesterol result. The ratio can be classified as follows:

Parameter	Value Range
Total Cholesterol / HDL Ratio	< 3.5
	3.5 to < 4.4
	4.4 to < 5
	≥ 5

Other Safety Endpoints

Corrected QT (QTc)

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

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

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

where uncorrected QT interval is also measured in msec.

Other Safety Endpoints

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

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

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 Maintenance Phase:
  - Exposure to oral 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 maintenance phase (up to but not including injections administered at Week 100)
  - Exposure to SOC oral bridging: Duration of the SOC ART medication taken as oral bridging during the Maintenance Phase. If the SOC oral bridging is taken in different periods during the Maintenance Phase, the duration will be calculated by the sum of the non-overlapped periods.
  - Exposure to CAB+RPV oral bridging: Duration of the CAB+RPV taken as oral bridging during the Maintenance Phase. If the CAB+RPV oral bridging is taken in different periods during the Maintenance Phase, the duration will be calculated by the sum of the non-overlapped periods.
  - Overall exposure to study treatment:
    For participants on Q4W arm: min [Date of Latest Maintenance Phase Visit up to and including Week 100, max (Date of Last Injection + 35, 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
    For participants on Q8W arm: min [Date of Latest Maintenance Phase Visit up to and including Week 100, 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

- For Maintenance + Extension Phase
  - Exposure to CAB LA + RPV LA = Number of IP injection visits received during Maintenance Phase and Extension Phase
  - Exposure to SOC or CAB+RPV oral bridging during the Maintenance and Extension Phase will be calculated similarly to that during the Maintenance Phase except that the exposure includes both Maintenance and Extension Phase.
  - Overall exposure to study treatment:

Other Safety Endpoints

For participants on Q4W arm: min [Date of Latest Maintenance/Extension Phase Visit, max (Date of Last Injection + 35, 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

For participants on Q8W arm: min [Date of Latest Maintenance/Extension Phase Visit, 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

- For Thigh Injection Phase
  - Exposure to CAB LA + RPV LA = Number of IP injection visits received during Thigh Injection Phase. Note that the planned Sub-study Week 16 injections belong to Return to Gluteal Injection Phase.
  - The SOC or CAB+RPV oral bridging are not allowed in this phase.
  - Overall exposure to IP:

    For participants on Q4W arm: min [Date of Latest Thigh Injection Phase Visit up to the Nominal Sub-study Week 16 Visit Date, max (Date of Last Injection + 35, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – Date of First Thigh Injection) + 1

    For participants on Q8W arm: min [Date of Latest Thigh Injection Phase Visit up to the Nominal Sub-study Week 16 Visit Date, max (Date of Last Injection + 63, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – Date of First Thigh Injection + 1

    Note that the Nominal Sub-study Week 16 visit date is defined in Section 15.6.1.
  - Overall exposure to IP = Overall exposure to Study Treatment.
- For Thigh Injection + Return to Gluteal Injection Phase
  - Exposure to CAB LA + RPV LA = Number of IP injection visits received during Thigh Injection or Return to Gluteal Injection Phase. Note that the injections received on the date of Sub-study Week 24 visit belong to the Extension Phase in main study.
  - The SOC or CAB+RPV oral bridging are not allowed in these two phases.
  - Overall exposure to IP:

    For participants on Q4W arm: min [End of Sub-study Date, max (Date of Last Injection + 35, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – Date of First Thigh Injection) + 1

    For participants on Q8W arm: min [End of Sub-study Date, max (Date of Last Injection + 63, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – Date of First Thigh Injection + 1

    Note that the End of Sub-study Date is defined in Section 15.6.1.
  - Overall exposure to IP = Overall exposure to Study Treatment.

- Last Injection and/or Last Dose of Oral CAB+RPV and/or Last Dose of SOC Oral Bridging are only applicable to those who permanently discontinued study treatment.

Other Safety Endpoints

- Duration of dosing in participant years will be calculated as the sum of participant duration of dosing in days (across all participants)/365.25
- Participants who were randomized but did not report an IP start date will be categorised as having zero days of exposure.

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 analysis are those after first injection. For participants requiring the oral CAB+RPV lead-in, the first injection is planned to be taken at Week 4B. For participants not requiring the oral CAB+RPV lead-in, the first injection is planned to be taken at Baseline/Day 1. For participants receiving the oral bridging and then returning to injections, if the first injection upon return is a reloading dose injection, the immediate next injection visit is planned to be four weeks after the reloading injection visit. If a participant has multiple oral bridging episodes, he or she may have more than one reloading dose injection visits during the study. 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 for summary are listed below:

< -14 days
-14 to - 8 days
-7 to - 4 days
-3 to -2 days
-1 day
0 day
1 day
2 to 3 days
4 to 7 days
8 to 14 days
>14 days
Missed Reloading Injection (Non-COVID-19)
Missed Reloading Injection (COVID-19)
Missed Injection w/o OB (Non-COVID-19)
Missed Injection w/o OB (COVID-19)
Missed Injection with CAB+RPV OB (Non-COVID-19)
Missed Injection with CAB+RPV OB (COVID-19)

Other Safety Endpoints
Missed Injection with SOC OB (COVID-19)
Columbia Suicide Severity Rating Scale (C-SSRS)
• Missing data will not have any imputation performed (Nilsson, 2013).

15.6.5. Pharmacokinetic

This document is intended for planning analysis of PK concentration data and PK parameters only. Population pharmacokinetics and identification of important determinants of variability will be described in a separate document.

Pharmacokinetic Analyses

Plasma CAB and RPV Concentration-time Data

Plasma samples for determination of CAB and RPV concentration will be collected throughout the Maintenance Phase, at Week 152 and at the withdrawal visit in the main study, and up to Week 17 in the sub-study. Additional samples will be collected for storage during the Long-Term Follow-Up Phase and for female participants who become pregnant during the study.

In rare occasions, PK samples are collected post-dose on the same day as the study treatment administration during the main study. The data from these PK samples will be excluded from the pre-dose and/or 1-week post-dose summaries in the main study. If time was not collected for the oral study treatment, the PK sample collected on the same day as the oral study treatment is assumed to be taken prior to the oral dose unless medical monitor or data querying informs otherwise.

PK data collected for liver event will be listed but will not be included in the summaries or figures.

Plasma CAB and RPV PK Parameters

The following PK parameters will be determined from the sub-study concentration-time data for each treatment, analyte and dosing interval, as data permit: maximum concentration (Cmax), time to Cmax (tmax), area under the plasma concentration-time curve through the end of the dosing interval (AUC(0-tau)). These PK parameters will be calculated by standard non-compartmental analysis according to current working practices and using Phoenix WinNonlin 8.3. All calculations of non-compartmental parameters will be based on actual sampling times. Derivation of PK parameters will be performed by, or under the direct auspices of, Clinical Pharmacology Modelling and Simulation (CPMS), GlaxoSmithKline.

In addition, the concentration at the end of a dosing interval (Ctau) will be obtained from the evaluable pre-dose (trough) concentration collected at start of the subsequent interval. For example, the Ctau for last thigh injection interval will be obtained from the evaluable pre-dose PK concentration collected at the Sub-study Week 16 visit.

Treatment Arm	Dosing Interval in Sub-study		
	Gluteal Injection	First Thigh Injection	Last Thigh Injection
Q8W	Week -8 to Day 1	Day 1 to Week 8	Week 8 to Week 16
Q4W	Week -4 to Day 1	Day 1 to Week 4	Week 12 to Week 16

Evaluable Concentration

Pharmacokinetic Analyses

PK concentration will be summarized in two ways: 'all data' without regard to timing relative to scheduled time and 'evaluable data'.

The 'evaluable data' are from the samples that met sample collection window criteria. Sampling windows are set relative to the previous dose as follows:

- 20-28 hrs after last oral dose taken and properly administered last 3 oral doses for pre-dose sample at Week 4B for participants requiring oral lead-in
- ± 4 days for pre-dose sample at visits other than Week 4B, and for pre-dose samples at Week 4B for participants not requiring oral lead-in (e.g. participants transitioning from ATLAS Q4W and remain on Q4W arm in this study)
- 3-10 days post last injection for 1-week post injection visits
- 21-35 days post last injection for 4-week post-dose samples (e.g. collected at sub-study Week -4, Week 4 and Week 12 visits). Note that 4-week post-dose samples will be collected from subjects on Q8W arm only.
- 1-3 hours post last injection for 2-hour post-dose samples
- Samples impacted by dosing errors (wrong dose) or oral bridging will also be excluded

Timepoint	Evaluable Window	For Programming:
Pre-dose: WK4B for participants requiring oral lead-in	20-28 hrs after last oral dose taken and the last 3 oral doses administered properly	20 hrs ≤ Time since Last Oral Dose ≤ 28 hrs and the last 3 oral doses administered on the three consecutive days prior to WK4B.
Pre-dose at other visits, Pre-dose WK4B for participants not requiring oral lead-in	± 4 days	For Q4W arm, Day 1 pre-dose, Week 8 for those transitioning from SOC (i.e. requiring oral lead-in), and the immediate next visit after reloading on Q8W arm: 24 days ≤ Days Since Last Injection ≤ 32 days For visits other than above on Q8W arm: 52 days ≤ Days Since Last Injection ≤ 60 days
1-WK-Post:	3-10 days post last injection	3 days ≤ Days Since Last Injection ≤ 10 days
4-WK-Post:	21-35 days post last injection	21 days ≤ Days Since Last Injection ≤ 35 days
2-HR-Post:	1-3 hours post last injection	1 hr ≤ Time since Last Oral Dose ≤ 3 hrs

Relative Time is calculated relative to the date and time of last dose. For example, if the time of the last dose (e.g. oral lead-in/oral bridging) is missing, then the relative time for PK sample will be set to missing and the sample will not be considered 'evaluable'.

Pharmacokinetic Analyses

If a pre-dose sample is collected on the same day as the first dose of oral bridging, the time of the first dose (not recorded in eCRF) is assumed to be 'after' the collection of pre-dose sample, unless medical monitor or Data querying informs otherwise.

The time-deviation (hours) from the targeted timepoint will be calculated for the post-dose samples using the following formula:

Time_deviation (hrs) for '2-Hour POST' = Sample date.time - last injection date.time - 2 hours

Time_deviation (hrs) for '1-Week POST' = Sample date.time - last injection date.time - 7*24 hours

Time_deviation (hrs) for '4-Week POST' = Sample date.time - last injection date.time - 28*24 hours

The following windows are for defining 'evaluable' Long-term Follow-up phase PK concentrations.

Timepoint	Evaluable Window	For Programming:
LTFU MONTH 1/WD	± 4 days	24 days ≤ Days Since Last Injection ≤ 32 days
LTFU MONTH 3	± 1 Weeks	77 days ≤ Days Since Last Injection ≤ 91 days
LTFU MONTH 6	± 2 Weeks	154 days ≤ Days Since Last Injection ≤ 182 days
LTFU MONTH 9	± 2 Weeks	238 days ≤ Days Since Last Injection ≤ 266 days
LTFU MONTH 12	± 2 Weeks	322 days ≤ Days Since Last Injection ≤ 350 days

15.6.6. Health Outcomes

HIVTSQs

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

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

Total Treatment Satisfaction Score

- Total Treatment Satisfaction Score is computed with items 1-11. Items 1-11 are summed to produce a score with a possible range of 0 to 66.
- Item 12 will not be included in Total Treatment Satisfaction Score. Instead, it will be treated as a stand-alone item only.
- Higher scores represent greater treatment satisfaction as compared to the past few weeks.
- A maximum of 5 items can be missing, which can be imputed to reflect the mean of the completed item scores. If 6 or more items are missing, then the treatment satisfaction scale score should not be computed and instead be imputed using LOCF.

Individual Item Scores

- Items are rated as 6 CCI to 0 CCI
- Higher scores represent greater satisfaction with each aspect of treatment
  - For individual item scores outputs, missing scores will not be computed (according to Page 7 of the [HIVTSQ User Guidelines, 2016]) and instead be imputed using LOCF.

HIVTSQc

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

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Total Treatment Satisfaction Score (change)

- Total Treatment Satisfaction Score is computed with items 1-11. Items 1-11 are summed to produce a score with a possible range of -33 to 33
- Item 12 will be computed as an individual item only.
- The higher the score, the greater the improvement in satisfaction with treatment; the lower the score, the greater the deterioration in satisfaction with treatment. A score of CCI
- A maximum of 5 items can be missing, the missing scores will be imputed with the mean of the completed item scores. If 6 or more items are missing, then the overall treatment satisfaction scale score should not be computed and will remain missing.

Individual Treatment Satisfaction Change Item Scores

- Items are rated as +3 CCI to -3 CCI
- The higher the score, the greater the improvement in satisfaction with each aspect of treatment and the lower the score, the greater the deterioration in satisfaction with each aspect of treatment.

Questionnaire Version

- In main study, three versions of the HIVTSQc questionnaire are available with the questions the same and only the overhead text is different.
  - Q4W ATLAS to Q4W ATLAS-2M: for participants who randomized to Q4W arm in ATLAS and then randomized to Q4W arm in ATLAS-2M
  - Q4W ATLAS to Q8W ATLAS-2M: for participants who randomized to Q4W arm in ATLAS and then randomized to Q8W arm in ATLAS-2M
  - SOC to Q4W or Q8W ATLAS-2M: for participants who either were randomized to SOC arm in ATLAS or did not participate in ATLAS
- If a participant takes a wrong version of the questionnaire in main study, the data collected from the wrong version will be considered invalid and will not be included in the summary.
- In sub-study, all participants will take the same version of the questionnaire.

PIN

Questionnaire (Each question is scored 1-5)

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Dimension Score (Chevat, 2008)

- Domains and Clusters
  - CCI
  - CCI
  - CCI
  - CCI
- 5 items not included in any of these domains and maintained as individual items (items CCI
- No overall score is calculated per the guidance
- The score of a domain is calculated as the mean of all items with the domain. Higher scores represent worse perception of injection.
- A maximum of <50% items can be missing within a domain, which can be imputed to reflect the mean of the completed item scores within the domain. Thus, if the number of missing items is ≥3 CCI), ≥2 CCI), ≥1 CCI , then the total score for the domain should not be computed and instead be imputed using LOCF (Section 15.7.2.2)

Individual Item Scores

- Items are rated on a 5-point scale, ranging from 1 CCI , etc.) to 5 (CCI

CCI [redacted] etc.).

- Lower scores represent worse perception of injection
- For individual item scores outputs, missing scores will not be computed and instead be imputed using LOCF (Section 15.7.2.2).

HAT-QoL (Holmes, 1999)

Questionnaire (Questions 1-14 are scored 1 to 5)

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

[redacted]

Life satisfaction, HIV medications, disclosure worries

- The ratings for Items (a, b, c, d, e) will be recoded as below for analysis:

  Response option Life Satisfaction Medication/disclosure worries

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

  [redacted]

- A maximum of 50% question items can be missing within a domain, which can be computed and replaced with the mean of the completed item scores within the domain. Thus, if there are more than 1 item missing for Life Satisfaction, and more than 2 items missing for

Medication/disclosure worries, then the total score for the domain should not be computed and instead be imputed using LOCF (Section 15.7.2.2). A computed score for missing value will be added to calculate a total score for the domain. Total score for each of the three domains will be calculated and will be denoted as 'LISAT' for life satisfaction, 'MEDWO' for medication worries, and 'DISWO' for disclosure worries.

- Transform each dimension's total imputed value score to the 0-100 scale using the following formulae:

  Life satisfaction: LISAT100=(100/(20-4))*(LISAT-4)

  Medication worries: MEDWO100=(100/(25-5))*(MEDWO-5)

  Disclosure worries: DISWO100=(100/(25-5))*(DISWO-5)

  The higher the score, the greater satisfaction to life and the less worry. The transformed dimension score for each domain will be summarized and analysed.

Individual Item Scores

- For individual item scores outputs, missing scores will not be computed and instead be imputed using LOCF (Section 15.7.2.2).

ACCEPT (Acceptance/General Dimension) (Gilet, 2014)

Questionnaire (Questions 1-3 constitute to Acceptance/General Dimension)

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

- Proportion of participants with individual item scores will be calculated.

Individual Item Scores

- Items are rated as 1 CCI) to 4 (CCI . and '5' with CCI
- Acceptance/General dimension score is calculated only if at least 2 items in the dimension are completed
- Items will be recoded to score as follows:

Rating	Recode
1. Totally disagree/Not at all acceptable/ Not at all convinced:	1
2. Somewhat disagree/Not very acceptable/ Not really convinced:	1
3. Somewhat agree/ Somewhat acceptable/ Somewhat convinced:	2
4. Totally agree/ Totally acceptable/ Totally convinced:	3
5. I don't know:	1

- The total score of the dimension is calculated as the mean of the recoded items of the dimension and then linearly transformed to be on a scale from 0 to 100: score, as below:

  Total Score = (mean of the recoded items in the dimension - 1)/2 *100

- For individual item scores outputs, missing scores will not be computed and instead be imputed

using LOCF (Section 15.7.2.2).

Preference

Questionnaire

1. Based on your experience which HIV treatment do you prefer?

□ Injectable Long-Acting HIV Treatment every 4 weeks
□ Injectable Long-Acting HIV Treatment every 8 weeks (only select this answer if you received the 8-week injectable regimen of CAB LA + RPV LA during study)
□ Oral daily HIV Treatment
□ No preference

If you selected no preference, skip questions 2 and 3.
If you selected any other response, please continue and complete all questions.

2. What is the main practical attribute of this HIV therapy supporting your preference?

□ Mode of administration
□ Frequency of administration
□ Time required for administration
□ Scheduling visits
□ Storing medications
□ Impact of side effects
□ Other, please specify

3. What is the main benefit related to this HIV therapy supporting your preference?

□ More convenient, easier to integrate into one's daily life
□ Less stressful
□ Less stigma
□ Easier to take the drug exactly as prescribed
□ More efficacious
□ Other, please specify

Questionnaire Version

- Two versions of questionnaire are available. The questions in each version of the questionnaire are the same and only the overhead text is different.
  - ATLAS (from Q4W ATLAS): for participants randomized to Q4W arm in ATLAS.
  - ATLAS-2M (from SOC ATLAS or out): for participants who either were randomized to SOC arm in ATLAS or did not participate in ATLAS.

Data Handling

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

Reasons for Oral Bridging and Preference

Questionnaire

This questionnaire will be administered to participants receiving oral bridging during the Maintenance and/or Extension phase. It includes three questions regarding contact mode, main reasons for switch back to daily oral HIV medication and the HIV treatment preference. For the preference question, it asks participants to provide the statements supporting their preference. The details can be found in the eCRF.

Data Handling

• Any missing values will remain missing (i.e. no imputation).
Preference Thigh Injection vs Gluteal Injection
Questionnaire
This questionnaire will be administered to sub-study participants. It includes two questions regarding injection site preference and contact mode. For the preference question, it asks participants to provide the statements supporting their preference. The details can be found in the eCRF.
Data Handling
• Any missing values will remain missing (i.e. no imputation).
Tolerability of Injection (NRS)
Questionnaire
• This questionnaire will be administered to sub-study participants. It includes two questions regarding the maximum level of pain experienced with the most recent injections and contact mode. The score for the maximum level of pain ranges from no pain (0) to extreme pain (10).
Data Handling
• Any missing values will remain missing (i.e. no imputation).
Reasons for Continuation/Switch
Questionnaires
• Reasons for Continuation questionnaire is collected for participants who were randomized to Q4W arm in ATLAS. • Reason for Switch questionnaire is collected for participants who either were randomized to SOC arm in ATLAS or did not participate in ATLAS.
Data Handling
• If a participant takes a wrong questionnaire, for example, the participant randomized to SOC arm in ATLAS took Reasons for Continuation questionnaire, the data collected from this wrong version will be considered invalid and will not be included in the summary. • If the questionnaire is taken beyond ± 2 weeks window from maintenance phase treatment start date (i.e. Study Day < -14 or Study Day > 14) will be consider not evaluable and will not be included in the summary. • Any missing values will remain missing (i.e. no imputation).

15.6.7. 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 CAB, BIC, RAL, EVG or DTG:

Amino Acids in HIV Integrase for Analysis	H51Y, **T66A/I/K**, **E92Q/V**/G, Q95K, T97A, **G118R**, **F121C/Y**, E138A/K/T, G140A/C/**R**/S**, **Y143C/H/R/K/S/G/A**, **P145S, Q146P, S147G, Q148H/K/R/**N, **V151**A/**L**, S153F/Y, **N155H**/S/T, E157Q, G163R/K, S230R, R263K, L68V/I*, L74I/M*, E138D*, V151I*, G193E*

NOTES:

- Draft listing; may be modified in case of additional substantive data availability.
- INI mutations listed taken from Stanford HIV Resistance Database (http://hivdb.stanford.edu/DR/cgi-bin/rules_scores_hivdb.cgi?class=INI cited 22Feb2021) and accessed on 28Mar2022.
- INI substitutions listed above in bold had a score of =60.

* Denotes additional INI mutations added as they were identified during in vitro passage of DTG or seen in a previous DTG study in INI-experienced participants (ING112574).

**G140R is potentially associated with CAB based on in-stream data monitoring of CVF participants.

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

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

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

- The pre-specified INSTI Mutations are identified as below:
  - Per 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

- 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
- Mutations per FDA request for Study 201584: Q146L, T124A

- The NNRTI resistance associated mutations (RAMs) are identified per IAS-USA NNRTI mutations (IAS-USA 2019 resistance mutations update volume 27 issue 3, 2019):
  - V90I, A98G, L100I, K101E/H/P, K103N/S, V106A/I/M/T, V108I, E138A/G/K/Q/R, V179D/F/L/T, Y181C/I/V, Y188C/H/L, G190A/E/S, H221Y, P225H, F227C/L/R, M230I/L, L234I
- The RPV RAMs are identified per IAS-USA NNRTI mutations (IAS-USA 2019 resistance mutations update volume 27 issue 3, 2019):
  - L100I, K101E/P, E138A/G/K/Q/R, V179L, Y181C/I/V, Y188L, H221Y, F227C, M230I/L

Phenotype

Phenotypic Susceptibility

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

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

Replication capacity is generated as part of standard phenotypic assays.

PhenoSense Algorithm

Drug	Abbreviation	Class	PhenoSense cutoff
Abacavir	ABC	NRTI	(4.5 – 6.5)[a]
Lamivudine	3TC	NRTI	3.5 [a]
Didanosine	ddI	NRTI	(1.3 – 2.2) [a]
Stavudine	d4T	NRTI	1.7 [a]
Zidovudine	AZT (ZDV)	NRTI	1.9
Emtricitabine	FTC	NRTI	3.5
Tenofovir	TDF (TAF)	NRTI	(1.4 – 4) [a]
Delavirdine	DLV	NNRTI	6.2
Efavirenz	EFV	NNRTI	3
Nevirapine	NVP	NNRTI	4.5
Etravirine	ETR	NNRTI	(2.9-10) [a]
Rilpivirine	RPV	NNRTI	2.0
Doravirine	DOR	NNRTI	3
Fosamprenavir/r	FPV/r	PI	(4-11) [a]
Atazanavir	ATV	PI	2.2[a]
Atazanavir/r	ATV/r	PI	5.2 [a]
Indinavir/r	IDV/r	PI	10 [a]
Lopinavir/r	LPV/r	PI	(9 – 55) [a]
Nelfinavir	NFV	PI	3.6

Saquinavir/r	SQV/r	PI	(2.3 – 12) [a]
Tipranavir/r	TPV/r	PI	(2 – 8) [a]
Darunavir/r	DRV/r	PI	(10 – 90) [a]
Ritonavir	RTV	PI	2.5
Enfuvirtide	T20	FI	6.48
Cabotegravir	CAB	INI	2.5
Raltegravir	RAL	INI	1.5
Elvitegravir	EVG	INI	2.5
Dolutegravir	DTG	INI	(4-13) [a]
Bictegravir	BIC	INI	(2.5- 10)

a. clinical cutoff (lower cutoff – higher cutoff).

Phenotypic Susceptibility

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

Full Sensitivity

Fold Change	Interpretation
> clinical lower cutoff or biological cutoff	resistant
≤ clinical lower cutoff or biological cutoff	sensitive

Partial Sensitivity

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

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

Genotypic and Net Assessment Susceptibility

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

15.7. Appendix 7: Reporting Standards for Missing Data

15.7.1. Premature Withdrawals

Element	Reporting Detail
General	● Participant study completion (i.e. as specified in the protocol) was defined as ○ Randomly assigned to either treatment group, completed the randomized Maintenance Phase including Week 100 and did not enter the Extension Phase; ○ Randomly assigned to either treatment group, completed the randomized Maintenance Phase including Week 100, and entered and completed the Extension Phase (defined as remaining on study until commercial supplies of CAB LA + RPV LA Q4W or Q8W regimen become locally available or development of CAB LA + RPV LA is terminated). Participants who withdraw from CAB LA + RPV LA and go into the LTFU Phase, and participants who withdraw from oral lead-in will be considered to have prematurely withdrawn from the study treatment. In addition to the 52-week Follow-Up phase required for participants who receive one or more injections with CAB LA or RPV LA, an in-clinic Follow-Up visit will be conducted approximately 4 weeks after the last dose of study medication for participants who withdraw during the oral lead-in period with ongoing AEs, and serious adverse events (SAEs) and also any laboratory abnormalities that are considered to be AEs or potentially harmful to the participant, at the last on-study visit. Assessments at the Follow-up visit should reflect any ongoing complaints (e.g., blood draws to follow a laboratory abnormality). Follow-Up visits are not required for successful completion of the study. ● Withdrawn participants 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 as per **Error! Not a valid result for table.**: Assessment Windows or will be summarised as withdrawal visits.

15.7.2. Handling of Missing Data

Element	Reporting Detail
General	● Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: ○ These data will be indicated by the use of a “blank” in 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.

15.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in participant listing displays.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment State. ○ Missing Stop Day: Last day of the month will be used, unless this is after the last contact date; in this case the last contact date will be used. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.
ART/Non-ART Medications or Medical History	• 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 eCRF as prior (e.g. recorded in prior ART or prior ATLAS ART forms), the earlier date of the imputed and the day prior to the maintenance phase treatment start date will be used, i.e. min (imputed stop date, maintenance phase treatment start date - 1). • For medications with completely missing start date, they will be considered started prior to the maintenance phase treatment start date. • For medications with completely missing stop date, they will be considered ongoing unless recorded in eCRF as prior (e.g. recorded in prior ART or prior ATLAS ART forms). • 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.
Health outcomes	• For the health outcomes questionnaire data, please refer to Section 12. • For the summary of individual item scores outputs, missing scores will not be computed.

15.7.2.2. Handling of Missing data for Statistical Analysis

Element	Reporting Detail
Snapshot	• In the Snapshot dataset, participants 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 RNA < 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 c/mL' (or ''HIV-1 RNA ≥ 200 c/mL') or 'No Virologic Data at Week X'; Appendix 9: Snapshot Algorithm Details for full details
LOCF	• In the LOCF dataset, missing values will be carried forward from the previous, non-missing available on-treatment assessment. If the baseline value is missing any missing values until the first non-missing value will remain missing.
Lipid LOCF	**Baseline for Lipids LOCF Analyses in main study**: • Last evaluable lipids assessment up to and including the start of IP, where 'evaluable' is defined as: Lipid-modifying agents not taken within 12 weeks of the date of assessment and Lipids are collected in a fasting state. **During the Maintenance or Extension Phase**: • If participants initiate serum lipid-modifying agents during the Maintenance or Extension Phase, then the last available fasted on-treatment lipid values prior to the initiation will be used in place of future, observed on-treatment values. • Imputation at planned visits will continue even if the participant discontinues the lipid-modifying agent. Missing assessments will not be imputed if there is no last available fasting on-treatment lipid value prior to the initiation of serum lipid-modifying agent. • If participants take lipid modifying agents within 12 weeks prior to the start of the study treatment, all the post-baseline values will be missing. **Baseline for Lipids LOCF Analyses in sub-study**: • Last evaluable lipids assessment up to and including the start of thigh injection, where 'evaluable' is defined as: Lipid-modifying agents not taken within 12 weeks of the date of assessment and Lipids are collected in a fasting state. **During the Thigh Injection or Return to Gluteal Injection Phase**: • If participants initiate serum lipid-modifying agents during the Thigh injection or Return to Gluteal Injection Phase, then the last available fasted on-treatment lipid values prior to the initiation will be used in place of future, observed on-treatment values in sub-study. • Imputation at planned visits will continue even if the participant discontinues the lipid-modifying agent. Missing assessments will not be imputed if there is no last available fasting on-treatment lipid value prior to the initiation of serum lipid-modifying agent. • If participants take lipid modifying agents within 12 weeks prior to the start of the thigh injection, all the post-baseline values in sub-study will be missing. **Analyses Evaluated with Lipid LOCF Dataset:**

Element	Reporting Detail
	Week 48 analysis: This dataset will be used to summarize fasting lipids parameters in the following displays: Summary of Fasting TC/HDL ratio Change from Baseline Summary of Fasting Lipids Percentage Changes from Baseline Summary of Chemistry Changes from Baseline Summary of Chemistry Values All other displays of lipids (e.g. toxicity tables and NCEP tables) will use observed fasting data, without LOCF imputation. Post-Week 48 analysis: Lipid LOCF dataset will be used for all lipid analysis except for the Summary of Maximum Post-Baseline Emergent Chemistry Toxicities.

