Clinical trial results:
A Phase IIIb, open-label, hybrid type III trial evaluating implementation strategies for long-acting cabotegravir plus long-acting rilpivirine every two months in HIV-1 infected, virologically suppressed adults in select European healthcare settings

Summary

EudraCT number	2020-000424-19
Trial protocol	FR DE NL BE
Global end of trial date	

Results information

Result version number	v1
This version publication date	28 March 2023
First version publication date	28 March 2023

Trial information

Trial identification

Sponsor protocol code	213199

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04399551
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great WestRoad, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GSK ResponseCenter, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	07 March 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 March 2022
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate acceptability, appropriateness, and feasibility of long-acting cabotegravir plus long-acting rilpivirine on the basis of staff study participants ratings.

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 September 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 71
Country: Number of subjects enrolled	France: 177
Country: Number of subjects enrolled	Germany: 54
Country: Number of subjects enrolled	Netherlands: 39
Country: Number of subjects enrolled	Spain: 96
Worldwide total number of subjects	437
EEA total number of subjects	437

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	427
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 437 patient study participants (PSPs) [people living with HIV] were enrolled. 430 PSP received study treatment and were included in the safety population. Staff Study Participants (SSP) (HIV care providers, nurses/staff performing injections administrators/clinic managers) are not counted in the enrolment.

Pre-assignment

Screening details:

SSP were randomized based on implementation strategy - Enhanced (Arm-E) and Standard (Arm -S). SSP provided input through surveys, semi-structured interviews and a selected group from the enhanced arm (Arm-E) participated in facilitation calls.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Patient Study Participants

Arm description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Arm type	Experimental
Investigational medicinal product name	CAB OLI
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral cabotegravir (CAB) was administered as a 30 milligram (mg) tablet, taken once daily with food from Day 1 to Month 1.

Investigational medicinal product name	RPV OLI
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral rilpivirine (RPV) was administered as a 25 mg tablet, taken once daily with food from Day 1 to Month 1.

Investigational medicinal product name	RPV LA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Long-acting rilpivirine (RPV LA) 900 mg (3 mL) was administered via intramuscular injection by a healthcare professional.

Investigational medicinal product name	CAB LA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Long-acting cabotegravir (CAB LA) 600 mg (3 mL) was administered via intramuscular injection by a healthcare professional.

Number of subjects in period 1[1]	Patient Study Participants
Started	430
Completed	306
Not completed	124
Consent withdrawn by subject	6
Physician decision	3
Adverse event, non-fatal	12
Protocol Deviation	2
Ongoing	100
Lost to follow-up	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: A total of 437 participants were enrolled and 430 participants received study treatment and were included in the safety population.

Baseline characteristics

Reporting groups

Reporting group title	Patient Study Participants

Reporting group description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Reporting group values	Patient Study Participants	Total	
Number of subjects	430	430	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	420	420	
From 65-84 years	10	10	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	44.2		
standard deviation	± 10.13	-	
Sex: Female, Male Units: Participants			
Female	115	115	
Male	315	315	
Race/Ethnicity, Customized Units: Subjects			
American Indian Or Alaska Native	7	7	
Asian	9	9	
Black Or African American	76	76	
White	336	336	
Multiple	2	2	

Subject analysis sets

Subject analysis set title	Staff Study Participants – Enhanced Implementation Arm
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, SWAT meeting with sponsor team and principal clinic stakeholders, on-demand SWAT meeting, monthly

continuous quality improvement (CQI) calls, face-to-face injection training, monthly FRAME assessment, access to patient and HCP level toolkit and CAB + RPV medical lead site visit.

Subject analysis set title	Staff Study Participants – Standard Implementation Arm
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.

Subject analysis set title	Staff Study Participants (SSP)
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

Subject analysis set title	Staff Study Participants
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

Subject analysis set title	Staff Study Participants – Standard Implementation Arm
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.

Subject analysis set title	Staff Study Participants (SSP)
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Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

Subject analysis set title	Patient Study Participants (PSPs)
Subject analysis set type	Full analysis

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Subject analysis set title	Patient Study Participants (PSPs)
Subject analysis set type	Safety analysis

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Reporting group values	Staff Study Participants – Enhanced Implementation Arm	Staff Study Participants – Standard Implementation Arm	Staff Study Participants (SSP)
Number of subjects	34	36	62
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units: Participants			
Female Male			
Race/Ethnicity, Customized Units: Subjects			
American Indian Or Alaska Native Asian Black Or African American White Multiple			

Reporting group values	Staff Study Participants	Staff Study Participants – Standard Implementation Arm	Staff Study Participants (SSP)
Number of subjects	69	35	18
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			

Age Continuous			
Units: Years			
arithmetic mean			23
standard deviation	±	±	±
Sex: Female, Male			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Units: Subjects			
American Indian Or Alaska Native			
Asian			
Black Or African American			
White			
Multiple			

Reporting group values	Patient Study Participants (PSPs)	Patient Study Participants (PSPs)	
Number of subjects	110	430	
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Years			
arithmetic mean		93	
standard deviation	±	±	
Sex: Female, Male			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Units: Subjects			
American Indian Or Alaska Native			
Asian			
Black Or African American			
White			
Multiple			

End points

End points reporting groups

Reporting group title	Patient Study Participants

Reporting group description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Subject analysis set title	Staff Study Participants – Enhanced Implementation Arm
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, SWAT meeting with sponsor team and principal clinic stakeholders, on-demand SWAT meeting, monthly continuous quality improvement (CQI) calls, face-to-face injection training, monthly FRAME assessment, access to patient and HCP level toolkit and CAB + RPV medical lead site visit.

