TITLE PAGE

Information Type: ViiV Healthcare Non-Interventional Study Protocol

Title:	C2C: COMBINE-2 for Cabotegravir+Rilpivirine LA Regimen - A Prospective Cohort Study to Monitor Effectiveness, Adherence and Resistance

Compound Number:	GSK1265744, TMC278
Development Phase	IV
Effective Date:	16-Aug-2021
Subject:	Long acting ARV, Cabotegravir, Rilpivirine, Clinical Effectiveness, Adherence, Discontinuation, Resistance

Author(s):

PPD : ViiV Healthcare
PPD : ViiV Healthcare
PPD : ViiV Healthcare
PPD : GlaxoSmithKline
PPD ; NEAT ID
PPD ; NEAT ID

PASS/PAES information

Title	C2C: COMBINE-2 for Cabotegravir+Rilpivirine LA Regimen - A Prospective Cohort Study to Monitor Effectiveness, Adherence and Resistance
Protocol version identifier	v1.0
Date of last version of protocol	[Date DD Month YYYY]
EU PAS (ENCEPP) register number	Study not registered yet
Active substance	Cabotegravir Rilpivirine
Medicinal product	VOCABRIA® 30 mg Film-coated tablets, VOCABRIA® 400 mg prolonged release suspension for injection (2 mL) VOCABRIA® 600 mg prolonged release suspension for injection.(3 mL) Edurant® 25 mg film-coated tablets Rekambys® 600 mg prolonged release suspension for injection. (2 mL) Rekambys® 900 mg prolonged release suspension for injection. (3 mL)
Product reference	Cabotegravir - EU/1/20/1481/001-003 Rilpivirine - EU/1/20/1482/001-002
Procedure number	Cabotegravir - EMEA/H/4976 Rilpivirine - EMEA/H/5060
Marketing authorisation Holder(s)	ViiV Healthcare B.V. Janssen-Cilag International NV
Joint PASS/PAES	Yes

Research question and objectives	Following the initiation of CAB+RPV LA regimen among people living with HIV (PLWH), the study will aim to assess effectiveness, discontinuation, and resistance over a 24-month period of follow up in approximately 1000 PLWH. **Objectives**: 1. Describe study population initiating CAB+RPV LA regimen, by baseline demographic and clinical characteristics 2. Assess adherence, durability and discontinuation for PLWH starting CAB+RPV LA regimen 3. Assess the clinical effectiveness (i.e. proportion of participants experiencing virologic failure) among PLWH who initiate CAB+RPV LA regimen and had suppressed viral load (VL <50 copies/mL) at regimen initiation 4. Monitor for resistance in case of VF while on CAB+RPV LA or after switching to a subsequent ARV regimen among individuals who switched off CAB+RPV LA regimen for any reason
Country(-ies) of study	UK, Spain, Italy, France, Belgium, Germany, Sweden and additional countries to be determined after feasibility assessment
Author	PPD, MBBS, MPH, PhD PPD, Epidemiology & Real World Evidence ViiV Healthcare 5 Moore Drive, 5.3C Research Triangle Park, NC 27709, USA Email: PPD Phone: PPD

MARKETING AUTHORISATION HOLDER(S)

Marketing authorisation holder(s)	**ViiV Healthcare B.V.** Van Asch Van Wijckstraat 55H Amersfoort Netherlands 3811 LP **Janssen-Cilag International N.V**. Turnhoutseweg 30 B-2340 Beerse Belgium
Person/Company authorised for communication on behalf of the MAH in the European Union	PPD GlaxoSmithKline R&D GSK House, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom Email PPD

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1. LIST OF ABBREVIATIONS

ADE	AIDS-defining events
AE	adverse event
ART	antiretroviral treatment
ARV	antiretroviral
BCG	Bacille Calmette-Guérin
BMI	body mass index
CAB	Cabotegravir
CD4	cluster of differentiation four
CKD	chronic kidney disease
CVD	cardiovascular disease
DAA's	direct-acting antivirals
EC	ethics committee
EMA	European Medicines Agency
ESLD	end-stage liver disease
GI	gastrointestinal
HBV	hepatitis B virus
HCP	healthcare provider
HCV	hepatitis C virus
HIV	human immunodeficiency virus
INI	integrase inhibitor
INSTI	integrase strand transfer inhibitor
IQR	interquartile range
LA	long acting
LOD	limit of detection
MAH	marketing authorization holder
MTCT	mother-to-child transmission
NADM	non-AIDS-defining malignancy
NNRTI	non-nucleoside reverse transcriptase inhibitor
PI	principal investigator
PK	pharmacokinetics
PMTCT	prevention of mother-to-child transmission
RNA	ribonucleic acid
RPV	Rilpivirine
SmPC	summary of product characteristics
SoC	standard of care
STI	structured treatment interruption
TB	tuberculosis
UK	United Kingdom
VL	viral load

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2. **RESPONSIBLE PARTIES:** SPONSOR INFORMATION PAGE

ViiV Healthcare UK Limited

Janssen-Cilag International NV

Sponsor Legal Registered Address:

ViiV Healthcare UK Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS
United Kingdom

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

SPONSOR SIGNATORY:

PPD

06-Aug-2021

Vani Vannappagari
Global Head, Epidemiology and Real World Evidence

Date

PPD

Aug 15, 2021

Nassrin Payvandi
VP & Head, Safety and Pharmacovigilance

Date

PPD

Aug 16, 2021

Jens-Ulrich Stegmann
ViiV QPPV

Date

INVESTIGATOR PROTOCOL AGREEMENT PAGE

- I confirm agreement to conduct the study in compliance with the protocol.
- I acknowledge that I am responsible for overall study conduct. I agree to personally conduct or supervise the described clinical study.
- I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations. Mechanisms are in place to ensure that site staff receives the appropriate information throughout the study.

Investigator Name: Dr. PPD

PPD

Investigator Signature

10-Aug-2021 | PPD

Date

3. ABSTRACT

Cabotegravir (CAB), a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), in combination with Rilpivirine (RPV), an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral (ARV) regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class. Prior to the initiation of CAB long acting (LA) injection, CAB tablets together with RPV tablets should be taken for approximately one month (at least 28 days) to assess tolerability to CAB and RPV.

The gathering of real world evidence in routine clinical practice to evaluate effectiveness, discontinuation, and resistance would further demonstrate the value of this regimen.

The Marketing Authorization Holder (MAH) proposes a prospective cohort study to monitor for clinical effectiveness, discontinuation and resistance among PLWH receiving CAB+RPV LA in routine clinical practice. The proposed multi-site study "Real-world evidence for effectiveness of Two Drug Regimen, Antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor Drug" (COMBINE-2) for the CAB+RPV LA regimen will be conducted through collaboration with NEAT ID Network, a well-established network of clinical sites across Europe.

Study Objectives: Following the initiation of CAB+RPV LA regimen among people living with HIV (PLWH), the study will aim to assess effectiveness, discontinuation, and resistance over 24-months of follow-up period in approximately 1000 PLWH.

The specific objectives are to:

1. Describe study population initiating CAB+RPV LA regimen, by baseline demographic and clinical characteristics

2. Assess adherence, durability and discontinuation for PLWH starting CAB+RPV LA regimen

3. Assess the clinical effectiveness (i.e. proportion individuals experiencing virologic failure) among study participants who initiate CAB+RPV LA regimen and had suppressed viral load (VL) at regimen initiation (<50 copies/mL)

4. Monitor for resistance in case of VF while on CAB+RPV LA or after switching to a subsequent ARV regimen among individuals who switched off CAB+RPV LA regimen for any reason over the 48 month follow up period.

4. AMENDMENTS AND UPDATES

Amendment or update no	Date	Section of study protocol	Amendment or update	Reason

5. MILESTONES

Milestone	Planned date
Draft Protocol Submission	Dec 31, 2020
Study Start (Protocol Approval)	Estimated - Jun 2021
1st Interim Report	Draft - Sep 2022 Final - Dec 2022
2nd Interim Report	Draft - Sep 2023 Final - Dec 2023
3rd Interim Report	Draft - Sep 2024 Final - Dec, 2024
4th Interim Report	Draft - Sep 2025 Final - Dec 2025
Data Collection Completion	Jun 2026 or 5 years following commercial availability of CAB
Final Report	Sep 2026
Supplemental Report	Depends on when the last individual discontinuing the CAB+RPV LA regimen completes 4-years of follow up

6. RATIONALE AND BACKGROUND

6.1. Background

Cabotegravir (CAB), a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), in combination with Rilpivirine (RPV), an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral (ARV) regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class. Prior to the initiation of CAB long acting (LA) injection, CAB tablets together with RPV tablets should be taken for approximately one month (at least 28 days) to assess tolerability to CAB and RPV.

Treatment with CAB+RPV LA should be prescribed by a physician experienced in the management of HIV infection. Each injection should be administered by a healthcare provider (HCP). Prior to starting the regimen, the HCP should carefully select PLWH who agree to the required injection schedule and counsel individuals about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance associated with missed doses. Following discontinuation of CAB in combination with RPV injection, it is essential to adopt an alternative, fully suppressive ARV regimen per the summary of product characterization (SmPC).

The Marketing Authorization Holder (MAH) proposes a prospective cohort study to monitor for clinical effectiveness, discontinuation and resistance among PLWH receiving CAB+RPV LA in routine clinical practice. The proposed multi-site study “Real-world evidence for effectiveness of Two Drug Regimen, Antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor Drug (COMBINE-2)” for the CAB+RPV LA regimen will be conducted through collaboration with NEAT ID Network, a well-established network of clinical sites across Europe.

The study will not require any changes to the standard of care that PLWH receive, and decisions on ARV treatment are made by the healthcare providers taking into account the treatment history, individual clinical characteristics and local guideline or recommendations. A detailed study protocol, once approved by EMA, will be implemented by the NEAT ID Network team.

6.2. Rationale

Adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses is critical for long term maintenance of viral suppression with the regimen. Impact of non-adherence on virologic failure and emergence of resistance need to be assessed in real world clinical setting. Discontinuations for other reasons such as individual choice , drug interactions and pregnancy will also be captured. The gathering of this real world evidence would further demonstrate the value of this regimen.

7. RESEARCH QUESTION AND OBJECTIVE(S)

Following the initiation of CAB+RPV LA regimen among people living with HIV (PLWH), the study will aim to assess effectiveness, discontinuation, and resistance over 24-months of follow-up period in approximately 1000 participants.