15.8. Appendix 8: Values of Potential Clinical Importance

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

15.9. Appendix 9: Snapshot Algorithm Details

Detailed Algorithm Steps

- Consider an analysis visit window for Week X as defined in Table 10 and Table 13.
- The HIV-1 RNA threshold of 50, 200 c/mL will be analysed, respectively, 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 'Week 48' and HIV-1 RNA threshold of '50 c/mL' are used for the purpose of illustration. A participant's Snapshot response and reason at Week 48 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
         Change in background therapy*
     COVID-19 related
         Discontinued for lack of efficacy
         Discontinued for other reason while not below 50
         Change in background therapy*

o  No Virologic Data at Week 48 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
```

* Note: since permanent change in ART are not permitted in this protocol, all such participants who permanently change ART will be considered 'HIV-1 RNA ≥ 50 c/mL' if the permanent change in ART is made prior to an analysis timepoint. Participants with protocol permitted temporary oral bridging treatment (CAB+RPV or SOC, the SOC oral bridging medication is permitted during COVID-19 pandemic due to the unavailability of the CAB/RPV IM injections and oral CAB+RPV) or a temporary change in ART by mistake prior to an analysis timepoint (e.g. participant took the ART different from study treatment during oral lead-in by mistake for a short period and then went back to the study treatment) will not be considered 'HIV-1 RNA ≥ 50 c/mL' due to 'change in ART'.

- The steps in determining response and reasons are indicated in 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 Per Snapshot algorithm (i.e. please exclude these scenarios from **Condition** 1-4).

- Dose reduction, dropping a component, or change in formulation (e.g. 'Tivicay + Kivexa' to 'Triumeq' with the identical ingredients)
- Protocol permitted temporary oral bridging, or temporary change in ART by mistake

Condition ('Week 48' indicates Week 48 window)	**Response**	**Reasons**
1. If non-permitted change in background therapy prior to Week 48		
1.1. If the change in background therapy is not due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (non-COVID-19 related)
1.2. If the change in background therapy is due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (COVID-19 related)
2. If permitted change[a] in background therapy prior to Week 48 AND the latest on-treatment VL prior to/on the date of change is ≥ 50 c/mL (NA to this study)		
2.1 If the change in background therapy is not due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (Non-COVID-19 related)
2.2 If the change in background therapy is due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (COVID-19 related)
3. If non-permitted change in background therapy during Week 48		
• Last on-treatment VL during Week 48 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 Week 48 prior to/on the date of change < 50 c/mL	HIV-1 RNA < 50	
• No VL during Week 48 prior to/on the date of change and the change in background therapy is not due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (Non-COVID-19 related)

• No VL during Week 48 prior to/on the date of change and the change in background therapy is due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (COVID-19 related)
4. If permitted change[a] in background therapy during Week 48 AND the last on-treatment VL prior to/on the date of change is ≥ 50 c/mL (NA to this study)		
4.1 This last on-treatment VL occurs prior to Week 48		
4.1.1 The change in background therapy is not due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (Non-COVID-19 related)
4.1.2 The change in background therapy is due to COVID-19	HIV-1 RNA ≥ 50	Change in background therapy (COVID-19 related)
4. 2 This last on-treatment VL occurs during Week 48 but prior to/on the date of change	HIV-1 RNA ≥ 50	Data in window not below 50
5. If none of the above conditions met		
5.1 On-treatment VL available during Week 48		
• Last on-treatment VL during Week 48 ≥ 50 c/mL	HIV-1 RNA ≥ 50	Data in window not below 50
• Last on-treatment VL during Week 48 < 50 c/mL	HIV-1 RNA < 50	
5.2 No on-treatment VL during Week 48		
5.2.1 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: Q8W arm: Min[max(Date of last injection + 63, Date of Last Dose of Oral Study Treatment (CAB+RPV, SOC Bridging + 1), Withdrawal Date, LTFU ART Start Date] Q4W arm: Min[max(Date of last injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV, SOC Bridging) + 1), Withdrawal Date, LTFU ART Start Date] , where 'Withdrawal Date' refers to the date the participant failed to complete or completed per study conclusion form.		

5.2.1.1 If no on-treatment VL during Week 48 is not due to COVID-19	No virologic data at Week 48 Window	On study but missing data in window (Non-COVID-19 related)
5.2.1.2 If no on-treatment VL during Week 48 is due to COVID-19	No virologic data at Week 48 Window	On study but missing data in window (COVID-19 related)
5.2.2 If participants withdraw[b] before/during Week 48 due to		
5.2.2.1 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 Week 48 Window	Disc due to AE/death (Non-COVID-19 related)
5.2.2.2 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 Week 48 Window	Disc due to AE/death (COVID-19 related)
5.2.2.3 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 Conclusion Form)		
• Last on-treatment VL <50 c/mL OR no on-treatment VL available during study	No virologic Data at Week 48 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)
5.2.2.4 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 Week 48 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

b. Including participants who either prematurely withdraw or complete the study per study conclusion form. In this study, participants who completed the Maintenance phase and decided not to enter the Extension phase without the reason beyond the completion of the study commitment are considered completers per study conclusion form.

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

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.*

15.10. Appendix 10: Variables Defined for Time to Event Analysis

Programming Instructions for the Kaplan-Meier analysis of treatment-related discontinuation equals failure (TRDF) for Week 24 IDMC / Week 24 / Week 48 / Week 96 Analyses		
Condition	**Censor Status**	**Event Description/AVAL**
1. Participant met CVF event criteria during the Maintenance Phase (based on derived CVF)	CNSR=0	EVNTDESC=CVF AVAL=Study Day of SVF* *immediately preceding CVF
2. Participant with Maintenance Phase withdrawal due to *'Lack of Efficacy', 'Treatment Related AE', 'Intolerability due to Injection',* or *'Protocol Defined Safety Stopping Criteria'* during Maintenance Phase Note: primary reason and/or standardized subreason for discontinuation based on Maintenance Conclusion form in the eCRF. 'Protocol Defined Safety Stopping Criteria' includes GSK defined liver chemistry stopping criteria, renal toxicity criteria and QTc withdrawal criteria. Treatment Related AE' is defined as participants who have primary reason for withdrawal =AE and who have at least one AE considered drug related and leading to withdrawal/permanent discontinuation of investigational product.	CNSR=0	EVNTDESC= terms in italic, respectively. For Q4W arm: AVAL= min [Study Day of Maintenance Phase Discontinuation, max (Study Day of Last Injection + 35, Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)] For Q8W arm: AVAL= min [Study Day of Maintenance Phase Discontinuation, max (Study Day of Last Injection + 63, Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)] Note: Date of Maintenance Phase discontinuation is from the Maintenance Phase Conclusion form in the eCRF.
If none of the above conditions met		
3. Participant with Maintenance Phase withdrawal due to other reasons	CNSR=1	EVNTDESC='Censored due to Study Discontinuation for Other Reasons' AVAL will be defined as the same as above 2

Programming Instructions for the Kaplan-Meier analysis of treatment-related discontinuation equals failure (TRDF) for Week 24 IDMC / Week 24 / Week 48 / Week 96 Analyses		
Condition	**Censor Status**	**Event Description/AVAL**
4. Participant who did not have premature withdrawal from the Maintenance Phase	CNSR=1	EVNTDESC='Censored due to data cutoff for analysis' AVAL = Study Day of last on-treatment date during the maintenance phase, which is defined as follows: For Q4W arm: min [Study Day of Nominal Week 100 Visit, Study Day of LTFU ART Start Date, Study Day of Last Contact Date at time of analysis, max (Study Day of Last Injection + 35, Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)] For Q8W arm min [Study Day of Nominal Week 100 Visit, Study Day of LTFU ART Start Date, Study Day of Last Contact Date at time of analysis, max (Study Day of Last Q8W IM Dose + 63, Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)]

Programming Instructions for the Kaplan-Meier analysis of treatment-related discontinuation equals failure (TRDF) for Week 152 Analysis		
Condition	**Censor Status**	**Event Description/AVAL**
1. Participant met CVF event criteria during the Maintenance and Extension Phase (based on derived CVF)	CNSR=0	EVNTDESC=CVF AVAL=Study Day of SVF* *immediately preceding CVF
2. Participant with study withdrawal due to *'Lack of Efficacy', 'Treatment Related AE', 'Intolerability due to Injection',* or *'Protocol Defined Safety Stopping Criteria'* Note: primary reason and/or standardized subreason for discontinuation based on	CNSR=0	EVNTDESC= terms in italic, respectively. For Q4W arm: AVAL= min [Study Day of Study Discontinuation, max (Study Day of Last Injection + 35, Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)] For Q8W arm: AVAL= min [Study Day of Study Discontinuation, max (Study Day of Last Injection + 63, Study Day of

Programming Instructions for the Kaplan-Meier analysis of treatment-related discontinuation equals failure (TRDF) for Week 152 Analysis		
Condition	**Censor Status**	**Event Description/AVAL**
Study Conclusion form in the eCRF. 'Protocol Defined Safety Stopping Criteria' includes GSK defined liver chemistry stopping criteria, renal toxicity criteria and QTc withdrawal criteria. Treatment Related AE' is defined as participants who have primary reason for withdrawal =AE and who have at least one AE considered drug related and leading to withdrawal/permanent discontinuation of investigational product.		Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)] Note: Date of Study discontinuation is from the Study Conclusion form in the eCRF.
If none of the above conditions met		
3. Participant with study withdrawal due to other reasons	CNSR=1	EVNTDESC='Censored due to Study Discontinuation for Other Reasons' AVAL will be defined as the same as above 2
4. Participant who did not have premature withdrawal	CNSR=1	EVNTDESC='Censored due to data cutoff for analysis' AVAL = Study Day of last on-treatment date, which is defined as follows: For Q4W arm: min [Study Day of LTFU ART Start Date, Study Day of Last Contact Date at time of analysis, max (Study Day of Last Injection + 35, Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)] For Q8W arm min [Study Day of LTFU ART Start Date, Study Day of Last Contact Date at time of analysis, max (Study Day of Last Q8W IM Dose + 63, Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1)]

Note that last injection and last dose of oral study treatment (CAB+RPV or SOC bridging) mentioned in table above are only applied to participants who permanently discontinued from the study treatment. The similar approach will be used to derive for Kaplan-Meier analysis of efficacy-related discontinuation equals failure (ERDF), except that the reason of withdrawal in Condition 2 will be restricted to 'Lack of Efficacy'.

15.11. Appendix 11: Identification of Adverse Events of Special Interest

The adverse events of special interest are identified based on MedDRA coded values and/or AE data available in the study database. The system organ classes (SOCs), preferred terms (PTs) or codes, Standardised MedDRA Queries (SMQs), High Level Group Terms (HLGTs), and High Level Terms (HLTs) below are from MedDRA 21.1. SMQs use narrow terms unless otherwise specified. In case there is a change to the version of MedDRA at time of reporting, the coded values based on the MedDRA version at the time of reporting will be used. The additional events may also be added based on the blinded review of AE data collected on study prior to the database freeze.

1. Hepatic Safety Profile: Assessment of risk of hepatoxicity

Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)

PT	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
Cholestatic liver injury	10067969
Chronic hepatic failure	10057573
Coma hepatic	10010075
Cryptogenic cirrhosis	10063075
Diabetic hepatopathy	10071265
Drug-induced liver injury	10072268
Duodenal varices	10051010
Gallbladder varices	10072319
Gastric variceal injection	10076237
Gastric variceal ligation	10076238
Gastric varices	10051012
Gastric varices haemorrhage	10057572
Hepatectomy	10061997
Hepatic atrophy	10019637
Hepatic calcification	10065274
Hepatic cirrhosis	10019641
Hepatic encephalopathy	10019660
Hepatic encephalopathy prophylaxis	10066599

PT	PT Code
Hepatic failure	10019663
Hepatic fibrosis	10019668
Hepatic hydrothorax	10067365
Hepatic infiltration eosinophilic	10064668
Hepatic lesion	10061998
Hepatic necrosis	10019692
Hepatic steato-fibrosis	10077215
Hepatic steatosis	10019708
Hepatitis fulminant	10019772
Hepatobiliary disease	10062000
Hepatocellular foamy cell syndrome	10053244
Hepatocellular injury	10019837
Hepatopulmonary syndrome	10052274
Hepatorenal failure	10019845
Hepatorenal syndrome	10019846
Hepatotoxicity	10019851
Intestinal varices	10071502
Intestinal varices haemorrhage	10078058
Liver and small intestine transplant	10052280
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
Non-alcoholic fatty liver	10029530
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

PT	PT Code
Portal vein cavernous transformation	10073979
Portal vein dilatation	10073209
Portopulmonary hypertension	10067281
Primary biliary cholangitis	10080429
Regenerative siderotic hepatic nodule	10080679
Renal and liver transplant	10052279
Retrograde portal vein flow	10067338
Reye's syndrome	10039012
Reynold's syndrome	10070953
Splenic varices	10067823
Splenic varices haemorrhage	10068662
Steatohepatitis	10076331
Subacute hepatic failure	10056956
Varices oesophageal	10056091
Varicose veins of abdominal wall	10072284
White nipple sign	10078438

Hepatitis, non-infectious (SMQ)

PT	PT Code
Acute graft versus host disease in liver	10066263
Allergic hepatitis	10071198
Alloimmune hepatitis	10080576
Autoimmune hepatitis	10003827
Chronic graft versus host disease in liver	10072160
Chronic hepatitis	10008909
Graft versus host disease in liver	10064676
Hepatitis	10019717
Hepatitis acute	10019727
Hepatitis cholestatic	10019754
Hepatitis chronic active	10019755
Hepatitis chronic persistent	10019759
Hepatitis fulminant	10019772
Hepatitis toxic	10019795
Immune-mediated hepatitis	10078962
Ischaemic hepatitis	10023025
Lupus hepatitis	10067737
Non-alcoholic steatohepatitis	10053219
Radiation hepatitis	10051015
Steatohepatitis	10076331

2. Hypersensitivity Reactions (HSR)

Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)

PT	PT Code
Drug reaction with eosinophilia and systemic symptoms	10073508
Pseudolymphoma	10037127

PTs (Selective)

PT	PT Code
Drug hypersensitivity	10013700
Hypersensitivity	10020751
Type IV Hypersensitivity reaction	10053613
Eosinophillia	10014950
Eye swelling	10015967
Eyelid oedema	10015993
Lip swelling	10024570
Angioedema	10002424
Circumoral oedema	10052250
Face oedema	10016029
Idiopathic angioedema	10073257
Lip oedema	10024558
Mouth swelling	10075203
Oedema mouth	10030110
Periorbital oedema	10034545
Swelling face	10042682
Periorbital swelling	10056647
Swelling of eyelid	10042690

3. Rash

Severe cutaneous adverse reactions (SMQ)

PT	PT Code
Acute generalised exanthematous pustulosis	10048799
Cutaneous vasculitis	10011686
Dermatitis bullous	10012441
Dermatitis exfoliative	10012455
Dermatitis exfoliative generalised	10012456
Drug reaction with eosinophilia and systemic symptoms	10073508

PT	PT Code
Epidermal necrosis	10059284
Erythema multiforme	10015218
Exfoliative rash	10064579
Oculomucocutaneous syndrome	10030081
Skin necrosis	10040893
Stevens-Johnson syndrome	10042033
Toxic epidermal necrolysis	10044223
Toxic skin eruption	10057970

PTs (Selective)

PT	PT Code
Eyelid rash	10074620
Genital rash	10018175
Mucocutaneous rash	10056671
Nodular rash	10075807
Perineal rash	10075364
Rash	10037844
Rash erythematous	10037855
Rash generalised	10037858
Rash macular	10037867
Rash maculo-papular	10037868
Rash maculovesicular	10050004
Rash morbilliform	10037870
Rash papular	10037876
Rash rubelliform	10057984
Rash scarlatiniform	10037890
Rash vesicular	10037898
Rash pruritic	10037884
Rash follicular	10037857
Rash pustular	10037888
Drug eruption	10013687

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

Torsade de pointes/QT prolongation (SMQ)

PT	PT Code
Electrocardiogram QT interval abnormal	10063748

PT	PT Code
Electrocardiogram QT prolonged	10014387
Long QT syndrome	10024803
Long QT syndrome congenital	10057926
Torsade de pointes	10044066
Ventricular tachycardia	10047302

PTs (Selective)

PT	PT Code
Electrocardiogram repolarisation abnormality	10052464

5. Suicidal Ideation/Behaviour

Suicide/self-injury (SMQ)

PT	PT Code
Assisted suicide	10079105
Columbia suicide severity rating scale abnormal	10075616
Completed suicide	10010144
Depression suicidal	10012397
Intentional overdose	10022523
Intentional self-injury	10022524
Poisoning deliberate	10036000
Self-injurious ideation	10051154
Suicidal behaviour	10065604
Suicidal ideation	10042458
Suicide attempt	10042464
Suicide threat	10077417
Suspected suicide attempt	10081704

6. Depression

Depression (excl suicide and self injury) (SMQ)

PT	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

PT	PT Code
Antidepressant therapy	10054976
Childhood depression	10068631
Decreased interest	10011971
Depressed mood	10012374
Depression	10012378
Depression postoperative	10012390
Depressive symptom	10054089
Dysphoria	10013954
Electroconvulsive therapy	10014404
Feeling guilty	10049708
Feeling of despair	10016344
Feelings of worthlessness	10016374
Helplessness	10077169
Major depression	10057840
Menopausal depression	10067371
Mixed anxiety and depressive disorder	10080836
Perinatal depression	10078366
Persistent depressive disorder	10077804
Post stroke depression	10070606
Postictal depression	10071324

7. Bipolar Disorder

HLGT Manic and Bipolar mood disorders and disturbances

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

8. Psychosis

Psychosis and psychotic disorders (SMQ)

PT	PT Code
Acute psychosis	10001022
Alcoholic psychosis	10001632

PT	PT Code
Alice in wonderland syndrome	10001666
Brief psychotic disorder with marked stressors	10048549
Brief psychotic disorder without marked stressors	10056395
Brief psychotic disorder, with postpartum onset	10006362
Charles Bonnet syndrome	10063354
Childhood psychosis	10061040
Clang associations	10009232
Cotard's syndrome	10059591
Delusion	10012239
Delusion of grandeur	10012241
Delusion of reference	10012244
Delusion of replacement	10012245
Delusional disorder, erotomanic type	10012249
Delusional disorder, grandiose type	10012250
Delusional disorder, jealous type	10012251
Delusional disorder, mixed type	10012252
Delusional disorder, persecutory type	10053195
Delusional disorder, somatic type	10012254
Delusional disorder, unspecified type	10012255
Delusional perception	10012258
Dementia of the Alzheimer's type, with delusions	10012295
Depressive delusion	10063033
Derailment	10012411
Epileptic psychosis	10059232
Erotomanic delusion	10015134
Flight of ideas	10016777
Hallucination	10019063
Hallucination, auditory	10019070
Hallucination, gustatory	10019071
Hallucination, olfactory	10019072
Hallucination, synaesthetic	10062824
Hallucination, tactile	10019074
Hallucination, visual	10019075
Hallucinations, mixed	10019079
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Hysterical psychosis	10062645
Ideas of reference	10021212
Illusion	10021403

PT	PT Code
Jealous delusion	10023164
Loose associations	10024825
Mixed delusion	10076429
Neologism	10028916
Neuroleptic-induced deficit syndrome	10075295
Paranoia	10033864
Paranoid personality disorder	10033869
Parkinson's disease psychosis	10074835
Paroxysmal perceptual alteration	10063117
Persecutory delusion	10034702
Postictal psychosis	10070669
Post-injection delirium sedation syndrome	10072851
Posturing	10036437
Psychosis postoperative	10065617
Psychotic behaviour	10037249
Psychotic disorder	10061920
Psychotic disorder due to a general medical condition	10061921
Reactive psychosis	10053632
Rebound psychosis	10074833
Schizoaffective disorder	10039621
Schizoaffective disorder bipolar type	10068889
Schizoaffective disorder depressive type	10068890
Schizophrenia	10039626
Schizophreniform disorder	10039647
Schizotypal personality disorder	10039651
Senile psychosis	10039987
Shared psychotic disorder	10040535
Somatic delusion	10041317
Somatic hallucination	10062684
Substance-induced psychotic disorder	10072388
Tangentiality	10043114
Thought blocking	10043495
Thought broadcasting	10052214
Thought insertion	10043496
Thought withdrawal	10043497
Transient psychosis	10056326
Waxy flexibility	10047853

9. Mood Disorders

HLGT Mood disorders and disturbances NEC, Psychiatric disorders SOC

PT	PT Code
Crying	10011469
Mood swings	10027951
Boredom	10048909
Mood altered	10027940
Apathy	10002942
Affective ambivalence	10077173
Emotional poverty	10014557
Euphoric mood	10015535
Premenstrual dysphoric disorder	10051537
Alexithymia	10077719
Laziness	10051602
Blunted affect	10005885
Constricted affect	10010778
Affect lability	10054196
Anger	10002368
Affective disorder	10001443
Lethargy	10024264
Listless	10024642
Inappropriate affect	10021588
Dysphoria	10013954
Mood disorder due to a general medical condition	10027944
Morose	10027977
Screaming	10039740
Steroid withdrawal syndrome	10042028
Emotional disorder	10014551
Irritability	10022998
Moaning	10027783
Premenstrual syndrome	10036618
Neuroleptic-induced deficit syndrome	10075295
Substance-induced mood disorder	10072387
Flat affect	10016759
Diencephalic syndrome of infancy	10012774
Emotional distress	10049119
Frustration tolerance decreased	10077753
Seasonal affective disorder	10039775

10. Anxiety

HLGT Anxiety disorders and symptoms

PT	PT Code
Acrophobia	10000605
Activation syndrome	10066817
Acute stress disorder	10001084
Aerophobia	10080300
Agitation	10001497
Agitation neonatal	10001500
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
Claustrophobia	10009244
Compulsions	10010219
Compulsive cheek biting	10076510
Compulsive handwashing	10071263
Compulsive hoarding	10068007
Compulsive lip biting	10066241
Compulsive shopping	10067948
Dermatillomania	10065701
Dysmorphophobia	10049096
Emetophobia	10070637
Fear	10016275
Fear of animals	10016276
Fear of closed spaces	10016277
Fear of crowded places	10050365
Fear of death	10066392

PT	PT Code
Fear of disease	10016278
Fear of eating	10050366
Fear of falling	10048744
Fear of injection	10073753
Fear of open spaces	10016279
Fear of pregnancy	10067035
Fear of weight gain	10016280
Fear-related avoidance of activities	10080136
Generalised anxiety disorder	10018075
Glossophobia	10080077
Haemophobia	10073458
Haphephobia	10067580
Hydrophobia	10053317
Hyperarousal	10080831
Immunisation anxiety related reaction	10075205
Kinesiophobia	10078430
Limited symptom panic attack	10024511
Mysophobia	10078769
Nail picking	10066779
Nervousness	10029216
Neurosis	10029333
Noctiphobia	10057946
Nocturnal fear	10057948
Nosophobia	10063546
Obsessive need for symmetry	10077179
Obsessive rumination	10056264
Obsessive thoughts	10029897
Obsessive-compulsive disorder	10029898
Obsessive-compulsive symptom	10077894
Ochlophobia	10050095
Osmophobia	10060765
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	10072147
Panic attack	10033664
Panic disorder	10033666
Panic reaction	10033670
Paruresis	10069024
Performance fear	10034432
Phagophobia	10050096
Pharmacophobia	10069423

PT	PT Code
Phobia	10034912
Phobia of driving	10056676
Phobia of exams	10034913
Phobic avoidance	10034918
Phonophobia	10054956
Photaugiaphobia	10064420
Post-traumatic stress disorder	10036316
Postpartum neurosis	10036419
Postpartum stress disorder	10056394
Procedural anxiety	10075204
Pseudoangina	10056610
Selective mutism	10039917
Separation anxiety disorder	10040045
Sitophobia	10080170
Social anxiety disorder	10041242
Social fear	10041247
Stress	10042209
Tension	10043268
Terminal agitation	10077416
Thanatophobia	10064723
Thermophobia	10075147
Trichotemnomania	10072752
Trichotillomania	10044629

11. Sleep Disorders

HLGT Sleep Disorders and Disturbances

PT	PT Code
Behavioural insomnia of childhood	10072072
Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Middle insomnia	10027590
Terminal insomnia	10068932
Breathing-related sleep disorder	10006344
Dyssomnia	10061827
Hypersomnia	10020765
Periodic limb movement disorder	10064600
Pickwickian syndrome	10035004

PT	PT Code
Poor quality sleep	10062519
Sleep apnoea syndrome	10040979
Somnolence	10041349
Somnolence neonatal	10041350
Stupor	10042264
Upper airway resistance syndrome	10063968
Cataplexy	10007737
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Narcolepsy	10028713
Sleep attacks	10040981
Sleep paralysis	10041002
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Confusional arousal	10067494
Exploding head syndrome	10080684
Loss of dreaming	10065085
Nightmare	10029412
Parasomnia	10061910
Rapid eye movement sleep behaviour disorder	10077299
Rapid eye movements sleep abnormal	10037841
Sleep inertia	10067493
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347
Hypersomnia related to another mental condition	10020767
Hypersomnia-bulimia syndrome	10053712
Insomnia related to another mental condition	10022443
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
Sopor	10058709

PT	PT Code
Advanced sleep phase	10001423
Circadian rhythm sleep disorder	10009191
Delayed sleep phase	10012209
Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Non-24-hour sleep-wake disorder	10078086
Shift work disorder	10078088

HLGT Sleep disturbances (incl subtypes)

PT	PT Code
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Confusional arousal	10067494
Loss of dreaming	10065085
Sleep inertia	10067493
Sleep paralysis	10041002
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347
Behavioural insomnia of childhood	10072072
Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Middle insomnia	10027590
Terminal insomnia	10068932
Advanced sleep phase	10001423
Circadian rhythm sleep disorder	10009191
Delayed sleep phase	10012209
Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Non-24-hour sleep-wake disorder	10078086
Shift work disorder	10078088
Cataplexy	10007737
Hypersomnia	10020765
Narcolepsy	10028713
Central-alveolar hypoventilation	10007982
Sleep apnoea syndrome	10040979

PT	PT Code
Breathing-related sleep disorder	10006344
Dyssomnia	10061827
Fatal familial insomnia	10072077
Microsleep	10076954
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
Sleep deficit	10080881
Sudden onset of sleep	10050014
Upper airway resistance syndrome	10063968

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

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

13. Seizures and Seizure-like Events

Convulsions (SMQ)

PT	PT Code
2-Hydroxyglutaric aciduria	10078971
Acquired epileptic aphasia	10052075
Acute encephalitis with refractory, repetitive partial seizures	10076948
Alcoholic seizure	10056347
Aspartate-glutamate-transporter deficiency	10079140
Atonic seizures	10003628
Atypical benign partial epilepsy	10056699
Automatism epileptic	10003831
Autonomic seizure	10049612
Baltic myoclonic epilepsy	10054895
Benign familial neonatal convulsions	10067866
Benign rolandic epilepsy	10070530
Biotinidase deficiency	10071434
Change in seizure presentation	10075606
Clonic convulsion	10053398
Convulsion in childhood	10052391

PT	PT Code
Convulsion neonatal	10010911
Convulsions local	10010920
Convulsive threshold lowered	10010927
CSWS syndrome	10078827
Deja vu	10012177
Double cortex syndrome	10073490
Dreamy state	10013634
Drug withdrawal convulsions	10013752
Early infantile epileptic encephalopathy with burst-suppression	10071545
Eclampsia	10014129
Epilepsy	10015037
Epilepsy surgery	10079824
Epilepsy with myoclonic-atonic seizures	10081179
Epileptic aura	10015049
Epileptic psychosis	10059232
Febrile convulsion	10016284
Febrile infection-related epilepsy syndrome	10079438
Focal dyscognitive seizures	10079424
Frontal lobe epilepsy	10049424
Generalised non-convulsive epilepsy	10018090
Generalised tonic-clonic seizure	10018100
Glucose transporter type 1 deficiency syndrome	10078727
Gray matter heterotopia	10080533
Hemimegalencephaly	10078100
Hyperglycaemic seizure	10071394
Hypocalcaemic seizure	10072456
Hypoglycaemic seizure	10048803
Hyponatraemic seizure	10073183
Idiopathic generalised epilepsy	10071081
Infantile spasms	10021750
Juvenile myoclonic epilepsy	10071082
Lafora's myoclonic epilepsy	10054030
Lennox-Gastaut syndrome	10048816
Migraine-triggered seizure	10076676
Molybdenum cofactor deficiency	10069687
Multiple subpial transection	10079825
Myoclonic epilepsy	10054859
Myoclonic epilepsy and ragged-red fibres	10069825
Partial seizures	10061334

PT	PT Code
Partial seizures with secondary generalisation	10056209
Petit mal epilepsy	10034759
Polymicrogyria	10073489
Post stroke epilepsy	10076982
Post stroke seizure	10076981
Postictal headache	10052470
Postictal paralysis	10052469
Postictal psychosis	10070669
Postictal state	10048727
Post-traumatic epilepsy	10036312
Schizencephaly	10073487
Seizure	10039906
Seizure anoxic	10039907
Seizure cluster	10071350
Seizure like phenomena	10071048
Severe myoclonic epilepsy of infancy	10073677
Simple partial seizures	10040703
Status epilepticus	10041962
Sudden unexplained death in epilepsy	10063894
Temporal lobe epilepsy	10043209
Tonic clonic movements	10051171
Tonic convulsion	10043994
Tonic posturing	10075125
Topectomy	10073488
Transient epileptic amnesia	10081728
Tuberous sclerosis complex	10080584
Uncinate fits	10045476

PTs (Selective)

PT	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

14. Weight Gain

HLT General nutritional disorders NEC (Selective)

PT	PT Code
Abdominal fat apron	10077983
Overweight	10033307
Abnormal weight gain	10000188
Central obesity	10065941
Obesity	10029883

HLT Physical examination procedures and organ system status (Selective)

PT	PT Code
Weight abnormal	10056814
Weight increased	10047899
Waist circumference increased	10064863
Body mass index abnormal	10074506
Body mass index increased	10005897

General signs and symptoms NEC (Selective)

PT	PT Code
Fat tissue increased	10016251

15. Rhabdomyolysis

Rhabdomyolysis/myopathy (SMQ)

PT	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

PT	PT Code
Rhabdomyolysis	10039020
Thyrotoxic myopathy	10081524

PTs (Selective)

PT	PT Code
Myalgia	10028411
Myositis	10028653

16. Pancreatitis

Acute pancreatitis (SMQ)

PT	PT Code
Cullen's sign	10059029
Grey Turner's sign	10075426
Haemorrhagic necrotic pancreatitis	10076058
Hereditary pancreatitis	10056976
Ischaemic pancreatitis	10066127
Oedematous pancreatitis	10052400
Pancreatic abscess	10048984
Pancreatic haemorrhage	10033625
Pancreatic necrosis	10058096
Pancreatic phlegmon	10056975
Pancreatic pseudoaneurysm	10081762
Pancreatic pseudocyst	10033635
Pancreatic pseudocyst drainage	10033636
Pancreatitis	10033645
Pancreatitis acute	10033647
Pancreatitis haemorrhagic	10033650
Pancreatitis necrotising	10033654
Pancreatitis relapsing	10033657
Pancreatorenal syndrome	10056277

17. Impact on Creatinine

Acute renal failure (SMQ)

PT	PT Code
Acute kidney injury	10069339
Acute phosphate nephropathy	10069688

PT	PT Code
Anuria	10002847
Azotaemia	10003885
Continuous haemodiafiltration	10066338
Dialysis	10061105
Foetal renal impairment	10078987
Haemodialysis	10018875
Haemofiltration	10053090
Hyponatriuria	10077515
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

Renal Failure and Impairment HLT

PT	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

PT	PT Code
Propofol infusion syndrome	10063181
Renal failure	10038435
Renal failure neonatal	10038447
Renal impairment	10062237
Renal impairment neonatal	10049776
Renal injury	10061481
Scleroderma renal crisis	10062553
Traumatic anuria	10044501

18. Safety in Pregnancy

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

19. Hyperglycaemia

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

PT	PT Code
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
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

