Statistical Analysis Plan

Main Study ID: 201584

Main Study Official Title: A Phase III, Randomized, Multicenter, Parallel-group, Open-Label Study Evaluating the Efficacy, Safety, and Tolerability of Long-Acting Intramuscular Cabotegravir and Rilpivirine for Maintenance of Virologic Suppression Following Switch from an Integrase Inhibitor Single Tablet Regimen in HIV-1 Infected Antiretroviral Therapy Naive Adult Participants

NCT ID for Main Study: NCT02938520

Sub-Study ID: 201584-001

Sub-Study Official Title: An Amendment to the FLAIR Study to Evaluate the Pharmacokinetics, Safety, Tolerability, Maintenance of Virological Suppression and Patient Reported Outcomes for Participants Receiving Cabotegravir (CAB 200 mg/mL) and Rilpivirine (300 mg/mL) Long-Acting Injections Following Sub-cutaneous (SC) Administration in the Anterior Abdominal Wall SC Tissue Compared With Intramuscular (IM) Administration in the Gluteus Medius Muscle in Adult Participants Living With HIV-1 Infection in the FLAIR Study

NCT ID for Sub-Study: NCT05896748

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

Title	:	201584: A Phase III, Randomized, Multicenter, Parallel-group, Open-Label Study Evaluating the Efficacy, Safety, and Tolerability of Long-Acting Intramuscular Cabotegravir and Rilpivirine for Maintenance of Virologic Suppression Following Switch from an Integrase Inhibitor Single Tablet Regimen in HIV-1 Infected Antiretroviral Therapy Naive Adult Participants
Compound Number	:	GSK1265744
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Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Subcutaneous Sub-study Clinical Study Report for Protocol 201584. Reporting details pertaining to the primary Week 48 and the earlier analyses (Week 96 and Week 124) have been retained for completeness.
- This version of the RAP includes amendments to the originally approved RAP.

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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 201584.

GlaxoSmithKline Document Number	Date	Version
2015N248866_00	2016-MAY-26	Original
2015N248866_01	2016-DEC-13	Amendment No. 1
The reasons for this amendment were to: added new primary Medical Monitor contact information; added lipid objective and endpoint back in to the table within the Synopsis section; added clarification of text for patient reported outcome endpoints; added additional clarification regarding provision of CAB LA and RPV LA until available through public/government health sectors; new text added to allow use of local labs to determine eligibility in exceptional circumstances; updated Time and Events Table to provide more clarity around assessments conducted during the Extension Phase, added 'X' to include collection of cardiovascular risk information at Screening, added temperature to Vital Signs row, added row for randomization, and clarified timings for completion of patient reported questionnaires relative to other clinical assessments in the table footnotes; clarified timing of dosing for abacavir/dolutegravir/lamivudine (ABC/DTG/3TC, Triumeq) for the Day 1 visit; added additional clarification that participants of child bearing potential must continue contraception for at least 52 weeks after the last injection; revised text to say that Investigators may provide 'bridging' supply after consultation with Medical Monitor (vs Medical Monitor authorizing bridging supply); provided clarification that cabotegravir and rilpivirine exposure may persist for more than one year in some participants after intramuscular administration (with added references); minor edits to prohibited medication information; added statement that drugs that cause Torsade de Pointes should be used with caution when taking rilpivirine; additional clarification that background NRTI therapy is not considered Investigational Product and accountability will not be done for NRTI background; changed film coat color for Tivicay (dolutegravir) from white (clinical trial material supply) to yellow (commercial supply) and removed statement to "protect from light" (for both Triumeq and Tivicay); sentence added for collection of additional details for the injection device used for IM administration; additional information included regarding randomization schedule; added text stating the investigator must discuss long-term commitment for the study with potential participants; added statement regarding serofast RPR results; allowed serum pregnancy testing where required locally (e.g. when urine testing is not available); removed duplicate text regarding monitoring for suicidal related events; added option for patient reported outcomes to be collected on paper instrument if needed; removed information in Appendix requiring collection of pregnancy information for female partners of male study participants; definition of ACCEPT, HIVTSQc, and HIVTSQs added to abbreviations table, duplication of ICH		

abbreviation removed; other minor corrections (e.g., updated references, adding cross reference to sections, correction of hyperlink to one table).		
2015N248866_02	2017-JUL-19	Amendment No. 2
The reasons for this amendment are as follow: update of contact information for secondary Medical Monitor; modify text to allow dose reduction for participants who have a decline in creatinine clearance to <50 mL/min; clarify that for participants not eligible to continue into the Maintenance Phase, only samples with HIV-1 RNA > 400 c/mL will be sent for resistance testing; add mitigation for ECG pad removal; clarify ± 3 day window is for all oral dosing (both Induction and Maintenance Phase); add "LA Arm" back to columns for Week 68, 76, 84, 92 on Time and Events Schedule (hidden when column was narrowed); clarify Week 104b visit is specific to those participants transitioning from oral IP to CAB LA + RPV LA; clarification added to footnote 'p' that genetics sample can be collected at any visit after signing informed consent, but Week [-20] preferred; correct footnote on Week 5 visit to reflect footnote 't'; add footnote 'y' back to Time and Events column for Withdrawal Visit (for Induction Phase); add clarification to Time and Events column that ISR assessments are only conducted for participants receiving injections; remove text from Section 12.2: 'In addition, all deaths related to an AE are to be classified as grade 5.' Administrative typographical errors corrected (e.g. clarification provided regarding genetics sample taken after participants are enrolled into the study [vs when participants are randomized]), and investigator brochure references updated.		
2015N248866_03	2018-JUN-25	Amendment No. 3
Changes for Amendment 3 were made to the protocol to manage and mitigate risks following identification of a potential safety issue related to neural tube defect in infants born to women with exposure to dolutegravir (DTG) at the time of conception. A Risk Assessment table was added to include language regarding risk and mitigation of neural tube defects seen with DTG. • The withdrawal criteria were updated to include a reminder that females of reproductive potential who change their minds and desire to be pregnant should also be withdrawn from the study. • The Time and Events table was updated to include a reminder for investigators to check at every visit that females of reproductive potential are avoiding pregnancy. Additionally, clarifications were provided for the following: • the DTG IB should be referenced for additional risks, safety information, drug interactions, etc.; • 'suspected' was added to the text prior to the bulleted definition of suspected virologic failure in Section 5.4.5.3.; • specific storage conditions were removed from the protocol for IP, and a statement added to store according to product label; • insulin was removed from the section regarding clinical assessments performed during the study;		

• timeframe for pregnancy reporting and follow-up were updated to 24 hours to align with current reporting process; • prescribing information and IB references were updated.		
2015N248866_04	2018-SEPT-24	Amendment No. 4
The primary reason for protocol amendment 04 is to allow an optional (vs mandatory) oral lead-in for participants randomized to the ABC/DTG/3TC arm who choose to continue into the Extension Phase of the study and receive CAB LA + RPV LA. The Appendix for contraceptive guidance and collection of pregnancy information was updated to be consistent with current protocol template text. Other minor clarifications were made as needed, e.g., the eCSSRs timing in the footnote for the Time and Events Table, updated abbreviations, etc.		
2015N248866_05	2020-MAY-20	Amendment No. 5
The reason for protocol amendment 05 is to include an Appendix with Covid-19 guidance for clinical trial continuity (participant and study management) during the pandemic. This appendix will replace the previous Appendix 9, and Appendix 9 "Protocol Amendment History," will be included as Appendix 10.		
TMF-13030701	2021-AUG-21	Amendment No. 6
The primary purposes of this amendment are: • To allow participants who become pregnant while in the study 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 antiretroviral 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 10 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. • Removal of the option for study treatment rechallenge following suspected drug-induced liver injury (DILI). • Clarification of which participants enter the LTFU phase when CAB+RPV LA marketed product is locally available. • Medical Device reporting requirement added. • Co-enrolment (only applicable for eligible female participants in South Africa in the ACTG A5392 study). • Updates to primary and secondary Medical Monitors.		

Other additional edits were made, for clarity and/or correction.		
TMF-147-28112	2022-JUN-17	Amendment No. 7
The primary purposes of this amendment are: • To include the Sub-Cutaneous Abdominal Injection Sub-Study appendix (only applicable for countries participating in the Sub-Study). • Clarification added: In Russia, subjects who become pregnant while on study may not elect to remain on study treatment and must withdraw and enter the LTFU Phase. Inclusion of Appendix 13: Mitigations for Geopolitical Situation in Russia/Ukraine		
TMF-15038148	2022-OCT-21	Amendment No. 8
This amendment is considered to be substantial based on the criteria defined in EU Clinical Trial Regulation No 536/2014 of the European Parliament and the Council of the European Union. Overall Rationale for the Amendment: The primary purposes of this amendment are: • • To include the Sub-Study Interim Analysis 1: ISR Monitoring Criteria into the Sub-Cutaneous Abdominal Injection Sub-Study appendix (only applicable to for countries participating in the Sub-Study). • • To include the Sub-Study Interim Analysis 2: Week 9 Safety and PRO Review into the Sub-Cutaneous Abdominal Injection Sub-Study appendix (only applicable for countries participating in the Sub-Study).		
TBD	TBD	Amendment No. 9
This amendment is considered to be substantial based on the criteria in EU Clinical Trial Regulation No 536/2014 of the European Parliament and the Council of the European Union. The primary purposes of this amendment are to update the Potential Risk of Clinical Significance of Hypersensitivity Reactions (HSR) when using integrase inhibitors, such as CAB.		

1.1. RAP Amendments

Revision chronology:

RAP Section	Amendment Details
Reporting and Analysis Plan_201584_Final_V1 [17-AUG-2018]	
Reporting and Analysis Plan_201584_Amendment_Final_V1 [17-SEPT-2018]	

RAP Section	Amendment Details
Reporting and Analysis Plan_201584_Amendment_2_Final_V1	
Japan Specific Reporting Requirements for Regulatory Submission	• Added data displays to be generated for Japan participants: study population, efficacy, safety, and pk. • Added details for the analysis of PK samples for participants in Japan, including estimation of PK parameters by non-compartmental methods using concentration-time day on Day 1. • Added analysis population for Japan PK.
Adverse Events of Special Interest	• Harmonized list of Adverse Events of Special Interest with that used in the Week 48 integrated analysis of safety summaries (with grouping based on clinical review of preferred terms and Standardized MedDRA Queries (SMQs))
Updated PK/PD analysis plan for Week 96	• Removed Last CAB/RPV Trough Concentration as a candidate predictor of efficacy outcomes at Week 96 (as this covariate is confounded with accumulation overtime). • Removed PK/PD efficacy displays related to Last CAB/RPV Trough Concentration (as this covariate is confounded with accumulation overtime). • Added condition that PK/PD efficacy analysis/displays will only be produced if the Week 96 dataset includes at least one new CVF since the Week 48 analysis • Clarified that the following PK/PD safety figures will not be produced at Week 96 given limited PK collection post W48: o Scatter Plot of Maximum Change from Maintenance Baseline (Day 1) in ALT/Bilirubin versus Last Trough CAB/RPV PK Concentrations o Box Plot of Maximum Toxicity Grades of Most Frequently Reported Non-ISR AEs versus Last Trough CAB/RPV PK Concentrations
Data Handling	• Minor update to the algorithm used to assign data to the Extension phase to account for direct to inject vs. start with oral lead-in. • Minor correction to W96 visit window for CD4+ cell count data and NRS questionnaire data.

RAP Section	Amendment Details	
		• Added Region (country grouping) and Baseline Integrase L74I mutation as subgroup variables • Clarified definition of Hepatitis B and C status at Baseline • Updated imputation rule for adverse events with partial end dates (to use last contact date instead of treatment stop date). • Clarified analysis visit assignment for LTFU PK samples. • Update the rationale for the prespecified list of mutations associated with resistance to integrase strand transfer inhibitors based on 2019 IAS-US guideline.
Data Displays		• The following data displays were added for Week 96: • Summary of Change from Plasma HIV-1 RNA (log10 c/mL) by Visit (Maintenance Phase) • Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA >= 50 c/mL (and <50 c/mL) at Week 96 by Selected Demographic Subgroups (Maintenance Phase) - Snapshot Analysis • Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA >= 50 c/mL (<50 c/ml) at Week 96 by Selected HIV Disease Characteristic Subgroups (Maintenance Phase) - Snapshot Analysis • Summary of Plasma CAB/RPV PK Concentration -Time Data by Treatment and Visit (Maintenance Phase) – Included Log-transformed Statistics by Hepatitis C Status at Induction Baseline • Individual Plasma CAB/RPV Concentration-Time Plots (Semi-Log) -- Post Last Injection for Subjects in LTFU • Listing of Plasma CAB/RPV PK Concentration-Time Data (LTFU Phase) • Listing of Concomitant Medications for Subjects with Confirmed Virologic Failure • Summary of Shift in BMI Categories at Week 96 • Summary of Shift in BMI from Induction Baseline (Week -20) to Maximum Post-baseline Category (Maintenance Phase)

RAP Section	Amendment Details

	• Scatter Plot of Maximum vs. Extension Baseline (Week 100) for ALT (Extension Phase) – Switch Q4W IM
	• Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin (Extension Phase) – Switch Q4W IM
	• Matrix Plot of Maximum Liver Chemistries (Extension Phase) – Switch Q4W group
	• Summary tables for Adverse Events of Special Interest
	• Listing of All Adverse Events
	• Listing of all Subjects Meeting Liver Stopping Criteria
	• Summary of HIVTSQs - Change from Maintenance Baseline (Day 1) in Individual Item Score by Visit - LOCF (Maintenance Phase)
	• Listing of All Genotypic Data
	• Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure (Maintenance + Extension Phase) — Randomized Q4W arm
	• Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria (Extension Phase) — Switch Q4W IM
	• Updated the following table to present minimum NCEP Category instead of Maximum:
	  ○ Summary of Changes in Maintenance Baseline (Day 1) NCEP Fasting Lipid Category to Minimum Maintenance Phase Category – HDL Cholesterol
	• Added further stratification by 'any history' vs. 'no history' for the following table:
	  ○ Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety and Suicidal Ideation/Behaviour at Screening
	• Updated some display titles in Appendix 14: List of Data Displays.

Reporting and Analysis Plan_201584_Amendment_3_Final_V1	
Data Handling and Data Displays for Week 124	• Clarified extension phase analyses window for AE data in Table 16

RAP Section	Amendment Details
	• Clarified derivation of Extension Phase extent of exposure in Section 14.6.2. • Added treatment group descriptors for Switch Q4W (Direct to Inject) and Switch Q4W (Oral Lead-In) in Table 3. • Added list of specific data displays to be produced for the Week 124 analysis to Section 14.15.
Reporting and Analysis Plan_201584_Amendment_4	
Data Handling and Data Displays for Sub-study	• Updated visit/phase slotting algorithms to handle the newly added sub-study 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 including a cut set of listings due to use of the RAPIDO DV.
Safety Analysis	• Added details of sub-study interim analyses including monitoring for ISRs of interest. • Added calculation methods for extent of exposure in sub-study. • Extended lipid LOCF approach to include both SC Injection and Return to Gluteal Injection phases in sub-study. • Added display shells for summaries of COVID-19 assessments including accommodation of possible scenarios of multiple COVID-19 case diagnoses per participant.
PK Analysis	• Added analysis methods for PK parameters derived from sub-study concentration-time data including interim analyses • 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/listings for data collected from the Transition to CAB + RPV LA Marketed Product Status eCRF form.
Health Outcomes Analysis	• Clarified that LOCF will no longer be used for HO analyses • Added analysis for the newly added questionnaires: 1. Preference Subcutaneous Injection vs Gluteal Injection questionnaire. 2. Reason for switch questionnaire • Interest in self administration questionnaire

RAP Section	Amendment Details
General Updates	• Added Endpoint & Estimand text for the Sub-study endpoints • Added sub-study Schedule of Activities per new protocol. • Added additional minor clarifications and corrections to typographical errors/formatting to RAP text.
Reporting and Analysis Plan_201584_Amendment_5	
Data Handling for Sub-study	• Updated visit/phase slotting algorithms to appropriately handle Adverse Events within the sub-study and clarified algorithm to ensure all records are associated with the correct visit.
General Updates	• 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 is a single deviation planned from protocol amendment #8 [(Dated: 21-OCT-2022)]. Due to delay in study enrolment for implementation of protocol amendment 8, interim analysis 2 will include PK summaries while the protocol indicates that no PK analyses will be included.

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
• Interim analysis 2 is planned to only summarize safety, tolerability, and HO data.	• PK data available around the Week 9 Safety timepoint will also be analyzed	• Delay in study start due to protocol amendment 8 necessitated the need for an earlier reporting of PK data.

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

Objectives	Endpoints
Primary	
To demonstrate the non-inferior antiviral activity of switching to intramuscular CAB LA + RPV LA every 4 weeks (monthly) compared to continuation of ABC/DTG/3TC over 48 weeks in HIV-1 antiretroviral naïve participants.	• Proportion of participants with a 'virologic failure' endpoint as per FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population).
Secondary	
To demonstrate the antiviral and immunologic activity of switching to intramuscular CAB LA + RPV LA every 4 weeks (monthly) compared to continuation of ABC/DTG/3TC.	• Proportion of participants with plasma HIV-1 RNA <50 copies/mL (c/mL) at Week 48 using the FDA Snapshot algorithm (Intent-to-Treat Exposed [ITT-E] population). • Proportion of participants with plasma HIV-1 RNA <200 c/mL at Week 48 using the FDA Snapshot algorithm (ITT-E population). • Proportion of participants with plasma HIV-1 RNA <200 c/mL and HIV-1 RNA <50 c/mL at Week 96 using the FDA Snapshot algorithm (ITT-E population). • Proportion of participants with a 'virologic failure' endpoint as per FDA Snapshot algorithm at Week 96. • Proportion of participants with confirmed

Objectives	Endpoints
	virologic failure at Week 48 and Week 96. • Absolute values and change from Baseline in plasma HIV-1 RNA (log_{10} copies/mL) at Week 48 and Week 96. • Absolute values and changes from Baseline in CD4+ cell counts over time including Week 48 and Week 96. • Incidence of disease progression (HIV-associated conditions, acquired immunodeficiency syndrome [AIDS] and death).
To evaluate the safety and tolerability of switching to CAB LA + RPV LA every 4 weeks (monthly) compared to continuation of ABC/DTG/3TC over time.	• Incidence and severity of adverse events (AEs) and laboratory abnormalities over time including Week 48 and Week 96. • Proportion of participants who discontinue treatment due to AEs over time including Week 48 and Week 96. • Absolute values and changes in laboratory parameters over time including Week 48 and Week 96.
To evaluate the effects of CAB LA + RPV LA every 4 weeks on fasting lipids over time compared to continuation of ABC/DTG/3TC over time.	• Change from Baseline in fasting lipids over time including Week 48 and Week 96.
To assess the development of viral resistance in participants experiencing protocol-defined virologic failure.	• Incidence of treatment emergent genotypic and phenotypic resistance to CAB, RPV, and other on-study ART at Week 48 and Week 96.
To characterize CAB and RPV concentrations and population pharmacokinetics (PK) and identify important determinants of variability.	• Plasma PK parameters for CAB LA and RPV LA (when evaluable, $C_{trough,}$ 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 (BMI), and relevant laboratory parameters will be evaluated as potential predictors of inter- and intra-participant variability for pharmacokinetic parameters.
To assess the acceptance of pain and injection site reactions following injections.	• Change from Week 5 in Dimension scores (e.g., “Bother of ISRs”, “Leg movement”,

Objectives	Endpoints
	"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 using the Perception of iNjection questionnaire (PIN). • Proportion of participants considering pain and local reactions following injection to be extremely or very acceptable based on the acceptability score over time using the Perception of iNjection questionnaire (PIN).
To assess treatment satisfaction of CAB LA + RPV LA compared to continuation of ABC/DTG/3TC.	• Change from baseline in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Questionnaire (status version) (HIVTSQs) at Week 4b, Week 24, Week 44, Week 96 (or Withdrawal). • Change in treatment satisfaction over time (using the HIVTSQc change version [HIVTSQc]) at Week 48 (or Withdrawal).
To assess degree of health-related quality of life (HR QoL).	• Change from Baseline in HR QoL using the HIV/AIDS targeted quality of life questionnaire (HAT-QoL) short format Week 24, Week 48, Week 96 (or Withdrawal).
To assess health status.	• Change from Baseline in health status at Week 24, Week 48, and Week 96 (or Withdrawal) using the 12-item Short Form Survey (SF-12).
To assess treatment acceptance.	• Change from Baseline in treatment acceptance at Week 8, Week 24, Week 48, Week 96 (or Withdrawal) using the "General Acceptance" dimension of the Chronic Treatment Acceptance (ACCEPT) questionnaire.
To assess tolerability of injections.	• Change from Week 4b in tolerability of injections at Week 5, Week 40, Week 41, and Week 96 using the Numeric Rating Scale (NRS) within the CAB LA + RPV LA

Objectives	Endpoints
	arm.
To evaluate the antiviral and immunologic effects, safety and tolerability, and development of viral resistance to CAB LA + RPV LA at Week 124 and over time for participants switching from ABC/DTG/3TC in the Extension Phase, *with and without optional oral lead-in.*	• Proportion of participants with HIV-1 RNA ≥ 50 c/mL at Week 124, with and without oral lead-in (FDA Snapshot algorithm, Extension Switch population). • Proportion of participants with plasma HIV-1 RNA <50 c/mL and HIV-1 RNA <200 c/mL time over. • Proportion of participants with confirmed virologic failure over time. • Incidence of treatment emergent genotypic and phenotypic resistance to CAB and RPV over time. • Absolute values and change from Baseline in CD4+ cell counts 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 change in laboratory parameters over time.
To evaluate the pharmacokinetics of CAB and RPV in the setting of no oral lead-in for participants switching from ABC/DTG/3TC in the Extension Phase.	• To evaluate plasma CAB and RPV concentrations over time (Week 100 [direct to inject without oral lead-in] and Week 104 [both direct to inject and optional oral lead-in participants])
Exploratory	
To explore the effect of participant characteristics on the virologic and immunologic response of CAB LA and RPV LA compared to continuation of ABC/DTG/3TC.	• Proportion of participants by patient subgroup(s) (e.g., by age, gender, BMI, race, HIV-1 subtype, Baseline CD4+) with Virologic Failure over time including Week 48, and 96 using the Snapshot algorithm for the ITT-E population. • Proportion of participants by subgroup(s) (e.g. by age, gender, BMI, race, HIV-1 subtype, Baseline CD4+) with plasma HIV-1 RNA <50 c/mL at Week 48 and Week 96. • Change from Baseline in CD4+ cell counts

Objectives	Endpoints
	by subgroups at Week 48 and Week 96.
To explore relationship(s) between plasma concentrations of CAB and RPV and pharmacodynamic endpoints.	• Relationship between plasma PK concentrations and virologic, immunologic responses, and/or occurrence of adverse events [AEs] over time may be explored.
To evaluate renal and bone biomarkers in participants receiving CAB LA and RPV LA compared to continuation of ABC/DTG/3TC over time.	• Absolute values and change from Baseline in renal (in urine and blood) and bone (in blood) biomarkers over time including Week 48 and Week 96.
To assess preference for CAB LA + RPV LA compared to oral antiretroviral (ARV) therapy using a single dichotomous preference question.	• For participants randomized to the "CAB LA + RPV LA" arm, preference for CAB LA + RPV LA compared to oral ARV regimen, at Week 48.

2.2.1. Subcutaneous Sub-study Objectives and Endpoints

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
Pharmacokinetic	
To evaluate PK of monthly dosing of CAB LA (200 mg/mL) with RPV LA (300 mg/mL) following SC administration in the anterior abdominal wall SC tissue compared with intramuscular administration in the gluteus medius muscle in HIV-1 infected participants currently enrolled in the FLAIR Phase 3 study	Plasma PK parameters for CAB LA 200 mg/mL and RPV LA 300 mg/mL (Ctau, concentrations 1-week post dose [~Cmax], and area under the curve [AUC (0-tau)]) for SC injections during the SC injection phase compared with similar PK parameters for gluteal IM injections
Secondary Objectives	**Secondary Endpoints**
Safety and tolerability	
To assess safety and tolerability of monthly dosing of CAB LA (200 mg/mL) administered with RPV (300 mg/mL) LA following SC administration in the anterior abdominal wall SC tissue compared with intramuscular injections in the gluteus medius muscle in HIV-1 infected participants currently enrolled in the FLAIR Phase 3 study To assess additional safety events including other AEs, SAEs, and safety labs of monthly dosing of CAB LA and RPV LA following SC injections in the	Incidence and severity of ISRs and AEs of special interest during the SC injection phase. Proportion of participants who discontinue treatment due to ISRs and AEs of special interest during the SC injection phase. Incidence of other AEs not of special interest, SAEs and change in laboratory parameters from the last IM gluteal injection (prior to the SC abdominal Injection Phase) to the end of the SC injection phase (week 12).

Objectives	Endpoints
abdominal wall SC tissue in HIV-1 infected participants currently enrolled in the FLAIR sub-study	
Virologic Response	
To assess the ability to maintain virologic suppression (HIV-RNA <50 copies) in participants who transition from IM to SC administrations of CAB LA (200 mg/mL) plus RPV LA (300 mg/mL) in the FLAIR sub-study. To assess virologic non-response (HIV-RNA ≥50 c/mL and ≥200 c/mL) in participants who transition from IM to SC administrations of CAB LA (200 mg/mL) plus RPV LA (300 mg/mL) in the FLAIR sub-study.	Proportion of participants with plasma HIV-1 RNA <50 copies at week 12 during the SC abdominal injection phase using the FDA Snapshot algorithm. Proportion of participants with plasma HIV-RNA ≥50 c/mL as per Food and Drug Administration (FDA) Snapshot algorithm at week 12 during the SC abdominal injection phase. Proportion of participants with protocol-defined confirmed virologic failure (CVF) of ≥200 c/mL at week 12 during the SC 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 SC injection phase.
Health Outcomes	
To assess patient reported outcomes during the SC injection phase by administering the following health outcome measurements: NRS, HIVTSQ (both s and c versions), and PIN.	**Numerical Rating Scale (NRS):** To assess the tolerability of injections during both the SC abdominal and IM Gluteal Injection Phases, separate for CAB LA and RPV LA. **HIVTSQ (both s and c versions):** To measure levels of satisfaction and detect change in satisfaction when switching from IM gluteal to SC abdominal injections in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Questionnaire (HIVTSQ) during the SC Injection Phase as well as change from SC during the Return to IM Gluteal Phase. **Perception of injection questionnaire (PIN):** To assess the acceptance of pain and injection site reactions following SC abdominal and IM gluteal injections separate for CAB LA and RPV LA.
To assess participant's preference of SC injections during the SC abdominal injection phase compared to IM gluteal injections.	**Preference Questionnaire:** To assess patient's preference, and reasons for preference, for injections received during the SC Injection Phase compared with prior IM gluteal injections as well as for injections received during the Return to Gluteal phase compared with prior SC injections.

Objectives	Endpoints
Exploratory Objectives	**Exploratory Endpoints**
To assess reasons for switch to SC from IM injection and interest in a potential option for self-administration of SC injections	Reasons for switch and interest for home administration options questions: To assess the reasons participants agreed to switch to a SC abdominal injection from a IM gluteal injection and their interest in a potential option for self-administration of SC injections.

2.2.1.1. Subcutaneous Sub-study Estimands

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
Primary Objective: To evaluate PK of monthly dosing of CAB LA (200 mg/mL) with RPV LA (300 mg/mL) following SC administration in the anterior abdominal wall SC tissue compared with intramuscular administration in the gluteus medius muscle in HIV-1 infected participants currently enrolled in the FLAIR Phase 3 study				
• Plasma PK parameters for CAB LA 200 mg/mL and RPV LA 300 mg/mL (Ctau, concentrations 1-week post dose [~Cmax], and area under the curve [AUC (0-tau)]) for SC injections during the SC injection phase compared with similar PK parameters for gluteal IM injections	Pharmacokinetic Parameter & Pharmacokinetic Concentration	CAB+RPV LA IM vs. CAB+RPV LA SC	Ratio of geometric least squares (GLS) means of PK parameters between SC and IM injections and the corresponding 90% CI estimated via a linear mixed-effects model <u>PK Concentration:</u> Arithmetic mean, median, sd, min, max, 90% Confidence Interval (CI) for the mean (or 95% CI) <u>PK parameters:</u> Arithmetic mean, median, sd, min, max, 90% CI for the arithmetic mean, geometric mean, sd (log),	• Study treatment discontinuation due to any reason: **While-on-treatment strategy** *Rationale*: Discontinuation of planned study treatment may bias the evaluation of Pharmacokinetic behaviour of study treatment so only samples collected while on treatment will be summarized.

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
			geometric %CV, 90% for the geometric mean Steady State: Point estimate and 90% CI of slope of log(concentration) vs. timepoint estimated via a linear mixed-effects model List summary statistics as needed	
Secondary Objective: To assess safety and tolerability of monthly dosing of CAB LA (200 mg/mL) administered with RPV (300 mg/mL) LA following SC administration in the anterior abdominal wall SC tissue compared with intramuscular injections in the gluteus medius muscle in HIV-1 infected participants currently enrolled in the FLAIR Phase 3 study To assess additional safety events including other AEs, SAEs, and safety labs of monthly dosing of CAB LA and RPV LA following SC injections in the abdominal wall SC tissue in HIV-1 infected participants currently enrolled in the FLAIR sub-study				
• Incidence and severity of ISRs and AEs of special interest during the SC injection phase.	Safety	CAB+RPV LA (SC & IM)	Frequency, percentages, and descriptive statistics	• Study treatment discontinuation due to any reason: **Treatment policy strategy** *Rationale*: Safety data will be monitored throughout the study after the start of treatment. There is interest in evaluating

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
• Proportion of participants who discontinue treatment due to ISRs and AEs of special interest during the SC injection phase. • Incidence of other AEs not of special interest, SAEs and change in laboratory parameters from the last IM gluteal injection (prior to the SC abdominal Injection Phase) to the end of the SC injection phase (week 12).				and reporting safety events regardless of whether participants have completed treatment course or not. Safety events will be appropriately labeled as occurring during the IM or SC phases based on injections dates and summarized accordingly.

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
Secondary Objective: To assess the ability to maintain virologic suppression (HIV-RNA <50 copies) in participants who transition from IM to SC administrations of CAB LA (200 mg/mL) plus RPV LA (300 mg/mL) in the FLAIR sub-study. To assess virologic non-response (HIV-RNA ≥50 c/mL and ≥200 c/mL) in participants who transition from IM to SC administrations of CAB LA (200 mg/mL) plus RPV LA (300 mg/mL) in the FLAIR sub-study. To assess viral resistance in participants experiencing protocol-defined confirmed virologic failure.				
• Proportion of participants with plasma HIV-1 RNA <50 copies at week 12 during the SC abdominal injection phase using the FDA Snapshot algorithm. • Proportion of participants with plasma HIV-RNA ≥50 c/mL as per Food and Drug Administration (FDA) Snapshot algorithm at week 12 during the SC	Safety	CAB+RPV LA SC	The proportion of participants with plasma HIV-RNA >= or < 50 copies/mL as per Food and Drug Administration (FDA) Snapshot algorithm at SC Injection Phase Week 12. The proportion of participants with confirmed virologic failure while on CAB+RPV LA SC.	• Study treatment discontinuation due to lack of efficacy or other reasons that impact the viral load outcome: **Composite strategy** *Rationale*: "The presence of missing data due to lack of efficacy or discontinuation for other reasons on the primary endpoint is adequately accounted for in the FDA Snapshot Algorithm which frames the outcome around these events. Please see Section 14.11 for details." • Rescue medication use/Change in Background ART strategy: **Composite strategy** *Rationale*: "The presence of missing data due to a change in background

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
abdominal injection phase. • Proportion of participants with protocol-defined confirmed virologic failure (CVF) of ≥200 c/mL at week 12 during the SC injection phase.				medication is adequately accounted for in the FDA Snapshot Algorithm which employs a composite strategy in this regard, conservatively assuming that any participants who changed background ART without a current viral load and without discontinuing are classified as having HIV-1 RNA >50c/mL. Please see Section 14.11 for details."
• Incidence of treatment emergent genotypic and phenotypic resistance to CAB, RPV during the SC injection phase.	Safety	CAB+RPV LA SC	Prevalence of (% of participants with) Treatment Emergent Resistance Mutations (frequency count) Prevalence of (% of participants with) Phenotype, Replication Capacity (frequency count)	• Missing data for any ICE including unevaluable sampling: **While-on-treatment strategy** *Rationale:* "Should there be missing genetic data, it would be expected that any data collected while a participant is off study IP would be impacted differently that when they are on study IP. Therefore, only data collected and available while the participant was on study IP will be analyzed."

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
Secondary Objective: To assess patient reported outcomes during the SC injection phase by administering the following health outcome measurements: NRS, HIVTSQ (both s and c versions), and PIN. To assess participant's preference of SC injections during the SC abdominal injection phase compared to IM gluteal injections. Exploratory Objective: To assess reasons for switch to SC from IM injection and interest in a potential option for self-administration of SC injections				
• **Numerical Rating Scale (NRS):** To assess the tolerability of injections during both the SC abdominal and IM Gluteal Injection Phases, separate for CAB LA and RPV LA. • **HIVTSQ (both s and c versions):** To measure levels of satisfaction and detect change in satisfaction when switching from IM gluteal to SC abdominal injections	Safety	CAB+RPV LA IM vs. CAB+RPV LA SC	Scale scores where prescribed, change from Baseline in repeated measures, frequency counts, and descriptive statistics	• Missing data for any ICE including study treatment discontinuation: **Treatment policy strategy** *Rationale*: "HO assessments are administered to align at treatment specific timepoints (SC vs LA). They also account for differences in treatment by design and thus, significant deviation from the administration window is not expected to impact the outcome and data can be assumed to be missing at random. There is interest in evaluating and reporting HO data regardless of whether participants have completed treatment course or not. Imputation is

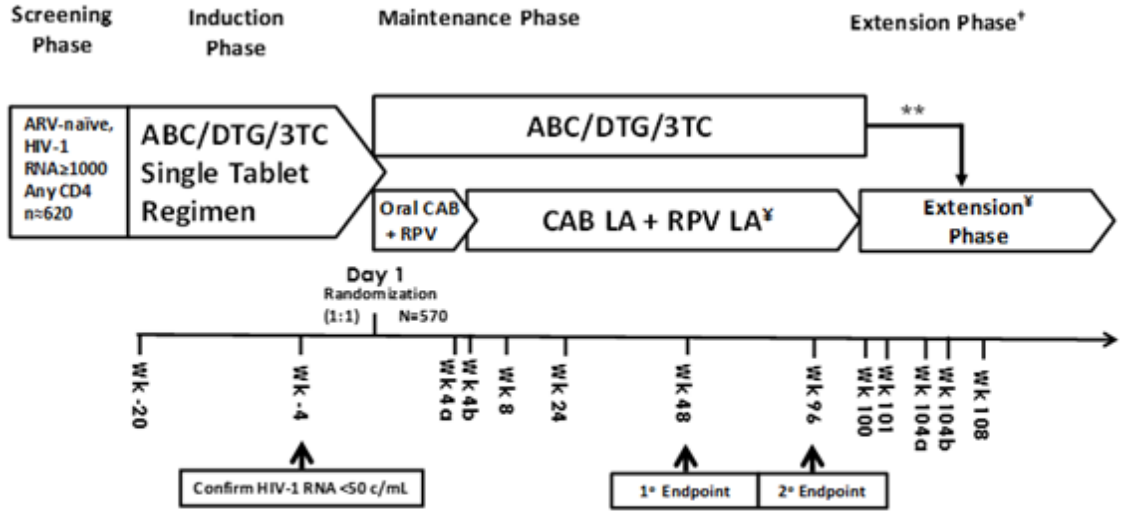
Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Questionnaire (HIVTSQ) during the SC Injection Phase as well as change from SC during the Return to IM Gluteal Phase. • **Perception of injection questionnaire (PIN):** To assess the acceptance of pain and injection site reactions following SC abdominal and IM gluteal injections separate for CAB LA and RPV LA. • **Preference Questionnaire:** To				not considered appropriate for any of these measures. "

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
assess patient's preference, and reasons for preference, for injections received during the SC Injection Phase compared with prior IM gluteal injections as well as for injections received during the Return to Gluteal phase compared with prior SC injections. • **Reasons for switch and interest for home administration options questions**: To assess the reasons participants agreed to switch to a SC abdominal				

Endpoint	Estimand			
	Population	**Treatment**	**Summary Measure**	**Intercurrent event (IE) / strategy / rationale**
injection from a IM gluteal injection and their interest in a potential option for self-administration of SC injections.				

2.3. Study Design

Overview of Study Design and Key Features



** Optional oral lead-in (investigator discretion) available from Week 100 to Week 104b

¥ Participants who withdraw from IM CAB LA + RPV LA must enter the 52-week Long Term Follow-Up Phase

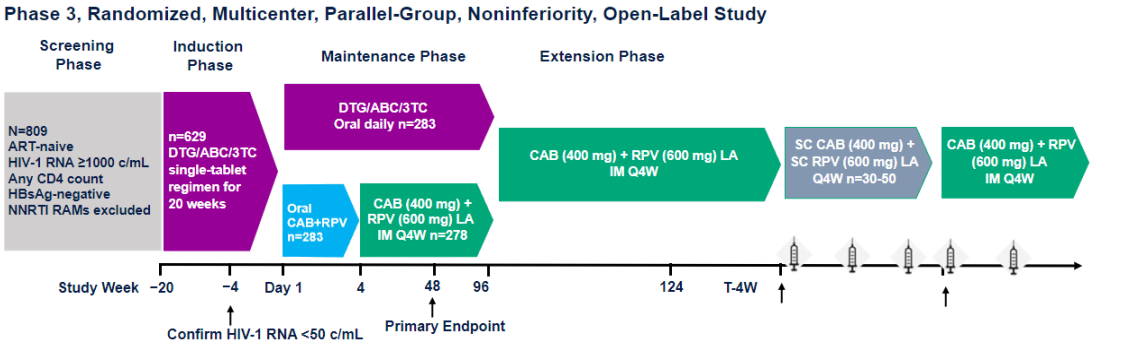
Design Features	• A Phase III, Randomized, Multicenter, Parallel-group, Open-Label, Switch from an Integrase Inhibitor Single Tablet Regimen in HIV-1 Infected Antiretroviral Therapy Naive Adult Participants • The FLAIR study comprises a Screening Phase (up to 35 days), an Induction Phase (Week [-20] to Day 1), a Maintenance Phase (Day 1 to Week 100), followed by an Extension Phase (post Week 100). 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 at least 52 weeks after the last dose of CAB LA and/or RPV LA.
Dosing	• Induction Phase: oral ABC/DTG/3TC • Maintenance Phase: 1:1 randomization to CAB LA + RPV LA vs. continue oral ABC/DTG/3TC. • Extension Phase: CAB LA + RPV LA
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• N =570 randomized at start of Maintenance Phase • At Week 100, participants randomised to the oral ABC/DTG/3TC arm meeting eligibility requirements will switch to CAB LA + RPV LA • GSK RandAll NG used to generate randomization schedules • Stratified Randomization by participants' Induction Baseline HIV-1 RNA (<100,000, ≥ 100,000 c/mL) and gender at birth.

Overview of Study Design and Key Features	
Interim Analysis	• IDMC analyses: • Futility analysis at 50% of participants completing Week 24 Continuous time monitoring of confirmed virologic withdrawal (CVF) until all participants complete Week 24 • No study summary data according to actual randomized treatment groups will be available to sponsor staff prior to the planned Week 48 analysis.
Planned Sponsor Analyses	• The main analysis will be conducted to evaluate the primary objective of the study at Week 48. • An additional planned analysis at Week 96 will be conducted to evaluate long-term antiviral activity, safety, and tolerability and participant satisfaction of the regimens. • Further data cuts and analyses may be conducted as necessary in order to support regulatory submissions and publications.

2.3.1. Subcutaneous Sub-Study Design

The FLAIR amendment (sub-study) will consist of three phases including a Screening/IM Gluteal injection Phase (T-4 weeks with 1 gluteal injection interval of 4 weeks), a Sub-Cutaneous Abdominal Injection Phase (12 weeks with 3 injection intervals of 4 weeks each) and a Return to Intramuscular Gluteal Injection Phase (8 weeks with 2 injection intervals of 4 weeks each). 80 participants will be targeted for enrollment in order to reach the 30-50 necessary to assess the primary PK endpoint as well as to achieve a more robust safety conclusion. At the conclusion of the sub-study, participants will have the option to continue on the FLAIR parent study or if commercial access is available, the participant can transition off the sub-study, complete their participation in the FLAIR study and proceed directly to commercially sourced CAB/RPV LA treatment.

Figure 1 Sub-Cutaneous Sub-Study Amendment Design (included as part of the Parent FLAIR Study)



- Single arm, non-randomized to CAB 200mg/mL (2mL) + RPV 300mg/mL (2mL). HCP administered
- **Primary objectives:** to describe the safety, PK and acceptability of SC CAB+RPV; **Secondary objectives**: VL outcomes, proportion remaining <50 cpm; **PROs** to include PIN, NRS and preference questionnaire and acceptance questionnaire to self-administer

2.4. Statistical Hypotheses / Statistical Analyses

This study is designed to show that the antiviral effect of oral ABC/DTG/3TC followed by intramuscular CAB LA + RPV LA regimen is non-inferior to continuation of ABC/DTG/3TC at Week 48 of maintenance treatment. Non-inferiority in the proportion of participants with HIV-1 RNA ≥ 50 c/mL at Week 48 for Intent-to-Treat Exposed (ITT-E) population (per FDA's snapshot algorithm) can be concluded if the upper bound of a two-sided 95% confidence interval for the difference in the proportion of participants with HIV-1 RNA ≥ 50 c/mL between the two treatment arms (CAB – ABC/DTG/3TC) is less than 6%.

If f_{la} is the proportion of participants with HIV-1 RNA ≥ 50 c/mL for the Q4W IM arm and f_c is the proportion of participants with HIV-1 RNA ≥ 50 c/mL (per FDA snapshot algorithm) for the ABC/DTG/3TC arm, then the hypotheses can be written as follows:

$$H_o: f_{la} - f_c \geq 6\% \quad H_1: f_{la} - f_c < 6\%$$

3. PLANNED ANALYSES

At least three analyses will be conducted to evaluate the objectives of the protocol: after all randomized participants have completed their visits at Week 48 and Week 96, respectively, and after all Extension switch participants have completed the Week 124 visit. The Week 48 analysis will be primary. Additional analysis will be conducted to evaluate the objectives of the sub-study after all participants have completed their EOS visit at Sub-study Week 20. A final End-of-Study analysis will be conducted when all participants have completed the study.

3.1. Interim Analyses

An Independent Data Monitoring Committee (IDMC) will be instituted 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 and study 201585.

An IDMC will evaluate accumulating efficacy, tolerability / safety, and PK of CAB LA + RPV LA at predetermined times during the study. An 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 CAB LA + RPV LA injectable regimen demonstrates non-inferiority to the continued ABC/DTG/3TC arm 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 criteria until all participants complete Week 24 to ensure that participants are not being sub-optimally treated in the CAB + RPV 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.

3.1.1. Subcutaneous Sub-Study Interim Analyses

The SC Sub-study will contain two interim analyses. Interim analysis 1 for ISR monitoring criteria will take place after 50% of participants (equating to 25 out of an expected 50) have experienced their first SC injection with a follow-up Week 1 visit. An in-stream safety data cut will be performed for ISR data including site reports of details of ISRs of interest which include grade 4 ISRs and grade 3 ISRs that include ulceration, secondary infection, phlebitis, sterile abscess, or drainage. The posterior probability that the rate of ISRs of interest will be calculated based on ISRs of interest collected through SC Week1 for each participant. If the Bayesian posterior probability that the true rate of ISRs of interest is >0.05 (equating to > 1 participant out of 25) is low (< 5%), then individual ISRs will undergo standard safety review. However, if the Bayesian posterior probability that the true rate of ISRs of interest is >0.05 is high (≥5%), then a formal review of all ISR safety data will take place by the VSLC with the potential consideration to pause SC injections. As enrollment will be staggered by country, if 3 participants

experience an ISR of interest prior to 25 participants reaching the SC Week 1 visit, VSLC review will automatically be triggered as 3 out of 25, or a sub-study rate of 0.12, would lead to the posterior probability of the rate of ISRs of interest >0.05 being >5%. Otherwise, VSLC will only be triggered based on the interim posterior probability being >5%. An evidence threshold of 5% gives us 95% confidence that the true rate of ISRs of interest is not >0.05 should our interim posterior probability not trigger a decision to bring forth formal VSLC review. For further analysis details, see Section 8.6.

Interim analysis 2 will take place within the subcutaneous sub-study once 50% of enrolled participants have completed their sub-study Week 9 visit. The 50% threshold will have been considered reached once 15-20 participants have completed their Week 9 visit as aligned with the targeted population of 30-50 to assess the primary endpoint. The analysis will consist of an internal review of key PK, safety/tolerability, and preference endpoints in order to assist in compound development. No formal stopping decisions will be made. No formal data cleaning activities will occur. Data will be processed in stream with what is available at the time of the data cut. Queries will be issued in extreme circumstances.

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 participants have completed Week 48 and had a re-test if necessary.
2. All required database cleaning activities have been completed and final database release and database freeze has been declared by Data Management.
3. All criteria for unblinding the randomisation codes have been met.
4. Randomization codes have been distributed according to Ramos NG procedures.

Further analyses will be conducted at Week 96, Week 124, a sub-study analysis, and a final End-of-Study analysis will be conducted when all participants have completed the study.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Subjects Screened Population	• Comprised of all participants screened for inclusion in the study. • Participants may be re-screened once, for which they will receive a new subject number. • Only the latest re-screening data will be included in the screening population summaries/analyses.	• Study Population
All Participants Enrolled	• All enrolled participants who receive at least one dose of study drug in the Induction Phase.	• Secondary population for some analyses
Intent-to-Treat Exposed Population (ITT-E)	• All randomized participants who receive at least one dose of IP during the Maintenance Phase of the study (on or after Day 1 visit). • Participants will be analyzed according to the randomized treatment regardless of what treatment was actually received.	• Study Population • Efficacy
Per-Protocol Exposed (PP)	• Consist of all participants in the ITT-E Population with the exception of major protocol violators. • Protocol deviations that would exclude participants from the PP-E population are defined in Section 4.1 (Protocol Deviations) and Appendix 1 (Protocol Deviation Management and Definition for Per-Protocol Population). • This population is not applicable for the W124 analysis.	• Efficacy (Sensitivity Analysis)
Safety	• All randomized participants who receive at least one dose of IP during the Maintenance Phase of the study (on or after Day 1 visit). • Participants will be assessed according to actual treatment received.	• Safety
PK Population	• All participants who receive CAB and / or RPV and undergo PK sampling during the study and provide evaluable CAB and /or RPV plasma concentration data (i.e., at least 1 non-missing PK assessment (Non-quantifiable [NQ] values will be considered as non-missing values)).	• PK

Population	Definition / Criteria	Analyses Evaluated
Confirmed Virologic Failure (CVF)	• Comprised of all participants in the ITT-E population who met Confirmed Virologic Failure (CVF) *CVF during the Maintenance and Extension Phases is defined as: Rebound as indicated by two consecutive plasma HIV-1 RNA levels ≥200 c/mL after prior suppression to <200 c/mL	• Genotypic • Phenotypic • IDMC CVF Analysis
All Participants Randomized Population	• All randomized participants	• Secondary population for some analyses
Extension Switch Population (ES)	• All randomized subjects from ABC/DTG/3TC arm who receive at least one dose of CAB and/or RPV during the Extension Phase of the study. • Participants will be assessed according to actual treatment received during the Extension Phase.	• Safety and efficacy of switching to CAB LA + RPV LA, with and without oral lead-in.
Long-Term Follow-up Population (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 a least one Long-Term Follow-up Phase clinic visit.	• Safety and PK during LTFU
Futility analysis population	• Comprised of all participants 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 participants who withdrew early but would have achieved Week 24).	• IDMC futility analysis
Japan PK Population	• All Japanese heritage participants (living in Japan) who receive CAB and / or RPV and undergo PK sampling and provide evaluable CAB and /or RPV plasma concentration data (i.e., at least 1 non-missing PK assessment (Non-quantifiable [NQ] values will be considered as non-missing values)). PK assay results from samples collected from a subject with emesis occurring within 4 hours of the dose will not be considered as evaluable.	• Japan PK displays
Sub-study Screened	• Comprised of all participants screened for inclusion in the sub-study.	• Study Population

Population	Definition / Criteria	Analyses Evaluated
	• All screened participants will continue using their subject numbers received in the main study.	
Sub-study Enrolled	• All participants who sign informed consent into the sub-study, excluding screen failures.	• Study Population
Sub-study Safety	• All enrolled participants who received at least one CAB and/or RPV SC injection.	• Study Population • Safety • Efficacy • Health Outcomes
Sub-study Pharmacokinetic Concentration (PC)	• All participants who received at least one CAB and/or RPV SC injection and provided at least one non-missing CAB and/or RPV plasma concentration value during the sub-study value (non-quantifiable values will be considered as non-missing values).	• PK Concentration and individual figures
Sub-study Pharmacokinetic Parameter (PP)	• All participants who received at least one CAB and/or RPV SC injection and had at least one evaluable PK parameter estimated during the sub-study.	• PK Parameters

NOTES:

- Please refer to Appendix 14: List of Data Displays for Week 48/Week 96, Appendix 15: List of Data Displays for Week 124, Appendix 19: List of Data Displays for the Subcutaneous Sub-Study, and Appendix 18: Japan-Specific Requirements which details the population to be used for each display being generated.
- In all documents, datasets and data displays the term “Subject” and “Participant” are interchangeable.

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

Randomized treatment groups will be displayed as shown in Table 2.

Table 2 Data Display Treatment Descriptors for Randomized Arms

Treatment Group Descriptions			
RandAll NG Randomization System		Data Displays for Reporting	
Code	Description	Description	Order in TLF
A	CAB LA + RPV LA	Q4W IM	1
B	ABC/DTG/3TC	ABC/DTG/3TC	2

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

- Q4W IM vs. ABC/DTG/3TC

In data displays of Induction Phase data for the All Enrolled Population and Extension Phase data for the Extension Switch population, respectively, study treatment will be displayed as shown in Table 3.

Table 3 Data Display Treatment Descriptors for All Enrolled Population and Extension Switch Population

Data Type	Descriptor
Induction Phase Data for All Enrolled Population	Induction Phase ABC/DTG/3TC
Extension Phase Data for Extension Switch Population	Switch Q4W IM (Direct to Inject) Switch Q4W IM (Oral Lead-In)

5.2. Baseline Definitions

For all assessments evaluated at Screening and/or Week -20 (including labs, vital signs, ECGs, virology assessments, etc.), the Induction Baseline (Week -20) value will be the latest valid (e.g., fasting for lipids) Pre-treatment value observed. This is generally expected to be from the Week -20 visit, although such values may be missing, or unscheduled assessments may be performed before treatment start; however, for virology data, this is generally expected to be from the Screening visit (except in the case of CVF for which virology data is expected at Week -20).

Electrocardiograms (ECGs) are to be performed in triplicate on Week -20 visit. The Induction Baseline (Week -20) value for an ECG parameter will be the mean of the last pre-treatment set of assessments from the same date.

If pre-treatment genotypic/phenotypic results are available from both the central laboratory and Monogram Biosciences, then Induction Baseline (Week -20) genotype/phenotype will be determined based only upon the data provided by Monogram assays.

The baseline value for each phase of the study is defined as the last valid (e.g., fasting for lipids) value observed, up to and including date of first dose of study treatment in the respective phase as described in Table 4.

Baseline values for the sub-cutaneous sub-study will be assigned as the last observation prior to the first CAB and/or RPV SC injection in the subcutaneous abdominal phase.

Table 4 Baseline Definitions for Each Study Phase

Definition	Reporting Details
Induction Baseline (Week -20)	Last available recorded value up to and including the date of first Induction Phase dose of IP
Maintenance Baseline (Day 1)	Last available recorded value up to and including the date of first Maintenance Phase dose of IP
Extension Baseline (Week 100)	Last available maintenance phase recorded value up to and including the date of first Extension Phase dose of IP (Oral CAB/RPV or CAB/RPV LA)

Definition	Reporting Details
	• only applicable to the Extension Switch population participants.

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-RNA greater than or equal to 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 sex at birth and Induction Baseline (Week -20) HIV-1 RNA (<100,000, ≥100,000 c/mL). 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. See Section 7.1.5 for more details on the statistical analysis methodology.
Other Subgroups/Covariates	See details in Section 5.4.2
Subcutaneous Sub-Study	
Covariate	Sub-study Baseline BMI The primary endpoint comparison between the SC and IM PK parameters as well as ISR incidence between SC and IM will be calculated considering Baseline BMI taken at the start of sub-study SC dosing as a covariate to account for potential individual differences in compound distribution. The following levels will be used: • BMI ≥ 30 kg/m^2 • BMI < 30 kg/m^2

5.4.2. Examination of Subgroups/Covariates

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 participants is small within a particular subgroup, then the subgroup categories may be combined prior to unblinding 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, 2013), 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 randomisation strata, key demographic and baseline characteristic factors, will 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:	
Stratified Randomisation Strata	• Induction Baseline (Week -20) HIV-1 RNA (<100,000, ≥100,000 c/mL) • Gender at birth (Male, Female) For analysis purposes, randomization strata will be derived 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:

Category	Covariates and / or Subgroups
	○ <35; 35-<50; ≥50 (for statistical modelling analysis, the first two groups will be combined, i.e., <50, ≥50) • Race: ○ White; Non-White (for statistical modelling analysis) ○ Black/ African American; Non- Black/ African American • Country (not used for statistical modelling) ○ Canada; ○ France; ○ Germany; ○ Italy; ○ Japan ○ The Netherlands; ○ Russian Federation; ○ South Africa; ○ Spain; ○ United Kingdom; ○ United States • Region ○ Western/Central Europe and North America (grouping of Canada, France, Germany, Italy, The Netherlands, Spain, United Kingdom, United States) ○ Japan; ○ Russian Federation; ○ South Africa. • Induction Baseline (Week -20) HIV-1 RNA c/mL ○ <1000; ○ 1000 to <10,000; ○ 10,000 to <50,000; ○ 50,000 to <100,000; ○ ≥100,000 to <200,000; ○ ≥ 200,000 c/mL The above subgroup with granular categories for viral load will not be used in statistical modelling. • Visit of First Suppression (HIV-1 RNA <50 c/mL)[a]: ○ Week -20 ○ Week -16; ○ Week -12; ○ Week -8;

Category	Covariates and / or Subgroups
	○ Week -4 • Maintenance Baseline (Day 1) HIV-1 RNA: ○ <50; ○ ≥ 50 c/mL. • Induction Baseline (Week -20) CD4+ cell count: ○ <200; ○ 200 to <350; ○ 350 to <500; ○ ≥ 500 cells/mm^3. • Maintenance Baseline (Day 1) CD4+ cell count: ○ <200; ○ 200 to <350; ○ 350 to <500; ○ ≥ 500 cells/mm^3. • Derived Maintenance Baseline (Day 1) Centers for Disease Control and Prevention (CDC) category: ○ Stage I; ○ Stage II; ○ Stage III • HIV-1 Subtype at Induction Baseline (Week -20) ○ A; ○ A1; ○ AE; ○ AG; ○ B; ○ C; ○ Other ○ Missing • K103N Mutation at Induction Baseline (Week -20): ○ Yes vs. No • Induction Baseline (Week -20) BMI (<30, ≥ 30 kg/m^2) • L74I Integrase Mutation at Induction Baseline (Week -20): ○ Yes vs. No (Note: do not derive is baseline integrase genotype is not available)
EMA Subgroup Category 3:	
Additional subgroup/covariates for PK/PD efficacy analysis	• Week 48 Analysis Only: Last CAB/RPV Trough (pre-dose) PK concentration by Week 48 (i.e., If pre-dose PK concentration at nominal Week 48 is missing, then last pre-dose PK concentration prior to Week 48 will be used)

Category	Covariates and / or Subgroups
	• Week 8 CAB/RPV Trough PK concentration (i.e., pre-dose PK concentration at nominal visit of Week 8 The above two covariates will be dichotomized into two subgroup factors as follows: • ≤ first Quartile vs > first quartile; • ≤ Median vs > Median • Needle length for CAB injection at Week 4b: (<2, ≥2 inch); • Needle length for RPV injection at Week 4b: (<2, ≥2 inch); See Section 8.5.1 for additional details regarding attribution of ISRs to causal agent (CAB/RPV) and Needle Length. • Induction Baseline (Week -20) BMI (<30, ≥ 30 kg/m^2)
Additional subgroup/covariates for PK/PD safety analysis – Week 48 Analysis Only	• Last CAB/RPV trough PK concentration For the plot of "Maximum Change from Maintenance Baseline (Day 1), CBF, 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 earliest Lab assessment corresponding to the maximum CFB during the Maintenance Phase. For the Plot of "Maximum Toxicity Grades of Most Frequently Reported 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 maximum graded AE (for each preferred term among non-ISR AEs occurring in ≥5% of participants in the Q4W arm during the Maintenance Phase). If a participant does not experience the corresponding preferred term event during the Maintenance Phase, then the last trough value during the Maintenance Phase will be used for the plot.

