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

Title	:	Reporting and Analysis Plan for A qualitative hybrid III implementation study to identify and evaluate strategies for successful implementation of the cabotegravir + rilpivirine long-acting injectable regimen in the US
Compound Number	:	GSK1265744
Clinical Study Identifier	:	209493
Effective Date	:	29-OCT-2020

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 209493, specifically for clinical data. Any implementation science/health outcome analyses will be detailed in a separate Evidera SAP.

- This RAP will be provided to the study team members to convey the content pertaining to clinical data for the Month 12 and End of Study (EOS) analyses.

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1.   INTRODUCTION

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

Revision Chronology:		
2018N382441_00	02-JAN-2019	Original
2018N382441_01	02-APR-2019	Amendment No. 1
The reasons for this amendment include: addition of exclusion criterion regarding known major resistance mutations at Screening, clarification of timing for collection of visit length, removal of consent requirement for study staff, correction to allowable window around the Month 3 dosing visit, clarification of pregnancy testing requirements at Screening, clarification of wording to allow a single re-screen per subject, removal of color of vial stopper in product description to allow flexibility of packaging for cabotegravir and rilpivirine suspension, clarification of ECG collection during the study, clarification of wording to allow qualitative analyses to be performed by a CRO under GSK oversight.		
2018N382441_02	15-MAY-2020	Amendment No.2
The purpose of this amendment is to include an Appendix related to COVID-19 Pandemic and Clinical Trial Continuity. This appendix will replace the previous Appendix 11, and "Protocol Amendment History," will be included as Appendix 12.		

2.   SUMMARY OF KEY PROTOCOL INFORMATION

2.1.   Changes to the Protocol Defined Statistical Analysis Plan

There were no changes or deviations to the originally planned statistical analysis specified in protocol amendment 02 [(Dated: 15/May/2020)].

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

Objectives	Estimands / Endpoints
Primary	**Primary**
• To evaluate acceptability, appropriateness, and feasibility of delivering CAB+RPV LA	• Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM). Assessed quantitatively by staff study participants at baseline- prior to any Month 1 visits, after at least 4 monthly facilitation calls and upon completion of all Month 12 visits at that site.
	• Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM). Assessed quantitatively by patient study participants at Month 1 prior to first injection, Month 4 and Month 12
Secondary	**Secondary**
• To evaluate organizational facilitators and barriers	• Facilitators/Barriers: Semi-Structured Interview (SSI) conducted with staff study participants at baseline- prior to any Month 1 visits, after at least 4 monthly facilitation

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Objectives	Estimands / Endpoints
	calls and upon completion of at least 50% of Month 12 visits at that site. • Barriers, facilitators and best practice sharing amongst clinics assessed by short-term facilitation (coaching calls) for at least 6 months. These will be a combination of structured questions and open-ended questions. • Use of support materials/toolkit assessed via Survey responses of staff study participants prior to any Month 1 visits, after at least 4 monthly facilitation calls and upon completion of all Month 12 visits at a site. • Use of support materials/toolkit assessed via Survey responses of patient study participants via Survey responses at Month 1 and Month 4 and Month 12, as well as SSI responses prior to Month 1 and at Month 12.
• Patient Facilitators and Barriers	• Facilitators/Barriers: Semi-Structured Interviews (SSI) conducted with patient study participants prior to Month 1 and at Month 12.
• Implementation Fidelity	• Injections occurring within target window from the expected injection date • Use of support materials/toolkit assessed through SSI of staff study participants at Day 1, after at least 4 monthly facilitation calls and upon completion of at least 50% of Month 12 visits at that site
• Implementation Sustainability	• Program Sustainability Assessment Tool (PSAT) assessed by staff study participants at Month 12
• To measure patient satisfaction with process (timeliness of visits, length of visit, patient education)	• Patient Survey responses at Month 1, Month 4 and Month 12. • Patient SSI responses prior to Month 1 and at Month 12 • Length of patient visit from arrival until departure from clinic at Month 1, Month 5 and Month 11
• To evaluate the antiviral and immunologic effects, safety and tolerability, and viral resistance of CAB LA + RPV LA for all patients	• Proportion of participants with plasma HIV-1 RNA <50 c/mL over time • Proportion of participants with confirmed virologic failure (CVF) over time • Incidence of treatment emergent genotypic and phenotypic resistance to CAB and RPV in patients with CVF • Incidence and severity of AEs and laboratory abnormalities over time • Proportion of participants who discontinue treatment due to AEs over time • Reported injection site reactions over time • Absolute values and changes in laboratory parameters over time

2.3.   Study Design

Overview of Study Design and Key Features
N=115 patients; Open label with respect to treatment; patients randomized to CAB LA+RPV LA Interview: CAB LA + RPV LA Non-Interview

Design Features	• A qualitative hybrid III implementation study to identify and evaluate strategies for successful implementation of the cabotegravir + rilpivirine long-acting injectable regimen in the US • The CUSTOMIZE study comprises of screening phase (up to 21 days), Intervention Phase from Day 1 to Month 12, including Oral Lead-in, long term follow-up (LTFU) phase, and extension phase. During screening phase all clinical and laboratory assessments of eligibility must be performed and reviewed. Participants may be re-screened once
Dosing	• Intervention Phase is Open label with respect to treatment; • Intervention Phase: randomized 1:3 to CAB LA+RPV LA Interview:CAB LA + RPV LA Non-Interview • Randomized at Day 1 (1:3) to receive CAB LA + RPV LA Interview or CAB LA + RPV LA Non-interview respectively • GSK Randall NG used to generate randomization schedule for interview group assignments
Time & Events	• Refer to Appendix 2: Schedule of Activities
Treatment Assignment	• CAB LA+RPV LA (N=115)
Interim Analysis	• Analysis at Month 4 to provide preliminary data to inform planning for the initial commercial availability of the CAB LA + RPV LA regimen • Primary analysis will be conducted at Month 12

2.4.   Statistical Hypotheses / Statistical Analyses

No formal hypothesis testing is planned.

3.   PLANNED ANALYSES

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

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

At least two analyses will be conducted to evaluate primary and secondary objectives of the protocol: an interim analysis at Month 4 and a primary analysis at Month 12.

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

3.1.   Interim Analyses

One interim analysis at Month 4 was performed to provide preliminary data to inform planning for the initial commercial availability of the CAB + RPV LA regimen. No formal criteria for stopping or amending the study based on the interim analysis are envisioned. Analysis and reporting details can be found in the standalone Month 4 interim analysis RAP.

3.2.   Final Analyses

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

1. All participants have completed Month 12 of the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR), source data lock (SDL) and database freeze (DBF) have been declared by Data Management.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All participants who were screened for eligibility	• Study Population
Enrolled	• All participants who passed screening and entered the study (i.e. were administered study treatment).	• Study Population
Safety	• All participants who received at least one dose of study treatment.	• Study Population, Safety, Efficacy, Virology, PK, Other Assessments

Refer to Appendix 13: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

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

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan [Version 1.0,17-Jun-2019].

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

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

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

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions	
Data Displays for Reporting	
Description	Order in TLF
CAB LA +RPV LA	1

5.2. Baseline Definitions

For all endpoints the baseline value will be the latest pre-treatment (See Table 10) assessment with a non-missing value, including those from unscheduled visits. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as baseline.

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

5.3. Multicentre Studies

In this multicentre global study, enrolment will be presented by investigator and Site type.

5.4. Examination of Covariates, Other Strata and Subgroups

5.4.1. Covariates and Other Strata

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

Category	Details
Covariates	Site Type

5.4.2. Examination of Subgroups

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

- If the percentage of participants is small within a subgroup category, then the subgroup categories may be combined.

Subgroup	Categories
Site Type	AIDS Healthcare Foundation, Federally Qualified Health Center, Health Maintenance Organization, Private Practice, University

5.5. Other Considerations for Data Analyses and Data Handling Conventions

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

Section	Component
13.3	Appendix 3: Assessment Windows
13.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
13.5	Appendix 5: Data Display Standards & Handling Conventions
13.6	Appendix 6: Derived and Transformed Data
13.7	Appendix 7: Reporting Standards for Missing Data
13.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

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

Study population analyses including analyses of participant's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 13: List of Data Displays.

7. EFFICACY ANALYSES

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

7.1. Secondary Efficacy Analyses

7.1.1. Endpoint / Variables

- Proportion of participants with Plasma HIV-RNA < 50 copies/mL and plasma HIV-1 RNA ≥ 50 c/mL, respectively, over time using the FDA Snapshot Algorithm. See Section 13.9 for Snapshot Algorithm details.

Other secondary efficacy endpoints:
- Proportion of participants with confirmed virologic failure (CVF) over time
- Absolute values and changes from Baseline CD4+ cell count over time

7.1.2. Population of Interest

Secondary efficacy analyses will be based on the Safety population, unless otherwise specified.

7.1.3. Strategy for Intercurrent (Post-Randomization) Events

- Participants with last available HIV-1 RNA measurement less than 50 copies/mL while the participant is on treatment within the analysis visit window of interest are classified as HIV-1 RNA < 50 c/mL. Participants without evaluable HIV-RNA data for the visit of interest or who change treatment not permitted per protocol before the analysis window are considered non-responders.
- Participants with last available HIV-1 RNA measurement greater or equal to 50 copies/mL while the participant is on treatment within the analysis visit window of interest are classified as HIV-1 RNA ≥ 50 c/mL. Participants without evaluable HIV-RNA data for the visit of interest and who discontinue treatment for reasons not related to adverse event while having HIV-1 RNA ≥50 copies/mL at time of

discontinuation or who change study treatment not permitted per protocol before the analysis window are also classified as having HIV-RNA ≥50 copies/mL.

Missing viral load values for reasons related to COVID-19 issues (e.g. participant is unable to have viral load assessed due to barriers in attending the clinic during the pandemic or COVID-19 related adverse events leading to treatment discontinuation) will be imputed using an LOCF approach in which the last on-treatment viral load value will be carried forward and used in place of missing values.

7.1.4.   Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 13: List of Data Displays and will be based on GSK data standards and statistical principles.

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

7.1.4.1.   Statistical Methodology Specification

Endpoint / Variables
• Proportion of participants with plasma HIV-1 RNA < 50 c/mL over time using the FDA Snapshot algorithm (Safety population)   • Proportion of participants with plasma HIV-1 RNA ≥ 50 c/mL over time using the FDA Snapshot algorithm (Safety population)
Results Presentation
• The proportion of participants with HIV-1 RNA < 50 c/mL and HIV-1 RNA ≥ 50 c/mL, respectively, at each planned visit with corresponding 95% confidence intervals calculated using the Clopper-Pearson exact method.   • The proportion of participants in each Snapshot study outcome category and sub-category will be summarized at Month 12, in which default sub-categories have been expanded to present COVID-19 vs. non COVID-19 related impact (as described in Section 13.9).

8.   SAFETY ANALYSES

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

For the Month 12 analysis, safety displays will summarize data across the combined Intervention + Extension Phases, unless otherwise specified in the display title presented in Appendix 13: List of Data Displays.

8.1.   Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs), COVID-19 AEs, and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 13: List of Data Displays.

8.1.1. Injection Site Reaction Adverse Events

Injection Site Reaction (ISR) adverse events of interest are those from study drug injections.

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.

Common study drug ISR adverse events are defined by MedDRA preferred terms including injection site pain, injection site induration, injection site nodules and preferred terms of any other ISR reported by ≥5% of participants overall.

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 10: AESI identification and Appendix 13: List of Data Displays.

8.3. Clinical Laboratory Analyses

Laboratory evaluations will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 13: 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 13: List of Data Displays.

9. PHARMACOKINETIC ANALYSES

9.1. Drug Concentration Measures

Available concentration-time data for CAB and RPV will be presented in listings as specified in Appendix 13: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Refer Appendix 5: Data Display Standards & Handling Conventions (Section 13.5.3 Reporting Standards for Pharmacokinetic).

10. VIROLOGY

10.1. Genotypic and Phenotypic Data

Available genotypic and phenotypic data at all collection timepoints will be presented by subject (separately for CVF and Non-CVF subjects), as specified in Appendix 13: List of Data Displays.

11. OTHER ANALYSES

11.1. Study Visit Length

The details of the planned displays for study visit length data are in Appendix 13: List of Data Displays and will be based on GSK Data Standards and statistical principles.

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12.   REFERENCES

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

13. APPENDICES

13.1. Appendix 1: Exclusions from Per Protocol Population

Instream and final analysis population reviews as per SOP 130050 are not planned for this study because it does not include a Per-Protocol population.

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13.2.   Appendix 2: Schedule of Activities

13.2.1.   Protocol Defined Schedule of Events

13.2.1.1.   Schedule of Activities for Patient Study Participants (CAB LA + RPV LA Monthly Administration)

Procedures	Screening[a]	Intervention Period													WD[n]
		Day 1	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10[b]	Month 11[b]	Month 12[b]	
Written Informed Consent	X														
Demography	X														
Eligibility Verification	X														
Physical Exam	X														
Medical History	X														
Center for Disease Control and Prevention (CDC) Classification	X														
Randomization for interviews		X													
Rapid Plasma Reagin (RPR)	X														

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Procedures	Screening[a]	Intervention Period													WD[m]
		Day 1	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10[b]	Month 11[b]	Month 12[b]	
Symptom Directed Physical Exam and Medical Assessment[c]	X	X	X	X		X		X		X		X		X	X
Injection site reaction (ISR) assessment			X	X	X	X	X	X	X	X	X	X	X	X	X
Vital Signs (temperature, blood pressure [BP], heart rate [HR])[d]	X	X	X	X		X		X			X			X	X
Weight, Height & body mass index (BMI)[e]	X	X	X					X						X	X
HIV Associated Conditions, AE and serious adverse event (SAE) Assessments& Con Meds	X	X	X	X		X		X		X		X		X	X
12-Lead ECG[f]	X														X
Clinical Chemistry and	X	X	X	X		X		X			X			X	X

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Procedures	Screening[a]	Intervention Period													WD[m]
		Day 1	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10[b]	Month 11[b]	Month 12[b]	
Hematology															
Pregnancy Testing (U)rine or (S)erum[g]	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U
HIV-1 RNA	X	X	X	X		X		X		X		X		X	X
Plasma sample for storage[h]		X	X	X		X		X		X		X		X	X
CD4+cell counts	X	X	X	X		X		X			X			X	X
Urinalysis	X														X
Glucose	X														
Prothrombin time (PT)/ partial thromboplastin time (PTT)/ international normalized ratio (INR)	X														X
Oral study product dispensation		X													
LA study product administration[i]			X[1]	X	X	X	X	X	X	X	X	X	X	X	

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Procedures	Screening[a]	Intervention Period													WD[a]
		Day 1	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10[b]	Month 11[b]	Month 12[b]	
Participant Visit Reminder Contact	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Participant Contact Detail Confirmation	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Record study visit length[j]			X				X						X		
Patient Questionnaire			X			X								X	
Selected Patient Interviews (SSI)[k]		X												X	

See footnote "b" for continuation of visit schedule after Month 12, if required. Subjects will continue on study until the CAB + RPV LA regimen is either locally approved and commercially available, the participant no longer derives clinical benefit or meets a protocol-defined reason for discontinuation or until development is terminated.

a. A screening visit will be conducted within 21 days of Day 1. However, it is preferred for Day 1 to be conducted as soon as practical after all screening results are available.

b. Continue this pattern for visits for the remainder of the study if needed, until commercial CAB + RPV LA is available. For example, Month 13 will be conducted as per Month 10, Month 14 will be conducted as per Month 11, Month 15 will be conducted as per Month 12, Month 16 will be conducted as per Month 10, and so on. The exception to this pattern is that no questionnaires, study visit length collection, or patient interviews will be conducted after the Month 12 visit.

c. Physical exams should be conducted as part of normal routine clinical care but data will not be collected in the electronic case report form (eCRF). Medical assessments include any decisions the study staff must make for participant management.