Subject analysis set title	Staff Study Participants – Standard Implementation Arm
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.

Subject analysis set title	Staff Study Participants (SSP)
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

Subject analysis set title	Staff Study Participants
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

Subject analysis set title	Staff Study Participants – Standard Implementation Arm
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.

Subject analysis set title	Staff Study Participants (SSP)
Subject analysis set type	Full analysis

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

Subject analysis set title	Patient Study Participants (PSPs)
Subject analysis set type	Full analysis

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Subject analysis set title	Patient Study Participants (PSPs)
Subject analysis set type	Safety analysis

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Primary: Change from Baseline in Acceptability of Implementation Measure (AIM-Imp) Score in SSP at Month 12

End point title	Change from Baseline in Acceptability of Implementation Measure (AIM-Imp) Score in SSP at Month 12[1]

End point description:

The AIM-Imp was designed to assess the acceptability of an implementation process (i.e., perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory). The measure consists of four items/statements (1. The implementation support thus far meets my approval 2. The implementation support thus far is appealing to me 3. I like the implementation support I have received 4. I welcome implementation support for the CAB + RPV injection treatment), each with a five-point rating scale (1=completely disagree,2=disagree,3=neither agree nor disagree,4=agree,5=completely agree). The mean score ranges from 1 to 5 with 1 indicating the least acceptability and 5 the most acceptability. Analysis was performed on Full analysis set (FAS), which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Baseline (Month 1) and Month 12

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants – Enhanced Implementation Arm	Staff Study Participants – Standard Implementation Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	36		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline (Month 1)	3.8 (± 0.76)	3.9 (± 0.75)		
Month 12	0.28 (± 0.828)	0.33 (± 0.666)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Implementation Appropriateness Measure (IAM-

Imp) Score in SSPs at Month 12

End point title	Change from Baseline in Implementation Appropriateness Measure (IAM-Imp) Score in SSPs at Month 12[2]

End point description:

The IAM-Imp is designed to assess the appropriateness of an implementation process (i.e., the perceived fit, relevance, or compatibility of the innovation for a given practice setting, provider, or consumer, and the perceived fit of the innovation to address a particular issue or problem). The IAM-Imp is a four-item/statement measure (1. The implementation support thus far seems fitting 2. The implementation support seems suitable for using the CAB + RPV injection treatment 3. The implementation support seems applicable for the CAB + RPV injection treatment 4. The implementation support seems like a good match) with a five-point rating scale (1=completely disagree, 2=disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = completely agree). The mean score ranges from 1 to 5 with 1 indicating the least appropriateness and 5 the most appropriateness. Analysis was performed on FAS population.

End point type	Primary

End point timeframe:

Baseline (Month 1) and Month 12

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants – Enhanced Implementation Arm	Staff Study Participants – Standard Implementation Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	36		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline (Month 1)	3.8 (± 0.78)	3.9 (± 0.78)		
Month 12	0.22 (± 0.740)	0.31 (± 0.729)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Feasibility of Implementation Measure (FIM-Imp) Score at Month 12

End point title	Change from Baseline in Feasibility of Implementation Measure (FIM-Imp) Score at Month 12[3]

End point description:

The FIM-Imp was a four-item/statement (1. The implementation support seems implementable in our clinic/practice 2. The implementation support seems possible in our clinic/practice 3. The implementation support seems doable in our clinic/practice 4. The implementation support seems easy to use in our clinic/practice) and was measured on a five-point rating scale (1 = completely disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = completely agree). The mean score ranges from 1 to 5 with 1 indicating the least feasibility and 5 the most feasibility.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Baseline (Month 1) and Month 12

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants – Enhanced Implementation Arm	Staff Study Participants – Standard Implementation Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	36		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline (Month 1)	4.0 (± 0.66)	4.0 (± 0.64)		
Month 12	0.06 (± 1.047)	0.34 (± 0.773)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Staff Study Participants that discussed Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs)

End point title	Number of Staff Study Participants that discussed Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs)[4]

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the acceptability from the SSPs' perspective. The results for facilitators that are integral to successful implementation are presented. Patient Perspective was abbreviated as [PP]. Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Up to 12 Months

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: Participants				
Positive opinion	56			
Treatment and Implementation better than expected	18			
Patient satisfaction	30			