PT	PT Code
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
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
Hepatogenous diabetes	10085610
Maternally inherited diabetes and deafness	10086189
Neonatal hyperglycaemia	10086425
Acquired generalised lipodystrophy	10087376
Glycated serum protein increased	10087214
Hyperglycaemic crisis	10087319

15.12. Appendix 12: 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
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

15.13. Appendix 13: IDMC

Independent review will be provided by an IDMC to ensure external objective medical and/or statistical review of efficacy and safety in order to protect the ethical interests and well-being of participants and to protect the scientific validity of this study. An ad-hoc review of data by the IDMC will be triggered whenever the number of confirmed virologic failures in the Q8W arm exceeds thresholds pre-specified in the IDMC charter. Further, analyses including futility checking will be performed for the IDMC to evaluate the efficacy and safety when approximately 50% of participants have completed their visit at Week 24.

The list of required outputs is provided in the IDMC Charter, Section 12.3, Appendix C.

Data handing methods and derived data definitions will be the same as detailed in this RAP, unless otherwise stated.

15.13.1. Adhoc CVF IDMC Analyses

The number of participants meeting Confirmed Virologic Failure (CVF) Criterion per the protocol will be monitored and may result in ad-hoc IDMC data reviews.

The Statistics Data Analysis Centre (SDAC) will be notified by the study virologist in writing every time a CVF occurs in the study. The SDAC will track the number of participants on Q8W arm past Week 4. The rate of CVF will be monitored against the thresholds specified in IDMC Charter Table 1 (See IDMC Charter, Section 3.5.2).

15.13.2. Week 24 IDMC Analyses

Analyses including futility checking will be performed when approximately 50% of participants have completed their Week 24 visit.

A futility rule will assess the evidence that the CAB LA + RPV LA Q8W arm is non-inferior to the Q4W control arm. This rule will use the interim data (~ 50% participants completing Week 24) to calculate the Bayesian predictive probabilities that the CAB LA + RPV LA Q8W arm is non-inferior to the Q4W arm at Week 24. A 4% non-inferiority margin will be used. The details of statistical methods can be found in IDMC Charter, Section 12.6.1. The list of outputs is also provided in Section 15.15.4.

15.14. Appendix 14: Abbreviations & Trademarks

15.14.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
AESI	Adverse Events of Special Interest
BMI	Body Mass Index
CAB	Cabotegravir
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CMH	Cochran-Mantel-Haenszel
COVID	Coronavirus Disease
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
eC-SSRS	Electronic Columbia Suicide Severity Rating Scale
CVb	Coefficient of Variation (Between)
CVD	Cardiovascular Disease
CVF	Confirmed Virologic Failure
DAIDS	Division of AIDS
DBF	Database Freeze
DBL	Database Lock
DBR	Database Release
DOB	Date of Birth
DP	Decimal Place
DTG	Dolutegravir
eCRF	Electronic Case Record Form
eGFR	Estimated Glomerular Filtration Rate
EMA	European Medicines Agency
ERDF	Efficacy Related Discontinuation Failure
FDA	Food and Drug Administration
FSFV	First Subject First Visit
GSK	GlaxoSmithKline
GUI	Guidance
HAT-QoL	Health-related Quality of Life
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIVTSQc	Change Version of HIV Treatment Satisfaction Questionnaire
HIVTSQs	Status Version of HIV Treatment Satisfaction Questionnaire
HLGT	High Level Group Term
HLT	High Level Term
HSR	Hypersensitivity Reaction
ICH	International Conference on Harmonisation

IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
INI	Integrase Inhibitors
IP	Investigational Product
ITT	Intent-To-Treat
ITT-E	Intent-To-Treat Exposed
LA	Long Acting
LOCF	Last Observation Carries Forward
MMRM	Mixed Model Repeated Measures
NA	Not Applicable
NCEP	National Cholesterol Education Program
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NQ	Non Quantifiable
NRTI	Nucleoside Reverse Transcriptase Inhibitors
OC	Observed Case
PBMC	Peripheral Blood Mononuclear Cell
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PI	Protease Inhibitors
PIN	Perception of Injection
PK	Pharmacokinetic
PP	Per Protocol
PT	Preferred Term
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAM	Resistance Associated Mutation
RAMOS	Randomization & Medication Ordering System
RAP	Reporting & Analysis Plan
RPV	Rilpivirine
SAE	Serious Adverse Event
SAC	Statistical Analysis Complete
SD	Standard Deviation
SDAC	Statistics Data Analysis Centre
SDTM	Study Data Tabulation Model
SMQ	Standardised MedDRA Query
SOC	System Organ Class
SOP	Standard Operation Procedure
TFL	Tables, Figures & Listings
TRDF	Treatment Related Discontinuation Failure

15.14.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
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Triumeq

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15.15. Appendix 15: List of Data Displays

15.15.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.n	1.1 to 1.n
Efficacy	2.1 to 2.n	2.1 to 2.n
Safety	3.1 to 3.n	3.1 to 3.n
Pharmacokinetic	4.1 to 4.n	4.1 to 4.n
Pharmacokinetic / Pharmacodynamic	5.1 to 5.n	5.1 to 5.n
Health Outcomes	6.1 to 6.n	6.1 to 6.n
Virology	7.1 to 7.n	7.1 to 7.n
Section	**Listings**	
ICH Listings	1 to x	
Other Listings	y to z	

15.15.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required an example mock-up displays will be provided in a separate document.

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

Other example mock-up displays will be named using the following format.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Pharmacokinetic / Pharmacodynamic	PKPD_Fn	PKPD_Tn	PK/PD_Ln
Health Outcomes	HO_Fn	HO_Tn	HO_Ln
Virology	VIR_Fn	VIR_Tn	VIR_Ln

NOTES:

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

15.15.3. Deliverables

Delivery [1]	Description
IW24	IDMC analyses when approximately 50% participants have completed their Week 24 visits
W24	Week 24 when 100% participants have completed their Week 24 visits
HL	Headline at Week 48 or Week 96
W48	Week 48
W96	Week 96
W152	Week 152
Sub-study	Sub-study
EOS	End of study

NOTES:
1. Indicates order in which displays will be generated for the reporting effort

15.15.4. List of Data Displays for Week 24 IDMC and Week 24 Planned Analyses

For Week 24 planned analyses, the Week 24 Futility population will be replaced by the Intent-to-Treat Exposed population. In addition, unless otherwise specified, present the listings by prior exposure to CAB+RPV (i.e. rederived randomization strata, 0, 1-24, >24 weeks, refer to Section 15.6.2 for calculation details) except for study population listings.

15.15.4.1. Study Population Tables

Study Population Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition						
1.1	NA	Week 24 Futility	ES1	Summary of Subject Accountability: Maintenance Phase Conclusion Record - Week 24 Futility	ICH E3, GSKCTR, FDAAA, EudraCT, see also in 201585/primary_02/T1.7.	IW24
1.2	1.1	Intent-to-Treat Exposed	ES1	Summary of Subject Accountability: Maintenance Phase Conclusion Record - ITT-E	ICH E3, GSKCTR, FDAAA, EudraCT, see also in 201585/primary_02/T1.7.	IW24, W24
Demographic and Baseline Characteristics						
1.3	NA	Week 24 Futility	201585/primary_02/T1.16	Summary of Demographic Characteristics - Week 24 Futility	ICH E3, FDAAA, EudraCT	IW24
1.4	1.2	Intent-to-Treat Exposed	201585/primary_02/T1.16	Summary of Demographic Characteristics - ITT-E	ICH E3, FDAAA, EudraCT	IW24, W24
1.5	NA	Week 24 Futility	201584/idmc_03/T1.3	Summary of Prior Exposure to CAB+RPV - Week 24 Futility	Adjust footnote and row labels as appropriate.	IW24
1.6	1.3	Intent-to-Treat Exposed	201584/idmc_03/T1.3	Summary of Prior Exposure to CAB+RPV - ITT-E	Adjust footnote and row labels as appropriate.	IW24, W24
1.7	1.4	Intent-to-Treat Exposed	201584/idmc_03/T1.7	Summary of Prior Exposure to CAB+RPV by Country	Adjust footnote and row labels as appropriate.	IW24, W24
1.8	1.5	Intent-to-Treat Exposed	201585/primary_02/T1.19	Summary of Hepatitis Status at Entry	Add footnote as appropriate for subjects classified as Hepatitis B positive in analysis.	IW24, W24

15.15.4.2. Efficacy Tables

Efficacy Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	2.1	Week 24 Futility	201585/primary_02/T2.1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL at Week 24 and Posterior Predictive Probability of Success for the Q8W Arm - Snapshot Analysis	For Week 24 IDMC, add a column on right with 'Posterior Predictive Probability of Success" and adjust the footnotes as appropriate, also add a footnote “Target threshold for posterior predictive probability is 15%.”. For planned Week 24, remove ‘and Posterior Predictive Probability of Success for the Q8W Arm’ from the title, adjust the footnote as appropriate. For proportions, keep one decimal place. The adjustment is based on rederived randomization strata.	IW24, W24
2.2	2.2	Week 24 Futility	201585/primary_02/T2.4	Summary of Study Outcomes (50 c/mL Threshold) at Week 24 (Maintenance Phase) - Snapshot Analysis	For proportions, keep one decimal place.	IW24, W24
2.3	2.3	Week 24 Futility	201585/primary_02/T2.6	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL at Week 24 by Randomization Strata (Maintenance Phase) - Snapshot Analysis	Note that only by randomization strata summary is provided. Change the footnote to “[1] Difference: Proportion on Q8W - Proportion on Q4W. 95% CIs were calculated using an unconditional exact method with two inverted one-sided tests based on the score statistic.” Add Footnote "Note: Randomization strata are rederived using the prior exposure to CAB+RPV in Study 201585, collected from eCRF." For proportions, keep one decimal place.	IW24, W24

Efficacy Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.4	2.4	Week 24 Futility	201585/primary_02/T2.21	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure by Visit (Up to Week 24)	For proportions, keep one decimal place. Non-snapshot visit window will be used.	IW24, W24
2.5	2.5	Week 24 Futility	201585/primary_02/T2.21	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure by Visit and Randomization Strata (Up to Week 24)	Add column for 'Analysis Strata', add footnote for randomization strata similar to T2.3. For proportions, keep one decimal place. Non-snapshot visit window will be used.	IW24, W24
2.6	2.6	Intent-to-Treat Exposed	201585/primary_02/T2.21	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure during the Maintenance Phase	Note that this is overall summary, not by visit. Replace the column 'Timepoint' with 'CVF Category'. For proportions, keep one decimal place.	IW24, W24
2.7	2.7	Intent-to-Treat Exposed	201584/idmc_03/T2.7	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure by Randomization Strata during the Maintenance Phase	Adjust footnote and row labels as appropriate. For proportions, keep one decimal place. Use rederived Randomization strata.	IW24, W24
2.8	2.8	Week 24 Futility	EFF_T1	Summary of Kaplan-Meier Estimates of Proportion of Subjects without CVF at Week 24 - Treatment Related Discontinuation = Failure	The non-snapshot visit window for Week 24 will be used.	IW24, W24

Efficacy Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.9	2.9	Week 24 Futility	EFF_T2	Summary of Kaplan-Meier Estimates of Proportion of Subjects without CVF at Week 24 - Efficacy Related Discontinuation=Failure	The non-snapshot visit window for Week 24 will be used.	IW24, W24
2.10	2.10	Intent-to-Treat Exposed	201584/idmc_03/T2.10	Proportion of Subjects with Plasma HIV-1 RNA < 50 c/mL by Visit - Observed Case Analysis	Adjust the footnote as appropriate. The non-snapshot visit window will be used. For W24, add '(Up to Week 24)' to the title, only display visits up to Week 24.	IW24, W24
2.11	2.11	Intent-to-Treat Exposed	201584/idmc_03/T2.11	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit and Randomization Strata - Observed Case Analysis	Adjust footnote and row labels as appropriate. The non-snapshot visit window and rederived randomization strata will be used. For W24, add '(Up to Week 24)' to the title, only display visits up to Week 24.	IW24, W24

15.15.4.3. Efficacy Figures

Efficacy Figures						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	2.1	Week 24 Futility	201584/idmc_03/F2.1	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit for Subjects Who are in the Category of 'Viral Load ≥50 c/mL' at Week 24 per Snapshot Algorithm	Adjust the x-axis label and footnote as appropriate. The x-values are based on study day of the assessment.	IW24, W24
2.2	2.2	Intent-to-Treat Exposed	201584/idmc_03/F2.2	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit for Subjects with a Viral Load ≥50 c/mL during the Maintenance Phase	Adjust the x-axis label and footnote as appropriate. The x-values are based on study day of the assessment.	IW24, W24

15.15.4.4. Safety Tables

Safety Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Adverse Events						
3.1	3.1	Safety	AE3	Summary of All Adverse Events by Overall Frequency - Maintenance Phase	See also in 201585/primary_02/T3.20.	IW24, W24
3.2	3.2	Safety	AE1	Summary of All Drug-Related Adverse Events by System Organ Class - Maintenance Phase	See also in 201585/primary_02/T3.16.	IW24, W24
3.3	3.3	Safety	AE3	Summary of Grade 3-5 Adverse Events by Overall Frequency - Maintenance Phase	See also in 201585/primary_02/T3.20.	IW24, W24
Serious and Other Significant Adverse Events						
3.4	3.4	Safety	AE1	Summary of Serious Adverse Events by System Organ Class - Maintenance Phase	See also in 201585/primary_02/T3.21.	IW24, W24
3.5	3.5	Safety	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class - Maintenance Phase	See also in 201585/primary_02/T3.31.	IW24, W24
Injection Site Reaction Adverse Events						
3.6	3.6	Safety	201585/primary_02/T3.40	Summary of Injection Site Reaction Adverse Events (Event-Level Summary) - Maintenance Phase	For W24, add ‘Study Drug’ before ‘Injection’ in the title and only summarize ISR from study drug injections.	IW24, W24

Safety Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.7	3.7	Safety	201585/primary_02/T3.43	Summary of Subject-Level Characteristics of Injection Site Reaction Adverse Events - Overall and Common (Maintenance Phase)	Common ISR adverse events includes injection site pain, injection site induration, injection site nodules and any other ISR with ≥5% subjects in either treatment arm. For W24, add 'Study Drug' before 'Injection' in the title and only summarize ISR from study drug injections.	IW24, W24
Laboratory: Chemistry and Hematology						
3.8	3.8	Safety	201584/idmc_03/T3.8	Summary of Maximum Post-Baseline Emergent Clinical Chemistry Toxicities Parameters of Special Interest - Maintenance Phase	Replace "Day 1" with "Study Day 1" in the first footnote. Use the same parameter list as the one in 201584/idmc_03/T3.8.	IW24, W24
3.9	3.9	Safety	201584/idmc_03/T3.9	Summary of Maximum Post-Baseline Emergent Hematology Toxicities Parameters of Special Interest - Maintenance Phase	Replace "Day 1" with "Study Day 1" in the first footnote. Adjust the second footnote to be: "Note: Parameters of Special Interest include Hemogoblin, Leukocytes, Neutrophils, and Platelets." In output, change the parameter label 'White Blood Cell count' to 'Leukocytes'.	IW24, W24

15.15.4.5. Safety Figures

Safety Figures						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Laboratory: Hepatobiliary (Liver)						
3.1	3.1	Safety	201584/idmc_03/F3.2	Scatter Plot of Maximum Maintenance Phase vs. Baseline for ALT	Adjust the legend as needed. Change the first footnote to “Axes are on a log10 scale”. Remove the second footnote. Adjust the treatment label from empty triangle to solid triangle.	IW24, W24
3.2	3.2	Safety	201584/idmc_03/F3.1	Matrix Plot of Maximum Liver Chemistries - Maintenance Phase	Replace “>5.1” with “>5.0” in the second footnote. Make treatment labels in the plot consistent across figures.	IW24, W24

15.15.4.6. Pharmacokinetic Tables

Pharmacokinetic Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	4.1	Pharmacokinetic	201585/primary_02/T4.1	Summary of Plasma CAB PK Concentrations (ug/mL) - Time Data by Treatment and Visit - Including Log-Transformed Statistics	Remove the first footnote "Note:…".	IW24, W24
4.2	4.2	Pharmacokinetic	201585/primary_02/T4.2	Summary of Plasma RPV PK Concentrations (ng/mL) - Time Data by Treatment and Visit - Including Log-Transformed Statistics	Remove the first footnote "Note:…"..	IW24, W24
4.3	NA	Pharmacokinetic	201584/idmc_03/T4.3	Proportion of Subjects with Evaluable PK Concentration below Expected Values		IW24

15.15.4.7. Pharmacokinetic Figures

Pharmacokinetic Figures						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	NA	Pharmacokinetic	201584/idmc_03/ F4.1	Scatter Plot of Evaluable PK Concentrations in Relation to Occurrence of CVF up to Week 16 for Subjects on Q8W Arm by Visit and Randomization Strata	Note that this plot is by visit and rederived randomization strata. Add footnote for strata as appropriate.	IW24

15.15.4.8. Virology Tables

Virology Tables						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
7.1	7.1	Confirmed Virologic Failure	201585/primary_02/T8.1	Summary of the Prevalence of Known INI Resistance Mutations at Time of CVF (Maintenance Phase) - Plasma Sample		IW24, W24
7.2	7.2	Confirmed Virologic Failure	201585/primary_02/T8.2	Summary of the Prevalence of Major Resistance Mutations of NNRTI, NRTI, and PI Class at Time of CVF (Maintenance Phase) - Plasma Sample		IW24, W24
7.3	7.3	Confirmed Virologic Failure	201585/primary_02/T8.3	Summary of Phenotypic Susceptibility at Time of CVF (Maintenance Phase) - Plasma Sample		IW24, W24
7.4	7.4	Confirmed Virologic Failure	201585/primary_02/T8.7	Summary of Fold Change to CAB and RPV at Time of CVF (Maintenance Phase) - Plasma Sample		IW24, W24
7.5	7.5	Confirmed Virologic Failure	201585/primary_02/T8.8	Summary of Viral Load, Genotypic and Phenotypic Data for Subjects Who Met Confirmed Virologic Failure Criteria during the Maintenance Phase	Remove the Columns ‘ARTs’ and ‘FC for ARTs’. Remove the footnotes [1] and [2]. Adjust the footnote as appropriate.	IW24, W24

15.15.4.9. ICH Listings

Note: Both unique subject ID and latest subject ID for a subject will be included in the listings, unless otherwise specified.

ICH Listings						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population						
1	1	Randomized	201584/idmc_03/L1.3	Listing of Randomized and Actual Strata and Treatment Assignment	Randomized and Actual Treatments will include oral lead-in information (e.g. Oral followed by Q4W). For W24 analyses, remove column for Futility Population.	IW24, W24
Efficacy						
2	2	Week 24 Futility	201585/primary_02/L11	Listing of Study Outcomes (50 c/mL Threshold) at Week 24 - Snapshot Analysis		IW24, W24
Adverse Events						
3	3	Safety	201585/primary_02/L17	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product - Maintenance Phase	Remove “Time Since Last Dose” from the column header.	IW24, W24
4	4	Safety	201585/primary_02/L17	Listing of All Serious Adverse Events - Maintenance Phase	Remove “Time Since Last Dose” from the column header.	IW24, W24
Laboratory						
5	NA	Safety	201584/idmc_03/L3.5	Listing of All Parameters of Special Interest Laboratory Data for Subjects with Grade 3 or 4 Maintenance Phase Emergent Toxicities for Parameters of Special Interest	Replace ‘Day 1’ with ‘Study Day 1’ in the second footnote.	IW24

ICH Listings						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
PK						
6	5	Pharmacokinetic	201584/idmc_03/L4.1	Listing of Plasma CAB PK Concentration-Time Data	Change the first footnote to "Relative Time is calculated relative to the date and time of last previous dose. If the time of the last previous dose (e.g. oral lead-in/oral bridging) is missing, then the relative time will be set to missing and the sample will not be considered 'evaluable'." Remove the second footnote. Change column header 'Visit' to 'Analysis Visit/Nominal Visit' to include both visits.	IW24, W24
7	6	Pharmacokinetic	201584/idmc_03/L4.2	Listing of Plasma RPV PK Concentration-Time Data	Change the first footnote to "Relative Time is calculated relative to the date and time of last previous dose. If the time of the last previous dose (e.g. oral lead-in/oral bridging) is missing, then the relative time will be set to missing and the sample will not be considered 'evaluable'." Remove the second footnote. Change column header 'Visit' to 'Analysis Visit/Nominal Visit' to include both visits.	IW24, W24

15.15.4.10. Non-ICH Listings

Note: Both unique subject ID and latest subject ID for a subject will be included in the listings, unless otherwise specified.

Non-ICH Listings						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population						
8	7	Intent-to-Treat Exposed	ES2	Listing of Reasons for Maintenance Phase Withdrawal	See also in 201585/primary_02/L30.	IW24, W24
9	8	Screened	Shell POP_L2	Listing of Subjects Who Were Rescreened		IW24, W24
10	9	Intent-to-Treat Exposed	201584/idmc_03/L1.1	Listing of Prior Antiretroviral Therapy	Remove the column 'Treatment Phase/Treatment State'. Add a column for Route.	IW24, W24
11	10	Intent-to-Treat Exposed	201584/idmc_03/L1.2	Listing of Concomitant Antiretroviral Therapy	Change column 'Treatment Phase/Actual Treatment State' to 'Phase during Which Concomitant', remove 'Induction Study Day' from column headers, and remove 'Maintenance' from 'Maintenance Study Day' in column headers.	IW24, W24
Efficacy						
12	11	Confirmed Virologic Failure	201585/primary_02/L40	Listing of All Plasma HIV-1 RNA Viral Load Data for Subjects with Confirmed Virologic Failure during the Maintenance Phase	Non-snapshot visit window will be used for deriving the visits in Column 'Actual Relative Time'. Replace 'Period' in column header with 'Phase'.	IW24, W24

Non-ICH Listings						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
13	12	Week 24 Futility	201585/primary_02/L40	Listing of All Plasma HIV-1 RNA Viral Load Data for Subjects Who are in the Category of 'Viral load ≥50 c/mL' at Week 24 per Snapshot Algorithm	Non-snapshot visit window will be used for deriving the visits in Column 'Actual Relative Time'. Replace 'Period' in column header with 'Phase'.	IW24, W24
Adverse Events						
14	13	Safety	201585/primary_02/L17	Listing of All Drug-Related Adverse Events - Maintenance Phase	Remove "Time Since Last Dose" from the column header.	IW24, W24
15	14	Safety	201585/primary_02/L17	Listing of All Grade 3-5 Adverse Events - Maintenance Phase	Remove "Time Since Last Dose" from the column header.	IW24, W24
16	15	Safety	201585/primary_02/L17	Listing of All Adverse Events - Long-term Follow-up Phase	Remove "Time Since Last Dose" from the column header.	IW24, W24
PK						
17	NA	Pharmacokinetic	201584/idmc_03/L4.3	Listing of Plasma CAB PK Concentration-Time Data for Subjects with CAB Concentration <1.35 ug/mL (~8 X PAIC90) at Visits up to Week 16	Change the first footnote to "Relative Time is calculated relative to the date and time of last previous dose. If the time of the last previous dose (e.g. oral lead-in/oral bridging) is missing, then the relative time will be set to missing and the sample will not be considered 'evaluable'." Remove the second footnote. Change column header 'Visit' to 'Analysis Visit/Nominal Visit' to include both visits.	IW24

Non-ICH Listings						
No. in IW24	**No. in W24**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
18	NA	Pharmacokinetic	201584/idmc_03/L4.4	Listing of Plasma CAB PK Concentration-Time Data for Subjects with CAB Concentration <0.166 ug/mL (PAIC90) at Visits up to Week 16	The same note as in Listing 17.	IW24
19	NA	Pharmacokinetic	201584/idmc_03/L4.5	Listing of Plasma RPV PK Concentration-Time Data for Subjects with RPV Concentration <12 ng/mL (PAIC90) at Visits up to Week 16	The same note as in Listing 17.	IW24
Virology						
20	16	Confirmed Virologic Failure	201584/idmc_03/L7.1	Listing of Genotypic Mutation Data at All Timepoints		IW24, W24
21	17	Confirmed Virologic Failure	201584/idmc_03/L7.2	Listing of Phenotypic Data at All Timepoints		IW24, W24

15.15.5. List of Data Displays for Week 48/96/End-of-Study Planned Analyses

15.15.5.1. Study Population Tables

Study Population Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition							
1.1	1.1	1.1	Randomized	NS1	Summary of Number of Subjects Enrolled by Country and Site ID	'No Treatment' column is not needed.	W48, W96, EOS
1.2	1.2	1.2	Screened	ES6	Summary of Screening Status and Reasons for Screening Failures		W48, W96
1.3	1.3	1.3	Intent-to-Treat Exposed	ES1	Summary of Subject Accountability: Study Conclusion Record	For WK 96 and EOS: Add a footnote [1] for Subject Status: "[1] Subject Status is derived based on the data collected from the Study Conclusion eCRF form. "COMPLETED" subjects are those completing the study without reasons beyond the completion of the study commitment. "WITHDRAWN" subjects are those either withdrawn from Maintenance / Extension phase, or those who completed Maintenance phase and decided not to enter Extension phase due to reasons beyond the completion of the study commitment (Subjects xxx, xxx, and xxx are in this group and	W48, W96, EOS

Study Population Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
						their primary reasons for withdrawal are xxx, xxx and xxx respectively.)." Update the numbering of other footnotes accordingly. Footnotes may be adjusted as appropriate. Add a section "Type of Adverse Events Which Led to Study Withdrawal" with categories "COVID-19" and "Non-COVID-19".	
1.4	1.4	NA	Intent-to-Treat Exposed	ES1	Summary of Subject Accountability: Maintenance Phase Conclusion Record	For W96: Add a section "Type of Adverse Events Which Led to Study Withdrawal" with categories "COVID-19" and "Non-COVID-19".	HL, W48, W96
NA	1.5	1.4	Intent-to-Treat Exposed	ES1	Summary of Subject Accountability: Maintenance + Extension Phase Conclusion Record	For subject status, refer to 201584/primary_07/T1.10 for the layout. For W96 and EOS: Add a section "Type of Adverse Events Which Led to Study Withdrawal" with categories "COVID-19" and "Non-COVID-19".	W96, EOS
1.5	1.6	1.5	Long-term Follow-up	ES1	Summary of Subject Accountability: Long-term Follow-up Phase Conclusion Record	For W96 and EOS: Add a section "Type of Adverse Events Which Led to Study Withdrawal" with categories	W48, W96, EOS

Study Population Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
						"COVID-19" and "Non-COVID-19".	
1.6	1.7	1.6	Intent-to-Treat Exposed	ES4	Summary of Subject Disposition at Each Study Phase	Replace 'Epoch' with 'Phase' in column header. Screening Phase will not be included. Add a footnote "Note: Entry into Long-Term Follow-up is based on presence of a long-term follow-up visit in the eCRF (i.e. LTFU Month 1, LTFU Month 3, etc.) or evidence of filling out the long-term follow-up phase conclusion form." For WK96 and EOS, update the last part of the footnote to be "…or evidence of filling out the long-term follow-up phase conclusion form or indication of continuing into the long-term follow-up phase in the subject continuation form."	W48, W96, EOS
1.7	1.8	1.7	Intent-to-Treat Exposed	ES5	Summary of Reasons for Withdrawal at Each Study Phase	The same comment as above.	W48, W96, EOS
1.8	1.9	1.8	Intent-to-Treat Exposed	201584/primary_01/T1.9	Summary of Subject Accountability: Withdrawals by Visit (Maintenance + Extension Phase)		W48, W96, EOS

Study Population Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.9	1.10	1.9	Intent-to-Treat Exposed	ES1	Summary of Study Drug Discontinuation	Update the row label to 'Primary Reason[1]/Subreason[2] for Study Drug Discontinuation'. For W96 and EOS: Add a section "Type of Adverse Events Which Led to Study Drug Discontinuation" with categories "COVID-19" and "Non-COVID-19".	W48, W96, EOS
1.10	1.11	NA	Intent-to-Treat Exposed	DV1a	Summary of Important Protocol Deviations		W48, W96, EOS
NA	1.12	1.10	Intent-to-Treat Exposed	DV1a	Summary of Important Protocol Deviations (Maintenance + Extension Phase)		W96, EOS
1.11	1.13	1.11	Intent-to-Treat Exposed	IE1	Summary of Inclusion/Exclusion Criteria Deviations		W48, W96
1.12	1.14	1.12	Screened	201585/primary_02/T1.1	Summary of Study Populations	Adjust the footnote as appropriate.	HL, W48, W96, EOS
1.13	1.15	NA	Intent-to-Treat Exposed	201585/primary_02/T1.14	Summary of Protocol Deviations Leading to Exclusion from the Per-Protocol Population		W48, W96
NA	1.36	1.32	Intent-to-Treat Exposed	DV1a	Summary of Important COVID-19 Related Protocol Deviations	Update the label for the first row to be "ANY IMPORTANT COVID-19 RELATED PROTOCOL DEVIATIONS".	W96, EOS

Study Population Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
NA	1.37	1.33	Intent-to-Treat Exposed	DV1a	Summary of Important Non-COVID-19 Related Protocol Deviations	Update the label for the first row to be "ANY IMPORTANT NON-COVID-19 RELATED PROTOCOL DEVIATIONS".	W96, EOS
Demographic and Baseline Characteristics							
1.14	1.16	1.13	Intent-to-Treat Exposed	201585/primary_02/T1.16	Summary of Demographic Characteristics		HL, W48, W96, EOS
1.15	1.17	1.14	Randomized	DM11	Summary of Age Ranges	Also refer to 201585/primary_02/T1.4. Follow the footnote in 201585/primary_02/T1.4.	W48, W96
1.16	1.18	1.15	Intent-to-Treat Exposed	DM5	Summary of Race and Racial Combinations		W48, W96, EOS
1.17	1.19	1.16	Intent-to-Treat Exposed	DM6	Summary of Race and Racial Combinations Details		W48, W96, EOS
1.18	1.20	1.17	Intent-to-Treat Exposed	201585/primary_02/T1.19	Summary of Hepatitis Status at Entry	Add footnote as appropriate for subjects classified as Hepatitis B positive in analysis.	W48, W96
1.19	1.21	1.18	Intent-to-Treat Exposed	201585/primary_02/T1.20	Summary of Derived Baseline CDC Stages of HIV Infection		W48, W96
1.20	1.22	1.19	Intent-to-Treat Exposed	201585/primary_02/T1.21	Summary of Baseline Cardiovascular Risk Assessments		W48, W96

Study Population Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.21	1.23	1.20	Intent-to-Treat Exposed	201585/primary_02/T1.22	Distribution of CD4+ Cell Count Results at Screening and Baseline		W48, W96
1.22	1.24	1.21	Intent-to-Treat Exposed	Shell POP_T1	Summary of Prior Exposure to CAB+RPV		W48, W96
1.23	1.25	1.22	Intent-to-Treat Exposed	201585/primary_02/T1.36	Summary of HIV Risk Factors		W48, W96
Medical Conditions and Medications							
1.24	1.26	1.23	Intent-to-Treat Exposed	MH1	Summary of Current Medical Conditions		W48, W96, EOS
1.25	1.27	1.24	Intent-to-Treat Exposed	MH1	Summary of Past Medical Conditions		W48, W96, EOS
1.26	1.28	1.25	Intent-to-Treat Exposed	MH4	Summary of Current Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders		W48, W96, EOS
1.27	1.29	1.26	Intent-to-Treat Exposed	MH4	Summary of Past Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders		W48, W96, EOS
1.28	1.30	1.27	Intent-to-Treat Exposed	201585/primary_02/T1.28	Summary of Prior ART Medications	Remove the footnote. Follow definitions in Section 6.2 to	W48, W96

Study Population Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
						determine the prior ART medications.	
1.29	1.31	NA	Intent-to-Treat Exposed	CM8	Summary of Concomitant Non-ART Medication Ingredient Combinations (Maintenance Phase)		W48, W96
NA	1.32	1.28	Intent-to-Treat Exposed	CM8	Summary of Concomitant Non-ART Medication Ingredient Combinations (Maintenance + Extension Phase)		W96, EOS
1.30	1.33	1.29	Intent-to-Treat Exposed	201585/primary_02/T1.33	Summary of Lipid Modifying Agent Use at Baseline		W48, W96
1.31	1.34	1.30	Intent-to-Treat Exposed	201585/primary_02/T1.34	Summary of Lipid Modifying Agent Use Started during the Maintenance Phase		W48, W96
1.32	1.35	1.31	Intent-to-Treat Exposed	201585/primary_02/T1.35	Summary of Substance Use at Entry		W48, W96

15.15.5.2. Efficacy Tables

Note: For subgroup analyses, include rederived randomization strata (i.e. prior exposure to CAB+RPV: 0, 1-24, >24 weeks), all demographic and baseline characteristic subgroups as mentioned in EMA Subgroup Category 2 in Section 5.4.2, unless otherwise specified. Not all subjects on Q8W arm are planned to have viral load data collected at Week 4 (Week 4A or 4B), so leave Week 4 data blank for Q8W arm in by-visit snapshot analysis.

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Primary Efficacy Analyses							
2.1	2.1	NA	Intent-to-Treat Exposed	201584/primary_01/T2.1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis – ITT-E	Adjust the footnotes as appropriate. For WK96, replace 'Week 48' with 'Week 96' in title.	HL, W48, W96
2.2	2.2	NA	Per-Protocol	201584/primary_01/T2.2	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis – Per-Protocol	Adjust the footnotes as appropriate. For WK96: replace 'Week 48' with 'Week 96' in title.	HL, W48, W96