Additional subgroup for Bone Marker analysis	• Induction Baseline (Week -20) BMI (kg/m^2)
	  ○ <30;
	  ○ ≥ 30
	• Smoking status at Screening:
	  ○ Never;
	  ○ Current;
	  ○ Former

Category	Covariates and / or Subgroups
	• Tenofovir Disoproxil Fumarate (TDF) Use at Maintenance Baseline (Day 1) o Yes; o No
Additional subgroup for ISR	For each common ISR preferred term (pain, induration, nodules and any other ISR with >=5% participants during the Maintenance Phase, Maintenance + Extension Phase (for Randomized Q4W), and Extension Phase (for Switch Q4W), respectively: • 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 phase(s) of interest: (<2, ≥2 inch); • 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 phase(s) of interest: (<2, ≥2 inch); The above subgroup variables will be produced for each common ISR preferred term. Note: If there is no ISR of interest reported during the phase(s) of interest for a participant, these subgroup variables will be derived using the needle length of the participant's last injection during the phase(s) of interest.
Subcutaneous Sub-Study subgroups	
Demographic, Efficacy, Safety, PK, & HO Subgroups	• Age: <35; 35-<50; ≥50 • Sex at birth Male, Female • Race/Ethnicity White: Non-Hispanic, White: Hispanic, Black, Asian, Other • Sub-study Baseline BMI <30 kg/m^2, ≥30kg/m^2

a) Based on any HIV-1 RNA <50 c/mL within the assessment window defined in Table 14.

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 Q4W IM will be declared non-inferior to ABC/DTG/3TC if the upper end of a two-sided 95% confidence interval for the difference between the two groups (Q4W IM– ABC/DTC/3TC) in the

proportion of participants with HIV-RNA ≥50 c/mL at Week 48 (defined by the US FDA snapshot algorithm) lies below 6%.

The primary comparison of interest is the comparison between Q4W IM and ABC/DTC/3TC for the primary endpoint in the ITT-E population. This analysis will be adjusted for by the stratification factor applied at randomization.

If the primary analysis shows non-inferiority, then a superiority hypothesis will be tested at the two-sided 5% level of significance. Superiority favoring CAB LA + RPV LA will be declared if the upper end 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.

5.5.2. Other Comparisons of Interest

The analysis described above will also be performed using the PP population and the results will be compared for consistency with the results from the ITT-E population.

5.5.3. Secondary Comparisons

If the primary comparison of interest (Section 5.5.1) using the ITT-E population demonstrates non-inferiority of Q4W compared to ABC/DTG/3TC then the following key secondary comparisons using the ITT-E population will be tested:

- Treatment with Q4W IM will be declared non-inferior to ABC/DTG/3TC with respect to the proportion of participants with HIV-1 RNA < 50 copies/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 in response rates (Q4W IM– ABC/DTG/3TC) lies above -10%.

- Superiority of Q4W IM compared to ABC/DTG/3TC with respect to change from maintenance baseline (Day 1) HIVTSQs total score at Week 44 using a two-sided 5% level of significance.

- Changes in the PIN acceptance score within the Q4W arm over time using separate two-sided 5% level of significance tests for the change from Week 5 to Week 41 and change from Week 5 to Week 48, respectively.

There are no planned adjustments for multiple comparisons or multiplicity.

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.

In addition to the primary and the key secondary comparisons, the comparisons between two treatment arms for ACCEPT (general acceptance score), SF-12 (health status), and

HAT-QoL (Life satisfaction) 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.

5.5.3.1. Week 124 Extension Switch Analysis

For the Week 124 Extension Switch population analysis, antiviral response will be assessed according to the proportion of participants with and without oral lead-in, respectively, who have HIV-1 RNA ≥50 c/mL at Week 124 (i.e., 24 weeks from initiation of CAB LA + RPV LA, +/- 6 week analysis window, using the FDA Snapshot algorithm), with corresponding 95% confidence interval. The primary efficacy endpoint of interest for this analysis is the proportion of participants without oral lead-in who have HIV-1 RNA ≥50 c/mL at Week 124. No formal statistical comparisons with respect to safety and efficacy outcomes will be performed.

5.5.3.2. Subcutaneous Sub-Study Analysis

For the Subcutaneous sub-study analysis, select pharmacokinetic parameters from both the gluteal phase and the subcutaneous phase will be informally compared with a geometric mean ratio and corresponding 90% confidence interval. No formal statistical comparisons with respect to safety and efficacy outcomes will be performed.

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
Section 14.2	Appendix 2: Schedule of Activities
Section 14.3	Appendix 3: Assessment Windows
Section 14.4	Appendix 4: Study Phases and Treatment State
Section 14.5	Appendix 5: Data Display Standards & Handling Conventions
Section 14.6	Appendix 6: Derived and Transformed Data
Section 14.7	Appendix 7: Reporting Standards for Missing Data
Section 14.8	Appendix 8: Values of Potential Clinical Importance
Section 14.9	Appendix 9: Population Pharmacokinetic (PopPK) Analyses
Section 14.10	Appendix 10: Pharmacokinetic / Pharmacodynamic Analyses
Section 14.11	Appendix 11: Snapshot Algorithm Details
Section 14.14	Appendix 14: List of Data Displays for Week 48/Week 96
Section 14.15	Appendix 15: List of Data Displays for Week 124
Section 14.16	Appendix 16: IDMC
Section 14.17	Appendix 17: Variables Defined for Time to Event Analysis
Section 14.18	Appendix 18: Japan-Specific Requirements
Section 14.19	Appendix 19: List of Displays for the Subcutaneous Sub-study

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

Details of the planned study population displays for the Week 124 analysis are provided in Appendix 15: List of Data Displays for Week 124.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 treatment accountability will be based on GSK Core Data Standards.

Table 5 provides an overview of the planned study population analyses, with full details of data displays being presented in Appendix 14: List of Data Displays.

Table 5 Overview of Planned Study Population Analyses

Display Type	Data Displays Generated	
	Table	Listing
Randomisation		
Randomisation [1]		Y[2]
Subject Disposition		
Study Populations [3]	Y	
Study Recruitment [3]	Y	
Reasons for Screening Failures [3]	Y	Y
History of Rescreened Participants [3]		
Age categories	Y	
Subject Disposition	Y[4][5]	
Reasons for Withdrawal by Visit	Y[4][5]	Y
IP discontinuation	Y	Y
Important Protocol Deviations	Y	Y
Deviations leading to exclusion from PP	Y	Y
Inclusion and Exclusion Criteria Deviations	Y	Y
Demography and Baseline		
Demographics Characteristics [6]	Y	Y
Race & Racial Combinations [7]	Y	Y
Hepatitis Status at Induction Baseline (Week -20)	Y	
CDC Classification of HIV infection (2014) at Maintenance Baseline (Day 1)	Y	
Cardiovascular Risk Assessments at Induction Baseline (Week -20)	Y	

Display Type	Data Displays Generated	
	Table	Listing
Distribution of CD4+ Cell Counts at Maintenance Baseline (Day 1)	Y	
Distribution of Quantitative Plasma HIV-1 RNA and CD4+ Cell Counts at Screening and Induction Baseline (Week -20)	Y	
HIV-1 Subtype at Induction Baseline (Week -20)	Y	
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 Antiretroviral Therapy		Y
Concomitant Antiretroviral Therapy during Induction and Maintenance Phase, respectively		Y
ART Regimen at Randomization	Y	Y
Lipid Modifying Agents (Maintenance Baseline (Day 1) and During Maintenance Phase)	Y	
Substance use at Screening	Y	
Medical History of Seizure		Y
Other		
Study Treatment Accountability [11]		Y
Transition to CAB+RPV LA Marketed Product		Y

NOTES:

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

a. All Participants Randomized population
b. One listing of participants randomized but not treated, and one listing of planned and actual treatment strata.
c. All Subjects screened population.
d. 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.
e. Analysis of subject disposition will be performed for each study Phase separately, as well as for overall study conclusion.
f. Age and ethnicity collected at Screening; weight and height collected at Baseline (Week -20)
g. 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.
h. Medical conditions will be coded using the Medical Dictionary for Regulatory Activities (MedDRA).
i. Sub conditions are Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, and Nervous System Conditions
j. summarised by, Ingredient combinations
k. Dispensation information (dates and number of tablets dispensed and returned).

6.2. Subcutaneous Sub-Study Population Analyses

Participant sub-study enrollment, protocol deviations, concomitant medications, and sub-study disposition for the SC injection phase, return to gluteal phase, and overall will be summarized for the sub-study screening, enrolled, and safety populations where

appropriate. Time on prior CAB+RPV treatment though the start of the SC abdominal injection phase will be summarized. Oral Bridging will not be summarized as participants requiring oral bridging will discontinue the sub-study per the protocol. Transition either back to the parent study or to commercial product will be summarized as applicable for sub-study participants. See Appendix 19: List of Data Displays for Subcutaneous Sub-Study Analysis for further details.

7. EFFICACY ANALYSES

Details of the planned efficacy displays for the Week 124 analysis are provided in Appendix 15: List of Data Displays for Week 124.

7.1. Primary Efficacy Analyses

7.1.1. Endpoint / Variables

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); see Section 14.11 for additional details.

7.1.2. Summary Measure

Difference in the proportion of participants with HIV-RNA ≥50 c/mL at Week 48 (defined by the US FDA snapshot algorithm) between each treatment group (Q4W IM – ABC/DTG/3TC).

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

7.1.5. Statistical Analyses / Methods

Table 6 provides an overview of the planned efficacy analyses. Details of the planned displays are provided in Appendix 14: List of Data Displays and will be based on GSK data standards and statistical principles.

Table 6 Overview of Planned Primary Efficacy Analyses

Endpoints	Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L
Proportion of Participants with 'HIV-1 ≥ 50 c/mL' at Week 48 – Snapshot							
Primary analysis comparison between the two groups (Q4W IM – ABC/DTG/3TC) in 'HIV-1 RNA≥50 c/mL' rates at Week 48	Y[1]			Y[1,2]	Y[4]		Y[2]
Treatment Heterogeneity across randomization strata	Y						
By Subgroup [3] (Exploratory analysis to support primary analysis)				Y[5]	Y[4]		

NOTES:

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

1. Generated using the 'Intent-to-Treat Exposed' (primary) and 'Per-Protocol' (sensitivity) populations.
2. Study outcomes (i.e., response below 50 c/mL, 'HIV-1 RNA≥50' or reason for no data in the window) based on the snapshot algorithm.
3. Randomisation Strata, Demographic and Baseline Characteristics (refer to Section 5.4.2).
4. Plot of the difference in proportion of participants with HIV-1 RNA ≥50 c/mL (Snapshot algorithm) and its 95% confidence intervals for 'overall' (on the top of the figure) and by subgroup at Week 48.
5. Study outcomes based on the Snapshot algorithm by subgroup at Week 48 will also be produced.

7.1.5.1. Statistical Methodology Specification

Primary Statistical Analyses
Endpoint
• Proportion of Participants with Plasma HIV-1 ≥ 50 c/mL at Week 48 using the Snapshot algorithm for the ITT-E population. 'HIV-1 RNA≥50' are based on the Snapshot algorithm includes participants 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-RNA <50' or '≥ 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 17). In addition, participants 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-RNA ≥ 50 c/mL'. • Full details of the Snapshot algorithm are provided in Section 14.11.

Primary Statistical Analyses

Model Specification

- The primary efficacy endpoint will be analysed using a stratified analysis with Cochran-Mantel-Haenszel (CMH) weights, adjusting for Induction Baseline (Week -20) HIV-1 RNA (<100,000, ≥100,000 c/mL) and gender at birth.
- 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 of the following four analysis strata:
  - Induction Baseline (Week -20) HIV-1 RNA < 100 000 c/mL AND Male gender at birth
  - Induction Baseline (Week -20) HIV-1 RNA < 100 000 c/mL AND Female gender at birth
  - Induction Baseline (Week -20) HIV-1 RNA ≥ 100 000 c/mL AND Male gender at birth
  - Induction Baseline (Week -20) HIV-1 RNA ≥ 100 000 c/mL AND Female gender at birth
- If n_k is the number of CAB LA + RPV LA treated participants, m_k is the number of ABC/DTG/3TC control arm treated participants, and $N_k = n_k + m_k$ is the total number of participants in the *k*th 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, $f_{la} - f_c$ for the *kth* stratum.

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

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

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

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

Primary Statistical Analyses

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

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 CAB LA + RPV LA and ABC/DTG/3TC control arm, respectively, for the *kth* stratum.

Model Results Presentation

- Adjusted CMH estimate of the difference in the proportion of participants with 'HIV-1 RNA≥50' between each treatment group (CAB LA + RPV LA – ABC/DTG/3TC) and corresponding 95% confidence interval.
- Non-inferiority will be concluded if the upper bound of the two-sided 95% confidence interval (CI) for the CMH adjusted difference in proportion of participants with 'HIV-1 RNA≥50' in the CAB LA + RPV LA group minus proportion of participants with 'HIV-1 RNA≥50' in the ABC/DTG/3TC group is less than 6%.
- If the analysis shows non-inferiority, then a superiority hypothesis will be tested at the two-sided 5% level of significance. Superiority favoring CAB LA + RPV LA will be declared if the upper end 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 randomization strata:
    - 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 fla or fc 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. Tests of homogeneity will be assessed at the one-sided 10% level of significance.
2. Exploration of Subgroups
    - An analysis for demographic and baseline characteristic subgroups listed in Section 5.4.2 will be performed. This will show the proportion of participants 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., response below 50 c/mL, 'HIV-1 RNA≥50'or reason for no data in the window) by subgroup will be produced.

Primary Statistical Analyses
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. Endpoint / Variables

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).

Subcutaneous sub-study efficacy endpoints for the study are listed below:

- Proportion of participants with plasma HIV-1 RNA < 50 c/mL at Week 12 using the FDA Snapshot algorithm during the Sub-study Subcutaneous Abdominal Injection phase (Sub-study Safety population)
- Proportion of participants with plasma HIV-1 RNA ≥ 50 c/mL at Week 12 using the FDA Snapshot algorithm during the Sub-study Subcutaneous Abdominal Injection phase
- Proportion of participants with protocol-defined confirmed virologic failure (CVF) of ≥200 c/mL through Week 12 of the Sub-study Subcutaneous Abdominal Injection phase
- Incidence of treatment emergent genotypic and phenotypic resistance to CAB, RPV during the SC injection phase.

The incidence of observed genotypic and phenotypic resistance to NRTIs and INIs, PIs, and NNRTIs will be summarized for subjects meeting confirmed virologic failure criteria.

The proportion of participants with HIV-1 RNA ≥50 c/mL and HIV-1 RNA <50 c/mL at Week 12 of the SC injection phase will be summarized using FDA Snapshot algorithm for the Safety population in the sub-study. Proportion of participants with protocol-defined confirmed virologic failures at Week 12 will also be summarized. Summaries will be presented by subgroup as needed where data allow.

7.2.2. Summary Measure

Difference in the proportion of participants with HIV-RNA < 50 c/mL at Week 48 (defined by the US FDA snapshot algorithm) between each treatment group (Q4W IM – ABC/DTC/3TC).

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

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.

7.2.5. Statistical Analyses / Methods

Table 7 provides an overview of the planned efficacy analyses. Details of the planned displays are provided in Appendix 14: List of Data Displays and will be based on GSK data standards and statistical principles.

Table 7 Overview of Planned Secondary Efficacy Analyses

Endpoints	Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L
Proportion of Participants with 'HIV-1 ≥ 50 c/mL' at Week 96 – Snapshot [1]							
	Y[2]			Y[2,3]	Y[5]		Y[3]
Treatment Heterogeneity across randomization strata	Y						
By Subgroup [4] (Exploratory analysis)				Y[6]	Y[5]		
Proportion of Participants with Plasma HIV-1 < 50 c/mL at Week 48/Week 96 – Snapshot [1]							
Key Secondary Analysis (Week 48)	Y[2]			Y[2, 3]	Y		Y[3]
Treatment Heterogeneity across randomization strata	Y						
Proportion of Participants without efficacy-related discontinuation (ERDF) or treatment-related discontinuation (TRDF) failure at Week 48/Week 96 (refer to Section 14.6.4)							
Kaplan-Meier estimate				Y			
Proportion of Participants with Plasma HIV-1 RNA ≥ 50 copies/mL over time (Maintenance Phase)– Snapshot							
by Visit				Y	Y[7]		
by Visit and Subgroup[4]				Y	Y[9]		
Proportion of Participants with Plasma HIV-1 RNA < 50 copies/mL over time (Maintenance Phase)– Snapshot							
by Visit				Y	Y[8]		
by Visit and Subgroup [4]				Y	Y[9]		
Proportion of Participants with Plasma HIV-1 RNA < 200 copies/mL over time (Maintenance Phase)– Snapshot							
by Visit				Y[10]	Y[11]		
Proportion of Participants with Plasma HIV-1 RNA ≥ 200 copies/mL over time – Snapshot							
by Visit				Y[10]	Y[11]		
Proportion of Participants with Plasma HIV-1 RNA < 50 copies/mL at Week 48 by delay in IP injection [12] - Snapshot (exploratory analysis)							
by Delay in IP injection				Y			
Proportion of Participants with Plasma HIV-1 RNA < 2 copies/mL (exploratory analysis)							
by Visit - Observed Case Analysis				Y[13]			

Endpoints	Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L
Time from First HIV-1 RNA < 50 copies/mL until Initiation of Maintenance Phase Treatment							
				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 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. This analysis will be performed using the same approach as described for the primary analysis in Section 7.1.
2. Generated using the 'Intent-to-Treat Exposed' (primary) and 'Per-Protocol' (sensitivity) populations.
3. Study outcomes (i.e., response below 50 c/mL, 'HIV-1 RNA≥50' or reason for no data in the window) based on the snapshot algorithm.
4. Randomisation Strata, Demographic and Baseline Characteristics (refer to Section 5.4.2).
5. Plot of the difference in proportion of participants with HIV-1 RNA ≥50 c/mL (Snapshot algorithm) and its 95% confidence intervals for 'overall' (on the top of the figure) and by subgroup at Week 96.
6. Study outcomes based on the Snapshot algorithm by subgroup at Week 96 will also be produced.
7. Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥50c/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.
8. Line plots, with 95% confidence intervals, for the proportion of participants with HIV-1 RNA<50c/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.
9. Plot of the unadjusted treatment difference and its 95% confidence intervals (Snapshot algorithm) overall and by subgroup at Week 48/Week 96.
10. Study outcomes (i.e., HIV-1 RNA< 200 c/mL, HIV-1 RNA≥200c/mL, or reason for no data in the window) based on the snapshot algorithm by subgroup for Week 48/Week 96 will also be produced.
11. Line plots, with 95% confidence intervals, for the proportion of participants with HIV-1 RNA <200c/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
12. Delay in IP injection (days) is defined in Section 14.6.4
13. Using observed case (OC) data which contains the data that is available at a particular time point, with no imputation for missing values and expanded ± 6-week window for W48/W96 and last value in window (see Section 14.6.4).

Table 8 Overview of Additional Secondary Efficacy Analyses

Endpoints	Absolute							Change from Maintenance 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 Over Time														
Observed [1]				Y[8]		Y[2]	Y[3]				Y			
Detected vs Non-detected by Visit [1,5]				Y			Y[6]							
Confirmed Virologic Failure (CVF)														
CVF Overall				Y										
CVF by Visit				Y			Y							

Endpoints	Absolute							Change from Maintenance Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L	T	F	L	T	F	F	L
HIV-1 RNA at time of suspected and confirmed Virologic Failure				Y										
CD4+ & CD8+ Cell Counts Over Time														
CD4+ observed				Y[7]							Y[7]			
CD8+ observed				Y[7]							Y[7]			
CD4+/CD8+ ratio observed				Y[7]										
HIV-1 Conditions and Disease Progression														
HIV Conditions including/excluding Recurrences as recorded in eCRF				Y			Y							
HIV Disease Progressions [4]				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 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. Using observed case (OC) data which contains the data that is available at a particular time point, with no imputation for missing values and expanded ± 6 week window for W48/W96 and last value in window (see Section 14.6.4).
2. 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.
3. For CVF participants (during the Induction and Maintenance Phase, respectively, and participants with viral load ≥ 50 c/mL at any time during the Maintenance Phase).
4. HIV disease progressions (Section 14.6.4)
5. See Section 14.6.4 for a definition of "Target Detected" and "Target Non-detected".
6. Included in the Observed HIV-1 RNA listing
7. Using observed case (OC) data which contains the data that is available at a particular time point, with no imputation for missing values
8. Using log10 transformed values

7.2.5.1. Statistical Methodology Specification

Key Secondary Statistical Analyses
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)
Snapshot Dataset
• As described in Section 7.1.5.1 and Section 14.11
Model Specification
• As specified in Section 7.1.5.1 but with Snapshot HIV-1 RNA <50 c/mL replacing Snapshot HIV-1 $\geq$ 50 c/mL
Model Results Presentation
• Adjusted CMH estimate of the difference in the proportion of participants with plasma HIV-1 RNA <50 c/mL at Week 48 between each treatment group (Q4W IM – ABC/DTG/3TC) 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 (Q4W IM – ABC/DTG/3TC) is greater than -10%.
Subgroup Analyses
• Treatment Heterogeneity across randomization strata: o As specified in Section 7.1.5.1 but with Snapshot HIV-1 RNA <50 c/mL replacing Snapshot HIV-1 RNA $\geq$ 50 c/mL.
Sensitivity and Supportive Analyses
• 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.

8. SAFETY ANALYSES

Details of the planned safety displays for the Week 124 analysis are provided in Appendix 15: List of Data Displays for Week 124.

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

For the Week 48 primary analysis, a set of separate outputs will also be presented for the oral lead-in period at Maintenance Phase, including summary of adverse events, SAE, AE leading to withdrawal, emergent chemistry/haematology abnormality, participants with hepatobiliary abnormality criteria.

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 14: List of Data Displays.

8.2. Adverse Events of Special Interest Analyses

A comprehensive list of MedDRA terms based on clinical review will be used to identify Adverse Events of Special Interest (AESI). [Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional adverse events of special interest, therefore the list of terms to be used for each event of interest and the specific events of interest will be based on the safety review team (SRT) agreements in place at the time of reporting.] The details of the current planned grouping, including Standardized MedDRA Query (SMQ) values (as applicable), and planned displays are provided in Appendix 12: AESI identification and Appendix 14: List of Data Displays.

8.3. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 14: 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 14: List of Data Displays.

ECG Values of Potential Clinical Interest are defined as a QTc of > 550ms.

8.5. Planned Safety Analysis

Table 9 provides an overview of the planned analyses, with further details of data displays being presented in Appendix 14: List of Data Displays.

Table 9 Overview of Planned Safety Analyses

Endpoint	Absolute				Change from Maintenance Baseline				Max Post Maintenance BL			
	Summary		Individual		Summary		Individual		Summary		Individual	
	T	F	F	L	T	F	F	L	T	F	F	L
Exposure												
Extent of Exposure[1]	Y			Y[2]								
Adherence to Q4W Dosing Schedule [1]	Y											
Injection Needle												
Length and Gauge	Y											
Adverse Events[3]												
All AEs by SOC	Y											
All AEs by SOC and Toxicity[3]	Y[24]			Y[4]								
Common AEs by freq [5]	Y	Y[6]										
Common Grade 2-5 AEs [5] by freq	Y											
All Drug-Related AEs by SOC and toxicity[3]	Y											
Common Drug-related Grade 2-5 AEs [5]	Y											
All AEs				Y								
Serious and other significant adverse events												
All SAEs by SOC	Y[24]											
Reason for Considering as a Serious Adverse Event (FDA)				Y								
All Drug-Related SAEs by SOC	Y											
Fatal SAEs				Y								
Non-Fatal SAEs	Y			Y								
Drug-related non-fatal SAEs	Y											
Withdrawal AEs	Y[24]			Y								
Common Non-Serious AEs (FDAAA)	Y											
Number of occurrences of Common Non-serious AEs by SOC (EudraCT)	Y											
Number of occurrences of SAEs, Fatal SAEs,	Y											

Endpoint	Absolute				Change from Maintenance Baseline				Max Post Maintenance BL			
	Summary		Individual		Summary		Individual		Summary		Individual	
	T	F	F	L	T	F	F	L	T	F	F	L
and Drug-related SAEs (EudraCT)												
Cumulative AEs by visit	Y											
Depression, Suicidal and Self-Injury AEs by Prior History	Y[25]											
Suicidality assessment												
PSRAE				Y[7]								
Columbia suicidality (C-SSR)	Y											
Injection Site Reaction Adverse Events [12]												
ISR AEs (Event-Level) [17]	Y											
ISR AEs (Subject-Level) [18]	Y	Y										
ISR AEs (Subject-Level) by Visit and Severity	Y	Y[19]										
Maximum ISR AE Grade by Needle Length [21]	Y											
Laboratory: Chemistry and Hematology												
Clinical Chemistry & Renal Biomarkers [11]	Y				Y				Y [23]			
%Lipids[22]					Y							
NCEP shifts in lipids		Y							Y			
Hematology	Y				Y				Y[23]			
Laboratory: Urinalysis (regardless of fasting status)												
Urine Dipstick	Y[8]											
Urine Concentration & Renal biomarkers[12]					Y							
Laboratory: Hepatobiliary												
Liver Assessment				Y [14]								
Hepatobiliary Abnormality criteria	Y[15]			Y								
Liver Chemistries				Y[16]						Y[9]		
Laboratory: Markers												
Bone markers					Y[10]							

Endpoint	Absolute				Change from Maintenance Baseline				Max Post Maintenance BL			
	Summary		Individual		Summary		Individual		Summary		Individual	
	T	F	F	L	T	F	F	L	T	F	F	L
ECG												
ECG findings	Y			Y								
ECG values					Y							
QTC values by Category	Y				Y				Y			
Other												
Vital Signs					Y							
Weight & BMI					Y[24]							
Abacavir HSR				Y[13]								
Participants who became Pregnant				Y								
Patient Profiles				Y[20]								
Dosing Errors and IP Device Malfunctions				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 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. Refer to Section 14.6.2 for defining Extent of Exposure and adherence to Q4W dosing intervals,
2. Includes reason for any dose change/interruption.
3. For AEs reported more than once by a participant, the most severe intensity will be included. Separate summary tables including and excluding injection site adverse reactions.
4. One listing of all AEs including verbatim text and preferred term, one showing the relationship between verbatim text, preferred term and SOC and another giving subject numbers for individual all treatment emergent AEs.
5. Common AEs are those with ≥5% incidence in either treatment group summarised by frequency.
6. Plots of incidence rates and relative risk with 95% CI for Q4W IM vs. ABC/DTG/3TC.
7. Four PSRAE listings: Event and Description (Section 1 and Section 2), Possible Cause (Section 3), Section 4 and Section 5 - Section 8.
8. Shift table summarising Maintenance Baseline (Day 1) vs. maximum Maintenance Phase result for urine dipstick protein.
9. Scatter plot of baseline vs. maximum post-baseline for ALT. Scatter plot of maximum ALT vs. maximum Bilirubin. Matrix plot of maximum liver chemistries.
10. Bone markers including: Bone-specific alkaline phosphatase, procollagen type 1 N-propeptide, type 1 collagen cross-linked C-telopeptide, osteocalcin, 25 hydroxy-Vitamin D.
11. Renal markers: Urine Retinol Binding Protein, Retinol Binding Protein, Cystatin C. CKD-EP1 GFR using Cystatin C (derived in Section 14.6.3) will also be summarized
12. Repeat for CAB/RPV, CAB, RPV respectively.
13. Separate listings for exposure to abacavir, history of drug allergies, family conditions, skin rash, symptoms, vital signs, individual symptoms, and diagnostic category assignment.
14. Separate listings for time of event, RUCAM score, biopsy, imaging, past/ current conditions and follow up
15. One summary of participants and another table showing Subject Ids. Table of participants meeting hepatobiliary abnormally criteria during the maintenance oral lead-in Phase will also be produced.
16. Patient profiles for participants meeting protocol defined liver stopping criteria and for patients with virologic failure. Patient profiles can also be provided for any other participants, as necessary for medical review.
17. Event-level summary: Percentages based on total number of ISR events within each treatment group including distribution of grade, duration, and event characteristics;

18. Subject-Level summary: Characteristics of ISR AE (Overall and by Common ISRs); Percentage based on number of participants within each treatment group; Includes distribution of grade and max grade, event characteristics, number of events per subject, rate of number of events per injection visit;
19. A corresponding plot of all grades and a separate plot of grade 3-5 events will be produced
20. Patient profiles are not planned. But it can be produced post hoc, as necessary.
21. Please refer to Section 5.4.2 "Additional subgroup for ISR" for derivation of needle length used in this summary
22. Please refer to Section 14.6.3 for defining percentage change from Maintenance Baseline (Day 1) in Lipids
23. Separate tables will be produced for Maintenance Phase data and Oral Lead-in period data (see Table 28 and Table 29)
24. Change from Induction Baseline (Week -20) for BMI and Weight.
25. By SOC and Maximum Toxicity, and history based on prior/current medical conditions collected at Screening

8.5.1. Injection Site Reactions

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

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

Drug-related ISRs (based on investigator discretion) 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.

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

Common ISR includes injection site pain, injection site induration, injection site nodules and any other ISR occurring in ≥5% of participants (for Q4W arm only). The same set of common terms will be applied to 'overall' (CAB and/or RPV), CAB alone, RPV alone.

8.5.2. Statistical Analyses/Methods

Statistical Analyses
Endpoints
• Change from Maintenance Baseline (Day 1) in Bone Markers at Week 48
Covariates
• Treatment (Q4W IM, ABC/DTG/3TC) • Induction Baseline (Week -20) HIV-1 RNA (<100,000, ≥100,000 c/mL), Gender at Birth, TDF use at Maintenance Baseline (Day 1), Age, body mass index category at Induction Baseline (Week -20), smoking status, and Log-transformed bone marker value at Maintenance Baseline (Day 1) (as defined in Section 5.4.2)
Data Handling
• All data remains as is (observed).
Model Specification
• Bone marker results will be log-transformed. The change in the log-transformed data at week 48 from Maintenance baseline (i.e., log of ratio of post-baseline value over Maintenance baseline value) for each bone marker will be analysed for the comparison between the two treatment arms. • Analysis of covariance (ANCOVA) model will be used with the above covariates/subgroups. Age and Log-transformed bone marker value at Maintenance Baseline (Day 1) will be included as continuous variables in the model and all other covariates will be included as categorical variables.
Model Results Presentation
• The estimated coefficients of the ANCOVA model will be transformed back (exponential transform) to reflect the change in the ratio of post-baseline value over Maintenance Baseline (Day 1) value rather than the change in the log ratio. The change in the ratio can then be translated into percent change from maintenance baseline (Day 1) (e.g., the ratio bb_{48}/bb_{bl} = 1.3 can be translated into 30% increase from baseline). • For each treatment, adjusted (geometric) means of ratio and corresponding confidence intervals will be presented. Adjusted point estimates will be derived as LSMEAN S using the observed margins (OM) option within PROC MIXED in SAS. • The adjusted (geometric mean) difference of the ratio (post-baseline value)/(baseline value) between the two treatments with the corresponding confidence interval and *p*-value will be presented • Interactions between treatment and each of the covariates will be investigated but not included in the main model. If interactions are found to be significant (p-value <0.10), results will be presented separately by subgroup.

NOTES:

- Statistical analysis will only be performed when all expected data through Week 48 has been received from the laboratory.

8.6. Subcutaneous Sub-Study Safety Analyses

The proportion of participants reporting AEs will be tabulated for each injection type. This will include the following AE summaries:

- Incidence and severity of ISRs and AEs of special interest during the SC injection phase
  - This includes incidence of Grade 4 ISRs and Grade 3 ISRs including ulceration, secondary infection, phlebitis, sterile abscess, or drainage affecting Interim 1 monitoring criteria.
- Proportion of participants who discontinue treatment due to ISRs and proportion of AEs of special interest during the SC injection phase
- Incidence and severity of AEs not of special interest
- Incidence of SAEs
- Dimensional characteristics (length & width in mm) of SC ISRs of erythema, redness, induration, and swelling
- Change from baseline (latest non-missing value prior to the first SC injection) in laboratory parameters will be summarized by visit through the end of the SC phase.

AE and ISR summaries will be repeated for the following subgroups: Age (<50 vs >=50), Sex at Birth (Female vs Male), Race/Ethnicity (White: Non-Hispanic, White: Hispanic, Black, Asian, Other), Sub-study Baseline BMI (<30, >=30).

Incidence Rate ratios and their 95% CIs for the incidence of ISRs between SC and IM will also be calculated using a Poisson regression model that accounts for within-subject variation by using a repeated effect of subject. Categorical Baseline BMI (<30, >=30) will be included as a covariate in the model. These informal comparisons will be graphically displayed overall and for each subgroup. Results will be repeated for Grade 1+ ISRs as well as for Grade 2+ ISRs. Sub-study participant data will be matched to their individual IM data via the following comparisons:

1. The first 2 SC injections vs. the two IM injections post-SC dosing
2. All 3 SC injections vs. the first 3 IM injections in the parent study

ISRs of interest will be simply tabulated (i.e., Grade 3+ ulceration, secondary infection, phlebitis, abscess, drainage or a Grade 4 ISR) at interim analysis 1 for ISR monitoring. Once counted, the posterior probability that the true rate of ISRs of interest is >0.05 will be calculated using a Bayesian Beta-Binomial model to produce posterior hyperparameters α' successes and β' failures as indicated below.

$$a' = a + \sum_{i=1}^{n} x_i$$

$$\beta' = \beta + \sum_{i=1}^{n} N_i - \sum_{i=1}^{n} x_i$$

Where prior α = 0.001 and prior β = 79 based on previous and ongoing studies mentioned in protocol amendment 8, Section 12.12.1.3, x_i is the total number of participants with an event, and N_i is the total number of participants with an SC injection at the interim.

The posterior probability that the true rate of ISRs of interest is >0.05 will then be calculated from a Beta Distribution CDF using the posterior hyperparameters α′ and β′ and summarized for determination of formal VSLC review of all data for ISRs of interest.

9. PHARMACOKINETIC AND PHARMACOKINETIC/PHARMACODYNAMIC ANALYSES

Details of the planned PK displays for the Week 124 analysis are provided in Appendix 15: List of Data Displays for Week 124.

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

All PK and PK/PD displays will be based on the PK Population.

9.1. Primary Pharmacokinetic Analyses

9.1.1. Endpoint / Variables

9.1.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 14.5.3 Reporting Standards for Pharmacokinetic)

9.1.1.2. Derived Pharmacokinetic Parameters

A population-based PK analysis will be described under separate Population-PK Reporting and Analysis Plans for CAB LA and RPV LA.

9.1.2. Planned Analyses

Table 10 provides an overview of the planned analyses based on observed plasma CAB/RPV concentration data only with full details being presented in Section Appendix 14: List of Data Displays.

Unless otherwise specified, drug concentration and pharmacodynamic measures will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

Table 10 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 [8]				Y[1]			

Pharmacokinetic/Pharmacodynamic							
CAB/RPV last trough and Week 8 concentrations by Snapshot virologic Response at Week 48				Y	Y		
CAB/RPV Week 8 concentrations by Snapshot virologic Response at Week 96 [7]				Y	Y		
Analysis of Snapshot 'HIV-1 RNA≥50' at Week 48 by last trough CAB/RPV concentration, Week 8 trough concentration, and subgroups [6] – Univariable analysis /multivariable analysis	Y						
Analysis of Snapshot 'HIV-1 RNA≥50' at Week 96 by Week 8 CAB/RPV trough concentration, and subgroups [6] – Univariable analysis /multivariable analysis [7]	Y						
Individual CAB/RPV Concentration-Time Profiles for Participants with HIV-1 RNA ≥ 50 c/mL at Week 48 (or Week 96)					Y		
Change from Maintenance Baseline (Day 1) in 2hr post-dose QTc and 2-hour post-dose CAB & RPV concentration at Week 4b, Week 48, Week 96						Y	
Maximum Change from Maintenance Baseline (Day 1) in ALT/Total Bilirubin versus Last Trough CAB/RPV Concentrations [8]						Y	
Maximum Toxicity Grades of Most Frequently Reported AEs versus Last Trough CAB/RPV PK Concentrations [8]						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 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.

3. For both 'all' concentration and the 'evaluable' concentration. The evaluable concentration is derived from samples collected within pre-specified Time window (Section 14.6.5) and not affected by dosing errors or oral bridging.
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, median, minimum, and maximum). For Logarithmically transformed data, the summary statistics (i.e., geometric mean, coefficient of variation on geometric mean, 95% confidence interval for the geometric mean and standard deviation) will also be calculated.
6. Please refer to Section 5.4.2. i.e., randomisation strata, baseline and demographic factors, and additional subgroups for PK/PD analyses
7. Will be produced only if at least one new CVF has occurred since Week 48 (randomized Q4W arm).
8. Produced for Week 48 only.

9.1.3. Statistical Analyses/Methods

Planned PK statistical analysis
Steady State Concentration
Endpoints
• log_e-transformation of the Trough/Pre-dose plasma concentrations (CAB/RPV) on Week 16-48
Covariates
• Study Week
Data Handling
• All data remains as is (observed).
Model Specification
• A mixed effects ANOVA model will be fitted with 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 day effect on the log_e-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, 20, 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 day effect on the log_e-scale, its Standard error and 90% interval will be presented.
Population PK Analysis
• A population-based PK analysis will be done under separate Population-PK Reporting and Analysis plans.
Exposure - antiviral activity analysis (PK/PD)
Endpoints
• Snapshot 'HIV-1 RNA≥50' at Week 48 (or W96)

Covariates
• Randomisation strata, demographic, and baseline characteristics (as specified in Section 5.4.2), and the following additional subgroup/covariates for PK/PD efficacy analysis o last CAB/RPV trough concentration (Week 48 analysis only) o CAB/RPV trough concentration at the nominal Week 8 visit, Induction Baseline (Week -20) BMI, needle length for CAB/RPV injections at Week 4b) o See "Additional subgroup/covariates for PK/PD efficacy analysis" in Section 5.4.2 for derivation details. • For the W96 CSR, this exploratory analysis will be performed only if at least one new CVF has occurred since Week 48.
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') at Week 48 and the covariates/subgroups. This logistic regression analysis will be performed for each covariate, separately (univariable analysis), and will also be performed with one multivariable analysis using Backward stepwise selection approach to identify the covariates potentially affecting virologic response.
Model Checking & Diagnostics
• For the multivariable analysis, a logistic regression model that best predicts the dependent variable (i.e., 'HIV-1 RNA≥50') from the independent variables (i.e., covariates/factors with P <0.15 from univariable analysis) will be determined using the backward stepwise selecting approach. The last trough and 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 Fisher's exact test (univariate analysis) and exact logistic regression (multivariable analysis) may be used.
Model Results Presentation
• The odds ratio, 95% confidence interval, and p-value will be presented. Estimated effect represents the change in log odds for a two-unit increase in PK concentration.

9.2. Subcutaneous Sub-Study

9.2.1. Endpoint / Variables

- Plasma PK parameters for CAB LA 200 mg/mL and RPV LA 300 mg/mL (Ctau, concentrations 1-week post dose [~Cmax], and area under the curve [AUC (0-tau)])

for SC injections during the SC injection phase compared with similar PK parameters for gluteal IM injections

Plasma CAB and RPV concentration values will be summarized with descriptive statistics by dosing interval and planned timepoint for the PK Concentration Population (PC). These concentration values will be determined directly from concentration-time data from each analyte. Descriptive statistics including the n, mean with associated 95% CI, standard deviation, median, minimum, maximum, geometric mean with associated 95% CI, standard deviation of logarithmically transformed data, $5^{th}/95^{th}$ percentiles and the geometric coefficient of variation (CV%).

Individual concentration-time profiles and median/mean profiles from each analyte in each dosing interval will be plotted for the PK Concentration (PC) Population. Each of the figures will contain one plot on the untransformed scale (i.e., a linear plot) and one plot on the log transformed scale (i.e., semi-log plot). Actual assessment times will be used in the individual concentration-time plots. Nominal times will be used for the purposes of summarization and in mean and median plots. See Appendix 4: Data Display Standards & Handling Conventions. for details on pharmacokinetic figure and table displays

Pharmacokinetic parameters will be derived by standard non-compartmental analysis according to current working practices and using the currently supported version of WinNonlin 6.3 or higher (Pharsight, Inc., Cary, NC). All calculations of non-compartmental PK parameters will be based on actual sampling times. Pharmacokinetic parameters listed will be determined from the plasma concentration-time data, as data permits. Cτ will be taken from CAB and RPV concentration data at the prescribed timepoint. The following PK parameters will be derived and displayed for the PP Population as data permits:

Table 11a Derived PK Parameters

Parameter	Parameter Description	Gluteal Injection	SC Injection 1	SC Injection 2	SC Injection 3
C_{max}	Maximum observed concentration during the dosing interval	Week-4 - Day 1	Day 1 – Week 4	Week 4 – Week 8	Week 8 – Week 12
t_{max}	Time of occurrence of C_{max}				
$AUC_{0-\tau}$	Area under the concentration time curve from time zero to the end of the dosing interval				
Cτ	Trough concentrations (Cτ) at the end of the dosing interval	Day 1	Week 4	Week 8	Week 12

NOTES: NA: Not Applicable

- Additional parameters may be included as required.

All the derived pharmacokinetic parameters will be summarized and listed for the PP population by study phase and treatment. For each of these PK parameters, with the exception of t_{max}, the following descriptive summary statistics will be calculated for each treatment: n, arithmetic mean with associated 95% CI, standard deviation, median, minimum, maximum, geometric mean with associated 95% CI, standard deviation of

logarithmically transformed data, and the geometric coefficient of variation (CV_b(%)). For t_{max}, the n, median, minimum, and maximum summary statistics will be provided. Where $AUC_{0-\tau}$ is collected out of the appropriate window, AUC_{0-t} (the last quantifiable concentration) will be used in place of $AUC_{0-\tau}$.

Interim analysis 2 will include descriptive summaries and graphs of PK concentration and parameters as data permit. PK summaries will be presented by subgroup as needed where data allow. Data display specifications for derived PK parameter summaries and listings are given in Appendix 19 of this RAP

PK samples collected outside the protocol defined time-windows and/or other protocol deviations will be reviewed by the study team to determine whether the sample will be excluded from PK analyses.

9.2.2. Planned Analyses

The primary objective of this sub-study is to evaluate the pharmacokinetics of cabotegravir LA (200 mg/mL) and rilpivirine (RPV) LA (300 mg/mL) for monthly dosing as a SC injection in the anterior abdominal Wall SC Tissue versus an IM injection into the gluteal muscle in HIV-1 infected participants currently enrolled in the FLAIR study.

An estimation approach will be taken and point estimates and confidence intervals will be constructed for the ratio of the geometric mean of SC abdominal injection PK parameters to the geometric mean of the IM gluteal injection PK parameters.

The primary analysis is to compare the abdominal SC injection with gluteal IM injection using the ratio of the geometric mean of SC injection to the geometric mean of IM injection for a PK parameter within each analyte (CAB, RPV). The primary PK parameters of interest include concentrations at the end of the dosing interval [Ctau], concentrations 1-week post dose [~Cmax], and area under the curve for the dosing interval [AUC (0-tau)] (Table 24). CAB and RPV concentrations and parameters will be summarized descriptively.

Following log-transformation, C_{max}, C_{tau} and $AUC(0-_{tau})$ will be separately analyzed by analyte using a mixed effects model with fixed effect term for type of injection (SC, gluteal) and BMI ($\geq$30 Kg/m^2, <30 Kg/m^2) in addition to a random effect term for subject. As it is suspected that varying participant BMI may impact the PK concentration distribution, BMI is being included in the model as a covariate to control for any potential impact beyond the effect of injection type. In each model, only participants with PK parameter estimates from corresponding both SC and gluteal injections are included. For example, in the model for comparing C_{max} between the first CAB SC injection vs gluteal CAB injection, only participants with C_{max} estimates from both first CAB SC injection and CAB gluteal injection are included.

Point estimates and their associated 90% confidence intervals will be constructed for the differences between the SC injection and the gluteal injection. The point estimates and their associated 90% confidence intervals from the log-transformed analysis will then be back-transformed to provide point estimates and 90% confidence intervals for the ratios between

the SC injection and the gluteal injection on the original scale. This analysis will be performed using the PK Parameter (PP) population for the dosing intervals given in Table 11b using the Gluteal parameters as the reference variables and each SC injection-based set of parameters as the test variables. While no formal bioequivalence testing will be performed, parameters can be assumed to be similar if the geometric mean ratio and its 90% CI fall within 0.80 – 1.25.

Table 11b Parameters and dosing

Parameters (CAB 200mg/mL + RPV 300mg/mL)	**Q Monthly Dosing**		
Cmax (1-week post injection), Ctau (end of dosing interval) AUC(0-tau)	SC Injection 1: gluteal injection	SC Injection 2: gluteal injection	SC Injection 3: gluteal injection

The point estimate of the slope of Cτ following the last IM injection through 3rd SC injection will also be determined to assess changes in steady state conditions established previously. This will be performed using another mixed-effects model with concentration timepoint as a predictor variable of concentration and a random effect of subject. The model will initially include all concentration values from Day 1 – Week 12 and will then be repeated, removing the earliest timepoint in each run until the last two timepoints remain, Week 9 – Week 12. Point estimates and 90% confidence intervals for the slope will be presented in tabular format.

9.2.3. Statistical Analyses/Methods

PK Parameters
Endpoints
Geometric Mean Ratio: • As data permit, Log_e-transformation of the PK parameters (Ctau, Cmax and AUC(0-tau) for each sub-study dosing interval for participants in the sub-study PK Concentration Population Steady State: • log_e-transformation of the Trough/Pre-dose plasma concentrations (CAB/RPV) on all appropriate dosing intervals
Model Specification
Geometric Mean Ratio: • 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 vs 1st, 2nd, and 3rd SC injection) and Sub-study Baseline BMI (<50 kg/m^2, ≥ 30 kg/m^2) as fixed effects and subject as a random effect. 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 SC injection interval with Cmax estimated from the gluteal injection interval, only the subjects with evaluable Cmax estimates from both first CAB SC injection interval and gluteal injection interval are included.

Steady State:

- A mixed effects ANOVA model will be fitted with Day / Week (categorical variable) as a fixed effect and subject as a random effect for each analyte. The Kenward & Roger (KR) degrees of freedom approach will be used. The coefficient for the slope of the day effect on the $\log_e$-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. The model will be initially run with all timepoints from Day 1 – Week 12, removing the earliest timepoint at each iteration until the last two timepoints remain, Week 9 - Week 12. Only evaluable concentrations will be included in the analysis.

Model Checking & Diagnostics

Geometric Mean Ratio:

- Model assumptions will be applied, but appropriate adjustments may be made based on the data. Parameters can be assumed to be similar if the geometric mean ratio and its 90% CI fall within 0.80 – 1.25

Steady State:

- 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. Concentrations from earlier timepoints (e.g., Day 1, Week 1 etc.) will be dropped in sequence and the analysis repeated until only two timepoints remain.

Model Results Presentation

Geometric Mean Ratio:

- 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.

Steady State:

- The coefficient for the slope of the day / week effect on the $\log_e$-scale, its Standard error and 90% interval will be presented

10. PHARMACOKINETIC ANALYSES (DAY 1 JAPAN)

For Japanese participants in the study, blood samples for CAB will be taken at the Day 1 visit at each of the sampling times shown in Table 11c, in addition to sparse samples collected at other visits as specified in the protocol for all CAB LA + RPV LA randomized participants.

Table 11c Additional PK Visit and Sample Times for Japanese Participants

Day	Time (Related to Dosing of Study agent)
Oral Cabotegravir	
Day 1 (following first oral dose during lead-in phase)	Pre-dose, 1, 2, 3, 4, 8, and 24 hours post-dose

10.1. Primary Pharmacokinetic Analyses

Pharmacokinetics of CAB following a single 30 mg dose using the Phase 3 formulation in Japanese in 201584 (FLAIR) will be evaluated. Approximately 20 Japanese participants will be enrolled and randomized 1:1 to CAB or ABC/DTG/3TC to achieve ~10 participants who receive oral CAB.

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

10.1.1. Endpoint / Variables

10.1.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 14.5.3 Reporting Standards for Pharmacokinetic).

Assay results from Day 1 samples collected from a subject with emesis occurring within 4 hours of the dose will not be considered as evaluable and will be excluded from all data displays and PK analyses.

10.1.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters for Japanese participants randomized to CAB LA + RPV LA will be calculated using plasma concentration-time data on Day 1 by standard non-compartmental analysis according to current working practices and using the currently supported version of WinNonlin. All calculations of non-compartmental parameters will be based on actual sampling times. Pharmacokinetic parameters listed will be determined from the concentration-time data, as data permits.

Parameter	Parameter Description
AUC(0-t)	The area under the plasma concentration-time curve from time zero to the last quantifiable concentration following the first dose, determined using the linear trapezoidal rule for increasing concentrations and the logarithmic trapezoidal rule for decreasing concentrations
Cmax	The first occurrence of the maximum observed plasma concentration determined directly from the raw concentration-time data.
C24	Concentration observed at 24-hours post dose (±30 mins) determined directly from the raw concentration-time data.
tlag	The time of sample preceding first quantifiable concentration, determined directly from the raw concentration-time data.
tmax	The time at which Cmax is observed, determined directly from the raw concentration-time data.
tlast	The time of last quantifiable concentration

NOTES:

- Additional parameters may be included as required.

10.1.2. Summary Measure

For plasma CAB concentrations, the following summary statistics will be calculated by planned sampling time: n, mean, standard deviation (SD), coefficient of variation (%CV), median, minimum and maximum, geometric mean, 95% confidence interval and the between-subject CV (%CVb) based on the geometric mean for the $\log_e$-transformed values.

For PK parameters, except for tmax, tlag, and tlast, the following summary statistics will be calculated: n, mean, standard deviation (SD), coefficient of variation (%CV), median, minimum and maximum, geometric mean, 95% confidence interval and the between-subject CV (%CVb) based on the geometric mean for the loge-transformed values. For tmax, tlag, and tlast, the following summary statistics will be calculated: median, maximum, minimum, arithmetic mean, and standard deviation.

10.1.3. Population of Interest

The primary pharmacokinetic analyses will be based on the Japan Pharmacokinetic population, unless otherwise specified.

10.1.4. Strategy for Intercurrent (Post-Randomization) Events

Data following the intercurrent event of randomized treatment discontinuation will not be used in the analysis as the concentrations and PK parameters to be estimated is while on-treatment.

10.1.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 1: Japan-Specific Requirements and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 9.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

PK parameters that have mass in the units should be reported in μg/mL and μg•h/mL.

Deviations from planned times will be examined for scheduled assessments. PK parameters will be calculated using actual assessment times. Actual assessment times will be used in the individual concentration-time plots. Nominal times will be used for the purposes of summarization and in mean and median plots. Concentration-time data will be listed using actual assessment times.

All available data will be summarized, with no imputation for missing data.

10.1.5.1. Statistical Methodology Specification

No formal hypothesis will be tested. Descriptive statistics will be used to summarize data.

11. HEALTH OUTCOMES ANALYSES

11.1. Endpoint / Variables

- Change from Maintenance Baseline (Day 1) in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Status Questionnaire (HIVTSQs);
- Change in treatment satisfaction over time (using the HIVTSQc change version) at Week 48;
- Change from Week 5 in Dimension Scores and proportion of participants considering pain and local reactions following injection using PIN (Perception of Injection Questionnaire) (Q4W arm only);
- Change from Maintenance Baseline (Day 1) in Subscale of Life satisfaction, HIV medication, and disclosure worries using HAT-QoL;
- Change from Maintenance Baseline (Day 1) in Mental health component (MCS) and physical component summary (PCS) using SF-12;
- Change from Maintenance Baseline (Day 1) in treatment acceptance using ACCEPT;
- Change from Week 4b in tolerability of injections using NRS (Q4W arm only)

11.1.1. Summary Measure

Mean treatment difference (Q4W IM – ABC/DTG/3TC) at visits of interest through to Week 96 (i.e., the assessment visits detailed in Table 12), excluding PIN and NRS endpoints.

Mean change at visits of interest through to Week 96 (i.e., the assessment visits detailed in Table 12), for PIN and NRS endpoints.

11.1.2. Population of Interest

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

11.1.3. Strategy for Intercurrent (Post-Randomization) Events

If a participant discontinues treatment prior to the timepoint of interest such that there is no evaluable on-treatment assessment for the timepoint of interest (see Table 30 for definition of on-treatment), the data will be computed or imputed (see Section 14.6.6).

11.1.4. Planned Health Outcomes Analyses

Table 12 provides an overview of the planned analyses. Details of the planned displays are provided in Appendix 14: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Table 12 Overview of Planned Health Outcome Analyses

Endpoints	Absolute							Change from Maintenance Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L	T	F	L	T	F	F	L
Perception of Injection (PIN) at Week 5, 41, 48, 96, Withdrawal (Q4W arm only)														
Individual Item Scores				Y										
Domain of 'Bother from injection site reactions', 'Leg movement', 'Sleep', 'Acceptability'	Y[4]			Y							Y[5]			
Health-related quality of life (HATQoL) at Day 1, Week 24, 48, 96, Withdrawal														
Individual Item Scores				Y										
Subscale of Life satisfaction, HIV medication, and disclosure worries				Y				Y	Y[1]		Y			
Health Status (SF-12) at Day 1, Week 24, 48, 96, Withdrawal														
Individual Item Scores				Y										
Mental health component (MCS) and physical component summary (PCS)[2]				Y				Y	Y[1]		Y			

Endpoints	Absolute							Change from Maintenance Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L	T	F	L	T	F	F	L
Treatment Satisfaction Score (HIVTSQs) at Day 1, Week 4b, 24, 44, 96, Withdrawal														
Individual Item Scores				Y										
Individual Item Scores by Subgroup[3]				Y										
Treatment Satisfaction Score	Y			Y				Y	Y[1]		Y			
Treatment Satisfaction Score Change (HIVTSQc) at Week 48, Withdrawal														
Individual Item Scores				Y										
Treatment Satisfaction Score Change	Y			Y										
Treatment Acceptance (ACCEPT) at Day 1, Week 8, 24, 48, 96, Withdrawal														
Proportion of Individual item score				Y										
Acceptance/General Dimension Score				Y				Y	Y[1]		Y			
Tolerability of injection (NRS) at Week 4b, 5, 40, 41, 96 (Q4W arm only)														
Proportion of Individual item score				Y										
Tolerability Score (Q4W IM only)				Y							Y			
Treatment Preference at Week 48 (Q4W arm only)														
Treatment: Monthly injection vs Daily oral ART				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 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. Line Plot of Adjusted Mean (95% CI) for each treatment arm, as well as the adjusted mean difference (95% CI) between the two treatment arms (if questionnaire was used for both arms during Maintenance Phase).
2. Component scores will be calculated form Computer Software purchased from QualityMetric.
3. Subgroups: Induction Baseline (Week -20) HIV-1 RNA (<100,000, ≥100,000 c/mL), gender at birth, age (<35; 35-<50; ≥50), Maintenance Baseline (Day 1) CD4+ cell count <200; 200 to <350; 350 to <500; ≥ 500 cells/mm3), and race (i.e., white, non-white).
4. Statistical analysis (i.e., p-value) produced only for the acceptance score comparing Week 40/41/96 to Week 5.
5. Change versus Week 5 for PIN.