[PP] Not worrying about taking medication	14			
Discreet treatment	11			
[PP] Not being reminded about HIV	11			
Patient travel facilitation	10			
Patient adherence	8			
Innovative treatment	8			
Medication efficacy	8			
[PP] Gaining a sense of freedom/liberation	6			
[PP]Not having to take treatment every day	6			
New treatment option	6			
Patient quality of life improvement	6			
No resistance to implementing CAB+RPV LA	27			
Administration in Other Clinical Setting	6			
Home Administration by HCP-Patient Interest	16			
Self-injection-Patient interest	12			
Information on medication characteristics	8			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Staff Study Participants that discussed Barriers for Acceptability Assessed via SSIs

End point title	Number of Staff Study Participants that discussed Barriers for Acceptability Assessed via SSIs[5]

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the acceptability from the SSPs' perspective. The results for barriers that are integral to successful implementation are presented.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Up to 12 Months

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: Participants				
Medication tolerability and side effects	29			
Injection side effects	6			
Home Administration by HCP-No patient interest	9			
Self-injection-Injection site	7			
Self-injection-Adherence	6			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Staff Study Participants that discussed Facilitators for Appropriateness Assessed via SSIs

End point title	Number of Staff Study Participants that discussed Facilitators for Appropriateness Assessed via SSIs[6]

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the appropriateness from the SSPs' perspective. The results for facilitators that are integral to successful implementation are presented.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Up to 12 Months

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: Participants				
Not being reminded of HIV status	15			
Discreet treatment	14			
Sense of freedom/liberation	10			
Travel facilitation	10			
No need to think/worry about pills	9			
Adherent patients	30			
No particular patient profile	13			
Patients non-adherent to oral medication	13			

Patients seeking discreet treatment	10			
Patients with non-resistant HIV	10			
Patients seeking to change oral treatment	8			
Young patients	8			
Frequently travelling patients	6			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Staff Study Participants that discussed Facilitators for Feasibility Assessed via SSIs

End point title	Number of Staff Study Participants that discussed Facilitators for Feasibility Assessed via SSIs[7]

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the feasibility from the SSPs' perspective. The results for facilitators that are integral to successful implementation are presented.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Up to 12 Months

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: Participants				
Medication delivery from pharmacy	15			
Additional staff	13			
Room and/or space	13			
Training	11			
Responsibilities and/or multitasking	10			
Specific time and/or day for injection visits	9			
Scheduling strategies	8			
Additional refrigerator	7			
Clinic hours	7			
Non-covid Oral bridging	7			
Staff characteristics	14			
No supplemental materials Developed	11			
Supplemental materials Developed	8			

No staffing and workload issues in the past	19			
No current staffing and workload issues	13			
No issues designated space availability	34			
No current issues with space availability	7			
No coordination with pharmacy issues in the past	40			
No issues with medication supply	31			
No current issues with medication supply	7			
No issues with clinic working hours in the past	41			
ViiV supportive in implementation	55			
Administration in General Practitioner office	13			
Administration in healthcare centers	11			
Administration in private practice	6			
Injection training	10			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Staff Study Participants that discussed Barriers for Appropriateness Assessed via SSIs

End point title	Number of Staff Study Participants that discussed Barriers for Appropriateness Assessed via SSIs[8]

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the appropriateness from the SSPs' perspective. The results for barriers that are integral to successful implementation are presented.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Up to 12 Months

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: Participants	7			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Staff Study Participants that discussed Barriers for Feasibility Assessed via SSIs

End point title	Number of Staff Study Participants that discussed Barriers for Feasibility Assessed via SSIs[9]

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the feasibility from the SSPs' perspective. The results for barriers that are integral to successful implementation are presented.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Primary

End point timeframe:

Up to 12 Months

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: Participants				
Staffing and workload issues	15			
Appointment duration	15			
Appointment scheduling	9			
Number of visits	7			
Room and/or space issues	6			
Staffing and workload issues in the past	32			
Current staffing and workload issues	11			
Issues with space availability in the past	20			
Current issues with space availability	12			
Coordination with pharmacy issues in the past	13			
Current coordination with pharmacy issues	6			
Issues with supply and storage in the past	12			
Issues with clinic working hours in the past	6			
Medication collection, cold chain, and storage	6			
Injection technique	21			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Modifications Reported by SSPs Assessed via FRAME-IS

End point title	Number of Modifications Reported by SSPs Assessed via FRAME-IS

End point description:

The Framework for Reporting Adaptations and Modifications to Evidence-based interventions – Implementation Strategies (FRAME-IS) was a seven-question measure (contained both open and closed categorical questions) used to record details the modifications made to the implementation of the CAB LA + RPV LA injection treatment procedures.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12

End point values	Staff Study Participants – Enhanced Implementation Arm	Staff Study Participants – Standard Implementation Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	35		
Units: Number of Modifications				
Month 2	15	7		
Month 3	10	2		
Month 4	5	2		
Month 5	1	1		
Month 6	3	0		
Month 7	4	0		
Month 8	0	0		
Month 9	3	0		
Month 10	0	0		
Month 11	3	1		
Month 12	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Plan, Do, Study, Act (PDSA) Cycles Developed During the Continuous Quality Improvement (CQI) Calls Course

End point title	Number of Plan, Do, Study, Act (PDSA) Cycles Developed During the Continuous Quality Improvement (CQI) Calls Course