2.3	2.3	NA	Intent-to-Treat Exposed	201584/primary_01/T2.3	Summary of Study Outcomes (50 c/mL Threshold) at Week 48 (Maintenance Phase) – Snapshot Analysis	For WK96: replace 'Week 48' with 'Week 96' in title. Use shell EFF_T5 for mock-up.	HL, W48, W96
2.4	2.4	NA	Intent-to-Treat Exposed	Shell EFF_T3	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 48 (Maintenance Phase) - Snapshot Analysis	For WK96, replace 'Week 48' with 'Week 96' in title.	HL, W48, W96

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.5	2.5	NA	Intent-to-Treat Exposed	201584/primary_01/T2.5	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 48 by Subgroup (Maintenance Phase) - Snapshot Analysis	Adjust the footnote/column header label as appropriate. For WK96, replace 'Week 48' with 'Week 96' in title. Do not include rederived randomization strata in the table.	W48, W96
2.6	2.6	NA	Intent-to-Treat Exposed	Shell EFF_T4	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 48 among Subjects with >=1 Weeks Prior Exposure to CAB+RPV (Maintenance Phase) - Snapshot Analysis	For WK96, replace 'Week 48' with 'Week 96' in title.	W48, W96
2.7	2.7	NA	Intent-to-Treat Exposed	201584/primary_01/T2.6	Summary of Study Outcomes (50 c/mL Threshold) at Week 48 by Subgroup (Maintenance Phase) – Snapshot Analysis	For WK96: replace 'Week 48' with 'Week 96' in title. Use shell EFF_T5 for mock-up of each subgroup's study outcomes.	W48, W96
Secondary and Exploratory Efficacy Analyses							
2.8	2.8	NA	Intent-to-Treat Exposed	201584/primary_01/T2.7	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis – ITT-E	Adjust the footnotes as appropriate. For WK96, replace 'Week 48' with 'Week 96' in title.	HL, W48, W96
2.9	2.9	NA	Per-Protocol	201584/primary_01/T2.8	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis – Per-Protocol	Adjust the footnotes as appropriate. For WK96, replace 'Week 48' with 'Week 96' in title.	HL, W48, W96

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.10	2.10	NA	Intent-to-Treat Exposed	Shell EFF_T3	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 (Maintenance Phase) - Snapshot Analysis	Replace 'Number of HIV-1 RNA >=50 c/mL' with 'Number of HIV-1 RNA <50 c/mL' in column header. For WK96, replace 'Week 48' with 'Week 96' in title.	HL, W48, W96
2.11	2.11	NA	Intent-to-Treat Exposed	201584/primary_01/T2.10	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 by Subgroup (Maintenance Phase) - Snapshot Analysis	Adjust the footnote/column header label as appropriate. For WK96, replace 'Week 48' with 'Week 96' in title. Do not include rederived randomization strata in the table.	W48, W96
2.12	2.12	NA	Intent-to-Treat Exposed	Shell EFF_T4	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 among Subjects with >=1 Weeks Prior Exposure to CAB+RPV (Maintenance Phase) - Snapshot Analysis	Replace 'Number of HIV-1 RNA >=50 c/mL' with 'Number of HIV-1 RNA <50 c/mL' in column header. For WK96, replace 'Week 48' with 'Week 96' in title.	W48, W96
2.13	2.13	NA	Intent-to-Treat Exposed	201584/primary_01/T2.11	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.14	2.14	NA	Intent-to-Treat Exposed	201584/primary_01/T2.12	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Subgroup and Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.15	2.15	NA	Intent-to-Treat Exposed	201584/primary_01/T2.15	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.16	2.16	NA	Intent-to-Treat Exposed	201584/primary_01/T2.16	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Subgroup and Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.17	2.17	NA	Intent-to-Treat Exposed	201584/primary_01/T2.17	Proportion of Subjects with Plasma HIV-1 RNA <200 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.18	2.18	NA	Intent-to-Treat Exposed	201584/primary_01/T2.17	Proportion of Subjects with Plasma HIV-1 RNA >=200 c/mL by Visit (Maintenance Phase) – Snapshot Analysis	Adjust column headers as appropriate. Keep one decimal place for proportion.	W48, W96
2.19	2.19	NA	Intent-to-Treat Exposed	Shell EFF_T1	Summary of Kaplan-Meier Estimates of Proportion of Subjects Without Confirmed Virologic Failure at Week 48 - Treatment Related Discontinuation = Failure	Adjust the row labels and footnotes as appropriate. For WK96, replace 'Week 48' with 'Week96' in title.	W48, W96
2.20	2.20	NA	Intent-to-Treat Exposed	Shell EFF_T2	Summary of Kaplan-Meier Estimates of Proportion of Subjects Without Confirmed Virologic Failure at Week 48 - Efficacy Related Discontinuation = Failure	Adjust the row labels and footnotes as appropriate. For WK96, replace 'Week 48' with 'Week96' in title.	W48, W96

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.21	2.21	NA	Intent-to-Treat Exposed	201585/primary_02/T2.19	Proportion of Subjects with HIV-1 RNA >=50 c/mL at Week 48 (Snapshot) by Last Delay in IP Injection (Maintenance Phase)	Display both arms. Change the footnote to 'The last delay in IP injection will be the delay in IP injection at Week 48, or the delay in last IP injection prior to Week 48 if a participant did not receive Week 48 injection (i.e. missing visit or withdrawal).'. For WK96, replace 'Week 48' with 'Week 96' in the title and footnote accordingly.	W48, W96
2.22	2.22	2.1	Intent-to-Treat Exposed	201585/primary_02/T2.20	Summary of Plasma HIV-1 RNA (log10 c/mL) by Visit (Maintenance + Extension Phase)		W48, W96, EOS
2.23	2.23	NA	Intent-to-Treat Exposed	201585/primary_02/T2.21	Cumulative Proportion of Subjects Meeting Confirmed Virology Failure Criteria by Visit during the Maintenance Phase (Up to Week 48)	For WK96, remove 'Up to Week 48' in title.	HL, W48, W96
2.24	2.24	2.2	Intent-to-Treat Exposed	201584/primary_01/T2.21	Cumulative Proportion of Subjects Meeting Confirmed Virology Failure Criteria (Maintenance + Extension Phase)		HL, W48, W96, EOS
2.25	2.25	NA	Confirmed Virologic Failure	201584/primary_01/T2.24	Distribution of Quantitative Plasma HIV-1 RNA Results at Suspected and Confirmation of Confirmed Virologic Failure (Maintenance Phase)		W48, W96

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.26	2.26	NA	Intent-to-Treat Exposed	201585/primary_02/T2.34	Proportion of Subjects with Plasma HIV-1 RNA <2 c/mL by Visit (Maintenance Phase)	Change footnote to 'Note: Data come from BioMontr low-level assay. Only visits with available data from this assay are included.'	W48, W96
2.27	2.27	NA	Intent-to-Treat Exposed	201584/primary_01/T2.51	Summary of Study Outcomes (200 c/mL Threshold) at Week 48 (Maintenance Phase) – Snapshot Analysis	For WK96: replace 'Week 48' with 'Week 96' in title. Use shell EFF_T5 for mock-up.	W48, W96
2.28	2.28	NA	Intent-to-Treat Exposed	201585/primary_02/T2.37	Summary of Subjects per Viral Load Category by Visit (Maintenance Phase)	Refer to 'Summary for Participants per Viral Load Category by Visit' in Section 15.6.3. Remove footnote [2]. Add a footnote "Note: The visit windows are based on snapshot analysis windows'.	W48, W96
2.29	2.29	2.3	Intent-to-Treat Exposed	201585/primary_02/T2.25	Summary of Change from Baseline in CD4+ Cell Count (cells/mm^3) by Visit (Maintenance + Extension Phase)		W48, W96, EOS
2.30	2.30	NA	Intent-to-Treat Exposed	201585/primary_02/T2.38	Summary of Change from Baseline in CD4+ Cell Count (cells/mm^3) at Week 48 by Subgroup (Maintenance Phase)	For WK96, replace 'Week 48' with 'Week 96' in title.	W48, W96
2.31	2.31	2.4	Intent-to-Treat Exposed	201585/primary_02/T2.26	Summary of CD4+ Cell Count (cells/mm^3) by Visit (Maintenance + Extension Phase)		W48, W96, EOS
2.32	2.32	2.5	Intent-to-Treat Exposed	201585/primary_02/T2.28	Summary of Change from Baseline in CD8+ Cell Count (cells/mm^3) by Visit (Maintenance Phase)		W48, W96, EOS

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.33	2.33	2.6	Intent-to-Treat Exposed	201585/primary_02/T2.27	Summary of CD8+ Cell Count (cells/mm^3) by Visit (Maintenance Phase)		W48, W96, EOS
2.34	2.34	2.7	Intent-to-Treat Exposed	201585/primary_02/T2.29	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit (Maintenance Phase)	Ratio will be taken when both CD4+ and CD8+ are available on the same date.	W48, W96, EOS
2.35	2.35	NA	Intent-to-Treat Exposed	201585/primary_02/T2.30	Summary of HIV-1 Associated Conditions Including Recurrences (Maintenance Phase)		W48, W96
NA	NA	2.8	Intent-to-Treat Exposed	201585/primary_02/T2.30	Summary of HIV-1 Associated Conditions Including Recurrences (Maintenance +Extension Phase)		EOS
2.36	2.36	NA	Intent-to-Treat Exposed	201585/primary_02/T2.31	Summary of HIV-1 Associated Conditions Excluding Recurrences (Maintenance Phase)		W48, W96
NA	NA	2.9	Intent-to-Treat Exposed	201585/primary_02/T2.31	Summary of HIV-1 Associated Conditions Excluding Recurrences (Maintenance +Extension Phase)		EOS
2.37	2.37	NA	Intent-to-Treat Exposed	201584/primary_01/T2.47	Summary of HIV-1 Disease Progression and/or Deaths (Maintenance Phase)	For WK96: add a superscript [1] to the first n and add a footnote: “Note: It is the denominator for all percentages.”	W48, W96

Efficacy Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
NA	NA	2.10	Intent-to-Treat Exposed	207966/primary_02/T2.37	Summary of HIV-1 Disease Progression and/or Deaths (Maintenance + Extension Phase)	Replace “maintenance” with “maintenance and extension” in the footnote; add a superscript [1] to the first n and add a footnote: “Note: It is the denominator for all percentages.”	EOS
2.38	2.38	2.11	Intent-to-Treat Exposed	207966/primary_02/T2.38	Summary of Change from Baseline in Plasma HIV-1 RNA (log10 c/mL) by Visit (Maintenance + Extension Phase)		W48, W96, EOS

15.15.5.3. Efficacy Figures

Note: For subgroup analyses, include rederived randomization strata (i.e. prior exposure to CAB+RPV: 0, 1-24, >24 weeks), all demographic and baseline characteristic subgroups as mentioned in EMA Subgroup Category 2 in Section 5.4.2, unless otherwise specified. Not all subjects on Q8W arm are planned to have viral load data collected at Week 4 (Week 4A or 4B), so leave Week 4 data blank for Q8W arm in by-visit snapshot analysis.

Efficacy Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Primary Efficacy Analyses							
2.1	2.1	NA	Intent-to-Treat Exposed	201585/primary_02/F2.1	Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		HL, W48, W96
2.2	2.2	NA	Intent-to-Treat Exposed	201584/primary_01/F2.2	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL at Week 48 by Subgroup – Snapshot Analysis	Non-inferiority margin is 4%. Adjust the footnotes, reference line and labels as appropriate. For WK96, replace 'Week 48' with 'Week 96' in title.	W48, W96
Secondary and Exploratory Efficacy Analyses							
2.3	2.3	NA	Intent-to-Treat Exposed	201585/primary_02/F2.3	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		HL, W48, W96
2.4	2.4	NA	Intent-to-Treat Exposed	201584/primary_01/F2.4	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL at Week 48 by Subgroup – Snapshot Analysis	Adjust the footnotes, reference line and labels as appropriate. For WK96, replace 'Week 48' with 'Week 96' in title.	W48, W96

Efficacy Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.5	2.5	NA	Intent-to-Treat Exposed	201585/primary_02/F2.10	Proportion (95% CI) of Subjects with HIV-1 RNA >=200 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.6	2.6	NA	Intent-to-Treat Exposed	201585/primary_02/F2.5	Proportion (95% CI) of Subjects with HIV-1 RNA <200 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.7	2.7	2.1	Intent-to-Treat Exposed	207966/idmc_03/F2.1	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit – for CVF Subjects		HL, W48, W96, EOS
2.8	2.8	NA	Intent-to-Treat Exposed	207966/idmc_03/F2.1	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit for subjects Who are in the Category of 'HIV-1 RNA >=50 c/mL' at Week 48 per Snapshot Algorithm	For WK96, replace 'Week 48' with 'Week 96' in the title.	HL, W48, W96

15.15.5.4. Safety Tables

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Exposure							
3.1	3.1	3.1	Safety	201585/primary_02/T3.1	Summary of Extent of Exposure to Investigational Product (Maintenance Phase)	No need for the first two footnotes. Update the last footnote to be below: Note: The injection at nominal visit of Week 100 was not included in the summary of Exposure (No. of IP injections). For W96 and EOS: Replace "Investigational Product" with "Study Treatment including SOC Oral Bridging" in the title; Add sections after Section "Exposure (No. of IP injection visits)" for exposure to CAB+RPV oral bridging and exposure to SOC oral bridging similarly to exposure to oral lead-in; Add sections for overall exposure to IP similarly to overall exposure; the levels for categorical summaries will be selected as appropriate.	W48, W96
NA	3.2	3.2	Safety	201585/primary_02/T3.1	Summary of Extent of Exposure to Investigational Product (Maintenance + Extension Phase)	Remove the footnotes. For W96 and EOS: update similarly to the table above.	W96, EOS
3.2	3.3	NA	Safety	201585/primary_03/T3.102	Summary of Needle Length and Gauge for CAB Injection (Maintenance Phase)	Display both arms.	W48, W96
3.3	3.4	NA	Safety	201585/primary_03/T3.103	Summary of Needle Length and Gauge for RPV Injection (Maintenance Phase)	Display both arms.	W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.4	3.5	NA	Safety	201585/primary_02/T3.6	Summary of Adherence to CAB/RPV Injection Dosing Schedule (Maintenance Phase)	Display both arms. Adjust the footnotes as appropriate. For W96, present "Missed Injection with CAB+RPV Oral Bridging" and "Missed Injection with SOC Oral Bridging" separately.	W48, W96
Adverse Events							
3.5	3.6	NA	Safety	201585/primary_02/T3.7	Summary of All Adverse Events by System Organ Class (Maintenance Phase)		W48, W96
3.6	3.7	NA	Safety	201585/primary_02/T3.8	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Maintenance Phase)		HL, W48, W96
NA	3.8	3.3	Safety	201585/primary_02/T3.8	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W96, EOS
3.7	3.9	NA	Safety	201585/primary_02/T3.8	Summary of All Adverse Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity (Maintenance Phase)		HL, W48, W96
NA	NA	3.4	Safety	201585/primary_02/T3.8	Summary of All Adverse Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		EOS
NA	NA	3.5	Long-term Follow-up	201585/primary_02/T3.8	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Long-term Follow-up Phase)		EOS
3.8	3.10	NA	Safety	201585/primar	Summary of All On-treatment Adverse		W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				y_02/T3.11	Events by System Organ Class and Maximum Toxicity (Maintenance Phase)		
3.9	NA	NA	Oral Lead-in	201585/primary_02/T3.13	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Oral Lead-in Period during the Maintenance Phase)	Remove the footnote. Display both arms.	W48
3.10	3.11	NA	Safety	201585/primary_02/T3.14	Summary of Common Adverse Events (>=5%) by Overall Frequency (Maintenance Phase)		W48, W96
3.11	3.12	NA	Safety	201585/primary_02/T3.15	Summary of Common Grade 2-5 Adverse Events (>=1%) by Overall Frequency (Maintenance Phase)		W48, W96
3.12	3.13	NA	Safety	201585/primary_02/T3.16	Summary of All Drug-related Adverse Events by System Organ Class (Maintenance Phase)		W48, W96
3.13	3.14	NA	Safety	201585/primary_02/T3.17	Summary of All Drug-related Adverse Events by System Organ Class and Maximum Toxicity (Maintenance Phase)		HL, W48, W96
NA	3.15	3.6	Safety	201585/primary_02/T3.17	Summary of All Drug-related Adverse Events by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W96, EOS
3.14	3.16	NA	Safety	201585/primary_02/T3.101	Summary of All Drug-related Adverse Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity (Maintenance Phase)		HL, W48, W96
NA	NA	3.7	Safety	201585/primar	Summary of All Drug-related Adverse		EOS

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				y_02/T3.101	Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		
3.15	3.17	NA	Safety	201585/primary_02/T3.20	Summary of All Drug-Related Grade 2-5 Adverse Events by Overall Frequency (Maintenance Phase)		W48, W96
Serious and Other Significant Adverse Events							
3.16	3.18	NA	Safety	201585/primary_02/T3.21	Summary of Serious Adverse Events by System Organ Class (Maintenance Phase)		HL, W48, W96
NA	3.19	3.8	Safety	201585/primary_02/T3.21	Summary of Serious Adverse Events by System Organ Class (Maintenance + Extension Phase)		W96, EOS
3.17	3.20	3.9	Long-term Follow-up	201585/primary_02/T3.24	Summary of Serious Adverse Events by System Organ Class (Long-term Follow-up Phase)		W48, W96, EOS
3.18	NA	NA	Oral Lead-in	201585/primary_02/T3.25	Summary of Serious Adverse Events by System Organ Class (Oral Lead-in Period during the Maintenance Phase)	Display both arms.	W48
3.19	3.21	NA	Safety	201585/primary_02/T3.26	Summary of Drug-related Serious Adverse Events by System Organ Class (Maintenance Phase)		W48, W96
NA	3.22	3.10	Safety	201585/primary_02/T3.26	Summary of Drug-related Serious Adverse Events by System Organ Class (Maintenance + Extension Phase)		W96, EOS
3.20	3.23	NA	Safety	201585/primary_02/T3.29	Summary of Non-Fatal Serious Adverse Events by Overall Frequency (Maintenance		W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
					Phase)		
3.21	3.24	NA	Safety	201585/primary_02/T3.30	Summary of Drug-related Non-Fatal Serious Adverse Events by Overall Frequency (Maintenance Phase)		W48, W96
3.22	3.25	NA	Safety	201585/primary_02/T3.31	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class (Maintenance Phase)		HL, W48, W96
NA	3.26	3.11	Safety	201585/primary_02/T3.31	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class (Maintenance + Extension Phase)		W96, EOS
3.23	NA	NA	Oral Lead-in	201585/primary_02/T3.34	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class (Oral Lead-in Period during the Maintenance Phase)	Remove the footnote. Display both arms.	W48
3.24	3.27	NA	Safety	201585/primary_02/T3.35	Summary of Common (>=5%) Non-Serious Adverse Events (Maintenance Phase)		W48, W96
3.25	3.28	NA	Safety	201585/primary_02/T3.36	Summary of Subjects and Number of Occurrences of Common (>=5%) Non-Serious Adverse Events by System Organ Class (Maintenance Phase)		W48, W96
3.26	3.29	NA	Safety	201585/primary_02/T3.37	Summary of Subjects and Number of occurrences of SAEs, Fatal SAEs, and Drug-related SAEs (Maintenance Phase)		W48, W96
3.27	3.30	NA	Safety	201585/primar	Summary of Cumulative Adverse Events	Note that this table only display AEs	W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				y_02/T3.38	by Visit (Maintenance Phase)	occurring >=5% subjects during Maintenance Phase.	
Study Drug Injection Site Reaction Adverse Events (display for both arms)							
3.28	3.31	NA	Safety	201585/primary_02/T3.40	Summary of Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - Maintenance Phase		HL, W48, W96
NA	3.32	3.12	Safety	201585/primary_02/T3.40	Summary of Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - Maintenance + Extension Phase		W96, EOS
3.29	3.33	NA	Safety	201585/primary_02/T3.43	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common (Maintenance Phase)		W48, W96
NA	3.34	3.13	Safety	201585/primary_02/T3.43	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common (Maintenance + Extension Phase)		W96, EOS
3.30	3.35	NA	Safety	201585/primary_02/T3.46	Summary of Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity – Overall and Common (Maintenance Phase)	Change the second footnote to 'Note: Common ISR includes pain, induration, nodules and any other ISR with >=5% subjects in either treatment arm.' Footnote may be adjusted for clarifications.	W48, W96
3.31	3.36	NA	Safety	201585/primary_02/T3.47	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - CAB		W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
					(Maintenance Phase)		
3.32	3.37	NA	Safety	201585/primary_02/T3.48	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events (Maintenance Phase) - Overall and Common (CAB)		W48, W96
3.33	3.38	NA	Safety	201585/primary_02/T3.49	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity (Maintenance Phase) - CAB	Footnote may be adjusted for clarifications.	W48, W96
3.34	3.39	NA	Safety	201585/primary_02/T3.50	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length (Maintenance Phase) – Common (CAB)	Update the needle length in column header to be "<=1.5 inches', '>1.5 to <2 inches' and '>=2 inches' respectively. Change the first footnote to 'Note: Common ISR includes pain, induration, nodules and any other ISR with >=5% subjects in either treatment arm.'. Remove the second footnote.	W48, W96
3.35	3.40	NA	Safety	201585/primary_02/T3.51	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - RPV (Maintenance Phase)		W48, W96
3.36	3.41	NA	Safety	201585/primary_02/T3.52	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events (Maintenance Phase) - Overall and Common (RPV)		W48, W96
3.37	3.42	NA	Safety	201585/primary_02/T3.53	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction	Footnote may be adjusted for clarifications.	W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
					Adverse Events by Visit and Maximum Severity (Maintenance Phase) - RPV		
3.38	3.43	NA	Safety	201585/primary_02/T3.54	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length (Maintenance Phase) – Common (RPV)	Update the needle length in column header to be "<=1.5 inches', '>1.5 to < 2 inches' and '>=2 inches' respectively. Change the first footnote to 'Note: Common ISR includes pain, induration, nodules and any other ISR with >=5% subjects in either treatment arm.'. Remove the second footnote.	W48, W96
Laboratory: Chemistry and Hematology							
3.39	3.44	3.14	Safety	201585/primary_02/T3.55	Summary of Chemistry Changes from Baseline by Visit (Maintenance + Extension Phase)	Present GFR, lipids and glucose in both conventional and standard units. Change 'Post Baseline' to 'Post-baseline' in the footnote.	W48, W96, EOS
3.40	3.45	3.15	Safety	201585/primary_02/T3.59	Summary of Chemistry Values by Visit (Maintenance + Extension Phase)	Present GFR, lipids and glucose in both conventional and standard units. Change 'Post Baseline' to 'Post-baseline' in the footnote.	W48, W96, EOS
3.41	3.46	3.16	Safety	201585/primary_02/T3.60	Summary of Hematology Changes from Baseline by Visit (Maintenance + Extension Phase)	Change 'Post Baseline' to 'Post-baseline' in the footnote.	W48, W96, EOS
3.42	3.47	3.17	Safety	201585/primary_02/T3.59	Summary of Hematology Values by Visit (Maintenance + Extension Phase)	Remove the first footnote. Change 'Post Baseline' to 'Post-baseline' in the footnote.	W48, W96, EOS
3.43	3.48	NA	Safety	201585/primar	Summary of Maximum Post-Baseline	Add "Emergent is relative to last	W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				y_02/T3.61	Emergent Chemistry Toxicities (Maintenance Phase)	toxicity up to and including baseline." to the end of the second footnote.	
NA	3.49	3.18	Safety	201585/primary_02/T3.61	Summary of Maximum Post-Baseline Emergent Chemistry Toxicities (Maintenance + Extension Phase)	Adjust the footnote similar to above.	W96, EOS
3.44	NA	NA	Oral Lead-in	201585/primary_02/T3.64	Summary of Maximum Post-Baseline Emergent Chemistry Toxicities - Oral Lead-in Period during the Maintenance Phase	Display both arms. Adjust the footnote similarly to above.	W48
3.45	3.50	NA	Safety	201585/primary_02/T3.65	Summary of Maximum Post-Baseline Emergent Hematology Toxicities (Maintenance Phase)	Adjust the footnote similarly to above.	W48, W96
NA	3.51	3.19	Safety	201585/primary_02/T3.65	Summary of Maximum Post-Baseline Emergent Hematology Toxicities (Maintenance + Extension Phase)	Adjust the footnote similarly to above.	W96, EOS
3.46	NA	NA	Oral Lead-in	201585/primary_02/T3.68	Summary of Maximum Post-Baseline Emergent Hematology Toxicities - Oral Lead-in Period during the Maintenance Phase	Display both arms. Adjust the footnote similarly to above.	W48
NA	3.114	NA	Safety	Shell SAF_T2	Summary of Expected and Missed Visits (Maintenance Phase) - Hematology and Chemistry		W96
Laboratory: Urinalysis							
3.47	3.52	3.20	Safety	201585/primary_02/T3.69	Summary of Urinalysis Dipstick Results by Visit (Maintenance Phase)	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96
3.48	3.53	3.21	Safety	201585/primary_02/T3.70	Summary of Urine Concentrations Changes from Baseline by Visit (Maintenance Phase)	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.49	3.54	NA	Safety	201585/primary_02/T3.71	Summary of Changes in Proteinuria Baseline Laboratory Result to Maximum Post-Baseline Laboratory Result (Maintenance Phase)	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96
Laboratory: Lipid							
3.50	3.55	NA	Safety	201585/primary_02/T3.72	Summary of Changes in Baseline NCEP Fasting Lipid Category to Maximum Post-Baseline Category – Triglycerides (Maintenance Phase)	For WK96, update the title to be "… Category (Triglycerides, Lipids LOCF) – Maintenance Phase".	W48, W96
3.51	3.56	NA	Safety	201585/primary_02/T3.73	Summary of Changes in Baseline NCEP Fasting Lipid Category to Maximum Post-Baseline Category – Total Cholesterol (Maintenance Phase)	For WK96, update the title to be "… Category (Total Cholesterol, Lipids LOCF) – Maintenance Phase".	W48, W96
3.52	3.57	NA	Safety	201585/primary_02/T3.74	Summary of Changes in Baseline NCEP Fasting Lipid Category to Minimum Post-Baseline Category – HDL Cholesterol (Maintenance Phase)	For WK96, update the title to be "… Category (HDL Cholesterol, Lipids LOCF) – Maintenance Phase".	W48, W96
3.53	3.58	NA	Safety	201585/primary_02/T3.75	Summary of Changes in Baseline NCEP Fasting Lipid Category to Maximum Post-Baseline Category – LDL Cholesterol (Maintenance Phase)	For WK96, update the title to be "… Category (LDL Cholesterol, Lipids LOCF) – Maintenance Phase".	W48, W96
3.54	3.59	NA	Safety	201585/primary_02/T3.58	Summary of Fasting Lipids Percentage Changes from Baseline by Visit (Maintenance Phase) - Lipids LOCF	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96
3.55	3.60	NA	Safety	201585/primary_02/T3.76	Summary of Fasting TC/HDL ratio Changes from Baseline (Maintenance Phase) – Lipids LOCF	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Laboratory: Hepatobiliary (Liver)							
3.56	3.61	NA	Safety	201585/primary_02/T3.80	Summary of Liver Monitoring/Stopping Event Reporting (Maintenance Phase)	For WK96: Remove "Monitoring/" from the title, remove liver monitoring related text, footnote and section in the table.	W48, W96
3.57	3.62	NA	Safety	201585/primary_02/T3.81	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria (Maintenance Phase)		W48, W96
NA	3.63	3.22	Safety	201585/primary_02/T3.81	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria (Maintenance +Extension Phase)		W96, EOS
3.58	NA	NA	Oral Lead-in	201585/primary_02/T3.84	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria – Oral Lead-in Period during the Maintenance Phase	Display both arms.	W48
ECG							
3.59	3.64	3.23	Safety	201585/primary_02/T3.85	Summary of ECG Findings (Maintenance Phase)	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96
3.60	3.65	3.24	Safety	201585/primary_02/T3.88	Summary of Change from Baseline in ECG values by Visit (Maintenance Phase)	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96
3.61	3.66	3.25	Safety	201585/primary_02/T3.91	Summary of QTc Values by Category (Maintenance Phase)	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96
3.62	3.67	3.26	Safety	201585/primary_02/T3.94	Summary of Change from Baseline QTc Values by Category (Maintenance Phase)	Change 'Post Baseline' to 'Post-Baseline' in the footnote.	W48, W96
Vital Signs and eC-SSRS							
3.63	3.68	NA	Safety	201585/primar	Summary of Change from Baseline in Vital	Change 'Post Baseline' to 'Post-	W48, W96

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				y_02/T3.97	Signs by Visit (Maintenance Phase)	Baseline' in the footnote.	
3.64	3.69	NA	Safety	SAFE_T1	Summary of BMI Shift from Baseline by Visit (Maintenance Phase)	For WK96: Add "Sex and" before "Visit" in the title.	W48, W96
NA	3.70	NA	Safety	207966/primary_02/T3.64	Summary of BMI Shift from Baseline by Strata and Visit (Maintenance Phase)	Display by strata instead of sex (i.e. prior exposure to CAB + RPV: All, 0, 1-24, >24 weeks) and visit, add a footnote for strata.	W96
NA	3.71	NA	Safety	207966/primary_02/T3.63	Summary of Change from Baseline in Weight and BMI by Strata and Visit (Maintenance Phase)	Display by strata (i.e. prior exposure to CAB + RPV: All, 0, 1-24, >24 weeks) and parameter, add a footnote for strata.	W96
3.65	3.72	NA	Safety	201585/primary_02/T3.99	Summary of Subjects with eC-SSRS Suicidal Ideation or Behaviour (Maintenance Phase)	Change 'post baseline' to 'post-baseline' in the row header.	W48, W96
Adverse Event of Special Interest (AESI)							
3.66	3.73	NA	Safety	201585/primary_02/T3.100	Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and Prior History of Depression, Anxiety and Suicidal Ideation at Screening (Maintenance Phase)	For WK96, follow display 207966/primary_13/T3.98.	W48, W96
NA	3.74	3.27	Safety	207966/primary_13/T3.98	Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and Prior History of Depression, Anxiety and Suicidal Ideation at Screening (Maintenance + Extension		W96, EOS

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
					Phase)		
3.67-3.83	3.75-3.91	NA	Safety	209522/iss_01/T3.38-3.49, T3.51-3.55	Summary of XXX Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrence) – Maintenance Phase	Only display data from this study, no need for showing study number. For 'XXX', refer to Table 4.	W48, W96
NA	3.92-3.108	3.28-3.44	Safety	207966/primary_02T3.67-3.83	Summary of XXX Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrence) – Maintenance + Extension Phase		W96, EOS
3.84	3.109	NA	Safety	209522/iss_01/T3.62	Summary of Characteristics of Common Adverse Events of Special Interest – Maintenance Phase	Only display data from this study, no need for showing study number. Present by individual common AESI. For WK96, add a footnote, "Note: Percentages are based on the Number of subjects with Event. For Event Characteristics, Outcome and Action Taken sections, a subject can be counted in more than one category."	W48, W96
NA	3.110	3.45	Safety	207966/primary_02/T3.84	Summary of Characteristics of Common Adverse Events of Special Interest – Maintenance + Extension Phase	For WK96, add a similar footnote to Table 3.109.	W96, EOS
NA	3.111	3.46	Safety	207966/regqry_2019_01/T3.207	Summary of Syncope and Presyncope Adverse Events - Maintenance + Extension Phase	Replace row label "Syncope or Presyncope" with "Number of Subjects with Syncope or Presyncope".	W96, EOS
NA	3.112	3.47	Safety	207966/regqry	Summary of Syncope and Presyncope	Row labels and footnotes may be	W96, EOS

Safety Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				_2019_01/T3.208	Adverse Events and Injection Visits - Maintenance + Extension Phase	adjusted as appropriate.	
COVID-19 Adverse Event							
NA	3.113	3.48	Safety	207966/primary_02/T3.6	Summary of COVID-19 Adverse Events by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W96, EOS
NA	3.115	3.49	Safety	Shell SAF_T3	Summary of COVID-19 Assessments (Maintenance + Extension Phase)		W96, EOS

15.15.5.5. Safety Figures

Note: Unless otherwise specified, display both arms.

Safety Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.1	3.1	NA	Safety	201585/primary_02/F3.1	Plot of Common Adverse Events and Relative Risk - Q8W vs. Q4W (Maintenance Phase) – Excluding Study Drug ISRs	Remove the second footnote.	HL, W48, W96
NA	NA	3.1	Safety	207966/primary_02/F3.1	Plot of Common Adverse Events and Relative Risk - Q8W vs. Q4W (Maintenance + Extension Phase) – Excluding Study Drug ISRs		EOS
3.2	3.2	NA	Safety	201585/primary_02/F3.1	Plot of Common Study Drug Injection Site Reaction Adverse Events and Relative Risk - Q8W vs. Q4W (Maintenance Phase)	Remove the second footnote.	HL, W48, W96
NA	NA	3.2	Safety	207966/primary_02/F3.2	Plot of Common Study Drug Injection Site Reaction Adverse Events and Relative Risk - Q8W vs. Q4W (Maintenance +Extension Phase)		EOS
3.3	3.3	NA	Safety	201585/primary_02/F3.5	Plot of Onset, Duration, and Severity of Overall and Common Study Drug Injection Site Reaction AEs by Maximum Grade — CAB and/or RPV (Maintenance Phase)		W48, W96
3.4	3.4	NA	Safety	201585/primary_02/F3.6	Plot of Onset, Duration, and Severity of Overall and Common Drug-related Study Drug Injection Site Reaction AEs by Maximum Grade — CAB (Maintenance Phase)		W48, W96
3.5	3.5	NA	Safety	201585/primary_02/F3.7	Plot of Onset, Duration, and Severity of Overall and Common Drug-related Study Drug Injection Site Reaction AEs by Maximum Grade — RPV (Maintenance Phase)		W48, W96
3.6	3.6	NA	Safety	201585/primar	Plot of Incidence of Maintenance Phase Study	Footnote may be adjusted for	W48, W96

Safety Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				y_02/F3.8	Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV	clarifications.	
NA	NA	3.3	Safety	207966/primary_02/F3.6	Plot of Incidence of Maintenance and Extension Phase Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV		EOS
3.7	3.7	NA	Safety	201585/primary_02/F3.9	Plot of Incidence of Maintenance Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB	Footnote may be adjusted for clarifications.	W48, W96