The specific objectives are to:

1. Describe study population initiating CAB+RPV LA regimen, by baseline demographic and clinical characteristics

2. Assess adherence, durability and discontinuation for PLWH starting CAB+RPV LA regimen
    - Proportion of participants discontinuing the CAB+RPV LA regimen and lost to follow-up will be assessed.
        - Reasons for discontinuation will be assessed.
    - Non adherence to dosing schedule will be assessed by
        a. Estimating the number of participants that missed one or more consecutive injections without taking daily oral bridging therapy or any other oral ARV regimen while not on CAB+RPV LA regimen and mean and median number of injections missed during a 12-month period
        b. Estimating the number of participants who received the injections seven or more days later than their scheduled injection visit and median duration of delayed injections

3. Assess the clinical effectiveness (i.e. proportion of participants experiencing virologic failure) among PLWH who initiate CAB+RPV LA regimen and had suppressed viral load (VL <50 copies/mL) at regimen initiation
    - Estimate the proportion of participants with virologic failure, during the first 6 months after initiation of CAB+RPV LA regimen
    - Estimate the proportion of participants with virologic failure at 6, 12 and 24 months after initiation of CAB+RPV LA regimen

4. Monitor for resistance in case of VF while on CAB+RPV LA or after switching to a subsequent ARV regimen among individuals who switched off CAB+RPV LA regimen for any reason
    - Describe the ARV regimen participants are switched to after discontinuation of CAB+RPV LA regimen
    - Describe virologic outcomes at 12, 24, 36 and 48 months after discontinuation of CAB+RPV LA regimen
    - Monitor for virologic failure and resistance during the 48 months following the switch
        - Resistance test to be done for all participants with virologic failure during the follow-up period

- HIV subtype test to be done for participants with virologic failure during the follow-up period, if subtype data is not available

8. RESEARCH METHODS

8.1. Study Design

A prospective cohort study using data from individual medical records from participating clinical sites will be conducted to meet the study objectives.

For this non-interventional study, treatment decisions will be made by the treating physician according to standard practice, taking into account the treatment history, individual clinical characteristics, the approved SmPC for CAB and RPV oral and LA formulations and for the contemporary regimen and local guidelines or recommendations. Only clinical sites whose standard of care guidance includes HIV subtype testing and resistance testing among individuals with virologic failure will be include in the study to ensure collecting resistance data. Resistance and subtype testing (if not already done) will also be part of the routine clinical care, required of the clinical sites, so the individuals who discontinue the regimen and have virological failure during the 48 month period after discontinuation will have the requisite resistance testing data.

8.2. Study Population and Setting

8.2.1. Study Setting

Potential NEAT ID investigational sites across Europe will be contacted for feasibility and resistance testing practices as part of their SoC. Clinical sites with resistance testing following virologic failure as part of SoC and the ability to perform the tests will be selected to participate in this study. Follow-up period will start from the date of starting the treatment regimen after approval and commercial availability of the regimen.

NEAT ID Network team will perform site monitoring activities to assess protocol issues, consent, data quality and Study Management quality performance.

8.2.2. Inclusion Criteria

The study population will consist of HIV positive male or female aged 18 years or over from NEAT ID Network clinical sites who are prescribed CAB+RPV LA regimen and:

- Virologically suppressed (HIV-1 RNA <50 copies/mL) at the time of regimen initiation.
- No evidence of prior virological failure with agents of the NNRTI and INI class
- No evidence of present or past documented viral resistance to, agents of the NNRTI and INI class

8.2.3 Participant Identification and Consent

The study aims to include at least 1000 people living with HIV (PLWH) across Europe, initiating CAB+RPV LA regimen. Once all relevant approvals are in place for the protocol, selected investigational sites will prospectively identify individuals initiating CAB+RPV LA regimen. Consent procedures will be undertaken as required by country specific regulations and local procedures for the collection of study data. The study participants will not need to attend any additional visits or undergo any procedures above their routine standard of care.

8.3. Variables

8.3.1. Exposure definitions

All new users of CAB+RPV LA regimen treated per the approved SmPC for CAB and RPV oral and LA formulations will be included in the study. The study period will include the month-long oral lead-in, followed by injectable long acting regimen use.

8.3.2. Outcome definitions

Table 1. Regimen discontinuation: Reasons for discontinuation as tabulated below will be collected for all participants switching off CAB+RPV LA regimen.

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure (multiple blips, low level viraemia)
1.3	Immunological failure - CD4 drop (25% or more)
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
3.3	Weight gain
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I tract
5.1	Toxicity - Liver
5.2	Toxicity - Pancreas
6	Toxicity, predominantly from nervous system
6.1	Toxicity - peripheral neuropathy
6.2	Toxicity - neuropsychiatric

6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemia/lactic acidosis
11	Bone toxicity
12	Social contra-indication
13	Contra-indication unspecified
14	Pregnancy - toxicity concerns (during pregnancy)
15	Pregnancy - switch to a more appropriate regimen for PMTCT
16	Death
17	Toxicity, unspecified
18	Availability of more effective treatment (not specifically failure or side effect related)
18.1	Simplified treatment available
18.2	Treatment too complex
19	Drug interaction
19.1	Drug interaction - commencing TB/BCG treatment
20	Injection fatigue (not related to safety)
21	Injection Site Reaction
22	Non-adherence
23	Drug not available
24	Other causes, not specified above
25	Lost to follow-up
26	Defaulter
27	Individual's wish/decision, not specified above
28	Physician decision to discontinue due to confirmed low level viremia (50-200)
29	Physician's decision, not specified above
99	Unknown

2. <u>Clinical effectiveness</u>: assessed using the following measures:

1. Proportion of individuals, virologically suppressed/undetectable (<50 copies/mL) at 6,12 and 24 months following initiation of CAB+RPV LA regimen

2. Proportion of individuals with VL of <200 copies/mL at 6,12 and 24 months following initiation of CAB+RPV LA regimen

3. Proportion of individuals with confirmed virologic failure (CVF) during the first 6 months, and at 6,12 and 24 months following initiation of CAB+RPV LA regimen defined as

- Two consecutive HIV RNA VL levels ≥200 copies/mL **or**
- One HIV RNA VL level ≥200 copies/mL and regimen discontinuation within 4 months of VL ≥200 copies/mL

3. Resistance Testing: This is a non-interventional study aiming to capture SoC for PLWH in real world setting. Testing for resistance and subtype at virologic failure is part of SoC and the study will include only the clinical sites that follow the guidance for resistance testing.

- Resistance testing along with subtype will be done for all participants with virologic failure during the 24 month follow-up period while on CAB+RPV LA
- Resistance testing along with subtype will also be done during the 48 months following any switch from CAB+RPV LA in all participants with subsequent virologic failure on their new regimen(s) during the follow up period

8.3.3. Confounders and effect modifiers

The study will examine the effect of the following potential confounders and effect modifiers on the risk for outcomes of interest.

Demographic variables

- Age
- Sex
- Route of HIV Infection
- Ethnic origin
- Geographic region
- Number of years since HIV diagnosis
- Date of ART initiation
- Date CAB+RPV LA started

Virologic variables at regimen initiation

- HIV VL at initiation of CAB+RPV LA regimen
  - Categorical:
    - <50 copies/mL
    - Individuals with ≥50 copies/mL at regimen initiation should not be included in the study. copies/mL

Immunologic variables at regimen initiation

- CD4 cell count at initiation of CAB+RPV LA regimen
  - Continuous (cells/µL)
  - Categorical:
    - CD4 ≥ 500 cells/µL
    - CD4 count ≥350 to <500 cells/µL
    - CD4 count <350 cells/µL

- CD4 nadir prior to initiation of CAB+RPV LA

Clinical variables at regimen initiation

- HIV Subtype
- History of previous use of integrase inhibitor-based or NNRTI-based regimen
- History of previous virological failure
- History of previous HIV drug resistance and any historical HIV-1 subtype information, where available
- Body Mass Index (BMI), height, weight
- History of AIDS-defining Events (ADE)
- Concurrent medications (Etravirine, Carbamazapine, Oxcarbazepine, Phenytoin, Phenobarbital, Rifampicin, Rifapentine, Rifabutin, Ethinyl estradiol and Levonorgestrel, Norethindrone, Ribavirin, Ketoconazole, Fluconazole, Itraconazole, Posaconazole, Voriconazole, Clarithromycin, Erythromycin, Dexamethasone, Methadone, Digoxin, Metformin, Paracetamol, Atorvastatin, Sildenafil, Vardenafil, Tadalafil)

- Comorbidities
    - HCV co-infection
    - HBV co-infection
    - ESLD (hepatocellular carcinoma, ascites, hepatorenal syndrome, grade III/IV hepatic encephalopathy, unspecified liver decompensation, oesophageal variceal bleeding, spontaneous bacterial peritonitis, liver transplantation)
    - CVD (myocardial infarction, stroke, invasive coronary procedure)
    - CKD (confirmed [>3 months apart] eGFR <60/ml/min/1.73m^2 in persons with eGFR at regimen initiation $\geq$60/ml/min/1.73m^2 and confirmed 25% decline in eGFR in persons with eGFR at regimen initiation < 60/ml/min/1.73m^2)
    - NADM (excluding hepatocellular carcinoma)

8.4. Study size

The study will aim to enroll 1000 PLWH with VL <50 copies/mL, without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class initiating CAB+RPV LA regimen.

There is no formal statistical hypothesis to be tested in these analyses. The study will focus on absolute effectiveness estimation. Confidence intervals, constructed using the exact Clopper-Pearson method based on the cumulative probabilities of the binomial distribution, are presented in Table 2, 3, 4 and are designed to give estimates of precision.

It is anticipated that data from 1000 participants are thought adequate to meet the study objectives. In the ATLAS study[1] in which participants switched from their PI, NNRTI, or INSTI based oral triple therapy regimen to CAB+RPV LA regimen, the percentage of participants with virologic failure (2 confirmed HIV RNA ≥50 copies/mL) and treatment discontinuation were, respectively, 1.6% (95% CI 0.5 to 3.4) and 8.4% (95% CI 5.6 to 12.1) at week 48. Among the 3 individuals with confirmed virological failure, all selected drug resistance mutations. For resistance, we assume a 50% resistance rate at month-24 among those with virological failure.

With 1000 individuals, the precision for the estimation of virologic failure rate will range between 0.9 and 1.5% for a failure rate ranging from 2 to 6% as shown below in Table 2.

Confidence Level	Sample Size (N)	CI Width	Virologic Failure (P)	Lower Limit	Upper Limit
0.95	1000	0.019	0.02	0.012	0.031
0.95	1000	0.023	0.03	0.020	0.043
0.95	1000	0.025	0.04	0.029	0.054
0.95	1000	0.028	0.05	0.037	0.065
0.95	1000	0.031	0.06	0.046	0.077

The corresponding precision for the discontinuation rate will range between 1.7 to 2.3 for a rate ranging from 8 to 16% as shown below in Table 3.