11.1.5. Statistical Analyses/Methods

Statistical Analyses
Endpoints

• Change from Maintenance Baseline (Day 1) in
  • HIVTSQs total treatment satisfaction score 24, 44, and 96
  • ACCEPT general acceptance score at Week 8, 24, 48, and 96
  • SF-12: physical component summary (PCS) and mental component summary (MCS) at week 24, 48, and 96
  • HATQoL (Life satisfaction, HIV medications, disclosure worries) at Week 24, 48, and 96.

Model Specification
• An analysis of covariance (ANCOVA) model will be used at each visit at Maintenance Phase with covariates: treatment, age (<50, ≥ 50 years old), Induction Baseline (Week -20) HIV-1 RNA (<100,000, ≥100,000 c/mL), gender at birth, race (i.e., white, non-white) and Maintenance Baseline (Day 1) 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. • No adjustment for multiplicity will be applied as these analyses 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 (Q4W IM – ABC/DTG/3TC), 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 Maintenance Baseline (Day 1) (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
• 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), Induction Baseline (Week -20) HIV-1 RNA (<100,000 c/mL, ≥ 100,000 c/mL), Gender at birth, and Race (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 (Q4W IM – ABC/DTG/3TC).
Statistical Analyses
PIN
• Change from Week 5 in the PIN acceptance score at Week 41 and Week 48 (Q4W arm only)
Statistical Test
• The Wilcoxon Signed-Rank Test will be used to evaluable whether the change from Week 5 to Week 41 and to Week 48, respectively, is statistically different than zero based on a two-sided p<0.05. Separate tests will be performed for the change from Week 5 to Week 41 and for the change from Week 5 to Week 48.
Dataset
• LOCF dataset will be used
Results Presentation
• Summary statistics at each timepoint (Week 5, Week 41 and W48) and p-value for each comparison (W48/W41) versus scores at Week 5

11.2. Subcutaneous Sub-Study Endpoint / Variables

- Change from gluteal to SC in total "treatment satisfaction" score, and individual item scores of the HIV Treatment Satisfaction Status Questionnaire (HIVTSQs) during the SC Injection phase as well as the change from SC to gluteal during the Return to Gluteal Injection phase
- Change from gluteal to SC using the HIV Treatment Satisfaction Change (HIVTSQc) questionnaire at Sub-study Week 9

- Changes in the tolerability of injections (NRS) over time during the sub-study, separate for CAB LA and RPV LA
- Changes in the perception of injections (PIN) over time during the sub-study, separate for CAB LA and RPV LA
- Preference for SC injections compared with prior gluteal injections and the injections received during the Return to Gluteal Injection phase respectively.
- Reasons for switch to SC from IM
- Interest for home administration options

11.2.1. Summary Measure

The health outcomes analyses include analyses of data collected from the following questionnaires, HIVTSQ (both s and c versions), NRS, PIN, and Preference between SC and gluteal injections. The reasons for switch to SC from IM injections will be assessed, as well as the interest in a potential option for self-administration of SC injections. Health Outcomes assessments will be summarized, where applicable, by study drug (CAB and RPV), domain, and item. Summaries will be presented by subgroup as needed where data allow.

For the sub-study, the change from sub-study Baseline in Total Treatment Satisfaction and Individual Item scores as well as the mean difference between SC injections and gluteal injections from visits of interest will be presented for the HIVTSQs (Baseline vs. Week 9 and Week 17). Change from sub-study Baseline will be presented for the NRS and the PIN (Domain and Individual Item scores). Descriptive statistics and frequency counts will be presented as appropriate for all measures.

Results for the Preference questionnaire, the HIVTSQs, the PIN, and the NRS will be displayed by subgroup (age group, sex, race/ethnicity, Baseline BMI).

Descriptive NRS and Preference score statistics will also be presented at interim analysis 2.

11.2.2. Statistical Analyses/Methods

Statistical Analyses
NRS/PIN/HIVTSQs
• Change from Sub-study Baseline in the NRS, PIN domain and item scores, and HIVTSQs total treatment satisfaction score at all available subsequent sub-study timepoints • The mean difference between SC injections and IM injections from all visits in a phase will be calculated between all SC results and all return to IM results for the NRS, PIN, and HIVTSQs.
Statistical Test
• The Wilcoxon Signed-Rank Test will be used to evaluate: 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 $p<0.05$. Separate tests will be

Statistical Analyses
performed for the change from Baseline to Week 9, for the change from Baseline to Week 17, and for the change from Week 9 (SC phase) to Week 17 (return to IM phase). For the PIN domains, whether the change from Sub-study Baseline to each post-baseline sub-study visit is statistically different from zero based on a two-sided $p<0.05$. Separate tests will be performed for the change from Baseline to Week 1, Baseline to Week 9, and Baseline to Week 13, and for the change from Week 9 (SC phase) to Week 13 (return to IM phase) by treatment (CAB vs RPV).
Dataset
• Observed values will be used for all measures
Results Presentation
• For HIVTSQs, summary statistics at Sub-study Baseline, Sub-study Week 9, and Sub-study Week 17 a p-value for the comparison between scores at each post-baseline sub-study visit with scores at Sub-study Baseline will be presented. • For the PIN domains, summary statistics at Sub-study Baseline, Sub-study Weeks 1, 9, and 13 a p-value for the comparison between scores at each post-baseline sub-study visit with scores at Sub-study Baseline will be presented.

12. VIROLOGY

Details of the planned virology displays for the Week 124 analysis are provided in Appendix 15: List of Data Displays for Week 124.

Virology displays for the subcutaneous sub-study will be produced when data is available. Further details available in Appendix 19: List of Data Displays for Subcutaneous Sub-Study Analysis.

The virology analyses will be for the CVF populations using genotype and phenotype data based on population sequencing assay, unless otherwise specified.

Table 13 provides an overview of the planned analyses, with further details of data displays being presented in Appendix 14: List of Data Displays.

Table 13 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 [4]
Prevalence of Emergent Resistance Mutations – Relative to Genotype at Baseline (Week -20) [5]	Y [2]			
Phenotypic resistance at time of CVF[1]				
Prevalence of Phenotype	Y [3]			Y [4]
Fold Change for CAB, RPV, DTG	Y			
Change from Induction Baseline (Week -20) in Fold Change to CAB, RPV, DTG.	Y			
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]
Prevalence of Resistance Mutations at Induction Baseline (Week -20)	Y [2]			
All Genotypic Data				Y

NOTES:

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e., modelling) conducted.
- Summary = Represents TFL related to any summaries (i.e., descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual 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 date, 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 will not be tested for resistance.
2. No. and percentage of participants with IN resistance mutations or major mutations in the classes of NNRTI, NRTI, PI, respectively, as defined in 14.6.7
3. Separate outputs by phenotypic cut-off and by number of drugs to which participants are resistant.
4. Includes the following at all available timepoints (including screening, Week -20, and all post-baseline samples): HIV-1 subtype (Induction Baseline (Week -20)), resistance mutations and fold change to EFV/ETR/RPV, DTG/RAL/EVG/CAB and ARTs (for the ABC/DTG/3TC arm) received during the Maintenance Phase. Non-CVF participants may include those with genotype/phenotype data upon withdrawal from treatment with last on-treatment HIV-1 RNA ≥200 c/mL.
5. Emergent Mutations defined in Section 14.6.7

Additional analyses for HIV-1 resistance may be carried out on peripheral blood mononuclear cell (PBMC) samples collected at Day 1 and Week 96 (or withdrawal if prior to Week 96).

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.

13. REFERENCES

Chan, I. S. F. and Zhang, Z. (1999), "Test-Based Exact Confidence Intervals for the Difference of Two Binomial Proportions," Biometrics, 55, 1202–1209.

Chevat C, Viala-Danten M, Dias-Barbosa C, Nguyen VH. Development and psychometric validation of a self-administered questionnaire assessing the acceptance of influenza vaccination: the Vaccinees' Perception of Injection questionnaire. Health Qual Life Outcomes. 2008 mar 4; 7:21

D'Agostino RB, Vasan RS, Pencina MJ, et al. General Cardiovascular Risk Profile for Use in Primary Care (The Framingham Heart Study). Circulation 2008; 117: 743-753.

EMA/CHMP/539146/2013, Guideline on the investigation of subgroups in 4 confirmatory clinical trials, 23 January 2014

Fleiss J.L. Statistical Methods for Rates and Proportions. 2nd ed. New York:John Wiley; 1981.

Gilet H, Arnould B. Acceptance by the patients of their treatment (ACCEPT) Questionnaire, 2014.

Grundy S.M., et al. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA. 2001;285 (19):2486-2497.

HIVTSQ user guidelines, Health Psychology Research Unit, Royal Holloway, University of London, 2016

Holmes WC, HIV/AIDS-Targeted Quality of Life Instrument 1999.

Kalbfleisch J.D., Prentice R.L. *The Statistical Analysis of Failure Time Data.* 1st ed. New York: John Wiley & Sons; 1980.

Levey AI, Christopher HS, Hocine T, John HE, Harold IF, Tom G, et al. Estimating Glomerular Filtration Rate from Serum Creatinine and Cystatin C. N Engl J Med 2012, 367: 20-29.

Lui K.J., Kelly C. A Revisit on Tests for Homogeneity of the Risk Difference, Biometrics, 2000;56:309-315.

Mary E. Nilsson, Shailaja Suryawanshi, Cristiana Gassmann-Mayer, Sarah, Dubrava, Paul McSorley, and Kaihong Jiang. Columbia–Suicide Severity Rating Scale, Scoring and Data Analysis Guide, 2013

Nilsson ME, Suryawanshi S, Gassmann-Mayer C et al, Columbia–Suicide Severity Rating Scale, Scoring and Data Analysis Guide, 2013.

Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *Am J Psychiatry*. 2007;164:1035–1043.

Ralph B. D'Agostino, Ramachandran S. Vasan, Michael J. Pencina, Philip A. Wolf, Mark Cobain, Joseph M. Massaro, William B. Kannel. 2008. General Cardiovascular Risk Profile for Use in Primary Care (The Framingham Heart Study). Circulation 2008; 117: 743-753.

Sato T. On the variance estimator for the Mantel-Haenszel risk difference. *Biometrics.* 1989;42:311-323.

SF-12 (v2) Health Survey 1994, 2002 Medical Outcomes Trust and QualityMetric Incorporated, 2018

Wensing AM et al, 2019 Update of the Drug Resistance Mutations in HIV-1, Volume 27 Issue 3 July/August 2019.

14. APPENDICES

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

14.1.1. 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 protocol deviations which, if they occur prior to an analysis timepoint of interest (e.g., Week 48/96), 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 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 non-compliance with IP (including IM dosing errors) or took/received incorrect IP (i.e., other than the one to which they were randomized) up to an analysis timepoint of interest (i.e., Week 48/96), meeting the following conditions: Maintenance Phase: 1. Maintenance Phase Week 48 analysis only: • Two or more injection intervals affected by over dosage deviations (e.g., extra injection or excessive volume administered, length of time between injections less than 3 weeks, excluding split doses) up to the analysis visit of interest; or 2. Week 96 analysis only: • For participants discontinuing injections by Week 52: Two or more injection intervals affected by over dosage deviations (e.g., extra injection or excessive volume administered, length of time between injections less than 3 weeks, excluding split doses) up to the analysis visit of interest. • For participants receiving injections beyond Week 52: Three or more injection intervals affected by over dosage deviations (e.g., extra injection or excessive volume administered, length of time

Number	Exclusion Description
	between injections less than 3 weeks, excluding split doses) up to the analysis visit of interest; or 3. At least 10% of total time on-treatment with under dosing deviations in the Maintenance Phase up to the analysis visit of interest (i.e. Week 48/96), where the % with non-compliance is derived the ratio of the total number of non-compliant under dosing days occurring as of the date of the last analysis timepoint snapshot viral load (i.e. last on-treatment viral load during the Maintenance Phase up to Study Day 378 for W48 and up to Study Day 714 for W96) divided by the number of days on-treatment from start of Maintenance Phase treatment to the date of the last analysis timepoint snapshot viral load, and non-compliance days are defined as follows: **ABC/DTG/3TC Arm:** a. Duration of interruptions in ABC/DTG/3TC arm ART for reasons other than treatment-related adverse events/laboratory abnormalities (based on Exposure eCRF forms); **Q4W IM Arm:** a. Length of time (in days) until next injection from date of dosage/administration deviation potentially resulting in under dosage (e.g., 1ml administered instead of 2ml) b. 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) c. Length of time (in days) in excess beyond 35 days from last injection until start of oral bridging post Week 12 and exceeding 4 weeks for Week 8 and Week 12
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 Conclusion form).
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).

14.2. Appendix 2: Schedule of Activities

14.2.1. Protocol Defined Schedule of Events

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
Clinical and Other Assessments																																
Written Informed Consent	X																															
Eligibility Verification (Inclusion / Exclusion Criteria)	X	X			X [b]																	X [b]										
Randomization							X																									
Demography	X																															

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
Medical History[c]	X																															
Medication History / Prior ART History	X																															
Symptom Directed Physical Exam and Medical Assessment [d]	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	X	X	X	X	X	X
Weight, BMI, and Height [e]		X				X										X						X					X				X	
Cardiovascular Risk Assessment	X	X																														

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
Vital Signs (BP, HR, temperature) [f]	X	X				X	X									X						X						X				X	
12-Lead ECG [g]	X	X pre-dose x3				X	X		X [g]							X [g]						X						X				X	
CDC Classification	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	X	X	X	X	X	X

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
AE and SAE Assessment, Con Meds	X [h]	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	X	X	X	X	X
ISR Assessment (LA Arm Only)									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 If applicable
Columbia Suicide Severity Rating Scale (eC-SSRS) [i]	X	X			X	X	X		X		X	X	X	X		X			X	W 72	W84	X									X	
Clinical Chemistry and	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

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
Hematology																																
Rapid Plasma Reagin (RPR)	X	X																														
Pregnancy Testing[j]	S	U	S	S	S	S	U	S	U		S	S	S	S		S	S	S	S	S	S	S	S Uj		S	S	U	S	S	S - Q4W		S	S
HIV-1 RNA and sample for storage[k]	X k	X	X	X	X	X	X		X		X	X	X	X		X	S k	X	X	X		X	Sk		X		X	X	X		X	X	X
CD4+	X	X	X	X	X	X	X		X		X	X	X	X		X		X	X	X		X					X	X	X		X	X	X
CD8+		X			X		X		X			X				X						X					X					X	
Urinalysis[l]		X					X	X				X				X						X				X						X	

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
Fasting Lab Assessments: Glucose, Cholesterol (Total, HDL and LDL) and Triglycerides [m]		X					X									X						X					X			X	
Hepatitis B (HBsAg), Anti-HBc, and Anti-HBsAG Hepatitis C (anti-HCV Ab)	X																															

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
*HLA-B*5701*	X																															
PT/PTT/INR	X	X																														
Renal and Bone marker analytes (blood/urine)[n]							X									X						X									X	
Peripheral Blood Mononuclear Cells (PBMCs)[o]							X															X									X	
Genetic Sample[p]		X																														

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
Pharmacokinetics (CAB + RPV only)																																
PK Sample (S)= Storage sample									X v w	X[t] v	X	X	X	X	X v	X v	X	X	X	S		X v	X	X v	X v		X v w	S				X	S
Investigational Products																																
Oral CAB and Oral RPV Dispensation							X	X															X[x] OLI Only			X[x] OLI Only							
ABC/DTG/3TC Dispensation (or DTG alternate)		X	X	X	X q r		X	X			X	X	X	X		X		X		X		X										

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week																Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
Study Treatment Accountability (pill counts)			X	X	X[r]	X	X	X	X[u]		X	X	X	X		X		X		X		X	XOLIOnly			XOLIOnly	X[u]						
IM Study Treatment Administration – Q4W throughout Maintenance and Extension Phase									X		X	X	X	X		X	X	X	X	X	X	X	X		X	X	X[s]	X	X	X – cont dosing Q4W			
Patient Reported Outcomes[z]																																		
HAT-QoL (short form)							X					X				X						X										X	

Procedures	Screening a	Induction Phase by Week					Maintenance Phase by Week															Extension Phase by Week								Withdrawal[Y]	Long-Term Follow-Up
		Baseline (-20)	(-16)	(-12, -8)	(-4)	WDy	Day 1	4a	4b – LA arm	5t – LA arm	8, 12, 16, 20	24	28, 32, 36	40, 44	41 – LA arm	48	52 - LA Arm	56	60 – LA Arm	64, 72, 80, 88	68,76, 84, 92 - LA Arm	96	100	101 – Direct to Inject Arm	104a – Direct to Inject Arm	104a LA and Oral Lead-In Arm	104b - Oral Lead-In Arm	108	112, 116, 120,124	Q4W after 108 (LA Arm) or after 124 (Switch Arm)	Q12W beginning 112 (LA Arm)		
SF-12							X					X				X						X									X	
ACCEPT							X				W 8	X				X						X									X	
HIVTSQ(s)							X		X			X		W4 4								X									X	
HIVTSQ(c)																X															X	
PIN (LA Arm Only)[aa]										X					X	X						X									X	
NRS (LA Arm Only)									X	X				W4 0	X							X										
Preference (LA Arm Only)																X																

Follow Up Visit: Conduct ~4 weeks after the last dose of oral IP. Required only if the participant has ongoing AEs / lab abnormalities at the last on-study visit. This visit may be conducted by telephone.
Direct to Inject: Participants transitioning into the Extension Phase who do *not* use the optional CAB + RPV oral lead-in beginning at Week 100.
Oral Lead-In: Participants transitioning into the Extension Phase who do use the optional CAB + RPV oral lead-in beginning at Week 100.
LA Arm: Participants who were originally randomized to CAB LA + RPV LA at Day 1.
Switch Arm: All participants who transition into the Extension Phase from ABC/DTG/3TC (or DTG + 2 NRTI's) at Week 100 – e.g., both direct to inject and oral lead-in participants.

Note: BMI- Body mass Index, 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

a. Complete all Screening assessments within 35 days. Participants may begin the Induction Phase as soon as all Screening assessments are complete. Participants may be rescreened once and will be assigned a new participant number. Confirmation of eligibility to enter the Maintenance Phase, eligibility to enter the Extension Phase.
b. 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 and neurologic disorders.
c. Physical exams should be conducted as part of normal routine clinical care but data will not be collected in the eCRF. Medical assessments include any decisions the study staff must make for participant management and / or care.
d. Height collected at Baseline only.
e. Measure vital signs after about 5 minutes of rest in a semi-supine position.
f. A 12-lead ECG will be performed after resting in a semi-supine position for at least 5 minutes. Perform ECG at Baseline (Week [-20]) in triplicate prior to dosing. For participants randomized to CAB LA + RPV LA, at Week 4b and Week 48, a second ECG will be obtained approximately 2 hours after the last injection and just prior to the 2 hour post dose PK sampling.
g. Collect SAEs at Screen only if associated to study participation.
h. On Day 1, the eC-SSRS is to be administered prior to randomization. During the Maintenance Phase, the eC-SSRS will be administered at each Q4W visit through the Week 48 primary endpoint, and then followed by Q12W assessments for CAB LA + RPV LA arm, thereafter through Week 96 (LA: Week 60, 72, 84, 96). The ABC/DTG/3TC arm will have assessments at Week 72 and Week 96). Preferably completed at the beginning of the visit following administration of other patient reported questionnaires required prior to injections.
i. Conduct pregnancy tests for only women of childbearing potential at every visit throughout the study, including Q4W during the Extension Phase. Remind females of reproductive potential of the need to avoid pregnancy while in study and adherence to the study's contraception requirements. A negative urine pregnancy test is required prior to beginning the Induction Phase (Week [-20]), on Day 1 (preferably prior to randomization), and at Week 4b (or Week 104b for participants transitioning from ABC/DTG/3TC) prior to the first injection. Serum pregnancy test can substitute for urine pregnancy test if locally required but must be appropriately timed to confirm pregnancy status prior to e.g. randomization and first IM administration. S=Serum/U=Urine.

j. Plasma for storage will be used: to determine genotypic eligibility at Screen, for possible future analyses, as back- up in case samples are lost or damaged in transit to the lab and for genotypic and phenotypic analyses in cases of virologic failure. HIV-1 RNA will not be collected for analysis at Week 52 and Week 100 (Week 48 or Week 96 retest will be captured as unscheduled visit). Plasma for storage will be collected at Week 52 and Week 100.
k. A morning specimen is preferred. To assess biomarkers: urine albumin/creatinine ratio; urine protein/creatinine ratio; and urine phosphate.
l. Overnight fast is preferred; however, a minimum of a 6 hour fast is acceptable.
m. Blood sample for renal and bone biomarker assessments: **Renal:** Cystatin C; Retinol Binding Protein (RBP); **Bone:** bone specific alkaline phosphatase, procollagen type 1-N-propeptide, type 1 collagen cross-linked C-telopeptide, osteocalcin, 25 hydroxy-Vitamin D
n. Whole blood/Peripheral Blood Mononuclear Cell collection samples may be used for virologic analyses. PBMCs will be collected at Day 1, Week 96, Withdrawal visits.
o. 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 Week [-20] visit.
p. Instruct participants to continue to take the ABC/DTG/3TC regimen until Day 1 of the Maintenance Phase. Participants will be randomized at Day 1 to continue on ABC/DTG/3TC arm or begin oral CAB + oral RPV. Day 1 dosing should occur after randomization to determine defined treatment for the Maintenance Phase.
q. Remind participants of the potential change in study treatment and visit frequency beginning at Day 1.
r. Visit Week 104b is only required for participants transitioning from the ABC/DTG/3TC arm.
s. The Week 5 visit should be performed approximately 7 days after the first injections at Week 4b (3 to 10-day window allowed).
t. For oral CAB + RPV only.
u. Take PK samples pre-dose. At Week 4b (and Week 104b for participants transitioning to LA from ABC/DTG/3TC using the optional oral lead-in), the pre-dose PK sample should be taken after review of the PK diary and prior to the final oral CAB + RPV dose. A sample will be also be taken at Week 4b, Week 48, and Week 96 (and Week 100 [direct to inject] or Week 104b [using CAB + RPV oral lead-in]), approximately 2 hours post-injections. The Week 5, Week 41, and Week 101 visit can be performed at any time from 3 to 10 days after the Week 4b, Week 40, and Week 100 injection, respectively. PK samples at Week 5, Week 41, and Week 101 can be taken at any time during the visit.
v. Participants should take the last dose of oral CAB+RPV at Week 4b (and Week 104b for participants transitioning to LA from ABC/DTG/3TC if using the optional oral lead-in) in the clinic after PK sampling. Participants should take the last dose of ABC/DTG/3TC at Week 100 if transitioning directly to injections at Week 100. Injections should be administered within 2 hours of the last oral dose where possible.
w. For participants transitioning to CAB LA + RPV LA from ABC/DTG/3TC only.
x. Follow Up Visit: Conduct approximately 4 weeks after the last dose of oral 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.
y. With the exception of the NRS questionnaire, patient reported questionnaire/surveys are recommended to be administered at the beginning of the visit before any other clinical assessments are conducted, and prior to completion of the eCSSRs assessments. Only conduct questionnaires/surveys at Withdrawal if occurring prior to Week 96 (The NRS will <u>not</u> be collected at Withdrawal).
z. The PIN, Preference, and NRS questionnaires are to be administered only to participants receiving CAB LA + RPV LA injections. The NRS should be collected 30 to 60 minutes post-injection (and at Week 5 and Week 41, one-week post-injections) - the participant should record the maximum level of pain experienced with the most recent injections.

14.2.2. Protocol Defined Schedule of Events for the Subcutaneous Sub-Study

Procedures	Screening Phase [d]		SC Abdominal Injection Phase [d]						Return to IM Gluteal Injection Phase [d]				
	Screening Week -4	Week -3	Day 1	Week 1	Week 4	Week 5	Week 8	Week 9	Week 12	Week 13	Week 16	Week 17	Week 20
IM Gluteal Administration	X								X [k]		X		
SC Abdominal Administration [k]			X		X		X						
Written Informed Consent	X												
Eligibility Verification Inclusion / Exclusion Criteria	X												
Symptom directed physical exam and medical assessment [a]	X		X		X		X		X		X		
Height, Weight and BMI			X						X				

Procedures	Screening Phase [d]		SC Abdominal Injection Phase [d]						Return to IM Gluteal Injection Phase [d]				
	Screening Week -4	Week -3	Day 1	Week 1	Week 4	Week 5	Week 8	Week 9	Week 12	Week 13	Week 16	Week 17	Week 20
Vital Signs, BP, HR, temp [b]	X		X	X	X	X	X	X	X	X	X	X	
12 EKG [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	X
ISR assessments for IM injections	X	X	X						X	X	X	X	
ISR assessments for SC injections			X	X	X	X	X	X	X				
Clinical Chemistry and Hematology	X		X		X		X		X		X		
Pregnancy testing, serum [e]	X		X		X		X		X		X		

Procedures	Screening Phase [d]		SC Abdominal Injection Phase [d]						Return to IM Gluteal Injection Phase [d]				
	Screening Week -4	Week -3	Day 1	Week 1	Week 4	Week 5	Week 8	Week 9	Week 12	Week 13	Week 16	Week 17	Week 20
HIV-1 RNA and sample for storage (S)	X		X		X		X		X		X		
CD4+ cell count	X		X		X		X		X		X		
CD8+ cell count			X						X				
Urinalysis [f]	X		X						X				
Fasting lab assessments: glucose, cholesterol (total, HDL and LDL) and triglycerides [g]	X		X						X				
PK Sample Collection [j]													
Pre dose PK samples for CAB and RPV	X		X		X		X		X		X		
Post dose PK sampling (~C_{max})		X		X		X		X		X		X	

Procedures	Screening Phase [d]		SC Abdominal Injection Phase [d]						Return to IM Gluteal Injection Phase [d]				
	Screening Week -4	Week -3	Day 1	Week 1	Week 4	Week 5	Week 8	Week 9	Week 12	Week 13	Week 16	Week 17	Week 20
PROs [m]													
HIVTSQc								X					
HIVTSQs [l]		X [m]						X				X	
NRS [h]	X	X	X	X			X	X	X	X			
PIN [i]		X		X				X		X			
Preference SC Abdominal injection vs IM Gluteal injection								X				X	
Reason for switch		X											
Interest for home administration								X					

a. Physical exams should be conducted as part of normal routine clinical care.
b. Measure vital signs 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.

d. All injection visits during the sub-study should be 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 where 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. To be assessed separately for CAB LA and RPV LA
i. To be assessed separately for CAB LA and RPV LA.
j. PK window allowed for sample collection: For 1-week post dose sample (3 to 10 days post dose).
k. During the SC phase (and for the first IM injection in the return to IM injection phase), the dosing window can be -7 days, however, it cannot be +7 days from the projected visit date. Once SC injections begin, the next SC administration can be 3-4 weeks later, however, SC administration may not take place 5 weeks later. See details in Section 12.12.1.2. and Section 12.12.4.3.
l. All Patient Reported Outcome Questionnaires/Surveys will be administered via paper instrument (in exception circumstances, the questionnaires could be completed via telephonic interview, please refer to the COVID19 appendix for additional details) at the beginning of the visit before any other assessments are conducted, with the exception of the NRS.
m. For $HIVTSQ_S$, we want to measure satisfaction with IM gluteal injection prior to switch to sub-cutaneous. This will be assessed at week -3 (questionnaire can be administered at any time during the visit).

14.3. Appendix 3: Assessment Windows

14.3.1. Definitions of Assessment Windows

AEs, SAEs and concomitant medications to be assessed pre-dose. IM administration itself and all other assessments will be considered part of the parent study, and should be completed as per the study time and events tables in Section 14.2.

Laboratory data, vital signs, ECGs, NRS questionnaire (health outcomes) assessments, protocol deviations, 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, induction, maintenance, extension, sub-study screening, SC injection, return to gluteal injection, or Long Term Follow Up) based on the tables in Section 14.4.1 and treatment state based on Section 14.4.2.

Induction Phase and Maintenance Phase assessments are assigned based on the Induction Phase Study Day and Maintenance Phase Study Day, respectively, as shown in Table 14 and Table 15. 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 are assigned based on the Maintenance Phase Study day for participants continuing Q4W IM dosing into the Extension Phase and based on the Extension Phase Study Day for participants switching from the control arm to Q4W IM dosing for the Extension Phase as shown in in Table 16. 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).

Assessment windows at key analysis time points for the snapshot efficacy data are shown in Table 17.

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 A. The assessment visit windows for HIV-1 RNA data are defined in Table B, and the snapshot windows for visits up to Sub-study Week 12 are defined in Table C.Long-term Follow-up Phase assessments are assigned based on the LTFU study day as shown in Table 20. See Section 14.6.1 for derivation of Induction, Maintenance, Extension and LTFU Study Day.

14.3.2. Definitions of Assessment Windows for Data Other than Health Outcomes and PK

Table 14 Assessment Windows for Screening and Induction Phase Data

Analysis Set / Domain	Parameter	Target Study Day	Analysis Window	Analysis Timepoint
All	All	The day of earliest record	Induction Study Day ≤1	Screening
		1	Last available recorded value up to and including the date of first Induction Phase dose of IP	Induction Baseline (Week -20)
		29	2 ≤ Induction Study Day ≤ 42	Week -16
		57	43 ≤ Induction Study Day ≤ 70	Week -12
		85	71 ≤ Induction Study Day ≤ 98	Week -8
		113	99 ≤ Induction Study Day ≤ 126	Week -4
		141	127 ≤ Induction Study Day ≤ Induction ART Stop Day[a] + 1	Day 1
			For Participants not continuing into Maintenance Phase: Induction Study Day > (Induction ART Stop Day[a] +1)	Follow-up

NOTES:

- For parameters which are not scheduled to be assessed at particular visits, the all-inclusive windows defined will still be used. Assessments at unscheduled visits will be included for 'any time On-treatment' time points and in data listings.

a. ABC/DTG/3TC stop day: the last permanently stop day among all ARTs taken during Induction Phase.

Table 15 Assessment Windows Maintenance Phase Data

All Parameters expect where noted [f]	Analysis Window	Target Study Day	Analysis Timepoint
	Last available recorded value up to and including the date of first Maintenance Phase dose of IP	1	Maintenance Baseline (Day 1)
ECG, CD8, CD4/CD8 ratio	2 ≤ Study Day ≤ 70	29	Week 4
	2 ≤ Study Day ≤ 42		
	43 ≤ Study Day ≤ 70	57	Week 8
	71 ≤ Study Day ≤ 98	85	Week 12
	99 ≤ Study Day ≤ 126	113	Week 16
	127 ≤ Study Day ≤ 154	141	Week 20
CD8, CD4/CD8 ratio	155 ≤ Study Day ≤ 210	169	Week 24
	155 ≤ Study Day ≤ 182		
	183 ≤ Study Day ≤ 210	197	Week 28
	211 ≤ Study Day ≤ 238	225	Week 32
	239 ≤ Study Day ≤ 266	253	Week 36
	267 ≤ Study Day ≤ 294	281	Week 40
	295 ≤ Study Day ≤ 322	309	Week 44
ECG, CD8, CD4/CD8 ratio, Urinalysis [c], Renal and Bone marker analytes [d], Lipids [e], Weight, Height, Vital Signs	323 ≤ Study Day ≤ 378	337	Week 48
	323 ≤ Study Day ≤ 350		
	351 ≤ Study Day ≤ 378	365	Week 52
	379 ≤ Study Day ≤ 406	393	Week 56
	407 ≤ Study Day ≤ 434	421	Week 60
	435 ≤ Study Day ≤ 476	449	Week 64
	477 ≤ Study Day ≤ 532	505	Week 72
	533 ≤ Study Day ≤ 588	561	Week 80
	589 ≤ Study Day ≤ 644	617	Week 88
ECG, CD4, CD8, CD4/CD8 ratio, Urinalysis [c], Renal and Bone marker analytes [d], Lipids [e], Weight, Height, Vital Signs	645 ≤ Study Day ≤ 714	673	Week 96
	645 ≤ Study Day ≤ 686		

All Parameters expect where noted [f]	Analysis Window	Target Study Day	Analysis Timepoint
ECG, CD4, CD8, CD4/CD8 ratio, Urinalysis [c], Renal and Bone marker analytes [d], Lipids [e], Weight, Height, Vital Signs	For 'ABC/DTG/3TC' arm: 715 ≤ Study Day ≤ Maintenance ABC/DTG/3TCStop Day[b] + 1 For 'Q4W' arm: 715 ≤ Study Day ≤ Max (Day of Last Q4W IM Dose + 35, Last Oral dose Day + 1) [a]	701	Week 100
	For 'ABC/DTG/3TC' arm: 687 ≤ Study Day ≤ Maintenance ABC/DTG/3TCStop Day[b] + 1 For 'Q4W' arm: 687 ≤ Study Day ≤ Max (Day of Last Q4W IM Dose + 35, Last Oral dose Day + 1) [a]	701	Week 100
	For 'Q4W' arm: a) For participants who discontinued from oral lead-in during Maintenance Phase: Study Day > (Day of last oral lead-in dose+1) b) For participants who are not continuing into the extension phase and who received at least one CAB/RPV injection: Study Day > Max (Day of Last Q4W IM Dose + 35, Last Oral dose Day + 1) For 'ABC/DTG/3TC' arm: Participants discontinued from ABC/DTG/3TC' and not continuing into the Extension Phase: Study Day > (Maintenance ABC/DTG/3TC Stop Day[b] +1)		Follow-up

NOTES:

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

a. Last Q4W IM / last oral dose is only applied to participants who permanently discontinue from study treatment

b. ABC/DTG/3TCstop day: the last permanently stop day among all ARTs taken during Maintenance Phase.

c. **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.

d. **Bone Marker**: Bone Specific Alkaline Phosphatase, Osteocalcin, Procollagen 1 N-Terminal Propeptide, Vitamin D, Type I C-Telopeptides. **Renal marker**: Cystatin C, Retinol Binding Protein.

e. **Lipids**: Cholesterol, HDL Cholesterol Direct, LDL Cholesterol Calculation, LDL Cholesterol Direct, Total Cholesterol/HDL Cholesterol Ratio, Triglycerides

f. Analysis windows for parameters with sparse collection are noted.

Table 16 Assessment Windows for Extension Phase Data

All Parameters expect where noted [b]	Analysis Window	Target Extension Phase Study Day	Target Study Day	Analysis Timepoint
Participants Continuing Randomized Q4W IM Regimen				
Adverse Events [c]	Study day of Nominal Week 100 visit ≤ Study Day ≤ 742		729	Week 104
Urinalysis [a]	Study day of Nominal Week 100 visit < Study Day ≤ 770			
	Study day of Nominal Week 100 visit < Study Day ≤ 742			
	743≤ Study Day ≤770		757	Week 108
	771≤ Study Day ≤826		785	Week 112
	(7*w - 41) ≤ Study Day ≤ (7*w + 42)		7*w + 1	Week w w = 124,136, 148,…
	For participants who permanently discontinue extension phase study treatment: Study Day > Max (Day of Last Q4W IM Dose + 35, Day of Last Oral Dose Day + 1)			Follow-up
Participants Switching to Q4W IM Dosing				
	Last available recorded value up to and including the date of first Extension Phase dose of IP	1		Extension Baseline (W100)
ECG, CD4, CD8, CD4/CD8 ratio,	2 ≤ Extension Study Day ≤ 70	29		Week 104

All Parameters expect where noted [b]	Analysis Window	Target Extension Phase Study Day	Target Study Day	Analysis Timepoint
Urinalysis [a], Weight, Vital Signs				
	2 ≤ Extension Study Day ≤ 42			
Excluding: ECG, CD4, CD8, CD4/CD8 ratio, Urinalysis [a], Weight, Vital Signs	43 ≤ Extension Study Day ≤ 70	57		Week 108
	71 ≤ Extension Study Day ≤ 98	85		Week 112
	99 ≤ Extension Study Day ≤ 126	113		Week 116
	127 ≤ Extension Study Day ≤ 154	141		Week 120
	155 ≤ Extension Study Day ≤ 210	169		Week 124
	211 ≤ Extension Study Day ≤ 294	253		Week 136
	(7*(w-100) - 41) ≤ Study Day ≤ (7*(w-100) + 42)	7*(w-100) + 1		Week w w = 148, 160,…
	For participants who permanently discontinue extension phase study treatment: Study Day > Max (Day of Last Q4W IM Dose + 35, Day of Last Oral Dose Day + 1)			Follow-up

NOTES:

- For parameters which are not scheduled to be assessed at particular visits, the all-inclusive windows defined will still be used. Assessments at unscheduled visits will be included for 'any time On-treatment' time points and in data listings, as well as algorithms that make use of additional data (e.g., Snapshot).
- Nominal Week 100 visit is the original visit from eCRF (i.e., the VISIT variable as opposed to AVISIT)

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. Analysis windows for parameters with sparse collection are noted.

c. For ISR specific displays, ISRs will be assigned to analysis timepoints based on onset date to the most recent planned IM injection visit prior or equal to the AE onset date.

Table 17 Assessment Windows for Summary of Snapshot Data — Data assigned to Maintenance Phase Only

Snapshot Analysis Windows (if no viral load data in default window, expand upper bound to + 6 weeks)		Analysis Timepoint
Default (midpoint between planned visits) [a]	**Expanded +6 Week upper window**	
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	Maintenance Baseline (Day 1)
2 ≤ Study Day ≤ 42	2 ≤ Study Day ≤ 70	Week 4
43 ≤ Study Day ≤ 70	43 ≤ Study Day ≤ 98	Week 8
71 ≤ Study Day ≤ 98	71 ≤ Study Day ≤ 126	Week 12
99 ≤ Study Day ≤ 126	99 ≤ Study Day ≤ 154	Week 16
127 ≤ Study Day ≤ 154	127 ≤ Study Day ≤ 182	Week 20
155 ≤ Study Day ≤ 182	155 ≤ Study Day ≤ 210	Week 24
183 ≤ Study Day ≤ 210	183 ≤ Study Day ≤ 238	Week 28
211 ≤ Study Day ≤ 238	211 ≤ Study Day ≤ 266	Week 32
239 ≤ Study Day ≤ 266	239 ≤ Study Day ≤ 294	Week 36
267 ≤ Study Day ≤ 294	267 ≤ Study Day ≤ 322	Week 40
295 ≤ Study Day ≤ 322	295 ≤ Study Day ≤ 350	Week 44
295 ≤ Study Day ≤ 378	295 ≤ Study Day ≤ 378	Week 48
379 ≤ Study Day ≤ 406	379 ≤ Study Day ≤ 434	Week 56
407 ≤ Study Day ≤ 434	407 ≤ Study Day ≤ 462	Week 60
435 ≤ Study Day ≤ 476	435 ≤ 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

NOTES:
Apply Snapshot analysis windows only to viral load data that is on-treatment (per Table 30) within the Maintenance Phase (Per Table 25)
a. ± 6 Week window always used at key analysis timepoints (Week 48 and Week 96)

Table 18 For W124 Analysis: Extension Switch Population Assessment Windows for Snapshot Viral Load Data up to Week 124 — Data assigned to Extension Phase Only

Snapshot Analysis Windows (if no viral load data in default window, expand upper bound to + 6 weeks)		Analysis Timepoint
Default (midpoint between planned visits) [a]	**Expanded +6 Week upper window**	
Last available recorded value up to and including the date of first Extension Phase dose of IP (oral lead-in or injection, whichever occurs first)	Last available recorded value up to and including the date of first Extension Phase dose of IP (oral lead-in or injection, whichever occurs first)	Extension Baseline (Week 100)
2 ≤ Extension Study Day ≤ 42	2 ≤ Extension Study Day ≤ 70	Week 104
43 ≤ Extension Study Day ≤ 70	43 ≤ Extension Study Day ≤ 98	Week 108
71 ≤ Extension Study Day ≤ 98	71 ≤ Extension Study Day ≤ 126	Week 112
99 ≤ Extension Study Day ≤ 126	99 ≤ Extension Study Day ≤ 154	Week 116
127 ≤ Extension Study Day ≤ 154	127 ≤ Extension Study Day ≤ 182	Week 120
127 ≤ Extension Study Day ≤ 210	127 ≤ Extension Study Day ≤ 210	Week 124
For participants who permanently discontinue extension phase study treatment: Extension Study Day > Max (Day of Last Q4W IM Dose + 35, Day of Last Oral Dose Day + 1)		Follow-up

NOTES:
Apply Snapshot analysis windows only to viral load data that is on-treatment (per Table 30) within the Extension Phase (Per Table 25)
a. ± 6 Week window always used at key analysis timepoints (Week 124)

Table 19 For W124 Analysis: ITT-E (Randomized Q4W arm) Assessment Windows for Snapshot Viral Load Data up to Week 124 — Data assigned to Maintenance and Extension Phase

Snapshot Analysis Windows (if no viral load data in default window, expand upper bound to + 6 weeks)		Analysis Timepoint
Default (midpoint between planned visits) [a]	**Expanded +6 Week upper window**	
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	Maintenance Baseline (Day 1)
2 ≤ Study Day ≤ 42	2 ≤ Study Day ≤ 70	Week 4
43 ≤ Study Day ≤ 70	43 ≤ Study Day ≤ 98	Week 8
71 ≤ Study Day ≤ 98	71 ≤ Study Day ≤ 126	Week 12
99 ≤ Study Day ≤ 126	99 ≤ Study Day ≤ 154	Week 16
127 ≤ Study Day ≤ 154	127 ≤ Study Day ≤ 182	Week 20
155 ≤ Study Day ≤ 182	155 ≤ Study Day ≤ 210	Week 24
183 ≤ Study Day ≤ 210	183 ≤ Study Day ≤ 238	Week 28
211 ≤ Study Day ≤ 238	211 ≤ Study Day ≤ 266	Week 32
239 ≤ Study Day ≤ 266	239 ≤ Study Day ≤ 294	Week 36
267 ≤ Study Day ≤ 294	267 ≤ Study Day ≤ 322	Week 40
295 ≤ Study Day ≤ 322	295 ≤ Study Day ≤ 350	Week 44
295 ≤ Study Day ≤ 378	295 ≤ Study Day ≤ 378	Week 48
379 ≤ Study Day ≤ 406	379 ≤ Study Day ≤ 434	Week 56
407 ≤ Study Day ≤ 434	407 ≤ Study Day ≤ 462	Week 60
435 ≤ Study Day ≤ 476	435 ≤ 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
715 ≤ Study Day ≤ 770	715 ≤ Study Day ≤ 798	Week 108
771 ≤ Study Day ≤ 826	771 ≤ Study Day ≤ 826	Week 112
827 ≤ Study Day ≤ 910	827 ≤ Study Day ≤ 910	Week 124

NOTES:
Apply Snapshot analysis windows only to viral load data that is on-treatment (per Table 30) within the Maintenance Phase and Extension Phases (Per Table 25)
a. ± 6 Week window always used at key analysis timepoints (Week 48 and Week 96)

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

All Parameters except for where noted[a]	Target Study Day	Analysis Window	Analysis Timepoint
	First Sub-study record	Study Day <7*w + 1	Sub-study Screening
All except ECG, Labs, Vitals	7*w + 1	Study Day = 7*w + 1	Sub-study Day 1

All Parameters except for where noted[a]	Target Study Day	Analysis Window	Analysis Timepoint
ECG, Labs, Vitals	7*w + 1	Last available recorded value up to and including the date of first SC injection.	Sub-study Baseline[b]
	7*(w+1) +1	7*w + 2 ≤ Study Day ≤ 7*(w+2)	Sub-study Week 1
	7*(w+4) +1	7*(w + 2) + 1≤ Study Day ≤ 7*(w+4) +1	Sub-study Week 4
Labs,CD4		7*w + 2 ≤ Study Day ≤ 7*(w+6)	
	7*(w+5) +1	7*(w + 4) + 2 ≤ Study Day ≤ 7*(w+6)	Sub-study Week 5
	7*(w+8) +1	7*(w + 6) + 1 ≤ Study Day ≤ 7*(w+8) + 1	Sub-study Week 8
Labs, CD4		7*(w + 6) + 1 ≤ Study Day ≤ 7*(w+10)	
	7*(w+9) +1	7*(w + 8) + 2 ≤ Study Day ≤ 7*(w+10)	Sub-study Week 9
	7*(w+12) +1	7*(w + 10) + 1 ≤ Study Day ≤ 7*(w+12) + 1	Sub-study Week 12
Labs, CD4		7*(w + 10) + 1 ≤ Study Day ≤ 7*(w+14)	
ECG, Weight, CD8, CD4/CD8 ratio Urinalysis, Fasting labs/lipids		7*w + 2 ≤ Study Day	
	7*(w+13) +1	7*(w + 12) + 2 ≤ Study Day ≤ 7*(w+14)	Sub-study Week 13
	7*(w+16) +1	7*(w + 14) + 1 ≤ Study Day ≤ 7*(w+16) + 1	Sub-study Week 16
Labs, CD4		7*(w + 14) + 1 ≤ Study Day ≤ 7*(w+18)	
	7*(w+17) +1	7*(w + 16) + 2 ≤ Study Day ≤ 7*(w+18)	Sub-study Week 17
	7*(w+20) +1	7*(w+18) + 1 ≤ Study Day	Sub-study Week 20
If a participant permanently discontinued study treatment:			
		Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 35)	Follow-up

NOTES:

- The "w" in the target study day calculation refers to the week number within the Sub-study, starting with Week 0. For example, the Sub-study Day 1 Analysis Timepoint would have a "w" of 0, to allow for a Target Study Day of 1.
- Follow-up will be derived only for participants who permanently discontinued study treatment.
- Sub-study Day 1 (Post Dose), Sub-study Week 4 and Sub-study Week 8 visits are SC Injection phase visits, Sub-study Week 12 and Week 16 are Return to Gluteal Injection phase visits.

[a] Analysis windows for parameters with sparse collection are noted.

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

Table B Assessment Windows for Sub-study Baseline, SC 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 SC injection	Sub-study Baseline
SC Injection	7*(w+4) + 1	7*w + 2 ≤ 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
Return to Gluteal Injection	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+18)	Sub-study Week 16
If a participant permanently discontinued study treatment:			
		Date > max (Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Date of Last Injection + 35)	Follow-up

NOTES:

- The "w" in the target study day calculation refers to the week number within the Sub-study, starting with Week 0, Day 0 being the day prior to the first SC injection. For example, the Sub-study Day 1 Analysis Timepoint would have a "w" of 0, to allow for a Target Study Day of 1.
- Follow-up will be derived only for participants who permanently discontinued study treatment.

Table C Assessment Windows for Summary of Snapshot Data Up to Week 12 in Sub-study— Data Assigned to SC Injection 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**	
Last available recorded value up to and including the date of first SC injection	Last available recorded value up to and including the date of first SC injection	Sub-study Baseline
7*w + 2 ≤ Study Day ≤ 7*(w+6)	7*w + 2 ≤ 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 ≤ min(7*(w+14), Day of First Return to Gluteal IM Injection)	7*(w+10) + 1 ≤ Study Day ≤ min(7*(w+18), Day of First Return to Gluteal IM Injection)	Sub-study Week 12

NOTES:

- The "w" in the target study day calculation refers to the week number within the Sub-study, starting with Week 0, Day 0 being the day prior to the first SC injection. For example, the Sub-study Day 1 Analysis Timepoint would have a "w" of 0, to allow for a Target Study Day of 1.
- 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 30) within the SC Injection Phase (per Table 24).
- 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 8 and Sub-study Week 12 visits.
- ± 6 Week window is always used at the key analysis timepoint, Sub-study Week 12 visit with the exclusion of HIV-1 RNA values collected on or after resuming IM injections. Only results collected while on SC injections will be considered.

Table 20 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 from Study Treatment

Day of Assessment	Assessment Window	Target Study Day of Window
1 ≤ LTFU Study Day ≤ 60	LTFU Month 1	30
61 ≤ 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 slotted to both LTFU and Maintenance /Extension Phase

14.3.3. Assessment Window for Study Conclusion

The study conclusion and Phase conclusion records in disposition data will be slotted based on Table 14 (for Induction Phase conclusion records), Table 15 (for Maintenance Phase conclusion records) and Table 16 (for extension Phase conclusion records). However, if the discontinuation date is post-treatment (based on Table 30), then the discontinuation will be slotted to the participants the last attained on-treatment analysis visit across all assessments (e.g., analysis visit corresponding to the last on-treatment lab assessment), rather than follow up.

14.3.4. Assessment Window for Health Outcome Data

14.3.4.1. NRS

NRS questionnaire assessments are assigned to analysis visits based on the windows defined in Table 21.

Table 21 Assessment Windows for Maintenance Phase NRS Questionnaire Data

Domain	Parameter	Target Date	Analysis Window	Analysis Timepoint
NRS	All	Date of 1st Injection	Assessment Date ≤ Date of 1st injection + 2	Week 4B
		Date of 1st injection+7	Date of 1st injection +3 ≤ Assessment Date ≤ Date of 1st injection + 42	Week 5
		Date of W40 Injection	**If participant received Week 40 injection:** Date of WK40 injection - 42 ≤ Assessment Date ≤ Date of W40 Injection + 2	Week 40
		Date of 1st Injection + 252	**If participant did not receive Week 40 injection:** Date of 1st injection + 210 ≤ Assessment Date ≤ Date of 1st injection + 280	
		Date of W40 Injection + 7	**If participant received Week 40 injection:** Date of W40 Injection + 3 ≤ Assessment Date ≤ Date of W40 Injection + 28	Week 41
		Date of 1st Injection + 644	Date of 1st Injection + 602 < Assessment Date ≤ Date of 1st Injection + 686	Week 96
Note: Apply NRS analysis windows only to assessments that are on-treatment (per Table 30) within the Maintenance Phase (Per Table 25)				

14.3.4.2. PIN/HATQoL/SF-12/HIVTSQs/HIVTSQc/ACCEPT/Treatment Preference

PIN, HATQoL, SF-12, HIVTSQs, HIVTSQc, ACCEPT, and Treatment Preference questionnaire assessments will be assigned to analysis visits as follows:

1. Maintenance Baseline (Day 1) will be defined as last available recorded value up to and including the date of first Maintenance Phase dose of study treatment (expected to be collected at Day 1).
2. If the nominal visit identifier as captured in the source dataset corresponds to a scheduled collection per the Time and Events Schedule (see Section 14.2 and Table 22) and the assessment is collected in the Maintenance Phase (per Table 25), then the nominal visit identifier will be kept as the analysis visit (excluding Day 1 which will normally be assigned to Maintenance Baseline (Day 1).
3. 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 25. Proceed to step b if the assessment is assigned to the Maintenance Phase.
    b) Identify the 'last nominal visit' with the HO assessment performed prior to the unscheduled/withdrawal visit to be slotted.
    c) The unscheduled/withdrawal visit will be slotted to the planned nominal visit subsequent to the 'last nominal visit'. If the 'last nominal visits' does

not exist (e.g., no records originate from a planned nominal visit), then the unscheduled/withdrawal visit will be slot to the first planned nominal visit after Day 1.

Example 1, for HATQoL, the planned nominal visits are Week 24, 48, and 96. 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 14.3.6.

Table 22 Planned Nominal Visit of Health Outcome Data

Endpoints	Day1	W4b	W5	W8	W24	W40	W41	W44	W48	W52	W96
PIN (Q4W)			x				x		x		x
HATQoL	x				x				x		x
SF-12	x				x				x		x
HIVTSQs	x	x (Q4W arm only)			x			x			x
HIVTSQc									x		
ACCEPT	x			x	x				x		x
NRS (Q4W)		x	x			x	x				x
Treatment preference (Q4W)									x		

14.3.4.3. Evaluable Criteria for Observed Case Displays — NRS and PIN

Post the visit slotting as described above, data that is assessed outside of 5-9 days post injection (relative to date of injection at Week 4b/40, respectively) at Week 5/41 for NRS/PIN, and data at Week 4b/40 for NRS that is not assessed on the same day as CAB+RPV injections (at Week 4b/40, respectively) are received will be excluded from Observed Case Displays (see Table 23). However, these data will still be used for LOCF displays.

Table 23 Evaluable Time Windows for Observed Cases Summary Tables

Endpoints	W4b	W5	W40	W41	W96
PIN (Q4W)		Within Day 5-9 post W4b injection		Within Day 5-9 post W40 injection	
NRS (Q4W)	On the same Day of W4b injection	Within Day 5-9 post W4b injection	On the same day of W40 injection	Within Day 5-9 post W40 injection	On the same day of W96 injection

14.3.4.4. HIVTSQs/HIVTSQc/PIN/Preference/Reason for Switch/Interest in Sub-study

HIVTSQs, HIVTSQc, PIN, Preference SC Injection vs Gluteal Injection, Reason for Switch, and Interest questionnaire assessments will be assigned to analysis visits as follows:

1. Sub-study Baseline will be defined as last available recorded value prior to the date of first SC injection. Baseline is not applicable for HIVTSQc, Preference SC Injection vs Gluteal Injection, Reason for Switch, or Interest assessments as they are not planned to be collected during the Sub-study Baseline.
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 14.2.2) and the assessment is collected in the planned phase (per Table 24, visits at/before Sub-study Week 12 belong to SC Injection phase, and visits after Sub-study Week 12 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 9 HIVTSQs assessment is conducted after the Week 12 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.

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

After assigning the phases per Table 24, the NRS assessments will be slotted to analysis visits per Table D.

Table D Assessment Window for NRS Data

Phase	Assessment Window	Visit
Sub-study Screening	Q4W: post-dose and on the Week -4 injection date	Sub-study Week -4
	Q4W: (Week -4 injection date+1, Week -4 injection date+14), inclusive	Sub-study Week -3
SC 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
	Post-dose and on the Week 8 injection date	Sub-study Week 8

Phase	Assessment Window	Visit
	(Week 8 injection date+1, Week 8 injection date+14), inclusive	Sub-study Week 9
Return to Gluteal	Post-dose and on the Week 12 injection date	Sub-study Week 12
	(Week 12 injection date+1, Week 12 injection date+14), inclusive	Sub-study Week 13

14.3.5. Assessment Window for PK concentration Data

14.3.5.1. Maintenance/Extension Phase Assessments

For PK concentration data at a nominal withdrawal/unscheduled/LTFU Month1 visits during Maintenance or Extension Phase (after assignment to study phase according to Table 25), the visit will be slotting to the analysis visit per the following steps:

1. Identify the 'last nominal PK visit' with the PK assessment performed prior to the visit to be slotted during the same study Phase
2. 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 (excluding timepoints with storage PK collection in which samples have not been analysed for all participants), that is subsequent to the 'last nominal PK visit' during the same study phase.
    - nominal visit of the next planned injection visit within the study phase occurring on or after the date of the PK assessment.