End point description:

CQI were a 60 minutes calls involved working through a plan to address the identified barriers, optimize processes, and evaluate these efforts. This process of addressing barriers was guided by a series of Plan, Do, Study, Act (PDSA) cycles. Number of PDSA cycles developed are presented.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at

least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 2 to Month 7

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: Cycles	23			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Spending Average Time in the Clinic/Practice for Each Injection Visit Assessed via Questionnaire

End point title	Number of Participants Spending Average Time in the Clinic/Practice for Each Injection Visit Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The average time was categorized as: Up to 20 Minutes, Up to 40 Minutes, Up to 60 Minutes, Up to 90 Minutes, More than 90 Minutes and missing. Missing include participants who did not provide a response for the question. Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Up to Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Up to 20 Minutes	71			
Up to 40 Minutes	134			
Up to 60 Minutes	99			
Up to 90 Minutes	48			
More than 90 Minutes	19			
Missing	8			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Spending Average Time in an Exam Room Waiting for a Nurse (or Other Healthcare Provider) to Get the Injection Administered Assessed via Questionnaire

End point title	Number of Participants Spending Average Time in an Exam Room Waiting for a Nurse (or Other Healthcare Provider) to Get the Injection Administered Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The average time was categorized as: Up to 10 Minutes, 11-20 Minutes, 21-30 Minutes, 31-45 Minutes, More than 45 Minutes and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Up to 10 Minutes	190			
11-20 Minutes	100			
21-30 Minutes	54			
31-45 Minutes	25			
More than 45 Minutes	5			
Missing	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with the Acceptability with the Amount of Time Spent in The Clinic/Practice for Each Injection Visit Assessed via Questionnaire

End point title	Number of Participants with the Acceptability with the Amount of Time Spent in The Clinic/Practice for Each Injection Visit Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The acceptability was categorized as extremely acceptable, very acceptable, somewhat acceptable, a little acceptable, not at all acceptable and missing. Missing include participants who did not provide a response for the question. Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Extremely acceptable	140			
Very acceptable	151			
Somewhat acceptable	72			
A little acceptable	11			
Not at all acceptable	0			
Missing	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Acceptability to Come to the Clinic/Practice Every 2 Months for the Injection Visit Assessed via Questionnaire

End point title	Number of Participants with Acceptability to Come to the Clinic/Practice Every 2 Months for the Injection Visit Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The acceptability was categorized as extremely acceptable, very acceptable, somewhat acceptable, a little acceptable, not at all acceptable and missing. Missing include participants who did not provide a response for the question. Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Extremely acceptable	163			
Very acceptable	154			
Somewhat acceptable	51			
A little acceptable	6			
Not at all acceptable	0			
Missing	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Taking Time Off from Work to Attend Appointment Assessed via Questionnaire

End point title	Number of Participants Taking Time Off from Work to Attend Appointment Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The time off responses were categorized as Whole day annual leave, Half day annual leave, Whole day sick leave, Half day sick leave, Whole day unpaid, Half day unpaid, Other, No time off and missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Whole day annual leave	27			
Half day annual leave	20			
Whole day sick leave	5			
Half day sick leave	3			
Whole day unpaid	9			
Half day unpaid	20			
Other	64			
No, I did not have to take time off	222			
Missing	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who Seek Additional Care from a Dependent to Attend Appointment Assessed via Questionnaire

End point title	Number of Participants who Seek Additional Care from a Dependent to Attend Appointment Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Yes, No, Not Applicable and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Yes	16			
No	318			
Not Applicable	39			
Missing	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Taking Time Off from Work to Recover from any Injection Site Reaction Issue Assessed via Questionnaire

End point title	Number of Participants Taking Time Off from Work to Recover from any Injection Site Reaction Issue Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The time off responses were categorized as No, On the day of receiving the treatment, One day after receiving the treatment, Two days after receiving the treatment, More than two days after receiving the treatment, Missing

response for Yes, Not Applicable and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
No	294			
Yes, on the day of receiving the treatment	45			
Yes, one day after receiving the treatment	9			
Yes, two days after receiving the treatment	7			
Yes, more than two days receiving the treatment	5			
Missing response for 'Yes'	2			
Not Applicable	16			
Missing	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Appointment Reminders Received Assessed via Questionnaire

End point title	Number of Participants with Appointment Reminders Received Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question.The responses were categorized as Phone calls, Text/SMS messages, Existing clinic app, E-mail, Reminder in the mail, Another reminder and I did not receive reminders.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Phone calls	80			
Text/SMS messages	275			
Existing clinic app	48			
E-mail	161			
Reminder in the mail	21			
Another reminder	3			
I did not receive reminders	14			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Things Tried to Reduce Soreness Following Injections Assessed via Questionnaire

End point title	Number of Participants with Things Tried to Reduce Soreness Following Injections Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Take over-the-counter pain relievers, Use a hot compress, Use a cold compress, Avoid sitting for long periods of time, Light stretching and exercise, None of the above, Other and I don't get sore after my injections.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Take over-the-counter pain relievers	139			
Use a hot compress	20			
Use a cold compress	19			
Avoid sitting for long periods of time	87			
Light stretching and exercise	71			
None of the above	61			
Other	31			
I don't get sore after my injections	72			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs with Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs)