Confidence Level	Sample Size (N)	CI Width	Discontinuation (P)	Lower Limit	Upper Limit
0.95	1000	0.035	0.08	0.064	0.099
0.95	1000	0.038	0.10	0.082	0.120
0.95	1000	0.041	0.12	0.101	0.142
0.95	1000	0.044	0.14	0.119	0.163
0.95	1000	0.046	0.16	0.138	0.184

If the virological failure rate is ranging from 2 to 6%, then the number of participants to be tested for genotypic resistance will range from 20 to 60 individuals. With these numbers of subjects, the precision for the estimation of resistance rate will range from 12.7% (with 60 individuals) to 21.9% (with 20 individuals) for resistance rate of 50%, as shown below in table 4.

Confidence Level	Sample Size (N)	CI Width	Resistance (P)	Lower Limit	Upper Limit
0.95	20	0.46	0.5	0.27	0.73

0.95	30	0.38	0.5	0.31	0.69
0.95	40	0.32	0.5	0.34	0.66
0.95	50	0.28	0.5	0.36	0.64
0.95	60	0.26	0.5	0.37	0.63

8.5. Data Collection

Following the approval of CAB LA and RPV LA, the study will collect follow up data prospectively on 1000 PLWH treated with the CAB+RPV LA regimen, for a follow-up period of 24 months. Participants who discontinue CAB+RPV LA regimen will be followed up for 48 months after switching to another ARV regimen. The NEAT ID Network coordinating center will receive data from the clinical sites per the protocol for the study. Detailed data collection form will be used to collect comprehensive data from clinical sites including dates of injections, clinical and laboratory parameters (virologic, immunologic, biochemistry, haematology and pathology), documented history of resistance at regimen initiation, resistance and HIV subtype data at virologic failure and after discontinuation and switching to another ARV regimen. Only clinical sites that, as SoC test all participants at virologic failure, for resistance and HIV subtype data and after discontinuation and switching to another ARV regimen will be included in the study.

In order to maintain confidentiality, the subject will be identified only by subject number. Subject data will be collected via extraction from individual medical record as source data by appropriately trained and authorised member(s) of the study team who must be identified and authorised in writing by the Principal Investigator (PI). A delegation of responsibility log will be updated accordingly.

Sites will provide / upload data every 6 months to the data management team who will store the data on a secure database with access to authorised personnel of the study management team only, maintained the log of authorised personnel by the sponsor representative.

8.6. Data management

8.6.1. Data handling conventions

Data will be handled in accordance with data handling guidelines provided to sites. The Study Monitor and Data Manager will review data on an on-going basis and raise any discrepancies with site staff as required. Identified only by subject number, the data are de-identified at all times.

8.6.2. Timings of Assessment during follow-up

Available data will be collected from enrolled participants every 6 months and de-identified data will be reported to the data coordinating centre.

8.7. Data analysis

All enrolled participants who receive at least one dose of the CAB+RPV LA regimen will be included in the analysis. Participants who are prescribed but never receive a dose of CAB+RPV LA regimen will be excluded from the analysis. Study results will be stratified by the regimen used (Q4/Monthly dosing vs Q8/Every 2 month dosing). Further, study results for co-infected patients with hepatitis B or C will be presented separately. All continuous variables will be summarized using the following descriptive statistics: n (non-missing sample size), mean, standard deviation, 1st quartile, median, 3rd quartile, maximum and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical variables. Data will be analyzed using SAS®, SPSS® or STATA®.

AIM 1. Describe PLWH initiating CAB+RPV LA regimen
Baseline characteristics including demographics, clinical, immunological and virological characteristics at baseline (i.e. at initiation of regimen) will be described using the following descriptive statistics: n (non-missing sample size), median, 1st quartile, and 3rd quartile. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical variables.

AIM 2. Assess adherence, durability and discontinuation for PLWH starting CAB+RPV LA regimen
The proportion of study participants discontinuing the regimen will be assessed at 6, 12- and 24-months using the Kaplan-Meier method. The two-sided 95% confidence intervals of the proportions will be calculated with Kalbfleisch and Prentice's formula. Time to event will be defined as the time between the date of the initiation of CAB+RPV LA regimen and the date of discontinuation of CAB+RPV LA regimen. Death, cause of death where available and lost to follow-up will be excluded from this analysis but will be tabulated and reported separately. Follow-up will be censored at the analysis time point. The estimated median time to discontinuation will be calculated with the two-sided 95% associated confidence interval. Reasons for discontinuation will be given and frequencies and percentages will be reported. Number of individuals that experience blips ≥50 to <200 copies/mL will be tabulated along with the number of individuals that have CVF and remain on regimen. Kaplan Meier curves will be plotted with the number of participants at risk at baseline, 6, 12, and 24-month.

The number and proportion and the two-sided 95% associated confidence interval of participants that missed one or more consecutive injections without taking daily oral bridging therapy or any other oral ARV regimen while not on CAB+RPV LA regimen will be calculated. The proportion will be estimated by the number of individuals who missed one or more consecutive injections divided by the total number of study participants in the analysis. The mean and median number of injections missed during a 12-month period will be described by median, 1st quartile, and 3rd quartile.

The number and proportion and the two-sided 95% confidence interval of proportion of individuals who received the injections seven or more days later than their scheduled

injection visit will be calculated. The proportion will be estimated by the number of individuals who received the injections seven or more days later than their scheduled injection visit divided by the total number of study participants in the analysis.
The duration of delayed injections will be described by median, 1st quartile, and 3rd quartile.

AIM 3. Assess the clinical effectiveness among PLWH who initiate CAB+RPV LA regimen

Given that this study involves PLWH in routine clinical care, and who may not attend clinic appointments at 6, 12 or 24 months, a window of 12 weeks around the date in question will be used for virologic failure. Thus, the proportion with virologic failure during first six months, at 6, 12 or 24 months $\pm$ 6 weeks will be used; and if none is available, the first measurement during first six months, after 6, 12 or 24 months (and at most 6 weeks after the measurement).

Proportion of participants who continue to be suppressed (VL of <50 copies/mL) at each time point (after 6, 12 and 24 months of follow up) will be estimated, as well as proportion of individuals with VL of <200 copies/mL. CD4 counts will also be assessed. The proportion of participants with virologic failure (2 consecutive HIV RNA VL ≥200 copies/mL or one HIV RNA VL level ≥200 copies/mL followed by a discontinuation of CAB+RPV LA regimen) will be estimated and time to failure will be assessed by the Kaplan-Meier method. The two-sided 95% associated confidence interval will be calculated with Kalbfleisch and Prentice's formula. Time to event will be defined as the time between the date of the initiation of CAB+RPV LA regimen and the date of virologic failure. Follow-up will be censored at the analysis time point, or the date of last study contact, or date of discontinuation of CAB+RPV LA regimen, or the date of lost to follow-up, whichever will occur first.

Genotypic resistance testing will be performed in participants with confirmed HIV RNA VL ≥200 copies/mL. Resistance interpretation will be given using the Stanford algorithm (https://hivdb.stanford.edu/hivdb/by-mutations). All drug resistance mutations identified will be described and number and percentage indicated. The proportion of participants with genotypic resistance viruses among those with virological failure will be estimated by the number of participants with genotypic resistance viruses divided by the total number of participants with virological failure. The associated two-sided 95% exact (Clopper–Pearson) confidence intervals will be calculated. The frequency of viral subtype among those with virologic failure will be reported.

AIM 4. Monitor for resistance and response to subsequent treatment regimen among individuals who switched off CAB +RPV LA regimen
The analysis will be performed in all individuals who switched off CAB+RPV LA regimen. The ARV regimen received after discontinuation of CAB+RPV LA regimen will be described and categorised as follows: 2NRTI+PI, 2NRTI+NNRTI, 2NRTI+INsTI, and other. All regimen changes during the 48 month follow-up period will be captured and summarized.

The proportion of participants with HIV RNA <50 copies/mL at 12, 24, 36 and 48 months after discontinuation of CAB+RPV LA regimen will be estimated by the number of participants with HIV RNA <50 copies/mL at each time point divided by the total number of participants with discontinuation of CAB+RPV LA regimen. CD4 counts will also be assessed. The associated two-sided 95% exact (Clopper–Pearson) confidence intervals will be calculated.

Assessment of factors associated with non-adherence, virologic failure, discontinuation and resistance

Univariable and multivariable analyses will be performed to identify factors that probably modified the effect of the study treatment on the risk of outcomes of interest. Cox regression models will be used to assess the factors associated with virologic failure, with non-adherence and with the discontinuation of CAB+RPV LA regimen. Logistic regression will be used to assess factors associated with drug resistance among participants with virological failure, if the number of events allow this analysis. Variables with univariable P<0.20 will be retained for the multivariable analysis.

All variables described at section 8.3.3 will be assessed. We will assess whether continuous variables will be better modelled as continuous variables or as terciles based on the lowest value of Akaike's information criterion (AIC) for the corresponding univariable Cox regression models or univariable logistic regression models according to the outcome of interest, and grouped together the closest values in order to obtain two classes for certain variables.

Sensitivity Analysis: As some parameters with missing data can influence the outcome of interest, to quantify the potential effect, we will create 5 datasets in which missing data will be replaced using Rubin's multiple imputation method. Instead of filling in a single value for each missing value, multiple imputation procedure replaces each missing value with a set of plausible values that represent the uncertainty about the right value to impute. Analyses will be run on each of the 5 data sets, and the results will be combined with Rubin's rules. Pooling the multiple parameter estimates from the 5 datasets into one estimate along with its variance (which combines the conventional sampling variance and the extra variance caused by the missing data) will help understand the effect of the missing data.

8.8. Quality control and Quality Assurance

Site selection and training of site staff will ensure suitably qualified personnel are involved at every stage of the data gathering process. Data will be analyzed using SAS, SPSS or STATA.

8.9. Limitations of the research methods

Limitations of this study are common to non-randomized non-interventional study. This is a study of routine clinical care and reflects treatment practice across NEAT ID Network clinical sites. Confounding by indication, whereby persons are selected for specific regimens, cannot be ruled out. While the study aims to include approximately 1000 PLWH on CAB+RPV LA regimen, market uptake of the regimen, individuals' willingness to participate will dictate how quickly data will be collected. Following up of study participants for 4 years after discontinuation of the CAB + RPV LA regimen will increase the potential for loss to follow up as would be expected, in a real world setting.The results from this study should be interpreted cautiously, with careful consideration given to the limitations of the observational study design.

9. PROTECTION OF HUMAN SUBJECTS

9.1. Ethical approval and subject consent

Before the start of data collection, this protocol and any accompanying material to be provided to the participants (subject information sheets, or descriptions of the study used to obtain informed consent) will be submitted to Ethics Committee (EC) in the relevant countries. The participating clinical sites will not begin any study activities until approval from the EC has been documented and the Sponsor (MAH) has provided as an activation letter to the clinical site investigator.