During the Maintenance or Extension Phase, the planned nominal visits for PK Pre-dose are Week 4b, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 80, 88, 96, 100 for the Q4W arm; and Week 100 (direct to inject group), Week 101 (direct to inject group),Week 104a (direct to inject group), and Week 104b (oral lead-in group) for the Switch Q4W IM group . Planned Injection visits are Week 4, Week 8, continuing every 4 weeks for the Q4W arm and every 4 weeks for the ABC/DTG/3TC arm starting at Week 100 (for direct to inject group) and Week 104b for oral lead-in group.

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

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

Example 2: If a participant has the 'last nominal PK visit' at Week 60 and then withdraws (around Week 88, with last injection at W84) with a Maintenance Phase PK assessment labelled as 'LTFU Month 1', then this assessment will be slotted the subsequent planned injection visit of Week 88 (next injection visit).

14.3.5.2. Long-Term Follow-up Phase Assessments:

PK concentration data at nominal visits other than LTFU MONTH 1/LTFU MONTH 3/LTFU MONTH 6/LTFU MONTH 9/LTFU MONTH 12/LIVER EVENT which have been assigned to the Long-Term Follow-up phase (according to according to Table 27) 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 unscheduled/withdrawal visit 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.

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

14.3.5.3. Sub-study Assessments

PK concentration plots based on Sub-Study Day as appropriate for each phase where concentration data is collected. Unscheduled sub-study assessments will not be slotted to any analysis visit, however, will be displayed based on Sub-Study Day in individual PK plots. There will be no slotting for planned nominal visits (i.e., analysis visit=visit). Unscheduled assessments will not be summarized outside of individual plots, however, will be listed.

14.3.6. Multiple assessments within an Analysis Window

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

For data other than health outcome/PK concentration:

- the assessment closest to the window target Study Day.
- 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.

NRS questionnaire health outcomes assessments:

- the assessment closest to the window target Study Day will be used.
- if there are multiple assessments equidistant from the target Day, then the earliest assessment will be used.

Other health outcome assessments (i.e., apart from NRS) and PK concentration data:

- if there are multiple assessments assigned to the same analysis visit, the assessment from the original planned nominal visit will be used for summary statistics.
- if there are multiple assessments assigned to the same analysis visit and none originate 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 assessments, irrespective of proximity to the target study day, will be used when categorizing values across visits, such as ‘maximum grade’ or ‘at any time’, and for any algorithm that has specific rules for which observation to use (e.g., snapshot algorithm or LOCF).

14.4. Appendix 4: Study Phases and Treatment State

14.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to the Treatment Start Date defined in Section 14.6.1.

AEs will be assigned to study Phases as defined in Table 24. For example, adverse events prior to start of Extension Phase IP/LTFU ART will be assigned to the Maintenance Phase.

Laboratory data (efficacy, safety, and virology), HIV associated/ AIDS-defining conditions, health outcomes assessments, vital signs, PK, and ECGs will be assigned to study phases as defined as in Table 25. For example, assessments/events occurring 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.

Table 24 Assignment of Study Phases for AEs

Study Phase	Date range
Screen	Date < Induction Treatment Start Date
Induction	**For participants continuing into Maintenance Phase:** Induction Treatment Start Date ≤ Date < Maintenance Treatment Start Date **For participants not continuing into Maintenance Phase:** Date ≥Induction Treatment Start Date
Maintenance	**DTG/ABC/3TC Arm:** **For participants continuing into Extension Phase:** Maintenance Treatment Start Date ≤ Date < min (Start Date of Extension Phase with Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) **For participants not continuing into Extension Phase:** Date ≥Maintenance Treatment Start Date

Study Phase	Date range
	Q4W IM Arm: **For participants continuing into Extension Phase:** Maintenance Treatment Start Date ≤ **Date** < Date of Nominal Week 100 Visit **For participants not continuing into Extension Phase:** Maintenance Treatment Start Date ≤ **Date** < LTFU ART Start Date

Study Phase	Date range
Extension	**For participants continuing into the Extension Phase and not entering the Sub-study:** **- Participants continuing into LTFU Phase:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W:** min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) ≤ **Date** < LTFU ART Start Date **- Participants continuing maintenance Q4W into Extension Phase:** Date of Nominal Week 100 Visit ≤ **Date** < LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) ≤ **Date** < Date of end of study +35 days **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit ≤ **Date** < Date of end of study +35 days **For participants continuing into the Extension Phase, entering the Sub-study but not returning to the Extension Phase:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) ≤ **Date** < Date of First Sub-study Record **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit ≤ **Date** < Date of First Sub-study Record **For participants continuing into the Extension Phase, entering the Sub-study and returning to the Extension Phase:** **- Before the sub-study:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) ≤ **Date** < Date of First Sub-study Record **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit ≤ **Date** < Date of First Sub-study Record **After the sub-study:** **- Participants continuing into LTFU Phase after return to extension phase:** End of sub-study date ≤ **Date** < LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** End of sub-study date ≤ **Date** < Date of end of study +35 days

Study Phase	Date range
Sub-study Screening	**For participants entering the sub-study and not receiving any SC injection:** If participants continued into Extension Phase after the sub-study, then Date of First sub-study record ≤ Date ≤ End of Sub-study Date **For participants entering the sub-study and receiving SC injection(s):** Date of First sub-study record ≤ Date < Date of First SC Injection
SC Injection	**For participants continuing into Return to Gluteal Injection Phase:** Date of First SC Injection ≤ Date < Date of Nominal Sub-study Week 12 Visit **For participants not continuing into Return to Gluteal Injection Phase:** **- Participants continued into Extension Phase after the sub-study:** Date of First SC Injection ≤ Date ≤ End of Sub-study Date **- Participants continuing into LTFU Phase after the sub-study:** Date of First SC Injection ≤ Date < LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** Date of First SC Injection ≤ Date ≤ End of Sub-study Date +35 days
Return to Gluteal Injection	**For participants continuing into Extension Phase after the sub-study:** Date of Nominal Sub-study Week 12 Visit ≤ Date ≤ End of Sub-study Date **For participants not continuing into Extension Phase after the sub-study:** **- Participants continuing into LTFU Phase after the sub-study:** Date of Nominal Sub-study Week 12 Visit ≤ Date < LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** Date of Nominal Sub-study Week 12 Visit ≤ Date ≤ End of Sub-study Date +35 days

- **Date** = AE Start date
- **Maintenance Treatment Start Date:** refer to Treatment Start Date in Section 14.6.1
- End of Sub-study Date and nominal Week 12 Visit Date are defined in Section 14.6.1.

Table 25 Assignment of Study Phases for Lab assessments, ECG, Vital Signs, PK, Health Outcomes, PDs, and HIV associated/AIDS-defining conditions

Study Phase	Date range
Screen	Date ≤ Induction Treatment Start Date
Induction	**For participants continuing into Maintenance Phase:** Induction Treatment Start Date < Date ≤ Maintenance Treatment Start Date **For participants not continuing into Maintenance Phase:** Date > Induction Treatment Start Date

Study Phase	Date range
Maintenance	**DTG/ABC/3TC Arm:** **For participants continuing into Extension Phase:** Maintenance Treatment Start Date < Date ≤ min (Start Date of Extension Phase Oral lead in of CAB + RPV, Date of first CAB/RPV injection) (expected to be nominal Week 100) **For participants <u>not</u> continuing into Extension Phase:** Date >Maintenance Treatment Start Date
	Q4W IM Arm: **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:** Maintenance Treatment Start Date < **Date** ≤ LTFU ART Start Date

Study Phase	Date range
Extension	**For participants continuing into the Extension Phase and not entering the Sub-study:** **- Participants continuing into LTFU Phase:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W:** min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) < **Date** ≤ LTFU ART Start Date **- Participants continuing maintenance Q4W into Extension Phase:** Date of Nominal Week 100 Visit < **Date** ≤ LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) < **Date** ≤ Date of end of study +35 days **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit < **Date** ≤ Date of end of study +35 days **For participants continuing into the Extension Phase, entering the Sub-study but not returning to the Extension Phase:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) < **Date** ≤ Date of First Sub-study Record **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit < **Date** ≤ Date of First Sub-study Record **For participants continuing into the Extension Phase, entering the Sub-study and returning to the Extension Phase:** **- Before the sub-study:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Min (Start Date of Extension Phase Oral lead-in of CAB + RPV, Date of first CAB/RPV injection) < **Date** ≤ Date of First Sub-study Record **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit < **Date** ≤ Date of First Sub-study Record **After the sub-study:** **- Participants continuing into LTFU Phase after return to extension phase:** End of sub-study date < **Date** ≤ LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** End of sub-study date < **Date** ≤ Date of end of study +35 days

Study Phase	Date range
Sub-study Screening	**For participants entering the sub-study and not receiving any SC injection:** If participants continued into Extension Phase after the sub-study, then Date of First sub-study record < Date ≤ End of Sub-study Date **For participants entering the sub-study and receiving SC injection(s):** Date of First sub-study record < Date ≤ Date of First SC Injection
SC Injection	**For participants continuing into Return to Gluteal Injection Phase:** Date of First SC Injection < **Date** ≤ Date of Nominal Sub-study Week 12 Visit **For participants not continuing into Return to Gluteal Injection Phase:** **- Participants continued into Extension Phase after the sub-study:** Date of First SC Injection < **Date** ≤ End of Sub-study Date **- Participants continuing into LTFU Phase after the sub-study:** Date of First SC Injection < **Date** LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** Date of First SC Injection < **Date** ≤ Date of end of Sub-study +35 days
Return to Gluteal Injection	**For participants continuing into Extension Phase after the sub-study:** Date of Nominal Sub-study Week 12 Visit < Date ≤ End of Sub-study Date **For participants continuing into LTFU Phase after the sub-study:** Date of Nominal Sub-Study Week 12 Visit < Date ≤ LTFU ART Start Date **For Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** Date of Nominal Sub-Study Week 12 Visit < Date ≤ Date of end of Sub-study +35 days

- D**ate** = start or assessment date
- **Maintenance Treatment Start Date:** refer to Treatment Start Date in Section 14.6.1
- End of Sub-study Date and nominal Week 12 Visit Date are defined in Section 14.6.1.
- The post-dose assessments (e.g., 2-hour post-dose PK and NRS) taken on the date of first SC injection will be assigned SC Injection Phase, instead of Sub-study Screening Phase.
- The post-dose assessment (e.g., NRS) taken on the date of Sub-study Week 12 injection will be assigned Return to Gluteal Injection Phase, instead of SC Injection Phase.

Table 26 Assignment of Study Phases for Concomitant medication/ART

Concomitant during:	Date range
Prior	**Medication Taken** < Induction Treatment Start Date

Concomitant during:	Date range
Induction	**For participants continuing into Maintenance Phase:** Induction Treatment Start Date ≤ **Medication Taken** < Maintenance Treatment Start Date **For participants not continuing into Maintenance Phase:** **Medication Taken** ≥ Induction Treatment Start Date *Note: ART stopped on the start date of Induction Treatment will be considered Prior ART and will not be considered concomitant during the Induction Phase.*
Maintenance	**DTG/ABC/3TC Arm:** **For participants continuing into Extension Phase:** Maintenance Treatment Start Date ≤ **Medication Taken** < Start Date of Extension Phase CAB + RPV (expected to be WK100) **For participants not continuing into Extension Phase:** **Medication Taken** ≥ Maintenance Treatment Start Date *Note: ART stopped on the start date of Maintenance Treatment will be considered concomitant during the Induction Phase and will not be considered concomitant during the Maintenance Phase.*
	Q4W IM Arms: **For participants continuing into Extension Phase:** Maintenance Treatment Start Date ≤ **Medication Taken** < Date of Nominal Week 100 visit **For participants <u>not</u> continuing into Extension Phase:** Maintenance Treatment Start Date ≤ **Medication Taken** < LTFU ART Start Date *Note: ART stopped on the start date of Maintenance Treatment will be considered concomitant during the Induction Phase and will not be considered concomitant during the Maintenance Phase.*

Extension	**For Participants continuing into the Extension Phase and not entering the Sub-study:** **- Participants continuing into LTFU Phase:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Start Date of Extension Phase CAB + RPV[a] ≤ **Medication Taken** < LTFU ART Start Date **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit[b] ≤ **Medication Taken** < LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** **- Participants Switching from Maintenance DTG/ACB/3TC Arm to Q4W IM:** Start Date of Extension Phase CAB + RPV[a] ≤ **Medication Taken** < Date of end of study +35 days **-Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit[b] ≤ **Medication Taken** < Date of end of study +35 days **For participants continuing into the Extension Phase, entering the Sub-study but not returning to the Extension Phase:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Start Date of Extension Phase CAB + RPV[a] ≤ **Medication Taken** < Date of First Sub-study Record **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit[b] ≤ **Medication Taken** < Date of First Sub-study Record **For participants continuing into the Extension Phase, entering the Sub-study and returning to the Extension Phase:** **- Before the sub-study:** **- Participants Switching from Maintenance DTG/ABC/3TC Arm to Q4W IM:** Start Date of Extension Phase CAB +RPV[a] ≤ **Medication Taken** < Date of First Sub-study Record **- Participants continuing maintenance Q4W IM into Extension Phase:** Date of Nominal Week 100 Visit[b] ≤ **Medication Taken** < Date of First Sub-study Record **After the sub-study:**

Concomitant during:	Date range
	- Participants continuing into LTFU Phase after return to extension phase: End of sub-study date[c] ≤ **Medication Taken** < LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** End of sub-study date[c] ≤ **Medication Taken** < Date of end of study +35 days
Long-Term Follow-Up	**For participants who received at least one CAB and/or RPV Injection:** **Medication Taken** ≥ LTFU ART Start Date
Sub-study Screening	**For participants entering the sub-study and not receiving any SC injection:** If participants continued into Extension Phase after the sub-study, then Date of First sub-study record[d] ≤ **Medication Start Date** < End of Sub-study Date **For participants entering the sub-study and receiving SC injection(s):** Date of First sub-study record[d] ≤ **Medication Start Date** < Date of First SC Injection
SC Injection	**For participants continuing into Return to Gluteal Injection Phase:** Date of First SC Injection[e] ≤ **Medication Start Date** < Date of Nominal Sub-study Week 12 Visit **For participants not continuing into Return to Gluteal Injection Phase:** **- Participants continued into Extension Phase after the Sub-study:** Date of First SC Injection[e] ≤ **Medication Start Date** < End of Sub-study Date **- Participants continuing into LTFU Phase after the sub-study:** Date of First SC injection[e] ≤ **Medication Start Date** < LTFU ART Start Date **- Participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** Date of First SC Injection[e] ≤ **Medication Start Date** < Date of end of Sub-Study +35 days
Return to Gluteal Injection	**For participants continuing into Extension Phase after the sub-study:** Date of Nominal Sub-study Week 12 Visit[f] ≤ **Medication Start Date** < End of Sub-study Date **For participants continuing into LTFU Phase after the sub-study:** Date of Nominal Sub-study Week 12 Visit[f] ≤ **Medication Start Date** < LTFU ART Start Date **For participants transitioning to marketed product/alternative HAART and did not withdraw the study for safety related reasons:** Date of Nominal Sub-study Week 12 Visit[f] ≤ **Medication Start Date** < Date of end of Sub-study +35 days

- [a] ART stopped on the start date of Extension Phase CAB + RPV will not be assigned to the Extension Phase.
- [b] ART taken stopped on the date of nominal Week 100 visit will be considered concomitant during the Maintenance Phase and will not be considered concomitant during the Extension Phase.
- [c] ART taken stopped on the end of Sub-study date will be considered concomitant during the previous sub-Study Phase and will not be considered concomitant during the Extension Phase.
- [d] ART stopped on the date of first Sub-study record not be assigned to the Sub-study Screening Phase.
- [e] ART stopped on the date of first SC Injection will not be assigned to the SC Injection Phase.
- [f] ART stopped on the date of Nominal Sub-study Week 12 Visit will not be assigned to the Return to Gluteal Injection Phase.

If a partial date for medication/ART is recorded in the eCRF, the following convention will be used to assign the medication:

- if the partial date is a start date, a '01' will be used for missing days and 'Jan' will be used for missing months;
- if the partial date is a stop date, a '28/29/30/31' will be used for the missing day (dependent on the month and year) and 'Dec' will be used for the missing month; for medications recorded separately in the eCRF as prior ART, the earlier of this imputed date or the day before IP start will be used.

The recorded partial date will be displayed in listings.

Table 27 Assignment to Long-Term Follow-Up Phase

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

- D**ate** = Assessment/Start Date

Note that the long-term follow-up Phase and maintenance/extension 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.

14.4.1.1. Study Periods

Certain displays will be produced for data collected during the oral-lead-in and during the first 52 weeks of the Maintenance Phase, respectively. These period variables are defined in Table 28 and Table 29 and will be reflected in the datasets in separate variables.

Table 28 Assignment of Study Period for AE Data

Study Period	Date range

Maintenance Phase up to Week 52	**ABC/DTG/3TC Arm:** **For participants continuing beyond Week 52:** Maintenance Treatment Start Date ≤ **Date** < Date of Study Day 378 (Upper Assessment Window for Week 52) **For participants <u>not</u> continuing beyond Week 52:** Date ≥ Maintenance Treatment Start Date
	Q4W IM Arm: **For participants continuing beyond Week 52:** Maintenance Treatment Start Date ≤ **Date** < Date of Study Day 378 (Upper Assessment Window for Week 52) **For participants <u>not</u> continuing beyond Week 52:** Maintenance Treatment Start Date ≤ **Date** < LTFU ART Start Date
Maintenance Phase Oral lead-in	**Q4W IM Arm:** **For participants receiving at least one Maintenance Phase Injection:** Maintenance Treatment Start Date ≤ **Date** < Date of First IM injection **For participants withdrawing prior to first Maintenance Phase Injection:** Date ≥ Maintenance Treatment Start Date
Extension Phase Oral lead-in	**Switch Q4W (Oral Lead-In Arm):** **For participants receiving at least one Extension Phase Injection:** Extension Oral CAB/RPV Start Date ≤ **Date** < Date of First IM injection **For participants withdrawing prior to first Extension Phase Injection:** **Date** ≥ Extension Oral CAB/RPV Start Date

Table 29 Assignment of Study Period for Lab assessments:

Period	Date range
Maintenance up to Week 52 [Note: this is derived for LAB assessments only]	**ABC/DTG/3TC Arm:** **For participants continuing beyond Week 52:** Maintenance Treatment Start Date < **Date** ≤ Date of Study Day 378 (Upper Assessment Window for Week 52) **For participants <u>not</u> continuing beyond Week 52:** Date >Maintenance Treatment Start Date

	Q4W IM Arm: **For participants continuing beyond Week 52:** Maintenance Treatment Start Date < **Date** ≤ Date of Study Day 378 (Upper Assessment Window for Week 52) **For participants <u>not</u> continuing beyond Week 52:** Maintenance Treatment Start Date < **Date** ≤ LTFU ART Start Date
Maintenance Oral lead-in [Note: this is derived for LAB assessments only]	**Q4W IM Arm:** **For participants receiving at least one Maintenance Phase Injection:** Maintenance Treatment Start Date < **Date** ≤ Date of First IM injection **For participants withdrawing prior to first Maintenance Phase Injection:** Date >Maintenance Treatment Start Date
Extension Phase Oral lead-in [Note: this is derived for LAB assessments only]	**Switch Q4W (Oral Lead-In) Arm:** **For participants receiving at least one Extension Phase Injection:** Extension Oral CAB/RPV Start Date < **Date** ≤ Date of First IM injection **For participants withdrawing prior to first Extension Phase Injection:** Date > Extension Oral CAB/RPV Start Date

14.4.2. Treatment State

Within each treatment study Phase (i.e., Induction, Maintenance and Extension—based on assignment of study Phase described in Section 14.4.1), only those assessments which occur within the ranges shown in Table 30 will be considered 'on-treatment' for the given Phase.

Table 30 Treatment State within Study Phases

Study Phase[a]	Treatment State	Date Range
Screen	Pre-treatment	All assessments/events within Phase
Induction	On-treatment	Date ≤ Induction Treatment Stop Date + 1

	Post-treatment	Date > Induction Treatment Stop Date + 1
Maintenance	On-treatment	ABC/DTG/3TC ART arm: Date ≤ Maintenance ART Stop Date + 1
		IM Q4W arm: Date ≤ max (Date of Last Q4W IM Dose + 35, Last Oral Dose Date + 1)
	Post-treatment	ABC/DTG/3TC arm: Date > ABC/DTG/3TC Stop Date + 1
		IM Q4W arm: Date > max (Date of Last Q4W IM Dose + 35, Last Oral Dose Date + 1)
Extension	On-treatment	Date ≤ max (Date of Last Q4W IM Dose + 35, Last Oral Dose Date + 1)
	Post-treatment	Date > Date of Last Q4W IM Dose + 35, Last Oral Dose Date + 1)
Long-Term Follow-up	On-treatment	Date ≤ min (LTFU ART start date, max (Last Injection Date + 35, Last Oral Dose Date + 1))
	Post-treatment	Date > min (LTFU ART start date, max (Last Injection Date + 35, Last Oral Dose Date + 1))

Note1: Treatment State is determined after data has been assigned to the study Phases as defined in Section 14.4.1
Note2: Last Q4W IM / last oral dose / Induction Treatment stop date/Maintenance ART Stop Date is only applied to participants who permanently discontinue from study treatment
Note3: Date = Assessment/Start Date.

- For Sub-study Screening, SC Injection and Return to Gluteal Injection phases, the same on-treatment and post-treatment algorithms as those in Extension Phase will be applied.

14.4.2.1. Treatment States for AE Data

For adverse events, partial AE start date will use imputation as described in Section 14.7.2.1. In the case of a completely missing start date, the event will be considered to have started On-treatment at Maintenance Phase unless an end date for the AE is provided which is before start of study treatment at Maintenance Phase; in such a case the AE is assigned as Pre-treatment.

Within each treatment study Phase, only those AE with onset date within the ranges shown in Table 30 will be considered 'on-treatment' for the given Phase. The onset date will be derived based on Table 31.

Table 31 AE onset date, AE duration and relation to study treatment

	Definition
Onset date/study day Since 1st Dose of each study Phase (Days)	If Treatment Start Date > AE Onset Date = AE Onset Date - Treatment Start Date If Treatment Start Date ≤ AE Onset Date = AE Onset Date - Treatment Start Date +1 Missing otherwise.
Duration (Days)	AE Resolution Date – AE Onset Date + 1
Drug-related	If relationship is marked 'YES' on Inform/CRF OR value is missing.

NOTES:

- Onset date/study day will be derived for each study Phase, respectively (refer to Section 14.6.1)

14.4.3. Combining Treatment Phases and States

On-treatment and Post-treatment assessments and events will be classified as occurring during the Induction, Maintenance Phase, Extension, or Long-term follow up Phase.

14.5. Appendix 5: Data Display Standards & Handling Conventions

14.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: us1salx00259
HARP Area	\ARPROD\GSK1265744\mid201584\primary_01 (W48 analysis) \ARPROD\GSK1265744\mid201584\primary_07 (W96 analysis) \ARPROD\GSK1265744\mid201584\primary_09 (Day 1 Japan PK analysis) \ARPROD\GSK1265744\mid201584\primary_17 (Week 124 analysis)
QC Spreadsheet	: \ARWORK\GSK1265744\mid201584\documents\qc\
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.1.3 & AdaM IG Version 1.0). • 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.	

14.5.2. 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
• All data displays (Tables, Figures & Listings) will use the term “Subject” which reflects CDISC and GSK Data Display Standards terminology.

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

• Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated. • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate. • Reporting for Data Listings: • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1). • Unscheduled or unplanned readings will be presented within the subject listings displays.
Unscheduled Visits
• Unscheduled visits will be assigned to a study visit using the all-inclusive windows defined in Section 14.3.2. • 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
Categorical Data	N, n, frequency, %

Graphical Displays
• Refer to IDSL Statistical Principals 7.01 to 7.13.

14.5.3. Reporting Standards for Pharmacokinetic

Pharmacokinetic Concentration Data	
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to IDSL Statistical Principle 6.06.1. NQ concentration values will be assigned a numeric value equal to the low limit of quantification (LLQ) (Refer to GUI_51487 for further details) for descriptive summary statistics/analysis and summarized graphical displays only. For Japan Day 1 PK concentrations, refer to the standard operating procedure, SOP-CPK-0001 and R&D Guideline: Non-Compartmental Analysis of Pharmacokinetic Data, GUI_51487 (3.0), for more information regarding the handling of plasma concentrations below the assay's lower limit of quantification (LLQ). Geometric mean, 95% CI of geometric mean, standard deviation (SD) of logged data and between geometric coefficient of variation (CVb (%)) will be reported. ○ CV_b (%) = $\sqrt{}$ (exp(SD^2) - 1) * 100, SD = SD of log transformed data)

14.6. Appendix 6: Derived and Transformed Data

14.6.1. General

Multiple Measurements at One Time Point
• If after window assignment there are multiple valid assessments of a parameter within the same window, then the following hierarchy will be used to determine the value to be used for summary statistics of observed values: o the assessment closest to the window target Study Day; o if there are multiple assessments equidistant from the target Study Day, then for continuous variables the mean of these values will be used and for categorical variables the worse assessment. For HIV-1 RNA, the geometric mean of the number of copies will be used as opposed to the arithmetic mean • Assessments not chosen for use in summary statistics by this algorithm will still appear in the associated listings. Also, such valid assessments will be used when determining values of potential clinical concern for the 'any time On-treatment' time point, and for any algorithm that has specific rules for which observation to use (e.g., Snapshot).
Treatment Start Date
Treatment start date is defined by Phase as follows: Induction Phase • Start date of DTG regimen entered onto the Induction Phase IP exposure CRF Maintenance Phase • For participants randomised to Q4W IM, maintenance treatment start date is the date of oral lead-in of CAB+RPV entered onto the Maintenance Phase IP exposure CRF • For participants randomised to ABC/DTG/3TC, maintenance treatment start is DTG regimen start date entered onto the Maintenance Phase IP exposure CRF Extension Phase • For participants randomised to Q4W IM, extension treatment start date is the date of Nominal Week 100 injection date. For participants randomised to ABC/DTG/3TC, extension treatment start date is the start date of oral lead-in of CAB+RPV entered onto the Extension Phase IP exposure CRF. SC Sub-Study • For participants enrolled in the SC sub-study, treatment start date is the date of their screening injection. For purposes of exposure calculations, the date of the first SC injection will be used. • For participants who received Sub-study Week 12 injection, nominal Sub-study Week 12 visit date is defined by the Sub-study Week 12 injection date. Otherwise, nominal Sub-study Week 12 visit date is defined by the date of latest Sub-study Week 12 assessment. • For participants who continued into Return to Gluteal Injection Phase however missed Sub-study Week 12 visit, nominal Sub-study Week 12 visit date is defined by the end of SC Injection Phase date (i.e., date for the SC Injection Phase conclusion record in the SDTM DS domain) for the analysis purpose.

- 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 or the Week 20 visit date, whichever comes first.

Induction Phase Study Day

The Induction Phase Study Day of an event (e.g., lab assessment, vital sign, ECG, start date of AE or HIV associated/AIDS-defining condition) will be derived as the number of days between the date of the event and the initial start date of DTG in the Induction Phase as follows:

if date of event ≥ start date of Induction Phase DTG, then

$$\text{Induction Phase Study Day} = \text{date of event - start date of Induction phase IP} + 1$$

if date of event < start date of Induction Phase DTG, then

$$\text{Induction Phase Study Day} = \text{date of event - start date of Induction phase IP}$$

if date of event > start date of Maintenance Phase DTG, then

Induction Phase Study Day will not be derived (i.e., will be set to missing).

Note that the initial start date of Induction Phase DTG is considered to be on Induction Phase Study Day 1 and the day before this is Induction Phase Study Day -1; i.e., there is no Induction Phase Study Day 0.

Study Day

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

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

- Study Day = Date of Event – Start Date of Maintenance Phase IP + 1

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

- Study Day = Date of Event – Start Date of Maintenance Phase IP

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

Extension Phase Study Day

The Extension Phase Study Day of an event (e.g., lab assessment, vital sign, ECG, start date of AE or HIV associated/AIDS-defining condition) will be derived as the number of days between the date of the event and the initial start date of Extension Phase IP as follows:

if date of event ≥ start date of extension Phase IP, then

$$\text{Extension Phase Study Day} = \text{date of event} - \text{start date of Extension phase IP} + 1$$

if date of event < start date of Extension Phase IP, then

$$\text{Extension Phase Study Day} = \text{date of event} - \text{start date of Extension phase IP}$$

Note that the start date of Extension Phase IP 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.

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/AIDS-defining condition) will be derived as the number of days between the date of the event and the end of IP treatment [i.e., max (Last IM Injection Date, Last Oral Bridging End Date)]

as follows:

If the onset of event falls in Long-term Follow up Phase, then

- $\text{LTFU Study Day} = \text{date of event} - \text{end date of IP}$

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 dates for each Phase are as follows:

- SC Injection Phase: Date of first SC injection
- Return to Gluteal Injection Phase: Date of the nominal sub-study Week 12 visit date

The SC injection date will serve as the reference date for the overall study day.

Study treatment/drugs

- Refers to either investigation product (CAB+RPV oral /CAB+ RPV LA) or ABC/DTG/3TC or DTG plus alternate NRTIs.

14.6.2. Study Population

Demographics
Age
• Age, in whole years, will be calculated with respect to the participant's 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,** using Height collected at Day 1.
Hepatitis B Status
• A participant will be considered positive for hepatitis B virus (HBV) if they have a positive surface antigen (i.e., "REACTIVE") and/or detectable HBV DNA ("HBV DNA DETECTED" or HBV DNA ≥ 116 copies/mL, with "HBV DNA DETECTED" taking precedence over HBV DNA reported as <116 copies/mL). If DNA result is available, then this will be used to qualify as positive or negative; otherwise, Hepatitis B status will be determined using the surface antigen result.
Hepatitis C Status
• Hepatitis C status will be determined using antibody (IgM or IgG) 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 ≥15 IU/mL. In the absence of an HBV RNA result, Hepatitis C antibody of "REACTIVE" or "BORDERLINE" will qualify as Hep C positive.
Lipid-modifying Agents

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

Framingham Risk Equation
• 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:** $\hat{p}_F = 1 - S_0(t)^{\exp\{2.32888 \times \log(\text{age}) + 1.20904 \times \log(TC) - 0.70833 \times \log(HDL) + 2.76157 \times \log(SBPu) + 2.82263 \times \log(SBPt) +}$

Demographics

$$0.52873 \times I_s + 0.69154 \times I_d - 26.1931\},$$

for males:

$$\hat{p}_M = 1 - S_0(t)^{\exp\{3.06117 \times \log(age) + 1.12370 \times \log(TC) - 0.93263 \times \log(HDL) + 1.93303 \times \log(SBPu) + 1.99881 \times \log(SBPt) + 0.65451 \times I_s + 0.57367 \times I_d - 23.9802\}},$$

where

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

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)

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

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

- 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 Induction Baseline (Week -20). 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 will be counted in the highest category of risk in the summary by category.

Extent of Exposure

- Exposure to CAB+RPV (oral lead-in), CAB LA+RPV LA, ABC/DTG/3TC (or DTG if alternate NRTI is used) will be calculated from the IP eCRF pages.

Maintenance Phase: Q4W IM arm	
Exposure to CAB + RPV (oral lead-in) =	Oral lead-in CAB/RPV Stop Date – Oral lead-in CAB/RPV Start Date +1
Exposure to CAB LA + RPV LA =	Number of IP injections received during Maintenance Phase (up to but not including Injections administered at Week 100)
Overall Exposure to IP =	min [Date of latest Maintenance Phase visit up to and including Week 100, max (Date of last IP injection +35 [a], Date of last oral CAB/RPV [a])] – Oral lead-in CAB/RPV Start Date +1
Maintenance + Extension Phase: Q4W IM arm	
Exposure to CAB LA + RPV LA =	Number of IP injections received during Maintenance Phase + Extension Phase
Overall Exposure to IP =	min [Min(Date of Last Study Contact, Long Term Follow Up HAART Start Date), max (Date of last IP injection +35 [a], Date of last oral CAB/RPV [a])] – Oral lead-in CAB/RPV Start Date +1
a. Last Q4W IM / last oral dose is only applied to participants who permanently discontinue from study	
Maintenance Phase: ABC/DTG/3TC arm	
Exposure = Min (Date of latest Maintenance Phase visit up to and including Week 100, Maintenance Phase Treatment Stop Date, Date of Maintenance Phase Discontinuation) – Maintenance Treatment Start Date + 1	
Extension Phase: Switch Q4W IM group (Extension Switch Population only)	
Exposure to CAB + RPV (oral lead-in) =	min (Date of Last Study Contact, Long Term Follow Up HAART Start Date, Oral lead-in CAB/RPV Stop Date) – Oral lead-in CAB/RPV Start Date +1
Exposure to CAB LA + RPV LA =	Number of IP injections received during Extension Phase
Overall Exposure to CAB + RPV =	min [min(Date of Last Study Contact, Long Term Follow Up HAART Start Date), max (Date of last IP injection +35 [a], Date of last oral CAB/RPV [a])] – min(Oral lead-in CAB/RPV Start Date, Date of First IP Injection) +1
a. Last Q4W IM / last oral dose is only applied to participants who permanently discontinue from study	

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

Extent of Exposure

- Participants who were randomised to CAB LA+RPV LA but did not report an IP start date will be categorised as having zero days of exposure.

SC Sub-study

- For SC Injection Phase
  - Exposure to CAB LA + RPV LA = Number of IP injection visits received during SC Injection Phase. Note that the planned Sub-study Week 12 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:
    min [Date of Latest SC Injection Phase Visit up to the Nominal Sub-study Week 12 Visit Date, max (Date of Last Injection + 35[a], Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – Date of First SC Injection) + 1
    Note that the Nominal Sub-study Week 12 visit date is defined in Section 14.6.1.
  - Overall exposure to IP = Overall exposure to Study Treatment.
- For SC Injection + Return to Gluteal Injection Phase
  - Exposure to CAB LA + RPV LA = Number of IP injection visits received during SC Injection or Return to Gluteal Injection Phase. Note that the injections received on the date of Sub-study Week 20 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:
    min [End of Sub-study Date, max (Date of Last Injection + 35[a], Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – Date of First SC Injection) + 1
    Note that the End of Sub-study Date is defined in Section 14.6.1.
  - Overall exposure to IP = Overall exposure to Study Treatment.

[a] Last Injection/ last oral dose is only applied to participants who permanently discontinue the study.

Adherence to CAB/RPV Injection Schedule

For participants in the randomized Q4W arm, Timeliness of Injections Relative to Date of Projected Dosing Visits are assessed by using "actual injection visit date - projected visit date from Week 4b".

For participants in the Switch Q4W Oral Lead-in group, Timeliness of Injections Relative to Date of Projected Dosing Visits are assessed by using "actual injection visit date - projected visit date from Week 104b".

For participants in the Switch Q4W Direct to Inject group, timeliness of Injections Relative to Date of Projected Dosing Visits are assessed by using "actual injection visit date - projected visit date from Week 100".

Extent of Exposure

For participants in the Sub-Study, timeliness of Injections Relative to Date of Projected Dosing Visits are assessed by using “actual injection visit date - projected visit date from Sub-study Week -4”.

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

Corrected QTC

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

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

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

where uncorrected QT interval is also measured in msec.

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

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

14.6.3. 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 2.0, November 2014, as specified in the protocol Appendix 12.2.
Laboratory Parameters
• If a laboratory value which is expected to have a numeric value for summary purposes, has a non-detectable level reported in the database, where the numeric value is missing, but typically a character value starting with '<x' or '>x' (or indicated as less than x or greater than x in the comment field) is present, the number of significant digits in the observed values will be used to determine how much to add or subtract in order to impute the corresponding numeric value. If a character value starting with "<=x", then the numeric value will be x. o Example 1: 2 Significant Digits = '< x ' becomes x – 0.01 o Example 2: 1 Significant Digit = '> x' or '>=x' becomes x + 0.1 o Example 3: 0 Significant Digits = '< x' becomes x – 1

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

- Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [Levey, 2012]. be used by the central laboratory to provide an estimate of GFR, in mL/min per 1.73 m2, 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 2.0, November 2014, as specified in the protocol of Appendix 12.2**

- Toxicities will be based on the Division of AIDS (DAIDS) grading system, Version 2.0, November 2014, as specified in the protocol of Appendix 12.2. Toxicity grades provided by the central laboratory do not distinguish between abnormally high or low criteria, when both are relevant for a particular parameter.
- When summarising toxicity grades for such parameters, they will be categorised as to whether they are above or below the midpoint of normal range.

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

National Cholesterol Education Program (NCEP) Lipid Categories

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

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

	5.18 to <6.21	200 to <240	Borderline High
	≥6.21	≥240	High
HDL Cholesterol	<1.04	<40	Low
	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

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

Percentage change for lipids

The percentage change from Maintenance Baseline (Day 1) is calculated as:

$$\% \text{ Change from Maintenance BL} = \frac{\text{Value at Week 48/Week 96} - \text{Maintenance BL value}}{\text{Maintenance BL value}} \times 100\ \%$$

The percentage change from Extension Baseline (Week 100) is calculated as:

$$\% \text{ Change from Maintenance BL} = \frac{\text{Value at Week 104} - \text{Extension BL value}}{\text{Extension BL value}} \times 100\ \%$$

Other Safety Endpoints

Columbia Suicide Severity Rating Scale (C-SSRS) (Posner, 2007)

- Missing data will not have any imputation performed (Nilsson, 2013)

14.6.4. 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 17) is determined by the last available HIV-1 RNA measurement in that window while the participant is On-treatment in the applicable phase(s), e.g., Maintenance Phase (as assigned based on Table 30).

Snapshot
• 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 a 'HIV-1 RNA≥50' 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 a 'HIV-1 RNA≥50 c/mL'. • Full details of the algorithm, including the handling of special cases, are included in Section 14.11.
Plasma HIV-1 RNA
• For summaries and analyses which use HIV-1 RNA level as a continuous measure, the logarithm to base 10 of the value will be used. • HIV-1 RNA results may be provided as censored values, such as <40 or >9,999,999 c/mL. For the purposes of summary statistics, such values will be replaced by the next value beyond the limit of detection, e.g., 39 or 10,000,000 c/mL, respectively, for the given examples. Data listings will show the censored values as provided.
Target Detected / Target Non- Detected/Super low viral load testing
• When a measurement of plasma HIV-1 RNA is below the limit of quantification (i.e., 40 c/mL) and is qualitatively observable that will be denoted as a "Target Detected" measure, while HIV-1 RNA below the limit of quantification that is not qualitatively observable that will be denoted as "Target Not Detected". Any measurements <40 c/mL characterised as "Target Not Detected" or "Target Detected" will be captured in the database. • Super low viral load will also be tested by BioMNTR lab for Viral loads below the limit of quantification (i.e., <2 c/mL) at some visits (e.g., Week 48).
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, at the end of the Week 48 analysis window per Table 15 (i.e., study day 350), 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, at the end of the Week 48 analysis window per Table 15 (i.e., study day 350), 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 Week 48 (i.e., study day 350) will be presented by treatment group, along with estimated difference in proportions between treatment groups

Snapshot
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 1: Variables Defined for Time to Event Analysis
Observed Case Viral Load (HIV-1 RNA) Category by Visit Summary Tables
• For each visit with scheduled viral load collection (per time and events schedule in the protocol), the Observed Case proportion is defined using available data, with no imputation for missing values. • Week 48 and Week 96: o Numerator: Number of participants with on-treatment HIV-1 RNA in the respective category (e.g., < 50 c/mL) based on the last viral load assessment collected within the analysis Snapshot window for Week 48 and Week 96, respectively. (i.e., Week 48 ±6 weeks and Week 96 ±6 weeks). o Denominator: Number of participants with on-treatment HIV-1 within the analysis Snapshot window for Week 48 and Week 96, respectively. (i.e., Week 48 ±6 weeks and Week 96 ±6 weeks). • Other Visits: o Numerator: Number of participants with on-treatment HIV-1 RNA in the respective category (e.g., < 50 c/mL) based on the last viral load assessment collected within the default analysis visit windows for Maintenance phase assessments (Table 15). o Denominator: Number of participants with on-treatment HIV-1 RNA collected within the default analysis visit windows for Maintenance phase assessments (Table 15). • Observed case proportions will be derived for the following HIV-1 RNA categories: RNA <40, 40 <= RNA <50, RNA < 40 & Target Detected, RNA <40 & Target Not Detected. • For Maintenance Baseline (Day 1), the last viral load collected prior to or equal to the date of first Maintenance Phase study treatment dose will be selected for determining the observed case proportion at this timepoint.
Confirmed Virologic Failure (CVF)
• The definition of CVF is provided in the Protocol, Section 5.4.4 – Definition of Virologic Failure
HIV-1 Disease progression Stage
• Categories: • CDC Stage I at Maintenance Baseline (Day 1) to CDC Stage II; • CDC Stage I at Maintenance Baseline (Day 1) to CDC Stage III; • CDC Stage II at Maintenance Baseline (Day 1) to CDC Stage III; • CDC Stage III at Maintenance Baseline (Day 1) to new CDC Stage III event; • CDC Stage I, II, III at Maintenance Baseline (Day 1) 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 Maintenance Baseline (Day 1) and at post-Day 1

Snapshot
during Maintenance Phase will be derived as below: • At Baseline (Week -20), the 'Baseline CDC stage' for each participant was assessed by investigator and recorded in the eCRF. However, for the analysis, Maintenance Baseline (Day 1) CDC stage will be derived based on Maintenance Baseline (Day 1) CD4+ values as well as whether any HIV-associated/AIDS-defining conditions present on the start date of maintenance treatment (i.e., started/stopped on Study Day 1 or ongoing through Study Day 1) per the Criteria's thresholds (Appendix 4 in Protocol). • To analyse disease progression, the most advanced Maintenance CDC stage 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 Maintenance Phase CD4+. • For example, If a participant with CDC 'Stage I' at Maintenance Baseline (Day 1) had the lowest Maintenance Phase CD4+ =120 cell/mm3 without new AIDs-defining conditions, then HIV disease progression for this participant would be considered as 'CDC stage I at Maintenance Baseline (Day 1) to CDC stage III'.If a participant with CDC 'Stage II' at Maintenance Baseline (Day 1) 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 would be considered as 'CDC stage II at Maintenance Baseline (Day 1) to CDC stage III'.
Delay in IP Injection
IM dosing is expected to occur every 4 weeks from Week 4b onwards (for the Q4W arm). The Delay in IP injection (days) will be calculated as: • Delay in IP injection(days) = Injection date - date of preceding injection – 28 days 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 does not receive Week 48 injection (i.e., missing visit or withdrawal).

14.6.5. Pharmacokinetic

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

Plasma CAB and RPV concentration-time data
Plasma samples for determination of CAB and RPV concentration will be collected throughout the Maintenance and Extension Phases of the study. Additional samples will be collected for storage during the Long-Term Follow-Up Phase.

Plasma CAB and RPV concentration-time data

PK analysis of the plasma CAB concentration-time data on Day 1 and Week 4b for Japan participants will be conducted using non-compartmental methods with WinNonlin (Version 5.2 or higher). Actual sampling and dosing times as recorded in the eCRF will be used for analysis.

Evaluable concentration

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, excluding samples affected by dosing errors/oral bridging. Sampling windows are determined relative to the previous dose as follows:

- 1-5 hours for 2-hour post dose samples;
- ± 3-10 days post last injection for 1-week post injection visits;
- ±4 day for pre-dose sample.
- Samples affected by dosing errors (e.g., wrong dose) or oral bridging will also be excluded.

Timepoint	Evaluable window	For Programming:
PRE-DOSE: WK4b/104b only	20-28 hrs after last oral dose taken and the last 3 oral doses administered properly	20 hrs ≤ Days Since Last Oral Dose ≤ 28 hrs and the last 3 oral doses administered on the three consecutive days prior to WK4b/104b.
2-HR-POST:	1-5 hrs	1 hr ≤ Hours Since Last Injection Dose ≤ 5 hrs
1-WK-POST:	3-10 days post last injection	3 d ≤ Days Since Last Dose ≤ 10 d
PRE-DOSE:	±4 days	24 d ≤ Days Since Last Dose ≤ 32d

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

If a pre-dose sample is collected on the same day as the first dose of oral bridging, and the time of the first dose (not recorded in eCRF) is confirmed to be 'after' the collection of pre-dose sample (by medical monitor or Data querying), then this PK sample will not be impacted by the oral bridging.

At Week 4b/104b, the evaluable window and relative time for 2-HR-POST will be derived based on last injection dose (not the last oral dose). The timing of last oral dose will not affect 'evaluable' status with the exception of the last oral dose taken after the 1st injection, i.e., if a participant took the last oral dose after the 1st injection, the 2-HR-POST will not be considered 'evaluable', because of the deviation from the IP administration sequence per protocol.

The time-deviation (hours) from the targeted timepoint will be calculated for the following timepoints:

Plasma CAB and RPV concentration-time data

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

Time_deviation (hrs) for '1-HR-POST' =Sample date.time-last previous injection date.time -1 hours

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

Time_deviation (hrs) for '4-HR-POST' =Sample date.time-last previous injection date.time -4 hours

Time_deviation (hrs) for '5-HR-POST' =Sample date.time-last previous injection date.time -5 hours Time_deviation (hrs) for '8-HR-POST' =Sample date.time-last previous injection date.time -8 hours

Time_deviation (hrs) for '24-HR-POST' =Sample date.time-last previous injection date.time -24 hours

For Long-term Follow-up Phase PK concentrations:

LTFU RPV concentrations for participants receiving oral RPV during the LTFU phase will be excluded from LTFU PK summary tables and mean/median concentration plot but will be included in data listings and PK concentration-time profiles plots (with footnotes indicate which participants were receiving oral RPV). Participants receiving inducers during the LTFU phase may also be excluded.

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

TIMEPOINT	EVALUABLE WINDOW	FOR PROGRAMMING:
LTFU MONTH 1	± 4 days	24d ≤ Days Since Last Injection ≤ 32d
LTFU MONTH 3	± 1 Week	77d ≤ Days Since Last Injection ≤ 91d
LTFU MONTH 6	± 2 Week	154d ≤ Days Since Last Injection ≤ 182d
LTFU MONTH 9	± 2 Week	238d ≤ Days Since Last Injection ≤ 266d
LTFU MONTH 12	± 2 Week	322d ≤ Days Since Last Injection ≤ 350d

Pharmacokinetic Parameters

- Population pharmacokinetics and identify important determinants of variability will be described in a separate document.

14.6.6. Health Outcome

HIVTSQs

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

Treatment Satisfaction Score

- Total Treatment Satisfaction Score is computed with items 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 (very satisfied, convenient, flexible, etc.) to 0 (very dissatisfied, inconvenient, inflexible, etc.).
- Higher scores represent greater satisfaction with each aspect of treatment
- For individual item scores outputs, missing scores will not be computed (according to Page 7 of the [HIVTSQ User Guidelines, 2016]) and instead be imputed using LOCF.

HIVTSQc

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[redacted]

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 0 represents no change.
- A maximum of 5 items can be missing, the missing scores will be imputed with the mean of the completed item scores. If 6 or more items are missing, then the overall treatment satisfaction scale score should not be computed and will remain missing.

Individual Treatment Change Item Scores

- Items are rated as +3 ('much more satisfied', 'much more convenient', 'much more flexible', etc.) to -3 ('much less satisfied', 'much less convenient', 'much less flexible', etc.).
- The higher the score, the greater the improvement in satisfaction with each aspect of treatment and the lower the score, the greater the deterioration in satisfaction with each aspect of treatment.

PIN

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Dimension Score (Chevat, 2008)

- Domains and Clusters
  - Bother from injection site reactions: items 3, 4, 5, 6, 7, 8
  - Leg movement: items 11, 12, 15, 16
  - Sleep: items 9, 10, 13, 14
  - Acceptability: items 17, 18
- 5 items not included in any of these domains and maintained as individual items (items 1, 2, 19, 20, 21) (anxiety before, pain, satisfaction, anxiety after, willingness)
- 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 (Bother from injection site reactions), ≥2 (Leg movement/Sleep), ≥1 (Acceptability), then the total score for the domain should not be computed and instead be imputed using LOCF (Section 14.7.2.2)
- LOCF will not be used for the SC sub-study

Individual Item Scores

- Items are rated on a 5-point scale, ranging from 1(very satisfied, not at all, etc.) to 5 (very dissatisfied, extremely, etc.).
- Higher scores represent worse perception of injection
- For individual item scores outputs, missing scores will not be computed and instead be imputed using LOCF (Section 14.7.2.2). Observed values will be used in the SC Sub-study.

SF-12

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Dimension Score

- Changes from Baseline at Week 48 in health-related quality of life (using SF-12) for the physical component summary (PCS) and the mental component summary (MCS) were assessed for the two treatment groups. Scores are created according to the manual [SF-12 (v2) Health Survey 1994, 2002 Medical Outcomes Trust and QualityMetric Incorporated] and the component scores were calculated using computer software purchased from QualityMetric.(http://www.qualitymetric.com/)
- Missing component scores will be imputed using LOCF (Section 14.7.2.2).

Individual Item Scores

- Items are rated as 5 except for Question 2. Question 2a and 2b are rated as 3
- Individual item missing scores will be imputed using LOCF (Section 14.7.2.2).

HATQoL (Holmes, 1999)

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Individual Item Scores

- For individual item scores outputs, missing scores will not be computed and instead be imputed using LOCF (Section 14.7.2.2).

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

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Tolerability of Injection (NRS)
Questionnaire with one single question for Q4W IM arm only
• Maximum level of pain experienced with the most recent injections. Ranking from no pain (0) to extreme pain (10). • Missing scores will be imputed using LOCF (Section 14.7.2.2). Observed values will be used in the SC Sub-study
Preference question
Questionnaire with one single dichotomous preference question at Week 48 (Q4W IM arm)
• Assess the treatment preference: Months injection vs daily oral current ART at Week 48 for 'Q4W IM' arm • Any missing values will remain missing (i.e., no imputation) • A preference questionnaire will also be administered to sub-study participants. It asks participants to state their preference between IM and SC injections and to check off potential reasons why.
Reasons for Switch Questionnaire
Reason for Switch questionnaire is collected for sub-study participants and asks the reasons they agreed to switch to SC injections. Any missing values will remain missing (i.e., no imputation).
Interest Questionnaire
The Interest questionnaire is collected for sub-study participants and asks how interested they would be to switch to SC injections at home on a 5 point scale ranging from 'Not at all interested' to 'Extremely interested.'. Any missing values will remain missing (i.e., no imputation).

14.6.7. Viral Genotype and Phenotype

Genotype

Amino Acid Changes

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

Representation of Amino Acid Changes

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

Resistance Associated Mutations

- Known INI mutations associated with the development of resistance to Integrase Strand Transfer Inhibitors:

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

NOTES:

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

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

Genotype

Class	Mutations
NRTIs	M41L, A62V, K65R/E/N, D67N, 69 insert, K70E/R, L74V, V75I, F77L, Y115F, F116Y, Q151M, M184V/I, L210W, T215Y/F, K219Q/E
NNRTIs	L100I, K101E/P, K103N/S, V106A/M, V108I, E138/A/G/K/Q/R, V179L, Y181C/I/V, Y188C/L/H, G190S/A, H221Y, P225H, F227C, M230I/L
PIs	D30N, V32I, M46I/L, I47A/V, G48V, I50V/L, I54V/M/L, Q58E, T74P, L76V, V82A/T/F/L/S, N83D, I84V, N88S, L90M

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

Treatment-Emergent Mutations Relative to Induction Baseline (Week -20)

- Treatment-emergent genotypic mutations are defined as mutations that appear between Induction Baseline (Week -20), i.e., prior to the start of Induction Phase study drug (inclusive), and an on-treatment assessment (e.g., at time of confirmed virologic failure). Note: If Monogram is not able to produce genotype at Week -20, then treatment-emergent will be determined relative to the screening genotype provided by the central laboratory.

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.
- Since the maximum assay limit for FC for each ART varies from assay to assay, FC values that are greater than the maximum assay limit (e.g., '>100') will be interpreted as having a value equal to the smallest maximum assay limit for that ART in the study population for data analysis. Censored values will be presented 'as is' in the listings. Phenotypic susceptibilities will be categorized according to FC as shown below (based on Monogram PhenoSense assay). Clinical cutoffs (where available) or biological cutoffs by PhenoSense will be used to define the phenotypic susceptibility of ART therapy 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

Genotype

Etravirine	ETR	NNRTI	(2.9-10) [a]
Rilpivirine	RPV	NNRTI	2.0
Fosamprenavir/r	FPV/r	PI	(4-11) [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]

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

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 biologic cutoff	resistance
≤ clinical lower cutoff or biologic cutoff	sensitive

Partial Sensitivity

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

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

Genotypic and Net Assessment Susceptibility

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

Induction Baseline (Week -20) HIV-1 Subtype

- For participants without confirmed virologic failure: Screening visit subtype from Q SQUARED, unless a subtype from MONOGRAM is available on the same date.

Genotype
• For participants with confirmed virologic failure: Select last pre-treatment subtype (expected to be the Week -20 result from MONOGRAM).

14.7. Appendix 7: Reporting Standards for Missing Data

14.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion (i.e., as specified in the protocol) was defined as: o Randomly assigned to either treatment group, completed the randomized Maintenance Phase including the Nominal Week 100 visit, and did not enter the Extension Phase; o Randomly assigned to either treatment group, completed the randomized Maintenance Phase including the Nominal Week 100 visit, and entered and completed the Extension Phase (defined as remaining on study until commercial supplies of CAB LA + RPV LA become locally available, or development of CAB LA + RPV LA is terminated). Participants who withdraw from CAB LA + RPV LA and go into the Long-Term Follow Up Phase will be considered to have prematurely withdrawn from the study, even if they complete the 52-week follow-up Phase. In addition to the 52-week Long-Term Follow-Up Phase required for participants randomized to CAB LA + RPV LA, an in-clinic Follow-Up visit will be conducted approximately 4 weeks after the last dose of study medication for participants randomized to the ABC/DTG/3TC arm with ongoing AEs, 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 Appendix 3: Assessment Windows or will be summarised as withdrawal visits.

14.7.2. 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: o These data will be indicated by the use of a “blank” in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as “Not applicable” and “Not evaluable” are not considered to be missing data and should be displayed as such.

Element	Reporting Detail
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.

14.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in subject listing displays.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: o 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. o 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. o Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.
Concomitant Medications/ Medical History	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: o If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month o 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. o For medications recorded in the eCRF as prior ART, the earlier of this imputed date or the day before Screening date will be used. • The recorded partial date will be displayed in listings.
Health outcomes	• For the health outcomes questionnaire data, please refer to Section 14.6.6. • For the summary of individual item scores outputs, missing scores will not be computed. • For the SC Sub-study going forward, missing data for all HO assessments will not be imputed using the LOCF technique. Observed values will be used unless otherwise specified.