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

e. Height collected at Day 1 only.

f. At Screening, ECGs should be performed in triplicate at least 5 minutes apart and following 5 minutes of rest in a semi-supine position. ECG evaluations performed at subsequent visits should be obtained after dosing, preferably 2-4 hours post dosing. ECG at Withdrawal should be performed following 5 minutes of rest in a semi-supine position.

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g. A (-) urine pregnancy test is required prior to any injection and as required by medical monitor after a treatment interruption. A (+) urine test should be confirmed with a stat serum test. If (+), participant will need to be withdrawn. A Serum pregnancy test should be performed at any time pregnancy is suspected by the Investigator and may be used in place of a urine test at the discretion of the investigator.

h. Plasma for storage samples are collected for possible future analyses, back-up in cases of loss/damage in transit, geno/pheno analyses for virologic failures or PK in the event of maladministration or virologic failure.

i. Monthly injections are 1 x CAB LA 600 mg IM + 1 x RPV LA 900 mg IM at Month 1. Subsequent injections beginning at Month 2 are 1 x CAB LA 400 mg IM + 1 x RPV LA 600 mg IM. If possible, injections should be spaced approximately 2 cm from one another and from the site of any previous injection and/or any injection site reaction. Bring RPV LA to approximately room temperature prior to injecting. Time and location of injection (right or left) as well as needle length used will be collected in the eCRF. **IM dosing is expected to occur during the month in which the participant's projected visit falls (as according to the Day 1 visit). A dosing window of +0 / -7 days from date of projected visit is stipulated for IM dosing at Month 2 and Month 3. A (+ or -) 7 day window from date of projected visit is stipulated for IM dosing beginning at Month 4. All decisions regarding dose interruption/ resumption must be discussed with the medical monitor in advance.**

j. Length of study visit from arrival until departure from clinic will be evaluated. Time of arrival, time of appointment, and departure times will be recorded in the eCRF.

k. The first semi-structured interview will be scheduled between Day 1 and prior to Month 1 visit. The end of study SSI will be scheduled within approximately 2 weeks following the Month 12 visit.

l. **Note:** Patient study participants with ≥ Grade 1 LFTs at screening and or day 1 must be discussed with the Medical Monitor prior to initiation of LA dosing; continuation in the study or progression onto LA dosing may require additional evaluations, including labs drawn after a period of oral dosing with CAB + RPV.

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

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13.2.1.2.   Schedule of Assessments Table for Staff Study Participants

Procedures	Prior to Enrollment	Intervention Period (Month)										
		Day 1	1	2	3	4	5	6	7	8	9	12
Staff Study Participant Questionnaire		Xa				Xb						Xb
Staff Study Participant Interviews (SSI)		Xa				Xb						Xb
Staff Study Participant Monthly Facilitation Callsc		X	X	X	X	X	X	X	X	X	X	

a.   Questionnaire and interview should be conducted prior to the first patient receiving their first CAB + RPV LA injection at that site.

b.   Questionnaire and interview should be conducted within approximately 4 weeks of the targeted subject visit at each site for Month 4 and after at least 50% of patient study participant visits at Month 12.

c.   Facilitation calls will continue during the enrollment period until the last enrolled subject achieves their Month 6 study visit.

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13.2.1.3. Schedule of Activities Table for Patient Study Participants (Long Term Follow Up) [a]

Procedures for Long-Term Follow Up[a]	Month 3	Month 6	Month 9	Month 12	WD	Notes
HIV Associated Conditions, AE and SAE Assessments, Con Meds	X	X	X	X	X	Every effort should be made to enter participants into the Long-Term Follow Up if they withdraw from or discontinue the study after receiving at least one dose of CAB LA and / or RPV LA.
HIV-1 RNA	X	X	X	X	X	a. The start of the 52-week follow-up period begins the day of the last CAB LA and/or RPV LA dose.
CD4+ cell counts	X	X	X	X	X	b. A PK sample for storage should be collected in the event of virologic failure during the LTFU phase
Plasma for Storage	X	X	X	X	X	c. Women of childbearing potential only. U=urine
PK Sample for Storage[b]						d. Women of childbearing potential should continue to receive counselling on the need to use adequate contraception for the entirety of the Long-Term Follow-Up Period.
Clinical Chemistry and Hematology	X	X	X	X	X	e. Investigators must discuss choice of HAART regimen and timing of initiation with the medical monitor before initiating.
Pregnancy Testing[c]	U	U	U	U	U	
Urinalysis				X	X	
PT/PTT/INR				X	X	
Contraception Counselling[d]	X	X	X	X	X	
HAART Dispensation[e]	X	X	X	X	X	

13.3.   Appendix 3: Assessment Windows

13.3.1.   Definitions of Assessment Windows for Analyses

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

Prior to visit slotting, assessments are first assigned to a study phase (Screening, Intervention Phase, Extension, or Long Term Follow Up) as defined in Section 13.4.1.

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

The nominal target study visit day is derived as

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

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

For parameters which are not scheduled to be assessed at visits, the all-inclusive assessment windows will still be used; however, data summaries will only report scheduled visits. Assessments at unscheduled visits will be included in summaries of worst-case values across visit (e.g. during the intervention phase) and in data listings, as well any algorithms that make use of additional data (e.g., Snapshot).

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

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	**Ending Timepoint**	
Day of earliest record	Assessment Study Day ≤1		Screening
For subjects discontinuing prior to receiving first injection:			
30	Assessment Study Day = 2	Study Day of Last CAB/RPV Oral Dose+1	Month 1
	Assessment Study Day > (Study Day of Last CAB/RPV Oral Lead-in Dose +1)		Follow-up
For subjects receiving first injection:			
Day of First Injection	Study Day = 2	M1 target day + *floor* [(M2 target day – M1 target day)/2]	Month 1
M2 Target Day	M1 target day + *floor* [(M2 target day – M1 target day)/2] + 1	M2 target day + *floor* [(M4 target day – M2 target day)/2]	Month 2
M4 Target Day	M2 target day + *floor* [(M4 target day – M2 target day)/2] + 1	M4 target day + *floor* [(M6 target day – M4 target day)/2]	Month 4
M6 Target Day	M4 target day + *floor* [(M6 target day – M4 target day)/2] + 1	M6 target day + *floor* [(M9 target day – M6 target day)/2]	Month 6
M9 Target Day	M6 target day + *floor* [(M9 target day – M6 target day)/2] + 1	M9 target day + *floor* [(M12 target day – M9 target day)/2]	Month 9
M12 Target Day	M9 target day + *floor* [(M12 target day – M9 target day)/2] + 1	M12 target day + *floor* [(M15 target day – M12 target day)/2]	Month 12
M15 Target Day	M12 target day + *floor* [(M15 target day – M12 target day)/2] + 1	M15 target day + *floor* [(M18 target day – M15 target day)/2]	Month 15
M18 Target Day	M15 target day + *floor* [(M18 target day – M15 target day)/2] + 1	M18 target day + *floor* [(M21 target day – M18 target day)/2]	Month 18
M*x* Target Day	M(*x-3*) target day - *floor* [(M*x* target day – M(*x-3*) target day)/2] + 1	M*x* target day + *floor* [(M(*x+3*) target day – M*x* target day)/2]	Month *x* For *x* = 21, 24, etc.
For subjects who permanently discontinue study treatment:			
	Assessment Study Day > Max (Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) + 1, Study Day of Last CAB + RPV Injection + 35)		Follow-up

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

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	**Ending Timepoint**	
Day of earliest record	Assessment Study Day ≤ 1		Screening
For subjects discontinuing prior to receiving first injection:			
28	Assessment Study Day = 2	Study Day of Last Oral Lead-in Dose +1	Month 1
	Assessment Study Day > (Study Day of Last CAB/RPV Oral Lead-in Dose +1)		Follow-up
For subjects receiving first injection:			
Date of First Injection	Study Day = 2	M1 target day + *floor* [(M2 target day – M1 target day)/2]	Month 1
M2 Target Day	M1 target day + *floor* [(M2 target day – M1 target day)/2] +1	M2 target day + *floor* [(M4 target day – M2 target day)/2]	Month 2
M4 Target Day	M2 target day + *floor* [(M4 target day – M2 target day)/2] + 1	M4 target day + *floor* [(M6 target day – M4 target day)/2]	Month 4
M6 Target Day	M4 target day + *floor* [(M6 target day – M4 target day + 1	M6 target day + *floor* [(M8 target day – M6 target day)/2]	Month 6
M8 Target Day	M6 target day + *floor* [(M8 target day – M6 target day)/2] + 1	M8 target day + *floor* [(M10 target day – M8 target day)/2]	Month 8
M10 Target Day	M8 target day + *floor* [(M10 target day – M8 target day)/2] + 1	M12 target day – 43	Month 10
M12 Target Day	M12 target day - 42	M12 target day + 42	Month 12
M13 Target Day	Assessment Study Day > M12 target day + 42		Month 13
For subjects who permanently discontinue study treatment during the Intervention Phase:			
	Assessment Study Day > Max (Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1, Study Day of Last CAB + RPV Injection + 35)		Follow-up

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

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	**Ending Timepoint**	
M13 Target Day	Study Day of Nominal Week 13 Visit	M13 target day - *floor* [(M15 target day – M13 target day)/2]	Month 13
M15 Target Day	M13 target day - *floor* [(M15 target day – M13 target day)/2] + 1	M15 target day + *floor* [(M17 target day – M15 target day)/2]	Month 15
M*x* Target Day	M(*x-2*) target day - *floor* [(M*x* target day – M(*x-2*) target day)/2] + 1	M*x* target day + *floor* [(M(*x+2*) target day – M*x* target day)/2]	Month *x* For *x* =17, 19 etc.
For subjects who permanently discontinue study treatment during the Extension Phase:			
	Assessment Study Day > Max (Study Day of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1, Study Day of Last CAB + RPV Injection + 35)		Follow-up

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

Target (Study Day)	Analysis Window		Analysis Timepoint
	Beginning Timepoint	**Ending Timepoint**	
Study Day of Actual M1 Injection	Study Day of Actual M1 Injection		Month 1
Study Day of Actual M5 Injection	Study Day of Actual M5 Injection		Month 5
Study Day of Actual M11 Injection	Study Day of Actual M11 Injection		Month 11
Study Day of Actual M14 Injection	Study Day of Actual M14 Injection		Month 14
Study Day of Actual M*x* Injection	Study Day of Actual M*x* Injection		Month *x* For *x*=17, 20, etc.
	If none of the above, then Analysis Timepoint = Other		

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

Day of Assessment	Assessment Window	Target LTFU Study Day of Window
1 ≤ LTFU Study Day ≤ 135	LTFU Month 3	90
136≤ LTFU Study Day ≤ 225	LTFU Month 6	180
226 ≤ LTFU Study Day ≤ 315	LTFU Month 9	270
316 ≤ LTFU Study Day ≤ 405	LTFU Month 12	360
(30*m-44) ≤ LTFU Study Day ≤ (30*m+45)	LTFU Month m M = 15, 18, 21	30*m

- LTFU Study Day is defined in 13.6.1

13.3.2.   Assessment Windows for PK Concentration Data

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

13.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events

13.4.1. Study Phases

AEs will be assigned to study phases as defined in Table 6. Laboratory data (efficacy, safety, and virology), HIV associated Conditions, health outcomes assessments, vital signs, and ECGs will be assigned to study phases as defined in Table 7.

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

Table 6   Study Phases for AEs

Study Phase	Definition
Screen	Date < Intervention Phase Treatment Start Date
Intervention	**For subjects continuing into the Extension Phase:** Intervention Phase Treatment Start Date ≤ Date < Date of Nominal Month 13 Visit **For subjects not continuing into the Extension Phase:** Intervention Phase Treatment Start Date ≤ Date < LTFU ART Start Date [a] For AEs leading to treatment withdrawal with start date equal to the LTFU ART Start Date, Intervention Phase instead of Long-term Follow-up Phase will be assigned.
Extension Phase	Date of Nominal Month 13 Injection ≤ Date < LTFU ART Start Date [a] For AEs leading to treatment withdrawal with start date equal to the LTFU ART Start Date, Extension Phase instead of Long-Term Follow-up Phase will be assigned.
Long Term Follow-Up	**For subjects who receive at least one CAB/RPV injection and permanently discontinue study treatment:** AE Start Date $\geq$ LTFU ART Start Date

AEs with completely missing start date:
   • If AE end date is $\leq$ Intervention Phase Treatment Start Date, then assign to Screening Phase;
   • Else if AE end date is completely missing or Intervention Phase Treatment Start Date < AE end date $\leq$ Date of Nominal Month 13 Injection, then assign to Intervention Phase;
   • Else if AE end date > Date of Nominal Month 13 Injection, then assign to Extension Phase.	

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

Table 7   Study Phases for Laboratory, PK, ECG, Vital Signs, HIV-1 Associated Conditions, and Protocol Deviation Data

Study Phase	Definition
Screen	Date ≤ Study Treatment Start Date
Intervention	**For subjects continuing into the Extension Phase:** Intervention Phase Treatment Start Date < Date < Date of Nominal Month 13 Visit **For subjects not continuing into the Extension Phase:** Intervention Phase Treatment Start Date < Date ≤ LTFU ART Start Date [a]
Extension Phase	**For subjects continuing into Extension Phase:** Date of Nominal Month 13 Visit ≤ Date ≤ LTFU ART Start Date [a]
Long Term Follow-Up	**For subjects who receive at least one CAB/RPV injection and permanently discontinue study treatment:** Assessment Date > LTFU ART Start Date

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

Study phase of discontinuation will be determined according to Table 8.

Table 8   Study Phases for Study Conclusion/IP Discontinuation

Study Phase	Definition
Intervention	Discontinuation Date is not missing, and no assessments collected at any extension phase nominal visits (i.e. Month 13, Month 15, Month 17 etc.).
Extension Phase	Discontinuation Date is not missing, and assessments collected at any extension phase nominal visits (i.e. Month 13, Month 15, Month 17 etc.).

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

Medication use will be classified as prior and concomitant with study treatment according to Table 9, noting that a medication can be assigned as "taken" during more than one study phase.

Table 9   Study Phases for Non-ART Medications/ART Medications

	Definition
Prior	Medication Taken < Intervention Treatment Start Date
Concomitant during Intervention Phase	**For subjects continuing into Extension Phase:** Intervention Treatment Start Date[a] ≤ Medication Taken < Date of Nominal Month 13 Visit **For subjects not continuing into Extension Phase[b]:** Intervention Treatment Start Date[a] ≤ Medication Taken < LTFU ART Start Date
Concomitant during Extension Phase	**For subjects continuing into Extension Phase[b]:** Date of Nominal Month 13 Visit ≤ Medication Taken < LTFU ART Start Date

	Definition
Received during Long-term Follow-up	**For subjects who received at least one CAB and/or RPV injection and have started LTFU ART:** Medication Taken ≥ LTFU ART Start Date

NOTES:
- Please refer to Appendix 7: Reporting Standards for Missing Data for handling of missing and partial dates for medications. Use the rules in this table if medication date is completely missing.
a. The ART medication stopped on start date of Intervention treatment will be considered a prior medication and will not be considered concomitant during the Intervention phase. If the stop date of ART medication is completely missing and this medication is recorded in eCRF as prior, it will be considered a prior medication and will not be considered concomitant during the intervention phase.
b. If subjects have missing LFTU ART start date, only the lower bound will be considered in the derivation.

13.4.2. Treatment State

Within each study phase (based on assignment of study phase described in Section 13.4.1), only those events/assessments which occur within the ranges shown in Table 10 will be considered 'on-treatment' for the given phase. No treatment states will be assigned to medications.

For adverse events, partial AE start date will use imputation as described in 13.7.2.1.

Table 10   Treatment State within Study Phases

Study Phase	State	Definition
Screen	Pre-Treatment	All assessments/events within phase
Intervention/Extension	On-treatment	Date ≤ max (Date of Last CAB LA +RPV LA IM Dose + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1)
	Post-Treatment	Date > max (Date of Last CAB LA +RPV LA IM Dose + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV or SOC Bridging) +1)
Long Term Follow-Up	Post-Treatment	All assessments/events within phase

NOTES:
- Date = Assessment/Start Date
a. Treatment State is determined after data has been assigned to the study phases as defined in Section 13.4.1.
b. Last injection and/or last dose of oral study treatment (CAB+RPV or SOC bridging) are only applied to participants who permanently discontinued the study treatment. The assessments for participants who did not permanently discontinue the study treatment will be considered 'On-treatment'. For participants continuing into extension phase, all data assigned to intervention phase per Section 13.4.1 will be considered 'On-treatment'

13.4.3. Oral Lead-in Period

Certain displays will be produced for data collected or events occurring during the oral-lead-in period as defined in Table 11 and Table 12.

Table 11   Oral Lead-in Period for AEs

Study Period	Date Range
Oral Lead-in	**For participants receiving at least one Injection:** Intervention Treatment Start Date ≤ Date [a] < Date of First IM Injection **For participants withdrawing prior to first Injection:** Date ≥ Intervention Treatment Start Date Note that the oral lead-in period is only applicable to the participants who received at least one dose of study treatment during the oral lead-in period in the study. Oral lead-in period is within the intervention phase.
[a] AEs with completely missing start date which have been assigned to the Intervention Phase based on Table 6 will not be assigned to the Oral Lead-in Period.	

NOTES:
- Date = AE Start date

Table 12   Oral Lead-in Period for Laboratory Data

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

NOTES:
- Date = Date of assessment

13.5. Appendix 5: Data Display Standards & Handling Conventions

13.5.1. Reporting Process

Software
• The currently supported versions of SAS software will be used.

Reporting Area	
HARP Server	us1salx00259
HARP Compound	\ARPROD\GSK1265744\mid209493\primary_01

Analysis Datasets
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.1).

Generation of RTF Files
• RTF files will be generated for all reporting efforts described in the RAP.

13.5.2. Reporting Standards

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

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

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

Unscheduled Visits
• Unscheduled visits will be assigned to an analysis visit using the all-inclusive windows defined in Section 13.3.

• However, data summaries will only report visits that are planned assessment time points for each parameter (according to the Schedule of Activities in Section 13.2.1). • Evaluable assessments at unscheduled visits will be used when categorizing values across visits, such as 'maximum grade during the intervention phase' or 'at any time post-baseline', and for any algorithm that has specific rules for which observation to use (e.g. snapshot algorithm, LOCF or CVF identification).	
Descriptive Summary Statistics	
Continuous Data	Refer to GSK Standard Statistical Display Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to GSK Standard Statistical Display Principals 7.01 to 7.13.	

13.5.3.   Reporting Standards for Pharmacokinetic

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

13.6.   Appendix 6: Derived and Transformed Data

13.6.1.   General

Multiple Measurements at One Analysis Time Point
• If there are two values within a time window (as per Section 13.3.1) the value closest to the target day for that window will be used. If values are the same distance from the target, then the mean (geometric mean for HIV-1 RNA, arithmetic mean for all other measurement) will be taken. • Assessments not chosen for use in summary statistics by this algorithm will still appear in the associated listings. • All applicable valid assessments, irrespective of proximity to the target study day, will be used when categorizing values across visits, such as 'maximum grade during the intervention phase' or 'at any time post-baseline', and for any algorithm that has specific rules for which observation to use (e.g. snapshot algorithm, LOCF or CVF identification). • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of "Any visit post-baseline" row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Treatment Start Date
• Intervention Phase Treatment Start Date = Earliest date of CAB + RPV oral lead-in entered in the IP exposure eCRF form
Nominal Month 13 Visit Date
• For participants who received Month 13 injection, the nominal Month 13 visit date is defined by the Month 13 injection date. • Otherwise, nominal Month 13 visit date is defined by the date of latest Month 13 assessment. • For participants who continued into Extension Phase but missed the Month 13 visit, the nominal Month 13 visit date is defined by the last contact date prior to the date of the first nominal extension phase visit (i.e. Month 15, Month 17, etc.).
Study Day

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

Long Term Follow-up Study Day

• The Long-Term Follow Up (LTFU) Study Day of an event (e.g., lab assessment, start date of AE or HIV associated condition) will be derived as the number of days between the date of the event and the end of IP treatment [i.e. max(Last IM Injection Date, Last Oral Bridging End Date)] as follows:
  ○ If the date of event falls in Long-term Follow up phase, then
    ▪ LTFU Study Day = Date of event - End date of IP + 1

Study Treatment
• Refers to CAB+RPV oral lead-in, CAB + RPV oral bridging, SOC bridging, CAB LA + RPV LA

13.6.2.   Study Population

Demographics
Age
• Age, in whole years, will be calculated with respect to the subject's Screening visit. • GSK standard IDSL algorithms will be used for calculating age where birth date will be imputed as follows: • Any subject with a missing date and month will have this imputed as '30th June'. • Birth date will be presented in listings as 'YYYY'. • Completely missing dates of birth will remain as missing, with no imputation applied. Consequently, the age of the subject will not be calculated and will remain missing.
Body Mass Index
• Calculated as Weight (kg)/Height (m)²
Hepatitis Status
• Hepatitis C status will be determined using antibody and/or hepatitis C virus (HCV) RNA assessments performed during screening or during the conduct of the study. • If both antibody and virus RNA assessments are available, then the latter will take precedence and positive/negative status will be based on whether HCV RNA is detectable (i.e., ≥ limit of quantification) or not. • A participant will be considered positive for hepatitis B virus (HBV) if they have a positive surface antigen or detectable HBV DNA result. "HBV DNA DETECTED" in the lab comment takes precedence over HBV DNA test result for positive hepatitis B status; for example, if a participant has HBV DNA test result below level of detection and the lab comment shows that HBV DNA detected, this participant will be considered positive for hepatitis B. If HBV DNA result is available, it will be used to qualify hepatitis B status as positive or negative (positive if ≥ limit of quantification); otherwise Hepatitis B status will be determined using the surface antigen result. • Hepatitis status at entry will be based on the assessments prior to/on the start of the study treatment.
Adherence to CAB/RPV Injection Schedule

• Timeliness of Injections relative to Date of Projected Dosing Visits are assessed by using "actual injection visit date - projected visit date from first injection". The injections of interest in adherence analysis are those after first injection at Month 1. (. Each injection visit is counted only once. Individual CAB and RPV injections administered at the same visit are not counted twice. "Extra" unscheduled injections are excluded from all derivations. For example, if during a scheduled visit a participant receives 1 ml of injection instead of 2 ml due to a dosing error, but this participant returns one week later for the remaining 1 ml injection, then the additional visit is excluded. If a participant receives an extra injection at an unscheduled visit by mistake, this visit will also be excluded.
• The categories of Timeliness of Injections relative to Date of Projected Dosing Visits are listed below:
  • < -14 days
  • -14 to - 8 days
  • -7 to 1
  • 0
  • 1 to 7 days
  • 8 to 14 days
  • >14 days
  • Missed Injection without Oral Bridging (COVID-19 related)
  • Missed Injection without Oral Bridging (Non COVID-19 related)
  • Missed Injection with Oral Bridging (COVID-19 related)

- Missed Injection with Oral Bridging (non COVID-19 related)

- Injection visits are expected monthly from Month 2 until the nominal month of a participant's last injection visit during the phase(s) of interest. For example:

  - If a participant discontinues study treatment with last injection visit occurring at nominal visit Month 6 (without oral bridging), then injection visits are expected at Month 2, Month 3, Month 4, Month 5 and Month 6.

- Missed injections occurring during periods of on-going oral bridging (e.g. oral bridging is ongoing at the time of the data analysis cutoff or participant discontinues study treatment where last study treatment received is oral bridging) are not considered to be expected visits.

Site Type
• AIDS Healthcare Foundation (Site Id.= PPD)
• Federally Qualified Health Center (Site Id.= PPD)
• Health Maintenance Organization (Site Id.= PPD)
• Private Practice (Site Id.= PPD)
• University (Site Id.= PPD)

13.6.3.   Efficacy

Efficacy
Snapshot
• The Snapshot algorithm is intended to be primarily a virologic assessment of the endpoint, and as such follows a "virology first" hierarchy.
• 'HIV-1 RNA < 50 c/mL' or 'HIV-1 RNA ≥ 50 c/mL' within an analysis window (see Table 2 and Table 3) is typically determined by the last available HIV-1 RNA measurement in that window while the participant is On-treatment in the Intervention Phase (as assigned based on Section 13.3).
• When no HIV-1 RNA data is available within a window, a participant cannot be assigned to the category of 'HIV-1 RNA < 50 c/mL'. Depending on the reason for lack of data, the participant will be classified as 'HIV-1 RNA ≥ 50 c/mL' or reported as 'No Virologic Data at Week X'; in the latter case, the algorithm further classifies the nature of the missing data. Typically, a participant withdrawn (i) due to AE or, (ii) for another reason yet was suppressed at the time, will be counted as 'No Virologic Data at Week X'. Should a participant withdraw for reasons other than AE and was not suppressed at the time, they will be categorized as 'HIV-1 RNA ≥ 50 c/mL'.
• Full details of the algorithm, including the handling of special cases, are included in Appendix 9: Snapshot Algorithm Details.
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.
Confirmed Virologic Failure (CVF)
• For the purposes of clinical management in this study, CVF is defined as:
o Rebound as indicated by two consecutive plasma HIV-1 RNA levels ≥ 200 c/mL.
• The CVF definition is provided in the protocol Section 7.1.3

Efficacy
• Only plasma HIV-1 RNA values determined by the central laboratory will be used to assess virologic failure.

CDC Classification for HIV-1 Infection (2014**)**
• CDC HIV-1 Classification at Baseline is collected in eCRF and no derivation with be performed programmatically for analysis purposes. Please refer to study protocol for detail description of CDC HIV-1 Classification.

13.6.4. Safety

Adverse Events
DAIDS Grading

• Clinical adverse events will be graded based on the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.1, March 2017, as specified in the protocol Appendix 10.2.
• If a grade value is expected per DAIDS but is missing in the eCRF, then the missing grade will be given an ordinal grade value of -1 for determining the maximum grade within and across preferred terms. For example:
   • if a participant has two separate instances of the same preferred term, one with grade 2 and one with missing grade, then the maximum grade for the preferred term will be set to grade 2.
   • if a participant reports two different AE preferred terms overall, one with grade 1 and one with missing grade (where a DAIDS grade is expected), then the maximum grade across preferred terms (i.e. in the ANY EVENT row) will be set to grade 1.
   • If a participant reports only one AE overall and this has a missing grade (where a DAIDS grade is expected), then this will be presented under a grade = missing category

Days since First Dose (Days)
• AE Start Date – Intervention Phase Treatment Start Date + 1
Days since Last Dose (Days)
• AE Start Date – Date of Last Dose of Study Treatment (CAB+RPV, SOC bridging, CAB/RPV IM Injection) prior to/on the Start Date of AE + 1
Days since Phase Start

• For AEs in Intervention/Extension Phase:
   o AE Start Date - Intervention Treatment Start Date + 1
• For AEs in Long-term Follow-up Phase:
   o AE Start Date – Date of Last Dose of Study Treatment
   o Date of Last Dose of Study Treatment = max (Last IM Injection Date, Last Oral Bridging End Date [CAB+RPV, SOC ART]), only applicable to participants who permanently discontinued study treatment.

Duration (Days)
• AE Resolution Date – AE Start Date + 1
Drug-related
• If relationship is marked 'YES' on Inform/eCRF • Injection site reactions will be considered as drug-related if the relationship to study drug value is missing in the eCRF.

Laboratory Parameters
• If a laboratory value which is expected to have a numeric value for summary purposes, has a non-detectable level reported in the database, where the numeric value is missing, but typically a character value starting with '<x' or '>x' (or indicated as less than x or greater than x in the comment field) is present, the number of significant digits in the observed values will be used to determine how much to add or subtract in order to impute the corresponding numeric value. If a character value starting with "<=x", then the numeric value will be x.

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

Lab Toxicities – DAIDS Grading

- Toxicities will be based on the Division of AIDS (DAIDS) grading system, Version 2.1, March 2.17, as specified in the protocol of Appendix 10.2
- Toxicity grades provided by the central laboratory do not distinguish between abnormally high or low criteria, when both are relevant for a particular parameter.
- When summarizing toxicity grades for such parameters, they will be categorized 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
Glucose	Hypoglycaemia	Hypoglycaemia
Sodium	Hyponatremia	Hyponatremia
Potassium	Hypokalaemia	Hypokalaemia

Other Safety Endpoints

Corrected QT (QTc)

- When not entered directly in the eCRF, corrected QT intervals by Bazett's (QTcB) and Fridericia's (QTcF) formulas will be calculated, in msec, depending on the availability of other measurements.
- If RR interval (in msec) is provided, then missing QTcB and/or QTcF will be derived as

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

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

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

Extent of Exposure

- Exposure to CAB+RPV (oral lead-in or oral bridging) and CAB LA+RPV LA will be calculated from the IP eCRF pages.

For Intervention Phase:

- **Exposure to CAB+RPV Oral Lead-in** = IP (oral lead-in) stop date - IP (oral lead-in) start date +1

Other Safety Endpoints

• **Exposure to CAB LA + RPV LA** = Number of IP injection visits received during the Intervention Phase (up to but not including injections administered at Month 13)
 	
• **Exposure to SOC oral bridging**: Duration of the SOC ART medication taken as oral bridging during the Intervention Phase. If the SOC oral bridging is taken in different periods during the Intervention Phase, the duration will be calculated by the sum of non-overlapped periods.
 	
• **Exposure to CAB+RPV Oral Bridging (COVID-19 Related)**: Duration of the CAB+RPV taken as oral bridging for reasons related to COVID-19 during the Intervention Phase. If COVID-19 related CAB+RPV oral bridging is taken in different periods during the Intervention Phase, the duration will be calculated by the sum of the non-overlapped periods.
 	
• **Exposure to CAB+RPV Oral Bridging (Non COVID-19 Related)**: Duration of the CAB+RPV taken as oral bridging for reasons not related to COVID-19 during the Intervention Phase. If non COVID-19 related CAB+RPV oral bridging is taken in different periods during the Intervention Phase, the duration will be calculated by the sum of the non-overlapped periods.
 	
• **Overall Exposure to Study Treatment**: min [Date of Latest Intervention Phase Visit up to and including Month 13, max (Date of Last Injection + 35, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – min (Start Date for Oral lead-in CAB+RPV, Date of First CAB/RPV Injection) + 1
      o Note: Conditions in the above formula pertaining to Last Injection/Last Dose of Oral CAB+RPV/Last Dose of SOC Oral Bridging are only applicable to those who permanently discontinued study treatment.
 	
• **Overall Exposure to CAB + RPV** = Overall Exposure to Study Treatment – Exposure to SOC Oral Bridging
 	
For Intervention ± Extension Phase:
• **Exposure to CAB LA + RPV LA** = Number of IP injection visits received during Intervention Phase and Extension Phase
 	
• Exposure to SOC or CAB+RPV Oral Bridging during the Intervention and Extension Phase will be calculated similarly to that during the Intervention Phase except that the exposure includes both Intervention and Extension Phase.
 	
• **Overall Exposure to Study Treatment**: min [Date of Latest Intervention/Extension Phase Visit, max (Date of Last Injection + 35, Date of Last Dose of Oral CAB+RPV, Date of Last Dose of SOC Oral Bridging)] – min (Start Date for Oral lead-in CAB+RPV, Date of First Study Injection) + 1
      o Note: Conditions in the above formula pertaining to Last Injection/Last Dose of Oral CAB+RPV/Last Dose of SOC Oral Bridging are only applicable to those who permanently discontinued study treatment.
 	
• **Overall Exposure to IP** = Overall Exposure to Study Treatment – Exposure to SOC Oral Bridging
 	
• Duration of dosing in participant years will be calculated as the sum of participant duration of dosing in days (across all participants)/365.25

13.6.5.   Virology

Genotype
Amino Acid Changes
• A mutation is considered present whenever the encoded amino acid residue differs from the amino acid that would have been encoded by the wild-type (e.g., HXB2, NL43) comparator gene; e.g., Q148K. • If the encoded amino acid is seen as a mixture of wild-type and mutant amino acid, e.g., Q148Q/K, the mutated amino acid is considered present at the codon of interest.

- If the encoded amino acid is seen as a mixture of two or more amino acids, which may or may not include wild type, e.g., Q184K/H or Q184K/H/Q, etc., for the purposes of calculating the number of mutated amino acids, only one mutation is considered to be present at the codon of interest.

Representation of Amino Acid Changes

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

Resistance Associated mutations

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

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

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

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

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

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

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13.6.6. Other Assessments

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

13.7.   Appendix 7: Reporting Standards for Missing Data

13.7.1.   Premature Withdrawals

Element	Reporting Detail
General	• Withdrawn participants were not replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified. • Withdrawal visits will be slotted according to Appendix 3: Assessment Windows (excluding PK data)

13.7.2.   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 participant 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.
Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.

13.7.2.1. Handling of Missing and Partial Dates

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

Element	Reporting Detail	

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

	Missing start day and month	• If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = January 1.
		• Else if study treatment start date is not missing:
		    ○ If year of start date = year of study treatment start date, then
		        ▪ If stop date contains a full date and stop date is earlier than study treatment start date, then set start date = January 1.
		        ▪ Else set start date = study treatment start date.
		    ○ Else set start date = January 1.

	Missing stop day	Last day of the month will be used.
	Missing stop day and month	No Imputation
	Completely missing start/end date	No imputation
	• Completely missing start or end dates will remain missing, with no imputation applied.	
Non-ART Medications	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention:	

	Missing start day	• If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = 1st of month.
		• Else if study treatment start date is not missing:
		    ○ If month and year of start date = month and year of study treatment start date, then
		        ▪ If stop date contains a full date and stop date is earlier than study treatment start date, then set start date= 1st of month.
		        ▪ Else set start date = study treatment start date.
		    ○ Else set start date = 1st of month.

	Missing start day and month	• If study treatment start date is missing (i.e. participant did not start study treatment), then set start date = January 1.
		• Else if study treatment start date is not missing:
		    ○ If year of start date = year of study treatment start date, then
		        ▪ If stop date contains a full date and stop date is earlier than study treatment start date, then set start date = January 1.
		        ▪ Else set start date = study treatment start date.
		• Else set start date = January 1.

	Missing end day	A '28/29/30/31' will be used for the day (dependent on the month and year)
	Missing end day and month	A '31' will be used for the day and 'Dec' will be used for the month.
	Completely missing start/end date	No imputation

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Element	Reporting Detail
	• The recorded partial date will be displayed in listings.
ART Medications	• Partial dates recorded in the eCRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month. ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. If medications recorded in the PRIOR ART form of the eCRF, then the earlier date of the imputed and the day prior to the Intervention phase treatment start date will be used, i.e. min (imputed stop date, Intervention phase treatment start date - 1). • For medications with completely missing start date, they will be considered started prior to the Intervention phase treatment start date. • For medications with completely missing stop date, they will be considered ongoing unless recorded in the PRIOR ART form of the eCRF. • For ART booster medications, the start and stop dates are not recorded in the database (i.e. missing), the dates will be imputed to be the same as the dates of their parent medications. • The recorded partial or missing date will be displayed in listings.

13.7.2.2. Handling of Missing Data for Statistical Analysis

Element	Reporting Detail
Snapshot	• In the Snapshot dataset, subjects without HIV – 1 RNA data in the assessment window for the visit of interest (due to missing data or discontinuation of IP prior to the visit window) do not belong to 'HIV-1< 50 c/mL (or 200 c/mL) The nature of this missing data will be further classified in Snapshot summaries as either 'HIV-1 RNA≥50' or 'No Virologic Data at Week X'; • See Appendix 9: Snapshot Algorithm Details
LOCF (COVID-19 Related)	• Missing HIV-1 RNA values within an analysis visit for reasons related to COVID-19 will be imputed using the last on-treatment value from earlier analysis timepoints. • This approach will be used in the primary snapshot analysis to address missing data due to COVID-19.

13.8.   Appendix 8: Values of Potential Clinical Importance

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

13.9.   Appendix 9: Snapshot Algorithm Details

Detailed Algorithm Steps

- Consider an analysis visit window for Month X as defined in Table 2.

- The HIV-1 RNA threshold of 50 will be analysed, in this study

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

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

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

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

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

- Background therapy is not given to participants while on study. The "change in background therapy" in detailed steps below refers to the "change in ART" in this study.

Detailed steps		
• Please note that the following scenarios will NOT be penalized in the Snapshot algorithm Oral bridging (CAB+RPV or SOC, where SOC oral bridging medication is permitted during COVID-19 pandemic due to the unavailability of the CAB/RPV IM injections and oral CAB+RPV)		
Condition ('Month 12' indicates Month 12 window)	**Response**	**Reasons**

1. If non-permitted change in background therapy prior to Month 12	HIV-1 RNA ≥ 50	Change in background therapy
2. If non-permitted change in background therapy during Month 12		
• Last on-treatment VL during Month 12 prior to/on the date of change ≥ 50 c/mL	HIV-1 RNA ≥ 50	Data in window not below 50
• Last on-treatment VL during Month 12 prior to/on the date of change < 50 c/mL	HIV-1 RNA < 50	
• No VL during Month 12 prior to/on the date of change	HIV-1 RNA ≥ 50	Change in background therapy
3. If none of the above conditions met		
3.1. On-treatment VL available during Month 12		
• Last on-treatment VL during Month 12 ≥ 50 c/mL	HIV-1 RNA ≥ 50	Data in window not below 50
• Last on-treatment VL during Month 12 < 50 c/mL	HIV-1 RNA < 50	
3.2. No on-treatment VL during Month 12		
3.2.1. If participants are still on study, i.e. a participant has not permanently discontinued the study treatment yet, or if a participant permanently discontinued the study treatment and the upper bound of analysis snapshot window is prior to the following date: • Min[max(Date of last injection + 35, Date of Last Dose of Oral Study Treatment (CAB+RPV, SOC Bridging) + 1), LTFU ART Start Date]		
3.2.1.1. If no on-treatment VL during Month 12 is not due to COVID-19	No virologic data at Month 12 Window	On study but missing data in window (Non-COVID-19 related)
3.2.1.2. If no on-treatment VL during Month 12 is due to COVID-19	No virologic data at Month 12 Window	On study but missing data in window (COVID-19 related)
3.2.2. If participants withdraw before/during Month 12 due to		
3.2.2.1. Non-COVID-19 related safety reasons (e.g. AE/death, liver chemistry stopping criteria, renal toxicity withdrawal criteria, QTc withdrawal criteria etc., as recorded in eCRF Conclusion form)	No virologic data at Month 12 Window	Disc due to AE/death (Non-COVID-19 related)
3.2.2.2. COVID-19 related safety reasons (e.g. AE/death, liver chemistry stopping criteria, renal toxicity withdrawal criteria, QTc withdrawal	No virologic data at Month 12 Window	Disc due to AE/death (COVID-19 related)

criteria etc., as recorded in eCRF Conclusion form)		
3.2.2.3. Non-safety and Non-COVID-19 related reasons (e.g. Lack of efficacy, protocol deviation, withdrew consent, loss to follow-up, study closed/terminated, investigator discretion etc., as recorded in eCRF Treatment Discontinuation Form)		
o Last on-treatment VL <50 c/mL OR no on-treatment VL available during study	No virologic Data at Month 12 Window	Disc for other reasons (Non-COVID-19 related)
o Last on-treatment VL ≥ 50 c/mL AND withdrawal due to Lack of efficacy	HIV-1 RNA ≥ 50	Disc. for lack of efficacy (Non-COVID-19 related)
o Last on-treatment VL ≥ 50 c/mL AND withdrawal due to all other non-safety related reasons	HIV-1 RNA ≥ 50	Disc. for other reason while not below 50 (Non-COVID-19 related)
3.2.2.4. Non-safety and COVID-19 related reasons (e.g. protocol deviation, withdrew consent, loss to follow-up, study closed/terminated, investigator discretion etc., as recorded in eCRF Conclusion Form)		
o Last on-treatment VL <50 c/mL OR no on-treatment VL available during study	No virologic Data at Month 12 Window	Disc for other reasons (COVID-19 related)
o Last on-treatment VL ≥ 50 c/mL AND withdrawal due to Lack of efficacy	HIV-1 RNA ≥ 50	Disc. for lack of efficacy (COVID-19 related)
o Last on-treatment VL ≥ 50 c/mL AND withdrawal due to all other non-safety related reasons	HIV-1 RNA ≥ 50	Disc. for other reason while not below 50 (COVID-19 related)

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

Examples from FDA guidance

Data in Window

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

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

No Data in Window

Discontinued study due to Adverse Event or Death:

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- Any patient who discontinues because of an AE or death before the window should be classified as *Discontinued due to AE or Death* (as appropriate), regardless of the HIV-1 RNA result, even if the HIV-1 RNA is below 50 c/mL at the time of discontinuation.

- However, if a patient has an HIV-1 RNA value in the time window and also discontinues in the time window, the viral load data should be used to classify the patient's response. This is the Virology First hierarchy:

    a. HIV-1 RNA below 50 c/mL at Day 336 and discontinues because of AE or even dies on Day 360 — this person is categorized as having HIV-1 RNA below 50 c/mL.

    b. HIV-1 RNA is 552 c/mL on Day 336 and the patient discontinues on Day 360, the patient is categorized as having HIV-1 RNA ≥ 50 c/mL.

Discontinued for Other Reasons:

- Only patients who have achieved virologic suppression can be counted as *Discontinued for Other Reasons.*

- If a patient discontinues the study before the time window because of *lack of efficacy,* then the patient should be included in the HIV-1 RNA ≥ 50 row and not in the Discontinued for Other Reasons row.

- If a patient discontinues because *participant withdrew consent* and his or her HIV-1 RNA result at the time of discontinuation was equal to or above 50 c/mL, then he or she should be categorized as HIV-1 RNA ≥ 50 and NOT as Discontinued for Other Reasons.

- If a patient discontinued because of *Lost to Follow-Up* and the last HIV-1 RNA result was 49 c/mL, then the patient can be categorized as Discontinued for Other Reasons.

- If patients changed background treatment — *not permitted by protocol*— they should be considered an efficacy failure and captured in the HIV-1 RNA ≥ 50 c/mL row.

On study but missing data in window:

- If there are no data during Days 294 to 377, but there is an HIV-1 RNA below 50 c/mL on Day 380, this patient should be considered *On Study but Missing Data in Window.*

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

13.10.   Appendix 10: AESI identification

SMQ and PT codes based on MedDRA dictionary version 23.0 for the Month 12 analysis.

13.10.1.   Hepatic Safety Profile

Medical concept of hepatic failure and hepatitis. Sub- SMQs (1) 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions' and (2) 'Hepatitis, non-infectious', both of parent SMQ 'Hepatic Disorders (SMQ code 20000005)'; only narrow terms selected from sub-SMQs. Some preferred terms, e.g. PT 'hepatitis fulminant' are duplicated.

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

Gallbladder varices	10072319
Gastric variceal injection	10076237
Gastric variceal ligation	10076238
Gastric varices	10051012
Gastric varices haemorrhage	10057572
Gastrooesophageal variceal haemorrhage prophylaxis	10066597
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
Immune-mediated cholangitis	10083406

Immune-mediated hepatic disorder	10083521
Intestinal varices	10071502
Intestinal varices haemorrhage	10078058
Liver dialysis	10076640
Liver disorder	10024670
Liver injury	10067125
Liver operation	10062040
Liver transplant	10024714
Lupoid hepatic cirrhosis	10025129
Minimal hepatic encephalopathy	10076204
Mixed liver injury	10066758
Nodular regenerative hyperplasia	10051081
Nonalcoholic fatty liver disease	10082249
Non-alcoholic steatohepatitis	10053219
Non-cirrhotic portal hypertension	10077259
Oedema due to hepatic disease	10049631
Oesophageal varices haemorrhage	10030210
Peripancreatic varices	10073215
Portal fibrosis	10074726
Portal hypertension	10036200
Portal hypertensive colopathy	10079446
Portal hypertensive enteropathy	10068923
Portal hypertensive gastropathy	10050897
Portal vein cavernous transformation	10073979
Portal vein dilatation	10073209
Portopulmonary hypertension	10067281
Primary biliary cholangitis	10080429
Regenerative siderotic hepatic nodule	10080679
Renal and liver transplant	10052279

Retrograde portal vein flow	10067338
Reye's syndrome	10039012
Reynold's syndrome	10070953
Splenic varices	10067823
Splenic varices haemorrhage	10068662
Steatohepatitis	10076331
Subacute hepatic failure	10056956
Sugiura procedure	10083010
Varices oesophageal	10056091
Varicose veins of abdominal wall	10072284
White nipple sign	10078438
SMQ: 'Hepatic Disorders'; SMQ Code: 20000005 Sub-SMQ: 'Hepatitis, non-infectious' Category: A Scope: Narrow	
Preferred Term	PT Code
Acute graft versus host disease in liver	10066263
Allergic hepatitis	10071198
Alloimmune hepatitis	10080576
Autoimmune hepatitis	10003827
Chronic graft versus host disease in liver	10072160
Chronic hepatitis	10008909
Graft versus host disease in liver	10064676
Hepatitis	10019717
Hepatitis acute	10019727
Hepatitis cholestatic	10019754
Hepatitis chronic active	10019755
Hepatitis chronic persistent	10019759
Hepatitis fulminant	10019772
Hepatitis toxic	10019795

Immune-mediated hepatitis	10078962
Ischaemic hepatitis	10023025
Lupus hepatitis	10067737
Non-alcoholic steatohepatitis	10053219
Radiation hepatitis	10051015
Steatohepatitis	10076331

13.10.2. Hyperglycaemia

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

SMQ: 'Hyperglycaemia/new onset diabetes mellitus '; SMQ Code: 20000041 Sub-SMQ: 'Hepatic failure, fibrosis and cirrhosis and other liver damage-related Category: A Scope: Narrow	
Preferred Term	PT Code
Acquired lipoatrophic diabetes	10073667
Blood 1,5-anhydroglucitol decreased	10065367
Blood glucose increased	10005557
Diabetes complicating pregnancy	10012596
Diabetes mellitus	10012601
Diabetes mellitus inadequate control	10012607
Diabetes with hyperosmolarity	10012631
Diabetic arteritis	10077357
Diabetic coma	10012650
Diabetic coronary microangiopathy	10080788
Diabetic hepatopathy	10071265
Diabetic hyperglycaemic coma	10012668
Diabetic hyperosmolar coma	10012669
Diabetic ketoacidosis	10012671
Diabetic ketoacidotic hyperglycaemic coma	10012672
Diabetic ketosis	10012673

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Diabetic metabolic decompensation	10074309
Diabetic wound	10081558
Euglycaemic diabetic ketoacidosis	10080061
Fructosamine increased	10017395
Fulminant type 1 diabetes mellitus	10072628
Gestational diabetes	10018209
Glucose tolerance impaired	10018429
Glucose tolerance impaired in pregnancy	10018430
Glucose urine present	10018478
Glycated albumin increased	10082836
Glycosuria	10018473
Glycosuria during pregnancy	10018475
Glycosylated haemoglobin abnormal	10018481
Glycosylated haemoglobin increased	10018484
Hyperglycaemia	10020635
Hyperglycaemic hyperosmolar nonketotic syndrome	10063554
Hyperglycaemic seizure	10071394
Hyperglycaemic unconsciousness	10071286
Impaired fasting glucose	10056997
Insulin resistance	10022489
Insulin resistant diabetes	10022491
Insulin-requiring type 2 diabetes mellitus	10053247
Ketoacidosis	10023379
Ketonuria	10023388
Ketosis	10023391
Ketosis-prone diabetes mellitus	10023392
Latent autoimmune diabetes in adults	10066389
Monogenic diabetes	10075980
Neonatal diabetes mellitus	10028933

New onset diabetes after transplantation	10082630
Pancreatogenous diabetes	10033660
Steroid diabetes	10081755
Type 1 diabetes mellitus	10067584
Type 2 diabetes mellitus	10067585
Type 3 diabetes mellitus	10072659
Urine ketone body present	10057597

13.10.3. Hypersensitivity Reactions

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

SMQ: Drug reaction with eosinophilia and systemic symptoms syndrome SMQ Code: 20000225 Category: A Scope: Narrow	
Preferred Term	PT Code
Drug reaction with eosinophilia and systemic symptoms	10073508
Pseudolymphoma	10037127
Additional preferred terms selected from HLGT 'Allergic conditions' under SOC 'Immune system disorders'; HLGT code 10001708	
Preferred Term	PT Code
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

13.10.4.   Rash including severe cutaneous adverse reactions

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

SMQ: Severe Cutaneous Adverse Reactions SMQ Code: 20000020 Category: A Scope: Narrow	
SMQ	PT Code
Acute generalised exanthematous pustulosis	10048799
Bullous haemorrhagic dermatosis	10083809
Cutaneous vasculitis	10011686
Dermatitis bullous	10012441
Dermatitis exfoliative	10012455
Dermatitis exfoliative generalised	10012456
Drug reaction with eosinophilia and systemic symptoms	10073508
Epidermal necrosis	10059284

Erythema multiforme	10015218
Erythrodermic atopic dermatitis	10082985
Exfoliative rash	10064579
Oculomucocutaneous syndrome	10030081
SJS-TEN overlap	10083164
Skin necrosis	10040893
Stevens-Johnson syndrome	10042033
Target skin lesion	10081998
Toxic epidermal necrolysis	10044223
Toxic skin eruption	10057970
Addition selected preferred terms from HLTs 'Rashes, eruptions and exanthems NEC', HLT Code 1005266; 'Pruritus NEC', HLT Code 10049293, 'Pustular conditions', HLT Code 10037573; 'Dermatitis ascribed to specific agent', HLT Code 10012437.	
Preferred Term	PT Code
Eyelid rash	10074620
Genital rash	10018175
Mucocutaneous rash	10056671
Nodular rash	10075807
Perineal rash	10075364
Rash	10037844
Rash erythematous	10037855
Rash generalised	10037858
Rash macular	10037867
Rash maculo-papular	10037868
Rash maculovesicular	10050004
Rash morbilliform	10037870
Rash papular	10037876
Rash rubelliform	10057984
Rash scarlatiniform	10037890

Rash vesicular	10037898
Rash pruritic	10037884
Rash follicular	10037857
Rash pustular	10037888
Drug eruption	10013687

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

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

SMQ: Torsade de pointes/QT prolongation SMQ Code: 20000001 Category: A Scope: Narrow	
Preferred Term	PT Code
Electrocardiogram QT interval abnormal	10063748
Electrocardiogram QT prolonged	10014387
Long QT syndrome	10024803
Long QT syndrome congenital	10057926
Torsade de pointes	10044066
Ventricular tachycardia	10047302
Additional selected preferred terms from HLT 'ECG investigations', HLT Code 10053104.	
Preferred Term	PT Code
Electrocardiogram repolarisation abnormality	10052464

13.10.6. Suicidal Ideation/Behaviour

Medical concept of suicidal ideation and behaviour. Sub-SMQ 'Suicide/self-injury' (SMQ) from parent SMQ of 'Depression and Suicide/Self Injury (SMQ Code 20000035)'. Only narrow terms from the sub-SMQ selected.

SMQ: 'Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Suicide/self-injury'	

Category: A Scope: Narrow	
Preferred Term	PT Code
Assisted suicide	10079105
Columbia suicide severity rating scale abnormal	10075616
Completed suicide	10010144
Depression suicidal	10012397
Intentional overdose	10022523
Intentional self-injury	10022524
Poisoning deliberate	10036000
Self-injurious ideation	10051154
Suicidal behaviour	10065604
Suicidal ideation	10042458
Suicide attempt	10042464
Suicide threat	10077417
Suspected suicide	10082458
Suspected suicide attempt	10081704

13.10.7. Depression

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

SMQ: ''Depression and Suicide/Self Injury' SMQ Code: 20000035 Sub-SMQ: 'Depression (excl suicide and self-injury)' Category: A Scope: Narrow	
Preferred Term	PT Code
Activation syndrome	10066817
Adjustment disorder with depressed mood	10001297
Adjustment disorder with mixed anxiety and depressed mood	10001299
Agitated depression	10001496

Anhedonia	10002511
Antidepressant therapy	10054976
Childhood depression	10068631
Decreased interest	10011971
Depressed mood	10012374
Depression	10012378
Depression postoperative	10012390
Depressive symptom	10054089
Dysphoria	10013954
Electroconvulsive therapy	10014404
Feeling guilty	10049708
Feeling of despair	10016344
Feelings of worthlessness	10016374
Helplessness	10077169
Major depression	10057840
Menopausal depression	10067371
Mixed anxiety and depressive disorder	10080836
Perinatal depression	10078366
Persistent depressive disorder	10077804
Post stroke depression	10070606
Postictal depression	10071324

13.10.8. Bipolar Disorder

Medical concept of bipolar disorder. All preferred terms from HLGT 'Manic and Bipolar mood disorders and disturbances' under SOC "Psychiatric disorders"; HLGT Code 10026753.

Preferred Term	PT Code
Bipolar I disorder	10004939
Bipolar II disorder	10004940
Bipolar disorder	10057667

Preferred Term	PT Code
Cyclothymic disorder	10011724
Hypomania	10021030
Mania	10026749

13.10.9. Psychosis

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

SMQ: 'Psychosis and psychotic disorders' SMQ Code: 20000117 Category: A Scope: Narrow	
Preferred Term	PT Code
Acute psychosis	10001022
Alcoholic psychosis	10001632
Alice in wonderland syndrome	10001666
Brief psychotic disorder with marked stressors	10048549
Brief psychotic disorder without marked stressors	10056395
Brief psychotic disorder, with postpartum onset	10006362
Charles Bonnet syndrome	10063354
Childhood psychosis	10061040
Clang associations	10009232
Cotard's syndrome	10059591
Delusion	10012239
Delusion of grandeur	10012241
Delusion of parasitosis	10012242
Delusion of reference	10012244
Delusion of replacement	10012245
Delusion of theft	10084030
Delusional disorder, erotomanic type	10012249
Delusional disorder, grandiose type	10012250

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Delusional disorder, jealous type	10012251
Delusional disorder, mixed type	10012252
Delusional disorder, persecutory type	10053195
Delusional disorder, somatic type	10012254
Delusional disorder, unspecified type	10012255
Delusional perception	10012258
Dementia of the Alzheimer's type, with delusions	10012295
Depressive delusion	10063033
Derailment	10012411
Epileptic psychosis	10059232
Erotomanic delusion	10015134
Flight of ideas	10016777
Hallucination	10019063
Hallucination, auditory	10019070
Hallucination, gustatory	10019071
Hallucination, olfactory	10019072
Hallucination, synaesthetic	10062824
Hallucination, tactile	10019074
Hallucination, visual	10019075
Hallucinations, mixed	10019079
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Hysterical psychosis	10062645
Ideas of reference	10021212
Illusion	10021403
Jealous delusion	10023164
Loose associations	10024825
Mixed delusion	10076429
Neologism	10028916

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

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Thought insertion	10043496
Thought withdrawal	10043497
Transient psychosis	10056326
Waxy flexibility	10047853

13.10.10. Mood Disorders

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

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

Laziness	10051602
Lethargy	10024264
Listless	10024642
Moaning	10027783
Mood altered	10027940
Mood disorder due to a general medical condition	10027944
Mood swings	10027951
Morose	10027977
Neuroleptic-induced deficit syndrome	10075295
Premenstrual dysphoric disorder	10051537
Premenstrual syndrome	10036618
Screaming	10039740
Seasonal affective disorder	10039775
Steroid withdrawal syndrome	10042028
Substance-induced mood disorder	10072387

13.10.11. Anxiety

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

Preferred Terms	PT Code
Acrophobia	10000605
Activation syndrome	10066817
Acute stress disorder	10001084
Aerophobia	10080300
Agitation	10001497
Agitation postoperative	10049989
Agoraphobia	10001502
Akathisia	10001540
Algophobia	10078056

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Animal phobia	10002518
Anniversary reaction	10074066
Anticipatory anxiety	10002758
Anxiety	10002855
Anxiety disorder	10057666
Anxiety disorder due to a general medical condition	10002859
Arachnophobia	10051408
Astraphobia	10078372
Autophobia	10071070
Body dysmorphic disorder	10052793
Burnout syndrome	10065369
Catastrophic reaction	10082329
Cibophobia	10082413
Claustrophobia	10009244
Compulsions	10010219
Compulsive cheek biting	10076510
Compulsive handwashing	10071263
Compulsive hoarding	10068007
Compulsive lip biting	10066241
Compulsive shopping	10067948
Cryophobia	10082662
Dermatillomania	10065701
Dysmorphophobia	10049096
Emetophobia	10070637
Fear	10016275
Fear of animals	10016276
Fear of closed spaces	10016277
Fear of crowded places	10050365
Fear of death	10066392

Fear of disease	10016278
Fear of eating	10050366
Fear of falling	10048744
Fear of injection	10073753
Fear of open spaces	10016279
Fear of pregnancy	10067035
Fear of weight gain	10016280
Fear-related avoidance of activities	10080136
Generalised anxiety disorder	10018075
Glossophobia	10080077
Haemophobia	10073458
Haphephobia	10067580
Herpetophobia	10081809
Hydrophobia	10053317
Hyperarousal	10080831
Immunisation anxiety related reaction	10075205
Kinesiophobia	10078430
Limited symptom panic attack	10024511
Mysophobia	10078769
Nail picking	10066779
Nervousness	10029216
Neurosis	10029333
Noctiphobia	10057946
Nocturnal fear	10057948
Nosocomephobia	10083993
Nosophobia	10063546
Obsessive need for symmetry	10077179
Obsessive rumination	10056264
Obsessive thoughts	10029897

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Obsessive-compulsive disorder	10029898
Obsessive-compulsive symptom	10077894
Ochlophobia	10050095
Osmophobia	10060765
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	10072147
Panic attack	10033664
Panic disorder	10033666
Panic reaction	10033670
Paruresis	10069024
Performance fear	10034432
Phagophobia	10050096
Pharmacophobia	10069423
Phobia	10034912
Phobia of driving	10056676
Phobia of exams	10034913
Phobic avoidance	10034918
Phonophobia	10054956
Photaugiaphobia	10064420
Postpartum anxiety	10082233
Postpartum neurosis	10036419
Postpartum stress disorder	10056394
Post-traumatic stress disorder	10036316
Procedural anxiety	10075204
Pseudoangina	10056610
Selective mutism	10039917
Separation anxiety disorder	10040045
Sitophobia	10080170
Social anxiety disorder	10041242

Social fear	10041247
Stress	10042209
Tension	10043268
Terminal agitation	10077416
Thanatophobia	10064723
Thermophobia	10075147
Trichotemnomania	10072752
Trichotillomania	10044629

13.10.12. Sleep Disorders

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

HLGT Sleep Disorders and Disturbances, HLGT Code 10040991	
Preferred Term	PT Code
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Advanced sleep phase	10001423
Behavioural induced insufficient sleep syndrome	10081938
Behavioural insomnia of childhood	10072072
Breathing-related sleep disorder	10006344
Cataplexy	10007737
Circadian rhythm sleep disorder	10009191
Confusional arousal	10067494
Delayed sleep phase	10012209
Dyssomnia	10061827
Exploding head syndrome	10080684
Hypersomnia	10020765
Hypersomnia related to another mental condition	10020767

Hypersomnia-bulimia syndrome	10053712
Hypnagogic hallucination	10020927
Hypnopompic hallucination	10020928
Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Insomnia related to another mental condition	10022443
Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Loss of dreaming	10065085
Middle insomnia	10027590
Narcolepsy	10028713
Nightmare	10029412
Non-24-hour sleep-wake disorder	10078086
Parasomnia	10061910
Paradoxical insomnia	10083337
Periodic limb movement disorder	10064600
Pickwickian syndrome	10035004
Poor quality sleep	10062519
Rapid eye movement sleep behaviour disorder	10077299
Rapid eye movements sleep abnormal	10037841
Shift work disorder	10078088
Sleep apnoea syndrome	10040979
Sleep attacks	10040981
Sleep disorder	10040984
Sleep disorder due to a general medical condition	10063910
Sleep disorder due to general medical condition, hypersomnia type	10040985
Sleep disorder due to general medical condition, insomnia type	10040986
Sleep disorder due to general medical condition, mixed type	10040987

Sleep disorder due to general medical condition, parasomnia type	10040988
Sleep inertia	10067493
Sleep paralysis	10041002
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347
Somnolence	10041349
Somnolence neonatal	10041350
Sopor	10058709
Stupor	10042264
Terminal insomnia	10068932
Upper airway resistance syndrome	10063968
HLGT Sleep disturbances (incl subtypes), HLGT code 10040998	
Abnormal dreams	10000125
Abnormal sleep-related event	10061613
Advanced sleep phase	10001423
Behavioural induced insufficient sleep syndrome	10081938
Behavioural insomnia of childhood	10072072
Breathing-related sleep disorder	10006344
Cataplexy	10007737
Central-alveolar hypoventilation	10007982
Circadian rhythm sleep disorder	10009191
Confusional arousal	10067494
Delayed sleep phase	10012209
Dyssomnia	10061827
Fatal familial insomnia	10072077
Hypersomnia	10020765

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Hyposomnia	10067530
Initial insomnia	10022035
Insomnia	10022437
Irregular sleep phase	10022995
Irregular sleep wake rhythm disorder	10080301
Loss of dreaming	10065085
Microsleep	10076954
Middle insomnia	10027590
Narcolepsy	10028713
Non-24-hour sleep-wake disorder	10078086
Periodic limb movement disorder	10064600
Pickwickian syndrome	10035004
Poor quality sleep	10062519
Rapid eye movement sleep behaviour disorder	10077299
Rapid eye movements sleep abnormal	10037841
Shift work disorder	10078088
Sleep apnoea syndrome	10040979
Sleep deficit	10080881
Sleep inertia	10067493
Sleep paralysis	10041002
Sleep sex	10067492
Sleep talking	10041009
Sleep terror	10041010
Sleep-related eating disorder	10067315
Somnambulism	10041347
Sudden onset of sleep	10050014
Terminal insomnia	10068932
Upper airway resistance syndrome	10063968

13.10.13. Injection site Reactions

Use eCRF terms for ISR.

13.10.14. Seizures

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

SMQ: 'Convulsions' SMQ Code: 20000079 Category: A Scope: Narrow	
Preferred Term	PT Code
1p36 deletion syndrome	10082398
2-Hydroxyglutaric aciduria	10078971
Acquired epileptic aphasia	10052075
Acute encephalitis with refractory, repetitive partial seizures	10076948
Alcoholic seizure	10056347
Alpers disease	10083857
Aspartate-glutamate-transporter deficiency	10079140
Atonic seizures	10003628
Atypical benign partial epilepsy	10056699
Automatism epileptic	10003831
Autonomic seizure	10049612
Baltic myoclonic epilepsy	10054895
Benign familial neonatal convulsions	10067866
Benign rolandic epilepsy	10070530
Biotinidase deficiency	10071434
CEC syndrome	10083749
CDKL5 deficiency disorder	10083005
Change in seizure presentation	10075606
Clonic convulsion	10053398

Congenital bilateral perisylvian syndrome	10082716
Convulsion in childhood	10052391
Convulsions local	10010920
Convulsive threshold lowered	10010927
CSWS syndrome	10078827
Deja vu	10012177
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
Gelastic seizure	10082918
Generalised onset non-motor seizure	10083376
Generalised tonic-clonic seizure	10018100
Glucose transporter type 1 deficiency syndrome	10078727
GM2 gangliosidosis	10083933
Grey matter heterotopia	10082084
Hemimegalencephaly	10078100
Hyperglycaemic seizure	10071394
Hypocalcaemic seizure	10072456

Hypoglycaemic seizure	10048803
Hyponatraemic seizure	10073183
Idiopathic generalised epilepsy	10071081
Infantile spasms	10021750
Juvenile myoclonic epilepsy	10071082
Lafora's myoclonic epilepsy	10054030
Lennox-Gastaut syndrome	10048816
Migraine-triggered seizure	10076676
Molybdenum cofactor deficiency	10069687
Multiple subpial transection	10079825
Myoclonic epilepsy	10054859
Myoclonic epilepsy and ragged-red fibres	10069825
Neonatal epileptic seizure	10082068
Neonatal seizure	10082067
Partial seizures	10061334
Partial seizures with secondary generalisation	10056209
Petit mal epilepsy	10034759
Polymicrogyria	10073489
Post stroke epilepsy	10076982
Post stroke seizure	10076981
Postictal headache	10052470
Postictal paralysis	10052469
Postictal psychosis	10070669
Postictal state	10048727
Post-traumatic epilepsy	10036312
Schizencephaly	10073487
Seizure	10039906
Seizure anoxic	10039907
Seizure cluster	10071350

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Seizure like phenomena	10071048
Severe myoclonic epilepsy of infancy	10073677
Simple partial seizures	10040703
Status epilepticus	10041962
Sudden unexplained death in epilepsy	10063894
Temporal lobe epilepsy	10043209
Tonic clonic movements	10051171
Tonic convulsion	10043994
Tonic posturing	10075125
Topectomy	10073488
Transient epileptic amnesia	10081728
Tuberous sclerosis complex	10080584
Uncinate fits	10045476
Additional selected preferred terms from HLT Disturbances in consciousness NEC, HLT code 10013509 and HLT Confusion and disorientation, HLT code 10010301.	
Preferred Term	PT Code
Confusional state	10010305
Loss of consciousness	10024855
Syncope	10042772
Sopor	10058709
Stupor	10042264
Altered state of consciousness	10050093
Depressed level of consciousness	10012373
Consciousness fluctuating	10050093

13.10.15. Weight Gain

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

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

13.10.16. Rhabdomyolysis

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

SMQ: 'Rhabdomyolysis/myopathy' SMQ Code: 20000002 Category: A Scope: Narrow	
Preferred Term	PT Code
Muscle necrosis	10028320
Myoglobin blood increased	10028625
Myoglobin blood present	10059888
Myoglobin urine present	10028631
Myoglobinaemia	10058735
Myoglobinuria	10028629
Myopathy	10028641
Myopathy toxic	10028648
Necrotising myositis	10074769
Rhabdomyolysis	10039020
Thyrotoxic myopathy	10081524
PTs (Select) from HGLT muscle disorders, HLGT Code 10028302	
Preferred Term	PT Code
Myalgia	10028411
Myositis	10028653

13.10.17. Pancreatitis

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

SMQ: 'Acute pancreatitis' SMQ Code: 20000022 Category: A	

Scope: Narrow	
Preferred Term	PT Code
Cullen's sign	10059029
Grey Turner's sign	10075426
Haemorrhagic necrotic pancreatitis	10076058
Hereditary pancreatitis	10056976
Immune-mediated pancreatitis	10083072
Ischaemic pancreatitis	10066127
Oedematous pancreatitis	10052400
Pancreatic abscess	10048984
Pancreatic cyst drainage	10082531
Pancreatic haemorrhage	10033625
Pancreatic necrosis	10058096
Pancreatic phlegmon	10056975
Pancreatic pseudoaneurysm	10081762
Pancreatic pseudocyst	10033635
Pancreatic pseudocyst drainage	10033636
Pancreatic pseudocyst haemorrhage	10083813
Pancreatic pseudocyst rupture	10083811
Pancreatitis	10033645
Pancreatitis acute	10033647
Pancreatitis haemorrhagic	10033650
Pancreatitis necrotising	10033654
Pancreatitis relapsing	10033657
Pancreatorenal syndrome	10056277

13.10.18. Impact on Creatinine

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

SMQ: 'Acute renal failure' SMQ Code: 20000003 Category: A Scope: Narrow	
Preferred Term	PT Code
Acute kidney injury	10069339
Acute phosphate nephropathy	10069688
Anuria	10002847
Azotaemia	10003885
Continuous haemodiafiltration	10066338
Dialysis	10061105
Foetal renal impairment	10078987
Haemodialysis	10018875
Haemofiltration	10053090
Neonatal anuria	10049778
Nephropathy toxic	10029155
Oliguria	10030302
Peritoneal dialysis	10034660
Prerenal failure	10072370
Renal failure	10038435
Renal failure neonatal	10038447
Renal impairment	10062237
Renal impairment neonatal	10049776
Subacute kidney injury	10081980
Renal Failure and Impairment HLT, HLT Code 10038443	
Preferred Term	PT Code
Acute Kidney injury	10069339
Anuria	10002847
Atypical haemolytic uraemic syndrome	10079840
Cardiorenal syndrome	10068230

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

13.10.19. Safety During Pregnancy

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

13.11. Appendix 11: Identification of COVID-19 Adverse Events

COVID-19 adverse events are identified based on MedDRA coded values and/or AE referenced in the COVID-19 Coronavirus Infection assessment. The Lowest Level Terms (LLTs) and codes, Preferred Terms (PTs), High Level Terms (HLTs), High Level Group Terms (HLGTs), and System Organ Classes (SOCs), below are from MedDRA 23.0. In case there is a change to the version of MedDRA at time of reporting, the coded values based on the MedDRA version at the time of reporting will be used. The additional events may also be added based on the blinded review of AE data collected on study prior to the database freeze.

SOC: Infections and infestations

LLT code	LLT	PT	HLT	HLGT
10084459	Asymptomatic COVID-19	Asymptomatic COVID-19	Coronavirus infections	Viral infectious disorders
10084467	Asymptomatic SARS-CoV-2 infection	Asymptomatic COVID-19	Coronavirus infections	Viral infectious disorders
10053983	Corona virus infection	Coronavirus infection	Coronavirus infections	Viral infectious disorders
10051905	Coronavirus infection	Coronavirus infection	Coronavirus infections	Viral infectious disorders
10084382	Coronavirus disease 2019	COVID-19	Coronavirus infections	Viral infectious disorders
10084268	COVID-19	COVID-19	Coronavirus infections	Viral infectious disorders
10084401	COVID-19 respiratory infection	COVID-19	Coronavirus infections	Viral infectious disorders
10084270	SARS-CoV-2 acute respiratory disease	COVID-19	Coronavirus infections	Viral infectious disorders
10084272	SARS-CoV-2 infection	COVID-19	Coronavirus infections	Viral infectious disorders
10084381	Coronavirus pneumonia	COVID-19 pneumonia	Coronavirus infections	Viral infectious disorders
10084380	COVID-19 pneumonia	COVID-19 pneumonia	Coronavirus infections	Viral infectious disorders
10084383	Novel COVID-19-infected pneumonia	COVID-19 pneumonia	Coronavirus infections	Viral infectious disorders
10084451	Suspected COVID-19	Suspected COVID-19	Coronavirus infections	Viral infectious disorders
10084452	Suspected SARS-CoV-2 infection	Suspected COVID-19	Coronavirus infections	Viral infectious disorders
10084461	SARS-CoV-2 carrier	SARS-CoV-2 carrier	Infectious disorders carrier	Ancillary infectious topics

13.12. Appendix 12: Abbreviations & Trade Marks

13.12.1. Abbreviations

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

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

13.12.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies	Trademarks not owned by the GlaxoSmithKline Group of Companies
NONE	SAS

13.13.   Appendix 13: List of Data Displays

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

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

13.13.1.   Data Display Numbering

The following numbering will be applied for RAP generated displays:

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

13.13.2.   Mock Example Shell Referencing

Nonstandard specifications will be referenced as indicated below (where a study specific mock shell is available) or the location of a similar display produced for a different study in the HARP reporting environment will be provided as reference. If required example mock-up displays provided in Appendix 14: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAF_Fn	SAF_Tn	SAF_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Virology	VIR_Fn	VIR_Tn	VIR_Ln
Other	OTR_Tn	OTR_Fn	OTR_Ln

13.13.3.   Deliverables

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

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13.13.4. Study Population Tables

No.	Population	GSK Standard / Example Shell	Title	Programming Notes	Deliverable
Study Population Tables					
Subject Disposition					
1.1.	Safety	ES1	Summary of Subject Disposition for the Subject Conclusion Record	ICH E3, FDAAA, EudraCT	HL, M12, EOS
1.2.	Safety	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment	ICH E3	M12, EOS
1.3.	Safety	ES4	Summary of Subject Disposition at Each Study Phase	ICH E3 Intervention/Extension phase: status and reason for withdrawal based on date and reason collected in the study treatment discontinuation form. Long term Follow-up: completion/withdrawal based on data collected in the Study Conclusion form.	M12, EOS
1.4.	Safety	ES5	Summary of Reason for Withdrawal at Each Study Phase	FDAAA, EudraCT	HL, M12, EOS
1.5.	Safety	ES11	Summary of Outcome of Adverse Events Which Led to Study Withdrawal/Treatment Discontinuation at Each Study Phase	EudraCT	M12, EOS
1.6.	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure	Journal Requirements	M12, EOS
1.7.	Enrolled	NS1	Summary of Number of Subjects by Country and Site ID	EudraCT/Clinical Operations	M12, EOS
1.8.	Screened	NS1	Summary of Number of Subjects by Site Type and Site ID	Replace Country with Site Type Add column for Investigator Name	M12, EOS
Protocol Deviation					
1.9.	Enrolled	DV1	Summary of Important Protocol Deviations	ICH E3	M12, EOS

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No.	Population	GSK Standard / Example Shell	Title	Programming Notes	Deliverable
Study Population Tables					
1.10.	Enrolled	DV1	Summary of Important COVID-19 Related Protocol Deviations	Update the label for the first row to be "ANY IMPORTANT COVID-19 RELATED PROTOCOL DEVIATIONS"	M12, EOS
1.11.	Enrolled	DV1	Summary of Important Non-COVID-19 Protocol Deviations	Update the label for the first row to be "ANY IMPORTANT NON-COVID-19 RELATED PROTOCOL DEVIATIONS"	M12, EOS
1.12.	Enrolled	DV1	Summary of All COVID-19 Protocol Deviations by Site	Update the label for the first row to be "ANY COVID-19 RELATED PROTOCOL DEVIATIONS". Summary for each site and 'Total' across sites.	HL, M12, EOS
1.13.	Enrolled	DV1	Summary of All Implementation Protocol Deviations by Site	Update the label for the first row to be "ANY IMPLEMENTATION RELATED PROTOCOL DEVIATIONS" Summary for each site and 'Total' across sites.	HL, M12, EOS
Population Analysed					
1.14.	Screened	SP1	Summary of Study Populations	GSK Statistical Display Standard	M12, EOS
1.15.	Enrolled	SP2	Summary of Exclusions from the Safety Population	GSK Statistical Display Standard	M12, EOS
Demographic and Baseline Characteristics					
1.16.	Safety	DM1	Summary of Demographic Characteristics	ICH E3, FDAAA, EudraCT	HL, M12, EOS
1.17.	Enrolled	DM11	Summary of Age Ranges	EudraCT	M12, EOS
1.18.	Safety	DM6	Summary of Race and Racial Combinations	ICH E3, FDA, FDAAA, EudraCT	M12, EOS
1.19.	Safety	BASELINE2	Distribution of CD4+ Cell Count Results at Screening and Baseline		M12, EOS
1.20.	Safety	BASELINE3	Summary of Hepatitis Status at Entry		M12, EOS

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Study Population Tables					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.21.	Safety	CDC1	Summary of CDC Classification of HIV-1 Infection at Baseline		M12, EOS
Prior and Concomitant Medications					
1.22.	Safety	MH1	Summary of Past Medical Conditions	ICH E3	M12, EOS
1.23.	Safety	MH4	Summary of Past Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders	ICH E3	M12, EOS
1.24.	Safety	MH1	Summary of Current Medical Conditions	ICH E3	M12, EOS
1.25.	Safety	MH4	Summary of Current Cardiac, Gastrointestinal, Metabolism and Nutrition, Psychiatric, Renal and Urinary, Nervous System Conditions, and Hepatobiliary Disorders	ICH E3	M12, EOS
1.26.	Safety	CM9	Summary of Concomitant Medications by Ingredient Combinations	ICH E3 See GSK Statistical Display Standard Multi-ingredient medications will be labelled according to the sum of their ingredients, i.e., Generic Term.	M12, EOS
1.27.	Safety	207966/primary_15/T1.30	Summary of Prior Antiretroviral Therapy Medications	Remove the footnote. Follow definitions in Section 13.4.1 to determine the prior ART medications.	M12, EOS
1.28.	Safety	201585/primary_02/T1.30	Summary of Antiretroviral Therapy Taken During Screening by Baseline Third Agent Class	Like Example shell but stratified by Baseline Third Agent Class (NNRTI, INI, PI); add 'Any' row under each class.	M12, EOS
1.29.	Safety	RF1	Summary of HIV Risk Factors		M12, EOS

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13.13.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Snapshot					
2.1.	Safety	EFF_T1 See Section 13.14	Summary of Study Outcomes (50 c/mL cutoff) at Month 12 (Intervention Phase) – Modified Snapshot Analysis with COVID-19 related LOCF	Missing HIV-1 RNA due to COVID-19 are imputing using last post baseline value carried forward.	HL, M12
2.2.	Safety	EFF_T2 See Section 13.14	Summary of Study Outcomes (50 c/mL cutoff) at Month 12 (Intervention Phase) –Snapshot Analysis	With expanded COVID-19 related/Non-related categories	HL, M12
2.3.	Safety	SNAPSHOT4	Proportion of Subjects with Plasma HIV-1 RNA ≥ 50 c/mL Over Time (Intervention Phase) – Modified Snapshot Analysis with COVID-19 related LOCF	Missing HIV-1 RNA due to COVID-19 are imputing using last post baseline value carried forward. Use Exact (Clopper-Pearson) method for 95% confidence Intervals.	M12
2.4.	Safety	SNAPSHOT4	Proportion of Subjects with Plasma HIV-1 RNA < 50 c/mL Over Time (Intervention Phase) – Modified Snapshot Analysis with COVID-19 related LOCF	Missing HIV-1 RNA due to COVID-19 are imputing using last post baseline value carried forward. Use Exact (Clopper-Pearson) method for 95% confidence Intervals.	M12
2.5.	Safety	SNAPSHOT7	Summary of Study Outcomes (50 c/mL cutoff) at Month 12 by Site Type (Intervention Phase) – Modified Snapshot Analysis with COVID-19 related LOCF	Missing HIV-1 RNA due to COVID-19 are imputing using last post baseline value carried forward.	M12
CVF					
2.6.	Safety	VF1	Cumulative Proportion of Subjects Meeting Confirmed Virologic Failure Criteria Over Time (Intervention Phase)		HL, M12

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No.	Population	GSK Standard/ Example Shell	Title	Programming Notes	Deliverable
Efficacy: Tables					
2.7.	Safety	VF2	Proportion of Subjects Meeting Confirmed Virologic Failure Criteria Over Time		M12, EOS
CD4					
2.8.	Safety	LB1	Summary of CD4+ Cell Count (cells/mm^3) by Visit		M12, EOS
2.9.	Safety	LB1	Summary of Change from Baseline in CD4+ Cell Count (cells/mm^3) by Visit		M12, EOS
HIV Associated Conditions					
2.10.	Safety	CDC2	Summary of Post-Baseline CDC Stage 3 HIV-1 Associated Conditions Including Recurrences		M12, EOS
2.11.	Safety	CDC2	Summary of Post-Baseline CDC Stage 3 HIV-1 Associated Conditions Excluding Recurrences		M12, EOS

13.13.6.   Efficacy Figures

No.	Population	GSK Standard / Example Shell	Title	Programming Notes	Deliverable
Efficacy: Figures					
2.1.	Safety	SNAPSHOT8	Percent (95% CI) of Subjects with Plasma HIV-1 RNA ≥ 50 copies/mL Over Time (Intervention Phase) – Modified Snapshot Analysis with COVID-19 related LOCF	Missing HIV-1 RNA due to COVID-19 are imputing using last post baseline value carried forward. Use Exact (Clopper-Pearson) method for 95% confidence Intervals.	M12, EOS

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			Efficacy: Figures		
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.2.	Safety	SNAPSHOT8	Percent (95% CI) of Subjects with Plasma HIV-1 RNA < 50 copies/mL Over Time (Intervention Phase) – Modified Snapshot Analysis with COVID-19 related LOCF	Missing HIV-1 RNA due to COVID-19 are imputing using last post baseline value carried forward. Use Exact (Clopper-Pearson) method for 95% confidence Intervals.	M12, EOS
2.3.	Safety	SNAPSHOT10	Individual Plasma HIV-1 RNA for Subjects Snapshot Algorithm Plasma HIV-1 RNA >= 50 copies/mL at Month 12 – Modified Snapshot Analysis with COVID-19 related LOCF	The 1st vertical line indicates start of study treatment at Intervention Phase. The second vertical reference line indicates last IP on-treatment study day. i.e. min (last IP injection dose+35 days, LTFU HAART start date, date of last oral CAB+RPV+1). This vertical line is only for subjects who withdraw from Intervention Phase/Extension phase.	M12
2.4.	Safety	SNAPSHOT10	Individual Plasma HIV-1 RNA for Subjects with Confirmed Virologic Failure	The 1st vertical line indicates start of study treatment at Intervention Phase. The second vertical reference line indicates last IP on-treatment study day. i.e. min (last IP injection dose+35 days, LTFU HAART start date, date of last oral CAB+RPV+1). This vertical line is only for subjects who withdraw from Intervention Phase/Extension phase.	M12, EOS

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13.13.7. Safety Tables

No.	Population	GSK Standard/ Example Shell	Title	Programming Notes	Deliverable
Safety: Tables					
Exposure					
3.1.	Safety	207966/primary _15/T3.1	Summary of Exposure to Study Treatment (Intervention Phase)		M12
3.2.	Safety	207966/primary _15/T3.1	Summary of Exposure to Study Treatment		M12, EOS
3.3.	Safety	SAF_T1 See Section 13.14	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Site Type and COVID-19 Impact /Non-Impact (Intervention Phase)	COVID Impact refers to missed or out of window injections for COVID-19 related reasons (as captured as COVID-19 related protocol deviations)	HL, M12
3.4.	Safety	SAF_T2 See Section 13.14	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Site ID and COVID-19 Impact /Non-Impact (Intervention Phase)	COVID Impact refers to missed or out of window injections for COVID-19 related reasons (as captured as COVID-19 related protocol deviations)	HL, M12
3.5.	Safety	SAF_T1 See Section 13.14	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Site Type and COVID-19 Impact /Non-Impact	COVID Impact refers to missed or out of window injections for COVID-19 related reasons (as captured as COVID-19 related protocol deviations)	EOS
3.6.	Safety	SAF_T2 See Section 13.14	Summary of Adherence to CAB LA + RPV LA Dosing Schedule by Visit, Site ID and COVID-19 Impact /Non-Impact	COVID Impact refers to missed or out of window injections for COVID-19 related reasons (as captured as COVID-19 related protocol deviations)	EOS
Adverse Events (AEs)					
3.7.	Safety	AE3	Summary of Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.8.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Maximum Grade	ICH E3	HL, M12, EOS

Safety: Tables					
No.	Population	GSK Standard/ Example Shell	Title	Programming Notes	Deliverable
3.9.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Maximum Grade — Excluding Study Drug Injection Site Reactions		M12, EOS
3.10.	Safety	AE5B	Summary of Adverse Events by System Organ Class and Maximum Grade (Oral Lead-in Period)		M12, EOS
3.11.	Safety	AE3	Summary of Common (>=5%) Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.12.	Safety	AE3	Summary of Common (>=1%) Grade 2-5 Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.13.	Safety	AE3	Summary Drug-Related Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.14.	Safety	AE5B	Summary of Drug-Related Adverse Events by System Organ Class and Maximum Grade	ICH E3	HL, M12, EOS
3.15.	Safety	AE5B	Summary of Drug-Related Adverse Events by System Organ Class and Maximum Grade — Excluding Study Drug Injection Site Reactions		M12, EOS
3.16.	Safety	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT	M12, EOS
3.17.	Safety	AE3	Summary of Common (>=1%) Drug-Related Grade 2-5 Adverse Events by Overall Frequency	ICH E3	M12, EOS
3.18.	Safety	AE3	Summary of Non-Serious Drug-Related Adverse Events by Overall Frequency	Plain Language Summary requirements.	M12, EOS

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Safety: Tables					
No.	**Population**	**GSK Standard/ Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Serious and Other Significant Adverse Events					
3.19.	Safety	AE5B	Summary of Serious Adverse Events by System Organ Class and Maximum Grade	ICH E3	HL, M12, EOS
3.20.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT	M12, EOS
3.21.	Safety	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by System Organ Class and Preferred Term	GSK Statistical Display Standard	HL, M12, EOS
3.22.	Safety	AE20	Summary of Serious Fatal and Non-Fatal Drug-Related Adverse Events by Overall Frequency	Plain Language Summary requirements.	M12, EOS
Injection Site Reaction Adverse Events					
3.23.	Safety	201584/primary_ 7/T3.40	Summary of Study Drug Injection Site Reaction Adverse Events (Event-level Summary)		HL, M12, EOS
3.24.	Safety	201584/primary_ 7/T3.43	Summary of Subject-level Characteristics of Study Drug Injection Site Reaction Adverse Events – Overall and Common		HL, M12, EOS
3.25.	Safety	201584/primary_ 7/T3.46	Summary of Study Drug Injection Site Reaction Adverse Events by Visit and Maximum Severity – Overall and Common		HL, M12, EOS
Laboratory: Chemistry					
3.26.	Safety	LB1	Summary of Chemistry Values	Includes pre-specified parameters repeated in conventional units. Includes baseline values	M12, EOS
3.27.	Safety	LB1	Summary of Chemistry Changes from Baseline	ICH E3	M12, EOS
3.28.	Safety	LB16	Summary of Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3	HL, M12, EOS

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No.	Population	GSK Standard/ Example Shell	Title	Programming Notes	Deliverable
Safety: Tables					
3.29.	Safety	LB16	Summary of Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline (Oral Lead-in Period)	ICH E3	M12, EOS
Laboratory: Hematology					
3.30.	Safety	LB1	Summary of Hematology Values	Includes pre-specified parameters repeated in conventional units.	M12, EOS
3.31.	Safety	LB1	Summary of Hematology Changes from Baseline	Includes pre-specified parameters repeated in conventional units. Includes baseline values	M12, EOS
3.32.	Safety	LB16	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3	M12, EOS
3.33.	Safety	LB16	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline (Oral Lead-in Period)	ICH E3	M12, EOS
Laboratory: Hepatobiliary (Liver)					
3.34.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting	GSK Statistical Display Standard	M12, EOS
3.35.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities	GSK Statistical Display Standard	HL, M12, EOS
3.36.	Safety	LIVER11	Summary of Liver Restart/Re-Challenges	GSK Statistical Display Standard	M12, EOS
Vital Signs					
3.37.	Safety	VS1	Summary of Change from Baseline in Vital Signs	ICH E3 Include Baseline values	M12, EOS
Cardiovascular Risk Factors					
3.38.	Safety	FH1	Summary of Family History of Cardiovascular Risk Factors	GSK Statistical Display Standard	M12, EOS
3.39.	Safety	SU1	Summary of Substance Use	GSK Statistical Display Standard	M12, EOS

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Safety: Tables					
No.	Population	GSK Standard/ Example Shell	Title	Programming Notes	Deliverable
COVID-19 Adverse Events					
3.40.	Safety	PAN1	Summary of COVID-19 Assessments for Subjects with COVID-19 Adverse Events	GSK Statistical Display Standard	M12, EOS
3.41.	Safety	PAN2	Summary of COVID-19 Additional Assessments for Subjects with COVID-19 Adverse Events	GSK Statistical Display Standard	M12, EOS
3.42.	Safety	PAN3	Summary of COVID-19 Symptoms for Subjects with COVID-19 Adverse Events	GSK Statistical Display Standard	M12, EOS
Adverse Events of Special Interest					
3.43.	Safety	201584/primary_27/T3.140	Summary of Depression, Anxiety and Suicidal or Suicidal Ideation/Behaviour Adverse Events by System Organ Class, Maximum DAIDS Toxicity Grade, and History of Depression, Anxiety or Suicidal Ideation/Behaviour at Screening		M12, EOS
3.44.	Safety	201584/primary_07/T3.122	Summary of Depression Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.45.	Safety	201584/primary_07/T3.125	Summary of Anxiety Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.46.	Safety	201584/primary_07/T3.128	Summary of Suicidal Ideation/Behaviour Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.47.	Safety	201584/primary_07/T3.134	Summary of Seizures Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS

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Safety: Tables					
No.	Population	GSK Standard/ Example Shell	Title	Programming Notes	Deliverable
3.48.	Safety	201584/primary_ 07/T3.137	Summary of Hepatic Safety Profile: Assessment of Risk of Hepatoxicity Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.49.	Safety	201584/primary_ 07/T3.140	Summary of Hypersensitivity Reactions (HSR) Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.50.	Safety	201584/primary_ 07/T3.143	Summary of Rash Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.51.	Safety	201584/primary_ 07/T3.146	Summary of Prolongation of the Corrected QT Interval of the ECG in Supratherapeutic Doses Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.52.	Safety	201584/primary_ 07/T3.149	Summary of Bipolar Disorder Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.53.	Safety	201584/primary_ 07/T3.152	Summary of Psychosis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.54.	Safety	201584/primary_ 07/T3.155	Summary of Mood Disorders Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.55.	Safety	201584/primary_ 07/T3.158	Summary of Sleep Disorders Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS

Safety: Tables					
No.	Population	GSK Standard/ Example Shell	Title	Programming Notes	Deliverable
3.56.	Safety	201584/primary_ 07/T3.161	Summary of Hyperglycaemia Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.57.	Safety	201584/primary_ 07/T3.161	Summary of Weight Gain Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.58.	Safety	201584/primary_ 07/T3.164	Summary of Rhabdomyolysis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.59.	Safety	201584/primary_ 07/T3.167	Summary of Pancreatitis Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.60.	Safety	201584/primary_ 07/T3.170	Summary of Impact on Creatinine Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.61.	Safety	201584/primary_ 07/T3.173	Summary of Safety in Pregnancy Adverse Events of Special Interest by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		M12, EOS
3.62.	Safety	207966/primary_ 15/T3.109	Summary of Characteristics of Adverse Events of Special Interest		M12, EOS

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13.13.8. Safety Figures

Safety: Figures					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Adverse Events					
3.1.	Safety	201584/primary_07/F3.14	Plot of Incidence of Intervention Phase Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) – CAB and/or RPV		M12, EOS
3.2.	Safety	201584/primary_07/F3.17	Plot of Incidence of Grade 3-5 Intervention Phase Study Drug Injection Site Reaction Adverse Events by Visit (Overall and Common) - CAB and/or RPV		M12, EOS
Laboratory					
3.3.	Safety	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT	GSK Statistical Display Standard	M12, EOS
3.4.	Safety	LIVER9	Scatter Plot of Maximum Total Bilirubin vs Maximum ALT – eDISH Plot	GSK Statistical Display Standard	M12, EOS

13.13.9. Virology Tables

No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
4.1.	Safety	20184/primary_17/T7.2	Viral load, Genotypic and Phenotypic data for Subjects Who Met Confirmed Virologic Failure Criteria		HL, M12, EOS
4.2.	Safety	20184/primary_17/T7.4	Viral Load, Genotypic and Phenotypic Data for Non-CVF Subjects	Only include subjects with available genotypic or phenotypic data.	M12, EOS

13.13.10. Other Tables

Study Visit Length					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
5.1.	Safety	OTR_T1	Summary of Study Visit Length (minutes) by Visit and Site Type (Intervention Phase)		HL, M12, EOS
5.2.	Safety	OTR_T1	Summary of Study Visit Length (minutes) by Visit and Site (Intervention Phase)		HL, M12, EOS

13.13.11. ICH Listings

ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.	Enrolled	ES2	Listing of Reasons for Study Withdrawal	ICH E3 Add column for Phase	M12, EOS
2.	Enrolled	SD2	Listing of Reasons for Study Treatment Discontinuation	ICH E3 Add column for Phase	HL, M12, EOS
Protocol Deviations					
3.	Enrolled	DV2	Listing of Important Protocol Deviations	ICH E3 Add column for Phase	M12, EOS

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No.	Population	GSK Standard / Example Shell	Title	Programming Notes	Deliverable
ICH: Listings					
				Add a column on the right for "COVID-19 Related". The possible values in this column are Y and N, where Y indicates the deviation is COVID-19 related and N indicates the deviation is non-COVID-19 related.	
4.	Enrolled	DV2	Listing of Protocol Deviations Related to COVID-19	FDA Request Add column for Phase	HL, M12, EOS
5.	Safety	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	ICH E3	M12, EOS
Populations Analysed					
6.	Enrolled	SP3	Listing of Subjects Excluded from Safety Population	ICH E3	M12, EOS
Demographic and Baseline Characteristics					
7.	Safety	DM2	Listing of Demographic Characteristics	ICH E3	M12, EOS
8.	Safety	DM9	Listing of Race	ICH E3	M12, EOS
Efficacy					
9.	Safety	SNAPSHOT11	Listing of Qualitative and Quantitative Plasma HIV-1 RNA Data		HL, M12, EOS
10.	Safety	SNAPSHOT12	Listing of Study Outcome (50 copies/mL cutoff) at Month 12 – Snapshot Analysis	Include both original and LOCF imputed outcomes	HL, M12, EOS
11.	Safety	VF4	Listing of Plasma HIV-1 RNA and CD4+ Cell Count for subjects with Confirmed Virologic Failure		M12, EOS
Exposure and Treatment Compliance					
12.	Safety	207966/primary_15/L12	Listing of Exposure Data	ICH E3 Remove Phase Day	M12, EOS

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ICH: Listings					
No.	**Population**	**GSK Standard / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Adverse Events					
13.	Safety	AE8	Listing of All Adverse Events	ICH E3 Add Phase/Period, Side/Drug, see gsk1265744/mid207966/primary_15/L19	HL, M12, EOS
14.	Safety	AE8	Listing of Grade 3-5 Adverse Events	Add Phase/Period, Side/Drug, see gsk1265744/mid207966/primary_15/L19	M12, EOS
15.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3	M12, EOS
16.	Safety	PSRAE1	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description (Section 1-Section 2)	Add Phase	M12, EOS
17.	Safety	PSRAE3	Listing of Possible Suicidality-Related Adverse Event Data: Possible Cause(s) (Section 3)	Add Phase	M12, EOS
18.	Safety	PSRAE4	Listing of Possible Suicidality-Related Adverse Event Data (Section 4)	Add Phase	M12, EOS
19.	Safety	PSRAE5	Listing of Possible Suicidality-Related Adverse Event Data (Section 5-Section 8)	Add Phase	M12, EOS
20.	Safety	201584/primary_07/L22	Listing of Changes in Intensity/Grades of Study Drug Injection Site Adverse Events	Remove phase treatment	M12, EOS
21.	Safety	AE8	Listing of COVID-19 Adverse Events	Add Phase/Period, Side/Drug, see gsk1265744/mid207966/primary_15/L19	HL, M12, EOS
22.	Safety	PAN12	Listing of COVID-19 Assessments and Symptom Assessments		M12, EOS
23.	Safety	PAN5	Country Level Listing of Start Dates of COVID-19 Pandemic Measures		M12, EOS
Serious and Other Significant Adverse Events					
24.	Safety	AE8	Listing of Fatal Serious Adverse Events	ICH E3	M12, EOS

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No.	Population	GSK Standard / Example Shell	Title	Programming Notes	Deliverable
ICH: Listings					
				Add Phase/Period, Side/Drug	
25.	Safety	AE8	Listing of Non-Fatal Serious Adverse Events	ICH E3 Add Phase/Period, Side/Drug	M12, EOS
26.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event	ICH E3	M12, EOS
27.	Safety	AE8	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment	ICH E3 Add Phase/Period, Side/Drug	M12, EOS
28.	Safety	AE8	Listing of All Adverse Events with Completely Missing Onset Date, Missing Relationship to Study Treatment, Severity and/or Grade	ICH E3 Add Phase/Period, Side/Drug, see gsk1265744/mid207966/primary_15/L19	M12, EOS
Laboratory					
29.	Safety	UR2	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance	ICH E3 Include Grade Note: Potential Clinical Importance is defined as: 1. Increase in Protein (dipstick) or Occult Blood (dipstick) post-baseline relative to baseline 2. Increase in any DAIDS graded values for Protein, Occult Blood or Glucose relative to baseline 3. If microscopy is performed.	M12, EOS

13.13.12. Non-ICH Listings

No.	Population	GSK Standard GSK Statistical Display Standard / Example Shell	Title	Programming Notes	Deliverable
Non-ICH: Listings					
Subject Disposition					
30.	Screened	ES7	Listing of Reasons for Screen Failure	Journal Guidelines	M12, EOS
31.	Screened	ES9	Listing of Subjects Who Were Rescreened		M12, EOS
32.	Safety	TA1	Listing of Planned and Actual Treatments	GSK Statistical Display Standard	M12, EOS
Prior and Concomitant Medications					
33.	Safety	207966/primary_15/Listing 36	Listing of Prior ART Medications	Remove the column 'Phase during Which Concomitant'	M12, EOS
34.	Safety	207966/primary_15/Listing 37	Listing of Concomitant ART Medications	In case the same medication is concomitant during both intervention and extension phases, list each of them in two separate rows. Add a column "SOC Oral Bridging?" which has values of "Yes" and "No".	HL, M12, EOS
35.	Safety	207966/primary_15/Listing 38	Listing of ART Medications Received during Long-term Follow-up Phase	Remove the column 'Phase during Which Concomitant' and "Start Date of the Long-term Follow-up ART/Study Day".	M12, EOS
Medical History					
36.	Safety	201584/primary_01/L43	Listing of Medical History of Seizure		M12, EOS
Efficacy					
37.	Safety	CDC4	Listing of CDC Classification of HIV-1 Infection at Baseline	Add Phase	M12, EOS

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No.	Population	GSK Standard GSK Statistical Display Standard / Example Shell	Title	Programming Notes	Deliverable
Non-ICH: Listings					
38.	Safety	CDC5	Listing of CDC Stage 3 HIV-1 Associated Conditions	Add Phase	
Hepatobiliary (Liver)					
39.	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting	GSK Statistical Display Standard	M12, EOS
40.	Safety	LIVER15	Liver Stopping Event Profile	GSK Statistical Display Standard	M12, EOS
41.	Safety	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline	GSK Statistical Display Standard	HL, M12, EOS
42.	Safety	LB12	Listing of ALT, AST, Bilirubin (including Total and Direct Bilirubin), INR, and ALP for Subjects Meeting Hepatobiliary Lab Abnormality Criteria	Add Phase	M12, EOS
ECG					
43.	Safety	EG3	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance	GSK Statistical Display Standard By default, the definition of PCI is defined based on QTc value (e.g., QTcF Interval, Aggregate) where a subject has a QTc value >450 or a QTc increase of >30msec.	M12, EOS
44.	Safety	EG5	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding	GSK Statistical Display Standard	M12, EOS
Other					
45.	Safety	207966/primary_15/L60	Listing of Exposure Data for Subjects Receiving Oral Bridging	Add column to identify COVID relatedness.	HL, M12, EOS
46.	Safety	207966/primary_15/L61	Listing of Dosing Errors and IP Device Malfunctions	Add Phase	M12, EOS
47.	Safety	PREG1	Listing of Subjects or Partners Who Became Pregnant During the Study	GSK Statistical Display Standard Add Phase/Period	M12, EOS

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No.	Population	GSK Standard GSK Statistical Display Standard / Example Shell	Title	Programming Notes	Deliverable
Non-ICH: Listings					
48.	Safety	201584/primary_17/L54	Listing of Replication Capacity in IN and PR/RT Region	Add Phase	M12, EOS
PK Endpoints					
49.	Safety	PK07	Listing of Plasma CAB Pharmacokinetic Concentration-Time Data		M12, EOS
50.	Safety	PK07	Listing of Plasma RPV Pharmacokinetic Concentration-Time Data		M12, EOS

13.14.   Appendix 14: Example Mock Shells for Data Displays

Data Display Specification will be made available on request