NA	NA	3.4	Safety	207966/primary_02/F3.7	Plot of Incidence of Maintenance and Extension Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB		EOS
3.8	3.8	NA	Safety	201585/primary_02/F3.10	Plot of Incidence of Maintenance Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV	Footnote may be adjusted for clarifications.	W48, W96
NA	NA	3.5	Safety	207966/primary_02/F3.8	Plot of Incidence of Maintenance and Extension Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV		EOS
3.9	3.9	NA	Safety	201585/primary_02/F3.11	Plot of Incidence of Grade 3-5 Maintenance Phase Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - CAB and/or RPV	Footnote may be adjusted for clarifications.	W48, W96
3.10	3.10	NA	Safety	201585/primary_02/F3.12	Plot of Incidence of Grade 3-5 Maintenance Phase Drug-related Study Drug Injection Site Reaction	Footnote may be adjusted for clarifications.	W48, W96

Safety Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
					Adverse Events by Visit (Overall and Common) - CAB		
3.11	3.11	NA	Safety	201585/primary_02/F3.13	Plot of Incidence of Grade 3-5 Maintenance Phase Drug-related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - RPV	Footnote may be adjusted for clarifications.	W48, W96
3.12	3.12	NA	Safety	201585/primary_02/F3.2	Scatter Plot of Maximum vs. Baseline for ALT (Maintenance Phase)	Display at log10 scale.	HL, W48, W96
NA	3.13	3.6	Safety	207966/primary_02/F3.12	Scatter Plot of Maximum vs. Baseline for ALT (Maintenance + Extension Phase)		W96, EOS
3.13	3.14	NA	Safety	201585/primary_02/F3.3	Scatter Plot of Maximum Total Bilirubin vs. Maximum ALT (Maintenance Phase)		HL, W48, W96
NA	3.15	3.7	Safety	207966/primary_02/F3.13	Scatter Plot of Maximum Total Bilirubin vs. Maximum ALT (Maintenance + Extension Phase)		W96, EOS
3.14	3.16	NA	Safety	201585/primary_02/F3.4	Matrix Plot of Maximum Liver Chemistries during the Maintenance Phase		HL, W48, W96
NA	3.17	3.8	Safety	207966/primary_02/F3.14	Matrix Plot of Maximum Liver Chemistries during the Maintenance and Extension Phase		W96, EOS
3.15	3.18	NA	Safety	201585/primary_02/F3.14	Bar Chart of Lipid NCEP Categories at Week 48 vs. Baseline – Triglycerides, Total Cholesterol, LDL Cholesterol	For WK96, replace 'Week 48' with 'Week 96' and add "(Lipids LOCF)" to the end of the title	W48, W96
3.16	3.19	NA	Safety	201585/primary_02/F3.15	Bar Chart of Lipid NCEP Categories at Week 48 vs. Baseline - HDL Cholesterol	For WK96, replace 'Week 48' with 'Week 96' and add "(Lipids LOCF)" to the end of the title.	W48, W96

Safety Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.17	3.20	NA	Safety	SAFE_F1	Histogram of Timeliness of Injections (Maintenance Phase)		W48, W96
3.18	3.21	NA	Safety	207966/primary_02/F3.18	Plot of Incidence of Maintenance Phase Study Drug Injection Site Reaction Adverse Events by Strata and Visit (Overall and Common) - CAB and/or RPV		W48, W96
NA	NA	3.9	Safety	207966/primary_02/F3.18	Plot of Incidence of Maintenance and Extension Phase Study Drug Injection Site Reaction Adverse Events by Strata and Visit (Overall and Common) - CAB and/or RPV		EOS
NA	3.22	3.10	Safety	207966/regqry_2019_01/F3.203	Patient Profile for Subjects with Syncope or Presyncope Adverse Events (Maintenance + Extension Phase)	Footnotes may be adjusted as appropriate.	WK96, EOS

15.15.5.6. Pharmacokinetic Tables

Note: For WK48 deliverable, data from visits up to Week 48 are included. For WK96 deliverable, except for Table 4.8- Table 4.9, add "(Maintenance Phase)" after visit in the title. Table 4.8- Table 4.9 will only be produced if additional LTFU PK storage samples since the last analysis data cut are planned to be analysed.

Pharmacokinetic Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	4.1	NA	Pharmacokinetic	201585/primary_ 02/T4.1	Summary of Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics	Remove the first footnote.	W48, W96
4.2	4.2	NA	Pharmacokinetic	201585/primary_ 02/T4.2	Summary of Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics	Remove the first footnote.	W48, W96
4.3	4.3	NA	Pharmacokinetic	201585/primary_ 02/T4.3	Summary of Evaluable Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics	Remove the first footnote.	W48, W96
4.4	4.4	NA	Pharmacokinetic	201585/primary_ 02/T4.4	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics	Remove the first footnote.	W48, W96
4.5	4.5	NA	Pharmacokinetic	201585/primary_ 02/T4.3	Summary of Evaluable Plasma CAB PK Concentration (ug/mL) -Time Data by Strata and Treatment and Visit – Including Log-transformed Statistics	Display by rederived randomization strata and add footnote for strata.	W48, W96
4.6	4.6	NA	Pharmacokinetic	201585/primary_ 02/T4.4	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) -Time Data by Strata and Treatment and Visit – Including Log-transformed Statistics	Display by rederived randomization strata and add footnote for strata.	W48, W96

Pharmacokinetic Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.7	NA	NA	Pharmacokinetic	201585/primary_ 02/T4.6	Summary of Results of Steady State Assessment by Strata for Q8W Arm- Evaluable Concentration	Display by rederived randomization strata and add footnote for strata. For Q8W arm only.	W48
NA	4.7	NA	Pharmacokinetic	Shell PK_T1	Summary of Expected and Missed Visits by Strata and Treatment (Maintenance Phase) – Plasma CAB PK Concentration		W96
NA	4.8	NA	Pharmacokinetic	Shell PK_T1	Summary of Expected and Missed Visits by Strata and Treatment (Maintenance Phase) – Plasma RPV PK Concentration		W96
NA	4.9	4.1	Long-term Follow-up	207966/primary_ 02/T4.1	Summary of Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit (Long-term Follow-up Phase) - Including Log-transformed Statistics	Remove the column 'Pl. Time' and the second footnote. Produce only if we have additional LTFU storage samples planned to be analysed since last analysis data cut.	W96, EOS
NA	4.10	4.2	Long-term Follow-up	207966/primary_ 02/T4.2	Summary of Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit (Long-term Follow-up Phase) - Including Log-transformed Statistics	Remove the column 'Pl. Time' and the second footnote. Produce only if we have additional LTFU samples planned to be analysed since last analysis data cut.	W96, EOS

15.15.5.7. Pharmacokinetic Figures

Note: Unless otherwise specified, display both arms. For WK96 deliverable, add "- Maintenance Phase" to the end of the title except for Figure 4.17; display Week 96 visit next to Week 48 visit in the mean and median summary figures and add a footnote as appropriate.

Pharmacokinetic Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	4.1	NA	Pharmacokinetic	201585/primary_02/ F4.1	Individual Plasma CAB Concentration-Time Plots (Linear and Semi-Log)	Also include prior exposure to CAB+RPV (e.g. 0, 1-24, >24 weeks) for each subject.	W48, W96
4.2	4.2	NA	Pharmacokinetic	201585/primary_02/ F4.2	Individual Plasma RPV Concentration-Time Plots (Linear and Semi-Log)	Also include prior exposure to CAB+RPV (e.g. 0, 1-24, >24 weeks) for each subject.	W48, W96
4.3	4.3	NA	Pharmacokinetic	201585/primary_02/ F4.3	Mean (SD) Plasma CAB Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.4	4.4	NA	Pharmacokinetic	201585/primary_02/ F4.5	Mean (SD) Plasma RPV Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.5	4.5	NA	Pharmacokinetic	201585/primary_02/ F4.7	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.6	4.6	NA	Pharmacokinetic	201585/primary_02/ F4.9	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.7	4.7	NA	Pharmacokinetic	201585/primary_02/ F4.7	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots by Strata (Linear and Semi-Log)	Display by rederived randomization strata and add footnote for strata. For WK48, data from visits up to Week 48 are included.	W48, W96
4.8	4.8	NA	Pharmacokinetic	201585/primary_02/	Mean (SD) Evaluable Plasma RPV	Display by rederived	W48, W96

Pharmacokinetic Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				F4.9	Concentration-Time Plots by Strata (Linear and Semi-Log)	randomization strata and add footnote for strata. For WK48, data from visits up to Week 48 are included.	
4.9	4.9	NA	Pharmacokinetic	201585/primary_02/ F4.4	Median (5th and 95th Percentile) Plasma CAB Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.10	4.10	NA	Pharmacokinetic	201585/primary_02/ F4.6	Median (5th and 95th Percentile) Plasma RPV Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.11	4.11	NA	Pharmacokinetic	201585/primary_02/ F4.8	Median (5th and 95th Percentile) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.12	4.12	NA	Pharmacokinetic	201585/primary_02/ F4.10	Median (5th and 95th Percentile) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log)	For WK48, data from visits up to Week 48 are included.	W48, W96
4.13	4.13	NA	Pharmacokinetic	201585/primary_02/ F4.8	Median (5th and 95th Percentile) Evaluable Plasma CAB Concentration-Time Plots by Strata (Linear and Semi-Log)	Display by rederived randomization strata and add footnote for strata. For WK48, data from visits up to Week 48 are included.	W48, W96
4.14	4.14	NA	Pharmacokinetic	201585/primary_02/ F4.10	Median (5th and 95th Percentile) Evaluable Plasma RPV Concentration-Time Plots by Strata (Linear and Semi-Log)	Display by rederived randomization strata and add footnote for strata. For WK48, data from visits up to Week 48 are included.	W48, W96
4.15	4.17	4.1	Long-term	207966/primary_02/	Plasma PK Concentration-Time since	For W96 and EOS: Plot by	W48, W96,

Pharmacokinetic Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Follow-up	F4.15	Last Injection Plots by Strata	treatment instead of by strata and change “Strata” to be “Treatment” in the title; Color-code different strata of prior exposure; exclude RPV concentrations on/after the start of LTFU oral RPV and add footnote for this exclusion; will only be produced if additional LTFU PK storage samples since the last analysis data cut are planned to be analysed.	EOS
4.16	4.15	NA	Pharmacokinetic	207966/primary_06/ F4.16	Median Evaluable Plasma CAB Trough PK Concentration (ug/mL) - Time Plots by Treatment and Strata (Linear and Semi-Log)		W48, W96
4.17	4.16	NA	Pharmacokinetic	207966/primary_06/ F4.17	Median Evaluable Plasma RPV Trough PK Concentration (ng/mL) - Time Plots by Treatment and Strata (Linear and Semi-Log)		W48, W96

15.15.5.8. Pharmacokinetic / Pharmacodynamic Tables

Note: Unless otherwise specified, display by treatment arm.

Pharmacokinetic / Pharmacodynamic Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
PK / PD Efficacy							
5.1	NA	NA	Pharmacokinetic	201584/primary_01/T5.1	Univariable Logistic Regression Analysis of Snapshot 'HIV-1 RNA ≥50 c/mL' at Week 48 by Trough PK Concentration and Subgroup for Subjects without Prior Exposure to CAB + RPV		W48
5.2	NA	NA	Pharmacokinetic	201584/primary_01/T5.2	Multivariable Logistic Regression Analysis of Predictors of Snapshot 'HIV-1 RNA ≥50 c/mL' at Week 48 for Subjects without Prior Exposure to CAB + RPV		W48
5.3	NA	NA	Pharmacokinetic	201584/primary_01/T5.5	Summary of Week 8 Trough CAB PK concentration by Snapshot 'HIV-1 RNA ≥50 c/mL' (Yes vs. No) at Week 48 for Subjects without Prior Exposure to CAB + RPV – Including Log-transformed Statistics		W48
5.4	NA	NA	Pharmacokinetic	201584/primary_01/T5.6	Summary of Week 8 Trough RPV PK concentration by Snapshot 'HIV-1 RNA ≥50 c/mL' (Yes vs. No) at Week 48 for Subjects without Prior Exposure to CAB + RPV – Including Log-transformed Statistics		W48

15.15.5.9. Pharmacokinetic / Pharmacodynamic Figures

Pharmacokinetic / Pharmacodynamic Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
PK / PD Efficacy Analyses							
5.1	NA	NA	Pharmacokinetic	201585/primary_02/F5.3	Scatter Plot of Week 8 Trough CAB PK Concentration by Snapshot 'HIV-1 RNA ≥50 c/mL' (Yes vs. No) at Week 48 for Subjects without Prior Exposure to CAB + RPV		W48
5.2	NA	NA	Pharmacokinetic	201585/primary_02/F5.4	Scatter Plot of Week 8 Trough RPV PK Concentration by Snapshot 'HIV-1 RNA ≥50 c/mL' (Yes vs. No) at Week 48 for Subjects without Prior Exposure to CAB + RPV		W48
5.3	5.1	NA	Pharmacokinetic	207966/internal_01/F5.1	Individual CAB Trough Concentration-time Profiles for Subjects with Snapshot 'HIV-1 RNA ≥50 c/mL' at Week 48 and Median, 5th & 95th Percentile of CAB Conc-Time Profiles for Other Subjects (Semi-Log)	For WK96, replace 'Week 48' with 'Week 96' and add "- Maintenance Phase" to the end of the title. Display by treatment arm.	W48, W96
5.4	5.2	NA	Pharmacokinetic	207966/internal_01/F5.2	Individual RPV Trough Concentration-time Profiles for Subjects with Snapshot 'HIV-1 RNA ≥50 c/mL' at Week 48 and Median, 5th & 95th Percentile of RPV Conc-Time Profiles for Other Subjects (Semi-Log)	For WK96, replace 'Week 48' with 'Week 96' and add "- Maintenance Phase" to the end of the title. Display by treatment arm.	W48, W96
5.5	NA	NA	Pharmacokinetic	201585/primary_02/F5.10	Scatter Plot of Week 8 Trough Concentration of CAB and RPV in Relation to Occurrence of Snapshot 'HIV-1 RNA ≥50 c/mL' at Week 48 for Subjects without Prior Exposure to CAB + RPV		W48

Pharmacokinetic / Pharmacodynamic Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
PK / PD Safety Analyses							
5.6	NA	NA	Pharmacokinetic	201585/primary_02/F5.13	Scatter Plot of Maximum Change from Baseline in ALT versus Last Trough CAB PK Concentrations by Strata and Treatment during the Maintenance Phase	Display by strata and treatment arm. Add footnote for rederived randomization strata.	W48
5.7	NA	NA	Pharmacokinetic	201585/primary_02/F5.14	Scatter Plot of Maximum Change from Baseline in ALT versus Last Trough RPV PK Concentrations by Strata and Treatment during the Maintenance Phase	Display by strata and treatment arm. Add footnote for rederived randomization strata.	W48
5.8	NA	NA	Pharmacokinetic	201585/primary_02/F5.15	Scatter Plot of Maximum Change from Baseline in Total Bilirubin versus Last Trough CAB PK Concentrations by Strata and Treatment during the Maintenance Phase	Display by strata and treatment arm. Add footnote for rederived randomization strata.	W48
5.9	NA	NA	Pharmacokinetic	201585/primary_02/F5.16	Scatter Plot of Maximum Change from Baseline in Total Bilirubin versus Last Trough RPV PK Concentrations by Strata and Treatment during the Maintenance Phase	Display by strata and treatment arm. Add footnote for rederived randomization strata.	W48
5.10	NA	NA	Pharmacokinetic	201585/primary_02/F5.17	Box Plot of Maximum Toxicity Grades of Most Frequently Reported Study Drug ISR Adverse Events versus Last Trough CAB PK Concentrations during the Maintenance Phase by Strata and Treatment	Display by strata and treatment arm. Add footnote for rederived randomization strata. Adjust the footnotes as appropriate.	W48

Pharmacokinetic / Pharmacodynamic Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
5.11	NA	NA	Pharmacokinetic	201585/primary_02/F5.18	Box Plot of Maximum Toxicity Grades of Most Frequently Reported Study Drug ISR Adverse Events versus Last Trough RPV PK Concentrations during the Maintenance Phase by Strata and Treatment	Display by treatment arm. Adjust the footnotes as appropriate.	W48

15.15.5.10. Health Outcomes Tables

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Perception of Injection (PIN)							
6.1	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.1	Proportion of Subjects with Each Individual Item Score in PIN by Visit –LOCF (Maintenance Phase)	Display both arms.	W48
6.2	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.2	Summary of PIN in Domain Scores (Bother of ISRs, Leg movement, Sleep, and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety After, Willingness) by Visit (Maintenance Phase)	Display both arms.	W48
6.3	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.3	Summary and Statistical Analysis of PIN in Domain Scores (Bother of ISRs, Leg movement, Sleep, and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety After, Willingness) by Visit - LOCF (Maintenance Phase)	Display both arms. Adjust the first half of the footnote to "[1] Week 24/48 was compared with the 1st visit (Week 8) based on Wilcoxon signed-rank test, respectively."	W48
6.4	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.4	Summary of PIN Change from Week 8 in Domain Scores (Bother of ISRs, Leg movement, Sleep, and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety After, Willingness) by Visit (Maintenance Phase)	Display both arms. Adjust the footnote to "Note: Actual values are shown at Week 8."	W48

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.5	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.5	Summary of PIN Change from Week 8 in Domain Scores (Bother of ISRs, Leg movement, Sleep, and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety After, Willingness) by Visit – LOCF (Maintenance Phase)	Display both arms. Adjust the footnote to "Note: Actual values are shown at Week 8."	W48
6.6	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.11	Statistical Analysis of PIN Change from Week 8 in Domain Scores (Bother of ISRs, Leg Movement, Sleep, and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety After, Willingness) by Visit – LOCF (Maintenance Phase)	Adjust the column header and the footnote as appropriate.	W48
Health-related Quality of Life (HAT-QoL)							
6.7	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.6	Proportion of Subjects with Each Individual Questionnaire Item Score in HAT-QoL by Visit - LOCF (Maintenance Phase)		W48
6.8	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.7	Summary of Quality of Life (HAT-QoL) Score in Life Satisfaction, HIV Medication, and Disclosure worries by Visit (Maintenance phase)		W48
6.9	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.8	Summary of Quality of Life (HAT-QoL) Score in Life Satisfaction, HIV Medication, and Disclosure worries by Visit - LOCF (Maintenance phase)		W48
6.10	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.9	Summary of Quality of Life Score (HAT-QoL)-Change from Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit (Maintenance Phase)		W48

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.11	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.10	Summary of Quality of Life Score (HAT-QoL)- Change from Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit – LOCF (Maintenance Phase)		W48
6.12	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.11	Statistical Analysis of Quality of Life Score (HAT-QoL)- Change from Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit for Subjects without Prior Exposure to CAB+RPV – LOCF (Maintenance Phase)	Adjust the column header and the footnote as appropriate.	W48
6.13	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.11	Statistical Analysis of Quality of Life Score (HAT-QoL)- Change from Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit for Subjects with Prior Exposure to CAB+RPV – LOCF (Maintenance Phase)	Adjust the column header and the footnote as appropriate.	W48
HIV Treatment Satisfaction Questionnaire Status Version (HIVTSQs)							
6.14	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.18	Proportion of Subjects with HIVTSQs - Individual Item Scores by Visit - LOCF (Maintenance Phase)		W48
6.15	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.19	Proportion of Subjects with HIVTSQs - Individual Item Scores by Visit and Subgroup - LOCF (Maintenance Phase)	The subgroup includes: prior exposure to CAB+RPV (0, 1-24, >=24 weeks), sex at birth, age (<35, 35 - <50, >=50), race (white, non-white), Baseline CD4+ cell count (<350, 350 – <500, >=500)	W48

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.16	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.20	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance Phase)		W48
6.17	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.21	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit – LOCF (Maintenance Phase)		W48
6.18	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.22	Summary of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit (Maintenance Phase)		W48
6.19	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.23	Summary of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit – LOCF (Maintenance Phase)		W48
6.20	NA	NA	Intent-to-Treat Exposed	201585/primary_03/T7.41	Summary of HIVTSQs - Change from Baseline in Individual Item Score by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit – LOCF (Maintenance Phase)		W48
6.21	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.24	Statistical Analysis of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Visit for Subjects without Prior Exposure to CAB+RPV - LOCF (Maintenance Phase)	Adjust column header and footnote as appropriate.	W48
6.22	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.24	Statistical Analysis of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Visit for Subjects with Prior Exposure to CAB+RPV - LOCF (Maintenance Phase)	Adjust column header and footnote as appropriate.	W48

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
HIV Treatment Satisfaction Questionnaire Change Version (HIVTSQc)							
6.23	NA	NA	Q4W ATLAS	201584/primary_01/T6.25	Proportion of Subjects with HIVTSQc - Individual Item Change Score at Week 48 (Maintenance Phase) for Subjects from Q4W ATLAS		W48
6.24	NA	NA	SOC	201584/primary_01/T6.25	Proportion of Subjects with HIVTSQc - Individual Item Change Score at Week 48 (Maintenance Phase) for Subjects from SOC		W48
6.25	NA	NA	Q4W ATLAS	201584/primary_01/T6.26	Summary of HIVTSQc – Total Treatment Satisfaction Change Score at Week 48 (Maintenance Phase) for Subjects from Q4W ATLAS		W48
6.26	NA	NA	SOC	201584/primary_01/T6.26	Summary of HIVTSQc – Total Treatment Satisfaction Change Score at Week 48 (Maintenance Phase) for Subjects from SOC		W48
6.27	NA	NA	Q4W ATLAS	201584/primary_02/T6.41	Summary of HIVTSQc – Individual Item Change Score at Week 48 (Maintenance Phase) for Subjects from Q4W ATLAS		W48
6.28	NA	NA	SOC	201584/primary_02/T6.41	Summary of HIVTSQc – Individual Item Change Score at Week 48 (Maintenance Phase) for Subjects from SOC		W48
6.29	NA	NA	Q4W ATLAS	201584/primary_01/T6.27	Statistical Analysis of HIVTSQc – Total Treatment Satisfaction Change Score at Week 48 (Maintenance Phase) for Subjects from Q4W ATLAS	Adjust column header and footnote as appropriate.	W48
6.30	NA	NA	SOC	201584/primary_01/T6.27	Statistical Analysis of HIVTSQc – Total Treatment Satisfaction Change Score at Week 48 (Maintenance Phase) for Subjects from SOC	Adjust column header and footnote as appropriate.	W48

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Treatment Acceptance (ACCEPT)							
6.31	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.28	Proportion of Subjects with ACCEPT - Individual Item Score by Visit - LOCF (Maintenance Phase)		W48
6.32	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.29	Summary of Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit (Maintenance Phase)		W48
6.33	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.30	Summary of Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit - LOCF (Maintenance Phase)		W48
6.34	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.31	Summary of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit (Maintenance Phase)		W48
6.35	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.32	Summary of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit - LOCF (Maintenance Phase)		W48
6.36	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.33	Statistical Analysis of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit for Subjects without Prior Exposure to CAB+RPV – LOCF (Maintenance Phase)	Adjust column header and footnote as appropriate.	W48

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.37	NA	NA	Intent-to-Treat Exposed	201585/primary_02/T7.33	Statistical Analysis of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit for Subjects with Prior Exposure to CAB+RPV – LOCF (Maintenance Phase)	Adjust column header and footnote as appropriate.	W48
Preference							
6.38	NA	NA	Q4W ATLAS	Shell HO_T1	Proportion of Subjects with Response to Each Individual Question in Preference Questionnaire at Week 48 (Maintenance Phase) for Subjects from Q4W ATLAS to Q8W ATLAS-2M	Only display Q8W arm.	HL, W48
6.39	NA	NA	Intent-to-Treat Exposed	Shell HO_T1	Proportion of Subjects with Response to Each Individual Question in Preference Questionnaire by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) at Week 48 for Subjects in Q8W ATLAS-2M (Maintenance Phase)	Only display Q8W arm.	W48
6.40	NA	NA	Intent-to-Treat Exposed	Shell HO_T1	Proportion of Subjects with Response to Each Individual Question in Preference Questionnaire at Week 48 for Subjects in Q4W ATLAS-2M (Maintenance Phase)	Only display Q4W arm.	W48
Reasons for Switch/Continuation							
6.41	NA	NA	SOC	201585/primary_02/T7.40	Reasons for Switch at Baseline for Subjects from SOC	Remove columns 'Analysis Visit' and 'Total'. For percentages, use the format 'xx / xx (xx%)' where the denominator is the number of subjects with available valid data from the questionnaire.	W48

Health Outcomes Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.42	NA	NA	Q4W ATLAS	201585/primary_02/T7.40	Reasons for Continuation at Baseline for Subjects from Q4W ATLAS	Remove columns 'Analysis Visit' and 'Total'. For percentages, use the format 'xx / xx (xx%)' where the denominator is the number of subjects with available valid data from the questionnaire.	W48

15.15.5.11. Health Outcomes Figures

Health Outcomes Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.1	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.1	Line Plot of Adjusted Mean (95% CI) Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time(ANCOVA) for Subjects without Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48
6.2	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.1	Line Plot of Adjusted Mean (95% CI) Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time(ANCOVA) for Subjects with Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48
6.3	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.2	Line Plot of Difference (95% CI) in Adjusted Mean Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) for Subjects without Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48
6.4	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.2	Line Plot of Difference (95% CI) in Adjusted Mean Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) for Subjects with Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48
6.5	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.5	Line Plot of Adjusted Mean (95% CI) Change from Baseline in HAT-QoL (Life Satisfaction, HIV medication, and Disclosure Worries) by Visit (ANCOVA) for Subjects without Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48

Health Outcomes Figures							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.6	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.5	Line Plot of Adjusted Mean (95% CI) Change from Baseline in HAT-QoL (Life Satisfaction, HIV medication, and Disclosure Worries) by Visit (ANCOVA) for Subjects with Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48
6.7	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.6	Line Plot of Difference in Adjusted Mean (95% CI) Change from Baseline in HAT-QoL (Life Satisfaction, HIV Medication, and Disclosure Worries) by Visit (ANCOVA) for Subjects without Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48
6.8	NA	NA	Intent-to-Treat Exposed	201585/primary_02/F7.6	Line Plot of Difference in Adjusted Mean (95% CI) Change from Baseline in HAT-QoL (Life Satisfaction, HIV Medication, and Disclosure Worries) by Visit (ANCOVA) for Subjects with Prior Exposure to CAB+RPV - LOCF	Adjust footnotes as appropriate. Include Baseline as a timepoint in x axis.	W48

15.15.5.12. Virology Tables

Note: If there is one or more CVFs during the Extension Phase, the tables included in "Genotype" and "Phenotype" below will also be produced for Maintenance and Extension Phase for Week 96 analysis.

Virology Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Genotype							
7.1	7.1	NA	Confirmed Virologic Failure	201585/primary_02/T8.1	Summary of the Prevalence of Known INI Resistance Mutations at time of CVF (Maintenance Phase) – Plasma Sample		W48, W96
7.2	7.2	NA	Confirmed Virologic Failure	201585/primary_02/T8.2	Summary of the Prevalence of Major Resistance Mutations of NRTI, NNRTI and PI Class at time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
7.3	7.3	NA	Confirmed Virologic Failure	201585/primary_02/T8.4	Summary of Genotypic Susceptibility at time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
Phenotype							
7.4	7.4	NA	Confirmed Virologic Failure	201585/primary_02/T8.3	Summary of Phenotype Susceptibility at time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
7.5	7.5	NA	Confirmed Virologic Failure	201585/primary_02/T8.6	Summary of Phenotype: Number of Drugs to Which Subject is Phenotypic Resistant or Partial Sensitive or Sensitive at Time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
7.6	7.6	NA	Confirmed Virologic Failure	201585/primary_02/T8.7	Summary of Fold Change to CAB and RPV at Time of CVF (Maintenance Phase) - Plasma Sample		W48, W96

Virology Tables							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
7.7	7.7	NA	Confirmed Virologic Failure	201585/primary_02/T8.5	Summary of Net Assessment at time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
Miscellaneousness							
7.8	7.8	NA	Confirmed Virologic Failure	201585/primary_02/T8.8	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria during the Maintenance Phase	Remove columns for 'ARTs', 'FC for ARTs'. Adjust the footnotes as appropriate. For W96: Include baseline genotypic data from ATLAS PBMC samples; label sample as appropriate.	HL, W48, W96
NA	7.9	7.1	Confirmed Virologic Failure	201585/primary_02/T8.8	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria during the Maintenance and Extension Phase	Remove columns for 'ARTs', 'FC for ARTs'. Adjust the footnotes as appropriate. For W96 and EOS: Include baseline genotypic data from ATLAS PBMC samples; label sample as appropriate.	W96, EOS
7.9	7.10	7.2	Safety	201585/primary_02/T8.8	Summary of Viral load, Genotypic and Phenotypic data for Non-CVF Subjects with Genotypic and/or Phenotypic Data	Remove columns for 'ARTs', 'FC for ARTs'. Adjust the footnotes as appropriate. For W96 and EOS: Include baseline genotypic data from ATLAS PBMC samples; label sample as appropriate; remove the last footnote from the same table in WK48 analysis.	W48, W96, EOS

15.15.5.13. ICH Listings

Note: Unless otherwise specified, both unique subject ID and latest subject ID for a subject will be included in the listings; display by prior exposure to CAB+RPV (0, 1-24, >24 weeks, refer to Section 15.6.2 for calculation details) for all listings except for study population listings.

ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population							
1	1	1	Randomized	201585/primary_02/L1	Listing of Subjects Randomized but Not Treated		W48, W96
2	2	2	Randomized	201585/primary_02/L2	Listing of Randomized and Actual Strata and Treatment Assignment	Randomized and Actual Treatments will include oral lead-in information (e.g. Oral followed by Q4W). Change the footnote # for column 'Dev.' to be [2]. Add a footnote for actual strata: [1] Actual strata are derived using the prior exposure to CAB+RPV in Study 201585, collected from eCRF.	W48, W96
3	3	3	Screened	201585/primary_02/L3	Listing of Reasons for Screen Failure		W48, W96
4	4	4	Intent-to-Treat Exposed	ES2	Listing of Reasons for Study Withdrawal	For WK96 and EOS: Add a footnote: "Note: This listing includes withdrawals per the data collected from the Study Conclusion eCRF form. It includes withdrawals from Maintenance or Extension Phase, and withdrawals from subjects who completed Maintenance phase and did not enter Extension phase with reasons beyond the	HL, W48, W96, EOS

ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
						completion of the study commitment."	
5	5	5	Intent-to-Treat Exposed	201585/primary_02/L5	Listing of Reasons for Study Drug Discontinuation		W48, W96, EOS
6	6	6	Intent-to-Treat Exposed	DV2	Listing of Important Protocol Deviations	For W96 and EOS: add a column on the right "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.	W48, W96, EOS
7	7	7	Intent-to-Treat Exposed	DV2	Listing of Protocol Deviations Leading to Exclusion from the Per-Protocol Population	Remove the last column on the right.	HL, W48, W96
8	8	8	Intent-to-Treat Exposed	201585/primary_02/L8	Listing of Subjects with Inclusion/Exclusion Criteria Deviations		W48, W96
9	9	9	Intent-to-Treat Exposed	201585/primary_02/L9	Listing of Demographic Characteristics		W48, W96, EOS
10	10	10	Intent-to-Treat Exposed	201585/primary_02/L10	Listing of Race		W48, W96, EOS
Efficacy							
11	11	11	Intent-to-Treat Exposed	201585/primary_02/L11	Listing of Study Outcome (50 c/mL Threshold) at Week 48 – Snapshot Analysis	For WK96: replace "48" with "96" in the title. Add a column "COVID-19 Relatedness" between Columns "Study	HL, W48, W96

ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
						Outcome" and "Subreason". Add a footnote "Note: Subjects XXXXX, XXXXX, and XXXXX took SOC oral bridging prior to/during Week 96 and their SOC oral bridging medications are considered part of the study treatment for the purpose of the snapshot. No snapshot penalty is applied to the temporary permitted switch to SOC oral bridging due to COVID-19."	
Safety: Exposure							
12	12	12	Safety	201585/primary_02/L12	Listing of Investigational Product Exposure Data		W48, W96, EOS
Safety: Adverse Events							
13	13	13	Safety	201585/primary_02/L13	Listing of Subject Numbers for Individual Adverse Events (Maintenance + Extension Phase)	For WK96 and EOS: Remove "(Maintenance + Extension Phase)" from the title (i.e. no phase restriction); display by Phase and prior exposure to CAB+RPV; adjust the column lengths for a better presentation.	W48, W96, EOS
14	14	14	Safety	201585/primary_02/L14	Listing of Reasons for Considering as a Serious Adverse Event (Maintenance + Extension Phase)	For WK96 and EOS: Remove "(Maintenance + Extension Phase)" from the title (i.e. no phase restriction).	W48, W96, EOS
15	15	15	Safety	201585/primary_02/L15	Listing of Fatal Adverse Events (Maintenance + Extension Phase)	Add Study Period to the 5th Column from the left. For WK96 and EOS: Remove "(Maintenance + Extension Phase)" from the title (i.e. no phase restriction).	W48, W96, EOS

ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
16	16	16	Safety	201585/primary_02/L16	Listing of Non-Fatal Serious Adverse Events (Maintenance + Extension Phase)	Add Study Period to the 5th Column from the left. For WK96 and EOS: Remove "(Maintenance + Extension Phase)" from the title (i.e. no phase restriction).	W48, W96, EOS
17	17	17	Safety	201585/primary_02/L17	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product (Maintenance + Extension Phase)	Add Study Period to the 5th Column from the left.	HL, W48, W96, EOS
18	18	18	Safety	201585/primary_02/L18	Listing of Changes in Intensity/Grades of Study Drug Injection Site Adverse Events (Maintenance + Extension Phase)	For WK96 and EOS: Remove "(Maintenance + Extension Phase)" from the title (i.e. no phase restriction).	W48, W96, EOS
19	19	19	Safety	201585/primary_03/L30	Listing of All Adverse Events (Maintenance + Extension Phase)	Add Study Period to the 5th Column from the left. For WK96 and EOS: Remove "(Maintenance + Extension Phase)" from the title (i.e. no phase restriction).	W48, W96, EOS
NA	66	66	Safety	207966/primary_02/L19	Listing of COVID-19 Adverse Events		W96, EOS
NA	67	67	Safety	SAF_L1	Listing of COVID-19 Assessments		W96, EOS
NA	68	68	Safety	SAF_L2	Listing of COVID-19 Symptoms		W96, EOS
Safety: Pregnancy							
20	20	20	Safety	201585/primary_02/L19	Listing of Subjects Who Became Pregnant during the Study (Maintenance + Extension Phase)	For EOS, remove "(Maintenance + Extension Phase)" from the title.	W48, W96, EOS

ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Safety: Hepatobiliary (Liver)							
21	21	21	Safety	201585/primary_02/L20	Listing of Medical Conditions for Subjects with Liver stopping Events		W48, W96, EOS
22	22	22	Safety	201585/primary_02/L21	Listing of Substance Use for Subjects with Liver Stopping Events		W48, W96, EOS
Safety: ECG							
23	23	23	Safety	201584/primary_01/L24	Listing of ECG Values for Subjects with a Value of Potential Clinical Importance	Remove Phase Treatment from the column header. Add change from baseline values for each of QTc assessment. Adjust the footnote as appropriate. A footnote may be added to clarify the classification of PCI values.	W48, W96
24	24	24	Safety	201584/primary_01/L25	Listing of ECG Findings	Remove the 'Phase Treatment' from the third column on the left.	W48, W96
Safety: eC-SSRS							
25	25	25	Safety	201585/primary_02/L24	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description (Section 1-Section 2)		W48, W96
26	26	26	Safety	201585/primary_02/L25	Listing of Possible Suicidality-Related Adverse Event Data: Possible Cause(s) (Section 3)		W48, W96
27	27	27	Safety	201585/primary_02/L26	Listing of Possible Suicidality-Related Adverse Event Data		W48, W96

ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
					(Section 4)		
28	28	28	Safety	201585/primary_02/L27	Listing of Possible Suicidality-Related Adverse Event Data (Section 5-Section 8)		W48, W96
PK							
29	29	29	Pharmacokinetic	201584/primary_01/L30	Listing of Plasma CAB PK Concentration-Time Data	Remove 'Phase Treatment' from the column header. Add a column "Excluded".	W48, W96, EOS
30	30	30	Pharmacokinetic	201584/primary_01/L31	Listing of Plasma RPV PK Concentration-Time Data	Remove 'Phase Treatment' from the column header. Add a column "Excluded".	W48, W96, EOS

15.15.5.14. Non-ICH Listings

Note: Unless otherwise specified, both unique subject ID and latest subject ID for a subject will be included in the listings; display by prior exposure to CAB+RPV (0, 1-24, >24 weeks, refer to calculation details in Section 15.6.2) for all listings except for study population listings.

Non-ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population							
31	31	31	Intent-to-Treat Exposed	201585/primary_02/L30	Listing of Reasons for Maintenance Phase Withdrawal		W48, W96
32	32	32	Oral Lead-in	201585/primary_02/L31	Listing of Reasons for Oral Lead-in Period Withdrawal		W48, W96
NA	33	33	Intent-to-Treat Exposed	201585/primary_02/L32	Listing of Reasons for Extension Phase Withdrawal		W96, EOS
33	34	34	Long-term Follow-up	201585/primary_02/L33	Listing of Reasons for Long-term Follow-up Phase Withdrawal		W48, W96, EOS
34	35	35	Screened	Shell POP_L2	Listing of Subjects Who were Rescreened		W48, W96
35	36	36	Intent-to-Treat Exposed	Shell POP_L1	Listing of Prior ART Medications	Remove the column 'Phase during Which Concomitant'	W48, W96
36	37	37	Intent-to-Treat Exposed	Shell POP_L1	Listing of Concomitant ART Medications	In case the same medication is concomitant during both maintenance and extension phases, list each of them in two separate rows. For W96 and EOS: add a column "SOC Oral	W48, W96, EOS

Non-ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
						Bridging?" which has values of "Yes" and "No".	
37	38	38	Intent-to-Treat Exposed	Shell POP_L1	Listing of ART Medications Received during Long-term Follow-up Phase	Remove the column 'Phase during Which Concomitant'. For W96 and EOS: add a column "Start Date of the Long-term Follow-up ART/Study Day".	W48, W96, EOS
38	39	39	Intent-to-Treat Exposed	201585/primary_02/L39	Listing of Investigational Product Accountability - Oral Regimens		W48, W96, EOS
39	40	40	Intent-to-Treat Exposed	201584/primary_01/L43	Listing of Medical History of Seizure		W48, W96
NA	65	65	Intent-to-Treat Exposed	DV2	Listing of COVID-19 Related Missed Visits and Missed Assessments Protocol Deviations		W96
Efficacy							
40	41	41	Confirmed Virologic Failure	201585/primary_02/L40	Listing of All Plasma HIV-1 RNA Data for Subjects with Confirmed Virologic Failure	In column headers, replace 'Period' with 'Phase', replace 'Sample Day' with 'Study Day'.	W48, W96, EOS
41	42	42	Intent-to-Treat Exposed	201585/primary_02/L41	Listing of All Plasma HIV-1 RNA Data for Subjects with Viral load >=50 c/mL during the Maintenance Phase	In column headers, replace 'Period' with 'Phase', replace 'Sample Day' with 'Study Day'.	HL, W48, W96, EOS
42	NA	NA	Oral Lead-in	201585/primary_02/L41	Listing of All Plasma HIV-1 RNA Data for Subjects with Viral load >=50 c/mL during the Maintenance Oral Lead-in Period	In column headers, replace 'Period' with 'Phase', replace 'Sample Day' with 'Study Day'.	W48
NA	64	64	Intent-to-	207966/primar	Listing of All Plasma HIV-1 RNA Data		W96, EOS

Non-ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Treat Exposed	y_02/L41			
43	43	43	Intent-to-Treat Exposed	201585/primary_02/L43	Listing of HIV-1 Associated Conditions (Maintenance + Extension Phase)	For WK96 and EOS: Do not restrict phases, i.e. remove "(Maintenance + Extension Phase" from the title; add "Phase" to the original "Treatment State" column header and present it as third column on the right.	W48, W96, EOS
Safety							
44	44	44	Safety	ABC_HSR_EXPO2	Listing of Abacavir Hypersensitivity Reaction Record - Exposure to Abacavir		W48, W96
45	45	45	Safety	ABC_HSR_DRUG2	Listing of Abacavir Hypersensitivity Reaction Record - Subject History of Drug Allergies		W48, W96
46	46	46	Safety	ABC_HSR_COND2	Listing of Abacavir Hypersensitivity Reaction Record - Subject and Family Conditions		W48, W96
47	47	47	Safety	ABC_HSR_RASH2	Listing of Abacavir Hypersensitivity Reaction Record - Skin Rash Details		W48, W96
48	48	48	Safety	ABC_HSR_SYMP4	Listing of Abacavir Hypersensitivity Reaction Record - Symptoms		W48, W96
49	49	49	Safety	VS4	Listing of Abacavir Hypersensitivity Reaction Record - Vital Signs		W48, W96
50	50	50	Safety	ABC_HSR_SYMP6	Listing of Abacavir Hypersensitivity Reaction Record - Individual Symptoms and Diagnostic Category Assignments (Excluding Other Symptoms)		W48, W96

Non-ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
51	51	51	Safety	ABC_HSR_SYMP7	Listing of Abacavir Hypersensitivity Reaction Record - Individual Symptoms and Diagnostic Category Assignments (Other Symptoms)		W48, W96
52	52	52	Safety	201585/primary_02/L52	Listing of Liver Monitoring/Stopping Event Reporting	For WK96, remove "Monitoring/" from the title.	W48, W96, EOS
53	53	53	Safety	201585/primary_02/L53	Listing of Liver Event Information for RUCAM Score		W48, W96, EOS
54	54	54	Safety	201585/primary_02/L54	Listing of Liver Biopsy Details		W48, W96, EOS
55	55	55	Safety	201585/primary_02/L55	Listing of Liver Imaging Details		W48, W96, EOS
56	56	56	Safety	201585/primary_02/L59	Listing of Subjects Meeting Hepatobiliary Lab Criteria	For WK96 and EOS: Follow 207966/primary_11/L1; display by phase and prior exposure to CAB+RPV. Screening and LTFU phases are not included.	W48, W96, EOS
57	57	57	Safety	201585/primary_02/L57	Listing of Potential QTc Interval Prolonging Events of Interest	Add Study Period to the 5th Column from the left.	W48, W96, EOS
58	58	58	Safety	201585/primary_02/L58	Listing of ECG values for Subjects with Potential QTc Interval Prolonging Events of Interest		W48, W96, EOS
59	59	59	Safety	201584/primary_01/L64	Listing of ALT, AST, Bilirubin (including Total and Direct Bilirubin), INR, and ALP for Subjects Meeting Hepatobiliary Lab Abnormality Criteria	Remove 'Only Q4W IM Subjects are presented in this listing.' from the footnote.	HL, W48, W96, EOS
60	60	60	Safety	201585/primar	Listing of Investigational Product Exposure		W48, W96, EOS

Non-ICH Listings							
No. in W48	**No. in W96**	**No. in EOS**	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				y_02/L63	Data for Subject Receiving Oral Bridging		
61	61	61	Safety	201584/primary_01/L66	Listing of Dosing Errors and IP Device Malfunctions		W48, W96, EOS
Virology							
62	62	62	Confirmed Virologic Failure	201585/primary_02/L64	Listing of Replication Capacity in IN and PR/RT Region	Remove 'of Maintenance Phase' from the column header 'Study Day of Maintenance Phase'.	W48, W96, EOS
NA	63	63	Safety	207966/primary_03/L1	Listing of Resistance Associated Mutations (Pre-specified INSTI and IAS-USA NNRTI)	Remove "Excluded from PRC (Yes/No) from the first left column; remove the second left column; remove Study Day; mutations are per definition in Section 15.6.7.	W96, EOS
PK							
63	69	69	Long-term Follow-up	207966/primary_02/L63	Listing of Plasma PK Concentration-Time Data since Last Injection	For WK96 and EOS: Remove age and add LTFU oral RPV start date; add asterisk to RPV concentration taken on/after the start of LTFU oral RPV and add a footnote explaining the asterisk, will be produced only if additional LTFU PK storage samples since last analysis data cut are planned to be analysed.	W48, W96, EOS

15.15.6. List of Data Displays for Week 152 Planned Analyses

15.15.6.1. Study Population Tables

Study Population Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.1	Randomized	NS1	Summary of Number of Subjects Enrolled by Country and Site ID	'No Treatment' column is not needed.	W152
1.2	Intent-to-Treat Exposed	207966/primary_15/T1.3	Summary of Subject Accountability: Study Conclusion Record	Add section for "COVID-19 Relatedness of the Withdrawal" with "Yes", "No" and "Unknown" categories.	W152
1.3	Intent-to-Treat Exposed	207966/primary_15/T1.4	Summary of Subject Accountability: Extension Phase Conclusion Record	Add section for "COVID-19 Relatedness of the Withdrawal" with "Yes", "No" and "Unknown" categories.	W152
1.4	Intent-to-Treat Exposed	207966/primary_15/T1.5	Summary of Subject Accountability: Maintenance + Extension Phase Conclusion Record	Add section for "COVID-19 Relatedness of the Withdrawal" with "Yes", "No" and "Unknown" categories.	W152
1.5	Long-term Follow-up	207966/primary_15/T1.6	Summary of Subject Accountability: Long-term Follow-up Phase Conclusion Record	Add section for "COVID-19 Relatedness of the Withdrawal" with "Yes", "No" and "Unknown" categories. If there are AEs leading to withdrawal, add sections for outcome and types similarly to 207966/primary_15/T1.5.	W152
1.6	Intent-to-Treat Exposed	207966/primary_15/T1.7	Summary of Subject Disposition at Each Study Phase		W152

Study Population Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.7	Intent-to-Treat Exposed	207966/primary_15/T1.8	Summary of Reasons for Withdrawal at Each Study Phase	Remove the last footnote in example shell.	W152
1.8	Intent-to-Treat Exposed	207966/primary_15/T1.9	Summary of Subject Accountability: Withdrawals by Visit (Maintenance + Extension Phase)		W152
1.9	Intent-to-Treat Exposed	201584/primary_15/T1.10	Summary of Study Drug Discontinuation	Add section for “COVID-19 Relatedness of the Study Drug Discontinuation” with “Yes”, “No” and “Unknown” categories.	W152
1.10	Screened	207966/primary_15/T1.14	Summary of Study Populations		W152
1.11	Intent-to-Treat Exposed	DV1a	Summary of Important Protocol Deviations		W152
1.12	Intent-to-Treat Exposed	DV1a	Summary of Important Protocol Deviations (Maintenance + Extension Phase)		W152
1.13	Intent-to-Treat Exposed	207966/primary_15/T1.15	Summary of Protocol Deviations Leading to Exclusion from the Per-Protocol Population		W152
1.14	Intent-to-Treat Exposed	207966/primary_15/T1.36	Summary of Important COVID-19 Related Protocol Deviations		W152
1.15	Intent-to-Treat Exposed	207966/primary_15/T1.37	Summary of Important Non-COVID-19 Related Protocol Deviations		W152
Demographic and Baseline Characteristics					

Study Population Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.16	Intent-to-Treat Exposed	207966/primary_15/T1.16	Summary of Demographic Characteristics		W152
1.17	Intent-to-Treat Exposed	DM5	Summary of Race and Racial Combinations		W152
1.18	Intent-to-Treat Exposed	DM6	Summary of Race and Racial Combinations Details		W152
Medical Conditions and Medications					
1.19	Intent-to-Treat Exposed	MH1	Summary of Current Medical Conditions		W152
1.20	Intent-to-Treat Exposed	MH1	Summary of Past Medical Conditions		W152
1.21	Intent-to-Treat Exposed	MH4	Summary of Current Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders		W152
1.22	Intent-to-Treat Exposed	MH4	Summary of Past Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders		W152

Study Population Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.23	Intent-to-Treat Exposed	207966/primary_15/T1.30	Summary of Prior ART Medications	Use “TENOFOVIR” for TDF and “TENOFOVIR ALAFENAMIDE” for TAF. Add a footnote “Note: TENOFOVIR refers to tenofovir disoproxil fumarate in the table.”.	W152
1.24	Intent-to-Treat Exposed	CM8	Summary of Concomitant Non-ART Medication Ingredient Combinations (Maintenance + Extension Phase)		W152
1.25	Intent-to-Treat Exposed	201585/primary_02/T1.33	Summary of Lipid Modifying Agent Use at Baseline		W152
1.26	Intent-to-Treat Exposed	201585/primary_02/T1.34	Summary of Lipid Modifying Agent Use Started during the Maintenance and Extension Phase		W152
Visits Impacted by COVID-19 Pandemic					
1.27	Intent-to-Treat Exposed	PAN4	Summary of COVID-19 Pandemic Visit Impacts		W152

15.15.6.2. Efficacy Tables

Note: For subgroup analyses, include rederived randomization strata (i.e. prior exposure to CAB+RPV: 0, 1-24, >24 weeks), all demographic and baseline characteristic subgroups as mentioned in EMA Subgroup Category 2 in Section 5.4.2, unless otherwise specified. Not all subjects on Q8W arm are planned to have viral load data collected at Week 4 (Week 4A or 4B), so leave Week 4 data blank for Q8W arm in by-visit snapshot analysis.

Efficacy Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	Intent-to-Treat Exposed	207966/primary_15/T2.1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 152 – Snapshot Analysis – ITT-E		W152
2.2	Per-Protocol	207966/primary_15/T2.2	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 152 – Snapshot Analysis – Per-Protocol		W152
2.3	Intent-to-Treat Exposed	207966/primary_15/T2.3	Summary of Study Outcomes (50 c/mL Threshold) at Week 152 – Snapshot Analysis		W152
2.4	Intent-to-Treat Exposed	207966/primary_15/T2.4	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 152 - Snapshot Analysis		W152
2.5	Intent-to-Treat Exposed	207966/primary_15/T2.5	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 152 by Subgroup - Snapshot Analysis		W152
2.6	Intent-to-Treat Exposed	207966/primary_15/T2.6	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL at Week 152 among Subjects with >=1 Weeks Prior Exposure to CAB+RPV - Snapshot Analysis		W152

Efficacy Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.7	Intent-to-Treat Exposed	207966/primary_15/T2.7	Summary of Study Outcomes (50 c/mL Threshold) at Week 152 by Subgroup – Snapshot Analysis		W152
2.8	Intent-to-Treat Exposed	207966/primary_15/T2.8	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 152 – Snapshot Analysis – ITT-E		W152
2.9	Per-Protocol	207966/primary_15/T2.9	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 152 – Snapshot Analysis – Per-Protocol		W152
2.10	Intent-to-Treat Exposed	207966/primary_15/T2.10	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 152 - Snapshot Analysis		W152
2.11	Intent-to-Treat Exposed	207966/primary_15/T2.11	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 152 by Subgroup - Snapshot Analysis		W152
2.12	Intent-to-Treat Exposed	207966/primary_15/T2.12	Treatment by Strata Tests of Homogeneity for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 152 among Subjects with >=1 Weeks Prior Exposure to CAB+RPV - Snapshot Analysis		W152
2.13	Intent-to-Treat Exposed	207966/primary_15/T2.13	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.14	Intent-to-Treat Exposed	207966/primary_15/T2.14	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Subgroup and Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152

Efficacy Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.15	Intent-to-Treat Exposed	207966/primary_15/T2.15	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.16	Intent-to-Treat Exposed	207966/primary_15/T2.16	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Subgroup and Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.17	Intent-to-Treat Exposed	207966/primary_15/T2.17	Proportion of Subjects with Plasma HIV-1 RNA <200 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.18	Intent-to-Treat Exposed	207966/primary_15/T2.18	Proportion of Subjects with Plasma HIV-1 RNA >=200 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.19	Intent-to-Treat Exposed	207966/primary_15/T2.27	Summary of Study Outcomes (200 c/mL Threshold) at Week 152 – Snapshot Analysis		W152
2.20	Intent-to-Treat Exposed	207966/primary_15/T2.19	Summary of Kaplan-Meier Estimates of Proportion of Subjects Without Confirmed Virologic Failure at Week 152 - Treatment Related Discontinuation = Failure	Replace “Week 96” with “Week 152” in row labels. Change the upper bound in the second footnote to be “study day 1092”.	W152
2.21	Intent-to-Treat Exposed	207966/primary_15/T2.20	Summary of Kaplan-Meier Estimates of Proportion of Subjects Without Confirmed Virologic Failure at Week 152 - Efficacy Related Discontinuation = Failure	Replace “Week 96” with “Week 152” in row labels. Change the upper bound in the first footnote to be “study day 1092”.	W152

Efficacy Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.22	Intent-to-Treat Exposed	207966/primary_15/T2.21	Proportion of Subjects with HIV-1 RNA >=50 c/mL at Week 152 (Snapshot) by Last Delay in IP Injection	Replace 'Week 96' with 'Week 152', and replace "(i.e. missing visit or withdrawal)" with "(e.g. missing visit, remote visit or withdrawal) in the footnote.	W152
2.23	Intent-to-Treat Exposed	207966/primary_15/T2.38	Summary of Change from Baseline in Plasma HIV-1 RNA (log10 c/mL) by Visit (Maintenance + Extension Phase)		W152
2.24	Intent-to-Treat Exposed	207966/primary_15/T2.22	Summary of Plasma HIV-1 RNA (log10 c/mL) by Visit (Maintenance + Extension Phase)		W152
2.25	Intent-to-Treat Exposed	207966/primary_15/T2.23	Cumulative Proportion of Subjects Meeting Confirmed Virology Failure Criteria by Visit (Up to Week 152, Maintenance + Extension Phase)		W152
2.26	Intent-to-Treat Exposed	207966/primary_15/T2.24	Cumulative Proportion of Subjects Meeting Confirmed Virology Failure Criteria (Maintenance + Extension Phase)		W152
2.27	Confirmed Virologic Failure	207966/primary_15/T2.25	Distribution of Quantitative Plasma HIV-1 RNA Results at Suspected and Confirmation of Confirmed Virologic Failure (Maintenance + Extension Phase)		W152
2.28	Intent-to-Treat Exposed	207966/primary_15/T2.26	Proportion of Subjects with Plasma HIV-1 RNA <2 c/mL by Visit (Maintenance + Extension Phase)		W152
2.29	Intent-to-Treat Exposed	207966/primary_15/T2.28	Summary of Subjects per Viral Load Category by Visit (Up to Week 152, Maintenance + Extension Phase)		W152

Efficacy Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.30	Intent-to-Treat Exposed	207966/primary_15/T2.29	Summary of Change from Baseline in CD4+ Cell Count (cells/mm^3) by Visit (Maintenance + Extension Phase)		W152
2.31	Intent-to-Treat Exposed	207966/primary_15/T2.30	Summary of Change from Baseline in CD4+ Cell Count (cells/mm^3) at Week 152 by Subgroup (Extension Phase)		W152
2.32	Intent-to-Treat Exposed	207966/primary_15/T2.31	Summary of CD4+ Cell Count (cells/mm^3) by Visit (Maintenance + Extension Phase)		W152
2.33	Intent-to-Treat Exposed	207966/primary_15/T2.32	Summary of Change from Baseline in CD8+ Cell Count (cells/mm^3) by Visit (Maintenance + Extension Phase)		W152
2.34	Intent-to-Treat Exposed	207966/primary_15/T2.33	Summary of CD8+ Cell Count (cells/mm^3) by Visit (Maintenance + Extension Phase)		W152
2.35	Intent-to-Treat Exposed	207966/primary_15/T2.34	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit (Maintenance + Extension Phase)		W152
2.36	Intent-to-Treat Exposed	207966/primary_15/T2.35	Summary of HIV-1 Associated Conditions Including Recurrences (Maintenance + Extension Phase)		W152
2.37	Intent-to-Treat Exposed	207966/primary_15/T2.36	Summary of HIV-1 Associated Conditions Excluding Recurrences (Maintenance + Extension Phase)		W152
2.38	Intent-to-Treat Exposed	207966/primary_15/T2.37	Summary of HIV-1 Disease Progression and/or Deaths (Maintenance + Extension Phase)	Replace “maintenance” with “maintenance and extension” in the second footnote.	W152

15.15.6.3. Efficacy Figures

Note: For subgroup analyses, include rederived randomization strata (i.e. prior exposure to CAB+RPV: 0, 1-24, >24 weeks), all demographic and baseline characteristic subgroups as mentioned in EMA Subgroup Category 2 in Section 5.4.2, unless otherwise specified. Not all subjects on Q8W arm are planned to have viral load data collected at Week 4 (Week 4A or 4B), so leave Week 4 data blank for Q8W arm in by-visit snapshot analysis.

Efficacy Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	Intent-to-Treat Exposed	207966/primary_15/F2.1	Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.2	Intent-to-Treat Exposed	207966/primary_15/F2.2	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL at Week 152 by Subgroup – Snapshot Analysis		W152
2.3	Intent-to-Treat Exposed	207966/primary_15/F2.3	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.4	Intent-to-Treat Exposed	207966/primary_15/F2.4	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL at Week 152 by Subgroup – Snapshot Analysis		W152
2.5	Intent-to-Treat Exposed	207966/primary_15/F2.5	Proportion (95% CI) of Subjects with HIV-1 RNA >=200 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.6	Intent-to-Treat Exposed	207966/primary_15/F2.6	Proportion (95% CI) of Subjects with HIV-1 RNA <200 c/mL by Visit (Up to Week 152, Maintenance + Extension Phase) – Snapshot Analysis		W152
2.7	Intent-to-Treat Exposed	207966/primary_15/F2.7	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit – for CVF Subjects		W152

Efficacy Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.8	Intent-to-Treat Exposed	207966/primary_15/F2.8	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit for subjects Who are in the Category of 'HIV-1 RNA >=50 c/mL' at Week 152 per Snapshot Algorithm		W152

15.15.6.4. Safety Tables

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Exposure					
3.1	Safety	207966/primary_15/T3.2	Summary of Extent of Exposure to Study Treatment including SOC Oral Bridging (Maintenance + Extension Phase)	The levels for categorical summaries except for oral lead-in will be selected as appropriate.	W152
3.2	Safety	207966/primary_15/T3.3	Summary of Needle Length and Gauge for CAB Injection (Maintenance + Extension Phase)		W152
3.3	Safety	207966/primary_15/T3.4	Summary of Needle Length and Gauge for RPV Injection (Maintenance + Extension Phase)		W152
3.4	Safety	207966/primary_15/T3.5	Summary of Adherence to CAB/RPV Injection Dosing Schedule (Maintenance + Extension Phase)	Replace rows for missed Injection with those specified in Section 15.6.4. Adjust the footnote as appropriate. For missed reloading rows, leave blank for Q4W.	W152
Adverse Events					
3.5	Safety	207966/primary_15/T3.6	Summary of All Adverse Events by System Organ Class (Maintenance + Extension Phase)		W152
3.6	Safety	207966/primary_15/T3.8	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W152
3.7	Safety	207966/primary_15/T3.8	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Extension Phase)		W152
3.8	Safety	207966/primary_15/T3.9	Summary of All Adverse Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity		W152

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			(Maintenance + Extension Phase)		
3.9	Safety	207966/primary_15/T3.10	Summary of All On-treatment Adverse Events by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W152
3.10	Safety	207966/primary_15/T3.11	Summary of Common Adverse Events (>=5%) by Overall Frequency (Maintenance + Extension Phase)		W152
3.11	Safety	207966/primary_15/T3.12	Summary of Common Grade 2-5 Adverse Events (>=1%) by Overall Frequency (Maintenance + Extension Phase)		W152
3.12	Safety	207966/primary_15/T3.13	Summary of All Drug-related Adverse Events by System Organ Class (Maintenance + Extension Phase)		W152
3.13	Safety	207966/primary_15/T3.15	Summary of All Drug-related Adverse Events by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W152
3.14	Safety	207966/primary_15/T3.15	Summary of All Drug-related Adverse Events by System Organ Class and Maximum Toxicity (Extension Phase)		W152
3.15	Safety	207966/primary_15/T3.16	Summary of All Drug-related Adverse Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W152
3.16	Safety	207966/primary_15/T3.17	Summary of All Drug-Related Grade 2-5 Adverse Events by Overall Frequency (Maintenance + Extension Phase)		W152
Serious and Other Significant Adverse Events					

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.17	Safety	207966/primary_15/T3.19	Summary of Serious Adverse Events by System Organ Class (Maintenance + Extension Phase)		W152
3.18	Long-term Follow-up	207966/primary_15/T3.20	Summary of Serious Adverse Events by System Organ Class (Long-term Follow-up Phase)		W152
3.19	Safety	207966/primary_15/T3.22	Summary of Drug-related Serious Adverse Events by System Organ Class (Maintenance + Extension Phase)		W152
3.20	Safety	207966/primary_15/T3.23	Summary of Non-Fatal Serious Adverse Events by Overall Frequency (Maintenance + Extension Phase)		W152
3.21	Safety	207966/primary_15/T3.24	Summary of Drug-related Non-Fatal Serious Adverse Events by Overall Frequency (Maintenance + Extension Phase)		W152
3.22	Safety	207966/primary_15/T3.26	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class (Maintenance + Extension Phase)	Adjust the footnote as needed, depending on the given data.	W152
3.23	Safety	207966/primary_15/T3.25	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class (Extension Phase)		W152
3.24	Safety	207966/primary_15/T3.27	Summary of Common (>=5%) Non-Serious Adverse Events (Maintenance + Extension Phase)		W152
3.25	Safety	207966/primary_15/T3.28	Summary of Subjects and Number of Occurrences of Common (>=5%) Non-Serious Adverse Events by System Organ Class		W152

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			(Maintenance + Extension Phase)		
3.26	Safety	207966/primary_15/T3.29	Summary of Subjects and Number of occurrences of SAEs, Fatal SAEs, and Drug-related SAEs (Maintenance + Extension Phase)		W152
Study Drug Injection Site Reaction Adverse Events					
3.27	Safety	207966/primary_15/T3.32	Summary of Study Drug Injection Site Reaction Adverse Events (Event-level Summary) – (Maintenance + Extension Phase)		W152
3.28	Safety	207966/primary_15/T3.34	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common (Maintenance + Extension Phase)		W152
3.29	Safety	207966/primary_15/T3.35	Summary of Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity – Overall and Common (Maintenance + Extension Phase)		W152
3.30	Safety	207966/primary_15/T3.36	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - CAB (Maintenance + Extension Phase)		W152
3.31	Safety	207966/primary_15/T3.37	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events (Maintenance + Extension Phase) - Overall and Common (CAB)		W152
3.32	Safety	207966/primary_15/T3.38	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity		W152

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			(Maintenance + Extension Phase) - CAB		
3.33	Safety	207966/primary_15/T3.39	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length (Maintenance + Extension Phase) – Common (CAB)	Replace “maintenance” with “maintenance and extension” in the footnote.	W152
3.34	Safety	207966/primary_15/T3.40	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - RPV (Maintenance + Extension Phase)		W152
3.35	Safety	207966/primary_15/T3.41	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events (Maintenance + Extension Phase) - Overall and Common (RPV)		W152
3.36	Safety	207966/primary_15/T3.42	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity (Maintenance + Extension Phase) - RPV		W152
3.37	Safety	207966/primary_15/T3.43	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length (Maintenance + Extension Phase) – Common (RPV)	Replace “maintenance” with “maintenance and extension” in the footnote.	W152
Laboratory: Chemistry and Hematology					
3.38	Safety	207966/primary_15/T3.44	Summary of Chemistry Changes from Baseline by Visit (Maintenance + Extension Phase)		W152
3.39	Safety	207966/primary_15/T3.45	Summary of Chemistry Values by Visit (Maintenance + Extension Phase)		W152
3.40	Safety	207966/primary_15/T3.46	Summary of Hematology Changes from		W152

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Baseline by Visit (Maintenance + Extension Phase)		
3.41	Safety	207966/primary_15/T3.47	Summary of Hematology Values by Visit (Maintenance + Extension Phase)		W152
3.42	Safety	207966/primary_15/T3.49	Summary of Maximum Post-Baseline Emergent Chemistry Toxicities (Maintenance + Extension Phase)		W152
3.43	Safety	207966/primary_15/T3.51	Summary of Maximum Post-Baseline Emergent Hematology Toxicities (Maintenance + Extension Phase)		W152
Laboratory: Urinalysis					
3.44	Safety	207966/primary_15/T3.52	Summary of Urinalysis Dipstick Results by Visit (Maintenance + Extension Phase)		W152
3.45	Safety	207966/primary_15/T3.53	Summary of Urine Concentrations Changes from Baseline by Visit (Maintenance + Extension Phase)		W152
3.46	Safety	207966/primary_15/T3.54	Summary of Changes in Proteinuria Baseline Laboratory Result to Maximum Post-Baseline Laboratory Result (Maintenance + Extension Phase)		W152
Laboratory: Lipid					
3.47	Safety	207966/primary_15/T3.55	Summary of Changes in Baseline NCEP Fasting Lipid Category to Maximum Post-Baseline Category (Triglycerides, Lipids LOCF) - Maintenance + Extension Phase	Replace “Maintenance” with “Maintenance and Extension” in the second footnote.	W152
3.48	Safety	207966/primary_15/T3.56	Summary of Changes in Baseline NCEP Fasting	Replace “Maintenance” with	W152

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Lipid Category to Maximum Post-Baseline Category (Total Cholesterol, Lipids LOCF) - Maintenance + Extension Phase	"Maintenance and Extension" in the second footnote.	
3.49	Safety	207966/primary_15/T3.57	Summary of Changes in Baseline NCEP Fasting Lipid Category to Minimum Post-Baseline Category (HDL Cholesterol, Lipids LOCF) - Maintenance + Extension Phase	Replace "Maintenance" with "Maintenance and Extension" in the second footnote.	W152
3.50	Safety	207966/primary_15/T3.58	Summary of Changes in Baseline NCEP Fasting Lipid Category to Maximum Post-Baseline Category (LDL Cholesterol, Lipids LOCF) - Maintenance + Extension Phase	Replace "Maintenance" with "Maintenance and Extension" in the second footnote.	W152
3.51	Safety	207966/primary_15/T3.59	Summary of Fasting Lipids Percentage Changes from Baseline by Visit (Maintenance + Extension Phase) - Lipids LOCF		W152
3.52	Safety	207966/primary_15/T3.60	Summary of Fasting TC/HDL ratio Changes from Baseline (Maintenance + Extension Phase) – Lipids LOCF		W152
Laboratory: Hepatobiliary (Liver)					
3.53	Safety	207966/primary_15/T3.61	Summary of Liver Stopping Event Reporting (Maintenance + Extension Phase)		W152
3.54	Safety	207966/primary_15/T3.63	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria (Maintenance +Extension Phase)		W152
ECG					
3.55	Safety	207966/primary_15/T3.64	Summary of ECG Findings (Maintenance + Extension Phase)		W152

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.56	Safety	207966/primary_15/T3.65	Summary of Change from Baseline in ECG values by Visit (Maintenance + Extension Phase)		W152
3.57	Safety	207966/primary_15/T3.66	Summary of QTc Values by Category (Maintenance + Extension Phase)		W152
3.58	Safety	207966/primary_15/T3.67	Summary of Change from Baseline QTc Values by Category (Maintenance + Extension Phase)		W152
Vital Signs					
3.59	Safety	207966/primary_15/T3.68	Summary of Change from Baseline in Vital Signs by Visit (Maintenance + Extension Phase)		W152
3.60	Safety	207966/primary_15/T3.69	Summary of BMI Shift from Baseline by Sex and Visit (Maintenance + Extension Phase)		W152
3.61	Safety	207966/primary_15/T3.70	Summary of BMI Shift from Baseline by Strata and Visit (Maintenance + Extension Phase)		W152
3.62	Safety	207966/primary_15/T3.71	Summary of Change from Baseline in Weight and BMI by Strata and Visit (Maintenance + Extension Phase)		W152
Adverse Event of Special Interest (AESI)					
3.63	Safety	207966/primary_15/T3.74	Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and Prior History of Depression, Anxiety and Suicidal Ideation at Screening (Maintenance + Extension Phase)	May need to adjust the footnote given the data.	W152
3.64-3.80	Safety	207966/primary_15/T3.92-3.108	Summary of XXX Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrence) –		W152

Safety Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Maintenance + Extension Phase		
3.81	Safety	207966/primary_15/T3.110	Summary of Characteristics of Common Adverse Events of Special Interest – Maintenance + Extension Phase		W152
3.82	Safety	207966/primary_15/T3.111	Summary of Syncope and Presyncope Adverse Events - Maintenance + Extension Phase		W152
3.83	Safety	207966/primary_15/T3.112	Summary of Syncope and Presyncope Adverse Events and Injection Visits - Maintenance + Extension Phase		W152
COVID-19 Adverse Event					
3.84	Safety	207966/primary_15/T3.113	Summary of COVID-19 Adverse Events by System Organ Class and Maximum Toxicity (Maintenance + Extension Phase)		W152
3.85	Safety	207966/primary_15/T3.115	Summary of COVID-19 Assessments (Maintenance + Extension Phase)	Place “Within” in front of “14” in the first footnote. If COVID-19 assessments are collected multiple times during the study, a combination of standard displays PAN1A and PAN2A with appropriate adjustments may be used.	W152

15.15.6.5. Safety Figures

Safety Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.1	Safety	207966/primary_15/F3.1	Plot of Common Adverse Events and Relative Risk - Q8W vs. Q4W (Maintenance + Extension Phase) – Excluding Study Drug ISRs		W152
3.2	Safety	207966/primary_15/F3.2	Plot of Common Study Drug Injection Site Reaction Adverse Events and Relative Risk - Q8W vs. Q4W (Maintenance +Extension Phase)		W152
3.3	Safety	207966/primary_02/F3.6	Plot of Incidence of Maintenance and Extension Phase Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV		W152
3.4	Safety	207966/primary_15/F3.7	Plot of Incidence of Maintenance and Extension Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB		W152
3.5	Safety	207966/primary_15/F3.8	Plot of Incidence of Maintenance and Extension Phase Drug-Related Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV		W152
3.6	Safety	207966/primary_15/F3.21	Plot of Incidence of Maintenance and Extension Phase Study Drug Injection Site Reaction Adverse Events by Strata and Visit (Overall and Common) - CAB and/or RPV		W152
3.7	Safety	207966/primary_15/F3.13	Scatter Plot of Maximum vs. Baseline for ALT (Maintenance + Extension Phase)		W152
3.8	Safety	207966/primary_15/F3.15	Scatter Plot of Maximum Total Bilirubin vs. Maximum ALT (Maintenance + Extension Phase)		W152
3.9	Safety	207966/primary_15/F3.18	Bar Chart of Lipid NCEP Categories at Week 152 vs. Baseline – Triglycerides, Total Cholesterol, LDL		W152

Safety Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Cholesterol (Lipids LOCF)		
3.10	Safety	207966/primary_15/F3.19	Bar Chart of Lipid NCEP Categories at Week 152 vs. Baseline - HDL Cholesterol (Lipids LOCF)		W152
3.11	Safety	207966/primary_15/F3.20	Histogram of Timeliness of Injections (Maintenance + Extension Phase)		W152
3.12	Safety	207966/primary_15/F3.22	Patient Profile for Subjects with Syncope or Presyncope Adverse Events (Maintenance + Extension Phase)		W152

15.15.6.6. Pharmacokinetic Tables

Pharmacokinetic Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	Pharmacokinetic	207966/primary_15/T4.1	Summary of Plasma CAB PK Concentration (ug/mL) - Time Data by Treatment and Visit (Maintenance + Extension Phase) – Including Log-transformed Statistics	Add Week 156 for Q4W, Week 160 for Q8W. Add following to the second footnote: PK samples were collected at Week 156 (for Q4W subjects) or Week 160 (for Q8W subjects) if Week 152 PK samples were missed (e.g. due to the delays in protocol amendment approvals or site errors).	W152
4.2	Pharmacokinetic	207966/primary_15/T4.2	Summary of Plasma RPV PK Concentration (ng/mL) - Time Data by Treatment and Visit (Maintenance + Extension Phase) – Including Log-transformed Statistics	Similar notes to above.	W152
4.3	Pharmacokinetic	207966/primary_15/T4.3	Summary of Evaluable Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit (Maintenance + Extension Phase) – Including Log-transformed Statistics	Similar notes to above.	W152
4.4	Pharmacokinetic	207966/primary_15/T4.4	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit (Maintenance + Extension Phase) – Including Log-transformed Statistics	Similar notes to above.	W152
4.5	Pharmacokinetic	207966/primary_15/T4.5	Summary of Evaluable Plasma CAB PK Concentration (ug/mL) -Time Data by Strata and Treatment and Visit (Maintenance + Extension Phase) – Including Log-transformed Statistics	Similar notes to above.	W152

Pharmacokinetic Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.6	Pharmacokinetic	207966/primary_15/T4.6	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) -Time Data by Strata and Treatment and Visit (Maintenance + Extension Phase) – Including Log-transformed Statistics	Similar notes to above.	W152
4.7	Long-term Follow-up	207966/primary_15/T4.1	Summary of Plasma CAB PK Concentration (ug/mL) - Time Data by Treatment and Visit (Long-term Follow-up Phase) - Including Log-transformed Statistics	Remove the column 'Pl. Time' and the second footnote.	W152
4.8	Long-term Follow-up	207966/primary_15/T4.2	Summary of Plasma RPV PK Concentration (ng/mL) - Time Data by Treatment and Visit (Long-term Follow-up Phase) - Including Log-transformed Statistics	Remove the column 'Pl. Time' and the second footnote.	W152

15.15.6.7. Pharmacokinetic Figures

Pharmacokinetic Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	Pharmacokinetic	207966/primary_15/F4.1	Individual Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase		W152
4.2	Pharmacokinetic	207966/primary_15/F4.2	Individual Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase		W152
4.3	Pharmacokinetic	207966/primary_15/F4.3	Mean (SD) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Treat Week 152 similarly to Week 96 on X axis and update the relevant footnote as "To save the plotting space, Week 96 is displayed next to Week 48 and Week 152 is displayed next to Week 152, with hashes to indicate the X axis break."	W152
4.4	Pharmacokinetic	207966/primary_15/F4.4	Mean (SD) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.5	Pharmacokinetic	207966/primary_15/F4.5	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.6	Pharmacokinetic	207966/primary_15/F4.6	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.7	Pharmacokinetic	207966/primary_15/F4.7	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots by Strata (Linear and Semi-Log) – Maintenance + Extension	Similar notes to above.	W152

Pharmacokinetic Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Phase		
4.8	Pharmacokinetic	207966/primary_15/F4.8	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots by Strata (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.9	Pharmacokinetic	207966/primary_15/F4.9	Median (5th and 95th Percentile) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.10	Pharmacokinetic	207966/primary_15/F4.10	Median (5th and 95th Percentile) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.11	Pharmacokinetic	207966/primary_15/F4.11	Median (5th and 95th Percentile) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.12	Pharmacokinetic	207966/primary_15/F4.12	Median (5th and 95th Percentile) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.13	Pharmacokinetic	207966/primary_15/F4.13	Median (5th and 95th Percentile) Evaluable Plasma CAB Concentration-Time Plots by Strata (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.14	Pharmacokinetic	207966/primary_15/F4.14	Median (5th and 95th Percentile) Evaluable Plasma RPV Concentration-Time Plots by Strata (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152

Pharmacokinetic Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.15	Pharmacokinetic	207966/primary_15/F4.15	Median Evaluable Plasma CAB Trough PK Concentration (ug/mL) - Time Plots by Treatment and Strata (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.16	Pharmacokinetic	207966/primary_15/F4.16	Median Evaluable Plasma RPV Trough PK Concentration (ng/mL) - Time Plots by Treatment and Strata (Linear and Semi-Log) – Maintenance + Extension Phase	Similar notes to above.	W152
4.17	Long-term Follow-up	207966/primary_02/F4.15	Plasma PK Concentration-Time since Last Injection Plots by Overall and Strata	Add plot for overall. Exclude RPV concentrations on/after the start of oral RPV that was received after the last injection. Add a footnote: "Note: For subjects who received oral RPV after the last injection, the RPV concentrations taken on or after the start of such oral RPV are excluded from the plot."	W152

15.15.6.8. Pharmacokinetic / Pharmacodynamic Figures

Pharmacokinetic / Pharmacodynamic Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
PK / PD Efficacy Analyses					
5.1	Pharmacokinetic	207966/primary_15/F5.1	Individual CAB Trough Concentration-time Profiles for Subjects with Snapshot 'HIV-1 RNA ≥50 c/mL' at Week 152 and Median, 5th & 95th Percentile of CAB Conc-Time Profiles for Other Subjects (Semi-Log) – Maintenance + Extension Phase		W152
5.2	Pharmacokinetic	207966/primary_15/F5.2	Individual RPV Trough Concentration-time Profiles for Subjects with Snapshot 'HIV-1 RNA ≥50 c/mL' at Week 152 and Median, 5th & 95th Percentile of RPV Conc-Time Profiles for Other Subjects (Semi-Log) – Maintenance + Extension Phase		W152
PK / PD Safety Analyses					
5.3	Pharmacokinetic	207966/primary_02/F5.6	Scatter Plot of Maximum Change from Baseline in ALT versus Last Trough CAB PK Concentrations by Strata and Treatment during the Maintenance and Extension Phase	Replace “Maintenance” with “Maintenance and Extension” in the first footnote.	W152
5.4	Pharmacokinetic	207966/primary_02/F5.7	Scatter Plot of Maximum Change from Baseline in ALT versus Last Trough RPV PK Concentrations by Strata and Treatment during the Maintenance and Extension Phase	Replace “Maintenance” with “Maintenance and Extension” in the first footnote.	W152
5.5	Pharmacokinetic	207966/primary_02/F5.8	Scatter Plot of Maximum Change from Baseline in Total Bilirubin versus Last Trough CAB PK Concentrations by Strata and Treatment during the Maintenance and Extension Phase	Replace “Maintenance” with “Maintenance and Extension” in the first footnote.	W152

Pharmacokinetic / Pharmacodynamic Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
5.6	Pharmacokinetic	207966/primary_02/F5.9	Scatter Plot of Maximum Change from Baseline in Total Bilirubin versus Last Trough RPV PK Concentrations by Strata and Treatment during the Maintenance and Extension Phase	Replace “Maintenance” with “Maintenance and Extension” in the first footnote.	W152
5.7	Pharmacokinetic	207966/primary_02/F5.13	Scatter Plot of Change from Baseline in Pre-dose QTcF versus CAB Trough PK Concentration at Week 152 by Treatment	Adjust the alignment of the footnote.	W152
5.8	Pharmacokinetic	207966/primary_02/F5.14	Scatter Plot of Change from Baseline in Pre-dose QTcF versus RPV Trough PK Concentration at Week 152 by Treatment	Adjust the alignment of the footnote.	W152

15.15.6.9. Health Outcomes Tables

Health Outcomes Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Perception of Injection (PIN)					
6.1	Intent-to-Treat Exposed	207966/primary_02/T6.1	Proportion of Subjects with Each Individual Item Score in PIN by Visit - LOCF (Maintenance + Extension Phase)		W152
6.2	Intent-to-Treat Exposed	207966/primary_02/T6.2	Summary of PIN in Domain Scores (Bother of ISRs, Leg Movement, Sleep and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety after and Willingness) by Visit (Maintenance + Extension Phase)		W152
6.3	Intent-to-Treat Exposed	207966/primary_02/T6.3	Summary and Statistical Analysis of PIN in Domain Scores (Bother of ISRs, Leg Movement, Sleep and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety after and Willingness) by Visit - LOCF (Maintenance + Extension Phase)	Adjust the first half of the footnote to "[1] Week 24/48/152 was compared with the 1st visit (Week 8) based on Wilcoxon signed-rank test, respectively."	W152
6.4	Intent-to-Treat Exposed	207966/primary_02/T6.4	Summary of PIN Change from Week 8 in Domain Scores (Bother of ISRs, Leg Movement, Sleep and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety after and Willingness) by Visit (Maintenance + Extension Phase)		W152

Health Outcomes Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.5	Intent-to-Treat Exposed	207966/primary_02/T6.5	Summary of PIN Change from Week 8 in Domain Scores (Bother of ISRs, Leg Movement, Sleep and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety after and Willingness) by Visit - LOCF (Maintenance + Extension Phase)		W152
6.6	Intent-to-Treat Exposed	207966/primary_02/T6.6	Statistical Analysis of PIN Change from Week 8 in Domain Scores (Bother of ISRs, Leg Movement, Sleep and Acceptance) and Individual Items Scores (Anxiety before, Pain, Satisfaction, Anxiety after and Willingness) by Visit - LOCF (Maintenance + Extension Phase)	Adjust second the footnote per modelling result.	W152
HIV Treatment Satisfaction Questionnaire Status Version (HIVTSQs)					
6.7	Intent-to-Treat Exposed	207966/primary_02/T6.14	Proportion of Subjects with HIVTSQs - Individual Item Scores by Visit - LOCF (Maintenance + Extension Phase)		W152
6.8	Intent-to-Treat Exposed	207966/primary_02/T6.15	Proportion of Subjects with HIVTSQs - Individual Item Scores by Visit and Subgroup - LOCF (Maintenance + Extension Phase)	The subgroup includes: prior exposure to CAB+RPV (0, 1-24, >=24 weeks), sex at birth, age (<35, 35 - <50, >=50), race (white, non-white), Baseline CD4+ cell count (<350, 350 – <500, >=500)	W152
6.9	Intent-to-Treat Exposed	207966/primary_02/T6.16	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance + Extension Phase)		W152

Health Outcomes Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.10	Intent-to-Treat Exposed	207966/primary_02/T6.17	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit - LOCF (Maintenance + Extension Phase)		W152
6.11	Intent-to-Treat Exposed	207966/primary_02/T6.18	Summary of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit (Maintenance + Extension Phase)		W152
6.12	Intent-to-Treat Exposed	207966/primary_02/T6.19	Summary of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit - LOCF (Maintenance + Extension Phase)		W152
6.13	Intent-to-Treat Exposed	207966/primary_02/T6.20	Summary of HIVTSQs - Change from Baseline in Individual Item Score by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit - LOCF (Maintenance + Extension Phase)		W152
6.14	Intent-to-Treat Exposed	207966/primary_02/T6.21	Statistical Analysis of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Visit for Subjects without Prior Exposure to CAB+RPV - LOCF (Maintenance + Extension Phase)	Adjust the second footnote based on the modelling result.	W152
6.15	Intent-to-Treat Exposed	207966/primary_02/T6.22	Statistical Analysis of HIVTSQs - Change from Baseline in Total Treatment Satisfaction Score by Visit for Subjects with Prior Exposure to CAB+RPV - LOCF (Maintenance + Extension Phase)	Adjust the second footnote based on the modelling result.	W152
Treatment Acceptance (ACCEPT)					

Health Outcomes Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.16	Intent-to-Treat Exposed	207966/primary_02/T6.31	Proportion of Subjects with ACCEPT - Individual Item Score by Visit - LOCF (Maintenance + Extension Phase)		W152
6.17	Intent-to-Treat Exposed	207966/primary_02/T6.32	Summary of Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit (Maintenance + Extension Phase)		W152
6.18	Intent-to-Treat Exposed	207966/primary_02/T6.33	Summary of Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit - LOCF (Maintenance + Extension Phase)		W152
6.19	Intent-to-Treat Exposed	207966/primary_02/T6.34	Summary of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit (Maintenance + Extension Phase)		W152
6.20	Intent-to-Treat Exposed	207966/primary_02/T6.35	Summary of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Prior Exposure to CAB+RPV (0 vs. >=1 Weeks) and Visit - LOCF (Maintenance + Extension Phase)		W152
6.21	Intent-to-Treat Exposed	207966/primary_02/T6.36	Statistical Analysis of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit for Subjects without Prior Exposure to CAB+RPV - LOCF (Maintenance + Extension Phase)	Adjust the second footnote based on the modelling result.	W152

Health Outcomes Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.22	Intent-to-Treat Exposed	207966/primary_02/T6.37	Statistical Analysis of Change from Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit for Subjects with Prior Exposure to CAB+RPV - LOCF (Maintenance + Extension Phase)	Adjust the second footnote based on the modelling result.	W152
Reasons for Oral Bridging and Preference					
6.23	Oral Bridging	Shell HO_T2	Proportion of Subjects with Response to Each Individual Question in Reasons for Oral Bridging and Preference Questionnaire at Week 152 (Extension Phase)		W152

15.15.6.10. Health Outcomes Figures

Health Outcomes Figures					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.1	Intent-to-Treat Exposed	207966/primary_02/F6.1	Line Plot of Adjusted Mean (95% CI) Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) for Subjects without Prior Exposure to CAB+RPV - LOCF		W152
6.2	Intent-to-Treat Exposed	207966/primary_02/F6.2	Line Plot of Adjusted Mean (95% CI) Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) for Subjects with Prior Exposure to CAB+RPV - LOCF		W152
6.3	Intent-to-Treat Exposed	207966/primary_02/F6.3	Line Plot of Difference (95% CI) in Adjusted Mean Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) for Subjects without Prior Exposure to CAB+RPV - LOCF		W152
6.4	Intent-to-Treat Exposed	207966/primary_02/F6.4	Line Plot of Difference (95% CI) in Adjusted Mean Change from Baseline in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) for Subjects with Prior Exposure to CAB+RPV - LOCF		W152

15.15.6.11. Virology Tables

Virology Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Genotype					
7.1	Confirmed Virologic Failure	207966/primary_15/T7.1	Summary of the Prevalence of Known INI Resistance Mutations at time of CVF (Maintenance + Extension Phase) – Plasma Sample		W152
7.2	Confirmed Virologic Failure	207966/primary_15/T7.2	Summary of the Prevalence of Major Resistance Mutations of NRTI, NNRTI and PI Class at time of CVF (Maintenance + Extension Phase) - Plasma Sample		W152
7.3	Confirmed Virologic Failure	207966/primary_15/T7.3	Summary of Genotypic Susceptibility at time of CVF (Maintenance + Extension Phase) - Plasma Sample		W152
Phenotype					
7.4	Confirmed Virologic Failure	207966/primary_15/T7.4	Summary of Phenotype Susceptibility at time of CVF (Maintenance + Extension Phase) - Plasma Sample		W152
7.5	Confirmed Virologic Failure	207966/primary_15/T7.5	Summary of Phenotype: Number of Drugs to Which Subject is Phenotypic Resistant or Partial Sensitive or Sensitive at Time of CVF (Maintenance + Extension Phase) - Plasma Sample		W152
7.6	Confirmed Virologic Failure	207966/primary_15/T7.6	Summary of Fold Change to CAB and RPV at Time of CVF (Maintenance + Extension Phase) - Plasma Sample		W152
7.7	Confirmed Virologic Failure	207966/primary_15/T7.7	Summary of Net Assessment at time of CVF (Maintenance + Extension Phase) - Plasma Sample		W152

Virology Tables					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Other					
7.8	Confirmed Virologic Failure	207966/primary_15/T7.9	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria during the Maintenance and Extension Phase		W152
7.9	Safety	207966/primary_15/T7.10	Summary of Viral load, Genotypic and Phenotypic data for Non-CVF Subjects with Genotypic and/or Phenotypic Data		W152

15.15.6.12. ICH Listings

Note: Unless otherwise specified, both unique subject ID and latest subject ID for a subject will be included in the listings; display by prior exposure to CAB+RPV (0, 1-24, >24 weeks, refer to Section 15.6.2 for calculation details) for all listings except for study population listings.

ICH Listings					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
1	Intent-to-Treat Exposed	207966/primary_15/L4	Listing of Reasons for Study Withdrawal		W152
2	Intent-to-Treat Exposed	207966/primary_15/L5	Listing of Reasons for Study Drug Discontinuation		W152
3	Intent-to-Treat Exposed	207966/primary_15/L6	Listing of Important Protocol Deviations		W152
4	Intent-to-Treat Exposed	207966/primary_15/L7	Listing of Protocol Deviations Leading to Exclusion from the Per-Protocol Population		W152
5	Intent-to-Treat Exposed	207966/primary_15/L9	Listing of Demographic Characteristics		W152
6	Intent-to-Treat Exposed	207966/primary_15/L10	Listing of Race		W152
7	Intent-to-Treat Exposed	207966/primary_15/L8	Listing of Subjects with Inclusion/Exclusion Criteria Deviations		W152
Efficacy					
8	Intent-to-Treat Exposed	207966/primary_15/L11	Listing of Study Outcome (50 c/mL Threshold) at Week 152 – Snapshot	Update the footnote per given data.	W152

ICH Listings					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Analysis		
Safety					
9	Safety	207966/primary_15/L12	Listing of Investigational Product Exposure Data		W152
10	Safety	207966/primary_15/L13	Listing of Subject Numbers for Individual Adverse Events		W152
11	Safety	207966/primary_15/L14	Listing of Reasons for Considering as a Serious Adverse Event		W152
12	Safety	207966/primary_15/L15	Listing of Fatal Adverse Events		W152
13	Safety	207966/primary_15/L16	Listing of Non-Fatal Serious Adverse Events		W152
14	Safety	207966/primary_15/L17	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product (Maintenance + Extension Phase)		W152
15	Safety	207966/primary_15/L18	Listing of Changes in Intensity/Grades of Study Drug Injection Site Adverse Events		W152
16	Safety	207966/primary_15/L19	Listing of All Adverse Events		W152
17	Safety	207966/primary_15/L66	Listing of COVID-19 Adverse Events		W152
18	Safety	207966/primary_15/L67	Listing of COVID-19 Assessments		W152
19	Safety	207966/primary_15/L68	Listing of COVID-19 Symptoms		W152
20	Safety	207966/primary_15/L20	Listing of Subjects Who Became Pregnant during the Study		W152

ICH Listings					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
21	Safety	207966/primary_15/L21	Listing of Medical Conditions for Subjects with Liver stopping Events		W152
22	Safety	207966/primary_15/L22	Listing of Substance Use for Subjects with Liver Stopping Events		W152
23	Safety	207966/primary_15/L23	Listing of ECG Values for Subjects with a Value of Potential Clinical Importance		W152
24	Safety	207966/primary_15/L24	Listing of ECG Findings		W152
PK					
25	Pharmacokinetic	207966/primary_15/L29	Listing of Plasma CAB PK Concentration-Time Data		W152
26	Pharmacokinetic	207966/primary_15/L30	Listing of Plasma RPV PK Concentration-Time Data		W152

15.15.6.13. Non-ICH Listings

Note: Unless otherwise specified, both unique subject ID and latest subject ID for a subject will be included in the listings; display by prior exposure to CAB+RPV (0, 1-24, >24 weeks, refer to calculation details in Section 15.6.2) for all listings except for study population listings.

Non-ICH Listings					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
27	Intent-to-Treat Exposed	207966/primary_15/L33	Listing of Reasons for Extension Phase Withdrawal		W152
28	Long-term Follow-up	207966/primary_15/L34	Listing of Reasons for Long-term Follow-up Phase Withdrawal		W152
29	Intent-to-Treat Exposed	207966/primary_15/L36	Listing of Prior ART Medications		W152
30	Intent-to-Treat Exposed	207966/primary_15/L37	Listing of Concomitant ART Medications	In case the same medication is concomitant during both maintenance and extension phases, list each of them in two separate rows.	W152
31	Intent-to-Treat Exposed	207966/primary_15/L38	Listing of ART Medications Received during Long-term Follow-up Phase		W152
32	Intent-to-Treat Exposed	207966/primary_15/L39	Listing of Investigational Product Accountability - Oral Regimens		W152
33	Intent-to-	207966/primary_15/L6	Listing of Non-important COVID-19 Related	Remove the column, “COVID-19	W152

Non-ICH Listings					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
	Treat Exposed		Protocol Deviations	Related".	
34	Intent-to-Treat Exposed	PAN5A	Country Level Listing of Dates of Waves of COVID-19 Pandemic Measures	Only include countries that are applicable to the study. The covidimt dataset from arenv/arcomn/covid uses the IMT alerts to determine when pandemic measures began. Use this dataset as source to obtain the start and end dates of pandemic measures. Follow the instructions available in the same location for appropriate data use.	W152
Efficacy					
35	Confirmed Virologic Failure	207966/primary_15/L41	Listing of All Plasma HIV-1 RNA Data for Subjects with Confirmed Virologic Failure		W152
36	Intent-to-Treat Exposed	207966/primary_15/L42	Listing of All Plasma HIV-1 RNA Data for Subjects with Viral load >=50 c/mL during the Maintenance and Extension Phase		W152
37	Intent-to-Treat Exposed	207966/primary_15/L64	Listing of All Plasma HIV-1 RNA Data		W152
38	Intent-to-Treat Exposed	207966/primary_15/L43	Listing of HIV-1 Associated Conditions		W152
Safety					
39	Safety	207966/primary_15/L52	Listing of Liver Stopping Event Reporting		W152

Non-ICH Listings					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
40	Safety	207966/primary_15/L53	Listing of Liver Event Information for RUCAM Score		W152
41	Safety	207966/primary_15/L54	Listing of Liver Biopsy Details		W152
42	Safety	207966/primary_15/L55	Listing of Liver Imaging Details		W152
43	Safety	207966/primary_15/L56	Listing of Subjects Meeting Hepatobiliary Lab Criteria	Only Maintenance and Extension phases are included.	W152
44	Safety	207966/primary_15/L57	Listing of Potential QTc Interval Prolonging Events of Interest		W152
45	Safety	207966/primary_15/L58	Listing of ECG values for Subjects with Potential QTc Interval Prolonging Events of Interest		W152
46	Safety	207966/primary_15/L59	Listing of ALT, AST, Bilirubin (including Total and Direct Bilirubin), INR, and ALP for Subjects Meeting Hepatobiliary Lab Abnormality Criteria		W152
47	Safety	207966/primary_15/L61	Listing of Dosing Errors and IP Device Malfunctions		W152
48	Safety	SAF_L3	Listing of Selected Study Treatment Data for Subjects Who Had Planned Reloading Injections		W152
Virology					
49	Confirmed Virologic Failure	207966/primary_15/L62	Listing of Replication Capacity in IN and PR/RT Region		W152
50	Safety	207966/primary_15/L63	Listing of Resistance Associated Mutations (Pre-specified INSTI and IAS-USA NNRTI)		W152
PK					
51	Long-term Follow-up	207966/primary_02/L63	Listing of Plasma PK Concentration-Time Data since Last Injection	Remove age and add “Start Date of Oral RPV after Last Injection” after “Baseline BMI (kg/m^2)” in the	W152

Non-ICH Listings					
No. in W152	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				second column from the left; add asterisk to RPV concentration taken on/after the start of such oral RPV. and add a footnote, “Note: the RPV concentrations marked with an asterisk were taken on/after the start date of the oral RPV.”	

15.15.7. List of Data Displays for Sub-study Analysis

Unless otherwise specified, in sub-study analysis, age refers to the age at the sub-study screening, Baseline weight and Baseline BMI refer to the weight and BMI at the sub-study baseline respectively, and the listings will not be presented by prior exposure to CAB + RPV as the shell.

15.15.7.1. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.1	Sub-study ITT-E	207966/primary_34/T1.1	Summary of Number of Sub-study Subjects Enrolled by Country and Site ID		Sub-study
1.2	Sub-study Screened	207966/primary_15/T1.2	Summary of Screening Status and Reasons for Sub-study Screening Failures		Sub-study
1.3	Sub-study ITT-E	207966/primary_34/T1.2	Summary of Subject Accountability: Sub-study Conclusion Record	Remove the first footnote. Re-number the footnotes and the corresponding numbers in the display.	Sub-study
1.4	Sub-study ITT-E	207966/primary_34/T1.3	Summary of Subject Accountability: Thigh Injection Phase Conclusion Record		Sub-study
1.5	Sub-study ITT-E	207966/primary_34/T1.3	Summary of Subject Accountability: Return to Gluteal Injection Phase Conclusion Record		Sub-study
1.6	Sub-study ITT-E	207966/primary_34/T1.6	Summary of Subject Disposition at Each Study Phase	Present following phases in order: Thigh Injection Phase, Extension Phase (after withdrawal from the Thigh Injection phase), Long-term Follow-up Phase (after withdrawal from the Thigh Injection phase), Return to Gluteal Injection Phase,	Sub-study

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Extension Phase (after withdrawal from the Return to Gluteal Injection phase or sub-study completion), Long-term Follow-up Phase (after withdrawal from the Return to Gluteal Injection phase or sub-study completion).	
1.7	Sub-study ITT-E	207966/primary_34/T1.9	Summary of Study Drug Discontinuation		Sub-study
1.8	Sub-study Screened	207966/primary_34/T1.10	Summary of Study Populations	Only include analysis populations used in the sub-study analysis.	Sub-study
1.9	Sub-study ITT-E	207966/primary_34/T1.11	Summary of Important Protocol Deviations in Sub-study		Sub-study
1.10	Sub-study ITT-E	207966/primary_34/T1.11	Summary of Important Protocol Deviations (Thigh Injection Phase)		Sub-study
1.11	Sub-study ITT-E	207966/primary_15/T1.13	Summary of Inclusion/Exclusion Criteria Deviations in Sub-study		Sub-study
1.12	Sub-study ITT-E	207966/primary_34/T1.14	Summary of Important COVID-19 Related Protocol Deviations in Sub-study		Sub-study
1.13	Sub-study ITT-E	207966/primary_34/T1.15	Summary of Important Non-COVID-19 Related Protocol Deviations in Sub-study		Sub-study
Demographic and Baseline Characteristics					
1.14	Sub-study ITT-E	207966/primary_34/T1.16	Summary of Demographic Characteristics	Add [1] after "Age (y)" and "Age group (y)"; add the footnote "[1] Age is calculated with respect to the first sub-study screening visit."; for Weight and BMI, change the label to be "Weight (kg) at Sub-study Baseline" and "BMI (kg/m^2) at Sub-study Baseline" respectively.	Sub-study

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.15	Sub-study ITT-E	207966/primary_34/T1.17	Summary of Race and Racial Combinations		Sub-study
1.16	Sub-study ITT-E	207966/primary_34/T1.18	Summary of Race and Racial Combinations Details		Sub-study
Medications and Smoking Status					
1.17	Sub-study ITT-E	Shell POP_T2	Summary of Extent of Exposure to Study Treatment including SOC Oral Bridging Prior to the First Thigh Injection		Sub-study
1.18	Sub-study ITT-E	207966/primary_34/T1.24	Summary of Concomitant Non-ART Medication Ingredient Combinations (Thigh Injection Phase)		Sub-study
1.19	Sub-study ITT-E	SU1	Summary of Smoking Status at Sub-study Baseline	Only include “History of smoking use” section.	Sub-study
Visits Impacted by COVID-19 Pandemic					
1.20	Sub-study ITT-E	207966/primary_34/T1.27	Summary of COVID-19 Pandemic Visit Impacts in Sub-study	Only include visits in sub-study. Remove the last footnote.	Sub-study

15.15.7.2. Efficacy Tables

Note: The following subgroups will be included in the subgroup analysis: Age (<50 vs >=50), Race (White vs Non-white), Sex at Birth (Female vs Male), Sub-study Baseline BMI (<30, >=30).

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	Sub-study ITT-E	207966/primary_34/T2.3	Summary of Study Outcomes (50 c/mL Threshold) at Sub-study Week 16 – Snapshot Analysis		Sub-study
2.2	Sub-study ITT-E	207966/primary_34/T2.7	Summary of Study Outcomes (50 c/mL Threshold) at Sub-study Week 16 by Subgroup – Snapshot Analysis		Sub-study
2.3	Sub-study ITT-E	207966/primary_34/T2.13	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Visit (Thigh Injection Phase) – Snapshot Analysis		Sub-study
2.4	Sub-study ITT-E	207966/primary_34/T2.14	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Subgroup and Visit (Thigh Injection Phase) – Snapshot Analysis		Sub-study
2.5	Sub-study ITT-E	207966/primary_34/T2.15	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (Thigh Injection Phase) – Snapshot Analysis		Sub-study
2.6	Sub-study ITT-E	207966/primary_34/T2.16	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Subgroup and Visit (Thigh Injection Phase) – Snapshot Analysis		Sub-study
2.7	Sub-study ITT-E	207966/primary_34/T2.23	Summary of Change from Sub-study Baseline in Plasma HIV-1 RNA (log10 c/mL) by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
2.8	Sub-study ITT-E	207966/primary_34/T2.24	Summary of Plasma HIV-1 RNA (log10 c/mL) by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.9	Sub-study ITT-E	207966/primary_34/T2.25	Cumulative Proportion of Subjects Meeting Confirmed Virology Failure Criteria by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
2.10	Sub-study CVF	207966/primary_34/T2.27	Distribution of Quantitative Plasma HIV-1 RNA Results at Suspected and Confirmation of Confirmed Virologic Failure (Thigh Injection + Return to Gluteal Injection Phase)	Produce only when data available for the population of interest.	Sub-study
2.11	Sub-study ITT-E	207966/primary_34/T2.29	Summary of Subjects per Viral Load Category by Visit (Thigh Injection Phase)		Sub-study
2.12	Sub-study ITT-E	207966/primary_34/T2.30	Summary of Change from Sub-study Baseline in CD4+ Cell Count (cells/mm^3) by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
2.13	Sub-study ITT-E	207966/primary_34/T2.31	Summary of Change from Sub-study Baseline in CD4+ Cell Count (cells/mm^3) at Sub-study Week 16 by Subgroup	Replace “Baseline” with “Sub-study baseline” in the footnote.	
2.14	Sub-study ITT-E	207966/primary_34/T2.32	Summary of CD4+ Cell Count (cells/mm^3) by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
2.15	Sub-study ITT-E	207966/primary_34/T2.33	Summary of Change from Sub-study Baseline in CD8+ Cell Count (cells/mm^3) by Visit (Thigh Injection Phase)	Replace “Baseline” with “Sub-study baseline” in the footnote.	Sub-study
2.16	Sub-study ITT-E	207966/primary_34/T2.34	Summary of CD8+ Cell Count (cells/mm^3) by Visit (Thigh Injection Phase)		Sub-study
2.17	Sub-study ITT-E	207966/primary_34/T2.35	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit (Thigh Injection Phase)		Sub-study
2.18	Sub-study ITT-E	207966/primary_34/T2.36	Summary of HIV-1 Associated Conditions Including Recurrences (Thigh Injection + Return to Gluteal Injection Phase)	Produce only when data available for the population of interest.	Sub-study

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.19	Sub-study ITT-E	207966/primary_34/T2.37	Summary of HIV-1 Associated Conditions Excluding Recurrences (Thigh Injection + Return to Gluteal Injection Phase)	Produce only when data available for the population of interest.	Sub-study
2.20	Sub-study ITT-E	207966/primary_34/T2.38	Summary of HIV-1 Disease Progression from Sub-study Baseline and/or Deaths (Thigh Injection + Return to Gluteal Injection Phase)	Replace "maintenance and extension phase" in the second footnote with "thigh injection or return to gluteal injection phase".	Sub-study

15.15.7.3. Efficacy Figures

Efficacy Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	Sub-study ITT-E	207966/primary_34/F2.1	Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL by Visit (Thigh Injection Phase) – Snapshot Analysis		Sub-study
2.2	Sub-study ITT-E	207966/primary_34/F2.3	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit (Thigh Injection Phase) – Snapshot Analysis		Sub-study
2.3	Sub-study CVF	207966/primary_34/F2.7	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit – for CVF Subjects	Produce only when data available for the population of interest. Replace the first footnote with "First vertical reference line corresponds to the date of first thigh injection."	Sub-study
2.4	Sub-study ITT-E	207966/primary_34/F2.8	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Visit for subjects Who are in the Category of 'HIV-1 RNA >=50 c/mL' at Sub-study Week 16 per Snapshot Algorithm	Produce only when data available for the population of interest. Replace the first footnote with "First vertical reference line corresponds to the date of first thigh injection."	Sub-study

15.15.7.4. Safety Tables

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Exposure					
3.1	Sub-study Safety	207966/primary_34/T3.1	Summary of Extent of Exposure to Study Treatment (Thigh Injection + Return to Gluteal Injection Phase)	Include both continuous and categorical summaries for Exposure (No. of Thigh Injection Visits), Exposure (No. of Return to Gluteal Injection Visits), Exposure (No. of Injection Visits), Overall Exposure to Study Treatment during the Thigh Injection Phase, Overall Exposure to Study Treatment during the Thigh Injection + Return to Gluteal Injection Phase. The levels for categorical summaries will be selected as appropriate. Remove the footnote.	Sub-study
3.2	Sub-study Safety	207966/primary_34/T3.2	Summary of Needle Length and Gauge for CAB Injection (Thigh Injection Phase)	Replace the “at Maintenance + Extension Phase” in footnote with “during the Thigh Injection phase”.	Sub-study
3.3	Sub-study Safety	207966/primary_34/T3.3	Summary of Needle Length and Gauge for RPV Injection (Thigh Injection Phase)	Replace the “at Maintenance + Extension Phase” in footnote with “during the Thigh Injection phase”.	Sub-study
3.4	Sub-study Safety	207966/primary_34/T3.4	Summary of Adherence to CAB/RPV Injection Dosing Schedule (Thigh Injection Phase)	Remove the missed Injection related rows from shell. Add “Missed Injection” row. Replace the footnote with "[1] The total number of expected thigh injection visits following the first thigh injection." Add a footnote “Note: Oral bridging is not allowed in the sub-study.”.	Sub-study

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.5	Sub-study Safety	207966/primary_34/T3.4	Summary of Adherence to CAB/RPV Injection Dosing Schedule (Thigh Injection + Return to Gluteal Injection Phase)	Remove the missed Injection related rows from shell. Add “Missed Injection” row. Replace the footnote with "[1] The total number of expected injection visits in sub-study following the first thigh injection." Add a footnote “Note: Oral bridging is not allowed in the sub-study.”.	Sub-study
Adverse Events					
3.6	Sub-study Safety	207966/primary_34/T3.6	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Thigh Injection Phase)		Sub-study
3.7	Sub-study Safety	207966/primary_34/T3.6	Summary of All Adverse Events by System Organ Class and Maximum Toxicity (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
3.8	Sub-study Safety	207966/primary_34/T3.8	Summary of All Adverse Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity (Thigh Injection Phase)		Sub-study
3.9	Sub-study Safety	207966/primary_34/T3.10	Summary of Common Adverse Events (>=5%) by Overall Frequency (Thigh Injection Phase)		Sub-study
3.10	Sub-study Safety	207966/primary_34/T3.11	Summary of Common Grade 2-5 Adverse Events (>=1%) by Overall Frequency (Thigh Injection Phase)		Sub-study
3.11	Sub-study Safety	207966/primary_34/T3.13	Summary of All Drug-related Adverse Events by System Organ Class and Maximum Toxicity (Thigh Injection Phase)		Sub-study

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.12	Sub-study Safety	207966/primary_34/T3.15	Summary of All Drug-related Adverse Events Excluding Study Drug Injection Site Reactions by System Organ Class and Maximum Toxicity (Thigh Injection Phase)		Sub-study
3.13	Sub-study Safety	207966/primary_34/T3.16	Summary of All Drug-Related Grade 2-5 Adverse Events by Overall Frequency (Thigh Injection Phase)		Sub-study
Serious and Other Significant Adverse Events					
3.14	Sub-study Safety	207966/primary_34/T3.17	Summary of Serious Adverse Events by System Organ Class (Thigh Injection Phase)		Sub-study
3.15	Sub-study Safety	207966/primary_34/T3.17	Summary of Serious Adverse Events by System Organ Class (Thigh Injection +Return to Gluteal Injection Phase)		Sub-study
3.16	Sub-study Safety	207966/primary_34/T3.19	Summary of Drug-related Serious Adverse Events by System Organ Class (Thigh Injection Phase)		Sub-study
3.17	Sub-study Safety	207966/primary_34/T3.22	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product or Withdrawal from Study by System Organ Class (Thigh Injection Phase)	Remove the footnote.	Sub-study
3.18	Sub-study Safety	207966/primary_34/T3.22	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class (Thigh Injection + Return to Gluteal Injection Phase)	Remove the footnote.	Sub-study
3.19	Sub-study	207966/primary_34/T3.25	Summary of Subjects and Number of		Sub-study

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
	Safety		Occurrences of Common (>=5%) Non-Serious Adverse Events by System Organ Class (Thigh Injection Phase)		
3.20	Sub-study Safety	207966/primary_34/T3.26	Summary of Subjects and Number of occurrences of SAEs, Fatal SAEs, and Drug-related SAEs (Thigh Injection Phase)		Sub-study
Study Drug Injection Site Reaction Adverse Events					
3.21	Sub-study Safety	207966/primary_34/T3.27	Summary of Study Drug Injection Site Reaction Adverse Events (Event-level Summary) – (Thigh Injection Phase)		Sub-study
3.22	Sub-study Safety	207966/primary_34/T3.28	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common (Thigh Injection Phase)		Sub-study
3.23	Sub-study Safety	207966/primary_34/T3.29	Summary of Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity – Overall and Common in Sub-study		Sub-study
3.24	Sub-study Safety	207966/primary_34/T3.30	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - CAB (Thigh Injection Phase)		Sub-study
3.25	Sub-study Safety	207966/primary_34/T3.31	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events (Thigh Injection Phase) - Overall and Common (CAB)		Sub-study
3.26	Sub-study Safety	207966/primary_34/T3.32	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction		Sub-study

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			Adverse Events by Visit and Maximum Severity in Sub-study - CAB		
3.27	Sub-study Safety	207966/primary_34/T3.33	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length (Thigh Injection Phase) – Common (CAB)	Replace “Mnt + Ext” with “Thigh Injection” in the footnote.	Sub-study
3.28	Sub-study Safety	207966/primary_34/T3.34	Summary of Drug-related Study Drug Injection Site Reaction Adverse Events (Event-level Summary) - RPV (Thigh Injection Phase)		Sub-study
3.29	Sub-study Safety	207966/primary_34/T3.35	Summary of Drug-related Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events (Thigh Injection Phase) - Overall and Common (RPV)		Sub-study
3.30	Sub-study Safety	207966/primary_34/T3.36	Summary of Overall and Common Drug-related Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity in Sub-study - RPV		Sub-study
3.31	Sub-study Safety	207966/primary_34/T3.37	Summary of Maximum Drug-related Study Drug Injection Site Reaction Adverse Event Grade by Needle Length (Thigh Injection Phase) – Common (RPV)	Replace “Mnt + Ext” with “Thigh Injection” in the footnote.	Sub-study
Laboratory: Chemistry and Hematology					
3.32	Sub-study Safety	207966/primary_34/T3.38	Summary of Chemistry Changes from Sub-study Baseline by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
3.33	Sub-study Safety	207966/primary_34/T3.39	Summary of Chemistry Values by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.34	Sub-study Safety	207966/primary_34/T3.40	Summary of Hematology Changes from Sub-study Baseline by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
3.35	Sub-study Safety	207966/primary_34/T3.41	Summary of Hematology Values by Visit (Thigh Injection + Return to Gluteal Injection Phase)		Sub-study
3.36	Sub-study Safety	207966/primary_34/T3.42	Summary of Maximum Post Sub-study Baseline Emergent Chemistry Toxicities (Thigh Injection Phase)	Add “sub-study” before “baseline” in the second footnote.	Sub-study
3.37	Sub-study Safety	207966/primary_34/T3.43	Summary of Maximum Post Sub-study Baseline Emergent Hematology Toxicities (Thigh Injection Phase)	Add “sub-study” before “baseline” in the footnote.	Sub-study
Laboratory: Urinalysis					
3.38	Sub-study Safety	207966/primary_34/T3.44	Summary of Urinalysis Dipstick Results by Visit (Thigh Injection Phase)		Sub-study
3.39	Sub-study Safety	207966/primary_34/T3.45	Summary of Urine Concentrations Changes from Sub-study Baseline by Visit (Thigh Injection Phase)	Add “sub-study” before “baseline” in the second footnote.	Sub-study
3.40	Sub-study Safety	207966/primary_34/T3.46	Summary of Changes in Proteinuria Baseline Laboratory Result to Maximum Post Sub-study Baseline Laboratory Result (Thigh Injection Phase)		Sub-study
Laboratory: Hepatobiliary (Liver)					
3.41	Sub-study Safety	207966/primary_34/T3.53	Summary of Liver Stopping Event Reporting (Thigh Injection Phase)		Sub-study
3.42	Sub-study	207966/primary_34/T3.54	Summary of Subjects Meeting Hepatobiliary		Sub-study

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
	Safety		Abnormality Criteria (Thigh Injection Phase)		
ECG					
3.43	Sub-study Safety	207966/primary_34/T3.55	Summary of ECG Findings (Thigh Injection Phase)		Sub-study
3.44	Sub-study Safety	207966/primary_34/T3.56	Summary of Change from Sub-study Baseline in ECG values by Visit (Thigh Injection Phase)	Add “sub-study” before “baseline” in the first footnote.	Sub-study
3.45	Sub-study Safety	207966/primary_34/T3.57	Summary of QTc Values by Category (Thigh Injection Phase)		Sub-study
3.46	Sub-study Safety	207966/primary_34/T3.58	Summary of Change from Sub-study Baseline QTc Values by Category (Thigh Injection Phase)		Sub-study
Vital Signs					
3.47	Sub-study Safety	207966/primary_34/T3.59	Summary of Change from Sub-study Baseline in Vital Signs by Visit (Thigh Injection Phase)	Add “sub-study” before “baseline” in the first footnote.	Sub-study
Adverse Event of Special Interest (AESI)					
3.48	Sub-study Safety	207966/primary_34/T3.63	Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and Prior History of Depression, Anxiety and Suicidal Ideation at Screening (Thigh Injection Phase)	May need to adjust the first footnote given the data. Add a footnote: “Note: The prior history of depression, anxiety and suicidal ideation was collected at the main study screening”.	Sub-study
3.49-3.66	Sub-study Safety	207966/primary_34/T3.64-3.80	Summary of XXX Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrence) – Thigh Injection Phase		Sub-study
3.67	Sub-study	207966/primary_34/T3.81	Summary of Characteristics of Common		Sub-study

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
	Safety		Adverse Events of Special Interest – Thigh Injection Phase		
COVID-19 Adverse Event					
3.68	Sub-study Safety	207966/primary_34/T3.84	Summary of COVID-19 Adverse Events by System Organ Class and Maximum Toxicity (Thigh Injection Phase)		Sub-study
3.69	Sub-study Safety	PAN1A	Summary of COVID-19 Assessments for Subjects with Suspected, Probable or Confirmed COVID-19 Case Diagnosis in Sub-study	Replace the first footnote with "[1] COVID-19 case diagnosis is based on WHO definition that was in effect at the time of diagnosis.". Add a footnote "Note: only the assessments with the associated COVID-19 adverse event (as recorded in the COVID-19 Coronavirus Infection Assessment eCRF form) started in the sub-study are included.".	Sub-study
3.70	Sub-study Safety	PAN2A	Summary of COVID-19 Additional Assessments for Subjects with Suspected, Probable or Confirmed COVID-19 Case Diagnosis in Sub-study	Add a footnote "Note: only the assessments with the associated COVID-19 adverse event (as recorded in the COVID-19 Coronavirus Infection Assessment eCRF form) started in the sub-study are included.".	Sub-study

15.15.7.5. Safety Figures

Safety Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.1	Sub-study Safety	213500/primary_03/F3.2	Plot of Incidence of Sub-study Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common)	Within each page, display CAB LA and/or RPV LA, CAB LA-Drug- Related, RPV LA-Drug-Related	Sub-study
3.2	Sub-study Safety	207966/primary_34/F3.7	Scatter Plot of Maximum vs. Sub-study Baseline for ALT (Thigh Injection Phase)	Add “Sub-study” to the front of “Baseline” in the x axis label.	Sub-study
3.3	Sub-study Safety	207966/primary_34/F3.8	Scatter Plot of Maximum Total Bilirubin vs. Maximum ALT (Thigh Injection Phase)		Sub-study
3.4	Sub-study Safety	207966/primary_34/F3.11	Histogram of Timeliness of Injections (Thigh Injection Phase)		Sub-study

15.15.7.6. Pharmacokinetic Tables

Pharmacokinetic Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	Sub-study PK Concentration	207966/primary_34/T4.1	Summary of Plasma CAB PK Concentration (ug/mL) - Time Data by Treatment and Visit in Sub-study - Including Log-transformed Statistics	Remove the last two footnotes.	Sub-study
4.2	Sub-study PK Concentration	207966/primary_34/T4.2	Summary of Plasma RPV PK Concentration (ng/mL) - Time Data by Treatment and Visit in Sub-study - Including Log-transformed Statistics	Remove the last two footnotes.	Sub-study
4.3	Sub-study PK Concentration	207966/primary_34/T4.3	Summary of Evaluable Plasma CAB PK Concentration (ug/mL) - Time Data by Treatment and Visit in Sub-study - Including Log-transformed Statistics	Remove the last footnote.	Sub-study
4.4	Sub-study PK Concentration	207966/primary_34/T4.4	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) - Time Data by Treatment and Visit in Sub-study - Including Log-transformed Statistics	Remove the last footnote.	Sub-study
4.5	Sub-study PK Parameter	PK06	Summary of Plasma CAB PK Parameters (non-transformed and log-transformed) by Treatment and Dosing Interval in Sub-study	Remove Column "{Additional time variable}". Replace treatment columns with columns for dosing intervals as specified in Section 15.6.5. Add Min and Max after %CVb for log-transformed data. Add %CV after SD for non-transformed data. Add Q1 and Q3 after Median to both types of data.	Sub-study

Pharmacokinetic Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.6	Sub-study PK Parameter	PK06	Summary of Plasma RPV PK Parameters (non-transformed and log-transformed) by Treatment and Dosing Interval in Sub-study	Similar notes to above.	Sub-study
4.7	Sub-study PK Parameter	Shell PK_T2	Statistical Analysis of Plasma CAB PK Parameters by Treatment in Sub-study		Sub-study
4.8	Sub-study PK Parameter	Shell PK_T2	Statistical Analysis of Plasma RPV PK Parameters by Treatment in Sub-study		Sub-study

15.15.7.7. Pharmacokinetic Figures

Pharmacokinetic Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	Sub-study PK Concentration	207966/primary_34/F4.1	Individual Plasma CAB Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Remove the second footnote.	Sub-study
4.2	Sub-study PK Concentration	207966/primary_34/F4.2	Individual Plasma RPV Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Remove the second footnote.	Sub-study
4.3	Sub-study PK Concentration	207966/primary_34/F4.5	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Remove the first footnote.	Sub-study
4.4	Sub-study PK Concentration	207966/primary_34/F4.6	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Remove the first footnote.	Sub-study
4.5	Sub-study PK Concentration	207966/primary_34/F4.11	Median (5th and 95th Percentile) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Remove the first footnote.	Sub-study
4.6	Sub-study PK Concentration	207966/primary_34/F4.12	Median (5th and 95th Percentile) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Remove the first footnote.	Sub-study
4.7	Sub-study PK Parameter	205696/final/F3.6	Geometric Mean Ratios and 90% CIs of Plasma CAB PK Parameters in Sub-study by Treatment and Comparison Type	Use "PK parameter name (n=xx)" for y axis label, add "Geometric Mean Ratio with 90% CI" for x axis label. Remove the footnotes from shell. Add Footnote: Note: The geometric mean ratios and 90% CIs come from the statistical analysis of the PK parameters using a mixed effects model as specified in the analysis plan.	Sub-study

Pharmacokinetic Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Page by Treatment and Parameter. The parameters include Ctau, Cmax and AUC(0-tau). Each page contains comparison types First Thigh vs. Gluteal and Last Thigh vs. Gluteal.	
4.8	Sub-study PK Parameter	205696/final/F3.6	Geometric Mean Ratios and 90% CIs of RPV PK Parameters in Sub-study by Treatment and Comparison Type	Similar notes to above.	Sub-study

15.15.7.8. Health Outcomes Tables

Health Outcomes Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
HIV Treatment Satisfaction Questionnaire Status or Change Version (HIVTSQs, HIVTSQc)					
6.1	Sub-study ITT-E	207966/primary_34/T6.7	Proportion of Subjects with HIVTSQs - Individual Item Scores by Visit in Sub-study		Sub-study
6.2	Sub-study ITT-E	207966/primary_34/T6.9	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit in Sub-study	Add a column “P Value [1]” to the right of the Column “Max.” Add the footnote: [1] Sub-study Week 16, Sub-study Week 24 (for Q8W arm) or 20 (for Q4W arm) are compared with the Sub-study Baseline using Wilcoxon signed-rank test.”	Sub-study
6.3	Sub-study ITT-E	207966/primary_34/T6.11	Summary of HIVTSQs - Change in Total Treatment Satisfaction Score in Sub-study	Remove the column 'Prior Exposure to CAB+RPV (weeks)'. Replace "Act. Rel. Time" With "Change", the new "Change" column includes "Change from Baseline to Week 16" for both arms, "Change from Baseline to Week 20" for Q4W and "Change from Baseline to Week 24" for Q8W, "Change from Week 16 to Week 20" for Q4W arm and "Change from Week 16 to Week 20" for Q8W. Remove the footnote.	Sub-study
6.4	Sub-study ITT-E	207966/primary_34/T6.13	Summary of HIVTSQs - Change in Individual Item Score in Sub-study	Similar notes to above.	Sub-study

Health Outcomes Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.5	Sub-study ITT-E	207966/primary_02/T6.23	Proportion of Subjects with HIVTSQc - Individual Item Change Score at Sub-study Week 16 (Thigh Injection Phase)		Sub-study
6.6	Sub-study ITT-E	207966/primary_02/T6.27	Summary of HIVTSQc - Individual Item Change Score at Sub-study Week 16 (Thigh Injection Phase)		Sub-study
6.7	Sub-study ITT-E	207966/primary_02/T6.25	Summary of HIVTSQc - Total Treatment Satisfaction Change Score at Sub-study Week 16 (Thigh Injection Phase)		Sub-study
Tolerability of Injection (NRS)					
6.8	Sub-study ITT-E	Shell HO_T3	Proportion of Subjects with Each Tolerability of Injection (NRS) Score by Visit in Sub-study		Sub-study
6.9	Sub-study ITT-E	201584/primary_01/T6.35	Summary of Tolerability of Injection (NRS) Score by Visit in Sub-study		Sub-study

Health Outcomes Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.10	Sub-study ITT-E	201584/primary_01/T6.37	Summary of Change in Tolerability of Injection (NRS) Score in Sub-study	Replace "Actual Relative Time" with "Change". In this column, for Q4W: "Change from Week -4 to Day 1", "Change from Week -3 to Week 1", "Change from Day 1 to Week 12", "Change from Week 1 to Week 13", Change from Week 12 to Week 16", "Change from Week 13 to Week 17", for Q8W: "Change from Week -8 to Day 1", "Change from Week -7 to Week 1", "Change from Day 1 to Week 8", "Change from Week 1 to Week 9", "Change from Week 8 to Week 16", "Change from Week 9 to Week 17".	Sub-study
Preference					
6.11	Sub-study ITT-E	Shell HO_T4	Proportion of Subjects with Response to Each Individual Question in Preference Thigh Injection vs Gluteal Injection Questionnaire by Visit in Sub-study		Sub-study

15.15.7.9. Virology Tables

Tables 7.1-7.6 will only be produced when at least one treatment group has >5 subjects in Sub-study CVF population. Tables 7.8-7.9 will only be produced when data are available.

Virology Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Genotype					
7.1	Sub-study CVF	207966/primary_34/T7.1	Summary of the Prevalence of Known INI Resistance Mutations at time of CVF (Thigh Injection + Return to Gluteal Injection Phase) – Plasma Sample		Sub-study
7.2	Sub-study CVF	207966/primary_34/T7.2	Summary of the Prevalence of Major Resistance Mutations of NRTI, NNRTI and PI Class at time of CVF (Thigh Injection + Return to Gluteal Injection Phase) - Plasma Sample		Sub-study
7.3	Sub-study CVF	207966/primary_34/T7.3	Summary of Genotypic Susceptibility at time of CVF (Thigh Injection + Return to Gluteal Injection Phase) - Plasma Sample		Sub-study
Phenotype					
7.4	Sub-study CVF	207966/primary_34/T7.4	Summary of Phenotype Susceptibility at time of CVF (Thigh Injection + Return to Gluteal Injection Phase) - Plasma Sample		Sub-study
7.5	Sub-study CVF	207966/primary_34/T7.5	Summary of Phenotype: Number of Drugs to Which Subject is Phenotypic Resistant or Partial Sensitive or Sensitive at Time of CVF (Thigh Injection + Return to Gluteal Injection Phase) - Plasma Sample		Sub-study
7.6	Sub-study CVF	207966/primary_34/T7.6	Summary of Fold Change to CAB and RPV at Time of CVF (Thigh Injection + Return to Gluteal Injection Phase) - Plasma Sample		Sub-study

Virology Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
7.7	Sub-study CVF	207966/primary_34/T7.7	Summary of Net Assessment at time of CVF (Thigh Injection + Return to Gluteal Injection Phase) - Plasma Sample		Sub-study
Other					
7.8	Sub-study CVF	207966/primary_34/T7.8	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria during the Thigh Injection or Return to Gluteal Injection Phase		Sub-study
7.9	Sub-study Safety	207966/primary_34/T7.9	Summary of Viral load, Genotypic and Phenotypic data for Non-CVF Subjects with Genotypic and/or Phenotypic Data in Sub-study		Sub-study

15.15.7.10. ICH Listings

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
1	Sub-study Screened	207966/primary_15/L3	Listing of Reasons for Screen Failure in Sub-study		Sub-study
2	Sub-study ITT-E	207966/primary_34/L1	Listing of Reasons for Sub-study Withdrawal		Sub-study
3	Sub-study ITT-E	207966/primary_34/L2	Listing of Reasons for Study Drug Discontinuation		Sub-study
4	Sub-study ITT-E	207966/primary_34/L3	Listing of Important Protocol Deviations		Sub-study
5	Sub-study ITT-E	207966/primary_34/L7	Listing of Subjects with Inclusion/Exclusion Criteria Deviations		Sub-study
6	Sub-study ITT-E	207966/primary_34/L5	Listing of Demographic Characteristics	Add "BMI (kg/m^2)" to the right of "Weight (kg)". Add the following sentence to footnote [1]: Age is calculated with respect to the subject's first sub-study screening visit. Add a footnote for BMI and Weight: [2] BMI and Weight are derived at Sub-study Baseline.	Sub-study
Efficacy					
7	Sub-study ITT-E	207966/primary_34/L8	Listing of Study Outcome (50 c/mL Threshold) at Sub-study Week 16 – Snapshot Analysis	Remove the footnote.	Sub-study
Safety					
8	Sub-study	207966/primary_34/L9	Listing of Investigational Product		Sub-study

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
	Safety		Exposure Data		
9	Sub-study Safety	207966/primary_34/L10	Listing of Subject Numbers for Individual Adverse Events		Sub-study
10	Sub-study Safety	207966/primary_34/L11	Listing of Reasons for Considering as a Serious Adverse Event		Sub-study
11	Sub-study Safety	207966/primary_34/L12	Listing of Fatal Adverse Events		Sub-study
12	Sub-study Safety	207966/primary_34/L13	Listing of Non-Fatal Serious Adverse Events		Sub-study
13	Sub-study Safety	207966/primary_34/L14	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product or Withdrawal from Study		Sub-study
14	Sub-study Safety	207966/primary_34/L15	Listing of Changes in Intensity/Grades of Study Drug Injection Site Adverse Events		Sub-study
15	Sub-study Safety	207966/primary_34/L16	Listing of All Adverse Events		Sub-study
16	Sub-study Safety	207966/primary_34/L17	Listing of COVID-19 Adverse Events		Sub-study
17	Sub-study Safety	207966/primary_34/L18	Listing of COVID-19 Assessments		Sub-study
18	Sub-study Safety	207966/primary_34/L19	Listing of COVID-19 Symptoms		Sub-study
19	Sub-study Safety	207966/primary_34/L20	Listing of Subjects Who Became Pregnant during the Study	Add a footnote: “Note: As pregnancy status is not collected in eCRF for the long-term follow-	Sub-study

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				up phase, this listing does not include subjects who became pregnant during the long-term follow-up phase."	
20	Sub-study Safety	207966/primary_34/L23	Listing of ECG Values for Subjects with a Value of Potential Clinical Importance in Sub-study	In footnote, add "sub-study" before the "baseline". Add following to the footnote, "The changes from baseline provided in this listing are with respect to the sub-study baseline."	Sub-study
PK					
21	Sub-study PK Concentration	207966/primary_34/L25	Listing of Plasma CAB PK Concentration-Time Data	Remove the Column "Excluded" and remove the first footnote. Present nominal visit before the analysis visit. Replace "Race Detail" with "Sub-study Baseline BMI (kg/m^2)" in the second column on the left.	Sub-study
22	Sub-study PK Concentration	207966/primary_34/L26	Listing of Plasma RPV PK Concentration-Time Data	Similar notes to above.	Sub-study

15.15.7.11. Non-ICH Listings

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
23	Sub-study ITT-E	207966/primary_34/L27	Listing of Reasons for Thigh Injection Phase Withdrawal		Sub-study
24	Sub-study ITT-E	207966/primary_34/L27	Listing of Reasons for Return to Gluteal Injection Phase Withdrawal		Sub-study
25	Sub-study LTFU	207966/primary_34/L28	Listing of Reasons for Long-term Follow-up Phase Withdrawal		Sub-study
26	Sub-study ITT-E	Shell POP_L2	Listing of Exposure to Study Treatment including SOC Oral Bridging Prior to the First Thigh Injection		Sub-study
27	Sub-study ITT-E	207966/primary_34/L30	Listing of Concomitant ART Medications		Sub-study
28	Sub-study ITT-E	207966/primary_34/L31	Listing of ART Medications Received during Long-term Follow-up Phase		Sub-study
29	Sub-study ITT-E	207966/primary_34/L34	Country Level Listing of Dates of Waves of COVID-19 Pandemic Measures for Countries Participating in Sub-study		Sub-study
30	Sub-study ITT-E	209493/final_02/L52	Listing of Transition to CAB + RPV LA Marketed Product Status	Replace "Subject Id." with "Latest Subject Id." in the column header.	Sub-study
Efficacy					
31	Sub-study CVF	207966/primary_34/L35	Listing of All Plasma HIV-1 RNA Data for Subjects with Confirmed Virologic Failure	Produce only when data are available.	Sub-study
32	Sub-study ITT-E	207966/primary_34/L36	Listing of All Plasma HIV-1 RNA Data for Subjects with Viral load >=50 c/mL during the Thigh Injection or Return to Gluteal Injection Phase		Sub-study

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
33	Sub-study ITT-E	207966/primary_34/L37	Listing of All Plasma HIV-1 RNA Data		Sub-study
34	Sub-study ITT-E	207966/primary_34/L38	Listing of HIV-1 Associated Conditions	Produce only when data are available.	Sub-study
Safety					
35	Sub-study Safety	207966/primary_34/L43	Listing of Subjects Meeting Hepatobiliary Lab Criteria (Thigh Injection + Return to Gluteal Injection Phase)	Present by phase.	Sub-study
36	Sub-study Safety	207966/primary_34/L45	Listing of ECG values for Subjects with Potential QTc Interval Prolonging Events of Interest in Sub-study		Sub-study
37	Sub-study Safety	207966/primary_34/L47	Listing of Dosing Errors and IP Device Malfunctions in Substudy		Sub-study
PK					
38	Sub-study PK Parameter	Shell PK_L1	Listing of Plasma PK Parameters in Sub-study		Sub-study

15.16. Appendix 16: Example Mock Shells for Data Displays

Available upon request

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