End point title	Number of PSPs with Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs)

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with facilitators for acceptability are presented.
Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Up to Month 12

End point values	Patient Study Participants (PSPs)			
Subject group type	Subject analysis set			
Number of subjects analysed	110			
Units: Participants				
Feeling informed about injection	105			
Overall positive experience	100			
Acceptable overall experience at clinic	82			
In-person communication with HCP	76			
Not worrying about taking medication	66			
Experienced injector	64			
Acceptable clinic hours to receive injections	51			
injection experience met expectations	43			
Patient travel facilitation	33			
injection experience better than expected	32			
Staff responsiveness	34			
Number of visits	30			
Satisfaction with rescheduling process	29			
Distance to clinic	27			
Not being reminded about HIV	26			
Acceptable time spent in clinic	25			
Treatment adherence	24			
Gaining a sense of freedom	24			

Discreet treatment	23			
Communication with staff	22			
Reduced stigma due to injection	22			
Reduction in injection pain	20			
PP Medication for pain management	19			
Reduced stress due to injection	19			
HCP advice on pain management	18			
PP Activities to avoid for pain management	16			
Website and/or internet	15			
Characteristics of HCP communication	14			
Written materials and brochures	14			
Study materials	14			
Time of informing	13			
Collection, storage and preparation	12			
Fewer side effects	12			
Time-saving approach	12			
Activities for injection pain management	11			
Administration in other clinical setting	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs with Barriers for Acceptability Assessed via SSIs

End point title	Number of PSPs with Barriers for Acceptability Assessed via SSIs

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with barriers for acceptability are presented.
Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Up to Month 12

End point values	Patient Study Participants (PSPs)			
Subject group type	Subject analysis set			
Number of subjects analysed	110			
Units: Participants				
Injection side effects (Treatment Components)	67			
Injection side effects (Treatment Challenges)	33			

Injection experience worse than expected	11			
Waiting time	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs with Barriers for Appropriateness Assessed via SSIs

End point title	Number of PSPs with Barriers for Appropriateness Assessed via SSIs

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with barriers for appropriateness are presented.
Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Up to Month 12

End point values	Patient Study Participants (PSPs)			
Subject group type	Subject analysis set			
Number of subjects analysed	110			
Units: Participants				
Patient fearing or squeamish about injections	22			
Patients not tolerating intramuscular injection	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs with Facilitators for Appropriateness Assessed via SSIs

End point title	Number of PSPs with Facilitators for Appropriateness Assessed via SSIs

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with Facilitators for appropriateness are presented.
Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Up to Month 12

End point values	Patient Study Participants (PSPs)			
Subject group type	Subject analysis set			
Number of subjects analysed	110			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs with Facilitators for Feasibility Assessed via SSIs

End point title	Number of PSPs with Facilitators for Feasibility Assessed via SSIs

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with facilitators for feasibility are presented.
Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Up to Month 12

End point values	Patient Study Participants (PSPs)			
Subject group type	Subject analysis set			
Number of subjects analysed	110			
Units: Participants				
Person to contact during CARISEL study	102			
PP Calendar, Diary, Notes and/or Reminders	69			
No missed appointment and rescheduling	65			
Target date explained	57			
Easy to contact	57			
Contacting clinic staff during CARISEL study	52			
Home administration by HCP	41			
No issues due to transportation and/or parking	37			

No challenges to receive injection	33			
Not contacting clinic staff during CARISEL study	31			
No issues due to work	28			
Clinic Reminder [all types]	27			
Term of target date helpful	25			
[PP] Setting reminders	23			
Injection administration at GP office	22			
Injection administration at healthcare centers	19			
No issues to attend visits due to childcare	16			
[PP] Arrangements at work	16			
Clinic reminder: Text and/or SMS	14			
[PP] Appointment scheduling strategies	14			
No issues due to clinic hours	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs with Barriers for Feasibility Assessed via SSIs

End point title	Number of PSPs with Barriers for Feasibility Assessed via SSIs

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with barriers for feasibility are presented.
Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Up to Month 12

End point values	Patient Study Participants (PSPs)			
Subject group type	Subject analysis set			
Number of subjects analysed	110			
Units: Participants				
Target date not explained	38			
Missed appointment and/or rescheduling	23			
Issues due to work	21			
Issues due to transportation and/or parking	14			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in The Acceptability of Intervention Measure (AIM) Score in PSPs at Month 12

End point title	Change from Baseline in The Acceptability of Intervention Measure (AIM) Score in PSPs at Month 12

End point description:

AIM assesses the acceptability of an intervention (i.e., perception among stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory). It is a four-item (1. The CAB+RPV injection treatment meets my approval for treating my HIV, 2. The CAB+RPV injection treatment is appealing to me, 3. I like the CAB+RPV injection treatment for my HIV, 4. I welcome the CAB+RPV injection treatment for my HIV) measure with a five-point rating scale, where 1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=completely agree. The mean score ranges from 1 to 5 with 1 indicating the least acceptability and 5 the most acceptability.
Analysis was performed on patient study participants (PSPs) who completed the surveys at the relevant timepoints. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Month 1) and Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	424			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline (Month 1)	4.55 (± 0.666)			
Month 12	0.10 (± 0.834)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Feasibility of Intervention Measure (FIM) Score in PSPs at Month 12