Any subsequent amendments that require review by EC will not be implemented until the EC grants the amendments a favourable opinion which will be disseminated to the investigator and sites (NOTE: amendments may also need to be reviewed and accepted by the regulatory agencies and/or local EC departments before they can be implemented in practice at sites) In accordance with the requirements of the EC, an annual progress report will be submitted as needed to the EC. NEAT ID team will notify the EC of the end of the study. If the study is ended prematurely, NEAT ID will notify the EC, including the reasons for the premature termination.

9.2. Subject confidentiality

All investigators and study site staff will comply with the requirements of the current Data Protection Regulations with regards to the collection, storage, processing and disclosure of personal information and will uphold the Regulation's core principles.

- Only deidentified data is reported to the central study database. Identifiable individual information (held only by the site investigator in routine medical records) will be kept secure at all times and maintained in line with local applicable standard operating procedures. Access to this will be to the minimum number of individuals necessary for quality control, and audit reasons. There will be no entry of any identifiable data into the study database at any time.

10. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

There is no potential to collect individual level data on serious and non-serious adverse events (AEs), pregnancy exposures, device deficiencies and device related events or incidents related to any ViiV Healthcare product during the conduct of this research, as the minimum criteria needed to report AEs, pregnancy exposures, and incidents are not collected. Specifically, the data are insufficient to establish attribution between a potential safety event and an individual using a ViiV Healthcare product as the study design is to analyse deidentified, secondary data collected from individual medical records. Therefore, a study specific pharmacovigilance plan will not be developed.

11. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

11.1. Milestones

This study-specific protocol will be submitted by 31 December 2020 for the EMA's review and endorsement. The study will start only after the protocol is approved by the EMA, and CAB LA and/or RPV LA is registered and commercially available in the relevant countries and is expected to continue through 2026 or later. Annual interim reports with cumulative data will be submitted and a final report is expected to be submitted in March 2027.

11.2. Target Audience

The target audience for these data includes healthcare providers, regulatory and health authorities.

11.3. Study reporting and publications

Interim and final study results will be included in safety and regulatory reports as appropriate. Study results will be made available externally through peer reviewed manuscript and conference presentation.

12. REFERENCES

1. Swindells S, Andrade-Villanueva JF, Richmond GJ, Rizzardini G, Baumgarten A, Masia M, et al. Long-Acting Cabotegravir and Rilpivirine for Maintenance of HIV-1 Suppression. N Engl J Med 2020; 382(12):1112-1123.

ANNEX 1. CASE REPORT FORM

C2C_V1

C2C

Subject Label Expression: BSL:DEMOG:SUBJID

Date of Birth Expression:

Gender Expression:

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Visit Schedule

	Baseline	Antiretroviral Treatment	Resistance Testing	CAB + RPV LA Regimen	HIV RNA Viral Load/CD4 Count	Regimen Follow-up	Post-Switch Follow-Up	End of Study	Source Data Upload	Central Administration
Demographics and Consent	1									
Regimen Initiation	1									
Previous Virological Failure	R									
AIDS-Defining Events	1									
Concurrent Medications	1									
Comorbidities	1									
Antiretroviral Treatment		R								
Resistance Testing			R							
CAB+RPV LA regimen				R						
CD4 Count					R					
HIV RNA Viral Load					R					
6 Month Regimen Follow-up						1				
12 Month Regimen Follow-up						1				
24 Month Regimen Follow-up						1				
12 Months Post-Switch Follow-up							1			
24 Months Post-Switch Follow-up							1			
36 Months Post-Switch Follow-up							1			
48 Months Post-Switch Follow-up							1			
End of Study								1		
Sign Off								1		
Source Data Upload									1	
Central Administration										1

Demographics and Consent

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID

Inclusion Criteria

Virologically suppressed (HIV-1 RNA <50 copies /mL) at the time of regimen initiation — ○ No ○ Yes INC_VS

No evidence of prior virological failure with agents of the NNRTI and INI class — ○ No ○ Yes INC_VF

No evidence of present or past recorded viral resistance to, and with agents of the NNRTI and INI class — ○ No ○ Yes INC_VR

Consent

Was patient consent required by local ethics approval? ○ No ○ Yes CONREQ

Was patient informed consent provided? ○ No ○ Yes CON

Consent Date CONDAT

Name of Consenting Clinician [ ] CONNAM

ICF Version Used [ ] ICFVER

Subjects at French Sites Only

Confirm that the subject has been notified in writing of their participation in the study and personal data processing ○ Yes SUBINF

Demographics

Age [ ] AGE

Sex ○ Male ○ Female SEX

Route of HIV Infection [ ] INFRT

Ethnicity ETHNIC

HIV Medical History

eForm Code: DEMOG eForm Title: Demographics and Consent - Annotations Table

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID	Subject ID	SUBJID	Text	10	See Appendix	
2	INC_VS	Virologically suppressed (HIV-1 RNA <50 copies /mL	INC_VS	Category	3		N=No Y=Yes
3	INC_VF	No evidence of prior virological failure with agen	INC_VF	Category	3		N=No Y=Yes
4	INC_VR	No evidence of present or past recorded viral resi	INC_VR	Category	3		N=No Y=Yes
5	CONREQ	Was patient consent required by local ethics appro	CONREQ	Category	3		N=No Y=Yes
6	CON	Was patient informed consent provided?	CON	Category	3		N=No Y=Yes
7	CONDAT	Consent Date	CONDAT	Date/Time	dd/mm/yyyy		
8	CONNAM	Name of Consenting Clinician	CONNAM	Text	100		
9	ICFVER	ICF Version Used	ICFVER	Text	10		
10	SUBINF	Confirm that the subject has been notified in writ	SUBINF	Category	3		Y=Yes
11	AGE	Age	AGE	Integer	#99		
12	SEX	Sex	SEX	Category	6		M=Male F=Female
13	INFRT	Route of HIV Infectio	INFRT	Text	100		
14	ETHNIC	Ethnicity	ETHNIC	Category	26		See Appendix

Is HIV diagnosis date known? ○ No ○ Yes DIAGDTYN

HIV diagnosis date DIAGDAT

If date not known, please estimate number of years since diagnosis [ ] DIAGYR

Date of ART initiation ARTINDAT

HIV Subtype ○ HIV-1 ○ HIV-2 HIVSUB

HIV Subtype Group (if known) [ ] HIVSUBGP

Has the subject previously used an integrase inhibitor-based or NNRTI-based regimen ○ No ○ Yes PREVNN

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Data Review Reason	Review Date	Notes for Next Review
[ ] CRREAS	[ ] CRDAT	[ ] CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
15	DIAGDTYN	Is HIV diagnosis date known?	DIAGDTYN	Category	3		N=No Y=Yes
16	DIAGDAT	HIV diagnosis date	DIAGDAT	Date/Time	dd/mm/yyyy		
17	DIAGYR	If date not known, please estimate number of years	DIAGYR	Integer	#9		
18	ARTINDAT	Date of ART initiation	ARTINDAT	Date/Time	dd/mm/yyyy		
19	HIVSUB	HIV Subtype	HIVSUB	Category	5		1=HIV-1 2=HIV-2
20	HIVSUBGP	HIV Subtype Group (if known)	HIVSUBGP	Text	50		
21	PREVNN	Has the subject previously used an integrase inhib	PREVNN	Category	3		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
22	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
23	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
24	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

Regimen Initiation

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Subject ID [ ] SUBJID_D

Regimen Initiation

Date CAB+RPV LA regimen started LASTDAT

Viral Load at Regimen Initiation

Please record sample taken on day of initiation, if possible.
Otherwise, please record last sample taken prior to regimen initiation

Date of sample VLDAT

Viral Load Greater Than or Less Than VLGL

HIV RNA viral load [ ] VLOAD

CD4 Count at Regimen Initiation

Please record sample taken on day of initiation, if possible.
Otherwise, please record last sample taken prior to regimen initiation

Date of Sample CD4DAT

CD4 Count [ ] CD4COUNT CD4 Count Unit CD4UNIT

CD4 nadir prior to initiation of CAB+RPV LA [ ] CD4NAD CD4 Nadir Unit CD4NADU

Height and Weight at Regimen Initiation

Are height and weight available at regimen initiation? ○ No ○ Yes HWAVAIL

Height (cm) [ ] HCM

Weight (kg) [ ] WKG

Is the BMI known? ○ No ○ Yes BMIYN

BMI [ ] BMI BMI (Derived) [ ] BMI_D

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ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	LASTDAT	Date CAB+RPV LA regimen started	LASTDAT	Date/Time	dd/mm/yyyy		
3	VLDAT	Date of sample	VLDAT	Date/Time	dd/mm/yyyy		
4	VLGL	Viral Load Equal To, Greater Than or Less Than	VLGL	Category	1, Optional		0=< 1=> 2==
5	VLOAD	HIV RNA viral load	VLOAD	Integer	######9		
6	CD4DAT	Date of Sample	CD4DAT	Date/Time	dd/mm/yyyy		
7	CD4COUNT	CD4 Count	CD4COUNT	Real	######9.9###		
8	CD4UNIT	CD4 Count Unit	CD4UNIT	Category	9		1=cells/uL 2=10^9/L 3=10^6/L 4=Cells/mm3 5=10^3/uL
9	CD4NAD	CD4 nadir prior to initiation of CAB+RPV LA	CD4NAD	Real	######9.9### ###		
10	CD4NADU	CD4 Nadir Unit	CD4NADU	Category	9		1=cells/uL 2=10^9/L 3=10^6/L 4=Cells/mm3 5=10^3/uL
11	HWAVAIL	Are height and weight available at regimen initiat	HWAVAIL	Category	3		N=No Y=Yes
12	HCM	Height (cm)	HCM	Integer	#99		
13	WKG	Weight (kg)	WKG	Integer	#99		
14	BMIYN	Is the BMI known?	BMIYN	Category	3		N=No Y=Yes
15	BMI	BMI	BMI	Integer	99		
16	BMI_D	BMI (Derived)	BMI_D	Integer	99	WKG/(HCM*HCM)	

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
17	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
18	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
19	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

Previous Virological Failure

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Has subject experienced previous virological failure? VFYN

- ○ No
- ○ Yes

Date sample taken	Viral Load Equal To, Greater Than or Less Than	HIV RNA viral load
VFDAT	VFGL	VFLOAD

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Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	VFYN	Has subject experienced previous virological failu	VFYN	Category	3		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
3	VFDAT	Date sample taken	VFDAT	Date/Time	dd/mm/yyyy		
4	VFGL	Viral Load Equal To, Greater Than or Less Than	VFGL	Category	1, Optional		0=< 1=> 2==
5	VFLOAD	HIV RNA viral load	VFLOAD	Integer	######9		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
6	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
7	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
8	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

AIDS-Defining Events

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Subject ID SUBJID_D

Has the subject experienced any AIDS Defining Events? ADEFYN

- ◯ No
- ◯ Yes

AIDS-Defining Event	Event Start Date
ADEFEVENT	ADEFDAT

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Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	ADEFYN	Has the subject experienced any AIDS Defining Even	ADEFYN	Category	3		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
3	ADEFEVENT	AIDS-Defining Event	ADEFEVENT	Category	110		See Appendix
4	ADEFDAT	Event Start Date	ADEFDAT	Date/Time	dd/mm/yyyy		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
5	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
6	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
7	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

Concurrent Medications

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Is the subject receiving any of the concurrent medications as specified in the protocol? CMYN

- ○ No
- ○ Yes

Medication	Dose	Unit	Frequency
CMTRT	CMDSTXT	CMDOSU	CMDOSFRQ

If other, specify	Start Date	Ongoing	End Date
CMDOSFRQTXT	CMSTDAT	CMONGO	CMENDAT

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Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	CMYN	Is the subject receiving any of the concurrent med	CMYN	Category	3		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
3	CMTRT	Medication	CMTRT	Category	36		See Appendix
4	CMDSTXT	Dose	CMDSTXT	Real	######9.9###		
5	CMDOSU	Unit	CMDOSU	Text	20		
6	CMDOSFRQ	Frequency	CMDOSFRQ	Category	17		1=Once Daily 2=Twice Daily 3=Three Times a Day 4=Four Times a Day 5=Other
7	CMDOSFRQTXT	If other, specify	CMDOSFRQTXT	Text	100		
8	CMSTDAT	Start Date	CMSTDAT	Date/Time	dd/mm/yyyy		
9	CMONGO	Ongoing	CMONGO	Category	3		N=No Y=Yes
10	CMENDAT	End Date	CMENDAT	Date/Time	dd/mm/yyyy		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
11	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
12	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
13	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

Comorbidities

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID_D

Has the subject experienced any of the comorbidities listed below? ○ No ○ Yes MHYN

HCV co-infection ○ No ○ Yes MHHCV

Is date of HCV diagnosis known? ○ No ○ Yes MHHCV_DTYN

Date of HCV diagnosis MHHCV_DT

Estimated number of years since HCV diagnosis [ ] MHHCV_YR

HBV co-infection ○ No ○ Yes MHHBV

Is date of HBV diagnosis known? ○ No ○ Yes MHHBV_DTYN

Date of HBV diagnosis MHHBV_DT

Estimated number of years since HBV diagnosis [ ] MHHBV_YR

ESLD
(hepatocellular carcinoma, ascites, hepatorenal syndrome, grade III/IV hepatic encephalopathy, unspecified liver decompensation, oesophageal variceal bleeding, spontaneous bacterial peritonitis, liver transplantation) ○ No ○ Yes MHESLD

Please specify condition MHESLD_SP

Is date of ESLD diagnosis known? ○ No ○ Yes MHESLD_DTYN

Date of ESLD diagnosis MHESLD_DT

Estimated number of years since ESLD diagnosis [ ] MHESLD_YR

CVD
(myocardial infarction, stroke, invasive coronary procedure) ○ No ○ Yes MHCVD

Please specify condition MHCVD_SP

Is date of CVD diagnosis known? ○ No ○ Yes MHCVD_DTYN

Date of CVD diagnosis MHCVD_DT

Estimated number of years since CVD diagnosis [ ] MHCVD_YR

CKD
(confirmed [>3 months apart] eGFR <60/ml/min/1.73m2 in persons with eGFR at regimen initiation >60/ml/min/1.73m2 and confirmed 25% decline in eGFR in persons with eGFR at regimen initiation < 60/ml/min/1.73m2) ○ No ○ Yes MHCKD

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	MHYN	Has the subject experienced any of the comorbiditi	MHYN	Category	3		N=No Y=Yes
3	MHHCV	HCV co-infection	MHHCV	Category	3		N=No Y=Yes
4	MHHCV_DTYN	Is date of HCV diagnosis known?	MHHCV_DTYN	Category	3		N=No Y=Yes
5	MHHCV_DT	Date of HCV diagnosi	MHHCV_DT	Date/Time	dd/mm/yyyy		
6	MHHCV_YR	Estimated number of years since HCV diagnosis	MHHCV_YR	Integer	#9		
7	MHHBV	HBV co-infection	MHHBV	Category	3		N=No Y=Yes
8	MHHBV_DTYN	Is date of HBV diagnosis known?	MHHBV_DTYN	Category	3		N=No Y=Yes
9	MHHBV_DT	Date of HBV diagnosi	MHHBV_DT	Date/Time	dd/mm/yyyy		
10	MHHBV_YR	Estimated number of years since HBV diagnosis	MHHBV_YR	Integer	#9		
11	MHESLD	ESLD	MHESLD	Category	3		N=No Y=Yes
12	MHESLD_SP	Please specify condition	MHESLD_SP	Category	35		See Appendix
13	MHESLD_DTYN	Is date of ESLD diagnosis known?	MHESLD_DTYN	Category	3		N=No Y=Yes
14	MHESLD_YR	Estimated number of years since ESLD diagnosis	MHESLD_YR	Integer	#9		
15	MHESLD_DT	Date of ESLD diagnosis	MHESLD_DT	Date/Time	dd/mm/yyyy		
16	MHCVD	CVD	MHCVD	Category	3		N=No Y=Yes
17	MHCVD_SP	Please specify condition	MHCVD_SP	Category	27		1=Myocardial infarction 2=Stroke 3=Invasive coronary procedure
18	MHCVD_DTYN	Is date of CVD diagnosis known?	MHCVD_DTYN	Category	3		N=No Y=Yes
19	MHCVD_DT	Date of CVD diagnosi	MHCVD_DT	Date/Time	dd/mm/yyyy		
20	MHCVD_YR	Estimated number of years since CVD diagnosis	MHCVD_YR	Integer	#9		
21	MHCKD	CKD	MHCKD	Category	3		N=No Y=Yes

Please specify condition [ ] MHCKD_SP

Is date of CKD diagnosis known? ○ No ○ Yes MHCKD_DTYN

Date of CKD diagnosis MHCKD_DT

Estimated number of years since CKD diagnosis [ ] MHCKD_YR

NADM (excluding hepatocellular carcinoma) ○ No ○ Yes MHNADM

Please specify condition [ ] MHNADM_SP

Is date of NADM diagnosis known? ○ No ○ Yes MHNADM_DTYN

Date of NADM diagnosis MHNADM_DT

Estimated number of years since NADM diagnosis [ ] MHNADM_YR

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Data Review Reason	Review Date	Notes for Next Review
[ ] CRREAS	[ ] CRDAT	[ ] CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
22	MHCKD_SP	Please specify condition	MHCKD_SP	Text	100		
23	MHCKD_DTYN	Is date of CKD diagnosis known?	MHCKD_DTYN	Category	3		N=No Y=Yes
24	MHCKD_DT	Date of CKD diagnosis	MHCKD_DT	Date/Time	dd/mm/yyyy		
25	MHCKD_YR	Estimated number of years since CKD diagnosis	MHCKD_YR	Integer	#9		
26	MHNADM	NADM	MHNADM	Category	3		N=No Y=Yes
27	MHNADM_SP	Please specify condition	MHNADM_SP	Text	100		
28	MHNADM_DTYN	Is date of NADM diagnosis known?	MHNADM_DTYN	Category	3		N=No Y=Yes
29	MHNADM_DT	Date of NADM diagnosis	MHNADM_DT	Date/Time	dd/mm/yyyy		
30	MHNADM_YR	Estimated number of years since NADM diagnosis	MHNADM_YR	Integer	#9		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
31	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
32	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
33	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

Antiretroviral Treatment

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_C

Please record:
Previous regimens received in the year prior to initiation of CAB+RPV LA regimen
Oral-bridging therapy or any other ARV regimen while on CAB+RPV LA regimen
Regimen the subject switched to after discontinuation of CAB+RPV LA regimen

Regimen type	Drug Name	If Other Regimen, Please Specify	Dose
ANTREGTYP	ANTDRUG	ANTDRUGOTH	ANTDOS

Unit	Frequency	If Other Frequency, Please Specify	Start Date	Ongoing	End Date	Reason for Stopping	If Other Reason, Please Specify
ANTUNIT	ANTFREQ	ANTFREQOTH	ANTSTDAT	ANTON	ANTENDAT	ANTSTREAS	ANTSTREASOTH

Please continue to record viral load and resistance test results in the Viral Load and Restsiance Testing eForms, using the links below

Viral Load

Resistance Testing

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

eForm Code: ART eForm Title: Antiretroviral Treatment - Annotations Table

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
2	ANTREGTYP	Regimen type	ANTREGTYP	Category	28		1=Prior regimen 2=Oral-bridging therapy 3=Post-discontinuation therapy
3	ANTDRUG	Drug Name	ANTDRUG	Category	67		See Appendix
4	ANTDRUGOTH	If Other Regimen, Please Specify	ANTDRUGOTH	Text	50		
5	ANTDOS	Dose	ANTDOS	Text	20		
6	ANTUNIT	Unit	ANTUNIT	Text	20		
7	ANTFREQ	Frequency	ANTFREQ	Category	17		1=Once Daily 2=Twice Daily 3=Three Times Daily 4=Four Times Daily 5=Other
8	ANTFREQOTH	If Other Frequency, Please Specify	ANTFREQOTH	Text	100		
9	ANTSTDAT	Start Date	ANTSTDAT	Date/Time	dd/mm/yyyy		
10	ANTON	Ongoing	ANTON	Category	3		N=No Y=Yes
11	ANTENDAT	End Date	ANTENDAT	Date/Time	dd/mm/yyyy		
12	ANTSTREAS	Reason for Stopping	ANTSTREAS	Category	24		See Appendix
13	ANTSTREASOTH	If Other Reason, Please Specify	ANTSTREASOTH	Text	100		
14	Hotlink			Hotlink		LA:HIVRNA	
15	Hotlink			Hotlink		BSL:RESTST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
16	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
17	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
18	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

Resistance Testing

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Please record all previous HIV drug resistance tests and any historic HIV-1 subtype information where available.

In the event of virological failure while on the CAB+RPV LA Regimen, please record the resistance tesing along with subtype information.

For patients who switch to another regimen, please record all resistance testing, with subtype information, carried out in the event of virological failure in the 48 months following the switch.