14.7.2.2. 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' or 'No Virologic Data at Week X'; Appendix 11: Snapshot Algorithm Details for full details.
LOCF	• In the LOCF dataset, missing values will be carried forward from the previous, non-missing on-treatment assessment.
Lipid LOCF	**1. Maintenance (both arms) and Maintenance + Extension Phase (randomized Q4W arm only):** **Maintenance Baseline (Day 1) for Lipids LOCF Analyses**: • Last evaluable lipids assessment up to and including the start of Maintenance Phase 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. Participants with unevaluable Maintenance Baseline (Day 1) for Lipids (as defined above) will be excluded from the analysis of Maintenance phase values and Maintenance + Extension phase values (Randomized Q4W arm). **During Maintenance + Extension phases** • If participants initiate serum lipid-lowering agents during the Maintenance + 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 visits with observed on-treatment values will continue even if the participant discontinues the lipid-lowering agent. Missing assessments will not be imputed. **Analyses Evaluated with Lipid LOCF dataset:** • This dataset will be used to summarize fasting lipids parameters in the following displays: o Summary of Chemistry Values by visit o Summary of Chemistry Change from Maintenance Baseline (Day 1) by visit o Summary of Fasting TC/HDL Ratio Change from Maintenance Baseline (Day 1) All other displays of lipids (i.e., toxicity tables and NCEP tables) will use observed fasting data, without LOCF imputation. **2. Extension Phase (Q4W Switch IM group):** **Extension Baseline (Week 100) for Lipids LOCF Analyses**: • Last evaluable lipids assessment up to and including the first dose of Extension phase CAB and/or RPV, where 'evaluable' is defined as: Lipid modifying agents not taken within 12 weeks of the date of assessment and

Element	Reporting Detail
	Lipids are collected in a fasting state. Participants with unevaluable Extension Baseline (Week 100) for Lipids (as defined above) will be excluded from the analysis of Extension phase values (Extension Switch population). **During Extension phase** • If participants initiate serum lipid-lowering agents during the 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 visits with observed on-treatment values will continue even if the participant discontinues the lipid-lowering agent. Missing assessments will not be imputed. **Baseline for Lipids LOCF Analyses in sub-study**: • Last evaluable lipids assessment up to and including the start of SC 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 SC Injection or Return to Gluteal Injection Phase**: • If participants initiate serum lipid-modifying agents during the SC 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 SC injection, all the post-baseline values in sub-study will be missing. **Analyses Evaluated with Lipid LOCF dataset:** • This dataset will be used to summarize fasting lipids parameters in the following displays: o Summary of Chemistry Values by Visit (Extension Switch population) o Summary of Chemistry Change from Extension Baseline (Week 100) by Visit o Summary of Fasting TC/HDL Ratio Change from Extension Baseline (Week 100) o Summary of Chemistry Changes from Sub-study Baseline by Visit (SC Injection + Return to Gluteal Injection Phase) o Summary of Chemistry Values by Visit (SC Injection + Return to Gluteal Injection Phase) All other displays of lipids (i.e., toxicity tables and NCEP tables) will use observed fasting data, without LOCF imputation.

14.8. Appendix 8: Values of Potential Clinical Importance

Element	Reporting Detail
Laboratory Values and Adverse Events	• The central laboratory will flag lab parameter toxicities directly in the provided datasets based on Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.0, November 2014.

14.9. Appendix 9: Population Pharmacokinetic (PopPK) Analyses

PopPK will be described in a separate document.

14.10. Appendix 10: Pharmacokinetic / Pharmacodynamic Analyses

PK/PD dataset specification and methodology will be described in a separate document.

14.11. Appendix 11: Snapshot Algorithm Details

Detailed Algorithm Steps

- Consider an analysis visit window for Week X (e.g., Week4, …Week 24, Week 48 et al). The Window for Week 24/48 visit is defined in Table 17 (e.g., window for Week 48 is $\pm$ 6 Week: 295 $\leq$ Study Day $\leq$ 378) and in Table 15 for other visits through to Nominal Week 52 at Maintenance Phase. The Snapshot Analysis at post Maintenance Phase will not be appropriate because a large portion of responders will be switched to other studies and not all participants would have the chance to reach same timepoint.
- The HIV1-RNA threshold of 50, 200 copies/mL will be analysed, respectively, in this study
- The analysis window 'Week 48' and HIV1-RNA threshold of '50 copies/mL' are used for the purpose of illustration. A participant's Snapshot response and reason at Week 48 are categorized as below.
    - HIV1-RNA < 50 copies/mL
    - HIV1-RNA ≥ 50 copies/mL
        - Data in window not below 50
        - Discontinued for lack of efficacy
        - Discontinued for other reason while not below 50
        - Change in background therapy*
    - No Virologic Data at Week 48 Window
        - Discontinued study due to AE or death
        - Discontinued study for other reasons
        - On study but missing data in window

* Note: since changes in ART are not permitted in this protocol, all such participants who change ART during the Maintenance Phase will be considered 'HIV1-RNA ≥ 50 copies/mL'. if the change in ART is made prior to an analysis timepoint. Participants with protocol permitted oral bridging treatment will not be considered 'HIV1-RNA ≥ 50 copies/mL' due to 'change in ART'.

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

Detailed steps

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

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

Condition ('Week 48' indicates Week 48 window)	Response	Reasons
1. If non-permitted change in background therapy prior to Week 48	HIV1-RNA ≥ 50	Change in background therapy

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/m (NA to this study)	HIV1-RNA ≥ 50	Change in background therapy
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	HIV1-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	HIV1-RNA < 50	
• No VL during Week 48 prior to/on the date of change	HIV1-RNA ≥ 50	Change in background therapy
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	HIV1-RNA ≥ 50	Change in background therapy
4. 2 this last on-treatment VL occurs during Week 48 but prior to/on the date of change	HIV1-RNA ≥ 50	Data in window not below 50
5: If none of the above conditions met		
5.1 VL available during Week 48		
• Last on-treatment VL during Week 48 ≥ 50 c/mL	HIV1-RNA ≥ 50	Data in window not below 50
• Last on-treatment VL during Week 48 <50 c/mL	HIV1-RNA < 50	
5.2 No VL during Week 48		
5.2.1 if participants still on study i.e. the upper bound of analysis snapshot window is prior to the following date: **For ABC/DTG/3TC arm:** Min (ABC/DTG/3TC Stop Date + 1, withdrawal date)	No virologic data at Week 48 Window	On study but missing data in window

For Q4W arm: Min[max(Date of last Q4W IM Dose + 35, Date of last oral dose+1), withdrawal date]		
5.2.2 If participants withdraw before/during Week 48 due to		
5.2.2.1 Safety reasons (e.g. AE/death, liver chemistry stopping criteria, renal toxicity withdrawal criteria, QTc withdrawal criteria et al, as recorded in eCRF Conclusion form)	No virologic data at Week 48 Window	Disc due to AE/death
5.2.2.2 Non-safety related reasons (e.g. Lack of efficacy, protocol deviation, withdrew consent, loss to follow-up, study closed/terminated, investigator discretion et al, as recorded in eCRF Conclusion Form)		
• Last on-treatment VL <50 c/mL OR no on-treatment VL available during study	No virologic Data at Week 48 Window	Disc for other reasons
• Last on-treatment VL ≥ 50 c/mL AND withdrawal due to Lack of efficacy	HIV1-RNA ≥ 50	Disc. for lack of efficacy
• Last on-treatment VL ≥ 50 c/mL AND withdrawal due to all other non-safety related reasons	HIV1-RNA ≥ 50	Dis. for other reason while not below 50

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

Examples from FDA guidance

1. Data in Window

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

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

2.No Data in Window

Discontinued study due to Adverse Event or Death:

- Any patient who discontinues because of an AE or death before the window should be classified as Discontinued due to AE or Death (as appropriate), regardless of the HIV-RNA result, even if the HIV-RNA is below 50 copies/mL at the time of discontinuation.
- However, if a patient has an HIV-RNA value in the time window and also discontinues in the time window, the viral load data should be used to classify the patient's response. This is the Virology First hierarchy:

a. HIV-RNA below 50 copies/mL at Day 336 and discontinues because of AE or even dies on Day 360 — this person is categorized as having HIV-RNA below 50 copies/mL.

b. HIV-RNA is 552 copies/mL on Day 336 and the patient discontinues on Day 360, the patient is categorized as having HIV-RNA greater than or equal to 50 copies/mL.

Discontinued for Other Reasons:

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

3.On study but missing data in window:

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

14.12. Appendix 12: AESI identification

SMQ and PT codes based on MedDRA dictionary version 22.0 for Week 96 CSR.

14.12.1. Hepatic Safety Profile

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

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions' Category: A Scope: Narrow	
Preferred Term	PT Code
Acquired hepatocerebral degeneration	10080860
Acute hepatic failure	10000804
Acute on chronic liver failure	10077305
Acute yellow liver atrophy	10070815
Ascites	10003445
Asterixis	10003547
Bacterascites	10068547
Biliary cirrhosis	10004659
Biliary fibrosis	10004664
Cardiohepatic syndrome	10082480
Cholestatic liver injury	10067969
Chronic hepatic failure	10057573
Coma hepatic	10010075
Cryptogenic cirrhosis	10063075
Diabetic hepatopathy	10071265
Drug-induced liver injury	10072268
Duodenal varices	10051010
Gallbladder varices	10072319
Gastric variceal injection	10076237

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions' Category: A Scope: Narrow	
Preferred Term	PT Code
Gastric variceal ligation	10076238
Gastric varices	10051012
Gastric varices haemorrhage	10057572
Hepatectomy	10061997
Hepatic atrophy	10019637
Hepatic calcification	10065274
Hepatic cirrhosis	10019641
Hepatic encephalopathy	10019660
Hepatic encephalopathy prophylaxis	10066599
Hepatic failure	10019663
Hepatic fibrosis	10019668
Hepatic hydrothorax	10067365
Hepatic infiltration eosinophilic	10064668
Hepatic lesion	10061998
Hepatic necrosis	10019692
Hepatic steato-fibrosis	10077215
Hepatic steatosis	10019708
Hepatitis fulminant	10019772
Hepatobiliary disease	10062000
Hepatocellular foamy cell syndrome	10053244
Hepatocellular injury	10019837
Hepatopulmonary syndrome	10052274
Hepatorenal failure	10019845
Hepatorenal syndrome	10019846
Hepatotoxicity	10019851

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions' Category: A Scope: Narrow	
Preferred Term	PT Code
Intestinal varices	10071502
Intestinal varices haemorrhage	10078058
Liver dialysis	10076640
Liver disorder	10024670
Liver injury	10067125
Liver operation	10062040
Liver transplant	10024714
Lupoid hepatic cirrhosis	10025129
Minimal hepatic encephalopathy	10076204
Mixed liver injury	10066758
Nodular regenerative hyperplasia	10051081
Nonalcoholic fatty liver disease	10082249
Non-alcoholic steatohepatitis	10053219
Non-cirrhotic portal hypertension	10077259
Oedema due to hepatic disease	10049631
Oesophageal varices haemorrhage	10030210
Peripancreatic varices	10073215
Portal fibrosis	10074726
Portal hypertension	10036200
Portal hypertensive colopathy	10079446
Portal hypertensive enteropathy	10068923
Portal hypertensive gastropathy	10050897
Portal vein cavernous transformation	10073979
Portal vein dilatation	10073209
Portopulmonary hypertension	10067281

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions' Category: A Scope: Narrow	
Preferred Term	PT Code
Primary biliary cholangitis	10080429
Regenerative siderotic hepatic nodule	10080679
Renal and liver transplant	10052279
Retrograde portal vein flow	10067338
Reye’s syndrome	10039012
Reynold’s syndrome	10070953
Splenic varices	10067823
Splenic varices haemorrhage	10068662
Steatohepatitis	10076331
Subacute hepatic failure	10056956
Varices oesophageal	10056091
Varicose veins of abdominal wall	10072284
White nipple sign	10078438

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 Sub-SMQ: 'Hepatitis, non-infectious’ Category: A Scope: Narrow	
Preferred Term	PT Code
Acute graft versus host disease in liver	10066263
Allergic hepatitis	10071198
Alloimmune hepatitis	10080576
Autoimmune hepatitis	10003827
Chronic graft versus host disease in liver	10072160
Chronic hepatitis	10008909
Graft versus host disease in liver	10064676
Hepatitis	10019717

SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions' Category: A Scope: Narrow	
Preferred Term	PT Code
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

14.12.2. Hypersensitivity Reactions

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

SMQ: Drug reaction with eosinophilia and systemic symptoms syndrome SMQ Code: 20000225 Category: A Scope: Narrow	
Preferred Term	PT Code
Drug reaction with eosinophilia and systemic symptoms	10073508
Pseudolymphoma	10037127

SMQ: Drug reaction with eosinophilia and systemic symptoms syndrome SMQ Code: 20000225 Category: A Scope: Narrow	
Preferred Term	PT Code
Additional preferred terms selected from HLGT 'Allergic conditions' under SOC 'Immune system disorders'	
Preferred Term	PT Code
Drug hypersensitivity	10013700
Hypersensitivity	10020751
Type IV Hypersensitivity reaction	10053613
Eosinophillia	10014950
Eye swelling	10015967
Eyelid oedema	10015993
Lip swelling	10024570
Angioedema	10002424
Circumoral oedema	10052250
Face oedema	10016029
Idiopathic angioedema	10073257
Lip oedema	10024558
Mouth swelling	10075203
Oedema mouth	10030110
Periorbital oedema	10034545
Swelling face	10042682
Periorbital swelling	10056647
Swelling of eyelid	10042690

14.12.3. Rash including severe cutaneous adverse reactions

Medical concept of rash including severe cutaneous adverse reactions. Only narrow terms from SMQ 'Severe cutaneous adverse reactions' selected. Plus several additional preferred terms selected from HLTs 'Rashes, eruptions and exanthems NEC', 'Pruritus

NEC', 'Pustular conditions', 'Dermatitis ascribed to specific agent' all under SOC 'Skin and subcutaneous tissue disorders'.

SMQ: Severe Cutaneous Adverse Reactions SMQ Code: 20000020 Category: A Scope: Narrow	
SMQ	PT Code
Acute generalised exanthematous pustulosis	10048799
Cutaneous vasculitis	10011686
Dermatitis bullous	10012441
Dermatitis exfoliative	10012455
Dermatitis exfoliative generalised	10012456
Drug reaction with eosinophilia and systemic symptoms	10073508
Epidermal necrosis	10059284
Erythema multiforme	10015218
Exfoliative rash	10064579
Oculomucocutaneous syndrome	10030081
Skin necrosis	10040893
Stevens-Johnson syndrome	10042033
Target skin lesion	10081998
Toxic epidermal necrolysis	10044223
Toxic skin eruption	10057970
Additional preferred terms selected from HLTs 'Rashes, eruptions and exanthems NEC', 'Pruritus NEC', 'Pustular conditions', 'Dermatitis ascribed to specific agent' all under SOC 'Skin and subcutaneous tissue disorders'.	
Preferred Term	PT Code
Eyelid rash	10074620
Genital rash	10018175
Mucocutaneous rash	10056671
Nodular rash	10075807

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

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

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

SMQ: Torsade de pointes/QT prolongation SMQ Code: 20000001 Category: A Scope: Narrow	
Preferred Term	PT Code

Electrocardiogram QT interval abnormal	10063748
Electrocardiogram QT prolonged	10014387
Long QT syndrome	10024803
Long QT syndrome congenital	10057926
Torsade de pointes	10044066
Ventricular tachycardia	10047302
Additional preferred terms selected from HGLT ' ECG investigations' under SOC ‘Investigations’.	
Preferred Term	PT Code
Electrocardiogram repolarisation abnormality	10052464

14.12.5. Suicidal Ideation/Behaviour

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

SMQ: 'Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Suicide/self-injury' Category: A Scope: Narrow	
Preferred Term	PT Code
Assisted suicide	10079105
Columbia suicide severity rating scale abnormal	10075616
Completed suicide	10010144
Depression suicidal	10012397
Intentional overdose	10022523
Intentional self-injury	10022524
Poisoning deliberate	10036000
Self-injurious ideation	10051154
Suicidal behaviour	10065604

Suicidal ideation	10042458
Suicide attempt	10042464
Suicide threat	10077417
Suspected suicide	10082458
Suspected suicide attempt	10081704

14.12.6. Depression

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

SMQ: ‘'Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Depression (excl suicide and self injury)' Category: A Scope: Narrow	
Preferred Term	PT Code
Activation syndrome	10066817
Adjustment disorder with depressed mood	10001297
Adjustment disorder with mixed anxiety and depressed mood	10001299
Agitated depression	10001496
Anhedonia	10002511
Antidepressant therapy	10054976
Childhood depression	10068631
Decreased interest	10011971
Depressed mood	10012374
Depression	10012378
Depression postoperative	10012390
Depressive symptom	10054089
Dysphoria	10013954
Electroconvulsive therapy	10014404
Feeling guilty	10049708

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

14.12.7. Bipolar Disorder

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

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

14.12.8. Psychosis

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

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

SMQ: 'Psychosis and psychotic disorders' SMQ Code: 20000117 Category: A Scope: Narrow	
Preferred Term	PT Code
Dementia of the Alzheimer’s type, with delusions	10012295
Depressive delusion	10063033
Derailment	10012411
Epileptic psychosis	10059232
Erotomanic delusion	10015134
Flight of ideas	10016777
Hallucination	10019063
Hallucination, auditory	10019070
Hallucination, gustatory	10019071
Hallucination, olfactory	10019072
Hallucination, synaesthetic	10062824
Hallucination, tactile	10019074
Hallucination, visual	10019075
Hallucinations, mixed	10019079
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Hysterical psychosis	10062645
Ideas of reference	10021212
Illusion	10021403
Jealous delusion	10023164
Loose associations	10024825
Mixed delusion	10076429
Neologism	10028916
Neuroleptic-induced deficit syndrome	10075295
Paranoia	10033864

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

SMQ: 'Psychosis and psychotic disorders' SMQ Code: 20000117 Category: A Scope: Narrow	
Preferred Term	PT Code
Thought blocking	10043495
Thought broadcasting	10052214
Thought insertion	10043496
Thought withdrawal	10043497
Transient psychosis	10056326
Waxy flexibility	10047853

14.12.9. Mood Disorders

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

Preferred Term	PT Code
Affect lability	10054196
Affective ambivalence	10077173
Affective disorder	10001443
Alexithymia	10077719
Anger	10002368
Apathy	10002942
Blunted affect	10005885
Boredom	10048909
Constricted affect	10010778
Crying	10011469
Diencephalic syndrome of infancy	10012774
Dysphoria	10013954
Emotional disorder	10014551
Emotional distress	10049119

Preferred Term	PT Code
Emotional poverty	10014557
Euphoric mood	10015535
Flat affect	10016759
Frustration tolerance decreased	10077753
Inappropriate affect	10021588
Irritability	10022998
Laziness	10051602
Lethargy	10024264
Listless	10024642
Moaning	10027783
Mood altered	10027940
Mood disorder due to a general medical condition	10027944
Mood swings	10027951
Morose	10027977
Neuroleptic-induced deficit syndrome	10075295
Premenstrual dysphoric disorder	10051537
Premenstrual syndrome	10036618
Screaming	10039740
Seasonal affective disorder	10039775
Steroid withdrawal syndrome	10042028
Substance-induced mood disorder	10072387

14.12.10. Anxiety

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

Preferred Terms	PT Code
Acrophobia	10000605
Activation syndrome	10066817
Acute stress disorder	10001084

Preferred Terms	PT Code
Aerophobia	10080300
Agitation	10001497
Agitation postoperative	10049989
Agoraphobia	10001502
Akathisia	10001540
Algophobia	10078056
Animal phobia	10002518
Anniversary reaction	10074066
Anticipatory anxiety	10002758
Anxiety	10002855
Anxiety disorder	10057666
Anxiety disorder due to a general medical condition	10002859
Arachnophobia	10051408
Astraphobia	10078372
Autophobia	10071070
Body dysmorphic disorder	10052793
Burnout syndrome	10065369
Catastrophic reaction	10082329
Cibophobia	10082413
Claustrophobia	10009244
Compulsions	10010219
Compulsive cheek biting	10076510
Compulsive handwashing	10071263
Compulsive hoarding	10068007
Compulsive lip biting	10066241
Compulsive shopping	10067948
Dermatillomania	10065701
Dysmorphophobia	10049096

Preferred Terms	PT Code
Emetophobia	10070637
Fear	10016275
Fear of animals	10016276
Fear of closed spaces	10016277
Fear of crowded places	10050365
Fear of death	10066392
Fear of disease	10016278
Fear of eating	10050366
Fear of falling	10048744
Fear of injection	10073753
Fear of open spaces	10016279
Fear of pregnancy	10067035
Fear of weight gain	10016280
Fear-related avoidance of activities	10080136
Generalised anxiety disorder	10018075
Glossophobia	10080077
Haemophobia	10073458
Haphephobia	10067580
Herpetophobia	10081809
Hydrophobia	10053317
Hyperarousal	10080831
Immunisation anxiety related reaction	10075205
Kinesiophobia	10078430
Limited symptom panic attack	10024511
Mysophobia	10078769
Nail picking	10066779
Nervousness	10029216
Neurosis	10029333

Preferred Terms	PT Code
Noctiphobia	10057946
Nocturnal fear	10057948
Nosophobia	10063546
Obsessive need for symmetry	10077179
Obsessive rumination	10056264
Obsessive thoughts	10029897
Obsessive-compulsive disorder	10029898
Obsessive-compulsive symptom	10077894
Ochlophobia	10050095
Osmophobia	10060765
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	10072147
Panic attack	10033664
Panic disorder	10033666
Panic reaction	10033670
Paruresis	10069024
Performance fear	10034432
Phagophobia	10050096
Pharmacophobia	10069423
Phobia	10034912
Phobia of driving	10056676
Phobia of exams	10034913
Phobic avoidance	10034918
Phonophobia	10054956
Photaugiaphobia	10064420
Postpartum anxiety	10082233
Postpartum neurosis	10036419
Postpartum stress disorder	10056394

Preferred Terms	PT Code
Post-traumatic stress disorder	10036316
Procedural anxiety	10075204
Pseudoangina	10056610
Selective mutism	10039917
Separation anxiety disorder	10040045
Sitophobia	10080170
Social anxiety disorder	10041242
Social fear	10041247
Stress	10042209
Tension	10043268
Terminal agitation	10077416
Thanatophobia	10064723
Thermophobia	10075147
Trichotemnomania	10072752
Trichotillomania	10044629

14.12.11. Sleep Disorders

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

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Preferred Term	PT Code
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Advanced sleep phase	10001423
Behavioural induced insufficient sleep syndrome	10081938
Behavioural insomnia of childhood	10072072
Breathing-related sleep disorder	10006344

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Preferred Term	PT Code
Cataplexy	10007737
Circadian rhythm sleep disorder	10009191
Confusional arousal	10067494
Delayed sleep phase	10012209
Dyssomnia	10061827
Exploding head syndrome	10080684
Hypersomnia	10020765
Hypersomnia related to another mental condition	10020767
Hypersomnia-bulimia syndrome	10053712
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Insomnia related to another mental condition	10022443
Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Loss of dreaming	10065085
Middle insomnia	10027590
Narcolepsy	10028713
Nightmare	10029412
Non-24-hour sleep-wake disorder	10078086
Parasomnia	10061910
Periodic limb movement disorder	10064600
Pickwickian syndrome	10035004
Poor quality sleep	10062519
Rapid eye movement sleep behaviour disorder	10077299

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Preferred Term	PT Code
Rapid eye movements sleep abnormal	10037841
Shift work disorder	10078088
Sleep apnoea syndrome	10040979
Sleep attacks	10040981
Sleep disorder	10040984
Sleep disorder due to a general medical condition	10063910
Sleep disorder due to general medical condition, hypersomnia type	10040985
Sleep disorder due to general medical condition, insomnia type	10040986
Sleep disorder due to general medical condition, mixed type	10040987
Sleep disorder due to general medical condition, parasomnia type	10040988
Sleep inertia	10067493
Sleep paralysis	10041002
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347
Somnolence	10041349
Somnolence neonatal	10041350
Sopor	10058709
Stupor	10042264
Terminal insomnia	10068932
Upper airway resistance syndrome	10063968
HLGT Sleep disturbances (incl subtypes), HLGT code 10040998	
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Advanced sleep phase	10001423

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Preferred Term	PT Code
Behavioural induced insufficient sleep syndrome	10081938
Behavioural insomnia of childhood	10072072
Breathing-related sleep disorder	10006344
Cataplexy	10007737
Central-alveolar hypoventilation	10007982
Circadian rhythm sleep disorder	10009191
Confusional arousal	10067494
Delayed sleep phase	10012209
Dyssomnia	10061827
Fatal familial insomnia	10072077
Hypersomnia	10020765
Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Loss of dreaming	10065085
Microsleep	10076954
Middle insomnia	10027590
Narcolepsy	10028713
Non-24-hour sleep-wake disorder	10078086
Periodic limb movement disorder	10064600
Pickwickian syndrome	10035004
Poor quality sleep	10062519
Rapid eye movement sleep behaviour disorder	10077299
Rapid eye movements sleep abnormal	10037841
Shift work disorder	10078088

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Preferred Term	PT Code
Sleep apnoea syndrome	10040979
Sleep deficit	10080881
Sleep inertia	10067493
Sleep paralysis	10041002
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347
Sudden onset of sleep	10050014
Terminal insomnia	10068932
Upper airway resistance syndrome	10063968

14.12.12. Injection site Reactions

Use eCRF terms for ISR.

14.12.13. Seizures

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

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

SMQ: 'Convulsions' SMQ Code: 20000079 Category: A Scope: Narrow	
Preferred Term	PT Code
Double cortex syndrome	10073490
Dreamy state	10013634
Drug withdrawal convulsions	10013752
Early infantile epileptic encephalopathy with burst-suppression	10071545
Eclampsia	10014129
Epilepsy	10015037
Epilepsy surgery	10079824
Epilepsy with myoclonic-atonic seizures	10081179
Epileptic aura	10015049
Epileptic psychosis	10059232
Febrile convulsion	10016284
Febrile infection-related epilepsy syndrome	10079438
Focal dyscognitive seizures	10079424
Frontal lobe epilepsy	10049424
Generalised non-convulsive epilepsy	10018090
Generalised tonic-clonic seizure	10018100
Glucose transporter type 1 deficiency syndrome	10078727
Grey matter heterotopia	10082084
Hemimegalencephaly	10078100
Hyperglycaemic seizure	10071394
Hypocalcaemic seizure	10072456
Hypoglycaemic seizure	10048803
Hyponatraemic seizure	10073183
Idiopathic generalised epilepsy	10071081
Infantile spasms	10021750

SMQ: 'Convulsions' SMQ Code: 20000079 Category: A Scope: Narrow	
Preferred Term	PT Code
Juvenile myoclonic epilepsy	10071082
Lafora's myoclonic epilepsy	10054030
Lennox-Gastaut syndrome	10048816
Migraine-triggered seizure	10076676
Molybdenum cofactor deficiency	10069687
Multiple subpial transection	10079825
Myoclonic epilepsy	10054859
Myoclonic epilepsy and ragged-red fibres	10069825
Neonatal epileptic seizure	10082068
Neonatal seizure	10082067
Partial seizures	10061334
Partial seizures with secondary generalisation	10056209
Petit mal epilepsy	10034759
Polymicrogyria	10073489
Post stroke epilepsy	10076982
Post stroke seizure	10076981
Postictal headache	10052470
Postictal paralysis	10052469
Postictal psychosis	10070669
Postictal state	10048727
Post-traumatic epilepsy	10036312
Schizencephaly	10073487
Seizure	10039906
Seizure anoxic	10039907
Seizure cluster	10071350

SMQ: ‘Convulsions’ SMQ Code: 20000079 Category: A Scope: Narrow	
Preferred Term	PT Code
Seizure like phenomena	10071048
Severe myoclonic epilepsy of infancy	10073677
Simple partial seizures	10040703
Status epilepticus	10041962
Sudden unexplained death in epilepsy	10063894
Temporal lobe epilepsy	10043209
Tonic clonic movements	10051171
Tonic convulsion	10043994
Tonic posturing	10075125
Topectomy	10073488
Transient epileptic amnesia	10081728
Tuberous sclerosis complex	10080584
Uncinate fits	10045476
Additional selected preferred terms from HLT 'Disturbances in consciousness NEC' under SOC 'Nervous systems disorders' and HLT 'Confusion and disorientation' under SOC 'Psychiatric disorders'.	
Preferred Term	PT Code
Confusional state	10010305
Loss of consciousness	10024855
Syncope	10042772
Sopor	10058709
Stupor	10042264
Altered state of consciousness	10001854
Depressed level of consciousness	10012373
Consciousness fluctuating	10050093

14.12.14. Weight Gain

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

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

14.12.15. Rhabdomyolysis

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

SMQ: 'Rhabdomyolysis/myopathy' SMQ Code: 20000002 Category: A Scope: Narrow	
Preferred Term	PT Code
Muscle necrosis	10028320
Myoglobin blood increased	10028625
Myoglobin blood present	10059888
Myoglobin urine present	10028631
Myoglobinaemia	10058735

SMQ: 'Rhabdomyolysis/myopathy' SMQ Code: 20000002 Category: A Scope: Narrow	
Preferred Term	PT Code
Myoglobinuria	10028629
Myopathy	10028641
Myopathy toxic	10028648
Necrotising myositis	10074769
Rhabdomyolysis	10039020
Thyrotoxic myopathy	10081524
Additional selected preferred terms from HLGT 'muscle disorders' under SOC 'Musculoskeletal and connective tissue disorders'	
Preferred Term	PT Code
Myalgia	10028411
Myositis	10028653

14.12.16. Pancreatitis

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

SMQ: 'Acute pancreatitis' SMQ Code: 20000022 Category: A Scope: Narrow	
Preferred Term	PT Code
Cullen’s sign	10059029
Grey Turner’s sign	10075426
Haemorrhagic necrotic pancreatitis	10076058
Hereditary pancreatitis	10056976
Ischaemic pancreatitis	10066127
Oedematous pancreatitis	10052400

SMQ: 'Acute pancreatitis' SMQ Code: 20000022 Category: A Scope: Narrow	
Preferred Term	PT Code
Pancreatic abscess	10048984
Pancreatic cyst drainage	10082531
Pancreatic haemorrhage	10033625
Pancreatic necrosis	10058096
Pancreatic phlegmon	10056975
Pancreatic pseudoaneurysm	10081762
Pancreatic pseudocyst	10033635
Pancreatic pseudocyst drainage	10033636
Pancreatitis	10033645
Pancreatitis acute	10033647
Pancreatitis haemorrhagic	10033650
Pancreatitis necrotising	10033654
Pancreatitis relapsing	10033657
Pancreatorenal syndrome	10056277

14.12.17. Impact on Creatinine

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

SMQ: ‘Acute renal failure’ SMQ Code: 20000003 Category: A Scope: Narrow	
Preferred Term	PT Code
Acute kidney injury	10069339
Acute phosphate nephropathy	10069688

SMQ: 'Acute renal failure' SMQ Code: 20000003 Category: A Scope: Narrow	
Preferred Term	PT Code
Anuria	10002847
Azotaemia	10003885
Continuous haemodiafiltration	10066338
Dialysis	10061105
Foetal renal impairment	10078987
Haemodialysis	10018875
Haemofiltration	10053090
Neonatal anuria	10049778
Nephropathy toxic	10029155
Oliguria	10030302
Peritoneal dialysis	10034660
Prerenal failure	10072370
Renal failure	10038435
Renal failure neonatal	10038447
Renal impairment	10062237
Renal impairment neonatal	10049776
Subactute kidney injury	10081980

SMQ: ‘Acute renal failure’ SMQ Code: 20000003 Category: A Scope: Narrow	
Preferred Term	PT Code
Plus, all PTs from HLT 'Renal failure and impairment' under SOC 'Renal and urinary disorders'	
Preferred Term	PT Code
Acute Kidney injury	10069339
Anuria	10002847
Atypical haemolytic uraemic syndrome	10079840
Cardiorenal syndrome	10068230
Chronic kidney disease	10064848
Crush syndrome	10050702
Diabetic end stage renal disease	10012660
End stage renal disease	10077512
Foetal renal impairment	10078987
Haemolytic uraemic syndrome	10018932
Hepatorenal failure	10019845
Hepatorenal syndrome	10019846
Nail-patella syndrome	10063431
Neonatal anuria	10049778
Oliguria	10030302
Pancreatorenal syndrome	10056277
Postoperative renal failure	10056675
Postrenal failure	10059345
Prerenal failure	10072370
Propofol infusion syndrome	10063181
Renal failure	10038435
Renal failure neonatal	10038447

SMQ: ‘Acute renal failure’ SMQ Code: 20000003 Category: A Scope: Narrow	
Preferred Term	PT Code
Renal impairment	10062237

SMQ: ‘Acute renal failure’ SMQ Code: 20000003 Category: A Scope: Narrow	
Preferred Term	PT Code
Renal impairment neonatal	10049776
Renal injury	10061481
Scleroderma renal crisis	10062553
Traumatic anuria	10044501

14.12.18. Safety During Pregnancy

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

14.13. Appendix 13: Abbreviations & Trade Marks

14.13.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
BMD	Bone Mineral Density
BMI	Body Mass Index
CAB	Cabotegravir
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CMH	Cochran-Mantel-Haenszel
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
C-SSRS	Columbia Suicide Severity Rating Scale
CTR	Clinical Trial Register
CVb	Coefficient of Variation (Between)
CVb / CVw	Coefficient of Variation (Between) / Coefficient of Variation (Within)
CVD	Cardiovascular Disease
CVF	Confirmed Virologic Failure
DAIDS	Division of AIDS
DBF	Database Freeze
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
ES	Extension Switch Population
FDA	Food and Drug Administration
FSFV	First Subject First Visit
GSK	GlaxoSmithKline
GUI	Guidance
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HSR	Hypersensitivity Reaction
IA	Interim Analysis
ICH	International Conference on Harmonisation
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System

Abbreviation	Description
INI	Integrase Inhibitors
IP	Investigational Product
ITT	Intent-To-Treat
ITT-E	Intent-To-Treat Exposed
LOCF	Last Observation Carries Forward
MMRM	Mixed Model Repeated Measures
NCEP	National Cholesterol Education Program
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NQ	Non Quantifiable
NRTI	Nucleoside Reverse Transcriptase Inhibitors
OC	Observed Case
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PI	Protease Inhibitors
PK	Pharmacokinetic
PopPK	Population PK
PP	Per Protocol
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAMOS	Randomisation & 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	Standardized MedDRA Queries
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings
TRDF	Treatment Related Discontinuation Failure

14.13.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
Dolutegravir
Triumeq

Trademarks not owned by the GlaxoSmithKline Group of Companies
NONMEM
Rilpivirine
SAS
WinNonlin

14.14. Appendix 14: List of Data Displays for Week 48/Week 96

All data displays (Tables, Figures & Listings) will use the term "Subject" which reflects CDISC and GSK Data Display Standards terminology.

14.14.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.01 to 1.n	1.01 to 1.n
Efficacy	2.01 to 2.n	2.01 to 2.n
Safety	3.01 to 3.n	3.01 to 3.n
Pharmacokinetic	4.01 to 4.n	4.01 to 4.n
Pharmacokinetic / Pharmacodynamic	5.01 to 5.n	5.01 to 5.n
Health Outcomes	6.01 to 6.n	6.01 to 6.n
Virology	7.01 to 7.n	7.01 to 7.n
Section	**Listings**	
ICH Listings	1 to x	
Other Listings	y to z	

14.14.2. Mock Example Shell Referencing

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

14.14.3. Deliverables

Delivery [1]	Description
HL	Headline at Week 48
W48	Week 48
W96	Week 96
EOS	End of study

NOTES:
1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort.

14.14.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.1.	All Subjects Screened	SA1	Summary of Study Populations	CS CORE For W96: add column for 'Switch Q4W'	HL, W48, W96, EOS
1.2.	All Subjects Screened	Shell TSP1	Summary of Subjects by Country and Investigator	For W96: add column for 'Switch Q4W'	W48, W96, EOS
1.3.	All Subjects Screened	ES6	Summary of Screening Status and Reasons for Screening Failures	CS CORE	W48, W96, EOS
1.4.	All Enrolled	EudraCT age	Summary of Age Categories	CS CORE	W48, W96, EOS
1.5.	ITT-E	ES1	Summary of Subject Accountability: Study Conclusion Record	ICH E3, GSK CTR, FDAAA, EudraCT For W96: add column for 'Switch Q4W'	W48, W96, EOS
1.6.	ITT-E	ES1	Summary of Study Drug Discontinuation	CS CORE For W96: add column for 'Switch Q4W'	W48, W96, EOS
1.7.	ITT-E	ES1	Summary of Subject Accountability: Maintenance Phase Conclusion Record	ICH E3, GSK CTR, FDAAA, EudraCT	HL, W48, W96
1.8.	LTFU	ES1	Summary of Subject Accountability: Long-term follow up Phase Conclusion Record	ICH E3, GSK CTR, FDAAA, EudraCT For W96: add column for 'Switch Q4W'	W48, W96, EOS

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.9.	ITT-E	HIV_ES1	Summary of Subject Accountability: Withdrawals by Visit - Maintenance Phase		W48, W96
1.10.	ITT-E	ES1	Summary of Subject Accountability: Maintenance and Extension Phase Conclusion Record (Randomized Q4W)	For Randomized Q4W arm only Add the following subcategories under subject status: a) Completed Maintenance and did not enter Extension b) Completed Extension c) Withdrawn from Maintenance d) Withdrawn from Extension.	W96, EOS
1.11.	ITT-E	HIV_ES1	Summary of Subject Accountability: Withdrawals by Visit – Maintenance and Extension Phase (Randomized Q4W)	For Randomized Q4W arm only	W96, EOS
1.12.	ES	ES1	Summary of Subject Accountability: Extension Phase Conclusion Record (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
1.13.	ES	HIV_ES1	Summary of Subject Accountability: Withdrawals by Visit – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
1.14.	All Participants Enrolled	ES4	Summary of Subject Disposition at Each Study Epoch	See Mid200056//wk96cdisc/Table 6.1006 For W96: add column for 'Switch Q4W'	W48, W96, EOS
1.15.	All Participants Enrolled	ES5	Summary of Reasons for Withdrawal at Each Epoch	See Mid200056//wk96cdisc/Table 6.1007 For W96: add column for 'Switch Q4W'	W48, W96, EOS

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.16.	ITT-E	DV1a	Summary of Important Protocol Deviations (Maintenance Phase)	CS CORE	W48, W96
1.17.	ITT-E	DV1a	Summary of Important Protocol Deviations - Maintenance and Extension Phase (Randomized Q4W)	CS CORE For Randomized Q4W arm only	W96, EOS
1.18.	ES	DV1a	Summary of Important Protocol Deviations – Extension Phase (Extension Switch Population)	CS CORE Switch Q4W IM group only	W96, EOS
1.19.	ITT-E	SP2	Summary of Protocol Deviations Leading to Exclusion from the Per-Protocol Population (Week X Analysis) [X =Week 48 or Week 96, depending on the deliverable)]	CS CORE Exclude deviations occurring during the Extension phase	W48, W96
1.20.	ITT-E	IE1	Summary of Inclusion/Exclusion Criteria Deviations		W48, W96, EOS
1.21.	All Participants Enrolled	ES1	Summary of Subject Accountability: Induction Phase Conclusion Record	ICH E3, GSK CTR, FDAAA, EudraCT	W48
Demography and Baseline					
1.22.	ITT-E	Shell TSP2	Summary of Demographic Characteristics	See also DM1 in IDSL Age categorization will include: <=18, 19-64, >=65 (FDAAA requirement) 18-64, 65-84, >=85 (EMA requirement)	HL, W48, W96, EOS
1.23.	ITT-E	DM5	Summary of Race and Racial Combinations	CS CORE	W48, W96, EOS

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.24.	ITT-E	DM6	Summary of Race and Racial Combinations Details	CS CORE	W48, W96, EOS
1.25.	ITT-E	Shell TSP3	Summary of Hepatitis Status at Induction Baseline (Week -20)		W48, W96, EOS
1.26.	ITT-E	CDC1	Summary of Derived CDC Stages of HIV Infection at Maintenance Baseline (Day 1)		W48, W96, EOS
1.27.	ITT-E	Shell TSP4	Summary of Induction Baseline (Week -20) Cardiovascular Risk Assessments		W48, W96, EOS
1.28.	ITT-E	Shell TSP5	Distribution of CD4+ Cell Count Results at Maintenance Baseline (Day 1)	Same presentation as shown in the mock shell for induction baseline.	W48, W96, EOS
1.29.	ITT-E	Shell TSP5	Distribution of Quantitative Plasma HIV-1 RNA and CD4+ Cell Count Results at Screening and Induction Baseline (Week -20)		W48, W96, EOS
Medical Conditions, Concomitant Medications & Antiretroviral Therapy					
1.30.	ITT-E	MH1	Summary of Current Medical Conditions	CS CORE	W48, W96, EOS
1.31.	ITT-E	MH1	Summary of Past Medical Conditions	CS CORE	W48, W96, EOS
1.32.	ITT-E	MH4	Summary of Current Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary disorders		W48, W96, EOS

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.33.	ITT-E	MH4	Summary of Past Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary disorders		W48, W96, EOS
1.34.	ITT-E	CM8	Summary of Concomitant Medication Ingredient Combinations (Maintenance Phase)		W48, W96
1.35.	ITT-E	CM8	Summary of Concomitant Medication Ingredient Combinations - Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
1.36.	ES	CM8	Summary of Concomitant Medication Ingredient Combinations – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
1.37.	ITT-E	Shell TSP11	Summary of Alternate Background NRTI Therapy at End of Induction Phase		W48, W96, EOS
1.38.	ITT-E	Shell TSP9	Summary of Lipid Modifying Agent Use at Maintenance Baseline (Day 1)	taken during the 12 weeks before the first Maintenance Phase dose of study drug	W48, W96, EOS
1.39.	ITT-E	Shell TSP10	Summary of Lipid Modifying Agent Use Started During Maintenance		W48, W96, EOS
1.40.	ITT-E	SU1	Summary of Substance Use at Entry		W48, W96, EOS
1.41.	ITT-E	Shell TSP12	Summary of HIV Risk Factor		W48, W96, EOS
1.42.	ITT-E	Shell TSP13	Summary of Time from First HIV-1 RNA < 50 copies/mL until Initiation of Maintenance Phase Treatment		W48, W96, EOS
1.43.	ITT-E	Shell CLAD1	Summary of the Prevalence of HIV-1 Subtype		W48, W96

14.14.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Primary Efficacy Analyses					
2.1.	ITT-E	Shell TPEF1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	HL, W48, W96
2.2.	Per-Protocol	Shell TPEF1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis (Per-Protocol Population)	For W96 deliverable, replace 'Week 48' with 'Week 96'	HL, W48, W96
2.3.	ITT-E	Shell TPEF2	Summary of Study Outcomes (50 c/mL cut-off) at Week 48 (Maintenance Phase) – Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	HL, W48, W96
2.4.	ITT-E	Shell TPEF3	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 W96 deliverable, replace 'Week 48' with 'Week 96'	HL, W48, W96
2.5.	ITT-E	Shell TPEF4	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL at Week 48 by Subgroup (Maintenance Phase) - Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	W48, W96
2.6.	ITT-E	Shell TPEF5	Summary of Study Outcomes (50 c/mL cut-off) at Week 48 by Subgroup (Maintenance Phase) – Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	W48, W96
Secondary Efficacy Analyses					
2.7.	ITT-E	Shell TPEF1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	HL, W48, W96
2.8.	Per-Protocol	Shell TPEF1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis (Per-Protocol Population)	For W96 deliverable, replace 'Week 48' with 'Week 96'	HL, W48, W96

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.9.	ITT-E	Shell TPEF3	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 W96 deliverable, replace 'Week 48' with 'Week 96'	W48, W96
2.10.	ITT-E	Shell TPEF4	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL at Week 48 by Subgroup (Maintenance Phase) - Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	W48, W96
2.11.	ITT-E	Shell TSEF2	Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.12.	ITT-E	Shell TSEF2.1	Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL by Subgroup and Visit (Maintenance Phase) – Snapshot Analysis		W48
2.13.	ITT-E	Shell TSEF7.0	Summary of Kaplan-Meier Estimates of Proportion of Subjects Without Confirmed Virologic Failure at Week 48 - *Treatment Related Discontinuation = Failure*	For W96 deliverable, replace 'Week 52' with 'Week 100'	W48, W96
2.14.	ITT-E	Shell TSEF7.1	Summary of Kaplan-Meier Estimates of Proportion of Subjects Without Confirmed Virologic Failure at Week 48 - *Efficacy Related Discontinuation = Failure*	For W96 deliverable, replace 'Week 52' with 'Week 100'	W48, W96
2.15.	ITT-E	Shell TSEF2.1	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.16.	ITT-E	Shell TSEF2	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Subgroup and Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.17.	ITT-E	Shell TSEF2	Proportion of Subjects with Plasma HIV-1 RNA <200 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.18.	ITT-E	Shell TSEF9	Proportion of Subjects with HIV-1 RNA≥50 c/mL at Week 48 (Snapshot) by Last Delay in IP Injection (Maintenance Phase)	For Q4W IM arm only. The last delay in IP injection is the delay in IP injection at Week 48, or delay in last IP injection prior to Week 48 if a subject has no injection at WK48 (e.g., missing visit or early withdrawal)	W48

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.19.	ITT-E	Shell TSEF8	Summary of Plasma HIV-1 RNA (log10 c/mL) by Visit (Maintenance Phase)		W48, W96 EOS
2.20.	ITT-E	Shell TSEF8	Summary of Change from Maintenance Baseline (Day 1) in Plasma HIV-1 RNA (log10 c/mL) by Visit (Maintenance Phase)		W96, EOS
2.21.	ITT-E	Shell TSEF3	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria by Visit During the Maintenance Phase (Up to Week 52)	For Week 96 deliverable, show all visit up to Week 100.	HL, W48, W96
2.22.	ITT-E	Shell TSEF3.1	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria During the Maintenance Phase		HL, W48, W96
2.23.	ITT-E	Shell TSEF3.1	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria During the Maintenance and Extension Phase (Randomized Q4W)	For Randomized Q4W arm only	W96, EOS
2.24.	ES	Shell TSEF3.1	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria During the Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
2.25.	CVF	Shell TSEF4	Distribution of Quantitative Plasma HIV-1 RNA Results at Suspected and Confirmation of Confirmed Virologic Failure – Maintenance Phase		W48, W96
2.26.	ITT-E	Shell TSEF5	Summary of Change from Maintenance Baseline (Day 1) in CD4+ Cell Count (cells/mm^3) by Visit -Maintenance Phase	Visits starting from Maintenance Baseline (Day 1), Week 4, …	W48, W96
2.27.	ITT-E	Shell TSEF5	Summary of Change from Maintenance Baseline (Day 1) in CD4+ Cell Count (cells/mm^3) by Visit - Maintenance and Extension Phase (Randomized Q4W)	Visits starting from Maintenance Baseline (Day 1), Week 4, …	EOS
2.28.	ES	Shell TSEF5	Summary of Change from Extension Baseline (Week 100) in CD4+ Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)		EOS

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.29.	ITT-E	Shell TSEF5	Summary of Change from Maintenance Baseline (Day 1) in CD4+ Cell Count (cells/mm^3) at Week 48 by Subgroup (Maintenance Phase)	Visits starting from Maintenance Baseline (Day 1), Week 4, … For W96 deliverable, replace 'Week 48' with 'Week 96'	W48, W96
2.30.	ITT-E	Shell TSEF5	Summary of CD4+ Cell Count (cells/mm^3) by Visit– Induction and Maintenance Phase	Visits starting from Induction Baseline (Week -20), Week -16,	W48, W96, EOS
2.31.	ITT-E	Shell TSEF5	Summary of CD4+ Cell Count (cells/mm^3) by Visit – Maintenance and Extension Phase (Randomized Q4W)	Visits starting from Induction Baseline (Week -20), Week -16,	EOS
2.32.	ES	Shell TSEF5	Summary of CD4+ Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)		EOS
2.33.	ITT-E	Shell TSEF5	Summary of CD8+ Cell Count (cells/mm^3) by Visit – Induction + Maintenance Phase	Visits starting from Induction Baseline (Week -20), Week -16,	W48, W96, EOS
2.34.	ITT-E	Shell TSEF5	Summary of CD8+ Cell Count (cells/mm^3) by Visit – Maintenance and Extension Phase (Randomized Q4W)	Visits starting from Induction Baseline (Week -20), Week -16,	EOS
2.35.	ES	Shell TSEF5	Summary of CD8+ Cell Count (cells/mm^3) by Visit– Extension Phase (Extension Switch Population)		EOS
2.36.	ITT-E	Shell TSEF5	Summary of Change from Maintenance Baseline (Day 1) in CD8+ Cell Count (cells/mm^3) by Visit – Maintenance Phase)	Visits starting from Induction Maintenance Baseline, Week 4, …	W48, W96,
2.37.	ITT-E	Shell TSEF5	Summary of Change from Maintenance Baseline (Day 1) in CD8+ Cell Count (cells/mm^3) by Visit – Maintenance and Extension Phase (Randomized Q4W)	Visits starting from Maintenance Baseline (Day 1), Week 4, …	EOS
2.38.	ES	Shell TSEF5	Summary of Change from Maintenance Baseline (Day 1) in CD8+ Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)		EOS
2.39.	ITT-E	Shell TSEF5	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit – Induction and Maintenance Phase	While both CD4+ and CD8+ are available on the same date	W48, W96

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.40.	ITT-E	Shell TSEF5	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit – Induction, Maintenance and Extension Phase (Randomized Q4W)	For Randomized Q4W arm only	EOS
2.41.	ES	Shell TSEF5	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)		EOS
2.42.	ITT-E	HIV1/Shell TSEF 6.0	Summary of Maintenance Phase HIV-1 Associated Conditions Including Recurrences		W48, W96
2.43.	ITT-E	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Including Recurrences - Maintenance and Extension Phase (Randomized Q4W)	For Randomized Q4W arm only	EOS
2.44.	ES	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Including Recurrences – Extension Phase (Extension Switch Population)		EOS
2.45.	ITT-E	HIV1/Shell TSEF 6.0	Summary of Maintenance Phase HIV-1 Associated Conditions Excluding Recurrences		W48, W96
2.46.	ITT-E	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Excluding Recurrences - Maintenance and Extension Phase (Randomized Q4W)	For Randomized Q4W arm only	EOS
2.47.	ES	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Excluding Recurrences – Extension Phase (Extension Switch Population)		EOS
2.48.	ITT-E	HIV2/Shell TSEF6.1	Summary of HIV-1 Disease Progression and/or Deaths (Maintenance Phase)		W48, W96
2.49.	ITT-E	HIV2/Shell TSEF6.1	Summary of HIV-1 Disease Progressions and/or Deaths - Maintenance and Extension Phase (Randomized Q4W)	For Randomized Q4W arm only	EOS
2.50.	ES	HIV2/Shell TSEF6.1	Summary of HIV-1 Disease Progressions – Extension Phase (Extension Switch Population)		EOS
2.51.	ITT-E	TSEF12	Proportion of Subjects with Plasma HIV-1 RNA <2 copies/mL by Visit - Observed Case Analysis (Maintenance Phase)		W48, W96
2.52.	ITT-E	Shell TPEF2	Summary of Study Outcomes (200 c/mL) at Week 48 (Maintenance Phase) – Snapshot Analysis	For W96 analysis, replace ‘Week 48’ with ‘Week 96’	W48, W96
2.53.	ITT-E	Shell TSEF11	Summary of Subjects per Viral Load Category by Visit – Maintenance Phase)		W48, W96

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.54.	All Participants Enrolled	Shell TSEF12	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (Observed data) – Induction Phase	Induction Baseline (Week -20), Week -16, Week -8, Week -4 and Day 1. Single arm for Induction ABC/DTG/3TC	W48

14.14.6. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Primary Efficacy Analyses					
2.1.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.2.	ITT - E	Shell FPEF2	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL at Week 48 by Subgroup – Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	W48, W96
2.3.	ITT-E	SNAPSHOT9B	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA >= 50 c/mL at Week 96 by Selected Demographic Subgroups (Maintenance Phase) - Snapshot Analysis	Include: Overall, Gender at Birth (Female, Male), Age (<35, 35-<50, >=50), Induction Baseline (Week -20) BMI (<30, >=30), Region (Western/Central Europe and North America, Russian Federation, Japan, South Africa).	W96

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.4.	ITT-E	SNAPSHOT9B	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA >= 50 c/mL at Week 96 by Selected HIV Disease Characteristic Subgroups (Maintenance Phase) - Snapshot Analysis	Include: Overall, Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000), Induction BL (Week -20) CD4+ cell count (<200, 200 to <350, 350 to <500, >=500), HIV-1 Subtype (A, A1, AE, Ag, B, C, Other)	W96
Secondary Efficacy Analyses					
2.5.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.6.	ITT-E	SNAPSHOT9B	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA < 50 c/mL at Week 96 by Selected Demographic Subgroups (Maintenance Phase) - Snapshot Analysis	Include: Overall, Gender at Birth (Female, Male), Age (<35, 35-<50, >=50), Induction Baseline (Week -20) BMI (<30, >=30), Region (Western/Central Europe and North America, Russian Federation, Japan, South Africa).	W96
2.7.	ITT-E	SNAPSHOT9B	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA < 50 c/mL at Week 96 by Selected HIV Disease Characteristic Subgroups (Maintenance Phase) - Snapshot Analysis	Include: Overall, Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000), Induction BL (Week -20) CD4+ cell count (<200, 200 to <350, 350 to <500, >=500), HIV-1 Subtype (A, A1, AE, Ag, B, C, Other)	W96
2.8.	ITT - E	Shell FPEF2	Unadjusted Treatment Difference in Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL at Week 48 by Subgroup – Snapshot Analysis	For W96 analysis, replace 'Week 48' with 'Week 96'	W48, W96

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.9.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA <200 c/mL by Visit (Maintenance Phase) – Snapshot Analysis		W48, W96
2.10.	ITT-E	Mid200056//wk 96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA (log10 copies/mL) Profiles by Visit– for CVF subjects (Randomized Q4W)	The first vertical line indicates start of Induction phase investigational product (ABC/DTG/3TC or DTG). The second vertical line indicates start of Maintenance phase investigational product (oral CAB + oral RPV). The third vertical reference line indicates last on-treatment study day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB+RPV+1), day of LTFU HAART start date). This line is only for participants who withdraw from the Maintenance/Extension phase.	HL, W48, W96, EOS

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.11.	ITT-E	Mid200056//wk96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA (log10 copies/mL) Profiles by Visit – for CVF subjects (Randomized ABC/DTG/3TC arm)	The first vertical line indicates start of Induction phase investigational product (ABC/DTG/3TC or DTG). The second vertical line indicates start of Maintenance phase investigational product (continuation of ABC/DTG/3TC or DTG). The third vertical reference line indicates last Maintenance phase on-treatment study day, i.e. day of last ABC/DTG/3TC (or DTG) dose + 1. This line is only for participants who withdraw or complete the Maintenance phase. The fourth vertical reference line indicates last Extension Phase on-treatment study day, i.e. min (max (day of last IP injection dose+35 days, day of last oral CAB+RPV+1), day of LTFU HAART start date). This line is only for participants who withdraw from the Extension phase.	HL, W48, W96, EOS

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.12.	ITT - E	Mid200056//wk96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA for subjects who are in the category of 'HIV-1 RNA ≥50 c/mL' at Week 48 per Snapshot algorithm (Randomized Q4W arm)	The first vertical line indicates start of Induction phase investigational product (ABC/DTG/3TC or DTG). The second vertical line indicates start of Maintenance phase investigational product (oral CAB + oral RPV). The third vertical reference line indicates last on-treatment study day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB+RPV+1), day of LTFU HAART start date). This line is only for participants who withdraw from the Maintenance/Extension phase. For W96 analysis, replace 'Week 48' with 'Week 96'	HL, W48, W96

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.13.	ITT - E	Mid200056//wk 96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA for subjects who are in the category of 'viral load ≥50 c/mL' at Week 48 per Snapshot algorithm (Randomized ABC/DTG/3TC arm)	The first vertical line indicates start of Induction phase investigational product (ABC/DTG/3TC or DTG). The second vertical line indicates start of Maintenance phase investigational product (continuation of ABC/DTG/3TC or DTG). The third vertical reference line indicates last Maintenance phase on-treatment study day, i.e. day of last ABC/DTG/3TC (or DTG) dose + 1. This line is only for participants who withdraw or complete the Maintenance phase. The fourth vertical reference line indicates last Extension Phase on-treatment study day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB+RPV+1), day of LTFU HAART start date). This line is only for participants who withdraw from the Extension phase. For W96 analysis, replace 'Week 48' with 'Week 96'	HL, W48, W96
2.14.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA >=200 c/mL by Visit – Snapshot Analysis		W48, W96