End point title	Change from Baseline in Feasibility of Intervention Measure (FIM) Score in PSPs at Month 12

End point description:

The four-item (1. The CAB+RPV injection treatment seems implementable in my life 2. The CAB+RPV injection treatment every 2 months is possible for me to use 3. The CAB+RPV injection treatment every 2 months seems doable in my life 4. The CAB+RPV injection treatment every 2 months seems easy to use in my life). FIM assesses perceived intervention feasibility. The items are measured on a five-point rating scale, where 1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=completely agree. The mean score ranges from 1 to 5 with 1 indicating the least feasibility and 5 the most feasibility.
Analysis was performed on patient study participants (PSPs) who completed the surveys at the relevant timepoints. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Month 1) and Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	424			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline (Month 1)	4.51 (± 0.672)			
Month 12	0.07 (± 0.857)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Confirmed Virologic Failure (CVF) Over Time

End point title	Number of Participants with Confirmed Virologic Failure (CVF) Over Time

End point description:

CVF was defined as rebound as indicated by two consecutive plasma HIV-1 RNA levels >=200 c/ml. Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

End point type	Secondary

End point timeframe:

Month 1, 2, 4, 8, 10 and 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	430			
Units: Participants				
Month 1	0			
Month 2	0			
Month 4	0			
Month 6	0			
Month 8	0			
Month 10	1			
Month 12	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of PSP Receiving Injections within Target Window

End point title	Percentage of PSP Receiving Injections within Target Window

End point description:

The target window for participants to receive injection was from Day -7 to Day 7.
Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

End point type	Secondary

End point timeframe:

Day -7 to Day 7

End point values	Patient Study Participants (PSPs)			
Subject group type	Subject analysis set			
Number of subjects analysed	430			
Units: Percentage of Participants	93			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs with Adverse Events (AEs) And Serious AEs (SAEs)

End point title	Number of PSPs with Adverse Events (AEs) And Serious AEs (SAEs)

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. An SAE is defined as any untoward medical occurrence that, at any dose may result in death or is life-threatening or requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity or is a congenital anomaly/birth defect or any other situation according to medical or scientific judgment or is associated with liver injury and impaired liver function.
Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

End point type	Secondary

End point timeframe:

Up to 12 Months

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	430			
Units: Participants				
Any AEs	420			
Any SAEs	15			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSPs Discontinuing Treatment Due to AEs

End point title	Number of PSPs Discontinuing Treatment Due to AEs

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention.
Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

End point type	Secondary

End point timeframe:

Up to 12 Months

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	430			
Units: Participants	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Implementation Leadership Scale (ILS) Score at Month 12

End point title	Change from Baseline in Implementation Leadership Scale (ILS) Score at Month 12

End point description:

The ILS is a 12-item (facilitate implementation, obstacles, clear department standards, knowledge, ability to answer questions, awareness of concept, recognition, support employee efforts to learn, support employee efforts to use intervention, persevere(s) through the ups and downs, carries on through the challenges and reaction to critical issues) measure that assesses SSP understanding of the degree to which leadership in their clinic/practice setting is proactive, knowledgeable, supportive, perseverant with regards to implementing the treatment in their settings. The items are measured on a five-point rating scale (1=very great extent,2=great extent,3=moderate extent,4=slight extent,5=not at all). The mean score ranges from 1 to 5. Higher the score means less understanding in leadership.
Analysis was performed on FAS, which included all SSPs who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed

End point type	Secondary

End point timeframe:

Baseline (Month 1) and Month 12

End point values	Staff Study Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline (Month 1)	2.1 (± 0.85)			
Month 12	-0.1 (± 1.19)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Implementation Climate Scale (ICS) Scores at Month 1 and Month 12

End point title	Absolute Values of Implementation Climate Scale (ICS) Scores at Month 1 and Month 12

End point description:

The ICS is a 9 item (team's main goals, importance of implementation, top priority, workshops, treatment training, training material, staff adaptability, flexibility, openness to new intervention) measure that assesses SSPs' perceptions of their team (i.e., the people that they work with) while using the CAB LA + RPV LA injection treatment in their clinic/practice setting. The items were measured on a five-point rating scale (1 = very great extent, 2 = great extent, 3 = moderate extent, 4 = slight extent, and 5 = not at all). The mean score ranges from 1 to 5. Higher the score means less seriousness for implementation in staff.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 1 and Month 12

End point values	Staff Study Participants – Enhanced Implementation Arm	Staff Study Participants – Standard Implementation Arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	35		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Month 1	2.5 (± 0.65)	2.8 (± 0.80)		
Month 12	2.7 (± 0.72)	2.6 (± 0.80)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Time it took them to Get to the Clinic where they receive HIV Treatment/Check-ups Assessed via Questionnaire