Resistance test carried out? ○ No ○ Yes RESYN

Date of resistance testing	Is test report available?	Was new resistance identified?	Class of ARV Drug	ARV Drug Name - 1 per row	List each mutation	Is subtype data available?	HIV Subtype
RESDAT	RESAVAIL	RESIDENT	RESCLASS	RESSPEC	RESMUT	SUBYN	HIVSUB

HIV Subtype Group (if known) HIVSUBGP

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	RESYN	Resistance test carried out?	RESYN	Category	3		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
3	RESDAT	Date of resistance testing	RESDAT	Date/Time	dd/mm/yyyy		
4	RESAVAIL	Is test report available?	RESAVAIL	Category	3		N=No Y=Yes
5	RESIDENT	Was new resistance identified?	RESIDENT	Category	3		N=No Y=Yes
6	RESCLASS	Class of ARV Drug	RESCLASS	Category	19		1=Protease/PI 2=NNRTI 3=NRTI/NtRTI 4=Integrase Inhibitor 5=Other
7	RESSPEC	ARV Drug Name - 1 per row	RESSPEC	Text	100		
8	RESMUT	List each mutation	RESMUT	Text	100		
9	SUBYN	Is subtype data available?	SUBYN	Category	3		N=No Y=Yes
10	HIVSUB	HIV Subtype	HIVSUB	Category	5		1=HIV-1 2=HIV-2
11	HIVSUBGP	HIV Subtype Group (if known)	HIVSUBGP	Text	50		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
12	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
13	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
14	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

CAB+RPV LA regimen

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Lead-in Regimen

Date lead-in regimen started LDSTDAT

Regimen used for lead-in LDREG

Did the subject adhere to the lead-in regimen? LDADHERE
- ◯ No
- ◯ Yes

If no, how many days were missed LDDYMISS

Did the subject continue on to receive the CAB+RPV LA regimen? LDCONT
- ◯ No
- ◯ Yes

If no, please give reason did not continue LDREAS

Dosing Schedule

Scheduled Injection Date	Dosing Type	Change in Dosing Schedule Type?	Reason for change in dosing schedule	Was the injection given?	Actual Injection Date	Did the subject take oral bridging therapy or any other oral ARV regimen?
DSCHEDDAT	DSTYPE	DSTYPECH	DSTYPEREAS	DGIVEN	DACTDAT	DBRID

Reason oral bridging therapy started	Did the subject resume the CAB+RPV LA regimen
DBRIDREAS	DSRESUME

eForm Code: LAREG eForm Title: CAB+RPV LA regimen - Annotations Table

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	LDSTDAT	Date lead-in regimen started	LDSTDAT	Date/Time	dd/mm/yyyy		
3	LDREG	Regimen used for lead-in	LDREG	Category	11		1=CAB and RPV 2=CAB Only 3=RPV Only
4	LDADHERE	Did the subject adhere to the lead-in regimen?	LDADHERE	Category	3		N=No Y=Yes
5	LDDYMISS	If no, how many days were missed	LDDYMISS	Integer	#9		
6	LDCONT	Did the subject continue on to receive the CAB+RPV	LDCONT	Category	3		N=No Y=Yes
7	LDREAS	If no, please give reason did not continue	LDREAS	Text	500		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
8	DSCHEDDAT	Scheduled Injection Date	DSCHEDDAT	Date/Time	dd/mm/yyyy		
9	DSTYPE	Dosing Type	DSTYPE	Category	10		1=Initiation 2=1-Monthly 3=2-Monthly
10	DSTYPECH	Change in Dosing Schedule Type?	DSTYPECH	Category	3		N=No Y=Yes
11	DSTYPEREAS	Reason for change in dosing schedule	DSTYPEREAS	Text	500		
12	DGIVEN	Was the injection given?	DGIVEN	Category	3		N=No Y=Yes
13	DACTDAT	Actual Injection Date	DACTDAT	Date/Time	dd/mm/yyyy		
14	DBRID	Did the subject take oral bridging therapy or any	DBRID	Category	3		N=No Y=Yes
15	DBRIDREAS	Reason oral bridging therapy started	DBRIDREAS	Text	500		
16	DSRESUME	Did the subject resume the CAB+RPV LA regimen	DSRESUME	Category	3		N=No Y=Yes

If the subject received oral bridging therapy or any other oral ARV regimen, please follow the link below to record this in the Antiretroviral Treatment page

Antiretroviral Treatment Page

Discontinuation

Did the subject discontinue the CAB+PRV LA regimen? ◯ No ◯ Yes DISCON

Date of discontinuation DISCONDAT

Please specify reason for discontinuation CMRSDISC

In the event of discontinuation, please complete the resistance test details on the Resistance Testing eForm, using the link below

Resistance Testing

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
17	Hotlink			Hotlink		visit:form	
18	DISCON	Did the subject discontinue the CAB+PRV LA regimen	DISCON	Category	3		N=No Y=Yes
19	DISCONDAT	Date of discontinuation	DISCONDAT	Date/Time	dd/mm/yyyy		
20	CMRSDISC	Please Specify Reason for Discontinuation	CMRSDISC	Category	90		See Appendix
21	Hotlink			Hotlink		BSL:RESTST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
22	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
23	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
24	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

CD4 Count

Subject ID SUBJID_D

Please record all CD4 counts for the follow-up timepoints, including CD4 count(s) associated with a virological failure

Date of Sample	CD4 Count	CD4 Count Unit	Is the CD4 count associated with a virological failure?
CD4DAT	CD4COUNT	CD4UNIT	CD4VF

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

eForm Code: CD4 eForm Title: CD4 Count - Annotations Table

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
2	CD4DAT	Date of Sample	CD4DAT	Date/Time	dd/mm/yyyy		
3	CD4COUNT	CD4 Count	CD4COUNT	Real	######9.9###		
4	CD4UNIT	CD4 Count Unit	CD4UNIT	Category	9		1=cells/uL 2=10^9/L 3=10^6/L 4=Cells/mm3 5=10^3/uL
5	CD4VF	Is the CD4 count associated wit a virological fai	CD4VF	Category	3		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
6	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
7	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
8	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

HIV RNA Viral Load

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Date of sample	Viral Load Equal To, Greater Than or Less Than	HIV RNA viral load	Assessed as Virological Failure	Was a retest carried out?
VLDAT	VLGL	VLOAD	VLVF	VLRET

In the event of virological failure, please complete the resistance test details on the Resistance Testing eForm, using the link below

Resistance Testing

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

eForm Code: HIVRNA eForm Title: HIV RNA Viral Load - Annotations Table

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
2	VLDAT	Date of sample	VLDAT	Date/Time	dd/mm/yyyy		
3	VLGL	Viral Load Equal To, Greater Tha or Less Than	VLGL	Category	1, Optional		0=< 1=> 2==
4	VLOAD	HIV RNA viral load	VLOAD	Integer	######9		
5	VLVF	Assessed as Virological Failure	VLVF	Category	3		N=No Y=Yes
6	VLRET	Was a retest carried out?	VLRET	Category	3		N=No Y=Yes
7	Hotlink			Hotlink		BSL:RESTST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
8	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
9	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
10	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

6 Month Regimen Follow-up

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID_D

Has all relevant regimen/discontinuation data been entered for this time period? ◯ No ◯ Yes REG6MO

If relevant regimen/discontinuation data need to be recorded, please use the link below

CAB+RPV LA Regimen Page

Has all relevant HIV RNA Viral Load data been entered for this time period? ◯ No ◯ Yes VL6MO

If relevant HIV RNA Viral Load data need to be recorded, please use the link below

HIV RNA Viral Load Page

Has all relevant CD4 data been entered for this time period? ◯ No ◯ Yes CD6MO

If relevant CD4 data need to be recorded, please use the link below

CD4 Count Page

Has all relevant resistance testing data been entered for this time period? ◯ No ◯ Yes RES6MO

If relevant resistance testing data need to be recorded, please use the link below

Resistance Testing Page

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
[ ] CRREAS	[ ] CRDAT	[ ] CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	REG6MO	Has all relevant regimen/discontinuation data been	REG6MO	Category	3		N=No Y=Yes
3	Hotlink			Hotlink		visit:LAREG	
4	VL6MO	Has all relevart HIV RNA Viral Load data been ente	VL6MO	Category	3		N=No Y=Yes
5	Hotlink			Hotlink		visit:HIVRNA	
6	CD6MO	Has all relevant CD4 data been entered for this ti	CD6MO	Category	3		N=No Y=Yes
7	Hotlink			Hotlink		visit:CD4	
8	RES6MO	Has all relevant resistance testing data been ente	RES6MO	Category	3		N=No Y=Yes
9	Hotlink			Hotlink		visit:RESTST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
10	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
11	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
12	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

12 Month Regimen Follow-up

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID_D

Has the subject already discontinued the CAB+RPV LA regimen? ◯ No ◯ Yes DIS12MO

If 'No', please complete below

Has all relevant regimen/discontinuation data been entered for this time period? ◯ No ◯ Yes REG12MO

If relevant regimen/dicontinuation data need to be recorded, please use the link below

CAB+RPV LA Regimen Page

Has all relevant HIV RNA Viral Load data been entered for this time period? ◯ No ◯ Yes VL12MO

If relevant HIV RNA Viral Load data need to be recorded, please use the link below

HIV RNA Viral Load Page

Has all relevant CD4 data been entered for this time period? ◯ No ◯ Yes CD12MO

If relevant CD4 data need to be recorded, please use the link below

CD4 Count Page

Has all relevant resistance testing data been entered for this time period? ◯ No ◯ Yes RES12MO

If relevant resistance testing data need to be recorded, please use the link below

Resistance Testing Page

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
[ ] CRREAS	[ ] CRDAT	[ ] CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	DIS12MO	Has the subject already discontinued the CAB+RPV L	DIS12MO	Category	3		N=No Y=Yes
3	REG12MO	Has all relevant regimen/discontinuat on data been	REG12MO	Category	3		N=No Y=Yes
4	Hotlink			Hotlink		visit:LAREG	
5	VL12MO	Has all relevant HIV RNA Viral Load data been ente	VL12MO	Category	3		N=No Y=Yes
6	Hotlink			Hotlink		visit:HIVRNA	
7	CD12MO	Has all relevant CD4 data been ente	CD12MO	Category	3		N=No Y=Yes
8	Hotlink			Hotlink		visit:CD4	
9	RES12MO	Has all relevant resistance testing data been ente	RES12MO	Category	3		N=No Y=Yes
10	Hotlink			Hotlink		visit:RESTST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
11	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
12	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
13	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

24 Month Regimen Follow-up

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID_D

Has the subject already discontinued the CAB+RPV LA regimen? ◯ No ◯ Yes DIS24MO

If 'No', please complete below

Has all relevant regimen/discontinuation data been entered for this time period? ◯ No ◯ Yes REG24MO

If relevant regimen/dicontinuation data need to be recorded, please use the link below

CAB+RPV LA Regimen Page

Has all relevant HIV RNA Viral Load data been entered for this time period? ◯ No ◯ Yes VL24MO

If relevant HIV RNA Viral Load data need to be recorded, please use the link below

HIV RNA Viral Load Page

Has all relevant CD4 data been entered for this time period? ◯ No ◯ Yes CD24MO

If relevant CD4 data need to be recorded, please use the link below

CD4 Count Page

Has all relevant resistance testing data been entered for this time period? ◯ No ◯ Yes RES24MO

If relevant resistance testing data need to be recorded, please use the link below

Resistance Testing Page

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
[ ] CRREAS	[ ] CRDAT	[ ] CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	DIS24MO	Has the subject already discontinued the CAB+RPV L	DIS24MO	Category	3		N=No Y=Yes
3	REG24MO	Has all relevant regimen/discontinuat on data been	REG24MO	Category	3		N=No Y=Yes
4	Hotlink			Hotlink		visit:LAREG	
5	VL24MO	Has all relevant HIV RNA Viral Load data been ente	VL24MO	Category	3		N=No Y=Yes
6	Hotlink			Hotlink		visit:HIVRNA	
7	CD24MO	Has all relevant CD4 data been entered for this ti	CD24MO	Category	3		N=No Y=Yes
8	Hotlink			Hotlink		visit:CD4	
9	RES24MO	Has all relevant resistance testing data been ente	RES24MO	Category	3		N=No Y=Yes
10	Hotlink			Hotlink		visit:RESTST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
11	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
12	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
13	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

12 Months Post-Switch Follow-up

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID_D

Have all components of the subject's ARV regimen been recorded? ◯ No ◯ Yes SWARV12MO

If relevant ARV Regimen data need to be recorded, please use the link below

Antiretroviral Treatment Page

Has all relevant HIV RNA Viral Load data been entered for this time period? ◯ No ◯ Yes SWVL12MO

If relevant HIV RNA Viral Load data need to be recorded, please use the link below

HIV RNA Viral Load Page

Has all relevant CD4 data been entered for this time period? ◯ No ◯ Yes SWCD12MO

If relevant CD4 data need to be recorded, please use the link below

CD4 Count Page

Has all relevant resistance testing data been entered for this time period? ◯ No ◯ Yes SWRES12MO

If relevant resistance testing data need to be recorded, please use the link below

Resistance Testing Page

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
[ ] CRREAS	[ ] CRDAT	[ ] CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	SWARV12MO	Have all components of the subject's ARV regimen b	SWARV12MO	Category	3		N=No Y=Yes
3	Hotlink			Hotlink		visit:ART(First)	
4	SWVL12MO	Has all relevart HIV RNA Viral Load data been ente	SWVL12MO	Category	3		N=No Y=Yes
5	Hotlink			Hotlink		visit:HIVRNA	
6	SWCD12MO	Has all relevant CD4 data been entered for this ti	SWCD12MO	Category	3		N=No Y=Yes
7	Hotlink			Hotlink		visit:CD4	
8	SWRES12MO	Has all relevant resistance testing data been ente	SWRES12MO	Category	3		N=No Y=Yes
9	Hotlink			Hotlink		visit:RESIST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
10	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
11	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
12	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

24 Months Post-Switch Follow-up

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID_D

Have all components of the subject's ARV regimen been recorded? ◯ No ◯ Yes SWARV24MO

If relevant ARV Regimen data need to be recorded, please use the link below

Antiretroviral Treatment Page

Has all relevant HIV RNA Viral Load data been entered for this time period? ◯ No ◯ Yes SWVL24MO

If relevant HIV RNA Viral Load data need to be recorded, please use the link below

HIV RNA Viral Load Page

Has all relevant CD4 data been entered for this time period? ◯ No ◯ Yes SWCD24MO

If relevant CD4 data need to be recorded, please use the link below

CD4 Count Page

Has all relevant resistance testing data been entered for this time period? ◯ No ◯ Yes SWRES24MO

If relevant resistance testing data need to be recorded, please use the link below

Resistance Testing Page

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	SWARV24MO	Have all components of the subject's ARV regimen b	SWARV24MO	Category	3		N=No Y=Yes
3	Hotlink			Hotlink		visit:ART(First)	
4	SWVL24MO	Has all relevant HIV RNA Viral Load data been ente	SWVL24MO	Category	3		N=No Y=Yes
5	Hotlink			Hotlink		visit:HIVRNA	
6	SWCD24MO	Has all relevant CD4 data been entered for this ti	SWCD24MO	Category	3		N=No Y=Yes
7	Hotlink			Hotlink		visit:CD4	
8	SWRES24MO	Has all relevant resistance testing data been ente	SWRES24MO	Category	3		N=No Y=Yes
9	Hotlink			Hotlink		visit:RESIST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
10	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
11	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
12	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

36 Months Post-Switch Follow-up

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Have all components of the subject's ARV regimen been recorded? SWARV36MO
- ◯ No
- ◯ Yes

If relevant ARV Regimen data need to be recorded, please use the link below

Antiretroviral Treatment Page

Has all relevant HIV RNA Viral Load data been entered for this time period? SWVL36MO
- ◯ No
- ◯ Yes

If relevant HIV RNA Viral Load data need to be recorded, please use the link below

HIV RNA Viral Load Page

Has all relevant CD4 data been entered for this time period? SWCD36MO
- ◯ No
- ◯ Yes

If relevant CD4 data need to be recorded, please use the link below

CD4 Count Page

Has all relevant resistance testing data been entered for this time period? SWRES36MO
- ◯ No
- ◯ Yes

If relevant resistance testing data need to be recorded, please use the link below

Resistance Testing Page

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	SWARV36MO	Have all components of the subject's ARV regimen b	SWARV36MO	Category	3		N=No Y=Yes
3	Hotlink			Hotlink		visit:ART(First)	
4	SWVL36MO	Has all relevant HIV RNA Viral Load data been ente	SWVL36MO	Category	3		N=No Y=Yes
5	Hotlink			Hotlink		visit:HIVRNA	
6	SWCD36MO	Has all relevant CD4 data been entered for this ti	SWCD36MO	Category	3		N=No Y=Yes
7	Hotlink			Hotlink		visit:CD4	
8	SWRES36MO	Has all relevant resistance testing data been ente	SWRES36MO	Category	3		N=No Y=Yes
9	Hotlink			Hotlink		visit:RESIST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
10	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
11	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
12	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

48 Months Post-Switch Follow-up

RESEARCH ORGANISATION (KC) LTD

Subject ID [ ] SUBJID_D

Have all components of the subject's ARV regimen been recorded? ◯ No ◯ Yes SWARV48MO

If relevant ARV Regimen data need to be recorded, please use the link below

Antiretroviral Treatment Page

Has all relevant HIV RNA Viral Load data been entered for this time period? ◯ No ◯ Yes SWVL48MO

If relevant HIV RNA Viral Load data need to be recorded, please use the link below

HIV RNA Viral Load Page

Has all relevant CD4 data been entered for this time period? ◯ No ◯ Yes SWCD48MO

If relevant CD4 data need to be recorded, please use the link below

CD4 Count Page

Has all relevant resistance testing data been entered for this time period? ◯ No ◯ Yes SWRES48MO

If relevant resistance testing data need to be recorded, please use the link below

Resistance Testing Page

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	SWARV48MO	Have all components of the subject's ARV regimen b	SWARV48MO	Category	3		N=No Y=Yes
3	Hotlink			Hotlink		visit:ART(First)	
4	SWVL48MO	Has all relevart HIV RNA Viral Load data been ente	SWVL48MO	Category	3		N=No Y=Yes
5	Hotlink			Hotlink		visit:HIVRNA	
6	SWCD48MO	Has all relevant CD4 data been entered for this ti	SWCD48MO	Category	3		N=No Y=Yes
7	Hotlink			Hotlink		visit:CD4	
8	SWRES48MO	Has all relevant resistance testing data been ente	SWRES48MO	Category	3		N=No Y=Yes
9	Hotlink			Hotlink		visit:RESIST	
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
10	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
11	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
12	CRNOT	Notes for Next Revie	CRNOT	Text	500, Optional		

End of Study

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Did the subject complete the study? ○ No ○ Yes COMP_DSTERM

Date of completion/withdrawal COMP_DSDAT

If no, please select reason WITH_DSTERM

If other, please specify WITHREAS

Cause of death, if known WITH_COD

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Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

eForm Code: EOS eForm Title: End of Study - Annotations Table

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	COMP_DSTERM	Did the subject complete the study?	COMP_DSTERM	Category	3		N=No Y=Yes
3	COMP_DSDAT	Date of completion/withdraw	COMP_DSDAT	Date/Time	dd/mm/yyyy		
4	WITH_DSTERM	If no, please select reason	WITH_DSTERM	Category	59		See Appendix
5	WITHREAS	If other, please specify	WITHREAS	Text	200		
6	WITH_COD	Cause of death, if known	WITH_COD	Text	200		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
7	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
8	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
9	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

Sign Off

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Central Data Manager Sign Off

I confirm that the central data review for the above participant has been completed and all relevant queries have been raised and resolved in a satisfactory manner

◯ Yes DMSIGN

Central Data Manager sign-off date DMSIGNDAT

Principal Investigator Sign Off

The Investigator signature on this form should be obtained after ALL the Electronic Case Report Forms for this participant have been completed and the central data review has been completed

I have reviewed all the Case Report Forms for the above participant and agree that they are accurate and complete.

◯ Yes PISIGN

Principal Investigator sign-off date PISDAT

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Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	DMSIGN	I confirm that the central data review fo the abo	DMSIGN	Category	3		Y=Yes
3	DMSIGNDAT	Central Data Manager sign-off date	DMSIGNDAT	Date/Time	dd/mm/yyyy		
4	PISIGN	I have reviewed all the Case Report Forms for the	PISIGN	Category	3		Y=Yes
5	PISDAT	Principal Investigator sign-off date	PISDAT	Date/Time	dd/mm/yyyy		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
6	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
7	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
8	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

Source Data Upload

Subject ID SUBJID_D

Is There Source Data to Upload? UPYN

- ○ No
- ○ Yes

Name of Monitor Requesting Upload	Monitor Requested Upload Details	Date Upload Requested	Upload description	Upload Date	Data have been de-identified	Subject ID included in file
UPMONNAM	UPMONDET	UPMONDAT	UPDES	UPDAT	DEIDENT	WRITID

Upload document

Attach

Qdoc

For Office Use Only

Data Review Reason	Review Date	Notes for Next Review
CRREAS	CRDAT	CRNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10	BSL:DEMOG:SUBJID	
2	UPYN	Is There Source Data to Upload?	UPYN	Category	3		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
3	UPMONNAM	Name of Monitor Requesting Upload	UPMONNAM	Text	100		
4	UPMONDET	Monitor Requested Upload Details	UPMONDET	Text	500		
5	UPMONDAT	Date Upload Requested	UPMONDAT	Date/Time	dd/mm/yyyy		
6	UPDES	Upload description	UPDES	Text	100		
7	UPDAT	Upload Date	UPDAT	Date/Time	dd/mm/yyyy		
8	DEIDENT	Data have been de-identified	DEIDENT	Category	3		N=No Y=Yes
9	WRITID	Subject ID included in file	WRITID	Category	3		N=No Y=Yes
10	Qdoc	Upload document	Qdoc	Multimedia	0		
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
11	CRREAS	Data Review Reason	CRREAS	Category	36, Optional		See Appendix
12	CRDAT	Review Date	CRDAT	Date/Time	dd/mm/yyyy, Optional		
13	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		

Central Administration

RESEARCH ORGANISATION (KC) LTD

Subject ID SUBJID_D

Has central review process started? ○ No ○ Yes CRSTART

Central Review Start Date	Central Review Status	Central Review Completion Date	Notes for Next Review
CRSTDAT	CRSTAT	CRENDAT	CRNOT

Has full central review process been completed? ○ No ○ Yes CRCOMP

Overall Review Notes

CROVNOT

ID	CODE	NAME	EXP.CODE	TYPE	FMT/LEN	DERIVATION	CAT. VALUES
1	SUBJID_D	Subject ID	SUBJID_D	Text	10, Optional	BSL:DEMOG:SUBJID	
2	CRSTART	Has central review process started?	CRSTART	Category	3, Optional		N=No Y=Yes
Repeating Question Group: , Borders: Yes, RowStatus: Yes, RowNumbers: Yes, DisplayRows: 3, InitialRows: 1, Min Repeats: 1, Max Repeats: 20, Main Row Type: Single-Line, Sub Row Type: Multi-Line							
3	CRSTDAT	Central Review Start Date	CRSTDAT	Date/Time	dd/mm/yyyy, Optional		
4	CRSTAT	Central Review Status	CRSTAT	Category	45, Optional		See Appendix
5	CRENDAT	Central Review Completion Date	CRENDAT	Date/Time	dd/mm/yyyy, Optional		
6	CRNOT	Notes for Next Review	CRNOT	Text	500, Optional		
7	CRCOMP	Has full central review process been completed?	CRCOMP	Category	3, Optional		N=No Y=Yes
8	CROVNOT	Overall Review Notes	CROVNOT	Text	500, Optional		

CODE	NAME	TYPE	EXPRESSION
ADEFEVENT	AIDS-Defining Event	Category Values	1=Candidiasis of bronchi, trachea, or lungs 2=Candidiasis, oesophageal 3=Cervical cancer, invasive 4=Coccidioidomycosis, disseminated or extrapulmonary 5=Cryptococcosis, extrapulmonary 6=Cryptosporidiosis, chronic intestinal (greater than 1 month's duration) 7=Cytomegalovirus disease (other than liver, spleen, or nodes) 8=Cytomegalovirus retinitis (with loss of vision) 9=Encephalopathy, HIV-related 10=Herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis 11=Histoplasmosis, disseminated or extrapulmonary 12=Isosporiasis, chronic intestinal (greater than 1 month's duration) 13=Kaposi's sarcoma 14=Lymphoma, Burkitt's (or equivalent term) 15=Lymphoma, immunoblastic (or equivalent term) 16=Lymphoma, primary, of brain 17=Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary 18=Mycobacterium tuberculosis, any site (pulmonary or extrapulmonary) 19=Mycobacterium, other species or unidentified species, disseminated or extrapulmonary 20=Pneumocystis carinii pneumonia 21=Pneumonia, recurrent 22=Progressive multifocal leukoencephalopathy 23=Salmonella septicemia, recurrent 24=Toxoplasmosis of brain 25=Wasting syndrome due to HIV
ANTDRUG	Drug Name	Category Values	1=Abacavir 2=Didanosine 3=Efavirenz 4=Lamivudine 5=Lamivudine + Zidovudine 6=Nelfinavir 7=Nevirapine 8=Ritonavir 9=Saquinavir 10=Saquinavir mesylate 11=Satvudine 12=Zalcitabine 13=Zidovudine 14=Amprenavir 15=Indinavir 16=Delavirdine mesylate 17=Lopinavir + Ritonavir 18=Abacavir + Lamivudine + Zidovudine 19=Tenofovir disoproxil fumarate 20=Adefovir dipivoxil 21=Enfuvirtide 22=Atazanavir 23=Emtricitabine 24=Fosamprenavir calcium 25=Abacavir + Lamivudine 26=Tenofovir disoproxil fumarate + Emtricitabine 27=Entecavir 28=Tipranavir 29=Efavirenz+Tenofovir disoproxil fumarate+Emtricitabine 30=Telbivudine 31=Darunavir 32=Raltegravir 33=Maraviroc 34=Etravirine 35=Rilpivirine 36=Rilpivirine+Emtricitabine+Tenofovir disoproxil fumarate 37=Elvitegravir+Cobicistat+Emtricitabine+Tenofovir disoproxil fumarate 38=Dolutegravir 39=Elvitegravir 40=Cobicistat 41=Abacavir+Dolutegravir+Lamivudine 42=Darunavir+Cobicistat 43=Atazanavir+Cobicistat 44=Lamivudine+Raltegravir 45=Elvitegravir+Cobicistat+Emtricitabine+Tenofovir alafenamide 46=Rilpivirine+Emtricitabine+Tenofovir alafenamide 47=Emtricitabine+Tenofovir alafenamide 48=Tenofovir alafenamide 49=Dolutegravir+ Rilpivirine 50=Efavirenz+Lamivudine+Tenofovir disoproxil fumarate 51=Lamivudine+Tenofovir disoproxil fumarate 52=Bictegravir+Emtricitabine+Tenofovir alafenamide 53=Doravirine 54=Doravirine+Lamivudine+Tenofovir disoproxil fumarate 55=Dolutegravir+Lamivudine+Tenofovir disoproxil fumarate 56=Dolutegravir+Lamivudine 57=Darunavir+Cobicistat+Emtricitabine+Tenofovir alafenaminde 58=Fostemsavir 59=Cabotegravir 60=Rilpivirine 61=Other regimen not listed above
ANTSTREAS	Reason for Stopping	Category Values	1=Virological Failure 2=Adverse Event 3=Drug Interaction 4=Clinical Trial Enrolment 5=Patient's Decision 6=Other
CMRSDISC	Please Specify Reason for Discontinuation	Category Values	R1=Treatment failure (i.e. virological, immunological, and/or clinical failure R1_1=Virological failure R1_2=Partial virological failure (multiple blips, low level viraemia) R1_3=Immunological failure - CD4 drop (25% or more) R1_4=Clinical progression R1_5=Resistance (based on test result) R2=Abnormal fat redistribution R3=Concern of cardiovascular disease R3_1=Dyslipidaemia R3_2=Cardiovascular disease R3_3=Weight gain R4=Hypersensitivity reaction (skin eruption etc.) R5=Toxicity, predominantly from abdomen/G-I tract R5_1=Toxicity - Liver R5_2=Toxicity - Pancreas R6=Toxicity, predominantly from nervous system R6_1=Toxicity - peripheral neuropathy R6_2=Toxicity - neuropsychiatric R6_3=Toxicity - headache R7=Toxicity, predominantly from kidneys R8=Toxicity, predominantly from endocrine system R8_1=Diabetes R9=Haematological toxicity (anemia etc.) R10=Hyperlactataemie/lactic acidosis R11=Bone toxicity R12=Social contra-indication R13=Contra-indication unspecified R14=Pregnancy - toxicity concerns (during pregnancy) R15=Pregnancy - switch to a more appropriate regimen for PMTCT R16=Death R17=Toxicity, unspecified R18=Availability of more effective treatment (not specifically failure or side effect related) R18_1=Simplified treatment available R18_2=Treatment too complex R19=Drug interaction R19_1=Drug interaction - commencing TB/BCG treatment R20=Injection fatigue (not related to safety) R21=Injection Site Reaction R22=Non-adherence R23=Drug not available R24=Other causes, not specified above R25=Lost to follow-up R26=Defaulter R27=Individual's wish/decision, not specified above R28=Physician decision to discontinue due to confirmed low level viremia (50-200) R29=Physician's decision, not specified above R99=Unknown
CMTRT	Medication	Category Values	1=Etravirine 2=Carbamazapine 3=Oxcarbazepine 4=Phenytoin 5=Phenobarbital 6=Rifampicin 7=Rifapentine 8=Rifabutin 9=Ethinyl estradiol and Levonorgestrel 10=Norethindrone 11=Ribavirin 12=Ketoconazole 13=Fluconazole 14=Itraconazole 15=Posaconazole 16=Voriconazole 17=Clarithromycin 18=Erythromycin 19=Dexamethasone 20=Methadone 21=Digoxin 22=Metformin 23=Paracetamol 24=Atorvastatin 25=Sildenafil 26=Vardenafil 27=Tadalafil
CRREAS	Data Review Reason	Category Values	1=Scheduled monitoring activity 2=Unscheduled monitoring activity 3=Scheduled data management activity 4=Unscheduled data management activity 5=Other
CRSTAT	Central Review Status	Category Values	1=Central Review For Interim Analysis Started 2=Central Review for Interim Analysis Completed

CODE	NAME	TYPE	EXPRESSION
ETHNIC	Ethnicity	Category Values	A=White European B=White and Black Caribbean C=White and Black African D=White and Asian E=Any Other Mixed Background F=Indian G=Pakistani H=Bangladeshi I=Any other Asian background J=Black Caribbean K=Black African L=Any other Black background M=Chinese N=Any other ethnic group Z=Not stated
MHESLD_SP	Please specify condition	Category Values	1=Hepatocellular carcinoma 2=Ascites 3=Hepatorenal syndrome 4=Grade III/IV hepatic encephalopathy 5=Unspecified liver decompensation 6=Oesophageal variceal bleeding 7=Spontaneous bacterial peritonitis 8=Liver transplantation
SUBJID	Subject ID	Derivation	substring(person:trialsite, 3, 3) & case((person:personid < 10 , '00'), (person:personid < 100 , '0'), (else , '')) & person:personid
WITH_DSTER	If no, please select reason	Category Values	1=Subject withdrew consent 2=Subject died 3=Subject lost to follow-up 4=Subject withdrawn for behavioural or administrative reasons 5=Withdrawal due to adverse event/serious adverse event 6=Subject did not meet Inclusion/Exclusion criteria 7=Virologicial Failure 8=Issues with Concomitant Medication 9=Other