14.14.7. Safety Tables

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
3.1.	Safety	Shell TS1.1	Summary of Extent of Exposure to Investigational Product – Maintenance Phase	CS Core	W48, W96, EOS
3.2.	Safety	Shell TS1.1	Summary of Extent of Exposure to Investigational Product – Maintenance Phase and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS
3.3.	ES	Shell TS1.1	Summary of Extent of Exposure to Investigational Product – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	W96, EOS
3.4.	Safety	Study 201584 (primary_02): Table 3.114	Summary of Categorized Needle Length and Gauge for CAB Injection - Maintenance Phase	Randomized Q4W arm only	W48, W96
3.5.	Safety	Study 201584 (primary_02): Table 3.115	Summary of Categorized Needle Length and Gauge for RPV Injection - Maintenance Phase	Randomized Q4W arm only	W48, W96
3.6.	Safety	Shell TS1.3	Summary of Adherence to Q4W IM Dosing Schedule - Maintenance Phase	(only for randomized Q4W arm) please refer to Section 14.6.2-- Adherence to CAB/RPV Injection Schedule	W48, W96
Adverse Events					
3.7.	Safety	AE1	Summary of All Adverse Events by System Organ Class – Maintenance Phase	CS Core	W48, W96
3.8.	Safety	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Maintenance Phase	CS Core	HL, W48, W96
3.9.	Safety	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.10.	ES	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	W96, EOS
3.11.	Safety	AE5B	Summary of All On-treatment Adverse Events by System Organ Class and Maximum Toxicity – Maintenance Phase	CS Core	W48, W96
3.12.	LTFU	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Long-term Follow-up Phase	CS Core	EOS
3.13.	Safety	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Oral Lead-in Period at Maintenance Phase	CS Core Randomized Q4W arm only	HL, W48
3.14.	Safety	AE3	Summary of Common Adverse Events (>=5%) by Overall Frequency – Maintenance Phase	CS Core	W48, W96
3.15.	Safety	AE3	Summary of Common Grade 2-5 Adverse Events (>=1%) by Overall Frequency – Maintenance Phase		W48, W96
3.16.	Safety	AE1	Summary of All Drug-Related Adverse Events by System Organ Class– Maintenance Phase		W48, W96
3.17.	Safety	AE5B	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Toxicity – Maintenance Phase	CS Core	HL, W48, W96
3.18.	Safety	AE5B	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS
3.19.	ES	AE5B	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	W96, EOS
3.20.	Safety	AE3	Summary of All Drug-Related Grade 2-5 Adverse Events by Overall Frequency – Maintenance Phase		W48, W96
Serious and Other Significant Adverse Events					
3.21.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class – Maintenance Phase	CS Core	HL, W48, W96

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.22.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS
3.23.	ES	AE1	Summary of Serious Adverse Events by System Organ Class – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	W96, EOS
3.24.	LTFU	AE1	Summary of Serious Adverse Events by System Organ Class – Long term follow up	CS Core	W48, W96, EOS
3.25.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class –– Oral Lead-in Period at Maintenance Phase	CS Core Randomized Q4W arm only	HL, W48
3.26.	Safety	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class – Maintenance Phase	CS Core	W48, W96
3.27.	Safety	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS
3.28.	ES	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM only	W96, EOS
3.29.	Safety	AE3	Summary of Non-Fatal Serious Adverse Events by Overall Frequency – Maintenance Phase		W48, W96
3.30.	Safety	AE3	Summary of Drug-Related Non-Fatal Serious Adverse Events by Overall Frequency – Maintenance Phase		W48, W96
3.31.	Safety	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class – Maintenance Phase	CS Core	HL, W48, W96
3.32.	Safety	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by SOC – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.33.	ES	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by SOC – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	W96, EOS
3.34.	Safety	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by SOC – Oral Lead-in Period at Maintenance Phase	CS Core Randomized Q4W arm only	W48, W96
3.35.	Safety	AE3	Summary of Common (>=5%) Non-Serious Adverse Events by Overall Frequency – Maintenance Phase	CS Core	W48, W96
3.36.	Safety	EudraCT Non-serious AE AE15	Summary of Subjects and Number of Occurrences of Common (>=5%) Non-Serious Adverse Events by System Organ Class – Maintenance Phase	CS Core for FDAAA and EMA disclosure requirements. EudraCT Use macro TD_AE4VCTR for New Data Disclosure HARP Reporting Tools	W48, W96
3.37.	Safety	EudraCT SAE AE16	Summary of Subjects and Number of Occurrences of SAEs, Fatal SAEs, and Drug-related SAEs – Maintenance Phase	CS Core for FDAAA and EMA disclosure requirements. EudraCT	W48, W96
3.38.	Safety	Shell TS2.1	Summary of Cumulative Adverse Events by Visit – Maintenance Phase	Please note this table only display AEs occurring >=5% subjects during Maintenance Phase	W48, W96
3.39.	All Participants Enrolled	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class – Induction Phase	CS Core	W48
Injection Site Reaction Adverse Events					
3.40.	Safety	Shell TS2.2	Summary of Injection Site Reaction Adverse Events (Event-Level Summary) – Maintenance Phase	Randomized Q4W arm only	HL, W48, W96
3.41.	Safety	Shell TS2.2	Summary of Injection Site Reaction Adverse Events (Event-Level Summary) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.42.	ES	Shell TS2.2	Summary of Injection Site Reaction Adverse Events (Event-Level Summary) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.43.	Safety	Shell TS2.3	Summary of Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Maintenance Phase	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W48, W96
3.44.	Safety	Shell TS2.3	Summary of Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W96, EOS
3.45.	ES	Shell TS2.3	Summary of Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (Switch Q4W IM group only)	W96, EOS
3.46.	Safety	Shell TS2.4	Summary of Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Maintenance Phase	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W48, W96
3.47.	Safety	Shell TS2.2	Summary of CAB Drug-Related Injection Site Reaction Adverse Events (Event-Level Summary) – Maintenance Phase	Randomized Q4W arm only	W48, W96
3.48.	Safety	Shell TS2.3	Summary of CAB Drug-Related Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Maintenance Phase	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for Q4W arm only)	W48, W96
3.49.	Safety	Shell TS2.4	Summary of CAB Drug-Related Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Maintenance Phase	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for Q4W arm only)	W48, W96

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.50.	Safety	Shell TS2.5	Summary of Maximum CAB Drug-Related Injection Site Reaction Adverse Event Grade by Needle Length (Common ISRs) – Maintenance Phase	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W48, W96
3.51.	Safety	Shell TS2.2	Summary of RPV Drug-Related Injection Site Reaction Adverse Events (Event-Level Summary) – Maintenance Phase		W48, W96
3.52.	Safety	Shell TS2.3	Summary of RPV Drug-Related Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Maintenance Phase	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W48, W96
3.53.	Safety	Shell TS2.4	Summary of RPV Drug-Related Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Maintenance Phase		W48, W96
3.54.	Safety	Shell TS2.5	Summary of Maximum RPV Drug-Related Injection Site Reaction Adverse Event Grade by Needle Length (Common ISRs) – Maintenance Phase	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for Q4W arm only)	W48, W96
Laboratory: Chemistry, Hematology and Renal Markers					
3.55.	Safety	LB1	Summary of Chemistry Changes from Maintenance Baseline (Day 1) by Visit – Maintenance Phase	CS Core (include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Cystatin C, and CKD-EP1 GFR using Creatinine, and CKD-EP1 using Cystatin C et al	W48, W96

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.56.	Safety	LB1	Summary of Chemistry Changes from Maintenance Baseline (Day 1) by Visit – Maintenance and Extension Phase (Randomized Q4W)	CS Core (include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Cystatin C, and CKD-EP1 GFR using Creatinine, and CKD-EP1 using Cystatin C et al) Randomized Q4W arm only	EOS
3.57.	ES	LB1	Summary of Chemistry Changes from Extension Baseline (Week 100) by Visit – Extension Phase (Extension Switch Population)	CS Core (include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Cystatin C, and CKD-EP1 GFR using Creatinine, and CKD-EP1 using Cystatin C et al) Switch Q4W IM group only	EOS
3.58.	Safety	LB1	Summary of Chemistry Values by Visit – Maintenance Phase	(include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Beta-2 Microglobulin, Cystatin C, et al)	W48, W96, EOS
3.59.	Safety	LB1	Summary of Chemistry Values by Visit – Maintenance and Extension Phase (Randomized Q4W)	(include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Beta-2 Microglobulin, Cystatin C, et al) Randomized Q4W arm only	EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.60.	ES	LB1	Summary of Chemistry Values by Visit – Extension Phase (Extension Switch Population)	(include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Beta-2 Microglobulin, Cystatin C, et al) Switch Q4W IM group only	EOS
3.61.	Safety	LB1	Summary of Hematology Changes from Maintenance Baseline (Day 1) by Visit – Maintenance Phase	CS Core	W48, 96, EOS
3.62.	Safety	LB1	Summary of Hematology Changes from Maintenance Baseline (Day 1) by Visit – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	EOS
3.63.	ES	LB1	Summary of Hematology Changes from Maintenance Baseline (Day 1) by Visit – Extension Phase (Extension Switch Population)	CS Core	EOS
3.64.	Safety	LB1	Summary of Hematology Values by Visit – Maintenance Phase	CS Core	W48, W96, EOS
3.65.	Safety	LB1	Summary of Hematology Values by Visit – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	EOS
3.66.	ES	LB1	Summary of Hematology Values by Visit – Extension Phase (Extension Switch Population)	CS Core	EOS
3.67.	Safety	Shell TS9.1	Summary of Maximum Maintenance Phase Emergent Chemistry Toxicities	CS Core	W48, W96
3.68.	Safety	Shell TS9.2	Summary of Maximum Maintenance and Extension Phase Emergent Chemistry Toxicities (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS
3.69.	ES	Shell TS9.3	Summary of Maximum Extension Phase Emergent Chemistry Toxicities – Extension Switch Population	CS Core Switch Q4W IM group only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.70.	Safety (Q4W IM only)	Shell TS9.2	Summary of Maximum Maintenance Phase Emergent Chemistry Toxicities – Maintenance Phase Oral Lead-in Period	CS Core Randomized Q4W arm only	W48
3.71.	Safety	Shell TS9.1	Summary of Maximum Maintenance Phase Emergent Hematology Toxicities	CS Core	W48, W96
3.72.	Safety	Shell TS9.2	Summary of Maximum Maintenance and Extension Phase Emergent Hematology Toxicities (Randomized Q4W)	CS Core Randomized Q4W arm only	W96, EOS
3.73.	ES	Shell TS9.3	Summary of Maximum Extension Phase Emergent Hematology Toxicities – Extension Switch Population	CS Core (for ABC/DTG/3TC arm only	W96, EOS
3.74.	Safety (Q4W IM only)	Shell TS9.2	Summary of Maximum Maintenance Phase Emergent Hematology Toxicities – Maintenance Phase Oral Lead-in Period	CS Core Randomized Q4W arm only	W48
3.75.	Safety	Shell TS16	Summary of Fasting Lipids Percentage Changes from Maintenance Baseline (Day 1) by Visit (Lipid LOCF) – Maintenance Phase		W48, W96
Laboratory: Urinalysis					
3.76.	Safety	UR3 or SHELL TS3	Summary of Urinalysis Dipstick Results by Visit – Maintenance Phase (Randomized Q4W)		W48, W96, EOS
3.77.	Safety	UR3 or SHELL TS3	Summary of Urinalysis Dipstick Results by Visit – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	EOS
3.78.	ES	UR3 or SHELL TS3	Summary of Urinalysis Dipstick Results by Visit – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	EOS
3.79.	Safety	LB1	Summary of Urine Concentrations Changes from Maintenance Baseline (Day 1) by Visit – Maintenance Phase	CS Core	W48, W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.80.	Safety	LB1	Summary of Urine Concentrations Changes from Maintenance Baseline (Day 1) by Visit – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	EOS
3.81.	ES	LB1	Summary of Urine Concentrations Changes from Maintenance Baseline (Day 1) by Visit – Extension Phase (Extension Switch Population)	CS Core	EOS
3.82.	Safety	Shell TS4	Summary of Changes in Proteinuria Maintenance Baseline (Day 1) Laboratory Result to Maximum Maintenance Phase Laboratory Result – Maintenance Phase		W48, W96

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: NCEP Lipid and Markers					
3.83.	Safety	Shell TS5	Summary of Changes in Maintenance Baseline (Day 1) NCEP Fasting Lipid Category to Maximum Maintenance Phase Category – Triglycerides		W48, W96
3.84.	Safety	Shell TS5	Summary of Changes in Maintenance Baseline (Day 1) NCEP Fasting Lipid Category to Maximum Maintenance Phase Category – Total Cholesterol		W48, W96
3.85.	Safety	Shell TS5	Summary of Changes in Maintenance Baseline (Day 1) NCEP Fasting Lipid Category to Minimum Maintenance Phase Category – HDL Cholesterol		W48, W96
3.86.	Safety	Shell TS5	Summary of Changes in Maintenance Baseline (Day 1) NCEP Fasting Lipid Category to Maximum Maintenance Phase Category – LDL Cholesterol		W48, W96
3.87.	Safety	Shell TS6	Summary of Fasting TC/HDL Ratio Changes from Maintenance Baseline (Day 1) (Maintenance Phase) – Lipids LOCF		W48, W96
3.88.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Maximum Extension Phase Category – Triglycerides (Extension Switch Population)	Switch Q4W IM (Oral Lead-In) group only	EOS
3.89.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Maximum Extension Phase Category – Total Cholesterol (Extension Switch Population)	Switch Q4W IM (Oral Lead-In) group only	EOS
3.90.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Minimum Extension Phase Category – HDL Cholesterol (Extension Switch Population)	Switch Q4W IM (Oral Lead-In) group only	EOS
3.91.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Maximum Extension Phase Category – LDL Cholesterol (Extension Switch Population)	Switch Q4W IM (Oral Lead-In) group only	EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.92.	ES	Shell TS6	Summary of Fasting TC/HDL Ratio Changes from Extension Baseline (Week 100) (Extension Phase) – Lipids LOCF (Extension Switch Population)	Switch Q4W IM (Oral Lead-In) group only	EOS
3.93.	Safety	Shell TS7	Summary of Bone Markers Changes from Maintenance Baseline (Day 1) – Maintenance Phase		W48, W96
3.94.	Safety	Shell TS7	Summary of Bone Markers Values – Maintenance Phase		W48, W96
3.95.	Safety	Shell TS8	Statistical Analysis of Log-Transformed Ratio to Maintenance Baseline (Day 1) in Bone Markers at Week 48 – Observed Case	For W96, replace Week 48 with W96.	W48, W96
Laboratory: Hepatobiliary (Liver)					
3.96.	Safety	Liver1 /Shell TS11	Summary of Liver Monitoring/Stopping Event Reporting - Maintenance Phase		W48, W96
3.97.	Safety	liver10/Shell TS12	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria - Maintenance Phase		W48, W96
3.98.	Safety	liver10/Shell TS12	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria - Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.99.	ES	liver10/Shell TS12	Summary of Subjects Meeting Hepatobiliary Abnormality – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	W96, EOS
3.100.	Safety (Q4W arm only)	liver10/Shell TS12	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria – Maintenance Phase Oral Lead-in Period	Randomized Q4W arm only	WK48
ECG					
3.101.	Safety	EG1	Summary of ECG Findings – Maintenance Phase		W48, W96
3.102.	ES	EG1	Summary of ECG Findings – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.103.	Safety	EG2	Summary of Change from Maintenance Baseline (Day 1) in ECG Values by Visit -Maintenance Phase		WK48, W96, EOS
3.104.	ES	EG2	Summary of Change from Extension Baseline (Week 100) in ECG Values by Visit – Extension Phase (Extension Switch Population)	Switch Q4W IM (Oral Lead-In) group only	EOS
3.105.	Safety	EG10	Summary of QTc Values by Category – Maintenance Phase	Mid200056/wk48idsl/Table 8.1043	W48, W96
3.106.	ES	EG10	Summary of QTc Values by Category – Extension Phase (Extension Switch Population)	Mid200056/wk48idsl/Table 8.1043 Switch Q4W IM (Oral Lead-In) group only	EOS
3.107.	Safety	EG10	Summary of Change from Maintenance Baseline (Day 1) QTc Values by Category – Maintenance Phase	Mid200056/wk48idsl/Table 8.1044	W48, W96
3.108.	ES	EG10	Summary of Change from Extension Baseline (Week 100) QTc Values by Category – Extension Phase (Extension Switch Population)	Mid200056/wk48idsl/Table 8.1044 Switch Q4W IM (Oral Lead-in) group only	EOS
eC-SSR and Others					
3.109.	Safety	VS1	Summary of Change from Maintenance Baseline (Day 1) in Vital Signs by Visit – Maintenance Phase	CS Core	W48, W96
3.110.	ES	VS1	Summary of Change from Extension Baseline (Week 100) in Vital Signs by Visit – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM (Oral Lead-in) group only	EOS
3.111.	Safety	Shell TS14	Summary of Subjects with eC-SSRS Suicidal Ideation or Behaviour During the Maintenance Phase		W48, W96
3.112.	Safety	VS1	Summary of Change from Induction Baseline (Week -20) in Weight and BMI by Visit – Maintenance Phase	CS Core	W48, W96

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.113.	Safety	See Safety Table 1.16 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Shift in BMI Categories at Week 96		W96
3.114.	Safety	See Safety Table 1.17 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Shift in BMI from Induction Baseline (Week -20) to Maximum Post-baseline Category – Maintenance Phase		W96
3.115.	ES	VS1	Summary of Change from Extension Baseline (Week 100) in Weight and BMI by Visit – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM (Oral Lead-in) group only	EOS
3.116.	Safety	AE5B	Summary of All Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Maintenance Phase	CS Core	HL, W48, W96
3.117.	Safety	AE5B	Summary of All Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)	CS Core Randomized Q4W arm only	EOS
3.118.	ES	AE5B	Summary of All Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	EOS
3.119.	Safety	AE5B	Summary of All Drug-Related Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Maintenance Phase	CS Core	HL, W48, W96

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.120.	Safety	AE5B	Summary of All Drug-Related Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	EOS
3.121.	ES	AE5B	Summary of All Drug-Related Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)	CS Core Switch Q4W IM group only	EOS
Adverse Events of Special Interest					
3.122.	Safety	See Safety Table 3.44 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.123.	Safety	See Safety Table 3.44 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.124.	ES	See Safety Table 3.44 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.125.	Safety	See Safety Table 3.48 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.126.	Safety	See Safety Table 3.48 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.127.	ES	See Safety Table 3.48 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.128.	Safety	See Safety Table 3.43 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.129.	Safety	See Safety Table 3.43 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.130.	ES	See Safety Table 3.43 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.131.	Safety	Shell TS14.1	Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety and Suicidal Ideation/Behaviour at Screening – Maintenance Phase	For W96 and EOS: include additional stratification by 'any history' vs. 'no history'.	W48, W96, EOS
3.132.	Safety	Shell TS14.1	Summary of Depression, Anxiety and Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety and Suicidal Ideation/Behaviour at Screening – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only For W96 and EOS: include additional stratification by 'any history' vs. 'no history'	W96, EOS
3.133.	ES	Shell TS14.1	Summary of Depression, Anxiety and Suicidal and Self-Injury Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety and Suicidal Ideation/Behaviour at Screening – Extension Phase (Extension Switch Population)	Switch Q4W IM group only For W96 and EOS: include additional stratification by 'any history' vs. 'no history'	W96, EOS
3.134.	Safety	See Safety Table 3.38 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Seizure Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.135.	Safety	See Safety Table 3.38 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Seizure Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.136.	ES	See Safety Table 3.38 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Seizure Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.137.	Safety	See Safety Table 3.39 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hepatic Safety Profile: Assessment of Risk of Hepatoxicity Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.138.	Safety	See Safety Table 3.39 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hepatic Safety Profile: Assessment of Risk of Hepatoxicity Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.139.	ES	See Safety Table 3.39 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hepatic Safety Profile: Assessment of Risk of Hepatoxicity Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.140.	Safety	See Safety Table 3.40 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hypersensitivity Reaction (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.141.	Safety	See Safety Table 3.40 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hypersensitivity Reaction (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.142.	ES	See Safety Table 3.40 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hypersensitivity Reaction (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.143.	Safety	See Safety Table 3.41 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.144.	Safety	See Safety Table 3.41 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.145.	ES	See Safety Table 3.41 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.146.	Safety	See Safety Table 3.42 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.147.	Safety	See Safety Table 3.42 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.148.	ES	See Safety Table 3.42 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.149.	Safety	See Safety Table 3.45 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.150.	Safety	See Safety Table 3.45 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.151.	ES	See Safety Table 3.45 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.152.	Safety	See Safety Table 3.46 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.153.	Safety	See Safety Table 3.46 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.154.	ES	See Safety Table 3.46 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.155.	Safety	See Safety Table 3.47 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Mood Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.156.	Safety	See Safety Table 3.47 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Mood Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.157.	ES	See Safety Table 3.47 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Mood Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.158.	Safety	See Safety Table 3.49 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Sleep Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.159.	Safety	See Safety Table 3.49 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Sleep Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.160.	ES	See Safety Table 3.49 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Sleep Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.161.	Safety	See Safety Table 3.51 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.162.	Safety	See Safety Table 3.51 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.163.	ES	See Safety Table 3.51 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.164.	Safety	See Safety Table 3.52 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.165.	Safety	See Safety Table 3.52 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.166.	ES	See Safety Table 3.52 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.167.	Safety	See Safety Table 3.53 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.168.	Safety	See Safety Table 3.53 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.169.	ES	See Safety Table 3.53 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.170.	Safety	See Safety Table 3.54 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.171.	Safety	See Safety Table 3.54 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS
3.172.	ES	See Safety Table 3.54 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS
3.173.	Safety	See Safety Table 3.55 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance Phase		W96, EOS
3.174.	Safety	See Safety Table 3.55 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)	Randomized Q4W arm only	W96, EOS

Safety Tables (Displays will be for both treatment arms, unless specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.175.	ES	See Safety Table 3.55 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)	Switch Q4W IM group only	W96, EOS

14.14.8. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
3.1.	Safety	AE10	Plot of Common Maintenance Phase Adverse Events and Relative Risk (Excluding ISRs) – Q4W vs ABC/DTG/3TC	CS CORE	HL, W48, W96
3.2.	Safety	LIVER9	Scatter Plot of Maximum vs. Maintenance Baseline (Day 1) for ALT – Maintenance Phase	CS CORE	HL, W48, W96
3.3.	Safety	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – Maintenance Phase	CS CORE	HL, W48, W96
3.4.	Safety	Shell FS2	Matrix Plot of Maximum Liver Chemistries – Maintenance Phase	CS CORE	HL, W48, W96
3.5.	Safety	LIVER9	Scatter Plot of Maximum vs. Maintenance Baseline (Day 1) for ALT – Maintenance and Extension Phase	CS CORE Randomized Q4W arm only	EOS
3.6.	Safety	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – Maintenance and Extension Phase	CS CORE Randomized Q4W arm only	EOS
3.7.	Safety	Shell FS2	Matrix Plot of Maximum Liver Chemistries – Maintenance and Extension Phase	CS CORE Randomized Q4W arm only	EOS
3.8.	ES	LIVER9	Scatter Plot of Maximum vs. Extension Baseline (Week 100) for ALT – Extension Phase (Extension Switch Population)	CS CORE Switch Q4W IM group only	W96, EOS
3.9.	ES	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – Extension Phase (Extension Switch Population)	CS CORE Switch Q4W IM group only	W96, EOS
3.10.	ES	Shell FS2	Matrix Plot of Maximum Liver Chemistries – Extension Phase (Extension Switch Population)	CS CORE Switch Q4W IM group only	W96, EOS
3.11.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance Phase Injection Site Reaction AEs by Maximum Grade — CAB and/or RPV	Randomized Q4W arm only	W48, W96

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.12.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – CAB	Randomized Q4W arm only	W48, W96
3.13.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – RPV	Randomized Q4W arm only	W48, W96
3.14.	Safety	Shell FS4	Plot of Incidence of Maintenance Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV	Randomized Q4W arm only	W48, W96
3.15.	Safety	Shell FS4	Plot of Incidence of Maintenance Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB	Randomized Q4W arm only	W48, W96
3.16.	Safety	Shell FS4	Plot of Incidence of Maintenance Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV	Randomized Q4W arm only	W48, W96
3.17.	Safety	Shell FS4/	Plot of Incidence of Grade 3-5 Maintenance Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) — CAB and/or RPV	Randomized Q4W arm only	W48, W96
3.18.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance and Extension Phase Injection Site Reaction AEs by Maximum Grade – CAB and/or RPV (Randomized Q4W)	Randomized Q4W arm only	EOS
3.19.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance and Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – CAB (Randomized Q4W)	Randomized Q4W arm only	EOS
3.20.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance and Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – RPV (Randomized Q4W)	Randomized Q4W arm only	EOS

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.21.	Safety	Shell FS4	Plot of Incidence of Maintenance and Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV (Randomized Q4W)	Randomized Q4W arm only	EOS
3.22.	Safety	Shell FS4	Plot of Incidence of Maintenance and Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB (Randomized Q4W)	Randomized Q4W arm only	EOS
3.23.	Safety	Shell FS4	Plot of Incidence of Maintenance and Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV (Randomized Q4W)	Randomized Q4W arm only	EOS
3.24.	Safety	Shell FS4	Plot of Incidence of Grade 3-5 Maintenance and Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) — CAB and/or RPV (Randomized Q4W)	Randomized Q4W arm only	EOS
3.25.	ES	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – CAB (Extension Switch Population)	Switch Q4W IM group only	EOS
3.26.	ES	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – RPV (Extension Switch Population)	Switch Q4W IM group only	EOS
3.27.	ES	Shell FS4	Plot of Incidence of Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV (Extension Switch Population)	Switch Q4W IM group only	EOS
3.28.	ES	Shell FS4	Plot of Incidence of Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB (Extension Switch Population)	Switch Q4W IM group only	EOS
3.29.	ES	Shell FS4	Plot of Incidence of Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV (Extension Switch Population)	Switch Q4W IM group only	EOS

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.30.	ES	Shell FS4/	Plot of Incidence of Grade 3-5 Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) — CAB and/or RPV (Extension Switch Population)	Switch Q4W IM group only	EOS
3.31.	Safety	Shell FS1	Bar Chart of Fasting Lipid NCEP Categories at Week 48 vs. Maintenance Baseline (Day 1) – Triglycerides, Total Cholesterol, LDL Cholesterol	For W96, replace W48 with W96 Example: arenv/arprod/gsk3365791/mid_dori_ph3/week48/outputs/Figure 3.062	W48, W96
3.32.	Safety	Shell FS1	Bar Chart of Fasting Lipid NCEP Categories at Week 48 vs. Maintenance Baseline (Day 1) - HDL Cholesterol	For W96, replace W48 with W96 Example: arenv/arprod/gsk3365791/mid_dori_ph3/week48/outputs/Figure 3.062	W48, W96

14.14.9. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The similar outputs below from study 200056 (week48idsl), unless otherwise specified	**Deliverable [Priority]**
PK					
14.1.	PK	PKCT1	Summary of Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit (Maintenance Phase) – Included Log-transformed Statistics	Table 10.1010 Visits up to W52 for the W48 deliverable.	W48, W96
14.2.	PK	PKCT1	Summary of Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit (Maintenance Phase) – Included Log-transformed Statistics	Table 10.1011 Visits up to W48 for the W48 deliverable.	W48, W96

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The similar outputs below from study 200056 (week48idsl), unless otherwise specified	**Deliverable [Priority]**
14.3.	PK	PKCT1	Summary of Evaluable Plasma CAB PK Concentration (ug/mL)-Time Data by Treatment and Visit (Maintenance Phase) – Included Log-transformed Statistics	Table 10.1012 Visits up to W48 for the W48 deliverable.	W48, W96
14.4.	PK	PKCT1	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit (Maintenance Phase) – Included Log-transformed Statistics	Table 10.1013 Visits up to W48 for the W48 deliverable.	W48, W96
14.5.	PK	Shell TPK01	Summary of Results of Steady State Assessment (Maintenance Phase)	Table 10.1005 Visits up to W48 for the W48 deliverable.	W48
14.6.	PK	Shell TPK01	Summary of Results of Steady State Assessment (Maintenance Phase) - Evaluable concentration	Table 10.1009 Visits up to W48 for the W48 deliverable.	W48
14.7.	PK	PKCT1	Summary of Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit (Maintenance Phase) – Included Log-transformed Statistics by Hepatitis C Status at Induction Baseline		W96
14.8.	PK	PKCT1	Summary of Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit (Maintenance Phase) – Included Log-transformed Statistics by Hepatitis C Status at Induction Baseline		W96
14.9.	ES	PKCT1	Summary of Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit (Included Log-transformed Statistics) – Extension Phase (Extension Switch Population)		EOS
14.10.	ES	PKCT1	Summary of Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit (Included Log-transformed Statistics) – Extension Phase (Extension Switch Population)		EOS

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The similar outputs below from study 200056 (week48idsl), unless otherwise specified	**Deliverable [Priority]**
14.11.	ES	PKCT1	Summary of Evaluable Plasma CAB PK Concentration (ug/mL)-Time Data by Treatment and Visit (Included Log-transformed Statistics) – Extension Phase (Extension Switch Population)		EOS
14.12.	ES	PKCT1	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit (Included Log-transformed Statistics) – Extension Phase (Extension Switch Population)		EOS
14.13.	LTFU	PKCT1	Summary of Long-Term Follow-up Phase Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit - Included Log-transformed Statistics	Table 10.1001 (WK96CDISC); For 'Total' treatment group (combining Q4W and Switch Q4W groups)	W96, EOS
14.14.	LTFU	PKCT1	Summary of Long-Term Follow-up Phase Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit - Included Log-transformed Statistics	Table 10.1002 (WK96CDISC) For 'Total' treatment group (combining Q4W and Switch Q4W groups)	W96, EOS

14.14.10. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The mock-up below from study 200056 (week48idsl)	**Deliverable [Priority]**
PK					
14.1.	PK	PKCF1	Individual Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1001 Visits up to W52 for the W48 deliverable.	W48, W96

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The mock-up below from study 200056 (week48idsl)	**Deliverable [Priority]**
14.2.	PK	PKCF1	Individual Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1002 Visits up to W52 for the W48 deliverable.	W48, W96
14.3.	PK	PKCF2	Mean (SD) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1003 Visits up to W52 for the W48 deliverable.	W48, W96
14.4.	PK	PKCF3	Median (5th and 95th percentile) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1004 Visits up to W52 for the W48 deliverable.	W48, W96
14.5.	PK	PKCF2	Mean (SD) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1005 Visits up to W52 for the W48 deliverable.	W48, W96
14.6.	PK	PKCF3	Median (5th and 95th percentile) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1006 Visits up to W52 for the W48 deliverable.	W48, W96
14.7.	PK	PKCF2	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1007 Visits up to W52 for the W48 deliverable.	W48, W96
14.8.	PK	PKCF3	Median (5th and 95th percentile) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1008 Visits up to W52 for the W48 deliverable.	W48, W96
14.9.	PK	PKCF2	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1009 Visits up to W52 for the W48 deliverable.	W48, W96
14.10.	PK	PKCF3	Median (5th and 95th percentile) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Maintenance Phase	Figure 10.1010 Visits up to W52 for the W48 deliverable	W48, W96

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The mock-up below from study 200056 (week48idsl)	**Deliverable [Priority]**
14.11.	PK	PKCF2	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Semi-Log) – Maintenance Phase	Figure 10.1011 Visits up to W52 for the W48 deliverable	W48, W96
14.12.	PK	PKCF2	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Semi-Log) – Maintenance Phase	Figure 10.1012 Visits up to W52 for the W48 deliverable	W48, W96
14.13.	LTFU	PKCF6	Individual Plasma CAB and RPV Concentration-Time Plots (Semi-Log) -- Post Last Injection for Subjects in LTFU	Overlay all subjects, across arms; use actual relative time since last injection as the x-variable, labelled as “Time post last injection (Weeks)”; one graph each for CAB and RPV, respectively, on the same page. Mark subjects who are receiving oral RPV during LTFU.	W96, EOS

14.14.11. Pharmacokinetic / Pharmacodynamic Tables

Pharmacokinetic / Pharmacodynamic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
Last Trough/ Nominal Week 8 Trough CAB/RPV Concentration and efficacy measures					
5.1.	PK	Shell TPK03/Table 11.1007 (see applicable subgroups in Section 5.4.2)	Logistic Regression Analysis of Snapshot 'HIV-1 RNA≥50 c/mL' at Week 48 by Trough PK Concentration and subgroup –univariable analysis	Last Trough Concentration and Nominal Week-8 trough PK concentration will be treated both as continuous variable and as a categorical subgroup. For W96 delivery, replace Week 48 with Week 96. For W96: This analysis will not be performed if no CVF cases have occurred since Week 48 (for the Q4W arm).	W48, W96
5.2.	PK	Shell TPK03/Table 11.1008	Multivariable Logistic Regression Analysis of Predictors of Snapshot 'HIV-1 RNA≥50 c/mL' at Week 48	For W96 delivery, replace Week 48 with Week 96; For W96: This analysis will not be performed if no CVF cases have occurred since Week 48 (for the Q4W arm).	W48, W96

Pharmacokinetic / Pharmacodynamic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
5.3.	PK	Shell TPK02	Summary of Last trough CAB PK concentration by Snapshot Virologic Response at Week 48– Included Log-transformed Statistics	The Virologic Response include: WK48 Snapshot HIV-1 RNA>=50 (Yes/No) For W96 delivery, replace Week 48 with Week 96	W48
5.4.	PK	Shell TPK02	Summary of Last trough RPV PK concentration by Snapshot Virologic Response at Week 48 – Included Log-transformed Statistics	Same as above	W48
5.5.	PK	Shell TPK02	Summary of Week 8 trough CAB PK concentration by Virologic Response at Maintenance– Included Log-transformed Statistics	The Virologic Response include: WK48 Snapshot HIV-1 RNA>=50 (Yes/No) For W96 delivery, replace Week 48 with Week 96; For W96: this summary will not be produced if no CVF cases have occurred since Week 48 (for the Q4W arm).	W48, W96

Pharmacokinetic / Pharmacodynamic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
5.6.	PK	Shell TPK02	Summary of Week 8 trough RPV PK concentration by Virologic Response at Maintenance– Included Log-transformed Statistics	Same as above For W96: this summary will not be performed if no CVF cases have occurred since Week 48 (for the Q4W arm).	W48, W96

14.14.12. Pharmacokinetic / Pharmacodynamic Figures

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
Last trough/Nominal Week 8 trough CAB/RPV concentration/parameters and efficacy measures					
5.1.	PK	Shell FPK01/Figure 11.1004	Scatter Plot of Last Trough CAB PK Concentration by Snapshot HIV-1 RNA ≥50c/mL (yes vs. no) at Week 48		W48
5.2.	PK	Shell FPK01/Figure 11.1005	Scatter Plot of Last Trough RPV PK Concentration by Snapshot HIV-1 RNA≥50 c/mL (yes vs. no) at Week 48		W48
5.3.	PK	Shell FPK01/Figure 11.1004	Scatter Plot of Week 8 Trough CAB PK Concentration by Snapshot 'HIV-1 RNA≥50 c/mL' (yes vs. no) at Week 48		W48
5.4.	PK	Shell FPK01/Figure 11.1005	Scatter Plot of Week 8 Trough RPV PK Concentration by Snapshot HIV-1 RNA≥50 c/mL (yes vs. no) at Week 48		W48
5.5.	PK	Figure 11.1006	Scatter Plot of Delay in last IP injection by Last Trough CAB Concentration at Week 48 at Maintenance Phase	Different symbols for Snapshot Non- 'HIV-1 RNA≥50' and 'HIV-1 RNA≥50'. X axis represents last trough CAB concentration, Y axis indicates Delay in last IP injection (Days)	W48

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
5.6.	PK	Figure 11.1006	Scatter Plot of Delay in last IP injection by Last Trough RPV Concentration at Week 48 at Maintenance Phase	Different symbols for Snapshot Non- 'HIV-1 RNA≥50' and 'HIV-1 RNA≥50' . X axis represents last trough RPV concentration, Y axis indicates Delay in last IP injection (Days)	W48
5.7.	PK	Figure 11.1002	Individual CAB trough concentration-time Profiles for subjects with Snapshot HIV-1 RNA≥50 c/mL at Week 48 with Median, 5th & 95th percentile of CAB Conc-Time Profiles for other subjects (Semi-Log)	For W96 delivery, replace Week 48 with Week 96	W48, W96
5.8.	PK	Figure 11.1003	Individual RPV trough concentration-time Profiles for subjects with Snapshot HIV-1 RNA≥50 c/mL at Week 48 with Median, 5th & 95th CAB Conc-Time Profiles for other subjects (Semi-Log)	For W96 delivery, replace Week 48 with Week 96	W48, W96
5.9.	PK	Shell FPK02	Scatter plot of Last Trough Concentration of CAB and RPV in relation to occurrence of Snapshot 'HIV-1 RNA≥50 c/mL' at Week 48	Quartiles of CAB and RPV last trough concentration will be marked with vertical and horizontal lines. Induction Baseline BMI category will also be marked For W96 delivery, replace Week 48 with Week 96	W48

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
5.10.	PK	Shell FPK02	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	Same as above. For W96: this figure will not be produced if no CVF cases have occurred since Week 48 (for the Q4W arm).	W48, W96
PK Concentration and safety measures					
5.11.	PK	shell FPK03	Scatter Plot of Change from Maintenance Baseline (Day 1) in 2-Hr QTc versus CAB 2-Hr Post-dose PK Concentrations at Week X [Week 4b and Week 48 for Week 48 delivery, Week 96 for W96 delivery]	For each visit (i.e. wk4b, 48, 96), produce separate plots of 2-Hr PK concentration vs QTcF and 'overall'. Missing QTcB/QTcF will be derived using RR, if RR is available. For 'overall' plot, if QTcF remains missing with derivation from RR, then other QTc parameters will be used in the order of QTcB, QTc-unspecified, with different colours to differentiate each parameter. (2hr post dose PK concentration at WK4b, week 48 vs CFB in QTc at these two visits) For W96 delivery, produce plot for Week 96 only	W48, W96

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
5.12.	PK	Shell FPK03	Scatter Plot of Change from Maintenance Baseline (Day 1) in 2-Hr QTc versus RPV 2-Hr Post-dose PK Concentrations at Week X *[Week4b and Week 48 for W48 delivery, Week 96 for W96 delivery]*	Similar to the above for CAB	W48, W96
5.13.	PK	shell FPK04	Scatter Plot of Maximum Change from Maintenance Baseline (Day 1) in ALT versus Last Trough CAB PK Concentrations during the Maintenance Phase	Last Trough CAB/RPV PK concentration is defined as the most recent trough PK concentration prior or equal to the date of ALT assessment with maximum CFB, at Maintenance Phase	W48
5.14.	PK	shell FPK04	Scatter Plot of Maximum Change from Maintenance Baseline (Day 1) in ALT versus Last Trough RPV PK Concentrations during the Maintenance Phase	Same as above for CAB	W48
5.15.	PK	shell FPK04	Scatter Plot of Maximum Change from Maintenance Baseline (Day 1) in Total Bilirubin versus Last Trough CAB PK Concentrations during the Maintenance Phase	Last Trough CAB/RPV PK concentration is defined as the most recent trough PK concentration prior or equal to the date of Total Bili assessment with maximum CFB, at Maintenance Phase	W48
5.16.	PK	shell FPK04	Scatter Plot of Maximum Change from Maintenance Baseline (Day 1) in Total Bilirubin versus Last Trough RPV PK Concentrations during the Maintenance Phase	Same as above for CAB	W48

Pharmacokinetic / Pharmacodynamic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell** The similar outputs below from study 200056 (week48idsl)	**Title**	**Programming Notes**	**Deliverable [Priority]**
5.17.	PK	shell FPK05	Box Plot of Maximum Toxicity Grades of Most Frequently Reported non-ISR AEs (e.g. Headache, Fever, Fatigue, Nausea, Dizziness) versus Last Trough CAB PK Concentrations during the Maintenance Phase	The AEs for this analysis should be the top 5 in incidence of non-ISR AEs within the Q4W arm during the Maintenance Phase. Last Trough CAB/RPV PK concentration is defined as the most recent trough PK concentration prior or equal to the onset date of the most frequently reported AE with maximum toxicity grade during the Maintenance Phase. If a subject has no AE most commonly reported, then the last trough value at Maintenance Phase will be used for the plot	W48
5.18.	PK	shell FPK05	Box Plot of Maximum Toxicity Grades of Most Frequently Reported AEs (e.g. Headache, Fever, Fatigue, Nausea, Dizziness) versus Last Trough RPV PK Concentrations during the Maintenance Phase	The same as above	W48

14.14.13. Health Outcomes Tables

Health Outcomes: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Perception of Injection Questionnaire (PIN)					
6.1.	ITT-E	THO2	Proportion of Subjects with each individual item score in PIN by Visit – LOCF (Maintenance Phase)		W48, W96
6.2.	ITT-E	THO1	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)		W48, W96
6.3.	ITT-E	THO10	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)	Wilcoxon Signed -rank test for analysis (acceptance score only)	W48, W96
6.4.	ITT-E	THO1	Summary of PIN Change from Week 5 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)		W48, W96
6.5.	ITT-E	THO1	Summary of PIN Change from Week 5 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)		W48, W96
Health-related quality of Life (HATQoL)					
6.6.	ITT-E	THO2	Proportion of Subjects with each Individual Questionnaire Item Score in HATQoL by Visit - LOCF (Maintenance Phase)		W48, W96

Health Outcomes: Tables					
6.7.	ITT-E	THO1	Summary of Quality of Life (HATQoL) Score in Life Satisfaction, HIV Medication, and Disclosure worries by Visit (Maintenance Phase)		W48, W96
6.8.	ITT-E	THO1	Summary of Quality of Life (HATQoL) Score in Life Satisfaction, HIV medication, and Disclosure worries by Visit - LOCF (Maintenance Phase)		W48, W96
6.9.	ITT-E	THO1	Summary of Quality of Life Score (HATQoL) – Change from Maintenance Baseline (Day 1) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase)		W48, W96
6.10.	ITT-E	THO1	Summary of Quality of Life Score (HATQoL) – Change from Maintenance Baseline (Day 1) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit - LOCF (Maintenance Phase)		W48, W96
6.11.	ITT-E	Shell THO3	Statistical Analysis of Quality of Life Score (HATQoL) – Change from Maintenance Baseline (Day 1) in Life Satisfaction, HIV medication, and Disclosure Worries by Visit – LOCF (Maintenance Phase)	ANCOVA for analysis	W48, W96
Health Status:12-item short form survey (SF-12)					
6.12.	ITT-E	THO2	Proportion of Subjects with SF-12 Individual Item Scores by Visit - LOCF (Maintenance Phase)		W48, W96
6.13.	ITT-E	THO1	Summary of SF-12 (MCS and PCS Scores) by Visit (Maintenance Phase)		W48, W96
6.14.	ITT-E	THO1	Summary of SF-12 (MCS and PCS Scores) by Visit - LOCF (Maintenance Phase)		W48, W96
6.15.	ITT-E	THO1	Summary of Change from Maintenance Baseline (Day 1) in SF-12 (MCS and PCS Scores) by Visit (Maintenance Phase)		W48, W96
6.16.	ITT-E	THO1	Summary of Change from Maintenance Baseline (Day 1) in SF-12 (MCS and PCS Scores) by Visit - LOCF (Maintenance Phase)		W48, W96

Health Outcomes: Tables					
6.17.	ITT-E	Shell THO3	Statistical Analysis of SF-12 Change from Maintenance Baseline (Day 1) in MCS, and PCS Score by Visit – LOCF (Maintenance Phase)	ANCOVA for analysis	W48, W96
Treatment Satisfaction (HIVTSQs)					
6.18.	ITT-E	Shell THO2	Proportion of Subjects with HIVTSQs – Treatment Satisfaction Individual Item Scores by Visit - LOCF) (Maintenance Phase)		W48, W96
6.19.	ITT-E	Shell THO2	Proportion of Subjects with HIVTSQs – Treatment Satisfaction Individual Item Scores by Visit and Subgroup - LOCF) (Maintenance Phase)	Subgroups: Induction Baseline (Week -20) HIV-1 RNA (<100,000, ≥100,000 c/mL), gender at birth, age (<35; 35-<50; ≥50), Maintenance Baseline (Day 1) CD4+ cell count (<200; 200 to <350; 350 to <500; ≥ 500 cells/mm3), and race (i.e. white, non-white).	W48, W96
6.20.	ITT-E	Shell THO1	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit) (Maintenance Phase)		W48, W96
6.21.	ITT-E	Shell THO1	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit - LOCF) (Maintenance Phase)		W48, W96
6.22.	ITT-E	Shell THO1	Summary of HIVTSQs - Change from Maintenance Baseline (Day 1) in Total Treatment Satisfaction Score by Visit (Maintenance Phase)		W48, W96
6.23.	ITT-E	Shell THO1	Summary of HIVTSQs - Change from Maintenance Baseline (Day 1) in Total Treatment Satisfaction Score by Visit – LOCF (Maintenance Phase)		W48, W96
6.24.	ITT-E	Shell THO3	Statistical Analysis of HIVTSQs - Change from Maintenance Baseline (Day 1) in Total Treatment Satisfaction Score by Visit – LOCF) (Maintenance Phase)	ANCOVA for analysis	W48, W96

Health Outcomes: Tables					
6.25.	ITT-E	See Table 6.40 in reporting effort: gsk1265744/201584/primary_02	Summary of HIVTSQs - Change from Maintenance Baseline (Day 1) in Individual Item Score by Visit - LOCF (Maintenance Phase)		W96
Treatment Satisfaction (HIVTSQc)					
6.26.	ITT-E	Shell THO2	Proportion of Subjects with HIV-Treatment Satisfaction Questionnaire Individual Item Scores change) (Maintenance Phase)		W48
6.27.	ITT-E	Shell THO1	Summary of HIV-Treatment Satisfaction Questionnaire in Treatment Satisfaction Score Change) (Maintenance Phase)		W48
6.28.	ITT-E	Shell THO5	Statistical Analysis of HIV-Treatment Satisfaction Questionnaire in Treatment Satisfaction Score Change at Week 48 (Maintenance Phase)	ANOVA for analysis	W48
Treatment Acceptance (ACCEPT)					
6.29.	ITT-E	Shell THO2	Proportion of Subjects with Treatment Acceptance Questionnaire (ACCEPT) Individual Item Scores by Visit - LOCF) (Maintenance Phase)		W48, W96
6.30.	ITT-E	Shell THO1	Summary of Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit (Maintenance Phase)		W48, W96
6.31.	ITT-E	Shell THO1	Summary of Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit – LOCF (Maintenance Phase)		W48, W96
6.32.	ITT-E	Shell THO1	Summary of Change from Maintenance Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit (Maintenance Phase)		W48, W96
6.33.	ITT-E	Shell THO1	Summary of Change from Maintenance Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit – LOCF (Maintenance Phase)		W48, W96

Health Outcomes: Tables					
6.34.	ITT-E	Shell THO3	Statistical Analysis of Change from Maintenance Baseline in Acceptance/General Dimension Score (ACCEPT Questionnaire) by Visit – LOCF (Maintenance Phase)	ANCOVA for analysis	W48, W96
Tolerability of Injection, NRS (for Q4W IM)					
6.35.	ITT-E	Shell THO2	Proportion of Subjects with Tolerability of Injection (NRS) Individual item scores by Visit – LOCF (Maintenance Phase)		W48, W96
6.36.	ITT-E	Shell THO9	Summary of Tolerability of Injection (NRS) scores by Visit (Maintenance Phase)		W48, W96
6.37.	ITT-E	Shell THO9	Summary of Tolerability of Injection (NRS) scores by Visit – LOCF (Maintenance Phase)		W48, W96
6.38.	ITT-E	Shell THO9	Summary of Tolerability of Injection (NRS) by Visit – Change from Week 4b Scores (Maintenance Phase)		W48, W96
6.39.	ITT-E	Shell THO9	Summary of Tolerability of Injection (NRS) by Visit – Change from Week 4b Scores - LOCF (Maintenance Phase)		W48, W96
Preferences (Dichotomous preference question) (for Q4W IM)					
6.40.	ITT-E	Shell THO8	Treatment Preference at Week 48 (Maintenance Phase)		W48

14.14.14. Health Outcomes Figures

Health Outcomes: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.1.	ITT-E	Shell FHO1	Line Plot of Adjusted Mean (95% CI) Change from Maintenance Baseline (Day 1) in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) – LOCF		W48, W96
6.2.	ITT-E	Shell FHO2	Line Plot of Difference (95% CI) in Adjusted Mean Change from Maintenance Baseline (Day 1) in HIVTSQs Total Treatment Satisfaction Score over Time (ANCOVA) – LOCF		W48, W96
6.3.	ITT-E	Shell FHO1	Line Plot of Adjusted Mean (95% CI) Change from Maintenance Baseline (Day 1) in SF-12 (MCS and PCS subscale) Score over Time (ANCOVA) – LOCF		W48, W96
6.4.	ITT-E	Shell FHO2	Line Plot of Difference (95% CI) in Adjusted Mean Change from Maintenance Baseline (Day 1) in SF-12 (MCS and PCS subscale) Score over Time (ANCOVA) – LOCF		W48, W96
6.5.	ITT-E	Shell FHO1	Line Plot of Adjusted Mean (95% CI) Change from Maintenance Baseline (Day 1) in HATQoL (Life Satisfaction, HIV medication, and Disclosure Worries) by Visit (ANCOVA) – LOCF		W48, W96
6.6.	ITT-E	Shell FHO2	Line Plot of Difference in Adjusted Mean (95% CI) Change from Maintenance Baseline (Day 1) in HATQoL (Life Satisfaction, HIV Medication, and Disclosure Worries) by Visit (ANCOVA) – LOCF		W48, W96

14.14.15. Virology Tables

Virology: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** (mock up below from study 200056\wk48idsl)	**Title**	**Programming Notes**	**Deliverable**
Genotype					
7.1.	CVF	Table 9.1001	Summary of the Prevalence of Known INI Resistance Mutations at time of CVF (Maintenance Phase) – Plasma Sample	Known INI resistance mutation per Section 14.6.6. Need to add small 'n' for actual no. of subjects included in the analysis. The % will be based on 'n' rather than 'N'	W48, W96
7.2.	CVF	Table 9.1002	Summary of the Prevalence of Treatment Emergent Known INI Resistance Mutations at time of CVF (Maintenance Phase) – Plasma Sample	Known INI resistance mutation per Section 14.6.6. Need to add small 'n' for actual no. of subjects included in the analysis. The % will be based on 'n' rather than 'N'	W48, W96
7.3.	CVF	Table 9.1003 (modify region to class)	Summary of the Prevalence of Major Resistance Mutations of NRTI, NNRTI and PI Class at time of CVF (Maintenance Phase) - - Plasma Sample	Major Mutation of NRTI, NNRTI, PI class per Section 14.6.6. Need to add small 'n' for actual no. of subjects included in the analysis. The % will be based on 'n' rather than 'N' (programming for defining class: can refer to arenv/arprod/gsk1349572/mid200304/week24/drivers/t_adpf_4001.sas	W48, W96

Virology: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** (mock up below from study 200056\wk48idsl)	**Title**	**Programming Notes**	**Deliverable**
7.4.	CVF		Summary of the Prevalence of Treatment-Emergent Major Resistance Mutations of NRTI, NNRTI and PI Class at time of CVF (Maintenance Phase) - - Plasma Sample	Major Mutation of NRTI, NNRTI, PI class per Section 14.6.6. Need to add small 'n' for actual no. of subjects included in the analysis. The % will be based on 'n' rather than 'N' (programming for defining class: can refer to arenv/arprod/gsk1349572/mid200304/week24/drivers/t_adpf_4001.sas	W48, W96
7.5.	ITT-E		Summary of the Prevalence of Major Resistance Mutations of NRTI, NNRTI and PI Class at Induction Baseline (Week -20) -- Plasma Sample	Major Mutation of NRTI, NNRTI, PI class per Section 14.6.6. Need to add small 'n' for actual no. of subjects included in the analysis. The % will be based on 'n' rather than 'N' (programming for defining class: can refer to arenv/arprod/gsk1349572/mid200304/week24/drivers/t_adpf_4001.sas	W48, W96
Phenotype					
7.6.	CVF	Table 9.1005	Summary of Phenotype by Phenotypic Cutoff at time of CVF (Maintenance Phase) - - Plasma Sample		W48, W96
7.7.	CVF	Table 9.1005	Summary of Genotypic Susceptibility at time of CVF (Maintenance Phase) - - Plasma Sample		W48, W96

Virology: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** (mock up below from study 200056\wk48idsl)	**Title**	**Programming Notes**	**Deliverable**
7.8.	CVF	Table 9.1005	Summary of Net Assessment at time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
7.9.	CVF	Table 9.1006	Summary of Phenotype: Number of Drugs to Which Subject are Resistant at Time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
7.10.	CVF	Table 9.1007	Summary of Fold Change to CAB, RPV and DTG at Induction Baseline (Week -20) and Time of CVF (Maintenance Phase) - Plasma Sample		W48, W96
7.11.	CVF	Table 9.1008	Summary of Change from Induction Baseline (Week -20) in Fold Change to CAB, RPV, and DTG (Maintenance Period)		W48, W96
7.12.	CVF	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria During the Maintenance Phase – Induction Baseline (Week -20) and Time of CVF		HL, W48, W96
7.13.	CVF	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure During the Maintenance and Extension Phase – Induction Baseline (Week -20) and Time of CVF (Randomized Q4W arm)	Randomized Q4W arm only	W96, EOS
7.14.	CVF	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria During the Extension Phase – Induction Baseline (Week -20) and Time of CVF (Switch Q4W IM)	Switch Q4W IM group only	W96, EOS

Virology: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** (mock up below from study 200056\wk48idsl)	**Title**	**Programming Notes**	**Deliverable**
7.15.	ITT-E	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Non-CVF Subjects	May include genotypic and phenotypic data on the last on-treatment isolates for participants with HIV-1 RNA ≥200 c/mL Include columns for phase, phase treatment, phase day.	W48, W96, EOS

14.14.16. ICH Listings

ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases).					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Study Population					
1.	Randomised	Shell LSP1	Listing of Subjects Randomised But Not Treated	CS CORE (related to 'Listing for exclusion from any population)	W48, W96, EOS
2.	Randomised	TA1	Listing of Randomised and Actual Strata and Treatment Assignment	CS CORE	W48, W96, EOS
3.	All Subjects Screened	ES7	Listing of Reasons for Screen Failure	CS CORE	W48, W96, EOS

ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases).					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.	ITT-E	ES2	Listing of Reasons for Study Withdrawal	CS CORE	HL, W48, W96, EOS
5.	ITT-E	ES2	Listing of Reasons for Study Drug Discontinuation	CS CORE	W48, W96, EOS
6.	All Enrolled	DV2	Listing of Important Protocol Deviations	CS CORE	W48, W96, EOS
7.	ITT-E	DV2	Listing of Protocol Deviations Leading to Exclusion from the Per-Protocol Population	CS CORE	HL, W48, W96, EOS
8.	All Enrolled	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	CS CORE	W48, W96, EOS
9.	ITT-E	DM2	Listing of Demographic Characteristics	CS CORE	W48, W96, EOS
10.	ITT-E	DM9	Listing of Race	CS CORE	W48, W96, EOS
Primary Efficacy					
11.	All Enrolled	Study 201584 (primary_02): Listing 33	Listing of All Plasma HIV-1 RNA Data		W96, EOS
12.	ITT-E	Shell LPEF1	Listing of Study Outcome (50 c/mL) at Week 48 – Snapshot Analysis		HL, W48, W96, EOS
Exposure					
13.	Safety	HIV_IP5	Listing of Investigational Product Exposure Data	CS CORE	W48, W96, EOS
Adverse Events					
14.	All Enrolled	AE8	Listing of All Adverse Events	CS CORE, Include LTFU AEs.	W96, EOS
15.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events	CS CORE	W48, W96, EOS
16.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event	CS CORE	W48, W96, EOS

ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases).					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
17.	Safety	AE8	Listing of Fatal Adverse Events	CS CORE	W48, W96, EOS
18.	All Enrolled	AE8	Listing of Non-Fatal Serious Adverse Events (Induction Phase)	CS CORE	W48, W96, EOS
19.	Safety	AE8	Listing of Non-Fatal Serious Adverse Events	CS CORE	W48, W96, EOS
20.	All Enrolled	AE8	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product (Induction Phase)	CS CORE	W48, W96, EOS
21.	Safety	AE8	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product	CS CORE	HL, W48, W96, EOS
22.	Safety	AE8	Listing of Changes in Intensity/Grades of Injection Site Related AE	Based on AE details inform page for changes in intensity of the same event.	W48, W96, EOS
23.	Safety	PREG1a	Listing of Subjects Who Became Pregnant During the Study (Maintenance +Extension Phase)		W48, W96, EOS
Laboratory					
Hepatobiliary (Liver)					
24.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver stopping Events		W48, W96, EOS
25.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events		W48, W96, EOS
ECG & Vital Signs					
26.	Safety	EG3	Listing of ECG Values for subjects with a value of potential clinical importance		W48, W96, EOS
27.	Safety	EG5	Listing of ECG Findings		W48, W96, EOS
eC-SSRS					
28.	Safety	PSRAE1	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description (Section 1-Section 2)		W48, W96, EOS
29.	Safety	PSRAE3	Listing of Possible Suicidality-Related Adverse Event Data: Possible Cause(s) (Section 3)		W48, W96, EOS

ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases).					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
30.	Safety	PSRAE4	Listing of Possible Suicidality-Related Adverse Event Data (Section 4)		W48, W96, EOS
31.	Safety	PSRAE5	Listing of Possible Suicidality-Related Adverse Event Data (Section 5-Section 8)		W48, W96, EOS
PK					
32.	PK	Study 200056 Listing 10.1001(wk48idsl)	Listing of Plasma CAB PK Concentration-Time Data	Add a variable of 'evaluable' (Y/N)	W48, W96, EOS
33.	PK	Study 200056 Listing 10.1002(wk48idsl)	Listing of Plasma RPV PK Concentration-Time Data	Add a variable of 'evaluable' (Y/N)	W48, W96, EOS
34.	LTFU	Study 200056 Listing 10.1001(wk48idsl)	Listing of Plasma CAB PK Concentration-Time Data (LTFU Phase)	Add a variable of 'evaluable' (Y/N)	W96, EOS
35.	LTFU	Study 200056 Listing 10.1002(wk48idsl)	Listing of Plasma RPV PK Concentration-Time Data (LTFU Phase)	Add a variable of 'evaluable' (Y/N)	W96, EOS
Other					
36.	All Enrolled	CM2	Listing of Concomitant Medications for Subjects with Confirmed Virologic Failure		W96, EOS

14.14.17. Non-ICH Listings

Non-ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Study Population					
37.	All Enrolled	ES2	Listing of Reasons for Induction Phase Withdrawal		W48, W96, EOS
38.	ITT-E	ES2	Listing of Reasons for Maintenance Phase Withdrawal		W48, W96, EOS
39.	ITT-E	ES2	Listing of Reasons for Maintenance Phase Oral Lead-in Period Withdrawal		W48, W96, EOS
40.	ITT-E	ES2	Listing of Reasons for Extension Phase Withdrawal		W96, EOS
41.	LTFU	ES2	Listing of Reasons for Long-term Follow Up Withdrawal		W48, W96, EOS
42.	All Enrolled	CA3	Listing of Prior ART Medications		W48, W96, EOS
43.	All Enrolled	CA3	Listing of Concomitant ART Medications Received during Induction Phase		WK48, W96, EOS
44.	ITT-E	CA3	Listing of Concomitant ART Medications Received during Maintenance Phase		W48, W96, EOS
45.	ITT-E	CA3	Listing of ART Medications Received during LTFU Phase		W48, W96, EOS
46.	ITT-E	CA3	Listing of subjects with changes in Concomitant ARTs during Maintenance Phase		W48, W96, EOS
47.	ITT-E	Shell LSP11	Listing of Investigational Product Accountability - Oral Regimens		W48, W96, EOS
48.	ITT-E	MHSZE	Listing of Medical History of Seizure		W48, W96, EOS
49.	All Enrolled		Listing of Subjects with Hepatitis C at Induction Baseline (Week -20)		W96
Secondary Efficacy					
50.	All Enrolled	Shell LSEF3	Listing of All Plasma HIV-1 RNA data for subjects with Confirmed Virologic Failure (Induction Phase)		W48, W96, EOS

Non-ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
51.	CVF	Shell LSEF3	Listing of All Plasma HIV-1 RNA data for subjects with Confirmed Virologic Failure		W48, W96, EOS
52.	ITT-E	Shell LSEF1	Listing of All Plasma HIV-1 RNA data for subjects with viral load >=50 c/mL at any time during the Maintenance Phase		HL, W48, W96, EOS
53.	ITT-E	Shell LSEF1	Listing of Plasma All HIV-1 RNA data for subjects with viral load >=50 c/mL during the Maintenance Oral lead-in Period		W48
54.	ITT-E	Shell LSEF5	Listing of HIV-1 Associated Conditions		W48, W96, EOS
Safety					
55.	Safety	ABC_HSR _EXPO2	Listing of Abacavir Hypersensitivity Reaction Record - Exposure to Abacavir		W48, W96, EOS
56.	Safety	ABC_HSR _DRUG2	Listing of Abacavir Hypersensitivity Reaction Record - Subject History of Drug Allergies		W48, W96, EOS
57.	Safety	ABC_HSR COND2	Listing of Abacavir Hypersensitivity Reaction Record - Subject and Family Conditions		W48, W96, EOS
58.	Safety	ABC_HSR _RASH2	Listing of Abacavir Hypersensitivity Reaction Record - Skin Rash Details		W48, W96, EOS
59.	Safety	ABC_HSR _SYMP4	Listing of Abacavir Hypersensitivity Reaction Record - Symptoms		W48, W96, EOS
60.	Safety	VS4	Listing of Abacavir Hypersensitivity Reaction Record - Vital Signs		W48, W96, EOS
61.	Safety	ABC_HSR _SYMP6	Listing of Abacavir Hypersensitivity Reaction Record - Individual Symptoms and Diagnostic Category Assignments (Excluding Other Symptoms)		W48, W96, EOS
62.	Safety	ABC_HSR _SYMP7	Listing of Abacavir Hypersensitivity Reaction Record - Individual Symptoms and Diagnostic Category Assignments (Other Symptoms)		W48, W96, EOS

Non-ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
63.	Safety	See Listing 3 in reporting effort: gsk1265744/mid209522/iss_01	Listing of all Subjects Meeting Liver Stopping Criteria		W96, EOS
64.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting		W48, W96, EOS
65.	Safety	LIVER6	Listing of Liver Event Information for RUCAM Score		W48, W96, EOS
66.	Safety	LIVER7	Listing of Liver Biopsy Details		W48, W96, EOS
67.	Safety	LIVER8	Listing of Liver Imaging Details		W48, W96, EOS
68.	Safety	Liver13	Listing Subjects Meeting Hepatobiliary Lab Criteria	Please also add those additional items shown in the summary of subjects meeting hepatobiliary lab criteria post-baseline (i.e. AST >3xULN and ALP <2xULN and BIL >=2xULN]; ALT+AST>=xx)	W48, W96, EOS
69.	Safety	AE8	Listing of Adverse Events Related to Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses		W48, W96, EOS
70.	Safety	EG3	Listing of ECG Values for Subjects with Adverse Events Related to Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses		W48, W96, EOS
71.	Safety	Latte2 WK96CDISC report	Listing of Each Subjects ALT, AST, Bilirubin (including total and direct Bilirubin), INR, and ALP for subject meeting Hepatobiliary Lab abnormality criteria	8.1037 (add AST, ALP, INR, and direct Bilirubin to the listing and only for subject meeting Hepatobiliary Lab abnormality criteria)	HL, W48, W96, EOS

Non-ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
72.	Safety	Latte2 WK96CDISC report	Listing of Investigational Product Exposure Data for Subject Receiving Oral Bridging	8.1038	W48, W96, EOS
73.	Safety	DEV1	Listing of Dosing Errors and IP Device Malfunctions		W48, W96, EOS
Virology (mock up below from study 200056\wk96cdisc), 'Study Phase' will be added as a column to the listing.					
74.	CVF	Listing 9.1005	Listing of Replication Capacity in IN and PR/RT Region		W48, W96, EOS
75.	All Enrolled	Table 9.1009	Listing of Genotypic Mutation Data at All Timepoints		W96, EOS

14.15. Appendix 15: List of Data Displays for Week 124

All data displays (Tables, Figures & Listings) will use the term "Subject" which reflects CDISC and GSK Data Display Standards terminology.

Unless stated otherwise, all Extension Switch population tables and figures will include treatment groups for direct to inject, oral lead-in and total.

14.15.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.01 to 1.n	1.01 to 1.n
Efficacy	2.01 to 2.n	2.01 to 2.n
Safety	3.01 to 3.n	3.01 to 3.n
Pharmacokinetic	4.01 to 4.n	4.01 to 4.n
Virology	7.01 to 7.n	7.01 to 7.n
Section	**Listings**	
ICH Listings	1 to x	
Other Listings	y to z	

14.15.2. Mock Example Shell Referencing

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

14.15.3. Deliverables

Delivery	Description
HL	Headline for Week 124
Week 124	Week 124

14.15.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.1.	All Subjects Screened	SA1	Summary of Study Populations		HL, W124
1.2.	All Subjects Screened	Shell TSP1	Summary of Subjects by Country and Investigator		W124
1.3.	ITT-E	ES1	Summary of Subject Accountability: Study Conclusion Record		W124
1.4.	ITT-E	ES1	Summary of Study Drug Discontinuation		W124
1.5.	LTFU	ES1	Summary of Subject Accountability: Long-term follow up Phase Conclusion Record		W124
1.6.	ITT-E	ES1	Summary of Subject Accountability: Maintenance and Extension Phase Conclusion Record (Randomized Q4W)	For Randomized Q4W arm only Add the following subcategories under subject status: a) Completed Maintenance and did not enter Extension b) Completed Extension c) Withdrawn from Maintenance d) Withdrawn from Extension.	W124
1.7.	ITT-E	HIV_ES1	Summary of Subject Accountability: Withdrawals by Visit – Maintenance and Extension Phase (Randomized Q4W)		W124
1.8.	ES	ES1	Summary of Subject Accountability: Extension Phase Conclusion Record (Extension Switch Population)		HL, W124

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.9.	ES	HIV_ES1	Summary of Subject Accountability: Withdrawals by Visit – Extension Phase (Extension Switch Population)		W124
1.10.	All Participants Enrolled	ES4	Summary of Subject Disposition at Each Study Epoch		W124
1.11.	All Participants Enrolled	ES5	Summary of Reasons for Withdrawal at Each Epoch		W124
1.12.	ITT-E	DV1a	Summary of Important Protocol Deviations - Maintenance and Extension Phase (Randomized Q4W)		W124

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.13.	ES	DV1a	Summary of Important Protocol Deviations – Extension Phase (Extension Switch Population)		W124
Demography and Baseline					
1.14.	ES	Shell TSP2	Summary of Demographic Characteristics (Extension Switch Population)	See also DM1 in IDSL Age categorization will include: <=18, 19-64, >=65 (FDAAA requirement) 18-64, 65-84, >=85 (EMA requirement)	HL, W124
1.15.	ES	DM5	Summary of Race and Racial Combinations (Extension Switch Population)	CS CORE	W124
1.16.	ES	DM6	Summary of Race and Racial Combinations Details (Extension Switch Population)	CS CORE	W124
1.17.	ES	Shell TSP3	Summary of Hepatitis Status at Induction Baseline (Week -20) – Extension Switch Population		W124
1.18.	ES	CDC1	Summary of Derived CDC Stages of HIV Infection at Extension Baseline (Week 100)		W124
1.19.	ES	Shell TSP5	Distribution of CD4+ Cell Count Results at Extension Baseline (Week 100) - Extension Switch Population	Same presentation as shown in the mock shell for induction baseline.	W124
Medical Conditions, Concomitant Medications & Antiretroviral Therapy					
1.20.	ES	MH4	Summary of Current Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary disorders (Extension Switch Population)		W124

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.21.	ES	MH4	Summary of Past Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary disorders (Extension Switch Population)		W124
1.22.	ITT-E	CM8	Summary of Concomitant Medication Ingredient Combinations - Maintenance and Extension Phase (Randomized Q4W)		W124
1.23.	ES	CM8	Summary of Concomitant Medication Ingredient Combinations – Extension Phase (Extension Switch Population)		W124
1.24.	ES	Shell TSP11	Summary of Alternate Background NRTI Therapy at End of Maintenance Phase (Extension Switch Population)		W124
1.25.	ES	Shell TSP9	Summary of Lipid Modifying Agent Use at Extension Baseline (Week 100) – Extension Switch Population		W124
1.26.	ES	Shell CLAD1	Summary of the Prevalence of HIV-1 Subtype at Induction Baseline (Week -20) - Extension Switch Population		W124

14.15.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Efficacy Analyses					
2.1.	ES	Shell TPEF2	Summary of Study Outcomes (50 c/mL cut-off) at Week 124 – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	HL, W124
2.2.	ES	Shell TSEF2	Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL by Visit (Extension Phase) – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥50c/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.	HL, W124

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.3.	ES	Shell TSEF2.1	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (Extension Phase) – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥50c/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.	HL, W124
2.4.	ES	Shell TSEF2	Proportion of Subjects with Plasma HIV-1 RNA <200 c/mL by Visit (Extension Phase) – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥50c/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.	W124

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.5.	ES	Shell TSEF3	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria by Visit During the Extension Phase (Up to Week 124) — Extension Switch Population	Oral Lead-In, Direct to Inject, Total show all planned extension phase visits up to Week 124.	HL, W124
2.6.	ES	Shell TSEF3.1	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria During the Extension Phase (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	HL, W124
2.7.	ES	Shell TSEF5	Summary of CD4+ Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	W124
2.8.	ES	Shell TSEF5	Summary of Change from Extension Baseline (Week 100) in CD4+ Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	W124
2.9.	ES	Shell TSEF5	Summary of CD8+ Cell Count (cells/mm^3) by Visit– Extension Phase (Extension Switch Population)	Oral Lead-In	W124
2.10.	ES	Shell TSEF5	Summary of Change from Extension Baseline (Week 100) in CD8+ Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)	Oral Lead-In	W124
2.11.	ES	Shell TSEF5	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit – Extension Phase (Extension Switch Population)	Oral Lead-In	W124
2.12.	ES	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Including Recurrences – Extension Phase (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	W124
2.13.	ES	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Excluding Recurrences – Extension Phase (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	W124
2.14.	ES	HIV2/Shell TSEF6.1	Summary of HIV-1 Disease Progressions and/or Deaths – Extension Phase (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	W124
2.15.	ES	Shell TPEF2	Summary of Study Outcomes (200 c/mL) at Week 124 – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total	W124
2.16.	ES	Shell TSEF11	Summary of Subjects per Viral Load Category by Visit (Extension Phase) — Extension Switch Population	Oral Lead-In, Direct to Inject, Total	W124

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.17.	ITT-E	Shell TPEF2	Summary of Study Outcomes (50 c/mL cut-off) at Week 124 – Snapshot Analysis (Randomized Q4W)		HL, W124
2.18.	ITT-E	Shell TSEF2	Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL by Visit (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)		W124
2.19.	ITT-E	Shell TSEF2.1	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)		W124
2.20.	ITT-E	Shell TSEF2	Proportion of Subjects with Plasma HIV-1 RNA <200 c/mL by Visit (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)		W124
2.21.	ITT-E	Shell TSEF3	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria by Visit During the Maintenance and Extension Phase (Up to Week 124) — Randomized Q4W	show all visits up to Week 124	W124
2.22.	ITT-E	Shell TSEF3.1	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria During the Maintenance and Extension Phase (Randomized Q4W)		HL, W124
2.23.	ITT-E	Shell TSEF5	Summary of Change from Maintenance Baseline (Day 1) in CD4+ Cell Count (cells/mm^3) by Visit - Maintenance and Extension Phase (Randomized Q4W)		W124
2.24.	ITT-E	Shell TSEF5	Summary of CD4+ Cell Count (cells/mm^3) by Visit – Maintenance and Extension Phase (Randomized Q4W)		W124
2.25.	ITT-E	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Including Recurrences - Maintenance and Extension Phase (Randomized Q4W)		W124
2.26.	ITT-E	HIV1/Shell TSEF 6.0	Summary of HIV-1 Associated Conditions Excluding Recurrences - Maintenance and Extension Phase (Randomized Q4W)		W124
2.27.	ITT-E	HIV2/Shell TSEF6.1	Summary of HIV-1 Disease Progressions and/or Deaths - Maintenance and Extension Phase (Randomized Q4W)		W124

Efficacy: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.28.	ITT-E	Shell TPEF2	Summary of Study Outcomes (200 c/mL) at Week 124 (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)		W124
2.29.	ITT-E	Shell TSEF11	Summary of Subjects per Viral Load Category by Visit (Maintenance and Extension Phase) — Randomized Q4W		W124

14.15.6. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.1.	ES	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL by Visit (Extension Phase) – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥50c/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.	HL, W124

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.2.	ES	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit (Extension Phase) – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA <50c/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.	HL, W124
2.3.	ES	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA <200 c/mL by Visit (Extension Phase) – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA <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%; otherwise, they are derived using the normal approximation.	W124

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.4.	ES	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA >=200 c/mL by Visit (Extension Phase) – Snapshot Analysis (Extension Switch Population)	Oral Lead-In, Direct to Inject, Total Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥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%; otherwise, they are derived using the normal approximation.	W124
2.5.	ES	Mid200056//wk96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA (log10 copies/mL) Profiles by Visit for CVF subjects (Extension Switch Population – Direct to Inject Group)	The first vertical line indicates extension phase day of first CAB/RPV injection. The second vertical reference line indicates last on-treatment extension phase day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB/RPV+1), day of LTFU HAART start date). This line is only for participants who discontinue from the Extension phase.	W124

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.6.	ES	Mid200056//wk96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA (log10 copies/mL) Profiles by Visit for CVF subjects (Extension Switch Population – Oral Lead-in Group)	The first vertical line indicates extension phase day for start of oral lead-in with oral CAB/RPV. The second vertical reference line indicates last on-treatment extension phase day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB/RPV+1), day of LTFU HAART start date). This line is only for participants who discontinue from the Extension phase.	W124
2.7.	ES	Mid200056//wk96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA Profiles by Visit for subjects who are in the category of 'viral load ≥50 c/mL' at Week 124 per Snapshot algorithm (Extension Switch Population – Direct to Inject Group)	The first vertical line indicates extension phase day of first CAB/RPV injection. The second vertical reference line indicates last on-treatment extension phase day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB/RPV+1), day of LTFU HAART start date). This line is only for participants who discontinue from the Extension phase.	HL, W124

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.8.	ES	Mid200056//wk96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA Profiles by Visit for subjects who are in the category of 'viral load ≥50 c/mL' at Week 124 per Snapshot algorithm (Extension Switch Population – Oral Lead-in Group)	The first vertical line indicates extension phase day for start of oral lead-in with oral CAB/RPV. The second vertical reference line indicates last on-treatment extension phase day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB/RPV+1), day of LTFU HAART start date). This line is only for participants who discontinue from the Extension phase.	HL, W124
2.9.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL by Visit (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)	Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥50c/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.	W124

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.10.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)	Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA < 50c/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.	W124
2.11.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA <200 c/mL by Visit (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)	Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA <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%; otherwise, they are derived using the normal approximation.	W124

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.12.	ITT - E	Shell FPEF1	Proportion (95% CI) of Subjects with HIV-1 RNA >=200 c/mL by Visit (Maintenance and Extension Phase) – Snapshot Analysis (Randomized Q4W)	Line plots, with 95% confidence intervals (CIs), for the proportion of participants with HIV-1 RNA ≥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%; otherwise, they are derived using the normal approximation.	W124
2.13.	ITT-E	Mid200056//wk 96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA (log10 copies/mL) Profiles by Visit) – for CVF subjects (Randomized Q4W)	The first vertical line indicates start of Induction phase investigational product (ABC/DTG/3TC or DTG). The second vertical line indicates start of Maintenance phase investigational product (oral CAB + oral RPV). The third vertical reference line indicates last on-treatment study day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB+RPV+1), day of LTFU HAART start date). This line is only for participants who withdraw from the Maintenance/Extension phase.	W124

Efficacy: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.14.	ITT - E	Mid200056//wk96cdisc/Figure 7.1007	Individual Plasma HIV-1 RNA Profiles by Visit for subjects who are in the category of 'HIV-1 RNA ≥50 c/mL' at Week 124 per Snapshot algorithm (Randomized Q4W arm)	The first vertical line indicates start of Induction phase investigational product (ABC/DTG/3TC or DTG). The second vertical line indicates start of Maintenance phase investigational product (oral CAB + oral RPV). The third vertical reference line indicates last on-treatment study day, i.e. min (max(day of last IP injection dose+35 days, day of last oral CAB+RPV+1), day of LTFU HAART start date). This line is only for participants who withdraw from the Maintenance/Extension phase.	HL, W124

14.15.7. Safety Tables – Extension Switch Population

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
3.1.	ES	Shell TS1.1	Summary of Extent of Exposure to Investigational Product – Extension Phase (Extension Switch Population)		HL, W124
3.2.	ES	Study 201584 (primary_02): Table 3.114	Summary of Categorized Needle Length and Gauge for CAB Injection - Extension Phase (Extension Switch Population)		W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.3.	ES	Study 201584 (primary_02): Table 3.115	Summary of Categorized Needle Length and Gauge for RPV Injection - Extension Phase (Extension Switch Population)		W124
3.4.	ES	Shell TS1.3	Summary of Adherence to Q4W IM Dosing Schedule - Extension Phase (Extension Switch Population)	Please refer to Section 14.6.2--Adherence to CAB/RPV Injection Schedule	W124
Adverse Events					
3.5.	ES	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)		HL, W124
3.6.	ES	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Extension Phase Oral Lead-in Period (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.7.	ES	AE3	Summary of Common Adverse Events (>=5%) by Overall Frequency – Extension Phase (Extension Switch Population)		W124
3.8.	ES	AE3	Summary of Common Grade 2-5 Adverse Events (>=1%) by Overall Frequency – Extension Phase (Extension Switch Population)		W124
3.9.	ES	AE5B	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)		HL, W124
3.10.	ES	AE3	Summary of All Drug-Related Grade 2-5 Adverse Events by Overall Frequency – Extension Phase (Extension Switch Population)		W124
Serious and Other Significant Adverse Events					
3.11.	ES	AE1	Summary of Serious Adverse Events by System Organ Class – Extension Phase (Extension Switch Population)		HL, W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.12.	ES	AE1	Summary of Serious Adverse Events by System Organ Class –– Extension Phase Oral Lead-in Period (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.13.	ES	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class – Extension Phase (Extension Switch Population)		W124
3.14.	ES	AE3	Summary of Non-Fatal Serious Adverse Events by Overall Frequency – Extension Phase (Extension Switch Population)		W124
3.15.	ES	AE3	Summary of Drug-Related Non-Fatal Serious Adverse Events by Overall Frequency – Extension Phase (Extension Switch Population)		W124
3.16.	ES	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by SOC – Extension Phase (Extension Switch Population)		HL, W124
3.17.	ES	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by SOC – Extension Phase Oral Lead-in Period (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.18.	ES	AE3	Summary of Common (>=5%) Non-Serious Adverse Events by Overall Frequency – Extension Phase (Extension Switch Population)		W124
3.19.	ES	EudraCT Non-serious AE AE15	Summary of Subjects and Number of Occurrences of Common (>=5%) Non-Serious Adverse Events by System Organ Class – Extension Phase (Extension Switch Population)	CS Core for FDAAA and EMA disclosure requirements. EudraCT Use macro TD_AE4VCTR for New Data Disclosure HARP Reporting Tools	W124
3.20.	ES	EudraCT SAE AE16	Summary of Subjects and Number of Occurrences of SAEs, Fatal SAEs, and Drug-related SAEs – Extension Phase (Extension Switch Population)	CS Core for FDAAA and EMA disclosure requirements. EudraCT	W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.21.	ES	AE5B	Summary of All Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)		W124
3.22.	ES	AE5B	Summary of All Drug-Related Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Extension Phase (Extension Switch Population)		W124
Injection Site Reaction Adverse Events					
3.23.	ES	Shell TS2.2	Summary of Injection Site Reaction Adverse Events (Event-Level Summary) – Extension Phase (Extension Switch Population)		HL, W124
3.24.	ES	Shell TS2.3	Summary of Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects	W124
3.25.	ES	Shell TS2.4	Summary of Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects	W124
3.26.	ES	Shell TS2.2	Summary of CAB Drug-Related Injection Site Reaction Adverse Events (Event-Level Summary) – Extension Phase (Extension Switch Population)		W124
3.27.	ES	Shell TS2.3	Summary of CAB Drug-Related Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects	W124
3.28.	ES	Shell TS2.4	Summary of CAB Drug-Related Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects	W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.29.	ES	Shell TS2.5	Summary of Maximum CAB Drug-Related Injection Site Reaction Adverse Event Grade by Needle Length (Common ISRs) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects	W124
3.30.	ES	Shell TS2.2	Summary of RPV Drug-Related Injection Site Reaction Adverse Events (Event-Level Summary) – Extension Phase (Extension Switch Population)		W124
3.31.	ES	Shell TS2.3	Summary of RPV Drug-Related Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects	W124
3.32.	ES	Shell TS2.4	Summary of RPV Drug-Related Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Extension Phase (Extension Switch Population)		W124
3.33.	ES	Shell TS2.5	Summary of Maximum RPV Drug-Related Injection Site Reaction Adverse Event Grade by Needle Length (Common ISRs) – Extension Phase (Extension Switch Population)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects	W124
Laboratory: Chemistry, Hematology and Renal Markers					
3.34.	ES	LB1	Summary of Chemistry Values by Visit – Extension Phase (Extension Switch Population)	(include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Beta-2 Microglobulin, Cystatin C, et al)	W124
3.35.	ES	LB1	Summary of Chemistry Changes from Extension Baseline (Week 100) by Visit – Extension Phase (Extension Switch Population)	CS Core (include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Cystatin C, and CKD-EP1 GFR using Creatinine, and CKD-EP1 using Cystatin C et al)	W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.36.	ES	Shell TS9.3	Summary of Maximum Extension Phase Emergent Chemistry Toxicities (Extension Switch Population)		W124
3.37.	ES	Shell TS9.2	Summary of Maximum Emergent Chemistry Toxicities – Extension Phase Oral Lead-in Period (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.38.	ES	LB1	Summary of Hematology Values by Visit – Extension Phase (Extension Switch Population)		W124
3.39.	ES	LB1	Summary of Hematology Changes from Extension Baseline (Week 100) by Visit – Extension Phase (Extension Switch Population)		W124
3.40.	ES	Shell TS9.3	Summary of Maximum Extension Phase Emergent Hematology Toxicities (Extension Switch Population)		W124
3.41.	ES	Shell TS9.2	Summary of Maximum Emergent Hematology Toxicities – Extension Phase Oral Lead-in Period (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.42.	ES	Shell TS16	Summary of Fasting Lipids Percentage Changes from Extension Baseline (Week 100) by Visit (Lipid LOCF) – Extension Phase (Extension Switch Population)		W124
Laboratory: Urinalysis					
3.43.	ES	UR3 or SHELL TS3	Summary of Urinalysis Dipstick Results by Visit – Extension Phase (Extension Switch Population)		W124
3.44.	ES	LB1	Summary of Urine Concentrations Changes from Extension Baseline (Week 100) by Visit – Extension Phase (Extension Switch Population)		W124
3.45.	ES	Shell TS4	Summary of Changes in Proteinuria Extension Baseline (Week 100) Laboratory Result to Maximum Extension Phase Laboratory Result – Extension Phase (Extension Switch Population)		W124
Laboratory: NCEP Lipid and Markers					

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.46.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Maximum Extension Phase Category – Triglycerides (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.47.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Maximum Extension Phase Category – Total Cholesterol (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.48.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Minimum Extension Phase Category – HDL Cholesterol (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.49.	ES	Shell TS5	Summary of Changes in Extension Baseline (Week 100) NCEP Fasting Lipid Category to Maximum Extension Phase Category – LDL Cholesterol (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.50.	ES	Shell TS6	Summary of Extension Phase Fasting TC/HDL Ratio Changes from Extension Baseline (Week 100) – Lipids LOCF (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
Laboratory: Hepatobiliary (Liver)					
3.51.	ES	Liver1 /Shell TS11	Summary of Liver Monitoring/Stopping Event Reporting – Extension Phase (Extension Switch Population)		W124
3.52.	ES	liver10/Shell TS12	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria – Extension Phase (Extension Switch Population)		W124
3.53.	ES	liver10/Shell TS12	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria – Extension Phase Oral Lead-in Period (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
ECG					
3.54.	ES	EG1	Summary of ECG Findings – Extension Phase (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.55.	ES	EG2	Summary of Change from Extension Baseline (Week 100) in ECG Values by Visit – Extension Phase (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.56.	ES	EG10	Summary of QTc Values by Category – Extension Phase (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.57.	ES	EG10	Summary of Change from Extension Baseline (Week 100) in QTc Values by Category – Extension Phase (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
Others					
3.58.	ES	VS1	Summary of Change from Extension Baseline (Week 100) in Vital Signs by Visit – Extension Phase (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.59.	ES	VS1	Summary of Change from Extension Baseline (Week 100) in Weight and BMI by Visit – Extension Phase (Extension Switch Population)	Switch Q4W Oral Lead-in Group Only	W124
3.60.	ES		Summary of Shift in BMI Categories at Week 104b	Switch Q4W Oral Lead-in Group Only	W124
Adverse Events of Special Interest					
3.61.	ES	See Safety Table 3.44 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.62.	ES	See Safety Table 3.48 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.63.	ES	See Safety Table 3.43 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.64.	ES	Shell TS14.1	Summary of Depression, Anxiety and Suicidal and Self-Injury Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety and Suicidal Ideation/Behaviour at Screening – Extension Phase (Extension Switch Population)	include additional stratification by 'any history' vs. 'no history'	W124
3.65.	ES	See Safety Table 3.38 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Seizure Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.66.	ES	See Safety Table 3.39 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hepatic Safety Profile: Assessment of Risk of Hepatotoxicity Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.67.	ES	See Safety Table 3.40 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hypersensitivity Reaction (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.68.	ES	See Safety Table 3.41 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.69.	ES	See Safety Table 3.42 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.70.	ES	See Safety Table 3.45 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.71.	ES	See Safety Table 3.46 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.72.	ES	See Safety Table 3.47 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Mood Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.73.	ES	See Safety Table 3.49 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Sleep Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.74.	ES	See Safety Table 3.51 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.75.	ES	See Safety Table 3.52 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.76.	ES	See Safety Table 3.53 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124
3.77.	ES	See Safety Table 3.54 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124

All Tables will have treatment columns for Oral lead-in, Direct-to-Inject and Total, unless otherwise specified)					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.78.	ES	See Safety Table 3.55 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Extension Phase (Extension Switch Population)		W124

14.15.8. Safety Tables – Maintenance + Extension Phase (Randomized Q4W Only)

No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
3.79.	Safety	Shell TS1.1	Summary of Extent of Exposure to Investigational Product – Maintenance and Extension Phase (Randomized Q4W)		W124
3.80.	Safety	Study 201584 (primary_02): Table 3.114	Summary of Categorized Needle Length and Gauge for CAB Injection – Maintenance and Extension Phase (Randomized Q4W)		W124
3.81.	Safety	Study 201584 (primary_02): Table 3.115	Summary of Categorized Needle Length and Gauge for RPV Injection – Maintenance and Extension Phase (Randomized Q4W)		W124
3.82.	Safety	Shell TS1.3	Summary of Adherence to Q4W IM Dosing Schedule – Maintenance and Extension Phase (Randomized Q4W)	please refer to Section 14.6.2-- Adherence to CAB/RPV Injection Schedule	W124
Adverse Events					
3.83.	Safety	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.84.	LTFU	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Long-term Follow-up Phase		W124
3.85.	Safety	AE3	Summary of Common Adverse Events (>=5%) by Overall Frequency – Maintenance and Extension Phase (Randomized Q4W)		W124
3.86.	Safety	AE3	Summary of Common Grade 2-5 Adverse Events (>=1%) by Overall Frequency – Maintenance and Extension Phase (Randomized Q4W)		W124
3.87.	Safety	AE5B	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)		W124
3.88.	Safety	AE3	Summary of All Drug-Related Grade 2-5 Adverse Events by Overall Frequency – Maintenance and Extension Phase (Randomized Q4W)		W124
Serious and Other Significant Adverse Events					
3.89.	Safety	AE1	Summary of Serious Adverse Events by System Organ Class – Maintenance and Extension Phase (Randomized Q4W)		W124
3.90.	Safety	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class – Maintenance and Extension Phase (Randomized Q4W)		W124
3.91.	Safety	AE3	Summary of Non-Fatal Serious Adverse Events by Overall Frequency – Maintenance and Extension Phase (Randomized Q4W)		W124
3.92.	Safety	AE3	Summary of Drug-Related Non-Fatal Serious Adverse Events by Overall Frequency – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.93.	Safety	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class – Maintenance and Extension Phase (Randomized Q4W)		W124
3.94.	Safety	AE3	Summary of Common (>=5%) Non-Serious Adverse Events by Overall Frequency – Maintenance and Extension Phase (Randomized Q4W)		W124
3.95.	Safety	EudraCT Non-serious AE AE15	Summary of Subjects and Number of Occurrences of Common (>=5%) Non-Serious Adverse Events by System Organ Class – Maintenance and Extension Phase (Randomized Q4W)	CS Core for FDAAA and EMA disclosure requirements. EudraCT Use macro TD_AE4VCTR for New Data Disclosure HARP Reporting Tools	W124
3.96.	Safety	EudraCT SAE AE16	Summary of Subjects and Number of Occurrences of SAEs, Fatal SAEs, and Drug-related SAEs – Maintenance and Extension Phase (Randomized Q4W)	CS Core for FDAAA and EMA disclosure requirements. EudraCT	W124
Injection Site Reaction Adverse Events					
3.97.	Safety	Shell TS2.2	Summary of Injection Site Reaction Adverse Events (Event-Level Summary) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.98.	Safety	Shell TS2.3	Summary of Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W124
3.99.	Safety	Shell TS2.4	Summary of Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.100.	Safety	Shell TS2.2	Summary of CAB Drug-Related Injection Site Reaction Adverse Events (Event-Level Summary) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.101.	Safety	Shell TS2.3	Summary of CAB Drug-Related Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for Q4W arm only)	W124
3.102.	Safety	Shell TS2.4	Summary of CAB Drug-Related Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for Q4W arm only)	W124
3.103.	Safety	Shell TS2.5	Summary of Maximum CAB Drug-Related Injection Site Reaction Adverse Event Grade by Needle Length (Common ISRs) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W124
3.104.	Safety	Shell TS2.2	Summary of RPV Drug-Related Injection Site Reaction Adverse Events (Event-Level Summary) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.105.	Safety	Shell TS2.3	Summary of RPV Drug-Related Subject-Level Characteristics of Injection Site Reaction Adverse Events (Overall and Common) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for randomized Q4W arm only)	W124
3.106.	Safety	Shell TS2.4	Summary of RPV Drug-Related Injection Site Reaction Adverse Events by Visit and Maximum Severity (Overall and Common) – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.107.	Safety	Shell TS2.5	Summary of Maximum RPV Drug-Related Injection Site Reaction Adverse Event Grade by Needle Length (Common ISRs) – Maintenance and Extension Phase (Randomized Q4W)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for Q4W arm only)	W124
3.108.	Safety	AE5B	Summary of All Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)		W124
3.109.	Safety	AE5B	Summary of All Drug-Related Adverse Events Excluding Injection Site Reactions by System Organ Class and Maximum Toxicity – Maintenance and Extension Phase (Randomized Q4W)		W124
Laboratory: Chemistry, Hematology and Renal Markers					
3.110.	Safety	LB1	Summary of Chemistry Values by Visit – Maintenance and Extension Phase (Randomized Q4W)	(include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Beta-2 Microglobulin, Cystatin C, et al)	W124
3.111.	Safety	LB1	Summary of Chemistry Changes from Maintenance Baseline (Day 1) by Visit – Maintenance and Extension Phase (Randomized Q4W)	CS Core (include lipids and glucose in Conventional Units, renal markers of Retinol Binding Protein, Cystatin C, and CKD-EP1 GFR using Creatinine, and CKD-EP1 using Cystatin C et al)	W124
3.112.	Safety	LB1	Summary of Hematology Values by Visit – Maintenance and Extension Phase (Randomized Q4W)		W124
3.113.	Safety	LB1	Summary of Hematology Changes from Maintenance Baseline (Day 1) by Visit – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.114.	Safety	Shell TS9.2	Summary of Maximum Maintenance and Extension Phase Emergent Chemistry Toxicities (Randomized Q4W)		W124
3.115.	Safety	Shell TS9.2	Summary of Maximum Maintenance and Extension Phase Emergent Hematology Toxicities (Randomized Q4W)		W124
Laboratory: Hepatobiliary (Liver)					
3.116.	Safety	Liver1 /Shell TS11	Summary of Liver Monitoring/Stopping Event Reporting – Maintenance and Extension Phase (Randomized Q4W)		W124
3.117.	Safety	liver10/Shell TS12	Summary of Subjects Meeting Hepatobiliary Abnormality Criteria - Maintenance and Extension Phase (Randomized Q4W)		W124
Urinalysis					
3.118.	Safety	UR3 or SHELL TS3	Summary of Urinalysis Dipstick Results by Visit – Maintenance and Extension Phase (Randomized Q4W)		W124
3.119.	Safety	LB1	Summary of Urine Concentrations Changes from Maintenance Baseline (Day 1) by Visit – Maintenance and Extension Phase (Randomized Q4W)		W124
3.120.	Safety	Shell TS4	Summary of Changes in Proteinuria Maintenance Baseline (Day 1) Laboratory Result to Maximum Maintenance Phase Laboratory Result – Maintenance and Extension Phase (Randomized Q4W)		W124
AEs of Special Interest					
3.121.	Safety	See Safety Table 3.44 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.122.	Safety	See Safety Table 3.48 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.123.	Safety	See Safety Table 3.43 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.124.	Safety	Shell TS14.1	Summary of Depression, Anxiety and Suicidal and Self-Injury Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety and Suicidal Ideation/Behaviour at Screening – Maintenance and Extension Phase (Randomized Q4W)	include additional stratification by 'any history' vs. 'no history'	W124
3.125.	Safety	See Safety Table 3.38 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Seizure Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.126.	Safety	See Safety Table 3.39 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hepatic Safety Profile: Assessment of Risk of Hepatotoxicity Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.127.	Safety	See Safety Table 3.40 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Hypersensitivity Reaction (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.128.	Safety	See Safety Table 3.41 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.129.	Safety	See Safety Table 3.42 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.130.	Safety	See Safety Table 3.45 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.131.	Safety	See Safety Table 3.46 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
3.132.	Safety	See Safety Table 3.47 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Mood Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.133.	Safety	See Safety Table 3.49 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Sleep Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.134.	Safety	See Safety Table 3.51 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.135.	Safety	See Safety Table 3.52 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.136.	Safety	See Safety Table 3.53 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124

No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.137.	Safety	See Safety Table 3.54 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124
3.138.	Safety	See Safety Table 3.55 in reporting effort: gsk1265744/mid209522/iss_01	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences) – Maintenance and Extension Phase (Randomized Q4W)		W124

14.15.9. Safety Tables – Long Term Follow Up

No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
3.139.	LTFU	AE1	Summary of Serious Adverse Events by System Organ Class – Long Term Follow Up Phase		W124

14.15.10. Safety Figures – Extension Switch Population

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
3.1.	ES	LIVER9	Scatter Plot of Maximum vs. Extension Baseline (Week 100) for ALT – Extension Phase (Extension Switch Population)		W124
3.2.	ES	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – Extension Phase (Extension Switch Population)		W124
3.3.	ES	Shell FS2	Matrix Plot of Maximum Liver Chemistries – Extension Phase (Extension Switch Population)		W124
3.4.	ES	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Extension Phase Injection Site Reaction AEs by Maximum Grade — CAB and/or RPV (Extension Switch Population)		W124
3.5.	ES	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – CAB (Extension Switch Population)		W124
3.6.	ES	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – RPV (Extension Switch Population)		W124
3.7.	ES	Shell FS4	Plot of Incidence of Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV (Extension Switch Population)		W124
3.8.	ES	Shell FS4	Plot of Incidence of Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB (Extension Switch Population)		W124
3.9.	ES	Shell FS4	Plot of Incidence of Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV (Extension Switch Population)		W124

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.10.	ES	Shell FS4/	Plot of Incidence of Grade 3-5 Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) — CAB and/or RPV (Extension Switch Population)		W124
3.11.	Safety	Shell FS1	Bar Chart of Fasting Lipid NCEP Categories at Week W104 vs. Extension Baseline (Week 100) – Triglycerides, Total Cholesterol, LDL Cholesterol	Switch Q4W Oral Lead-in Group Only	W124
3.12.	Safety	Shell FS1	Bar Chart of Fasting Lipid NCEP Categories at Week 104 vs. Extension Baseline (Week 100) - HDL Cholesterol	Switch Q4W Oral Lead-in Group Only	W124

14.15.11. Safety Figures – Maintenance + Extension Phase (Randomized Q4W)

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
3.13.	Safety	LIVER9	Scatter Plot of Maximum vs. Maintenance Baseline (Day 1) for ALT – Maintenance and Extension Phase		W124
3.14.	Safety	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – Maintenance and Extension Phase		W124
3.15.	Safety	Shell FS2	Matrix Plot of Maximum Liver Chemistries – Maintenance and Extension Phase		W124
3.16.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance and Extension Phase Injection Site Reaction AEs by Maximum Grade – CAB and/or RPV (Randomized Q4W)		W124
3.17.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance and Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – CAB (Randomized Q4W)		W124

Safety: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.18.	Safety	Shell FS3	Plot of Onset, Duration, and Severity of Overall and Common Maintenance and Extension Phase Drug-Related Injection Site Reaction AEs by Maximum Grade – RPV (Randomized Q4W)		W124
3.19.	Safety	Shell FS4	Plot of Incidence of Maintenance and Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV (Randomized Q4W)		W124
3.20.	Safety	Shell FS4	Plot of Incidence of Maintenance and Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB (Randomized Q4W)		W124
3.21.	Safety	Shell FS4	Plot of Incidence of Maintenance and Extension Phase Drug-Related Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV (Randomized Q4W)		W124
3.22.	Safety	Shell FS4	Plot of Incidence of Grade 3-5 Maintenance and Extension Phase Injection Site Reaction Adverse Events by Visit (Overall and Common) — CAB and/or RPV (Randomized Q4W)		W124

14.15.12. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The similar outputs below from study 200056 (week48idsl), unless otherwise specified	**Deliverable [Priority]**
PK					
4.1.	PK	PKCT1	Summary of Extension Phase Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics (Extension Switch Population)		W124

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The similar outputs below from study 200056 (week48idsl), unless otherwise specified	**Deliverable [Priority]**
4.2.	PK	PKCT1	Summary of Extension Phase Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics (Extension Switch Population)		W124
4.3.	PK	PKCT1	Summary of Evaluable Extension Phase Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics (Extension Switch Population)		W124
4.4.	PK	PKCT1	Summary of Evaluable Extension Phase Plasma RPV PK Concentration (ng/mL) -Time Data by Treatment and Visit – Including Log-transformed Statistics (Extension Switch Population)		W124
4.5.	PK	PKCT1	Summary of Extension Phase Plasma CAB PK Concentration (ug/mL) -Time Data by Visit and Hepatitis C Status at Induction Baseline – Including Log-transformed Statistics (Extension Switch Population)		W124
4.6.	PK	PKCT1	Summary of Extension Phase Plasma RPV PK Concentration (ng/mL) -Time Data by Visit and Hepatitis C Status at Induction Baseline – Including Log-transformed Statistics (Extension Switch Population)		W124
4.7.	LTFU	PKCT1	Summary of Long-Term Follow-up Phase Plasma CAB PK Concentration (ug/mL) -Time Data by Treatment and Visit - Included Log-transformed Statistics	Table 10.1001 (WK96CDISC); For 'Total' treatment group (combining Q4W and Switch Q4W groups)	W124
4.8.	LTFU	PKCT1	Summary of Long-Term Follow-up Phase Plasma RPV PK Concentration (ng/mL) -Time Data by Visit (Excluding Subjects Receiving Oral RPV in the LTFU Phase) - Including Log-transformed Statistics	Table 10.1002 (WK96CDISC) For 'Total' treatment group (combining Q4W and Switch Q4W groups)	W124

14.15.13. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The mock-up below from study 200056 (week48idsl)	**Deliverable [Priority]**
PK					
4.1.	PK	PKCF1	Individual Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.2.	PK	PKCF1	Individual Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.3.	PK	PKCF2	Mean (SD) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.4.	PK	PKCF3	Median (5th and 95th percentile) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.5.	PK	PKCF2	Mean (SD) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.6.	PK	PKCF3	Median (5th and 95th percentile) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.7.	PK	PKCF2	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.8.	PK	PKCF3	Median (5th and 95th percentile) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The mock-up below from study 200056 (week48idsl)	**Deliverable [Priority]**
4.9.	PK	PKCF2	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.10.	PK	PKCF3	Median (5th and 95th percentile) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.11.	PK	PKCF2	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.12.	PK	PKCF2	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Semi-Log) – Extension Phase (Extension Switch Population)		W124
4.13.	LTFU	PKCF6	Individual Plasma CAB and RPV Concentration-Time Plots (Semi-Log) -- Post Last Injection for Subjects in LTFU	Overlay all subjects, across arms; use actual relative time since last injection as the x-variable, labelled as “Time post last injection (Weeks)”; one graph each for CAB and RPV, respectively, on the same page. Mark subjects who are receiving oral RPV during LTFU.	W124

14.15.14. Virology Tables

Virology: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** (mock up below from study 200056\wk48idsl)	**Title**	**Programming Notes**	**Deliverable**
7.1.	ES		Summary of the Prevalence of Major Resistance Mutations of INI, NRTI, NNRTI and PI Class at Induction Baseline (Week -20) -- Plasma Sample (Extension Switch Population)	Major Mutation of NRTI, NNRTI, PI class, and known INI resistance mutations, per Section 14.6.6. Need to add small 'n' for actual no. of subjects included in the analysis. The % will be based on 'n' rather than 'N' (programming for defining class: can refer to arenv/arprod/gsk1349572/mid200304/week24/drivers/t_adpf_4001.sas	W124
7.2.	CVF	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure During the Maintenance and Extension Phase – Induction Baseline (Week -20) and Time of CVF (Randomized Q4W arm)	Randomized Q4W arm only	W124
7.3.	CVF (Extension Switch)	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria During the Extension Phase – Induction Baseline (Week -20) and Time of CVF (Extension Switch Population)	Switch Q4W IM group only	HL, W124

Virology: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell** (mock up below from study 200056\wk48idsl)	**Title**	**Programming Notes**	**Deliverable**
7.4.	ITT-E	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Non-CVF Subjects (Randomized Q4W)	May include genotypic and phenotypic data on the last on-treatment isolates for participants with HIV-1 RNA ≥200 c/mL Include columns for phase, phase treatment, phase day.	W124
7.5.	ES	Shell TV1	Summary of Viral load, Genotypic and Phenotypic data for Non-CVF Subjects (Extension Switch Population)	May include genotypic and phenotypic data on the last on-treatment isolates for participants with HIV-1 RNA ≥200 c/mL Include columns for phase, phase treatment, phase day.	W124

14.15.15. ICH Listings

ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases). Listings will present data for the Randomized Q4W arm (data collected in any study phase, where applicable) and the Extension Switch Q4W arm (data collected in the Extension and LTFU phases, where applicable).					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Study Population					
1.	ITT-E	ES2	Listing of Reasons for Study Withdrawal		W124
2.	ITT-E	ES2	Listing of Reasons for Study Drug Discontinuation		W124
3.	ITT-E	DV2	Listing of Important Protocol Deviations	Remove column for "Deviation Requires Exclusion from the Per Protocol Population".	W124
4.	ITT-E	DM2	Listing of Demographic Characteristics		W124
5.	ITT-E	DM9	Listing of Race		W124
Primary Efficacy					
6.	ITT-E	Study 201584 (primary_02): Listing 33	Listing of All Plasma HIV-1 RNA Data		W124
7.	ITT-E	Shell LPEF1	Listing of Study Outcome (50 c/mL) at Week 124 – Snapshot Analysis		HL, W124
Exposure					
8.	Safety	HIV_IP5	Listing of Investigational Product Exposure Data		HL, W124
Adverse Events					
9.	Safety	AE8	Listing of All Adverse Events		W124
10.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events		W124
11.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event		W124

ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases). Listings will present data for the Randomized Q4W arm (data collected in any study phase, where applicable) and the Extension Switch Q4W arm (data collected in the Extension and LTFU phases, where applicable).					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
12.	Safety	AE8	Listing of Fatal Adverse Events		W124
13.	Safety	AE8	Listing of Non-Fatal Serious Adverse Events		W124
14.	Safety	AE8	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product		HL, W124
15.	Safety	AE8	Listing of Changes in Intensity/Grades of Injection Site Related AE	Based on AE details inform page for changes in intensity of the same event.	W124
16.	Safety	PREG1a	Listing of Subjects Who Became Pregnant During the Study		W124
Laboratory					
Hepatobiliary (Liver)					
17.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver stopping Events		W124
18.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events		W124
ECG & Vital Signs					
19.	Safety	EG3	Listing of ECG Values for subjects with a value of potential clinical importance		W124
20.	Safety	EG5	Listing of ECG Findings		W124
eC-SSRS					
21.	Safety	PSRAE1	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description (Section 1-Section 2)		W124
22.	Safety	PSRAE3	Listing of Possible Suicidality-Related Adverse Event Data: Possible Cause(s) (Section 3)		W124
23.	Safety	PSRAE4	Listing of Possible Suicidality-Related Adverse Event Data (Section 4)		W124

ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases). Listings will present data for the Randomized Q4W arm (data collected in any study phase, where applicable) and the Extension Switch Q4W arm (data collected in the Extension and LTFU phases, where applicable).					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
24.	Safety	PSRAE5	Listing of Possible Suicidality-Related Adverse Event Data (Section 5-Section 8)		W124
PK					
25.	PK	Study 200056 Listing 10.1001(wk48idsl)	Listing of Plasma CAB PK Concentration-Time Data	Add a variable of 'evaluable' (Y/N)	W124
26.	PK	Study 200056 Listing 10.1002(wk48idsl)	Listing of Plasma RPV PK Concentration-Time Data	Add a variable of 'evaluable' (Y/N)	W124
27.	LTFU	Study 200056 Listing 10.1001(wk48idsl)	Listing of Plasma CAB PK Concentration-Time Data (LTFU Phase)	Add a variable of 'evaluable' (Y/N)	W124
28.	LTFU	Study 200056 Listing 10.1002(wk48idsl)	Listing of Plasma RPV PK Concentration-Time Data (LTFU Phase)	Add a variable of 'evaluable' (Y/N)	W124
Other					
29.	ITT-E	CM2	Listing of Concomitant Medications for Subjects with Confirmed Virologic Failure		W124

14.15.16. Non-ICH Listings

Non-ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases). Listings will present data for the Randomized Q4W arm (data collected in any study phase, where applicable) and the Extension Switch Q4W arm (data collected in the Extension and LTFU phases, where applicable), unless otherwise stated in the programming notes.					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Study Population					
30.	ITT-E	ES2	Listing of Reasons for Maintenance Phase Withdrawal (Randomized Q4W)		W124
31.	ITT-E	ES2	Listing of Reasons for Extension Phase Withdrawal (Randomized Q4W)		HL, W124
32.	ES	ES2	Listing of Reasons for Extension Phase Withdrawal (Extension Switch Population)		HL, W124
33.	LTFU	ES2	Listing of Reasons for Long-term Follow Up Withdrawal		W124
34.	ITT-E	CA3	Listing of Concomitant ART Medications Received during the Maintenance and/or Extension Phase		W124
35.	ITT-E	CA3	Listing of Subjects with Changes in Concomitant ARTs during the Maintenance Phase and/or Extension Phase (Randomized Q4W)		W124
36.	ES	CA3	Listing of Subjects with Changes in Concomitant ARTs during the Extension Phase (Extension Switch Population)		W124
37.	ITT-E	CA3	Listing of ART Medications Received during LTFU Phase		W124
38.	ES	Shell LSP11	Listing of Investigational Product Accountability - Oral Regimens (Extension Switch Population)		W124
39.	ITT-E		Listing of Subjects with Hepatitis C at Induction Baseline (Week -20)		W124
Efficacy					
40.	CVF	Shell LSEF3	Listing of All Plasma HIV-1 RNA Data for Subjects with Confirmed Virologic Failure		W124

Non-ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases). Listings will present data for the Randomized Q4W arm (data collected in any study phase, where applicable) and the Extension Switch Q4W arm (data collected in the Extension and LTFU phases, where applicable), unless otherwise stated in the programming notes.					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
41.	ITT-E	Shell LSEF1	Listing of All Plasma HIV-1 RNA data for subjects with viral load >=50 c/mL at any time during the Maintenance and/or Extension Phase		HL, W124
42.	ITT-E	Shell LSEF5	Listing of HIV-1 Associated Conditions		W124
Safety					
43.	Safety	See Listing 3 in reporting effort: gsk1265744/mid209522/iss_01	Listing of all Subjects Meeting Liver Stopping Criteria		W124
44.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting		W124
45.	Safety	LIVER6	Listing of Liver Event Information for RUCAM Score		W124
46.	Safety	LIVER7	Listing of Liver Biopsy Details		W124
47.	Safety	LIVER8	Listing of Liver Imaging Details		W124
48.	Safety	Liver13	Listing Subjects Meeting Hepatobiliary Lab Criteria	Please also add those additional items shown in the summary of subjects meeting hepatobiliary lab criteria post-baseline (i.e. AST >3xULN and ALP <2xULN and BIL >=2xULN]; ALT+AST>=xx)	W124
49.	Safety	AE8	Listing of Adverse Events Related to Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses		W124

Non-ICH: Listings (Global Programming Note: Include columns for phase, phase treatment, phase day, where data is collected in multiple phases). Listings will present data for the Randomized Q4W arm (data collected in any study phase, where applicable) and the Extension Switch Q4W arm (data collected in the Extension and LTFU phases, where applicable), unless otherwise stated in the programming notes.					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
50.	Safety	EG3	Listing of ECG Values for Subjects with Adverse Events Related to Prolongation of the Corrected QT Interval of the ECG in Supra Therapeutic Doses		W124
51.	Safety	Latte2 WK96CDISC report	Listing of Each Subjects ALT, AST, Bilirubin (including total and direct Bilirubin), INR, and ALP for subject meeting Hepatobiliary Lab abnormality criteria	8.1037 (add AST, ALP, INR, and direct Bilirubin to the listing and only for subject meeting Hepatobiliary Lab abnormality criteria)	W124
52.	Safety	Latte2 WK96CDISC report	Listing of Investigational Product Exposure Data for Subject Receiving Oral Bridging	8.1038	W124
53.	Safety	DEV1	Listing of Dosing Errors and IP Device Malfunctions		W124
Virology (mock up below from study 200056\wk96cdisc), 'Study Phase' will be added as a column to the listing.					
54.	CVF	Listing 9.1005	Listing of Replication Capacity in IN and PR/RT Region	Show data in all phases for randomized Q4W IM and extension switch IM participants.	W124
55.	ITT-E	Table 9.1009	Listing of Genotypic Mutation Data at All Timepoints	Show data in all phases for randomized Q4W IM and extension switch IM participants.	W124

14.16. Appendix 16: IDMC

An IDMC was instituted to perform a triggered periodic review of the accumulating data based on confirmed virologic failures to ensure that subjects are not being sub-optimally treated. In addition, the IDMC will review a futility analysis when 50% of subjects will have reached their Week 24 visit. See full details of the analysis and decision criteria in the IDMC charter.

A list of outputs required for each IDMC analysis was provided in the IDMC Charter, Section 12.3, Appendix C.

Data handing methods and derived data definitions were provided in a separate critical components RAP.

14.16.1. CVF Monitoring (Adhoc IDMC review)

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

The Statistics Data Analysis Centre (SDAC) is notified by the study virologist in writing every time a CVF occurs in either study. The SDAC will track the number of subjects 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).

14.17. Appendix 17: Variables Defined for Time to Event Analysis

Programming Instructions for the Kaplan-Meier analysis of treatment-related discontinuation equals failure (TRDF)		
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=Date 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 for discontinuation based on Maintenance Conclusion form in the eCRF. 'Treatment related AE' is defined as subjects that have primary reason for withdrawal =AE and that the participant has at least one AE considered drug related and leading to withdrawal/permanent discontinuation of investigational product.	CNSR=0	EVNTDESC= terms in italic, respectively. For ABC/DTG/3TC arm: AVAL= min [Study Day of Maintenance Phase Discontinuation, Study Day of Maintenance IP Stop Date + 1] For Q4W arm: AVAL= min [Study Day of Maintenance Phase Discontinuation, max(Study Day of Last Q4W IM Dose + 35, Study Day of Last Oral CAB/RPV Dose + 1)] Note: Last Q4W IM / last oral dose/ Maintenance IP Stop Date is only applied to subjects who permanently discontinue from study treatment. 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
4. Participant did not have premature withdrawal from the Maintenance Phase	CNSR=1	EVNTDESC='Censored due to data cutoff for analysis'

Programming Instructions for the Kaplan-Meier analysis of treatment-related discontinuation equals failure (TRDF)		
Condition	**Censor Status**	**Event Description/AVAL**
		AVAL = Last on-treatment date during the Maintenance Phase, For ABC/DTG/3TC arm: min [Study Day of Week 100 Visit, Day of Last Contact at time of analysis, Study Day of Maintenance IP stop Date + 1] For Q4W arm min [Study Day of Week 100 Visit, Study Day of Starting LTFU HAART, Study Day of Last Contact Date at time of analysis, max(Study Day of Last Q4W IM Dose + 35, Study Day of Last oral CAB/RPV dose + 1)]

Note: Last Q4W IM Dose & Last oral CAB/RPV dose is only applied to participants who permanently discontinue from study treatment.

The same approach as will be used to define 'ERDF', Efficacy-related discontinuation equals failure, except that the reason of withdrawal in Condition 2 will be restricted to 'Lack of Efficacy'.

14.18. Appendix 18: Japan-Specific Requirements

The following data displays will be produced to support reporting requirements for an expected regulatory submission in Japan.

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	11.01 to 11.n	11.01 to 11.n
Efficacy	12.01 to 12.n	12.01 to 12.n
Safety	13.01 to 13.n	13.01 to 13.n
Pharmacokinetic	14.01 to 14.n	14.01 to 14.n
Health Outcomes	15.01 to 15.n	15.01 to 15.n
Section	**Listings**	
ICH Listings	100 to y	
Other Listings	200 to z	

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

14.18.1. Study Population Tables - Japan

Study Population Japan: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Demography and Baseline					
11.1.	Intent-to-Treat Exposed (Japan)	Shell TSP2	Summary of Demographic Characteristics	See also DM1 in IDSL Age categorization will include: <=18, 19-64, >=65 (FDAAA requirement) 18-64, 65-84, >=85 (EMA requirement)	W48 Japan, W96 Japan

14.18.2. Efficacy Tables - Japan

Efficacy Japan: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
12.1.	Intent-to-Treat Exposed (Japan)	Shell TPEF1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	W48 Japan, W96 Japan
12.2.	Per-Protocol (Japan)	Shell TPEF1	Summary of Analysis for Proportion of Subjects with Plasma HIV-1 RNA ≥50 c/mL at Week 48 (Maintenance Phase) – Snapshot Analysis (Per-Protocol Population - Japan)	For W96 deliverable, replace 'Week 48' with 'Week 96'	W48 Japan, W96 Japan

Efficacy Japan: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
12.3.	Intent-to-Treat Exposed (Japan)	Shell TPEF2	Summary of Study Outcomes (50 c/mL cut-off) at Week 48 (Maintenance Phase) – Snapshot Analysis	For W96 deliverable, replace 'Week 48' with 'Week 96'	W48 Japan, W96 Japan

14.18.3. Safety Tables - Japan

Safety Japan: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
13.1.	Safety (Japan)	AE1	Summary of All Adverse Events by System Organ Class – Maintenance Phase	CS Core	W48 Japan, W96 Japan
13.2.	Safety (Japan)	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Maintenance Phase	CS Core	W48 Japan, W96 Japan
13.3.	Safety (Japan)	AE5B	Summary of All Adverse Events by System Organ Class and Maximum Toxicity – Oral Lead-in Period at Maintenance Phase	CS Core (for Q4W arm only)	W48 Japan, W96 Japan
13.4.	Safety (Japan)	AE3	Summary of All Grade 3 or Higher Adverse Events by Overall Frequency – Maintenance Phase		W48 Japan, W96 Japan
13.5.	Safety	AE3	Summary of All Grade 3 or Higher Adverse Events by Overall Frequency – Maintenance Phase (Safety Population)	New	W48 Japan, W96 Japan

Safety Japan: Tables					
13.6.	Safety (Japan)	AE1	Summary of All Drug-Related Adverse Events by System Organ Class– Maintenance Phase		W48 Japan, W96 Japan
13.7.	Safety (Japan)	AE5B	Summary of All Drug-Related Adverse Events by System Organ Class and Maximum Toxicity – Maintenance Phase	CS Core	W48 Japan, W96 Japan
Serious and Other Significant Adverse Events					
13.8.	Safety (Japan)	AE1	Summary of Serious Adverse Events by System Organ Class – Maintenance Phase	CS Core	W48 Japan, W96 Japan
13.9.	Safety (Japan)	AE1	Summary of Drug-Related Serious Adverse Events by System Organ Class – Maintenance Phase	CS Core	W48 Japan, W96 Japan
13.10.	Safety (Japan)	AE1	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by System Organ Class– Maintenance Phase	CS Core	W48 Japan, W96 Japan
Injection Site Reaction Adverse Events					
13.11.	Safety (Japan)	Shell TS2.2	Summary of Injection Site Reaction Adverse Events (Event-Level Summary) –Maintenance Phase	(for Q4W arm only)	W48 Japan, W96 Japan
13.12.	Safety (Japan)	Shell TS2.3	Summary of Subject-Level Characteristics of Injection Site Reaction Adverse Events – Overall and Common (Maintenance Phase)	Common ISR includes pain, induration, nodules and any other ISR with ≥5% subjects (for Q4W arm only)	W48 Japan, W96 Japan

14.18.4. Pharmacokinetic Tables - Japan

Pharmacokinetic Japan: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes** The similar outputs below from study 200056 (week48idsl), unless otherwise specified	**Deliverable [Priority]**
PK					
14.1.	Japan PK	PKCT1	Summary of Plasma CAB PK Concentrations (ug/mL) -Time Data (Q4W arm) – Day 1	Day 1 (following first oral CAB dose during lead-in phase): Pre-dose, 1, 2, 3, 4, 8, and 24 hours post-dose	W48 Japan
14.2.	Japan PK	PKCT1	Summary of Plasma CAB PK Concentration (ug/mL) - Time Data by Visit (Q4W arm) – Week 4b to Week 48	Table 10.1011	Japan W48
14.3.	Japan PK	PKCT1	Summary of Evaluable Plasma CAB PK Concentration (ug/mL) -Time Data by Visit (Q4W arm) – Week 4b to Week 48	Table 10.1011	Japan W48
14.4.	Japan PK	PKCT1	Summary of Plasma RPV PK Concentration (ng/mL) - Time Data by Visit (Q4W arm) – Week 4b to Week 48	Table 10.1011	Japan W48
14.5.	Japan PK	PKCT1	Summary of Evaluable Plasma RPV PK Concentration (ng/mL) -Time Data by Visit (Q4W arm) – Week 4b to Week 48	Table 10.1011	Japan W48
14.6.	Japan PK	PKPT4	Summary of Derived Plasma CAB PK Parameters at Day 1	GSK1265744/LAI117010, Table 3.3	

14.18.5. Pharmacokinetic Figures - Japan

Pharmacokinetic Japan: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK					
14.1.	Japan PK	PKCF1P	Individual Plasma CAB Concentration-Time Plots by Subject (Linear and Semi-Log) – Day 1	One plot per subject; Day 1 (following first oral CAB dose during lead-in phase): Pre-dose, 1, 2, 3, 4, 8, and 24 hours post-dose	Japan W48
14.2.	Japan PK	PKCF1P	Individual Plasma CAB Concentration-Time Plots by Treatment (Linear and Semi-Log) – Day 1	Overlay all subjects; Day 1 (following first oral CAB dose during lead-in phase): Pre-dose, 1, 2, 3, 4, 8, and 24 hours post-dose	Japan W48
14.3.	Japan PK	PKCF1P	Individual Plasma CAB Concentration-Time Plots by Subject (Linear and Semi-Log) – Week 4b to Week 48	One plot per subject	Japan W48
14.4.	Japan PK	PKCF1P	Individual Plasma CAB Concentration-Time Plots by Treatment (Linear and Semi-Log) – Week 4b to Week 48	Overlay all subjects	Japan W48, Japan W96
14.5.	Japan PK	PKCF1	Individual Plasma RPV Concentration-Time Plots by Subject (Linear and Semi-Log) – Week 4b to Week 48	One plot per subject	Japan W48, Japan W96
14.6.	Japan PK	PKCF1	Individual Plasma RPV Concentration-Time Plots by Treatment (Linear and Semi-Log) – Week 4b to Week 48	Overlay all subjects	Japan W48, Japan W96

Pharmacokinetic Japan: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.7.	Japan PK	PKCF2	Mean (SD) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Day 1	Figure 10.1003; Day 1 (following first oral CAB dose during lead-in phase): Pre-dose, 1, 2, 3, 4, 8, and 24 hours post-dose	Japan W48,
14.8.	Japan PK	PKCF3	Median (5th and 95th percentile) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Day 1	Figure 10.1004; Day 1 (following first oral CAB dose during lead-in phase): Pre-dose, 1, 2, 3, 4, 8, and 24 hours post-dose	Japan W48
14.9.	Japan PK	PKCF2	Mean (SD) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1003	Japan W48, Japan W96
14.10.	Japan PK	PKCF3	Median (5th and 95th percentile) Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1004	Japan W48, Japan W96
14.11.	Japan PK	PKCF2	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1003	Japan W48, Japan W96
14.12.	Japan PK	PKCF3	Median (5th and 95th percentile) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1004	Japan W48, Japan W96
14.13.	Japan PK	PKCF2	Mean (SD) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1005	Japan W48, Japan W96
14.14.	Japan PK	PKCF3	Median (5th and 95th percentile) Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1006	Japan W48, Japan W96

Pharmacokinetic Japan: Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14.15.	Japan PK	PKCF2	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1007 Visits up to W52 for the W48 deliverable.	Japan W48, Japan W96
14.16.	Japan PK	PKCF3	Median (5th and 95th percentile) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) – Week 4b to Week 48	Figure 10.1008 Visits up to W52 for the W48 deliverable.	Japan W48, Japan W96

14.18.6. Health Outcomes Tables - Japan

Health Outcomes Japan: Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Treatment Satisfaction (HIVTSQs)					
15.1.	Intent-to-Treat Exposed (Japan)	Shell THO2	Proportion of Subjects with HIVTSQs – Treatment Satisfaction Individual Item Scores by Visit - LOCF) (Maintenance Phase)		Japan W48, Japan W96
15.2.	Intent-to-Treat Exposed (Japan)	Shell THO1	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit - LOCF) (Maintenance Phase)		Japan W48, Japan W96
15.3.	Intent-to-Treat Exposed (Japan)	Shell THO1	Summary of HIVTSQs - Change from Maintenance Baseline (Day 1) in Total Treatment Satisfaction Score by Visit (Maintenance Phase)		Japan W48, Japan W96
15.4.	Intent-to-Treat Exposed (Japan)	Shell THO1	Summary of HIVTSQs - Change from Maintenance Baseline (Day 1) in Total Treatment Satisfaction Score by Visit - LOCF (Maintenance Phase)		Japan W48, Japan W96

Health Outcomes Japan: Tables					
Treatment Satisfaction (HIVTSQc)					
15.5.	Intent-to-Treat Exposed (Japan)	Shell THO2	Proportion of Subjects with HIVTSQc – Treatment Satisfaction Individual Item Scores at Week 48 (Maintenance Phase)		Japan W48
15.6.	Intent-to-Treat Exposed (Japan)	Shell THO1	Summary of HIVTSQc - Total Treatment Satisfaction Score at Week 48 (Maintenance Phase)		Japan W48
15.7.	Intent-to-Treat Exposed (Japan)	See Table 6.41 in reporting effort: gsk1265744/201584/primary_02	Summary of HIVTSQc Individual Item Scores at Week 48 (Maintenance Phase)		Japan W48
Preferences (Dichotomous preference question) (for Q4W IM)					
15.8.	Intent-to-Treat Exposed (Japan)	Shell THO8	Treatment Preference at Week 48 (Maintenance Phase)		Japan W48

14.18.7. ICH Listings - Japan

Non-ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetic					
100.	All Enrolled (Japan)	AE8	Listing of All Adverse Events (Induction + Maintenance Phase)		Japan W48, Japan W96
101.	All Enrolled (Japan)	Study 201584 (primary_02): Listing 33	Listing of All Plasma HIV-1 RNA Data		Japan W48, Japan W96

14.18.8. Non-ICH Listings - Japan

Non-ICH: Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetic					
200.	Japan PK	PKPL1	Listing of Derived Plasma CAB Pharmacokinetic Parameters – Day 1		Japan W48
201.	Japan PK	PKCL1	Listing of Plasma CAB Pharmacokinetic Concentration Time Data		Japan W48, Japan W96
202.	Japan PK	PKCL1	Listing of Plasma RPV Pharmacokinetic Concentration Time Data		Japan W48, Japan W96

14.19. Appendix 19: List of Data Displays for Subcutaneous 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.

All data displays (Tables, Figures & Listings) will use the term "Subject" which reflects CDISC and GSK Data Display Standards terminology. The RAPIDO Data Viewer will be utilized in this study at SAC and will take the place of many previously produced listings.

14.19.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.18	
Efficacy	2.1 to 2.20	2.1 to 2.4
Safety	3.1 to 3.75	3.1 to 3.13
Pharmacokinetic	4.1 to 4.12	4.1 to 4.8
Health Outcomes	6.1 to 6.21	
Virology	7.1 to 7.3	
Section	**Listings**	
ICH Listings	1 to 13	
Other Listings	14 to 20	

14.19.2. Mock Example Shell Referencing

For all displays referring to A2M (207966), remove treatment arm distinction from all shells (i.e. Q4W vs. Q8W) unless otherwise specified.

14.19.3. Deliverables

Delivery [1]	Description
SS-ISR	Sub-study ISR Monitoring Interim
SS-Interim	Sub-study Week 9 Interim Analysis
SS-HL	Headline at Sub-study SAC
SS-SAC	Sub-study SAC

14.19.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.1	Sub-study Enrolled	201584/primary_01/T1.2	Summary of Sub-study Subjects Enrolled by Country and Site ID	Remove Induction Phase column. Do not include countries and sites without any subjects enrolled in the sub-study.	SS-Interim SS-SAC
1.2	Sub-study Screened	207966/primary_46/T1.2	Summary of Screening Status and Reasons for Sub-study Screening Failures		SS-SAC
1.3	Sub-study Screened	201584/primary_01/T1.1	Summary of Sub-study Populations	Remove Induction Phase column. Only include analysis populations used in the sub-study analysis	SS-SAC
1.4	Sub-study Safety	207966/primary_46/T1.3	Summary of Subject Accountability: Sub-study Conclusion Record	Include counts of those transitioned to marketed product	SS-SAC
1.5	Sub-study Safety	207966/primary_46/T1.4	Summary of Subject Accountability: SC Injection Phase Conclusion Record		SS-SAC
1.6	Sub-study Safety	207966/primary_46/T1.5	Summary of Subject Accountability: Return to Gluteal Injection Phase Conclusion Record		SS-SAC
1.7	Sub-study Safety	207966/primary_46/T1.6	Summary of Subject Disposition at Each Study Phase	Replace Thigh Injection Phase with SC Injection Phase	SS-SAC
1.8	Sub-study Safety	207966/primary_46/T1.9	Summary of Important Sub-study Protocol Deviations		SS-SAC
1.9	Sub-study Safety	207966/primary_46/T1.10	Summary of Important Sub-study Protocol Deviations (SC Injection Phase)		SS-SAC
1.10	Sub-study Safety	207966/primary_46/T1.12	Summary of Important COVID-19 Related Sub-study Protocol Deviations		SS-SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.11	Sub-study Safety	207966/primary_46/T1.13	Summary of Important Non-COVID-19 Related Sub-study Protocol Deviations		SS-SAC
Demographic and Baseline Characteristics					
1.12	Sub-study Safety	207966/primary_46/T1.14	Summary of Demographic Characteristics	After the continuous BMI parameter, add a categorical BMI parameter (BMI < 30 kg/m^2, >=30 kg/m^2)	SS-HL SS-SAC
1.13	Sub-study Safety	207966/primary_46/T1.15	Summary of Race and Racial Combinations		SS-SAC
1.14	Sub-study Safety	207966/primary_46/T1.16	Summary of Race and Racial Combinations Details		SS-SAC
Medications / Other					
1.15	Sub-study Safety	207966/primary_46/T1.17	Summary of Extent of Exposure to Study Treatment including SOC Oral Bridging Prior to the First SC Injection	Replace references to ATLAS/A2M with FLAIR. Include FLAIR Maintenance randomization assignments in the columns.	SS-SAC
1.16	Sub-study Safety	207966/primary_46/T1.18	Summary of Concomitant Non-ART Medication Ingredient Combinations by Study Phase	Include columns for SC Phase, Return to Gluteal Phase, and Overall	SS-SAC
1.17	Sub-study Safety	207966/primary_46/T1.19	Summary of Smoking Status at Sub-study Baseline		SS-SAC
1.18	Sub-study Safety	207966/primary_46/T1.20	Summary of COVID-19 Pandemic Visit Impacts in Sub-study	Only include visits in sub-study	SS-SAC

14.19.5. Efficacy Tables

Note: The following subgroups will be included in subgroup summaries: Age (<35; 35-<50; >=50), Sex at Birth (Female vs Male), Race/Ethnicity (White: Non-Hispanic, White: Hispanic, Black, Asian, Other), Sub-study Baseline BMI (<30, >=30).

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	Sub-study Safety	207966/primary_46/T2.1	Summary of Study Outcomes (50 c/mL Threshold) at Sub-study Week 12 – Snapshot Analysis		SS-HL SS-SAC
2.2	Sub-study Safety	207966/primary_46/T2.2	Summary of Study Outcomes (50 c/mL Threshold) at Sub-study Week 12 by Subgroup – Snapshot Analysis		SS-SAC
2.3	Sub-study Safety	207966/primary_46/T2.3	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Visit (SC Injection Phase) – Snapshot Analysis	Observed values to be displayed prior to Week 12	SS-SAC
2.4	Sub-study Safety	207966/primary_46/T2.4	Proportion of Subjects with Plasma HIV-1 RNA >=50 c/mL by Subgroup and Visit (SC Injection Phase) – Snapshot Analysis	Observed values to be displayed prior to Week 12	SS-SAC
2.5	Sub-study Safety	207966/primary_46/T2.5	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Visit (SC Injection Phase) – Snapshot Analysis	Observed values to be displayed prior to Week 12	SS-SAC
2.6	Sub-study Safety	207966/primary_46/T2.6	Proportion of Subjects with Plasma HIV-1 RNA <50 c/mL by Subgroup and Visit (SC Injection Phase) – Snapshot Analysis	Observed values to be displayed prior to Week 12	SS-SAC
2.7	Sub-study Safety	207966/primary_46/T2.7	Summary of Change from Sub-study Baseline in Plasma HIV-1 RNA (log10 c/mL) by Visit (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
2.8	Sub-study Safety	207966/primary_46/T2.8	Summary of Plasma HIV-1 RNA (log10 c/mL) by Visit (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
2.9	Sub-study Safety	207966/primary_34/T2.25	Cumulative Proportion of Subjects Meeting Confirmed Virology Failure Criteria by Visit (SC Injection + Return to Gluteal Injection Phase)		SS-HL SS-SAC

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.10	Sub-study Safety	207966/primary_34/T2.27	Distribution of Quantitative Plasma HIV-1 RNA Results at Suspected and Confirmation of Confirmed Virologic Failure (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
2.11	Sub-study Safety	207966/primary_46/T2.11	Summary of Subjects per Viral Load Category by Visit (SC Injection Phase)		SS-SAC
2.12	Sub-study Safety	207966/primary_46/T2.12	Summary of Change from Sub-study Baseline in CD4+ Cell Count (cells/mm^3) by Visit (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
2.13	Sub-study Safety	207966/primary_46/T2.13	Summary of Change from Sub-study Baseline in CD4+ Cell Count (cells/mm^3) at Sub-study Week 12 by Subgroup		SS-SAC
2.14	Sub-study Safety	207966/primary_46/T2.14	Summary of CD4+ Cell Count (cells/mm^3) by Visit (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
2.15	Sub-study Safety	207966/primary_46/T2.15	Summary of Change from Sub-study Baseline in CD8+ Cell Count (cells/mm^3) by Visit (SC Injection Phase)		SS-SAC
2.16	Sub-study Safety	207966/primary_46/T2.16	Summary of CD8+ Cell Count (cells/mm^3) by Visit (SC Injection Phase)		SS-SAC
2.17	Sub-study Safety	207966/primary_46/T2.17	Summary of CD4+/CD8+ Ratio Cell Count (cells/mm^3) by Visit (SC Injection Phase)		SS-SAC
2.18	Sub-study Safety	207966/primary_46/T2.18	Summary of HIV-1 Associated Conditions Including Recurrences (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
2.19	Sub-study Safety	207966/primary_46/T2.19	Summary of HIV-1 Associated Conditions Excluding Recurrences (SC Injection + Return to Gluteal Injection Phase)		SS-SAC

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.20	Sub-study Safety	207966/primary_46/T2.20	Summary of HIV-1 Disease Progression from Sub-study Baseline and/or Deaths (SC Injection + Return to Gluteal Injection Phase)		SS-SAC

14.19.6. Efficacy Figures

Efficacy Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.1	Sub-study Safety	201584/primary_01/F2.1	Proportion (95% CI) of Subjects with HIV-1 RNA ≥50 c/mL by Visit (SC Injection Phase) – Snapshot Analysis		SS-SAC
2.2	Sub-study Safety	201584/primary_01/F2.3	Proportion (95% CI) of Subjects with HIV-1 RNA <50 c/mL by Visit (SC Injection Phase) – Snapshot Analysis		SS-SAC
2.3	Sub-study Safety	201584/primary_01/F2.6	Individual Plasma HIV-1 RNA (log10 c/mL) Profiles by Sub-study Visit – for CVF Subjects	Replace the first 2 footnotes with "First vertical reference line corresponds to the date of first SC injection."	SS-HL SS-SAC
2.4	Sub-study Safety	201584/primary_01/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 12 per Snapshot Algorithm	Replace the first 2 footnotes with "First vertical reference line corresponds to the date of first SC injection."	SS-SAC

14.19.7. Safety Tables

Note: The following subgroups will be included in subgroup summaries: Age (<35, 35-<50, >=50), Sex at Birth (Female vs Male), Race/Ethnicity (White: Non-Hispanic, White: Hispanic, Black, Asian, Other), Sub-study Baseline BMI (<30, >=30).

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Exposure					
3.1	Sub-study Safety	207966/primary_46/T3.1	Summary of Extent of Exposure to Study Treatment (SC Injection + Return to Gluteal Injection Phase)	Add footnote: "Note: Overall exposure includes 35 days since the last Q4W injection."	SS-HL SS-SAC
3.2	Sub-study Safety	207966/primary_46/T3.2	Summary of Needle Length and Gauge for CAB Injection (SC Injection Phase)		SS-SAC
3.3	Sub-study Safety	207966/primary_46/T3.3	Summary of Needle Length and Gauge for RPV Injection (SC Injection Phase)		SS-SAC
3.4	Sub-study Safety	207966/primary_34/T3.4	Summary of Adherence to CAB/RPV Injection Dosing Schedule (SC Injection Phase)		SS-SAC
3.5	Sub-study Safety	207966/primary_34/T3.5	Summary of Adherence to CAB/RPV Injection Dosing Schedule (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
3.6	Sub-study Safety	207966/primary_34/T3.4	Summary of Adherence to CAB/RPV Injection Dosing Schedule by Subgroup (SC Injection Phase)	Repeat Table 3.4 by subgroup	SS-SAC
Adverse Events					
3.7	Sub-study Safety	213199/final_01/T3.9	Adverse Event Overview by Study Phase and Overall	Do not include any LTFU information	SS-Interim SS-HL SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.8	Sub-study Safety	213199/final_01/T3.11	Summary of All Adverse Events by Study Phase, System Organ Class, and Maximum Toxicity	Repeat results for both study phases and overall.	SS-Interim SS-HL SS-SAC
3.9	Sub-study Safety	213199/final_01/T3.12	Summary of All Adverse Events by Study Phase, System Organ Class, and Maximum Toxicity – Excluding Injection Site Reactions	Repeat results for both study phases and overall.	SS-SAC
3.10	Sub-study Safety	213199/final_01/T3.11	Summary of All Adverse Events by Subgroup, System Organ Class, and Maximum Toxicity	Repeat results for both study phases and overall.	SS-SAC
3.11	Sub-study Safety	213199/final_01/T3.15	Summary of Common Adverse Events (>=5%) by Study Phase and Overall Frequency	Repeat results for both study phases and overall.	SS-SAC
3.12	Sub-study Safety	213199/final_01/T3.16	Summary of Common Grade 2-5 Adverse Events (>=1%) by Study Phase and Overall Frequency	Repeat results for both study phases and overall.	SS-SAC
3.13	Sub-study Safety	213199/final_01/T3.19	Summary of Drug-related Adverse Events by Study Phase, System Organ Class, and Maximum Toxicity	Repeat results for both study phases and overall.	SS-SAC
3.14	Sub-study Safety	213199/final_01/T3.22	Summary of Drug-related Adverse Events by Study Phase, System Organ Class, and Maximum Toxicity – Excluding Injection Site Reactions	Repeat results for both study phases and overall.	SS-SAC
3.15	Sub-study Safety	213199/final_01/T3.19	Summary of Drug-related Adverse Events by Subgroup, System Organ Class, and Maximum Toxicity	Repeat results for both study phases and overall.	SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.16	Sub-study Safety	213199/final_01/T3.24	Summary of Common Grade 2-5 Drug-Related Adverse Events (>=1%) by Study Phase and Overall Frequency	Repeat results for both study phases and overall.	SS-SAC
3.17	Sub-study Safety	213199/final_01/T3.9	Adverse Event Overview by Subgroup, Study Phase and Overall	Repeat Table 3.7 by subgroup Do not include any LTFU information	SS-SAC
Serious and Other Significant Adverse Events					
3.18	Sub-study Safety	213199/final_01/T3.27	Summary of Serious Adverse Events by Study Phase, System Organ Class, and Maximum Grade	Repeat results for both study phases and overall.	SS-HL SS-Interim SS-SAC
3.19	Sub-study Safety	213199/final_01/T3.30	Summary of Serious Adverse Events by Study Phase, System Organ Class, and Preferred Term (Number of Subjects and Occurrences)	Repeat results for both study phases and overall.	SS-SAC
3.20	Sub-study Safety	213199/final_01/T3.27	Summary of Serious Adverse Events by Study Phase, System Organ Class, and Maximum Grade – Excluding Injection Site Reactions	Repeat results for both study phases and overall.	SS-SAC
3.21	Sub-study Safety	213199/final_01/T3.27	Summary of Serious Adverse Events by Subgroup, System Organ Class, and Maximum Grade	Repeat results for both study phases and overall.	SS-SAC
3.22	Sub-study Safety	213199/final_01/T3.27	Summary of Drug-related Serious Adverse Events by Study Phase, System Organ Class, and Preferred Term	Repeat results for both study phases and overall.	SS-SAC
3.23	Sub-study Safety	213199/final_01/T3.27	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by Study Phase,	Repeat results for both study phases and overall.	SS-HL SS-Interim SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
			System Organ Class, and Maximum Grade		
3.24	Sub-study Safety	213199/final_01/T3.27	Summary of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by Study Phase, System Organ Class, and Maximum Grade – Excluding Injection Site Reactions	Repeat results for both study phases and overall.	SS-SAC
3.25	Sub-study Safety	213199/final_01/T3.27	Summary of Drug-related Serious Adverse Events by Subgroup, System Organ Class, and Preferred Term	Repeat results for both study phases and overall.	SS-SAC
3.26	Sub-study Safety	213199/final_01/T3.27	Summary of Serious Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product by Study Phase, System Organ Class, and Maximum Grade	Repeat results for both study phases and overall.	SS-SAC
3.27	Sub-study Safety	213199/final_01/T3.23	Summary of Common (>=5%) Non-Serious Adverse Events by Study Phase, System Organ Class, and Preferred Term (Number of Subjects and Occurrences)	Repeat results for both study phases and overall.	SS-SAC
Study Drug Injection Site Reaction Adverse Events					
3.28	Sub-study Safety	213199/final_01/T3.37	Summary of Study Drug Injection Site Reaction Adverse Events (Event-level Summary)	Report Study Phase in the columns Sort by CAB+RPV, CAB, RPV	SS-Interim SS-HL SS-SAC
3.29	Sub-study Safety	213199/final_01/T3.38	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common	Report Study Phase in the columns Sort by CAB+RPV, CAB, RPV >=5% is common threshold	SS-Interim SS-HL SS-SAC
3.30	Sub-study	213199/final_01/T3.39	Summary of Study Drug Injection Site	Report Study Phase in the columns	SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
	Safety		Reaction Adverse Events by Visit and Maximum Severity – Overall and Common in Sub-study	Sort by CAB+RPV, CAB, RPV >=5% is common threshold	
3.31	Sub-study Safety	213199/final_01/T3.37	Summary of Study Drug Injection Site Reaction Adverse Events by Subgroup (Event-level Summary) - Overall and Common	Report Study Phase in the columns Report only for CAB+RPV >=5% is common threshold	SS-SAC
3.32	Sub-study Safety	213199/final_01/T3.38	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events by Subgroup – Overall and Common	Report Study Phase in the columns Report only for CAB+RPV >=5% is common threshold	SS-SAC
3.33	Sub-study Safety	207966/primary_46/T3.27	Summary of Maximum Study Drug Injection Site Reaction Adverse Event Grade by Needle Length & Categorical BMI (SC Injection Phase) – Common (CAB)	Repeat results for each ISR, needle length, and BMI category within needle length (overall, >=30, <30)	SS-SAC
3.34	Sub-study Safety	207966/primary_46/T3.27	Summary of Maximum Study Drug Injection Site Reaction Adverse Event Grade by Needle Length & Categorical BMI (SC Injection Phase) – Common (RPV)	Repeat results for each ISR, needle length, and BMI category within needle length (overall, >=30, <30)	SS-SAC
3.35	Sub-study Safety	213199/final_01/T3.37	Summary of High Impact Study Drug Injection Site Reaction Adverse Events (Event-level Summary)	Report Study Phase in the columns Sort by CAB+RPV, CAB, RPV Add footnote “Note: High Impact ISRs include Grade 4 ISRs and Grade 3 ISRs of ulceration, secondary infection, phlebitis, drainage, or sterile abscess and may potentially lead to pausing or stopping SC injections.”	SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.36	Sub-study Safety	213199/final_01/T3.38	Summary of Subject-level Characteristics of High Impact Study Drug Injection Site Reaction Adverse Events	Report Study Phase in the columns Sort by CAB+RPV, CAB, RPV Add footnote "Note: High Impact ISRs include Grade 4 ISRs and Grade 3 ISRs of ulceration, secondary infection, phlebitis, drainage, or sterile abscess and may potentially lead to pausing or stopping SC injections."	SS-SAC
3.37	Sub-study Safety	213199/final_01/T1.15	Summary of Dimensions of Select, Measurable SC Injection Site Reaction Adverse Events (Erythema, Redness, Induration, & Swelling)	Report Study Phase in the columns Sort by CAB+RPV, CAB, RPV Report descriptive statistics of the diameter and width (mm) of the ISRs.	SS-SAC
3.38	Sub-study Safety	GSK3640254/208379/primary_01/T2.1	Summary of the Posterior Probability that the True Rate of SC ISRs of Interest >0.05 after 50% of Subjects Initiate SC Injections	Keep the first and last statistical categories, use only one column for SC, update study info to align with FLAIR ISR monitoring criteria.	SS-ISR
Laboratory: Chemistry and Hematology					
3.39	Sub-study Safety	207966/primary_46/T3.32	Summary of Chemistry Changes from Sub-study Baseline by Visit (SC Injection + Return to Gluteal Injection Phase)	Do not use lipid LOCF at interim, use actual values. Replace first footnote with "Note: Fasting data is shown for lipids and glucose. " Use lipid LOCF at SS-SAC.	SS-Interim SS-SAC
3.40	Sub-study Safety	207966/primary_46/T3.33	Summary of Chemistry Values by Visit (SC Injection + Return to Gluteal Injection Phase)	Use Lipid LOCF at SS-SAC.	SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.41	Sub-study Safety	207966/primary_46/T3.36	Summary of Maximum Post Sub-study Baseline Emergent Chemistry Toxicities (SC Injection Phase)		SS-SAC
3.42	Sub-study Safety	207966/primary_46/T3.34	Summary of Hematology Changes from Sub-study Baseline by Visit (SC Injection + Return to Gluteal Injection Phase)		SS-Interim SS-SAC
3.43	Sub-study Safety	207966/primary_46/T3.35	Summary of Hematology Values by Visit (SC Injection + Return to Gluteal Injection Phase)		SS-SAC
3.44	Sub-study Safety	207966/primary_46/T3.37	Summary of Maximum Post Sub-study Baseline Emergent Hematology Toxicities (SC Injection Phase)		SS-SAC
Laboratory: Urinalysis					
3.45	Sub-study Safety	207966/primary_46/T3.38	Summary of Urinalysis Dipstick Results by Visit (SC Injection Phase)		SS-SAC
3.46	Sub-study Safety	207966/primary_46/T3.39	Summary of Urine Concentrations Changes from Sub-study Baseline by Visit (SC Injection Phase)		SS-SAC
3.47	Sub-study Safety	207966/primary_46/T3.40	Summary of Changes in Proteinuria Baseline Laboratory Result to Maximum Post Sub-study Baseline Laboratory Result (SC Injection Phase)		SS-SAC
Laboratory: Hepatobiliary (Liver)					
3.48	Sub-study Safety	213199/final_01/T3.46	Summary of Liver Stopping Event Reporting (SC Injection Phase)		SS-SAC
3.49	Sub-study	207966/primary_46/T3.42	Summary of Subjects Meeting		SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
	Safety		Hepatobiliary Abnormality Criteria (SC Injection Phase)		
ECG					
3.50	Sub-study Safety	207966/primary_46/T3.43	Summary of ECG Findings (SC Injection Phase)		SS-SAC
3.51	Sub-study Safety	207966/primary_46/T3.44	Summary of Change from Sub-study Baseline in ECG values by Visit (SC Injection Phase)		SS-SAC
Vital Signs					
3.52	Sub-study Safety	207966/primary_46/T3.47	Summary of Change from Sub-study Baseline in Vital Signs by Visit (SC Injection Phase)	Include weight and BMI	SS-SAC
Adverse Event of Special Interest (AESI)					
3.53	Sub-study Safety	207966/primary_46/T3.48	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 (SC Injection Phase)		SS-SAC
3.54-3.70	Sub-study Safety	207966/primary_46/T3.50-3.66	Summary of XXX Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrence) – SC Injection Phase		SS-SAC
3.71	Sub-study Safety	207966/primary_46/T3.67	Summary of Characteristics of Adverse Events of Special Interest – SC Injection Phase		SS-SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
COVID-19 Adverse Event					
3.72	Sub-study Safety	213199/final_01/T3.11	Summary of COVID-19 Adverse Events by Study Phase, System Organ Class, and Maximum Toxicity	Repeat results for both study phases and overall.	SS-SAC
3.73	Sub-study Safety	213199/final_01/T3.52	Summary of COVID-19 Assessments for Subjects with COVID-19 Adverse Events		SS-SAC
3.74	Sub-study Safety	213199/final_01/T3.53	Summary of COVID-19 Additional Assessments for Subjects with COVID-19 Adverse Events		SS-SAC
3.75	Sub-study Safety	213199/final_01/T3.54	Summary of COVID-19 Symptoms for Subjects with COVID-19 Adverse Events		SS-SAC

14.19.8. Safety Figures

Safety Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.1	Sub-study Safety	207966/primary_34/F3.1	Plot of Common Adverse Events and Relative Risk – SC vs. IM, Excluding Study Drug ISRs (SC Sub-study)	Only IM events occurring during the sub-study should be included.	SS-SAC
3.2	Sub-study Safety	207966/primary_34/F3.2	Plot of Common Study Drug Injection Site Reaction Adverse Events and Relative Risk – SC vs. IM (SC Sub-study)	Only IM events occurring during the sub-study should be included.	SS-SAC
3.3	Sub-study Safety	AE10	Plot of Common Grade 1+ Injection Site Reaction Adverse Events and Relative Risk Overall & by Subgroup – SC vs. Pre-SC IM	Include ISRs from all SC injections and the first 3 IM injections of the parent study for each participant Report incidence rate ratios instead of risk ratios as mentioned in Section 8.6	SS-SAC
3.4	Sub-study Safety	AE10	Plot of Common Grade 1+ Injection Site Reaction Adverse Events and Relative Risk Overall & by Subgroup – SC vs. Post-SC IM	Include ISRs from the first 2 SC injections and the 2 IM injections subsequent to SC dosing for each participant Report incidence rate ratios instead of risk ratios as mentioned in Section 8.6	SS-SAC
3.5	Sub-study Safety	AE10	Plot of Common Grade 2+ Injection Site Reaction Adverse Events and Relative Risk Overall & by Subgroup – SC vs. Pre-SC IM	Include ISRs from all SC injections and the first 3 IM injections of the parent study for each participant Report incidence rate ratios instead of risk ratios as mentioned in Section 8.6	SS-SAC

Safety Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.6	Sub-study Safety	AE10	Plot of Common Grade 2+ Injection Site Reaction Adverse Events and Relative Risk Overall & by Subgroup – SC vs. Post-SC IM	Include ISRs from the first 2 SC injections and the 2 IM injections subsequent to SC dosing for each participant Report incidence rate ratios instead of risk ratios as mentioned in Section 8.6	SS-SAC
3.7	Sub-study Safety	207966/primary_34/F3.3	Plot of Incidence of Sub-study Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV	X-Axis timepoints to run from Screening to Week 20. Remove the second footnote.	SS-SAC
3.8	Sub-study Safety	207966/primary_34/F3.4	Plot of Incidence of Sub-study Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB	X-Axis timepoints to run from Screening to Week 20. Remove the second footnote.	SS-SAC
3.9	Sub-study Safety	207966/primary_34/F3.5	Plot of Incidence of Sub-study Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – RPV	X-Axis timepoints to run from Screening to Week 20. Remove the second footnote.	SS-SAC
3.10	Sub-study Safety	207966/primary_34/F3.6	Plot of Incidence of Sub-study Study Drug Injection Site Reaction Adverse Events by Subgroup and Visit – CAB and/or RPV	X-Axis timepoints to run from Screening to Week 20. Remove the second and third footnotes.	SS-SAC
3.11	Sub-study Safety	207966/primary_46/F3.2	Scatter Plot of Maximum vs. Sub-study Baseline for ALT (SC Injection Phase)		SS-SAC
3.12	Sub-study Safety	213199/final_01/F3.4	Scatter Plot of Maximum Total Bilirubin vs. Maximum ALT – eDISH Plot (SC Injection Phase)		SS-SAC
3.13	Sub-study Safety	207966/primary_46/F3.4	Histogram of Timeliness of Injections (SC Injection Phase)		SS-SAC

14.19.9. Pharmacokinetic Tables

Note: The following subgroups will be included in subgroup summaries: Age (<35; 35-<50; >=50), Sex at Birth (Female vs Male), Race/Ethnicity (White: Non-Hispanic, White: Hispanic, Black, Asian, Other), Sub-study Baseline BMI (<30, >=30).

Pharmacokinetic Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	Sub-study PK Concentration	208832/final_01/T4.3	Summary of Sub-study Plasma Cabotegravir PK Concentration (ug/mL)-Time Data by Study Phase and Nominal Timepoint		SS-Interim, SS-SAC
4.2	Sub-study PK Concentration	208832/final_01/T4.4	Summary of Sub-study Plasma Rilpivirine PK Concentration (ng/mL)-Time Data by Study Phase and Nominal Timepoint		SS-Interim, SS-SAC
4.3	Sub-study PK Parameter	207966/primary_46/T4.5	Summary of Sub-study Derived Plasma CAB PK Parameters by Dosing Interval	Parameters included are AUC(0-Tau), CMax, TMax, and CTau. Dosing intervals will include Screening Gluteal injection, 1st SC injection, 2nd, SC injection, and last SC injection. CTau will be taken from concentration data at Day 1 (gluteal), Week 4, and Week 12 (SC)	SS-Interim, SS-SAC
4.4	Sub-study PK Parameter	207966/primary_46/T4.6	Summary of Sub-study Derived Plasma RPV PK Parameters by Dosing Interval	Same notes as 4.3.	SS-Interim, SS-SAC
4.5	Sub-study PK Concentration	208832/final_01/T4.3	Summary of Sub-study Plasma Cabotegravir PK Concentration (ug/mL)-Time Data by Study Phase, Subgroup, and Nominal Timepoint	Repeat 4.1 with subgroups	SS-SAC

Pharmacokinetic Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.6	Sub-study PK Concentration	208832/final_01/T4.4	Summary of Sub-study Plasma Rilpivirine PK Concentration (ng/mL)-Time Data by Study Phase, Subgroup, and Nominal Timepoint	Repeat 4.2 with subgroups	SS-SAC
4.7	Sub-study PK Parameter	207966/primary_46/T4.5	Summary of Sub-study Derived Plasma CAB PK Parameters by Subgroup & Dosing Interval	Repeat 4.3 with subgroups	SS-SAC
4.8	Sub-study PK Parameter	207966/primary_46/T4.6	Summary of Sub-study Derived Plasma RPV PK Parameters by Subgroup & Dosing Interval	Repeat 4.4 with subgroups	SS-SAC
4.9	Sub-study PK Parameter	207966/primary_46/T4.7	Statistical Analysis of Plasma CAB PK Parameters by Treatment in Sub-study	GMR will be calculated for AUC(0-Tau), CMax, and CTau for SC Injection 1 / Gluteal Injection, SC Injection 2 / Gluteal Injection and SC Injection 3 / Gluteal Injection Add footnote: "GMR taken from exponentiated log values output from an ANCOVA with fixed effects of Phase and Sub-study Baseline BMI (<30, >=30) as a covariate and a random effect of subject."	SS-HL SS-SAC
4.10	Sub-study PK Parameter	207966/primary_46/T4.8	Statistical Analysis of Plasma RPV PK Parameters by Treatment in Sub-study	Same notes as 4.5.	SS-HL SS-SAC

Pharmacokinetic Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.11	Sub-study PK Concentration	GSK3739937/212548/final_01/T4.6	Summary Results of SC Steady State CAB Concentration Assessment	Model to begin with subcutaneous phase concentrations Day 1 – Week 12	SS-SAC
4.12	Sub-study PK Concentration	GSK3739937/212548/final_01/T4.6	Summary Results of SC Steady State RPV Concentration Assessment	Same note as 4.7.	SS-SAC

14.19.10. Pharmacokinetic Figures

Pharmacokinetic Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1	Sub-study PK Concentration	207966/primary_46/F4.1	Individual Plasma CAB Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Add to footnote: "The LLQ has been imputed for non-quantifiable values"	SS-SAC
4.2	Sub-study PK Concentration	207966/primary_46/F4.2	Individual Plasma RPV Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Add to footnote: "The LLQ has been imputed for non-quantifiable values"	SS-SAC
4.3	Sub-study PK Concentration	207966/primary_46/F4.3	Mean (SD) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Add to footnote: "The LLQ has been imputed for non-quantifiable values"	SS-Interim, SS-SAC
4.4	Sub-study PK Concentration	207966/primary_46/F4.4	Mean (SD) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Add to footnote: "The LLQ has been imputed for non-quantifiable values"	SS-Interim, SS-SAC
4.5	Sub-study PK Concentration	207966/primary_46/F4.5	Median (5th and 95th Percentile) Evaluable Plasma CAB Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Add to footnote: "The LLQ has been imputed for non-quantifiable values"	SS-Interim, SS-SAC
4.6	Sub-study PK Concentration	207966/primary_46/F4.6	Median (5th and 95th Percentile) Evaluable Plasma RPV Concentration-Time Plots (Linear and Semi-Log) in Sub-study	Add to footnote: "The LLQ has been imputed for non-quantifiable values"	SS-Interim, SS-SAC
4.7	Sub-study PK Parameter	207966/primary_46/F4.7	Geometric Mean Ratios and 90% CIs of Plasma CAB PK Parameters in Sub-study by Treatment and Comparison Type	The comparisons include First SC vs Gluteal, Second SC vs Gluteal and Last SC vs Gluteal.	SS-SAC
4.8	Sub-study PK Parameter	207966/primary_46/F4.8	Geometric Mean Ratios and 90% CIs of Plasma RPV PK Parameters in Sub-study by Treatment and Comparison Type	Same notes as Figure 4.7.	SS-SAC

14.19.11. Health Outcomes Tables

Note: The following subgroups will be included in subgroup summaries: Age (<35; 35-<50; >=50), Sex at Birth (Female vs Male), Race/Ethnicity (White: Non-Hispanic, White: Hispanic, Black, Asian, Other), Sub-study Baseline BMI (<30, >=30).
Note: LOCF should not be used for any Health Outcomes table.

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 Safety	207966/primary_46/T6.1	Proportion of Subjects with HIVTSQs - Individual Item Scores by Visit in Sub-study		SS-SAC
6.2	Sub-study Safety	207966/primary_46/T6.4	Summary of HIVTSQs - Change in Individual Item Score in Sub-study	Replace Weeks 16 and 24/20 with 9 and 17	SS-SAC
6.3	Sub-study Safety	207966/primary_46/T6.2	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit in Sub-study	Replace Weeks 16 and 24/20 with 9 and 17 Add the footnote: "[1] Sub-study Week 9 and Sub-study Week 17 are compared with the Sub-study Baseline using Wilcoxon signed-rank test."	SS-SAC
6.4	Sub-study Safety	207966/primary_46/T6.3	Summary of HIVTSQs - Change in Total Treatment Satisfaction Score in Sub-study	Replace Weeks 16 and 24/20 with 9 and 17.	SS-SAC
6.5	Sub-study Safety	207966/primary_46/T6.2	Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit & Subgroup in Sub-study	Repeat Table 6.3 by subgroup	SS-SAC
6.6	Sub-study Safety	207966/primary_46/T6.5	Proportion of Subjects with HIVTSQc - Individual Item Change Score at Sub-study Week 9 (SC Injection Phase)		SS-SAC
6.7	Sub-study Safety	207966/primary_46/T6.6	Summary of HIVTSQc - Individual Item Change Score at Sub-study Week 9 (SC Injection Phase)	Replace Week 16 with 9.	SS-SAC

Health Outcomes Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.8	Sub-study Safety	207966/primary_46/T6.7	Summary of HIVTSQc - Total Treatment Satisfaction Change Score at Sub-study Week 9 (SC Injection Phase)	Replace Week 16 with 9	SS-SAC
Tolerability of Injection (NRS)					
6.9	Sub-study Safety	208832/final_01/T6.3	Proportion of Subjects with Tolerability of Injection (NRS) Individual Item Scores by Visit in Sub-study	Replace Actual Relative Time values with Week -4, Week -3, Day 1, Week 1, Week 8, Week 9, Week 12, and Week 13	SS-SAC
6.10	Sub-study Safety	208832/final_01/T6.4	Summary of Tolerability of Injection (NRS) Scores by Visit in Sub-study	Replace Actual Relative Time values with same visits as Table 6.9	SS-Interim SS-SAC
6.11	Sub-study Safety	208832/final_01/T6.6	Summary of Tolerability of Injection (NRS) Change from Baseline Scores by Visit in Sub-study	Replace Actual Relative Time values with same visits as Table 6.9	SS-SAC
6.12	Sub-study Safety	208832/final_01/T6.4	Summary of Tolerability of Injection (NRS) Scores by Visit & Subgroup in Sub-study	Repeat Table 6.10 by subgroup	SS-SAC
Perception of Injection (PIN)					
6.13	Sub-study Safety	208832/final_01/T6.2	Proportion of Subjects with each individual item score in PIN by Visit and Item in Sub-study	Replace Day 8 with Week -3, Week 1, Week 9, and Week 13	SS-SAC
6.14	Sub-study Safety	201584/primary_01/T6.2	Summary of Perception of Injection (PIN) Questionnaire Results in Domain Scores and Individual Item Scores by Visit in Sub-study	Replace current visits with Week -3, Week 1, Week 9, and Week 13 Remove p-value column	SS-SAC
6.15	Sub-study Safety	201584/primary_01/T6.4	Summary of PIN Change from Baseline (Week -3) Results in Domain Scores and Individual Item Scores by visit in Sub-study	Replace current visits with Week -3, Week 1, Week 9, and Week 13	SS-SAC

Health Outcomes Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
6.16	Sub-study Safety	201584/primary_01/T6.2	Summary of Perception of Injection (PIN) Questionnaire Results in Domain Scores and Individual Item Scores by Visit & Subgroup in Sub-study	Repeat Table 6.14 by subgroup	SS-SAC
6.17	Sub-study Safety	201584/primary_01/T6.3	Summary and Statistical Analysis of PIN in Domain Scores and Individual Item Scores by Visit in Sub-study	Compare scores at Weeks 1, 9, and 13 to Baseline using the Wilcoxon Signed Rank test	SS-SAC
Preference					
6.18	Sub-study Safety	207966/primary_46/T6.11	Proportion of Subjects with Response to Each Individual Question in Preference SC Injection vs Gluteal Injection Questionnaire by Visit in Sub-study	Replace Weeks 8/12 and 24/20 with 9 and 17.	SS-Interim SS-HL SS-SAC
6.19	Sub-study Safety	207966/primary_46/T6.11	Proportion of Subjects with Response to Each Individual Question in Preference SC Injection vs Gluteal Injection Questionnaire by Visit & Subgroup in Sub-study	Repeat 6.18 by subgroup	SS-SAC
Reason for Switch					
6.20	Sub-study Safety	207966/primary_46/T6.11	Proportion of Subjects with Response to Each Reason in the Reason for Switch to SC Questionnaire in Sub-study	Map question and responses based on questionnaire	SS-SAC
Interest					
6.21	Sub-study Safety	207966/primary_46/T6.11	Proportion of Subjects with Each Response to the Interest in Home Administration Questionnaire in Sub-study	Map question and responses based on questionnaire	SS-SAC

14.19.12. Virology Tables

If no data are available, Virology Tables will be displayed with "No data to report."

Virology Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Genotype & Phenotype					
7.1	Sub-study Safety	213199/final_01/T2.9	Summary of the Prevalence of Treatment-Emergent Major Resistance Mutations of INI, NRTI, NNRTI and PI Class at time of CVF (SC Injection + Return to Gluteal Injection Phase) – Plasma Sample		SS-SAC
7.2	Sub-study Safety	213199/final_01/T2.10	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria during the SC Injection or Return to Gluteal Injection Phase		SS-SAC
7.3	Sub-study Safety	213199/final_01/T2.11	Summary of Viral load, Genotypic and Phenotypic data for Subjects Who Did Not Meet Confirmed Virologic Failure Criteria during the SC Injection or Return to Gluteal Injection Phase		SS-SAC

14.19.13. ICH Listings

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
1	Sub-study Screened	207966/primary_46/L1	Listing of Reasons for Screen Failure in Sub-study		SS-SAC
2	Sub-study Safety	213199/final_01/L1	Listing of Reasons for Sub-study Withdrawal		SS-SAC
3	Sub-study Safety	213199/final_01/L2	Listing of Reasons for Study Drug Discontinuation		SS-SAC
4	Sub-study Safety	207966/primary_46/L4	Listing of Important Protocol Deviations		SS-SAC
5	Sub-study Safety	213199/final_01/L8	Listing of Demographic Characteristics		SS-SAC
Efficacy					
6	Sub-study Safety	213199/final_01/L11	Listing of Study Outcome (50 c/mL Threshold) at Sub-study Week 12 – Snapshot Analysis		SS-SAC
Safety					
7	Sub-study Safety	207966/primary_46/L10	Listing of Serious Adverse Events and Reasons for Considering as a Serious Adverse Event		SS-SAC
8	Sub-study Safety	213199/final_01/L14	Listing of Adverse Events Leading to Withdrawal/Permanent Discontinuation of Investigational Product		SS-SAC
9	Sub-study	LB5A	Listing of all Laboratory Data for		SS-SAC

ICH Listings					
	Safety		Subjects with Any Value Outside Normal Range		
10	Sub-study Safety	207966/primary_46/L20	Listing of ECG Values for Subjects with a Value of Potential Clinical Importance in Sub-study		SS-SAC
11	Sub-study Safety	213199/final_01/L46	Listing of All Vital Signs Results	Include Weight and BMI	SS-SAC
PK					
12	Sub-study PK Concentration	207966/primary_46/L21	Listing of Plasma CAB PK Concentration-Time Data		SS-SAC
13	Sub-study PK Concentration	207966/primary_46/L22	Listing of Plasma RPV PK Concentration-Time Data		SS-SAC

14.19.14. Non-ICH Listings

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Study Population					
14	Sub-study Safety	213199/final_01/L31	Listing of Concomitant ART Medications During the Sub-study	Only list ART medications that were concomitant at any time during the sub-study.	SS-SAC
15	Sub-study Safety	207966/primary_46/L30	Listing of Transition to CAB + RPV LA Marketed Product Status		SS-SAC
Efficacy					
16	Sub-study Safety	207966/primary_34/L35	Listing of All Plasma HIV-1 RNA Data for Subjects with Confirmed Virologic Failure		SS-SAC
Safety					
17	Sub-study Safety	207966/primary_34/L43	Listing of Subjects Meeting Hepatobiliary Lab Criteria (SC Injection + Return to Gluteal Injection Phase)	Drop Treatment, Display by Phase	SS-SAC
PK					
18	Sub-study PK Parameter	208832/final_01/L34	Listing of Derived Plasma Cabotegravir PK Parameters by Sub-study Phase	Replace Treatment column with Phase/Dosing Interval	SS-SAC
19	Sub-study PK Parameter	208832/final_01/L35	Listing of Derived Plasma Rilpivirine PK Parameters by Sub-study Phase	Replace Treatment column with Phase/Dosing Interval	SS-SAC

14.20. Appendix 20: Example Mock Shells for Data Displays

Data Display Specification will be made available on Request.