End point title	Number of Participants with Time it took them to Get to the Clinic where they receive HIV Treatment/Check-ups Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The average time was categorized as Up to 15 minutes, 16-30 minutes, 31-45 minutes, 46-60 minutes, More than 60 minutes, and missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Up to 15 minutes	66			
16-30 minutes	138			
31-45 minutes	87			
46-60 minutes	44			
More than 60 minutes	39			
Missing	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants that endorsed type of transportation used to attend appointments

End point title	Number of participants that endorsed type of transportation used to attend appointments

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The means of transport were categorized as Transportation service, Dropped-off, Private vehicle, Bicycle/scooter/ skateboard/ walked, Public transport and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:
Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Taxi-Transportation service	13			
Taxi- Public transport	10			
Dropped-off	12			
Private vehicle	164			
Bicycle/ scooter/ skateboard/ walked	49			
Public transport	138			
Missing	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Rating Convenience of Clinic/Practice's Procedures for Scheduling Injections Assessed via Questionnaire

End point title	Number of Participants Rating Convenience of Clinic/Practice's Procedures for Scheduling Injections Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The convenience responses were categorized as Extremely convenient, Very convenient, Somewhat convenient, A little convenient, Not at all convenient, Not applicable; I did not have to schedule and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:
Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Extremely convenient	175			
Very convenient	154			
Somewhat convenient	43			
A little convenient	4			

Not at all convenient	0			
Not applicable; I did not have to schedule	0			
Missing	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Rating Convenience of Clinic/Practice's Procedures for Rescheduling Injections Assessed via Questionnaire

End point title	Number of Participants Rating Convenience of Clinic/Practice's Procedures for Rescheduling Injections Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The convenience responses were categorized as Extremely convenient, Very convenient, Somewhat convenient, A little convenient, Not at all convenient, Not applicable; I did not have to reschedule and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Extremely convenient	158			
Very convenient	153			
Somewhat convenient	25			
A little convenient	2			
Not at all convenient	0			
Not applicable; I did not have to schedule	39			
Missing	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Rating Feelings About Getting CAB+RPV Injection Treatment Assessed via Questionnaire

End point title	Number of Participants Rating Feelings About Getting CAB+RPV

	Injection Treatment Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Extremely positive, Very positive, Somewhat positive, A little positive, Not at all positive and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Extremely positive	234			
Very positive	112			
Somewhat positive	23			
A little positive	4			
Not at all positive	0			
Missing	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants that Rated Perceived Knowledge about CAB+RPV Injection Treatment Assessed via Questionnaire

End point title	Number of Participants that Rated Perceived Knowledge about CAB+RPV Injection Treatment Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Extremely knowledgeable, Very knowledgeable, Somewhat knowledgeable, A little knowledgeable, Not at all knowledgeable and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Extremely knowledgeable	124			
Very knowledgeable	188			
Somewhat knowledgeable	57			
A little knowledgeable	6			
Not at all knowledgeable	0			
Missing	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who rated helpfulness of Appointment outside of Typical Work Times Assessed via Questionnaire

End point title	Number of Participants who rated helpfulness of Appointment outside of Typical Work Times Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Extremely helpful, Very helpful, Somewhat helpful, A Little helpful, Not at all helpful and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Extremely helpful	135			
Very helpful	123			
Somewhat helpful	50			
A Little helpful	38			
Not at all helpful	28			
Missing	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants that Rated Agreement in Recommending the CAB+RPV Injections to Others Assessed via Questionnaire

End point title	Number of Participants that Rated Agreement in Recommending the CAB+RPV Injections to Others Assessed via Questionnaire

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Completely agree, Agree, Neutral, Disagree, Completely disagree and Missing. Missing include participants who did not provide a response for the question.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Completely agree	283			
Agree	75			
Neutral	15			
Disagree	1			
Completely disagree	1			
Missing	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Intervention Appropriateness Measure (IAM) Score in PSPs at Month 12

End point title	Change from Baseline in Intervention Appropriateness Measure (IAM) Score in PSPs at Month 12

End point description:

IAM assesses the appropriateness of an intervention (i.e., the perceived fit, relevance, or compatibility of the innovation for a given practice setting, provider, or consumer; and the perceived fit of the innovation to address a particular issue or problem). It is a four-item (1.The CAB+RPV injection treatment is fitting for my life, 2.The CAB+RPV injection treatment is suitable for my life, 3.The CAB+RPV injection treatment is applicable to my life, 4.The CAB+RPV injection treatment is a good match for my life) measure with a 5-point rating scale, where 1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=completely agree. The mean score ranges from 1 to 5 with 1 indicating the least appropriateness and 5 the most appropriateness.
Analysis was performed on PSPs, which included all participants who successfully completed the survey at the relevant timepoints. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:
Baseline (Month 1) and Month 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	423			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline (Month 1)	4.47 (± 0.762)			
Month 12	0.13 (± 0.928)			

Statistical analyses

No statistical analyses for this end point

Secondary: Associated Person Clinical Sustainability Assessment Tool (APCSAT) Total Score at Month 12

End point title	Associated Person Clinical Sustainability Assessment Tool (APCSAT) Total Score at Month 12

End point description:

The APCSAT is a 35-item measure that assesses SSP impressions of the data in their clinic. Sustainability refers to the ability to maintain and expand the CAB LA + RPV LA injection treatment and its benefits over time. SSPs were asked to rate their clinic/practice along a range of specific factors that affect sustainability, including: 'Engages Staff & Leadership,' 'Engaging Stakeholders,' 'Monitoring and Evaluation,' 'Implementation & Training,' 'Outcomes & Effectiveness,' 'Workflow Integration,' and 'Organizational Readiness.' Five items were presented to SSPs in each domain. The total score for the APCSAT was assessed on a scale of 1=program has sustainability to no extent to 7=program has sustainability to the full extent.
Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:
Month 12

End point values	Staff Study Participants (SSP)			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: Scores on a scale				
number (not applicable)	5.32			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of PSPs With Plasma HIV-1 Ribonucleic Acid (RNA) Less Than (<)50 Copies Per Milliliter (C/ml)

End point title	Percentage of PSPs With Plasma HIV-1 Ribonucleic Acid (RNA) Less Than (<)50 Copies Per Milliliter (C/ml)

End point description:

Plasma samples were collected from the participant at specific time points. Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

End point type	Secondary

End point timeframe:

Month 1, 2, 4, 8 and 12

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	430			
Units: Percentage of Participants				
number (confidence interval 95%)				
Month 1	99 (97.0 to 99.5)			
Month 2	96 (93.7 to 97.7)			
Month 4	93 (90.5 to 95.4)			
Month 8	86 (82.7 to 89.4)			
Month 12	87 (83.2 to 89.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of PSP with Preference for Therapy Assessed via Preference Questionnaire

End point title	Number of PSP with Preference for Therapy Assessed via Preference Questionnaire

End point description:

PSPs were asked to think about their experience of using the long-acting injectable medication versus the daily oral HIV medication, and to select their preferred treatment and all the reasons that support their preference. Results are categorized as: 'long-acting injectable HIV medication', 'daily oral HIV medication', 'no preference', Missing and Erroneous. Missing include participants who did not provide a response for the question. PSPs who completed this question incorrectly (i.e., checked reasons without a ticking a leading preference or checked more than one leading preference box) were included in Erroneous.
Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:
Up to 12 Months

End point values	Patient Study Participants			
Subject group type	Reporting group			
Number of subjects analysed	379			
Units: Participants				
Daily oral HIV medication	2			
Long-acting injectable HIV medication	275			
No preference	0			
Missing	2			
Erroneous	100			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs), non-serious AEs and all-cause mortality were collected up to Month 12. Data collection is still on-going and additional results will be provided after study completion.

Adverse event reporting additional description:

Adverse events were reported for safety population which comprised of all participants enrolled and who received at least 1 dose of CAB LA+RPV LA. Staff Study Participants (SSP) did not receive oral lead-in medication or CAB+RPV LA injections. Adverse events for SSP were not collected because it was not required per study design.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	.23.1

Reporting groups

Reporting group title	Patient Study Participants

Reporting group description:

Participants with HIV received one tablet of Cabotegravir (CAB) 30 milligrams (mg) + Rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

Serious adverse events	Patient Study Participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 430 (3.49%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Subdural haemorrhage			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Vascular disorders			
Aortic dissection			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Orthostatic intolerance			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Appendicitis noninfective			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Haematospermia			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Pneumothorax			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Major depression			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Yersinia infection			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			

subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	1 / 430 (0.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Patient Study Participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	380 / 430 (88.37%)		
Nervous system disorders			
Headache			
subjects affected / exposed	36 / 430 (8.37%)		
occurrences (all)	45		
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	342 / 430 (79.53%)		
occurrences (all)	1533		
Injection site induration			
subjects affected / exposed	43 / 430 (10.00%)		
occurrences (all)	74		
Injection site discomfort			
subjects affected / exposed	38 / 430 (8.84%)		
occurrences (all)	94		
Pyrexia			
subjects affected / exposed	37 / 430 (8.60%)		
occurrences (all)	48		
Injection site nodule			
subjects affected / exposed	32 / 430 (7.44%)		
occurrences (all)	57		
Injection site swelling			

subjects affected / exposed	27 / 430 (6.28%)		
occurrences (all)	38		
Asthenia			
subjects affected / exposed	25 / 430 (5.81%)		
occurrences (all)	29		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	27 / 430 (6.28%)		
occurrences (all)	32		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	33 / 430 (7.67%)		
occurrences (all)	33		
Infections and infestations			
COVID-19			
subjects affected / exposed	68 / 430 (15.81%)		
occurrences (all)	72		
Nasopharyngitis			
subjects affected / exposed	25 / 430 (5.81%)		
occurrences (all)	25		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 December 2020	Changes were made to correct discrepancies in the document and to update the statistical section based on Ethics Committee requirement.
01 July 2021	To allow participants who become pregnant while in the study to remain in the study and not be withdrawn due to pregnancy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported