Statistical Analysis Plan

Study ID: 214747

Official Title of Study: A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in U.S. community-based infusion centers or other alternate sites of administration

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A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or other Alternative Sites of Administration

Statistical Analysis Plan for Clinical Analyses

EVA-30466 | October 05, 2023 | Version 1.0

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Statistical Analysis Plan (SAP) Signature Page

SAP Title: A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or other alternate sites of administration. Statistical Analysis Plan for Clinical Analyses.

SAP Date and Version: October 05 2023; Version 1.0

This SAP with the title, number, and version indicated above has been reviewed and approved by the Evidera Principal Investigators and Project Managers.

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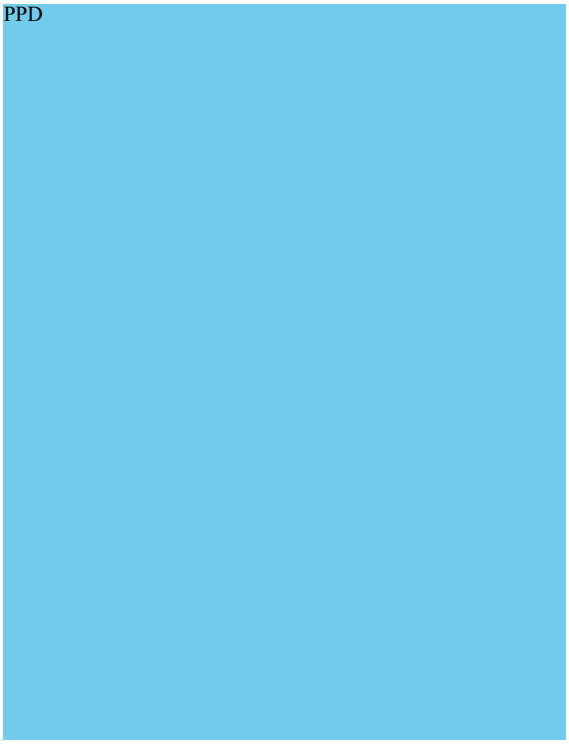

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List of Abbreviations

Abbreviation	Definition
ADR	Adverse drug reaction
AE	Adverse event
ALP	Alkaline phosphatase
ALT	Alanine aminotransferase
ART	Antiretroviral therapy
ASA	Alternative site of administration
AST	Aspartate aminotransferase
BMI	Body mass index
CAB	CABENUVA
CI	Confidence interval
DBL	Database lock
ECG	Electrocardiogram
eCRF	Electronic case report form
HIV	Human immunodeficiency virus
IC	Infusion center
ICF	Informed consent form
IM	Intramuscular
IQR	Interquartile range
MedDRA	Medical Dictionary for Regulatory Activities
PLWHIV	People living with human immunodeficiency virus
POT	Plan of treatment
PT	Preferred term
Q1M	Once monthly
Q2M	Once every -2 -months
RNA	Ribonucleic acid
RPV	EDURANT
SAE	Serious adverse event
SAP	Statistical analysis plan
SD	Standard deviation
SGOT	Serum glutamic-oxaloacetic transaminase
SGPT	Serum glutamic-pyruvic transaminase
SoA	Schedule of activities
SOC	System organ class
SRM	Study reference manual
ULN	Upper limit of normal
USPI	United States prescribing information

1 Introduction

CABENUVA is a two-drug, co-packaged product of cabotegravir plus rilpivirine, both administered as long-acting, intramuscular (IM) injections once every month or once every 2 months. CABENUVA is an approved treatment for human immunodeficiency virus (HIV). Clinical trial results have shown that CABENUVA, administered once monthly or once every 2-months, is a non-inferior alternative to the daily oral treatment for HIV.

Long-acting injectable treatments require changes in how HIV care is delivered. People living with human immunodeficiency virus (PLWHIV) need to attend appointments once a month or once every 2 months for their injections, increasing office visits over their normal monitoring visits. This poses new healthcare delivery challenges, including a shift in resources to this alternative means of delivering and receiving treatment—thus requiring the expansion of alternative injection facilities to include infusion centers (ICs) or other alternative sites of administration (ASAs). This has the potential to increase the workload for these facilities; however, it also has the potential to positively impact treatment engagement and retention for PLWHIV.

ICs/ASAs are an appealing option that will help ease the burden of additional appointments, administrative work, and drug ordering in HIV specialty clinics, as well as provide greater flexibility to PLWHIV in deciding where they receive their monthly or every-2-monthly injections. In this study, the intervention itself is the process of using an IC/ASA as the location to receive the CABENUVA IM injections.

The scope of this statistical analysis plan (SAP) is to examine the safety and effectiveness of CABENUVA IM injections in real-world settings through ICs/ASAs. This SAP details the planned analyses for the tertiary objectives that are related to the safety and effectiveness of CABENUVA, as outlined in Table 1 in Section 3. It implements the study's clinical objectives and endpoints and specifies the needed summary tables and other statistical results of the lab tests, other clinical metrics, CABENUVA-related adverse events (AEs), all AEs leading to participant discontinuation, all cardiovascular events, COVID-19 related, and all serious AEs (SAEs). Two analysis sets will be used for the study analyses: the Enrolled Set and the Safety Set. The Enrolled Set will include all participants who provided a signed informed consent form (ICF), met the eligibility criteria, and were enrolled in the study. The Safety Set will consist of all participants in the Enrolled Set who received at least one on-study CABENUVA injection(s).

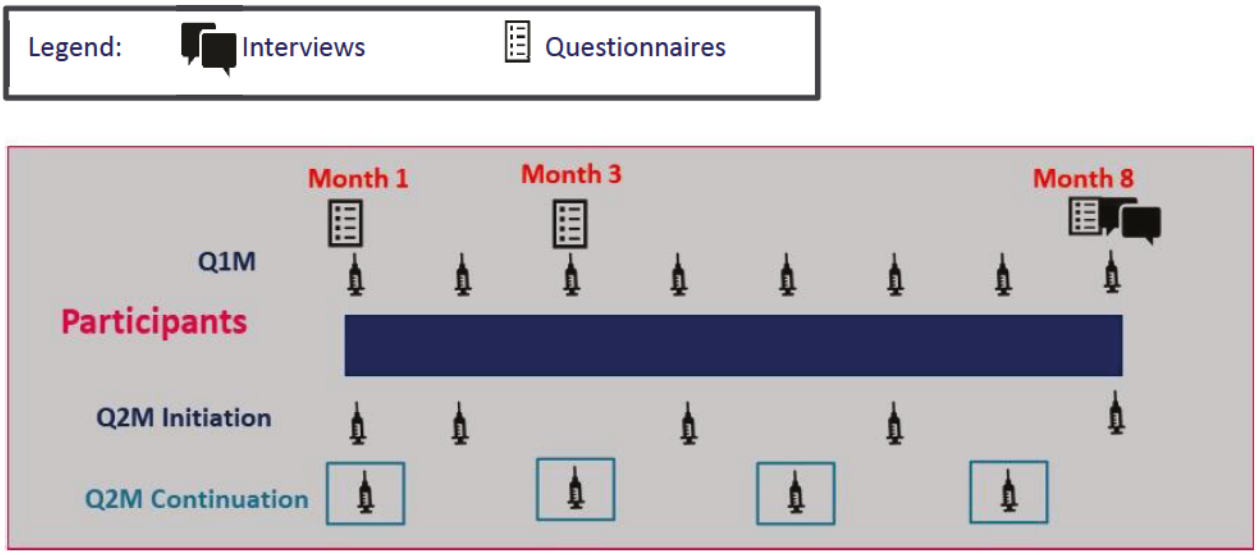
2 Study Design

This is a phase 4, single-arm, open-label, multicenter study examining the administration of CABENUVA IM in ICs/ASAs across the US. This study is being conducted following FDA approval and commercial availability of CABENUVA in the US.

This study will include no more than 120 eligible and consenting participants to receive monthly injections or every-2-monthly injections of CABENUVA for HIV-1 treatment at ICs/ASAs. The total study duration for each participant is approximately 8 months, from the time of their enrollment and receipt of the first

study-related administration of CABENUVA IM injections at the IC/ASA. For a detailed Schedule of Activities (SoA), refer to Appendix 7.1. CABENUVA dosing adherence is described in the US prescribing information (USPI) if CABENUVA injections were missed.

Figure 1. Study Design Schematic



Participant assessments are completed based on Month regardless of monthly (Q1M) vs. every-2-monthly (Q2M) dosing.
Note: Study design may not include all potential patterns of dosing.

2.1 Study Population

The study aims to recruit no more than 120 participants who have been prescribed CABENUVA by their HIV care provider. During their first visit to the IC/ASA, after signing an ICF, participants will complete baseline assessments to confirm participant eligibility and then receive their Month 1 injections. In subsequent months, participants are medically managed by their HIV care providers and receive their once-a-month or every-2-months injections at the IC/ASA.

Over time, participant treatment discontinuation as well as missed injections are expected. PLWHIV are allowed in the study if they have been prescribed CABENUVA per the USPI and meet all eligibility criteria (Section 2.1.1) at the Baseline/Month 1 visit. Participants who sign the ICF and meet all eligibility criteria will enter the study.

If a participant plans to miss the injections by more than 7 days, in consultation with the HIV care provider, oral CABENUVA plus EDURANT (CAB + RPV) or other antiretroviral therapy (ART) regimens should be taken daily to replace up to two consecutive planned missed monthly injection visits or every-2-month injection visit-doses. Dosing of oral bridging in the event of missed doses will be in accordance with the most recent CABENUVA USPI.

In consultation with the HIV care provider, participants may switch from monthly injections to an every-2-month continuation injection schedule, or from a 2-month continuation injection schedule to a monthly continuation dosing schedule. When switching dosing regimens, all instructions outlined in the most current USPI will be followed. The total duration for study participants is approximately 8 months from

the time of enrollment and receipt of the first study-related administration of CABENUVA IM injections at the IC/ASA. A participant is considered to have completed the study if they have finished all Month 8 assessments.

2.1.1 Eligibility Criteria

The eligibility criteria below are the most current as of the writing of the SAP.

2.1.1.1 Inclusion Criteria

Age

1. Adults (≥18 years old) at the time of signing the ICF

Type of Participant and Disease Characteristics

2. PLWHIV-1, prescribed CABNEUVA per the USPI. Participants can be enrolled:

- If they have been taking oral CAB + RPV or other ART for approximately 1 month (at least 28 days) prior to Baseline/Month 1, or
- Already taking CABENUVA prior to Baseline/Month 1 and the last injections were within a 1-month ± 7-day window, or for every-2-month injections, the timing will vary depending on when they are receiving the initiation injections (1 month ± 7 days) or the continuation injections (2 months ± 7 days) per the USPI, or
- Prescribed direct to inject and receive their first injection without an oral lead-in at the IC/ASA on the last day of any other ART

Informed Consent

3. Capable of giving signed informed consent as described in the protocol, which includes compliance with the requirements and restrictions listed in the ICF and in the protocol.

Other

4. Agree to receive CABENUVA IM injections at participating ICs/ASAs.

2.1.1.2 Exclusion Criteria

Participants may be excluded from the study, in consultation with the HIV care provider, based on information from the most current CABENUVA USPI at the time of study enrollment.

Contraindications, as per the current CABENUVA USPI

- Previous hypersensitivity reaction to cabotegravir or rilpivirine
- Contraindicated co-administered drugs:
  - Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
  - Antimycobacterials: rifabutin, rifampin, rifapentine
  - Glucocorticoid (systemic): dexamethasone (more than a single-dose treatment)
  - Herbal product: St John's wort (Hypericum perforatum)

New health condition / prohibited medication reported

- After discussion with the referring HIV care provider, a decision may be made not to enter participant into the study

Other reason at the discretion of the HIV care provider or IC/ASA staff

3 Objectives and Endpoints

The scope of this SAP is limited to the clinical objectives and endpoints related to the safety and effectiveness of CABENUVA as set forth in the protocol (see Table 1).

Table 1. Clinical Objectives and Endpoints

Clinical Objectives	Endpoints
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3.1 Primary Objectives

The primary objectives are beyond the scope of this clinical SAP. Three additional implementation research SAPs are planned and will cover the primary objectives, one each for participant type (participants living with HIV, healthcare providers and expert panel members, and infusion center staff).

3.2 Secondary Objectives

The secondary objectives are beyond the scope of this clinical SAP. Three additional implementation research SAPs are planned and will cover the secondary objectives, one each for participant type (participants living with HIV, healthcare providers and expert panel members, and infusion center staff).

3.3 Tertiary Objectives

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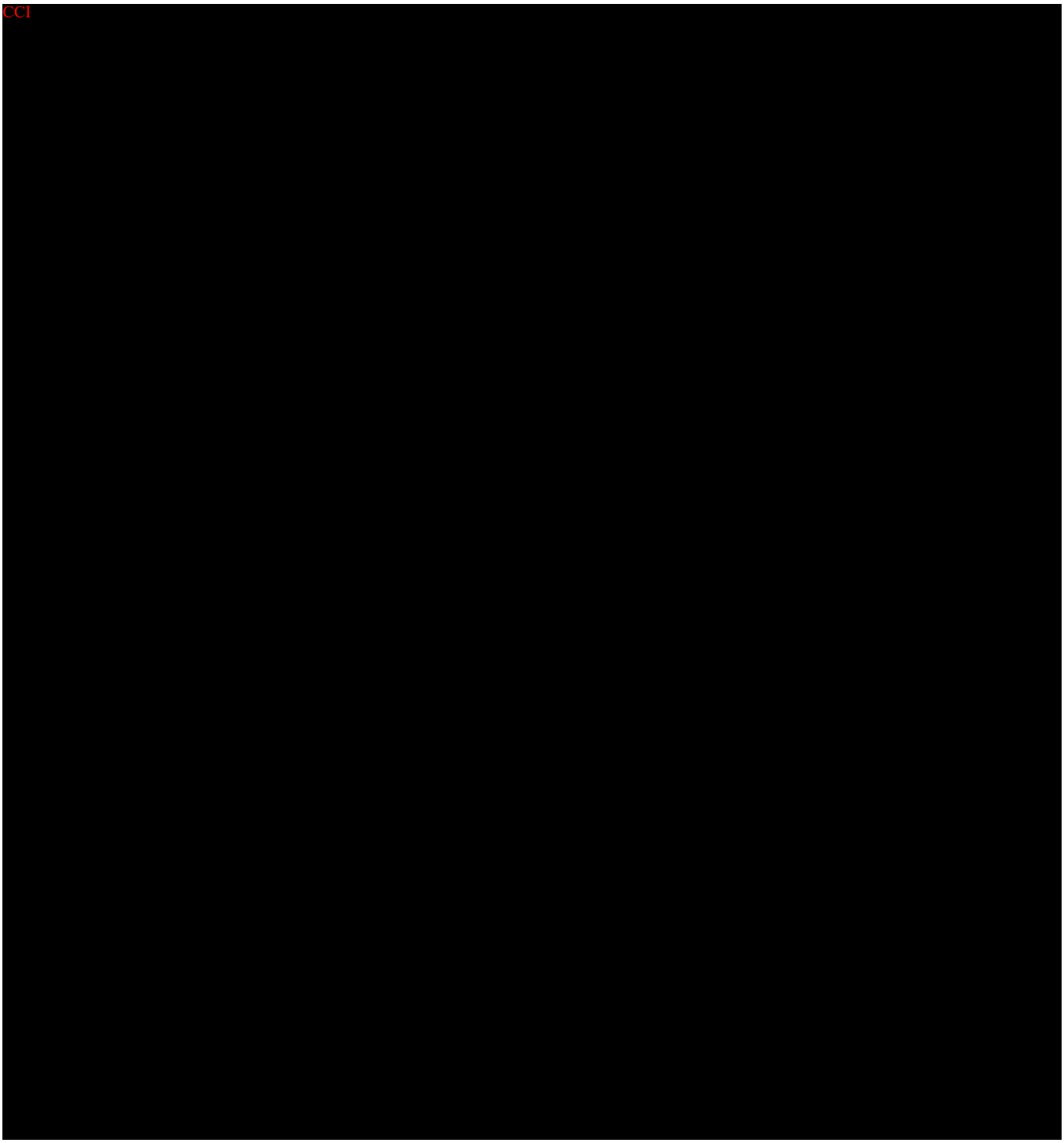

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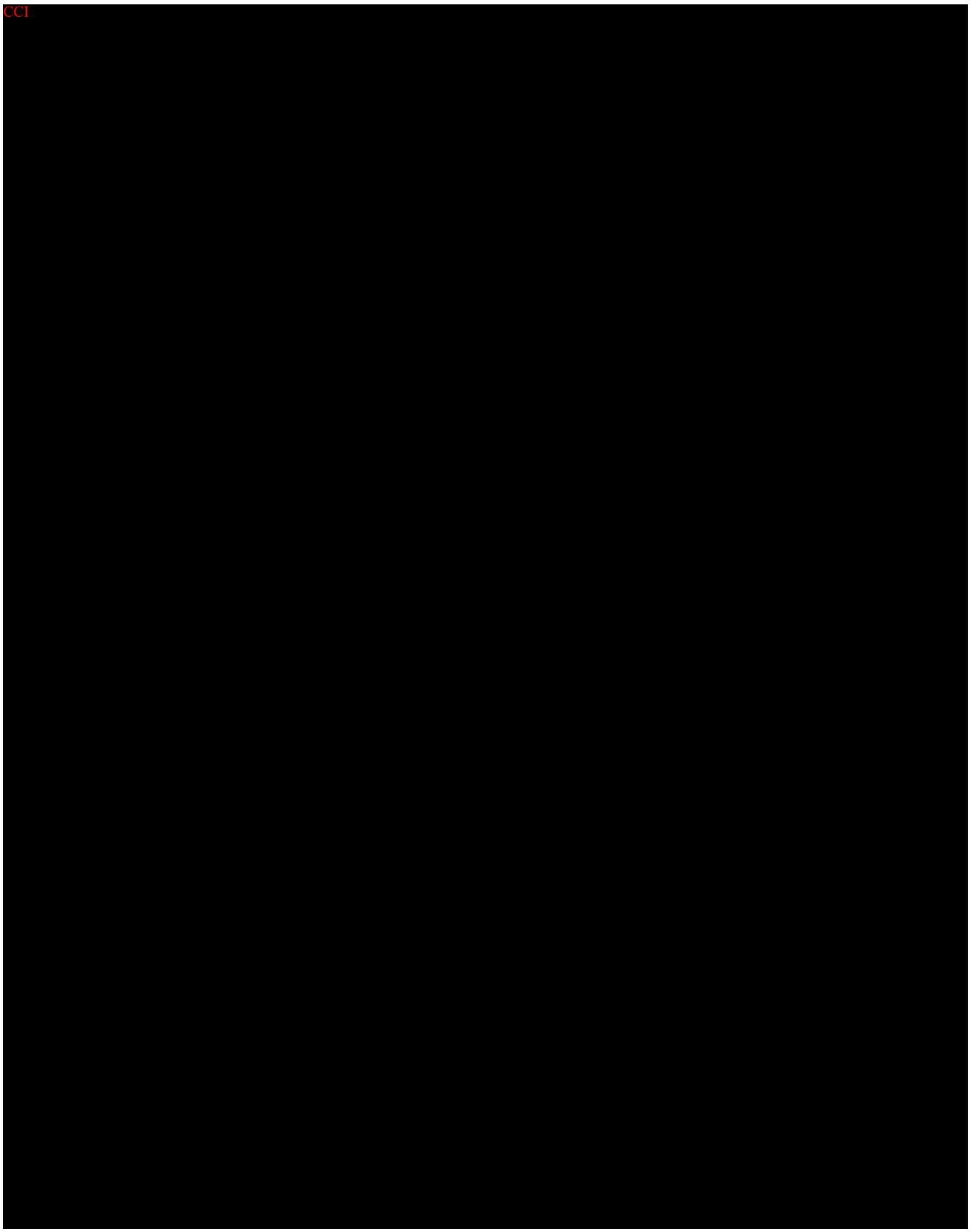

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4 Statistical Methods

4.1 General Statistical Considerations

Data will be analyzed on the nominal scheduled visits as recorded in the eCRF. Visit windowing will be used as required.

4.1.1 Descriptive Summary Statistics

If the number of non-missing observations is zero (i.e., n=0), then only n is displayed, no other statistics. Two-sided 95% confidence intervals (CIs) will be provided using normal approximation. But when normal approximation is deemed to be inappropriate, exact methods will be used instead.

4.1.1.1 Categorical Data

Tabulations for categorical data will be displayed in the form n (%) with non-zero percentages enclosed with parentheses.

The number of distinct participants with non-missing observations (n) at all levels of categories will be presented. If no participants are reported for a particular level of a category, n will be presented as zero. If for all levels of a category, data are missing for at least one participant, a "Missing" category level will be presented.

Percentages (%) will be presented when there is at least one non-missing observation. Percentages will not be presented for the "Missing" category level. Percentages >99.9% will be displayed as 100%; in other cases, they will be rounded to and displayed with one decimal place. Generally, the denominator for percentages will be the number of participants in the analysis group of interest for the specified analysis set. Other denominators will be described in a footnote when applicable.

4.1.1.2 Continuous Data

The following summary statistics will be reported for continuous data:

- n: number of distinct participants with non-missing observations
- Mean (standard deviation [SD]): arithmetic mean, SD)
- Median
- Interquartile range (IQR; i.e., 25th percentile [Q1] - 75th percentile [Q3])
- Min, Max: minimum, maximum

If n=1, SD will be displayed as "N/A" (i.e., not applicable) and CIs as "NE" (i.e., not estimable). SD will be rounded and displayed with two more decimal places than the reported value. All mean, median, Q1, and Q3 values will be rounded and displayed to one more decimal place than the reported value. CI values will be rounded and displayed to one more decimal place than the parameter estimate. Min and max values will be displayed consistent with the number of decimal places in the reported value.

4.1.2 Baseline Definition

Baseline will be defined as the date when a participant signs the ICF and completes the Baseline/Month 1 protocol procedures prior to receiving the first study-related CABENUVA injections at the IC/ASA.

All additional study visits will be anchored from each participant's Baseline/Month 1 visit, and will therefore reflect the months on study, regardless of what injection schedule they are on and regardless of whether they have missed any injections and received oral bridging.

Change from baseline will be calculated as the difference between the baseline and post-baseline values, which have the same number of decimal places. Percent change from baseline will be calculated by dividing change from baseline by non-zero baseline value, rounded and reported to one decimal place.

4.1.3 Missing Data Handling

For the purposes of classifying medications/therapies as prior or concomitant, or for AEs as pre-treatment, on-treatment, or post-treatment, incomplete dates may be imputed.

Details for handing missing AE relatedness, severity, seriousness, etc. are discussed in Section 4.7.1.1.

No other missing data will be imputed.

4.1.3.1 Imputation of Incomplete Dates

4.1.3.1.1 General Dates, including Start/Stop Dates of Concomitant Medications/Therapies

A partial event start date, or partial start dates of prior and concomitant medications/therapies, will be assumed to be the earliest possible date consistent with the partial date.

- If the day is missing, it will be assumed to be the first day of the month
- If the month is missing, it will be assumed to be January
- If the entire date is missing, assume exposure prior to dosing start and date will not be imputed

If the month and the year of the start date is the same month and year of the CABENUVA treatment start date, then the following imputation rules apply:

- If the stop date contains a full date and is earlier than the CABENUVA treatment start date, then the set start date = 1st of month
- Else, the set start date = the CABENUVA treatment start date

If the year of the start date is the same year of the CABENUVA treatment start date, then the following imputation rules apply:

- If the stop date contains a full date and is earlier than the CABENUVA treatment start date, then the set start date = January 1
- Else, the set start date = the CABENUVA treatment start date

Partial event or medication/therapy stop dates will be assumed to be the latest possible date consistent with the partial date.

- If the day is missing, it will be assumed to be the last day of the month
- If the month is missing, it will be assumed to be December
- If the entire date is missing, there will be no imputation

Note that if the concomitant medications/therapies end date is present, the imputed onset date will always be on or prior to the end date.

4.1.3.1.2 Onset and End Dates of Adverse Event

Incomplete AE onset and end dates will be imputed, respectively, as the earliest and latest possible date consistent with the partial date and assigned treatment period (pre-study, pre-treatment or on-treatment), where:

- Pre-study: The onset of the AE is on or after the CABENUVA treatment start date, but prior to enrollment in the study
- Post-enrollment, pre-treatment: The onset of the AE is prior to the on-study CABENUVA treatment start date

- Post-enrollment, on-treatment: The onset of the AE is on or after the on-study CABENUVA treatment start date

If the event start day is missing, assume the first day of the month. If the month or entire start date are missing, assume the event occurred on January 1 if the year of the start date is not the year of the CABENUVA treatment start. If the year of the start date is the year of CABENUVA treatment start, then the following imputation rules apply:

- If the stop date contains a full date and is earlier than the CABENUVA treatment start date, then the set start date = January 1
- Else, the set start date = the CABENUVA treatment start date

If the event end day is missing, assume the last day of the month. If the month or entire end date are missing, there will be no imputation.

Events that that begin on or after the date of on-study CABENUVA treatment initiation will be considered treatment-emergent events.

Note that if the AE end date is present, the imputed onset date will always be on or prior to the end date.

4.1.4 Power and Sample Size

The study sample size of up to 120 participants is based on the primary objective "To evaluate feasibility of CABENUVA administration at infusion centers/ASAs from participants" with an endpoint defined as "the proportion of participants that agree or completely agree (a score of 4 or higher) across all items on the Feasibility of Intervention Measure (FIM) at Month 8". Sample size calculations were not powered to evaluate clinical or safety outcomes.

4.2 Analysis Sets

4.2.1 Enrolled Set

"Enrolled" participants will include PLWHIV-1 who have agreed to participate in this clinical study, following the completion of the informed consent process, and have met the baseline eligibility criteria. If required, a legally acceptable representative may provide the participant's agreement to participate in the clinical study and sign the ICF.

The Enrolled Set will include all participants who provided a signed ICF, met the eligibility criteria, and were enrolled in the study. Some participants may meet the eligibility criteria but may not be enrolled for other reasons.

4.2.2 Safety Set

The Safety Set will consist of all participants in the Enrolled Set who received at least one on-study CABENUVA injection(s).

4.3 Disposition

4.3.1 Study Disposition

The study disposition will be summarized as the number and percentage of participants in each analysis set (i.e., Enrolled Set and Safety Set):

- Screen failed, and reason(s) such as:
  - AE
  - Did not meet inclusion/exclusion criteria
  - Referring physician decision and reason specified
  - Protocol deviation
  - Study terminated by sponsor
  - Withdrawal by participant and reason specified
- Met entry criteria but not enrolled
- Consented/reconsented, and enrolled
- Ongoing at the time of analysis
- Completed the study
- Discontinued treatment
  - AE
  - Lack of efficacy
  - Referring physician decision and reason specified
  - Protocol deviation
  - Sponsor terminated site
  - Sponsor terminated treatment
  - Study terminated by sponsor
  - Withdrawal by participant and reason specified
- Discontinued study
  - AE
  - Lack of efficacy
  - Referring physician decision and reason specified
  - Protocol deviation
  - Sponsor terminated site
  - Sponsor terminated treatment

- Study terminated by sponsor
- Withdrawal by participant and reason specified

- Lost to follow-up
  - Participant relocated
  - Participant incarcerated

A listing of all inclusion and exclusion criteria deviations will be provided for all participants in the Enrolled Set.

4.3.1.1 Lost to Follow-up

A participant will be considered lost to follow-up if they fail to return for one or more scheduled visits and is unable to be contacted by the IC/ASA or the HIV care provider.

The following actions must be taken if a participant fails to return to the IC/ASA for a required study visit:

- The IC/ASA must immediately contact the HIV care provider if a participant has missed a visit.
- The IC/ASA must attempt to contact the participant and reschedule the missed visit as soon as possible and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain whether or not the participant wishes to and/or should continue receiving monthly or every-2-monthly injections at the IC/ASA.
- Before a participant is deemed lost to follow-up, the IC/ASA and HIV care provider must make every effort to regain contact with the participant. These contact attempts should be documented in the participant's medical record.
- Should the participant continue to be unreachable, they will be considered to have withdrawn from the study with a primary reason of "Lost to Follow-up."

4.3.2 Protocol Deviations

Protocol deviations will be recorded within the Clinical Trial Management System and undergo cross-functional team review prior to final database lock (DBL). The Study Deviation Rules Document contains all potential protocol deviations, classified by Clinical Trial Management System subtype (see Section 7.2).

Important protocol deviations can be related to study eligibility criteria, study conduct, participant management, or participant assessments. Prior to DBL, important protocol deviations will be identified and documented based on a review of potential protocol deviations. The potential protocol deviations will be identified through programmatic checks of study data, as well as through review of selected data listings.

Protocol deviations may include the following:

- Prohibited medication use
- Prohibited ART
- Non-compliance with study treatment

- Non-compliance with protocol procedures
- Other protocol deviation

The number and percentage of participants with important protocol deviations will be summarized by type of deviation for the Enrolled Set. Individual protocol deviations will also be presented in a list.

4.4 Demographics and Baseline Characteristics

Descriptive summaries of demographic and selected baseline characteristics will be presented for participants in the Safety Set. Demographic and baseline characteristics data will include:

- Age at informed consent, and the age categories as follows:
  - 18 to <20 years
  - 20 to <50 years
  - ≥50 years
- Sex assigned at birth
- Gender identity at informed consent
- Child-bearing potential at informed consent, and
  - Pregnancy status at informed consent (when applicable)
- Race
- Ethnicity
- Height at baseline
- Weight at baseline
- Body mass index (BMI) and BMI categories at baseline as follows[2]
  - Severely Underweight: <16 kg/m^2
  - Underweight: 16 to <18 kg/m^2
  - Normal Weight: 18 to <25 kg/m^2
  - Overweight: 25 to <30 kg/m^2
  - Obesity Class I: 30 to <35 kg/m^2
  - Obesity Class II: 35 to <40 kg/m^2
  - Obesity Class III: ≥40 kg/m^2
- Vital signs at baseline
- History of tobacco use reported at baseline

A participant's age in years will be estimated using the year of informed consent and year of birth.

BMI will be calculated as (body weight in kilograms) / (height in meters)^2.

Participant demographics and baseline characteristics will also be presented in a listing.

4.5 Medical History

Medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 25.0 or higher. The number and percentage of participants by system organ class (SOC) and preferred term (PT) will be summarized.

Percentages will be calculated based on the number of participants in the Enrolled Set.

Participant medical history data, including specific details, will also be presented in a listing.

4.6 Prior and Concomitant Medications/Therapies, and Study Treatments

All medications will be coded according to the WHO Drug Dictionary version 2022 MAR or higher, and the GSK Drug Dictionary: Proprietary sponsor medication dictionary version 5.0 or higher.

A prior medication or ART will be defined as any medication/therapy that is taken or starts prior to the first dose of the study drug (whether stopped or continued after the first dose). A concomitant medication or ART will be defined as any medication/therapy taken on or after the date of first dose of study drug. Furthermore, a medication/therapy could be flagged as both a prior and concomitant medication if it was started prior to the first dose and continued after first dose of study medication.

4.6.1 Prohibited Medications

Prohibited medications, as described in the USPI include:

- Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Antimycobacterials: rifabutin, rifampin, rifapentine
- Glucocorticoid (systemic): dexamethasone (more than a single-dose treatment)
- Herbal product: St John's wort (Hypericum perforatum)

Reported use of prohibited medications will be listed for the Enrolled Set.

4.6.2 Prior Medications or Antiretroviral Therapies

Prior medications/therapies will be summarized for participants in the Enrolled Set. The total number of prior medications/therapies, as well as the number and percentages of participants with at least one prior medication/therapy will be presented and listed by Anatomical Therapeutic Chemical level 1 classification and PT.

Prior medications/therapies will be presented in a listing.

4.6.3 Concomitant Medications or Antiretroviral Therapies

Concomitant medications/therapies will be summarized for participants in the Safety Set. The total number of concomitant medications/therapies, as well as the number and percentages of participants

with at least one concomitant medication/therapies, will be presented and listed by Anatomical Therapeutic Chemical level 1 classification and PT.

Concomitant medications/therapies will be presented in a listing.

4.6.4 Study Treatment Initiation Method

Study treatment initiation methods as described in the protocol include the following:

- Have been taking oral CAB + RPV or other ART for approximately 1 month (at least 28 days) prior to Baseline/Month 1, or
- Had already been receiving CABENUVA prior to Baseline/Month 1 and the last injections were within a 1-month ± 7-day window or for every-2-month injections, the timing will vary they are receiving the initiation injections (1 month ± 7 days) or the continuation injections (2 months ± 7 days) per the USPI, or
- Had been prescribed direct to inject and received first injection without an oral lead-in at the IC/ASA on the last day of any other ART.

Initiation methods will be summarized and listed for all participants in the Safety Set.

4.6.5 Study Treatments

4.6.5.1 Duration of Exposure

Duration of exposure will be defined as the total number of days a participant is exposed to CABENUVA and will be presented as the total number of days from the first dose date to the last dose date (date of last dose minus the date of first dose + 1) as recorded for study discontinuation. If the last dose date for study discontinuation is not reported, the last available visit date or when lost to follow-up, the date of last contact will be used. For participants receiving CABENUVA prior to enrolling in the study, exposure will be counted from the date that therapy was initiated (which would predate study entry).

Because missed doses may occur during the study, exposure to the study drug will also be characterized by cumulative dose, which will be defined as the cumulative dose of CABENUVA injections administered to the participants.

A summary of each participant's exposure will be presented in a listing.

4.7 Analysis of Clinical Study Endpoints

4.7.1 Safety Analysis

All safety analyses will be presented for participants in the Safety Set.

4.7.1.1 Adverse Events

Treatment-emergent AEs are being collected in this study; i.e., all events that began on or after the date of on-study CABENUVA treatment initiation. Hereafter, these events will be referred to as AEs.

All AEs, AEs related to CABENUVA, AEs leading to CABENUVA discontinuation or study withdrawal, SAEs, and COVID-19 AEs will be classified by SOC and PT according to MedDRA version 25.0 or higher. AEs will be graded according to the DAIDS Table for Grading Adult and Pediatric Adverse Events, corrected version 2.1 dated July 2017.

Incidence will be reported for the overall cohort, as well as separately for the monthly and every-2-monthly injection groups. The number and percentage of participants experiencing at least one AE will be reported, along with DAID severity grade, AE category (injection site reaction, cardiovascular, liver, COVID-19, and pregnancy-related), action taken with study treatment, and outcome of event. If a participant switches between the monthly and every-2-monthly injection groups during the study, the participant will be summarized under the treatment group within which they began the study.

The overall incidence is defined as the number of patients in the Safety Set with at least one AE occurring after study enrollment divided by the total number of patients in the Safety Set. The AE data will be categorized and presented by SOC and PT.

If any summary table does not contain any AEs, then the summary table will be produced with a statement indicating that there are no AEs to report.

The DAID grading severity of events will be presented in the overall table, as well as the AE sub-tables. The possible severities are "Grade 1 – [redacted]," "Grade 2 – [redacted]," "Grade 3 – [redacted]," "Grade 4 – [redacted]," and "Grade 5 – [redacted]". If a participant reported multiple occurrences of the same AE, only the most severe grading will be presented. AEs that are missing severity will be presented in tables as "[redacted]" but will be presented in the data listing with a missing severity. The AE data will be categorized and presented by SOC, PT, and severity in a separate table.

The seriousness of an AE will be independently assessed by the investigator from the severity of the AE. An SAE will be defined as any untoward medical occurrence that at any dose results in death, is life-threatening, results in a congenital anomaly/birth defect, requires in-patient hospitalization or prolongation, or results in significant disability/incapacity. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered SAEs when, based upon medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. All SAEs will be presented in a table with the number and percentage of participants who experienced the event. The summary table will be displayed by SOC and PT.

Similarly, the following types of AE will be summarized in separate tables, if applicable:

- Baseline AEs reported at the Baseline/Month 1 visit beginning before informed consent and during the oral lead-in/injections that are considered related to oral CAB + RPV or the last CABENUVA injection
- Treatment-related AEs
- AEs leading to discontinuation
- Injection site reactions

- Cardiovascular events
- Liver monitoring/stopping events
- Pregnancy-related AEs
- COVID-19-related AEs

Other non-serious AEs that are considered not related to CABENUVA or do not lead to withdrawal are not documented in the eCRF, and therefore will not be summarized.

4.7.1.1.1 Baseline AEs

For participants taking CABENUVA prior to enrollment in the study, any previous AEs related to oral CAB + RPV lead in or previous injection beginning before informed consent will be recorded and reported separately from events occurring during the study.

4.7.1.1.2 Treatment-related AEs

AEs that are considered related to study treatment will be summarized in separate tables.

4.7.1.1.3 Adverse Events Leading to Discontinuation

AEs that are associated with discontinuation of treatment will be summarized in separate tables and listings.

4.7.1.1.4 Injection Site Reactions

Injections site reactions, such as redness, itching, pain or swelling or discomfort, will be recorded and summarized in a table as well as in listings.

4.7.1.1.5 Cardiovascular Event Status

Type of event and specific event characteristics for arrhythmias, congestive heart failure, stroke/transient ischemic attack, deep vein thrombosis/pulmonary embolism, myocardial infarction, peripheral arterial thromboembolism, pulmonary hypertension, revascularization, and valvulopathy will be collected and reported.

Participants may have a standard 12-lead electrocardiogram (ECG) performed during the study as clinically indicated for a cardiovascular event. ECG overall interpretation will be summarized. ECG data (e.g., result, significance, abnormalities present) will be presented in a listing.

4.7.1.1.6 Liver Monitoring / Stopping Events

Start and stopping dates/times of liver events, any available liver labs, imaging, and/or biopsies, and patient exposures near the time of the event will be recorded and summarized. Alcohol intake at onset of liver events will be presented in a table for participants in the Safety Set.

4.7.1.1.7 Pregnancy Status at Baseline and Pregnancy-related Adverse Events

Child-bearing potential and pregnancy status at baseline will be reported as part of baseline information in a table. Individuals who become pregnant over the course of the study will be reported in a separate

listing. Any participant who becomes pregnant while participating in the study will be assessed by their HIV care provider whether to continue or discontinue CABENUVA and whether to remain in the study.

While pregnancy characteristics and outcomes are not part of the study nor documented within the eCRF, the reported occurrence of pregnancy during the study will be reported to the sponsor within 24 hours of awareness. All pregnancies will then be followed up by Sponsor until outcome (including premature terminations and complications) for both mother and child. Pregnancy information will be collected by the Sponsor from Day 1 and followed for 52 weeks, including any post-study SAEs possibly related to CABENUVA.

Pregnancy-related AEs (pregnancy complications, elective termination for medical reasons, spontaneous abortion, fetal death, stillbirth, congenital anomalies, ectopic pregnancy) will be captured in the AE form and reported in a separate listing.

4.7.1.1.8 COVID-19-related Adverse Events

Any AEs that are also coded with a COVID-19 infection will be reported in a separate table and listing.

4.7.1.1.9 Serious Post-injection Reactions

Any serious post-injection reactions, including dyspnea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in blood pressure, will be recorded and will be presented in a listing.

4.7.2 Clinical Laboratory Assessments

Clinical laboratory values performed by local laboratories will be assessed at planned study visits. A summary table will present the count and percentage of subjects who have an abnormal value at each visit and overall.

When there are multiple values within a planned visit for a particular laboratory assessment, the observation closest to the analysis visit target study day should be used. If there are multiple assessments equidistant from the target study day, then the mean of these values will be used.

HIV-1 RNA and liver chemistries will be summarized. In addition, given adequate sample sizes, other lab assessments may be summarized to include:

- Hematology
- Chemistry
- CD4

Liver laboratory tests will be included with chemistry lab tests.

Summaries of hepatobiliary laboratory events including possible Hy's law cases will be provided. Possible Hy's law cases are defined as any elevated ALT ≥3 × upper limit of normal (ULN), total bilirubin ≥2 × ULN, and ALP <2 × ULN/missing. Total bilirubin ≥2 × ULN can be within 28 days following the ALT elevation and if direct bilirubin is available on the same day, it must be ≥35% of total bilirubin. ALP <2 × ULN/missing

means it is satisfied unless the ALP is ≥2 x ULN at the time of bilirubin elevation. The summary will be produced for worst-case post-baseline only.

In addition to liver chemistries, liver biopsy and imaging will also be presented in a listing.

Harmonization of Local Laboratory Values

Harmonization of local laboratory value has been referenced in various publications due to differences in the test measurements. Normal laboratory reference interval values vary based on several factors, including the demographics of the healthy population from which specimens were obtained and the specific methods and/or instruments used to assay these specimens. Laboratories that are accredited by the College of American Pathologists are required to establish and/or validate their own reference values. Thus, any given result should be interpreted based on the reference value of the laboratory in which the test was done. This study will receive the results from different laboratory centers. Therefore, the laboratory results should be interpreted based on the reference value of the laboratory in which the test was done since there is no central laboratory involved.

4.7.3 Changes in Vital Signs

Summary tables presenting observed values and changes from baseline for each visit will be presented for vital sign data, including systolic/diastolic blood pressure (mmHg), heart rate (beats/min), as well as height (cm), weight (kg), and BMI (kg/m^2). Vital signs will be assessed in a semi-supine position.

Vital signs, height, weight, and BMI will be presented in a listing.

4.7.4 Effectiveness

A summary of HIV-1 RNA results per visit will be provided. If HIV-1 RNA data is documented at unscheduled or early withdrawal visits, the data will be assigned to the closest scheduled visit. However, if data from a scheduled visit is already available from the same timepoint, this data is prioritized and data from the unscheduled/early withdrawal visit will not be used for analysis. All documented data on HIV-1 RNA (at scheduled and unscheduled visits) will be presented in the listings.

The number and percentage classified as virologically suppressed and confirmed virologic failure will as be reported as defined below.

Virological Suppression

Virological suppression will be defined as observing plasma HIV-1 RNA <50 copies/mL.

The proportion of participants with virologic suppression will be summarized using the Safety Set. 95% CIs will be calculated using Clopper-Pearson exact CI as appropriate for large and small sample sizes.

Confirmed Virologic Failure

Confirmed virologic failure will be defined as observing two consecutive plasma HIV-1 RNA ≥200 copies/mL.

The proportion of participants with confirmed virologic failure will be summarized using the Safety Set. 95% CIs will be calculated using Clopper-Pearson exact CI.

4.7.5 Use of Oral Bridging

When a participant plans for a missed injection, the participants may elect for oral bridging. Dosing of oral bridging in the event of missed doses will be in accordance with the most recent CABENUVA USPI.

A single occurrence of oral bridging will be defined as the period between two adjacent CABENUVA injections. If the participant is on oral bridging at the end of the study period, then the last occurrence of oral bridging is counted as between the last CABENUVA injection and the end of the study period. The duration of each oral bridging instance will be derived as the duration from start to end date of the use of oral HIV medication between two adjacent CABENUVA injections.

The number of occurrences and duration of each occurrence of oral bridging will be summarized in a table using the Safety Set.

Participants who have used oral bridging at least once will be summarized. This includes both the participants on a monthly injection schedule and an every-2-month injection schedule.

Frequency of the oral bridging occurrences will be summarized in a table and a histogram. This includes both the participants on a monthly injection schedule and an every-2-month injection schedule, while the max frequency for the former is eight and for the latter is four.

The missed injection rate at each visit for participants on oral bridging (proportion of participants who missed injection at scheduled visit N+1 while on oral bridging after visit N) will be summarized. Missed injection rate will be defined as one minus the adherence rate.

4.7.6 Impact of COVID-19 Pandemic

Incidence, severity, and outcome of COVID-19 diagnoses, changes to prescribing related to COVID-19, visit impact (e.g., missed visits, altered visit type), and study impact (e.g., need for remote visits, discontinuation of study treatment, discontinuation of study) will be listed.

4.7.7 Changes from Planned Analysis

As the data are analyzed, some deviation from expectations may occur. In instances where these deviations would make the proposed analyses inappropriate, modifications to the SAP—along with justifications for these changes—will be made and noted in the final report.

5 Limitations on Research Methods

This is a single-arm, real-world study for gathering information on the feasibility and acceptability of utilizing an IC/ASA to administer CABENUVA in the US. As such, participants may not necessarily be representative of the general population and certain demographics may be over- or under-represented.

6 References

1. World Health Organization. *Global Surveillance for human infection with novel coronavirus (2019-nCoV): interim guidance, 31 January 2020*. 2020. 2020. https://apps.who.int/iris/handle/10665/330857
2. Jan A, Weir CB. BMI Classification Percentile and Cut Off Points. *StatPearls: Treasure Island, FL, USA*. 2021;

7 Appendices

7.1 Schedule of Activities (SoA)

Procedure[1]	Baseline/ Month 1[2]	Treatment Period (Months)							E.D.[3]	Notes
		2	3	4	5	6	7	8		
1. The timing and number of planned study assessments may be altered during the study based on newly available data. 2. The following sequence of events must be followed for participants at the Baseline/Month 1 visit: 1) informed consent form (ICF) Consent 2) confirm inclusion and exclusion criteria 3) complete questionnaires and assessments, 4) receive first study-related intramuscular (IM) injections at the IC/ASA. Baseline is defined as the Month 1 visit. 3. E.D. = early discontinuation/withdrawal: This visit should only be conducted if the participant discontinues from the study, and the discontinuation/withdrawal reason should be recorded. NOTE: Carefully follow the **Instructions for Use** when preparing and administering CABENUVA IM to avoid accidental intravenous administration										
Clinical and Other Assessments										
Informed Consent	X									Written informed consent must be obtained from each potentially eligible participant by IC/ASA personnel prior to the initiation of any Baseline procedures as outlined in this protocol.
Inclusion and Exclusion Criteria	X									Inclusion/exclusion criteria will be fully assessed at the Baseline/Month 1 Visit.
Demography	X									
Pregnancy Status	X	X	X	X	X	X	X	X	X	Ask POCBP at each visit if they are pregnant and ask for the date of their LMP. See Protocol Section 10.3.11 for additional information. For participants on every-2-month injections, pregnancy status should be confirmed only at IC/ASA visits.
Height and Weight	X	X	X	X	X	X	X	X	X	Height will only be collected at Baseline. BMI will be calculated within the eCRF. If possible, the same scale should be used consistently throughout the study and participants should be asked to remove any excess clothing (i.e., coats and shoes).

										For participants on every-2-month injections, weight will be collected only at IC/ASA visits.
Vital Signs: Blood Pressure, Heart Rate	X	Vital signs will be measured according to the POT with the HIV care provider. All vital signs collected must be stored in the participants source documentation at the IC/ASA.								Vital signs are to be measured after resting in a semi-supine position for at least 5 minutes. For participants on every-2-month injections, vital signs will be collected only at IC/ASA visits.
Laboratory Assessments (HIV1-RNA, Liver Chemistries, Other Labs Per POT)	X							X	X	The Baseline/Month 1 labs should be collected prior to the first study injection (at the Baseline/Month 1 visit). See Section 10.1 for additional information The HIV care provider is responsible for monitoring and any follow-up of elevated HIV-1 RNA and liver chemistries in their PLWHIV and to let the IC/ASA know if there are any changes to the monthly or every-2-month injections. The HIV care provider can request that the IC/ASA draw labs at any time or they can perform local labs as required.
		Additional lab assessments may be obtained per blueprint and the POT with the HIV care provider. All lab reports must be stored in the participants source documentation at the IC. Fasting is not required unless otherwise required for a specific lab test.								
Study Treatment: All injections will be administered according to the CABENUVA USPI										
CABENUVA IM Injections initiated at IC/ASA, post oral lead-in (1st injections of CABENUVA at the IC/ASA)										The final oral doses of CAB + RPV, or other ART, should be taken on the same day when injections with CABENUVA are started. Questionnaires and procedures should be conducted prior to the injections.
Monthly Dosing (Post Oral Lead-In)	X	X	X	X	X	X	X	X		IM dosing is expected to occur on the same date of the month as determined by Dose 1 - Treatment Target Date. Dosing window is ± 7 days.
Every-2-month Dosing	X	X		X		X		X		Dosing window for every-2-months is ± 7 days.
CABENUVA IM Continuation injections: For those already receiving CABENUVA injections, and who are to get their subsequent injections at the IC/ASA.										Questionnaires and interviews should be conducted prior to the injections.

Note: To avoid having participants whose last injections are at Month 7 return to the IC/ASA at Month 8, the end of study assessments (Month 8) will be completed at Month 7. Questionnaires and potential interviews will be completed at Month 8.										
Monthly Dosing	X	X	X	X	X	X	X	X		The first study-related CABENUVA injections at the IC/ASA should be started within 1 month (±7 days) after the last injections. For participants switching from an every-2-month continuation injection schedule to a monthly continuation dosing schedule, follow the dosing instructions in the most recent USPI for CABENUVA.
Every-2-month Dosing (Participants Already Receiving Every-2-month Dosing)	X		X		X		X			Dosing window for every-2-month dosing is ±7 days. For participants switching from a monthly continuation injection schedule to an every-2-month continuation injection dosing schedule follow the dosing instructions in the most recent USPI for CABENUVA.
Concomitant Medication Review	X	==========							X	The IC/ASA will note all new concomitant medications and send to the HIV care provider. Contraindicated medications and concomitant medications with a potential for a DDI per CABENUNVA USPI will be recorded.
Adverse Event (AE) Review	X	==========							X	See Protocol Section 10 for more information on the DAIDS grading scale, Protocol Section 10.3.7 for guidelines on assessment of causality, and Protocol Section 10.3.10 for AE reporting requirements. Refer to the Protocol Annex 3 for definitions of AEs.
Serious AEs (SAEs)	X	==========							X	See Protocol Section 10 for more information on the DAIDS grading scale, Protocol Section 10.3.7 for guidelines on assessment of causality, and Protocol Section 10.3.10 for SAE reporting requirements. Refer to the Protocol Annex 3 for definitions of SAEs

Abbreviations: AE = adverse event; ART = antiretroviral therapy; ASA = alternative site of administration; DDI = drug-drug interaction; E.D. = early discontinuation/withdrawal; HIV = human immunodeficiency virus; IC = infusion center; ICF = informed consent form; IM = intramuscular; LMP = last menstrual period; POCBP = person of child-bearing potential; PLWHIV = People living with human immunodeficiency virus; POT = plan of treatment; RNA = ribonucleic acid; SAE = serious adverse event; USPI = United States prescribing information

7.2 Protocol Deviations Rules Document

[At DBL, will be placed in this appendix.]

7.3 Tables and Listings


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EVA 30466- Clinical Listing Shells_Final_

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A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or Alternate Sites of Administration

Statistical Analysis Plan: Infusion Center or Alternate Site of Administration Staff

EVA-30466 | March 4th, 2024| Version 4

Prepared For:

PPD, GSK

PPD, PhD | PPD, Global Implementation Research, ViiV Healthcare

Prepared By:

PPD, PhD

PPD PhD MPH

PPD PhD, MPH

Project Contact:

PPD

Statistical Analysis Plan (SAP) Signature Page

SAP Title: A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or Alternative Site of Administration. Statistical Analysis Plan: Infusion Center or Alternative Site of Administration Staff

SAP Date and Version: March 4th, 2024; Version 4.0

This SAP with the title, number, and version indicated above has been reviewed and approved by the Evidera Principal Investigators and Project Managers.

PPD

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Date

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Date

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Date

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Date

Table of Contents

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List of Abbreviations

Abbreviation	Definition
AIM	Acceptability of Intervention Measure
BL	Baseline
ASA	Alternative site of administration
CI	Confidence interval
FDA	Food and Drug Administration
EDC	Electronic data capture
FIM	Feasibility of Intervention Measure
FPFV	First participant first visit
HIV	Human immunodeficiency virus
IC	Infusion center
IM	Intramuscular
M3	Month 3
M8	Month 8
OCR	Optical character recognition
PDF	Portable document format
PLWHIV	Participants living with human immunodeficiency virus
QAP	Qualitative analysis plan
SAP	Statistical analysis plan
SD	Standard deviation
SoA	Schedule of Activities

1 Introduction

CABENUVA is a two-drug, co-packaged product of cabotegravir plus rilpivirine, both administered as long-acting, intramuscular (IM) injections, once-monthly or every two months; it is an approved treatment for human immunodeficiency virus (HIV). Clinical trial results have shown that CABENUVA administered once-monthly or every two months is non-inferior to the daily oral treatment for HIV.

Long-acting injectable treatments require changes in how HIV care is delivered. People living with HIV must attend appointments for their injections once a month or every two months, rather than seeing their providers several times per year for a prescription refill and monitoring visits. This poses new healthcare delivery challenges, including a shift in resources to this alternative means of delivering and receiving treatment—thus requiring the expansion of alternative injection facilities to include infusion centers (ICs) or alternate sites of administration (ASAs). This has the potential to impact workload capacity for these facilities, though it also has the potential to positively impact treatment engagement and retention for people living with HIV.

ICs/ASAs are an appealing option that can ease the burden of additional appointments, administrative work, and drug ordering in HIV specialty clinics, as well as provide people living with HIV with greater flexibility in where they receive their monthly or every two months injections. In this study, the intervention itself is the process of using an IC/ASA as the location to receive the CABENUVA IM injections. Specifically, the acceptability and feasibility of injection delivery at ICs/ASAs will be assessed from the perspectives of the participants living with HIV (PLWHIV), HIV care providers/clinical staff, and IC/ASA staff.

This statistical analysis plan (SAP) describes analyses for the acceptability and feasibility of an IC/ASA to deliver CABENUVA IM injections, as reported by IC/ASA staff. It also encompasses a tailored questionnaire that asks IC/ASA staff about their attitudes, concerns, and anticipated/implemented procedures regarding the use of CABENUVA/long-acting injectables administered by ICs/ASAs.

This is one of four SAPs for the following protocol: *Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in U.S. community-based infusion centers or alternate sites of administration*. The three additional SAPs are:

(1) analyses for HIV care providers and Expert Panel, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in U.S. community-based infusion centers or alternate sites of administration, Statistical Analysis Plan: HIV Care Providers and key personal who are involved in the patients' care (Clinical Staff) & Expert Panel;*

(2) analyses of the participant questionnaires and clinical data, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in U.S. community-based infusion centers or alternate sites of administration, Statistical Analysis Plan: Participants living with HIV for Implementation Science Questionnaires*; and

(3) an additional SAP for clinical characteristics /analyses for PLWHIV, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in U.S. community-based infusion centers or alternate sites of administration: Statistical Analysis Plan for Clinical Analyses.*

While there are no primary objectives involving IC/ASA staff for this study, this SAP will describe the planned analyses for the secondary objectives related to IC/ASA staff as outlined in Table A. Additionally, this plan will not incorporate the planned qualitative interview analyses at the end of study. These analyses are described in detail in the qualitative analysis plan (QAP) (currently under development).

Table A. Objectives and Endpoints for IC/ASA Staff

Objectives	Endpoints
Secondary	
To evaluate feasibility of CABENUVA administration at infusion centers or alternate sites of administration from IC/ASA staff	Proportion of IC/ASA staff that agree or completely agree (a score of 4 or higher) across all items on the FIM prior to Month 1, at Month 3, and Month 8
	Change over time in the FIM at Month 3, and Month 8 with IC/ASA staff
	Summary of other quantitative questionnaires assessed with IC/ASA staff prior to Month 1, at Month 3, and Month 8
	Qualitative interviews assessed at Month 8 with IC/ASA staff (QAP)
To evaluate acceptability of CABENUVA administration at infusion centers or alternate sites of administration from IC/ASA staff	Proportion of IC/ASA staff that agree or completely agree (a score of 4 or higher) across all items on the AIM prior to Month 1, at Month 3, and Month 8
	Change of IC/ASA staff respectively over time in the AIM at Month 3, and Month 8
	Summary of other quantitative questionnaires assessed prior to Month 1, at Month 3and Month 8 with IC/ASA staff
	Qualitative interviews assessed at Month 8 with IC/ASA staff (QAP)
To evaluate perceptions, facilitators, and barriers/concerns by IC/ASA staff	Summary of IC/ASA staff other quantitative questionnaires prior to Month 1, at Month 3, and Month 8
	Qualitative interviews assessed at Month 8 with IC/ASA staff (QAP)
To evaluate the usefulness of blueprint intervention by IC/ASA staff	Summary of usefulness of the blueprint intervention by IC/ASA staff other quantitative questionnaires prior to Month 1, at Month 3 and Month 8
	Qualitative interviews assessed at Month 8 with IC/ASA staff (QAP)
To evaluate overall opinion of receiving and administering the injection at an infusion center or alternate site of administration by IC/ASA staff	Summary of the overall opinion of administering the injection at an IC/ASA by IC/ASA staff other quantitative questionnaires prior to Month 1, at Month 3, and Month 8
	Qualitative interviews at Month 8 with IC/ASA staff (QAP)
To evaluate fidelity to treatment and dosing window	Proportion of injections occurring within target window from target date (± 7 days of target date) through Month 8
Other / Tertiary	
CCI [redacted]	

Abbreviations: AIM = Acceptability of Intervention Measure; ASA=Alternative Site of Administration; FIM = Feasibility of Intervention Measure; IC = infusion center; QAP = Qualitative Analysis Plan

2 Study Design

This is a Phase 4, single-arm, open-label, multi-center study examining the administration of CABENUVA IM in ICs/ASAs in the United States. This study is being conducted following Food and Drug Administration (FDA) approval and commercial availability of CABENUVA. Eligible and consenting participants will be followed for eight months to evaluate an implementation blueprint for IM administration of CABENUVA for HIV-1 treatment at ICs/ASAs. The total duration for study participants is approximately eight months from the time of enrollment and receipt of the first administration of CABENUVA IM injections at the IC/ASA.

Relevant to this SAP, key IC/ASA staff members involved in decision making and/or overseeing daily operations at the IC/ASA will be asked to complete questionnaires per the Schedule of Activities (SoA; see ANNEX 1 in protocol), as follows:

- Baseline/Month 1 questionnaires should be completed prior to enrollment of the first participant at each IC/ASA
- Baseline/Month 1 for each IC/ASA is defined when the first participant enrolls into the study at that specific IC/ASA, and the participant is administered the first injections of CABENUVA
- Months 3 and 8 will be defined after at least one participant, at their respective IC/ASA, has completed their Month 3, or 8 study visits, respectively
    - Questionnaires can be completed up to two weeks before or after the Month 3 or 8 study visits

Total duration of study participation for IC/ASA staff for completing questionnaires is approximately eight months from the time of enrollment of the last participant at that IC/ASA. IC/ASA staff questionnaires consist of the Feasibility of Intervention Measure (FIM) and the Acceptability of Intervention Measure (AIM), as well as a tailored questionnaire.

2.1 Description of the IC/ASA Staff Questionnaire and Schedule for Completion

The IC/ASA staff questionnaire consists of two validated instruments and tailored items written for this study. The validated instruments are the FIM and AIM, described below. The tailored items ask IC/ASA staff about a number of topics, including, but not limited to, their role, experience, and views on the CABENUVA/long-acting injectable model, as well as using ICs/ASAs to implement that model.

IC/ASA staff will be asked to complete a questionnaire at Baseline/ Month 1 (prior to first participant first visit [FPFV] at respective ICs/ASAs), and at Months 3 and 8 (see above).

Table B. Questionnaire Administration for IC/ASA Staff

Questionnaire	Baseline/ Month 1	Month 3	Month 8
Feasibility of Intervention Measure	x	x	x
Acceptability of Intervention Measure	x	x	x

Questionnaire	Baseline/ Month 1	Month 3	Month 8
IC Staff Tailored Items	x	x	x

Abbreviation: IC/ASA = infusion center/ alternate site of administration

2.1.1 Feasibility of Intervention Measure

The FIM (four items) is employed to evaluate the feasibility of an implementation strategy and assess perceived intervention feasibility. Items are measured on a five-point rating scale (1=CCI [redacted], 2=CCI [redacted], 3=CCI [redacted], 4=CCI [redacted], 5=CCI [redacted]). The FIM has been validated with other implementation outcome measures.[1] Higher scores indicate greater feasibility. There are no reverse-scored items on the FIM and the mean score for feasibility of the intervention is calculated by averaging the responses from the four items.

2.1.2 Acceptability of Intervention Measure

The AIM (four items) is employed to evaluate the acceptability of an implementation strategy and assesses perceived intervention acceptability. The items are measured on a five-point rating scale (1=CCI [redacted], 2=CCI [redacted], 3=CCI [redacted], 4=CCI [redacted], 5=CCI [redacted]). The AIM was validated with a suite of implementation outcome measures.[1] Higher scores indicate greater acceptability. There are no reverse-scored items on the AIM and the mean score for acceptability of the intervention is calculated by averaging the responses from the four items.

2.1.3 IC/ASA Staff Additional Questionnaire

The tailored IC/ASA staff questionnaire was developed specifically for this study and contains items regarding the staff member's role at the IC/ASA, as well as their attitudes, concerns, and anticipated/implemented procedures regarding the use of CABENUVA/long-acting injectable administered by IC/ASAs. The Baseline/ Month 1 IC/ASA staff questionnaire has 33 items, and the Month 3 questionnaire has 40 items (including the FIM and AIM), using several different response scales. Data Management

The Baseline/ Month 1 IC/ASA staff questionnaires will be completed on paper, uploaded in portable document format (PDF), sent to Evidera via SharePoint, then processed in DF Discovery. Subsequent questionnaires will be handled by electronic data capture (EDC). Queries will focus on issues with optical character recognition (OCR; legibility), missing data, or DF Discovery form elements required to include the data. Missing pages will be queried (by e-mail) to the IC/ASA staff member, to verify that all pages were scanned. If data is still missing, follow-up queries will be initiated by the study team with respective IC/ASA staff. Queries remaining open from unresponsive IC/ASA staff may be closed with GSK/ViiV review and approval.

2.2 Windows for Questionnaire Completion

Baseline/Month 1 questionnaires should be completed prior to enrollment of the first participant at each infusion center/alternative site of administration. Questionnaires at other months should be completed within +/- 14 days of the scheduled month.

Month 1 for each IC/ASA is defined when the first participant enrolls into the study at that specific IC/ASA and the participant is administered the first study related injections of CABENUVA.

Month 2 for potential interviews of approximately 5 IC/ASA staff is defined as after at least 1 participant, at their respective IC/ASA site, has completed their Month 2 study visits.

Month 3 and Month 8 is defined as after at least 1 participant, at their respective IC/ASA site, has completed their Month 3, or 8 study visits, respectively.

2.3 Conditions for Inclusion in Analytic Dataset

Duplicate Questionnaires

In the instance that duplicate questionnaires are present for the same participant at the same visit, the temporally first-administered questionnaire will be included in the analytical dataset if it is fully completed. If the first questionnaire is not fully completed and the temporally second-administered questionnaire is fully completed, then the second questionnaire will be included in the analytical dataset. If neither questionnaire is fully completed, the temporally first-administered questionnaire will be included in the analytical dataset.

Multiple Responses Regarding the Blueprint Questionnaire

In the instance that IC/ASA staff have multiple responses pertaining to the study Blueprint, the temporally first-offered responses following that participant receiving the Blueprint will be included in the analytical dataset.

IC/ASA Staff who were Discontinued:

For IC/ASA Staff who were discontinued/withdrawn from the study by the site or did not have a patient enroll/reach by month 3:

1. IC/ASA participants who were removed by their respective IC/ASA site prior to month 3 patient enrollment will have their month 3 questionnaires removed from the analytic dataset.

2. IC/ASA participants who did not have a patient at their clinic reach Baseline/ Month 1 will have their month 3 questionnaires removed from the analytic dataset.

Out-of-Window Questionnaires

Questionnaires will not be excluded for being out of temporal window (see Section 2). A sensitivity analysis will be performed for all analyses described in the current SAP that pertain to FIM or AIM items, with all out-of-window questionnaires removed. Results of these analyses will be compared to the main analyses, and the magnitude of differences will be summarized descriptively.

2.4 Implementation Science-Related Protocol Deviations

Implementation science-related protocol deviations will be reported, where numerators equal the number of IC/ASA staff experiencing the respective deviation type, and denominators equal the number of IC/ASA staff in analytic dataset. Deviations reported will include, but are not limited to, the following: questionnaires with missing data, questionnaires completed but not required at respective time point, questionnaires completed out of window (early), questionnaire completed out of window (late), and duplicate questionnaire completed. Missing data is considered a deviation if any item is missing, and the participant has not dropped out of the study. See section 2.3 and 3.1 for how deviations affect inclusion in analytic dataset.

3 Statistical Methods

This SAP has been developed to guide the analyses for the data collected and assumes that all data will be collected in adherence to the protocol developed by GSK/ViiV. The analysis population for this SAP is all responding IC/ASA staff who complete any portion of any questionnaire at any point in the study. As the data are analyzed, some deviation from expectations may occur. In instances where these deviations would make the proposed analyzes inappropriate, modifications to the SAP—along with justifications for these changes—will be made and noted in the final report.

Continuous and interval-like variables will be summarized using descriptive statistics (e.g., n, mean, standard deviation [SD], median, minimum, maximum, first and third quartiles, and confidence intervals [CI]). Data in tables will be tabulated relative to the source data. Mean, median, and quartiles will be tabulated to one more decimal place than the source data; minimum/maximum values will have the same decimal places as source data; percentages will be rounded to one decimal place after calculation. SD and CIs will be tabulated to two more decimal places than the source data. Categorical variables will be reported as frequency counts, the percentage of IC/ASA staff in corresponding categories, and 95% CIs.

Subgroup analysis will be performed to evaluate the effect of contextual factors on the variability of responses to feasibility and acceptability, for example stratifying by practice size. Other subgroup / sensitivity analyses may be added subsequent to completion of Baseline/ Month 1 data collections.

For the analyses of the proportion of IC/ASA staff responding agree or completely agree on all FIM items, this will include the IC/ASA staff members who select response option 4 CCI [redacted] or 5 CCI [redacted] for all four FIM items at a given time point, out of all IC/ASA staff who completed all four FIM items at that respective timepoint. The same definition applies to the analogous analysis for the AIM.

3.1 Missing Data Handling Scheme

Missing data at the multi-item scale level for standardized scales (FIM and AIM) will be addressed with standard proration rules[2]: if at least 50% of the items are completed the scale will be scored by taking the mean of the completed items, unless otherwise specified for a particular outcome. Following this,

partially completed FIM and AIM administrations will be scored if two, three, or four items are completed, and will not be scored if only one item is completed. Items not completed will be logged as missing data. No missing data will be imputed. Table shells for missing data from FIM and AIM scales can be found in Appendix A.

3.2 Cross-sectional Univariate Distributions of Study Variables and Features of Score Distributions

For questions with ordinal responses, a univariate distribution of every item will be tabulated. Standard distributional statistics will be tabulated for interval-like (ordinal) variables, including mean, SD, median, percentage missing, range (minimum and maximum of responses), percentage of the sample at the ceiling (highest possible score) and floor (lowest possible score), first and third quartiles, and 95% CIs. For questions with descriptive responses, a frequency distribution of all responses will be presented with n (%).

3.3 Distributions of Study Variables and Features of Score Distributions, Change from Baseline/ Month 1 for FIM and AIM

The univariate distribution of item change scores (Month 3 minus Baseline/ Month 1, Month 8 minus Baseline/ Month 1, and Month 8 minus Month 3) will be tabulated for the FIM and AIM, both in terms of distributional characteristics of change and frequency of responses. Distributional characteristic tables will include the SD of the change distribution, median change, first and third quartiles, and 95% CIs. Change analyses will be limited to those IC/ASA staff completing questionnaires at Baseline/ Month 1 and each respective timepoint. Categorical data for the FIM and AIM from IC/ASA staff questionnaires will be presented in shift analyses showing the frequency of change by the degree of shift across response categories and will be presented for Baseline/ Month 1 to Month 3, Baseline/ Month 1 to Month 8, and Month 3 to Month 8.

4 Qualitative Analysis

Qualitative analyses will be described in the qualitative analysis plan.

5 IC/ACA Site Metrics

Metrics as reported by IC/ASA sites will be described (Section 7). Metrics will include consent rate, participant show rate, rate of notifications from HIV care providers and participants, participant return visit rate, reach (proportion of eligible individuals that participate in receiving injections at the IC/ASA), adoption (proportion of clinics contacted by the IC/ASA that initiate referrals for the injections), and fidelity (proportion of injections occurring within target window from target date). Metrics will be described for each site and aggregated across sites. Tables will display the rate, numerator and denominator used to calculate the rate, and the CI of the estimate.

A feasibility composite score will be derived from the following data: 1) FIM score; 2) consent rate; 3) show rate; 4) participant notification (appointment level); 5) HIV care provider notification (appointment level); and 6) return rate. The mean for each component of the composite score will be calculated across all data collections for that score and each component mean will then be multiplied by 100. The mean of these scores will then be calculated, producing a composite score where each component receives equal weight and the scale range is 0 - 100. The univariate distribution of feasibility composite score will be tabulated. The distributional characteristic table will include the mean and SD of the distribution, median, first and third quartiles, and 95% Cis using clinics as the unit of observation. Cronbach's alpha coefficient will be calculated to assess if the items consistently measure feasibility of implementation as a scale.

6 References

1. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci.* 2017;12(1):108.
2. Cella D. *Manual of the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System—Version 4.* Evanston, IL: Center on Outcomes, Research & Education (CORE), Evanston Northwestern Healthcare and Northwestern University; 1997.

7 Table Shells: Baseline, Month 3, Month 8, and Change

Table 1.1.1. IC/ASA Staff Roles, Attitudes, and Anticipated Procedures in Implementing CABENUVA via IC/ASAs, Baseline (N=XX)

Question	Number of Participants at Baseline	Response	n (%)
1.What is your role at the infusion center?[1,2]	XX	Front Desk Staff	n (%)
		Nurse Manager	n (%)
		Clinic Nurse	n (%)
		Physician	n (%)
		Nurse Practitioner	n (%)
		Pharmacist	n (%)
		Patient Services	n (%)
		Other*	n (%)
		Missing	n (%)
2. How concerned are you from a personal safety perspective about administering CABENUVA to PLWHIV?[3]	XX	Extremely Concerned	n (%)
		Moderately Concerned	n (%)
		Somewhat concerned	n (%)
		Slightly concerned	n (%)
		Not concerned at all	n (%)
		Missing	n (%)
3. What are your concerns about treating PLWHIV or administering CABENUVA?[1,2]	XX	Treating HIV positive patients	n (%)
		Scheduling/Rescheduling in the correct treatment window	n (%)
		Difficulty of giving the gluteal medial injection	n (%)
		Ability to provide adequate privacy for patients	n (%)
		Volume of patients we may need to treat on CABENUVA	n (%)
		I have no concerns at all	n (%)
		Other*	n (%)
		Missing	n (%)
4. CABEBUVA must be administered within a two-week treatment window every month. 4a. How easy or difficult do you think the appointment scheduling will be?[3]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neutral	n (%)
		Somewhat challenging	n (%)
		Very challenging	n (%)
		Extremely challenging	n (%)

Question	Number of Participants at Baseline	Response	n (%)
		Missing	n (%)
4. CABEBUVA must be administered within a two-week treatment window every month. 4b. How easy or difficult do you think the appointment re-scheduling will be?[3]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neutral	n (%)
		Somewhat difficult	n (%)
		Very difficult	n (%)
		Extremely difficult	n (%)
		Missing	n (%)
5. How will you notify a provider when a patient gets CABENUVA on time?[1,2]	XX	Phone call	n (%)
		Email	n (%)
		Fax	n (%)
		Postal Letter	n (%)
		Secure electronic medical record message	n (%)
		Depends on provider preference	n (%)
		No communication necessary	n (%)
		Missing	n (%)
6. How will you notify providers if a patient misses a CABENUVA visit or gets it out of window?[1,2]	XX	Phone call	n (%)
		Email	n (%)
		Fax	n (%)
		Postal Letter	n (%)
		Secure electronic medical record message	n (%)
		Depends on provider preference	n (%)
		No communication necessary	n (%)
		Missing	n (%)
7. In your opinion, how easy or difficult do you think the CABENUVA administration will be to implement in your current work-flow?[3]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neutral	n (%)
		Somewhat difficult	n (%)
		Very difficult	n (%)
		Extremely difficult	n (%)
		Missing	n (%)
8. How many CABENUVA patients do you think your infusion center can handle in an average week?[3]	XX	0 – 2 patients	n (%)
		3 – 5 patients	n (%)
		6 – 10 patients	n (%)
		11 – 15 patients	n (%)
		16 – 25 patients	n (%)

Question	Number of Participants at Baseline	Response	n (%)
		26+ patients	n (%)
		Missing	n (%)
9. Overall, what is your opinion about administering CABENUVA for PLWHIV at your infusion center?[3]	XX	Extremely positive	n (%)
		Very positive	n (%)
		Somewhat positive	n (%)
		Neutral	n (%)
		Somewhat negative	n (%)
		Very negative	n (%)
		Extremely negative	n (%)
		Missing	n (%)

[1] Select all that apply

[2] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

[3] Select one response

Abbreviations: IC = infusion center; ASA = alternative site of administration; HIV = human immunodeficiency virus; PLWHIV = participants living with human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing and responses from participants who completed items which violated the prescribed skip pattern were omitted

*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.1.2. IC/ASA Staff Roles, Attitudes, and Anticipated Procedures in Implementing CABENUVA via IC/ASAs, Month 3 (N=XX)

Question	Number of Participants at Month 3	Response	n (%)
1. How concerned are you from a personal safety perspective about administering CABENUVA to people with HIV?[1]	XX	Extremely concerned	n (%)
		Moderately concerned	n (%)
		Somewhat concerned	n (%)
		Slightly concerned	n (%)
		Not concerned at all (skip to 2)	n (%)
		Unsure/not applicable to role (skip to 2)	n (%)
		Missing	n (%)
1a. What are your concerns about treating people with HIV or administering CABENUVA?[2,3]	XX	Treating HIV positive patients	n (%)
		Scheduling/Rescheduling in the correct treatment window	n (%)
		Difficulty of giving the gluteal injection	n (%)
		Ability to provide adequate privacy for patients	n (%)
		Volume of patients we may need to treat on CABENUVA	n (%)
		I have no concerns at all	n (%)
		Other*	n (%)
		Missing	n (%)
2. CABENUVA must be administered within a two-week treatment window (+/-7 days relative to the target treatment date). 2a. How easy or difficult has it been to schedule appointments for CABENUVA injections?[1]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neither easy nor difficult	n (%)
		Somewhat difficult	n (%)
		Very difficult	n (%)
		Extremely difficult	n (%)
		Unsure/not applicable to role (skip to 3)	n (%)
		Missing	n (%)
2b. How easy or difficult has it been to reschedule appointments for CABENUVA injections?[1,4]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neither easy nor difficult	n (%)
		Somewhat difficult	n (%)
		Very difficult	n (%)
		Extremely difficult	n (%)
		Unsure/not applicable to role (skip to 3)	n (%)
		Missing	n (%)
	XX	Phone call	n (%)

Question	Number of Participants at Month 3	Response	n (%)
3. How does your center notify providers when a patient gets CABENUVA on time?[2,3]		Email	n (%)
		Fax/FastFax	n (%)
		Postal Letter	n (%)
		Secure electronic medical record message	n (%)
		Depends on provider preference	n (%)
		No communication necessary	n (%)
		Unsure/not applicable to role	n (%)
		Missing	n (%)
4a. How does your infusion center notify providers if a patient misses a CABENUVA visit or is out of window?[2,3]	XX	Phone call	n (%)
		Email	n (%)
		Fax/FastFax	n (%)
		Postal Letter	n (%)
		Secure electronic medical record message	n (%)
		Depends on provider preference	n (%)
		No communication necessary	n (%)
		Unsure/not applicable to role (skip to 5)	n (%)
		Missing	n (%)
4b. How does your infusion center notify providers if a patient falls out of their window for their CABENUVA injection?[2,3,5]	XX	Phone call	n (%)
		Email	n (%)
		Fax/FastFax	n (%)
		Postal Letter	n (%)
		Secure electronic medical record message	n (%)
		Depends on provider preference	n (%)
		No communication necessary	n (%)
		Unsure/not applicable to role	n (%)
		Missing	n (%)
5. In your opinion, how easy or difficult has CABENUVA administration been to implement in your current work-flow?[1]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neither easy nor difficult	n (%)
		Somewhat difficult	n (%)
		Very difficult	n (%)
		Extremely difficult	n (%)
		Missing	n (%)
6. About how many CABENUVA patients does your infusion center currently see?[1]	XX	0 – 2 patients	n (%)
		3 – 5 patients	n (%)
		6 – 10 patients	n (%)
		11 – 15 patients	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		16 – 25 patients	n (%)
		26+ patients	n (%)
		Unsure/not applicable to role	n (%)
		Missing	n (%)
7. How many CABENUVA patients do you think your infusion center can handle in an average week?[1]	XX	0 – 2 patients	n (%)
		3 – 5 patients	n (%)
		6 – 10 patients	n (%)
		11 – 15 patients	n (%)
		16 – 25 patients	n (%)
		26+ patients	n (%)
		Unsure/not applicable to role	n (%)
		Missing	n (%)
8. Overall, what is your opinion about administering CABENUVA for PLWHIV at your infusion center?[1]	XX	Extremely positive	n (%)
		Very positive	n (%)
		Somewhat positive	n (%)
		Neither positive nor negative	n (%)
		Somewhat negative	n (%)
		Very negative	n (%)
		Extremely negative	n (%)
		Missing	n (%)

[1] Select one response

[2] Select all that apply

[3] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

[4]Only administered to respondents who did not endorse "Unsure/not applicable to role" for item 2a.

[5]Only administered to respondents who did not endorse "Unsure/not applicable to role" for item 4a.

Abbreviations: IC = infusion center; ASA = alternative site of administration; HIV = human immunodeficiency virus; PLWHIV = participants living with human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing and responses from participants who completed items which violated the prescribed skip pattern were omitted.

*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.1.3. IC/ASA Staff Roles, Attitudes, and Anticipated Procedures in Implementing CABENUVA via IC/ASAs, Month 8 (N=XX)

Table 1.2.1. IC/ASA Staff Concerns about CABENUVA Administration – Baseline (N=XX)

Item	Number of Participants at Baseline	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
1. Patients' willingness to travel to an infusion center for each injection visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Timely reporting to the provider when a patient receives CABENUVA	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. Timely reporting to the provider when a patient misses a CABENUVA visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Timely reporting of adverse events to HIV providers	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
5. Frequency of lab draws at the infusion center	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
6. Management of reporting of adverse events	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
7. Management of reporting abnormal lab results with HIV providers	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
8. Understanding of **when to** bridge patients with oral medication for planned missed doses	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
9. Understanding of **how** to bridge patients with oral medication for planned missed doses	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
10. Management of patient injection-related pain/soreness	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Item	Number of Participants at Baseline	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
11. Answering patient questions between visits	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
12. Managing patients who present to CABENUVA appointments with other care needs that need to be addressed	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
13. Management of scheduling appointments during correct treatment windows	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
14. Management of rescheduling appointments during correct treatment windows	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
15. Management of confirming patient insurance coverage	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
16. Patient insurance coverage clearing for payment	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

NOTE: all items are 'select one response'; Table will be sorted from highest to lowest percentage of IC/ASA staff indicating extremely concerned, followed by moderately concerned, somewhat concerned, slightly concerned, and not at all concerned

Abbreviation: IC = infusion center; ASA = alternative site of administration; HIV = human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. Cell percentages do not include missing.

Table 1.2.2. IC/ASA Staff Concerns about CABENUVA Administration – Month 3 (N=XX)

	Number of Participants at Month 3	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
1. Patients' willingness to travel to an infusion center on a monthly basis	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Timely reporting to the provider when a patient receives CABENUVA	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

	Number of Participants at Month 3	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
3. Timely reporting to the provider when a patient misses a CABENUVA visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Timely reporting of adverse events to HIV providers	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
5. Frequency of lab draws at the infusion center	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
6. Management of reporting of adverse events	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
7. Management of reporting abnormal lab results with HIV providers	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
8. Understanding of **when** patients should receive oral medication for planned missed doses	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
9. Understanding of **how** to provide patients with oral medication for planned missed doses	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
10. Management of patient injection-related pain/soreness	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
11. Answering patient questions between visits	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
12. Managing patients who present to CABENUVA appointments with other care needs that need to be addressed	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
13. Management of scheduling appointments during correct treatment windows	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
14. Management of rescheduling appointments during correct treatment windows	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
15. Management of confirming patient insurance coverage	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
16. Patient insurance coverage clearing for payment	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

NOTE: all items are 'select one response'; Table will be sorted from highest to lowest percentage, at baseline, of IC/ASA Staff indicating extremely concerned, followed by moderately concerned, somewhat concerned, slightly concerned, and not at all concerned. The top 5 items in terms of percent indicating extremely concerned at baseline will be **bolded** at all subsequent time points. Tables reporting subsequent time points will be sorted the same as baseline table.

Abbreviation: IC = infusion center; ASA = alternative site of administration; HIV = human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective

timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. Cell percentages do not include missing.

Table 1.2.3. IC/ASA Staff Concerns about CABENUVA Administration – Month 8 (N=XX)

Table 1.3.1. IC/ASA Staff Feedback on IC/ASA Administration Blueprint, Month 3 (N=XX)

Question	Number of Participants at Month 3	Response	n (%)
1. In which format did you receive the blueprint?[1,2]	XX	PowerPoint	n (%)
		Word document	n (%)
		Both	n (%)
		I did not receive the blueprint (skip remaining)	n (%)
		Missing	n (%)
2. Which format do you prefer for the blueprint?[1,2]	XX	PowerPoint	n (%)
		Word document	n (%)
		Either format	n (%)
		Missing	n (%)
3. How often do you use or refer to the blueprint?[1]	XX	Extremely often	n (%)
		Very often	n (%)
		Somewhat often	n (%)
		Seldom	n (%)
		I have never used or referred to the blueprint (skip remaining)	n (%)
		Missing	n (%)
4. How useful is the blueprint?[1]	XX	Extremely useful	n (%)
		Very useful	n (%)
		Somewhat useful	n (%)
		Neutral	n (%)
		Not very useful	n (%)
		Not at all useful	n (%)
		Missing	n (%)
5. The blueprint contains the information I need to administer CABENUVA at my infusion center.[1]	XX	Strongly agree	n (%)
		Agree	n (%)
		Neither agree nor disagree	n (%)
		Disagree	n (%)
		Strongly disagree	n (%)
		Missing	n (%)
6. There is information I need for administering CABENUVA in my	XX	Strongly agree (go to 6a)	n (%)
		Agree (go to 6a)	n (%)
		Neither agree nor disagree (go to 7)	n (%)

Question	Number of Participants at Month 3	Response	n (%)
infusion center that is missing from the blueprint.[1]		Disagree (go to 7)	n (%)
		Strongly disagree (go to 7)	n (%)
		Missing	n (%)
6a. What do you think is missing from the blueprint?[1,3,4]	XX	Open-ended text*	n (%)
		Missing	n (%)
7. What is your overall opinion of the blueprint?[1,5]	XX	Extremely positive	n (%)
		Very positive	n (%)
		Somewhat positive	n (%)
		Neutral	n (%)
		Somewhat negative	n (%)
		Very negative	n (%)
		Extremely negative	n (%)
		Missing	n (%)

[1] Select one response

[2] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents.

[3]Only administered to respondents who endorsed "Agree" or "Strongly agree" for item 6.

[4]Open-ended text responses indicating N/A were not included in analyses

[5]Only administered to respondents who endorsed "Neither agree nor disagree" or "Disagree" for item 6.

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. *"Other" responses and open-ended text responses will be presented in an appendix

Cell percentages do not include missing and responses from participants who completed items which violated the prescribed skip pattern were omitted.

Abbreviations: IC = infusion center; ASA = alternative site of administration

Table 1.3.2. IC/ASA Staff Feedback on IC/ASA Administration Blueprint, Month 8

Table 2.1. IC/ASA Staff Responding "Agree" or "Completely Agree" On All FIM Items at Baseline, Month 3, and Month 8: Proportions and Change

	Number completing all 4 FIM items	Number endorsing 4 or 5 on all FIM Items	% endorsing all FIM Items	% Point Change
Baseline[1]	XX	XX	XX%	-
Month 3[1]	XX	XX	XX%	-
Month 8[1]	XX	XX	XX%	-
Baseline to Month 3[2]	XX	BL=XX M3=XX	BL=XX%; M3=XX%	XX%
Baseline to Month 8[2]	XX	BL=XX; M8=XX	BL=XX%; M8=XX%	XX%
Month 3 to Month 8[2]	XX	M3=XX; M8=XX	M3=XX%; M8=XX%	XX%

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items

[2]Each change row is limited to those completing all 4 items at both respective timepoints, which may differ from reporting at each individual timepoint; numerator = number responding '4' or '5', denominator = number completing all 4 items.

Abbreviations: IC = infusion center; ASA = alternative site of administration; FIM = Feasibility of Intervention Measure; BL=baseline; M3 = Month 3; M8 = Month 8

Responses: 4=CCI 5=CCI

Table 2.2. IC/ASA Staff Responding "Agree" or "Completely Agree" On All AIM Items at Baseline, Month 3, and Month 8: Proportions and Change

	Number completing all 4 AIM items	Number endorsing 4 or 5 on all AIM Items	% endorsing all AIM Items	% Point Change
Baseline[1]	XX	XX	XX%	-
Month 3[1]	XX	XX	XX%	-
Month 8[1]	XX	XX	XX%	-
Baseline to Month 3[2]	XX	BL=XX; M3=XX	BL=XX%; M3=XX%	XX%
Baseline to Month 8[2]	XX	BL=XX; M8=XX	BL=XX%; M8=XX%	XX%
Month 3 to Month 8[2]	XX	M3=XX; M8=XX	M3=XX%; M8=XX%	XX%

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items

[2]Each change row is limited to those completing all 4 items at both respective timepoints, which may differ from reporting at each individual timepoint; numerator = number responding '4' or '5', denominator = number completing all 4 items.

Abbreviations: IC = infusion center; ASA = alternative site of administration; AIM = Acceptability of Intervention Measure; BL=baseline; M3 = Month 3; M8 = Month 8

Responses: 4=CCI ; 5=CCI

Table 3.1. IC/ASA Staff, Distributional Characteristics of Feasibility of Intervention Measure (FIM), N=XX

Item/ Scale	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (–Min, Max)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
FIM Mean Score	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
1. Administering CABENUVA seems implementable in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
2. Administering CABENUVA seems possible in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
3. Administering CABENUVA seems doable in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
4. Administering CABENUVA seems easy to implement in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)

Abbreviations: BL=Baseline; CI = Confidence interval; FIM = Feasibility of Intervention Measure; IC/ASA = Infusion center/alternate site of administration; M3 = Month 3; M8 = Month 8; SD = standard deviation.

Percent Floor for the mean score is the percent of respondents with a score of 1 (CCI [redacted]) out of all respondents replying to at least two FIM items at a given time point.

Percent Ceiling for the mean score is the percent of respondents with a score of 5 (CCI [redacted]) out of all respondents replying to at least one two items at a given time point.

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. Missing for the mean score counts any instance where a respondent completed one FIM item, not reaching the minimum of 2 items required to calculate a mean FIM score.

Cell percentages do not include missing.

Table 3.2. IC/ASA Staff, Distributional Characteristics of Acceptability of Intervention Measure (AIM), N=XX

Item/ Scale	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (–Min, Max)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
AIM Mean Score	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X,X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
1. The idea of providing CABENUVA at my infusion center meets my approval.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
2. The idea of providing CABENUVA at my infusion center is appealing to me.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)

Abbreviations: AIM = Acceptability of Intervention Measure; BL=Baseline; CI = Confidence interval; IC/ASA = Infusion center/alternate site of administration; M3 = Month 3; M8 = Month 8; PLWHIV = Participants living with human immunodeficiency virus; SD = Standard deviation; CABENUVA = Cabotegravir Long-Acting + Rilpivirine Long-Acting;.
Percent Floor for the mean score is the percent of respondents with a score of 1 (CCI [redacted]) out of all respondents replying to at least two AIM items at a given time point.
Percent Ceiling for the mean score is the percent of respondents with a score of 5 (CCI [redacted]) out of all respondents replying to at least two AIM items at a given time point.
NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. Missing for the mean score counts any instance where a respondent completed one AIM item, not reaching the minimum of 2 items required to calculate a mean AIM score.

Cell percentages do not include missing.

Table 4.1. IC/ASA Staff, Univariate Distribution of Feasibility of Intervention Measure (FIM), N=XX

Items	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Administering CABENUVA seems implementable in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Administering CABENUVA seems possible in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. Administering CABENUVA seems doable in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Administering CABENUVA seems easy to implement in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; IC/ASA = Infusion center/alternate site of administration; M3 = Month 3; M8 = Month 8

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. Cell percentages do not include missing.

Table 4.2. IC/ASA Staff, Univariate Distribution of Acceptability of Intervention Measure (AIM), N=XX

Items	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The idea of providing CABENUVA at my infusion center meets my approval.	BL	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. The idea of providing CABENUVA at my infusion center is appealing to me.	BL	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.	BL	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.	BL	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	xx	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; IC/ASA = Infusion center/alternate site of administration; M3 = Month 3; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. Cell percentages do not include missing.

Table 5.1. IC/ASA Staff, Distributional Characteristics of Change in Feasibility of Intervention Measure (FIM), N=XX

Item/Scale	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (–Min, Max)	95% CI (Lower, Upper)
FIM Mean Score	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
1. Administering CABENUVA seems implementable in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
2. Administering CABENUVA seems possible in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
3. Administering CABENUVA seems doable in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
4. Administering CABENUVA seems easy to implement in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)

[1] Only includes IC/ASA Staff who completed surveys at respective months

Abbreviations: BL=Baseline; CI = Confidence interval; IC/ASA = Infusion center/alternate site of administration; FIM = Feasibility of Intervention Measure; M3 = Month 3; M8 = Month 8; SD = Standard deviation

NOTE: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to complete a survey at the respective timepoint.

Missing for the mean score counts any instance where a respondent completed one FIM item, not reaching the minimum of 2 items required to calculate a mean FIM score.

Cell percentages do not include missing.

Table 5.2. IC/ASA Staff, Distributional Characteristics of Change in Acceptability of Intervention Measure (AIM), N=XX

Item/Scale	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (–Min, Max)	95% CI (Lower, Upper)
AIM Mean Score	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
1. The idea of providing CABENUVA at my infusion center meets my approval.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
2. The idea of providing CABENUVA at my infusion center is appealing to me.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)

[1] Only includes IC/ASA Staff who completed surveys at respective months

Abbreviations: AIM = Acceptability of Intervention Measure; BL=Baseline; CI = Confidence interval; IC/ASA = Infusion center/alternate site of administration; M3 = Month 3; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation

NOTE: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to complete a survey at the respective timepoint.

Missing for the mean score counts any instance where a respondent completed one AIM item, not reaching the minimum of 2 items required to calculate a mean AIM score.

Cell percentages do not include missing.

Table 6.1. IC/ASA Staff, Shift of Feasibility of Intervention Measure (FIM) Response Frequency by Item, N=XX

1.Administering CABENUVA seems implementable in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree	**Disagree N=(xx)**	**Neither agree nor**	**Agree (N=xx)**	**Completely Agree**	

		N=(xx)		disagree N=(xx)		(N=xx)	Missing (N=XX)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
2. Administering CABENUVA seems possible in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	Disagree N=(XX)	Neither agree nor disagree N=(XX)	Agree (N=XX)	Completely Agree (N=XX)	Missing[1] (N=XX)
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
3. Administering CABENUVA seems doable in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

4. Administering CABENUVA seems easy to implement in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**

				N=(xx)			
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

Abbreviations: FIM = Feasibility of Intervention Measure; IC = infusion center; ASA = alternative site of administration

[1]Missing at T1, completed at T2

[2]Missing at T2, completed at T1

Percentage calculations:

Non-missing cell %:

numerator = number selecting respective combination of Time 1 and Time 2 responses

denominator = number of participants responding within Time 1 response category at Time 1

Table 6.2. IC/ASA Staff, Shift of Acceptability of Intervention Measure (AIM) Response Frequency by Item, N=XX

1. The idea of providing CABENUVA at my infusion center meets my approval.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
2. The idea of providing CABENUVA at my infusion center is appealing to me.							
		Baseline					

		Completely Disagree N=(XX)	Disagree N=(XX)	Neither agree nor disagree N=(XX)	Agree (N=XX)	Completely Agree (N=XX)	Missing[1] (N=XX)
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

Month 8	**Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.

		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

Abbreviations: FIM = Feasibility of Intervention Measure; IC = infusion center; ASA = alternative site of administration; PLWHIV = participants living with human immunodeficiency virus

[1]Missing at T1, completed at T2

[2]Missing at T2, completed at T1

Percentage calculations:

Non-missing cell %:

numerator = number selecting respective combination of Time 1 and Time 2 responses

denominator = number of participants responding within Time 1 response category at Time 1

7 Table Shells: IC/ASA Metrics

Table 7.1 IC/ASA Metric Reporting

Item	Numerator (N)	Denominator (N)	Proportion (%)	95% CI[1]
Consent Rate: Proportion of participants that provide consent to participate in the study *Numerator: Number of participants consented* *Denominator: Number of participants referred to the IC/ASA to receive CABENUVA IM injections*	XX	XX	XX	(XX%-XX%)
Show Rate: Proportion of scheduled injection appointments that are not missed[2,3] *Numerator: Number of scheduled injection appointments that result in shows* *Denominator: Number of confirmed scheduled injection appointments for participants*	XX	XX	XX	(XX% -XX%)
Participant Notification – Appointment level: Proportion of missed appointments in which the infusion center contacts the participant[3,4] *Numerator: Number of missed appointments for which the participant was contacted* *Denominator: Number of missed appointments*	XX	XX	XX	(XX% -XX%)
HIV Care Provider Notification: Proportion of all appointments missed that are communicated to the HIV care provider[3,4] *Numerator: Number of missed appointments that are communicated to the appropriate HIV care provider* *Denominator: Total number of missed appointments*	XX	XX	XX	(XX% -XX%)
Return Rate at Visit N: Proportion of participants that completed any injection at Visit N after the completion of (N-1)th injection visit[5] *Numerator: Number of participants who returned to the IC/ASA and completed an injection at Visit N* *Denominator: Number of participants who completed an injection at the IC/ASA at the previous visit (N-1)* *— This definition is for any scheduled post-baseline visit. When N=1, the previous visit (N-1) is the baseline visit.*	XX	XX	XX	(XX% -XX%)
Reach: Proportion of participants receiving injections at the infusion center/ASA as compared to the number of eligible participants through Month 8 Numerator: Number of participants receiving their first injection Denominator: Number of eligible participants[6]	XX	XX	XX	(XX% -XX%)

Item	Numerator (N)	Denominator (N)	Proportion (%)	95% CI[1]
Adoption (Clinic level): Proportion of clinics contacted by the infusion center/ASA that initiate referrals for the injections *Numerator:* Number clinics initiation a referral *Denominator:* Number of clinical contacted to refer	XX	XX	XX	(XX% -XX%)
Adoption Provider level *Numerator:* Number providers who initiated a referral *Denominator:* Number of providers contacted by IC	XX	XX	XX	(XX% -XX%)
Fidelity: Proportion of injections occurring within target window from target date (+/-7 days of target date)[7] Numerator: Number injections in window Denominator: Number of injections[7]	XX	XX	XX	(XX% -XX%)

[1] Based on the normal approximation to the binomial distribution. Upper bound capped at 100% and lower bound capped at 0%.

[2] Injection appointments that result in shows were defined as an injection at visit N occurring during the target window. Baseline visits were excluded as no scheduled date was recorded. Participants who withdrew during the target window were counted as no shows.

[3] Missed appointments were defined as any appointment for which no injection occurred among participants who reached the target window prior to study discontinuation.

[4] No missed dose forms were completed, therefore participant and HIV care provider notification could not be determined.

[5] Return rate was determined by counting the number of participants receiving an injection at visit N based on the number expected according to the number of participants at the previous visit.

[6] Eligible participants included consented, declined study participation, not scheduled/lost to follow-up after referral. Eligible participants excluded those not receiving CABENUVA due to lack/change of insurance or cancellation by HCP, not enrolled due to site closure, not attending infusion center, and unknown and was prescribed CABENUVA every other month (before permitted in study) and <18 years of age.

[7] Target dates for injections were determined in accordance with the methodology implemented in the PLWHIV outputs.

Abbreviations: CI = Confidence interval; HIV = human immunodeficiency virus; IC/ASA = infusion center/ alternate site of administration; IM = intramuscular; N/A = Not available; NE= Not estimable

Table 7.2 IC/ASA Metric Reporting - Palmetto

Table 7.3 IC/ASA Metric Reporting - Medix

Table 7.4 IC/ASA Metric Reporting - Infusion Associates

Table 8. Distributional Characteristics of the Feasibility Composite Score

	Number of Clinics[1]	Missing	Mean	SD	Median (Q1, Q3)	Range (Min, Max)	95% CI (Lower, Upper)	Cronbach's α[2]
Feasibility Composite Score[3]	XX	XX	XX.X	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)	X.XX
FIM Score[4]	XX	XX	XX.X	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)	X.XX
Consent Rate	XX	XX	XX.X	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)	X.XX
Show Rate	XX	XX	XX.X	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)	X.XX
Return Rate	XX	XX	XX.X	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)	X.XX

Feasibility composite score includes FIM score, consent rate, show rate, participant notification appointment level, HIV care provider notification, and return rate across the entire study period within each clinic.
Participants are assigned to clinics based on the initial referral.

[1] Includes only clinics consenting one or more participants.

[2] Standardized Cronbach's α. For components, Cronbach's alpha if item deleted is presented.

[3] Feasibility composite score includes FIM score, consent rate, show rate, and return rate across the entire study period within each clinic. Participant notification appointment level, and HIV care provider notification were excluded as no missed dose forms were completed.

[4] Based on proportion of PLWHIV endorsing all FIM items at a level of 4 or 5 at any timepoint.

Participants are assigned to clinics based on the initial referral.

Abbreviations: CI = Confidence interval; FIM = Feasibility of Intervention Measure; SD = Standard deviation

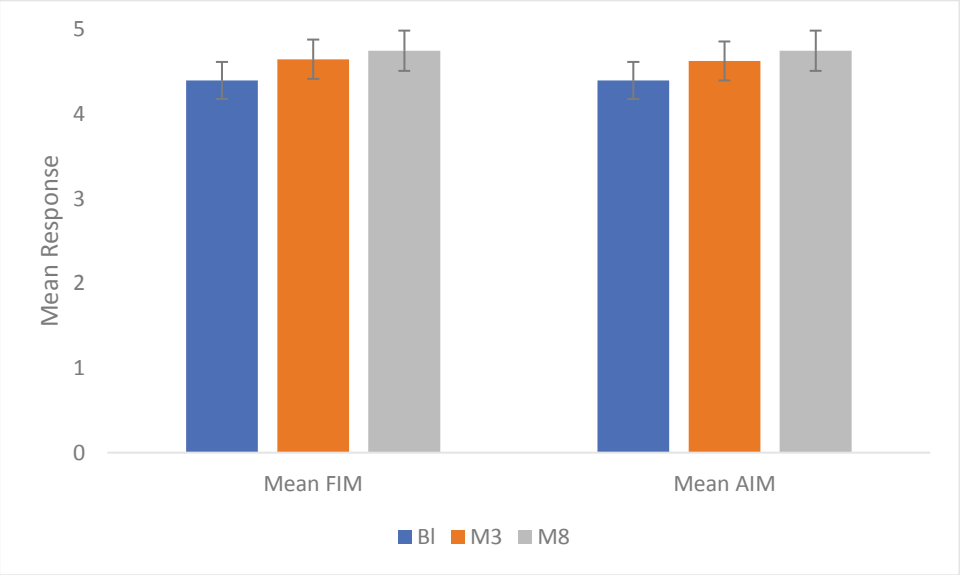
Table 9. Implementation Science-Related Protocol Deviations, N=XX

Protocol Deviation	IS-related Protocol Deviations For IC/ASA Staff (N= XX) n(%)
Total Sample IS-related Protocol Deviations	**xx (xx.x)**
Questionnaire missing data	xx (xx.x)
Questionnaire completed but not required	xx (xx.x)
Questionnaire completed out of window (early)	xx (xx.x)
Questionnaire completed out of window (late)	xx (xx.x)
Duplicate questionnaire completed	xx (xx.x)
Placeholder, other possible deviation	xx (xx.x)

Abbreviations: IC/ASA = infusion center/ alternate site of administration
[1]Deviations associated with incomplete IS questionnaires are for those initiated but not completed
Note: Numerators equal the number of IC/ASA staff experiencing respective deviation type, denominators equal the number of IC/ASA staff in analytic dataset

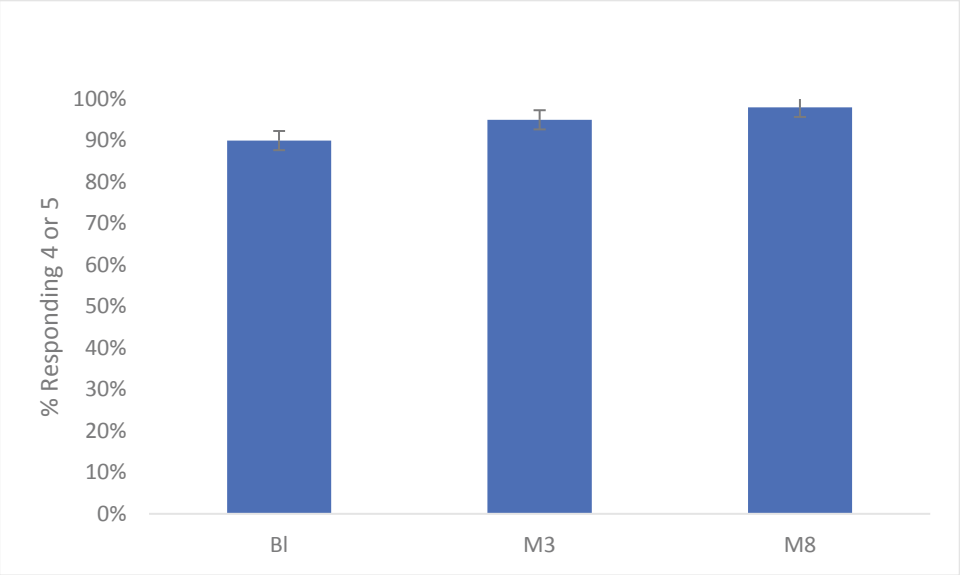
8 Figures

Figure 1. Bar Chart Showing Mean IC/ASA Staff FIM and AIM Responses at Baseline, Month 3, and Month 8



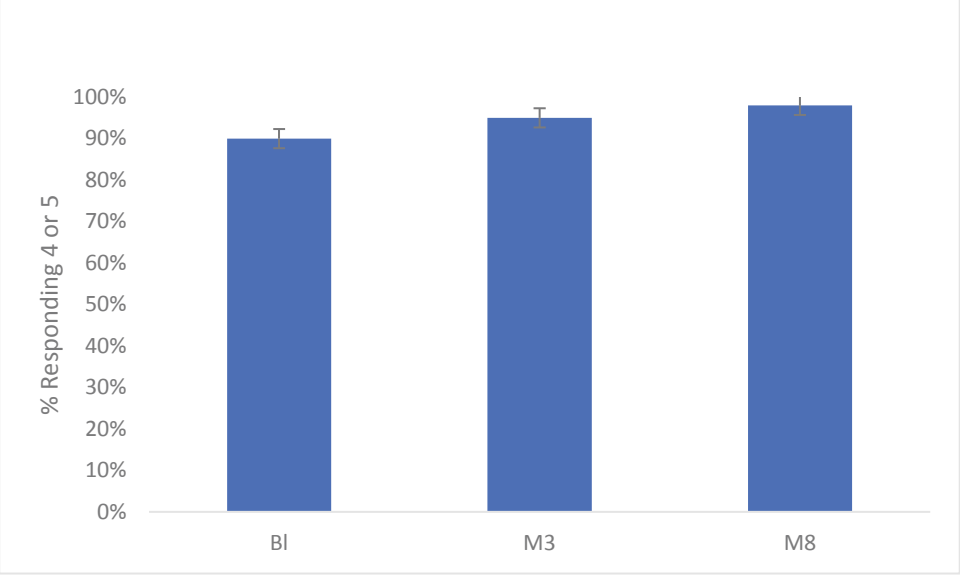
Abbreviations: IC/ASA = Infusion center/ alternate site of administration; FIM = Feasibility of Intervention Measure ; AIM = Acceptability of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Error Bars = Standard error

Figure 2. Bar Chart Showing Proportion of IC/ASA Staff Responding "Agree" or "Completely Agree" on All FIM Items at Baseline, Month 3, and Month 8



Abbreviations: IC/ASA = Infusion center/alternate site of administration; FIM = Feasibility of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Responses: 4=CCI 5=CCI
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

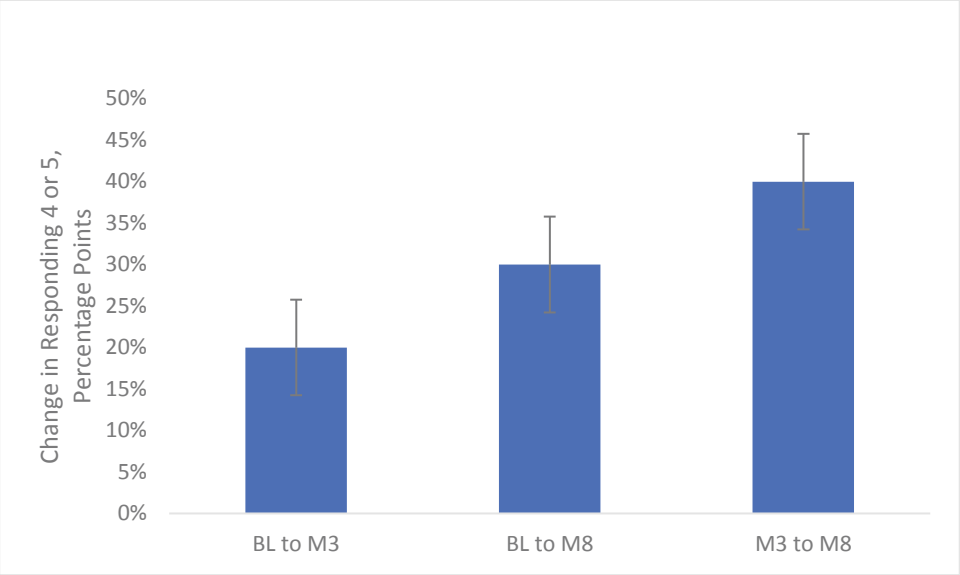
Figure 3. Bar Chart Showing Proportion of IC/ASA Staff Responding "Agree" or "Completely Agree" on All AIM Items at Baseline, Month 3, and Month 8



Abbreviations: IC/ASA = Infusion center/alternate site of administration; AIM = Acceptability of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Responses: 4=CCI , 5=CCI

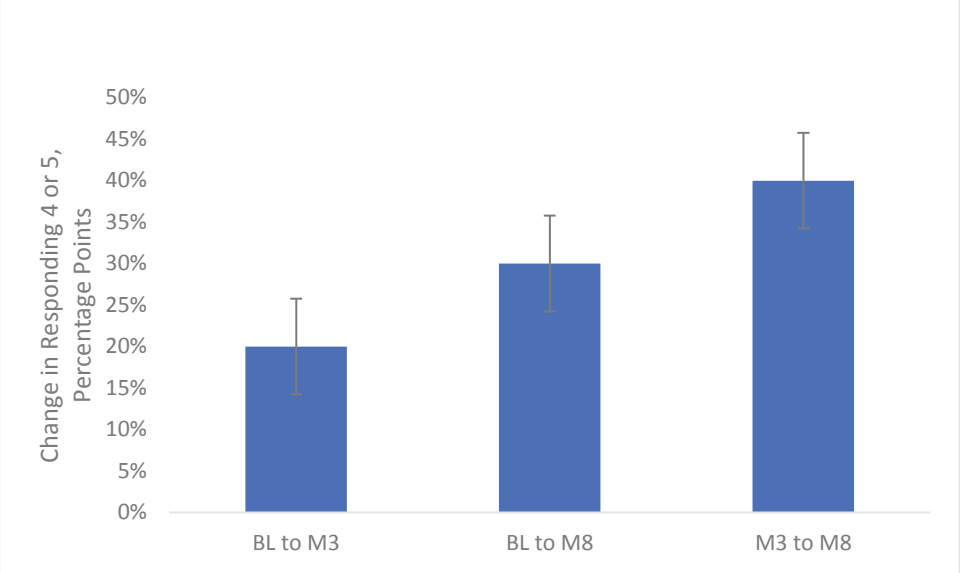
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 4. Bar Chart Showing Change in Proportion of IC/ASA Staff Responding "Agree" or "Completely Agree" on All FIM Items, Baseline to Month 3, Baseline to Month 8, and Month 3 to Month 8



Abbreviations: IC/ASA = Infusion center/alternate site of administration; FIM = Feasibility of Intervention Measure; BL=baseline; M3 = Month 3; M8 = Month 8
Responses: 4=CCI 5=CCI
Note: Each bar is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 5. Bar Chart Showing Change in Proportion of IC/ASA Staff Responding "Agree" or "Completely Agree" on All AIM Items, Baseline to Month 3, Baseline to Month 8, and Month 3 to Month 8



Abbreviations: IC/ASA = Infusion center/alternate site of administration; AIM = Acceptability of Intervention Measure; BL=baseline; M3 = Month 3; M8 = Month 8

Responses: 4=CCI 5=CCI

Note: Each bar is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items

Error Bars = Standard error

Appendix A. Missing Data

Table A1. Summary of Missing Data

Timepoint	Item	Completed n(%)	Missing n(%)
Baseline N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 3 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 8 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)

Abbreviations: AIM = Acceptability of Intervention Measure; FIM = Feasibility of Intervention Measure

Table A1. Summary of Free-text Responses

A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or Alternate Sites of Administration:

Statistical Analysis Plan: Participants Living with HIV for Implementation Science Questionnaires

EVA-30466 | March 4, 2024 | Version 4.0

Prepared For:

PPD, GSK

PPD, PhD | PPD, Global Implementation Research, ViiV Healthcare

Prepared By:

PPD, PhD

PPD, PhD MPH

PPD, PhD MPH

Project Contact:

PPD

Statistical Analysis Plan (SAP) Signature Page

SAP Title: A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or Alternative Site of Administration. Statistical Analysis Plan: Participants Living with HIV for Implementation Science Questionnaires.

SAP Date and Version: March 4th, 2024; Version 4.0

This SAP with the title, number, and version indicated above has been reviewed and approved by the Evidera Principal Investigators and Project Managers.

PPD

_____
Date

_____
Date

_____
Date

_____
Date

Table of Contents

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List of Abbreviations

Abbreviation	Definition
AIM	Acceptability of Intervention Measure
ART	Antiretroviral therapy
ASA	Alternative site of administration
BL	Baseline
CI	Confidence interval
EDC	Electronic data capture
FDA	Food and Drug Administration
FIM	Feasibility of Intervention Measure
HIV	Human immunodeficiency virus
IC	Infusion center
IM	Intramuscular
M3	Month 3
M8	Month 8
OCR	Optical character recognition
PDF	Portable document format
PLWHIV	Participants living with human immunodeficiency virus
QAP	Qualitative analysis plan
SAP	Statistical analysis plan
SD	Standard deviation
SoA	Schedule of Activities

1 Introduction

CABENUVA is a two-drug, co-packaged product of cabotegravir plus rilpivirine, both administered as long-acting, intramuscular (IM) injections once-monthly or every two months; it is an approved treatment for human immunodeficiency virus (HIV). Clinical trial results have shown that CABENUVA administered once-monthly or every two months is non-inferior to daily oral treatment for HIV.

Long-acting injectable treatments require changes in how HIV care is delivered. People living with HIV must attend appointments for their injections once a month or every two months, rather than seeing their providers several times per year for a prescription refill and monitoring visits. This poses new healthcare delivery challenges, including a shift in resources to this alternative means of delivering and receiving treatment—thus requiring the expansion of alternative injection facilities to include infusion centers (ICs) or alternate sites of administration (ASAs). This has the potential to impact workload capacity for these facilities, though it also has the potential to positively impact treatment engagement and retention for people living with HIV.

ICs/ASAs are an appealing option that can ease the burden of additional appointments, administrative work, and drug ordering in HIV specialty clinics, as well as provide people living with HIV with greater flexibility in where they receive their monthly or every two months injections. In this study, the intervention itself is the process of using an IC/ASA as the location to receive the CABENUVA IM injections. Specifically, the acceptability and feasibility of injection delivery at ICs/ASAs will be assessed from the perspectives of the participants living with HIV (PLWHIV), HIV care providers/clinical staff, and IC/ASA staff.

This statistical analysis plan (SAP) describes analyses for the acceptability and feasibility of an IC/ASA to deliver CABENUVA IM injections, as reported by study PLWHIV. It also encompasses a tailored questionnaire that asks PLWHIV about their experiences regarding their medication regimen, as well as their overall health, education, and employment status.

This is one of four SAPs for the following protocol: *Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based infusion centers or alternate sites of administration*. The three additional SAPs are:

(1) an additional SAP for clinical characteristics/analyses for PLWHIV, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based infusion centers or alternate sites of administration: Statistical Analysis Plan for Clinical Analyses,*

(2) analyses for HIV care providers and Expert Panel, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based infusion centers or alternate sites of administration, Statistical Analysis Plan: HIV Care Providers and key personal who are involved in the patients' care (Clinical Staff) & Expert Panel*; and

(3) analyses for IC/ASA staff, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based infusion centers or alternate sites of administration*, *Statistical Analysis Plan: Infusion Center Staff.*

This SAP will describe the planned analyses for the primary and secondary quantitative objectives related to implementation science for PLWHIV as outlined in Table A. Additionally, this plan will not incorporate the planned qualitative interview analyses at the end of study. These analyses are detailed in the qualitative analysis plan (QAP) (currently under development).

Table A. Objectives and Endpoints for Participants

Objectives	Endpoints
Primary	
To evaluate feasibility of CABENUVA administration at infusion centers or alternate sites of administration from participants	Proportion of participants that agree or completely agree (a score of 4 or higher) across all items on the FIM at Month 8
Secondary	
To evaluate feasibility of CABENUVA administration at infusion centers or alternate sites of administration from participants	Proportion of participants that agree or completely agree (a score of 4 or higher) across all items on the FIM at Month 1, Month 3
	Change over time in the FIM at Month 3 and Month 8 with participants
	Summary of other quantitative questionnaires assessed with participants at Month 1, Month 3, and Month 8
	Qualitative interviews assessed at Month 8 with participants (QAP)
To evaluate feasibility of the process of administering CABENUVA at the infusion center/ ASA	Summary of composite score of the feasibility process indications through Month 8
	Change over time through Month 8 in the composite score and each item of composite score.
To evaluate acceptability of CABENUVA administration at infusion centers or alternate sites of administration from participants	Proportion of participants that agree or completely agree (a score of 4 or higher) across all items on the AIM at Month 1, Month 3and Month 8
	Change of participants over time in the AIM at Month 3 and Month 8
	Summary of other quantitative questionnaires assessed at Month 1, Month 3, and Month 8 with participants
	Qualitative interviews assessed at Month 8 with participants (QAP)
To evaluate perceptions, facilitators, and barriers/concerns by participants	Summary of participant other quantitative questionnaires at Month 1, Month 3 and Month 8
	Qualitative interviews assessed at Month 8 with participants (QAP)
To assess the preference of participants on the location to receive CABENUVA	Summary of preference on the location to receive CABENUVA at Month 1, Month 3, and Month 8 assessed by participant other quantitative questionnaires
	Qualitative interviews assessed at Month 8 with participants (QAP)
To assess the advantages to receive or refer participants to receive CABENUVA at the infusion center or alternate site of administration from participants	Summary of advantages of receiving CABENUVA at IC/ASA at Month 1, Month 3, and Month 8 assessed by participant other quantitative questionnaires
	Qualitative interviews assessed at Month 8 with participants (QAP)
To assess the disadvantages about receiving CABENUVA at the infusion	Summary of disadvantages of receiving CABENUVA at ICs/ASAs from participant other quantitative questionnaires at Month 1, Month 3, and Month 8
	Qualitative interviews assessed at Month 8 with participants (QAP)

Objectives	Endpoints
center or alternate site of administration from participants	
To evaluate the acceptability of receiving and referring participants for CABENUVA injections at infusion centers or alternate sites of administration from participants	Summary of acceptability of the process of receiving injections at ICs/ASAs from participant other quantitative questionnaires at Month 1, Month 3and Month 8
	Qualitative interviews assessed at Month 8 with participants (QAP)
To evaluate overall opinion of receiving and administering the injection at an infusion center or alternate site of administration by participants	Summary of overall opinion of receiving CABENUVA at an infusion center or alternate site of administration by participant other quantitative questionnaires at Month 1, Month 3, and Month 8.
	Qualitative interviews at Month 8 with participants (QAP)

Abbreviations: AIM = Acceptability of Intervention Measure; ASA=Alternative Site of Administration; FIM = Feasibility of Intervention Measure; IC = infusion center; QAP = Qualitative Analysis Plan

2 Study Design

This is a Phase 4, single-arm, open-label, multi-center study examining the administration of CABENUVA IM in ICs/ASAs in the United States. This study is being conducted following Food and Drug Administration (FDA) approval and commercial availability of CABENUVA. Eligible and consenting PLWHIV will be followed for eight months to evaluate an implementation blueprint for IM administration of CABENUVA for HIV-1 treatment at ICs/ASAs. The total duration for study PLWHIV is approximately eight months from the time of enrollment and receipt of the first administration of CABENUVA IM injections at the IC/ASA.

Relevant to this SAP, up to 120 PLWHIV who have been prescribed CABENUVA by their HIV care provider will be asked to complete questionnaires per the Schedule of Activities (SoA; see ANNEX 1 in protocol), as follows:

- Baseline/Month 1 questionnaires should be completed prior to receiving the first CABENUVA injections
- Baseline/Month 1 for each PLWHIV is defined as the date when a PLWHIV signs the informed consent form and completes Baseline/Month 1 protocol procedures prior to receiving the first CABENUVA injections at the IC/ASA
- Months 3 and 8 will be anchored off of each PLWHIV Baseline/Month 1 visit, so it will reflect the Months on study, regardless of what dose they are on and regardless of whether they have missed any injections and received oral bridging.

PLWHIV questionnaires consist of the Feasibility of Intervention Measure (FIM) and the Acceptability of Intervention Measure (AIM), as well as a tailored questionnaire.

2.1 Description of the PLWHIV Questionnaire and Schedule for Completion

The PLWHIV questionnaire consists of two validated instruments and tailored items written for this study. The validated instruments are the FIM and AIM, described below. The tailored items ask PLWHIV about a number of topics, including preferences and attitudes regarding their medication regimen.

PLWHIV will be asked to complete a questionnaire at Baseline/ Month 1 and at Months 3 and 8 (see table above).

Table B. Questionnaire Administration for PLWHIV

Questionnaire	Baseline/ Month 1	Month 3	Month 8
Feasibility of Intervention Measure	x	x	x
Acceptability of Intervention Measure	x	x	x
PLWHIV Tailored Items	x	x	x

Abbreviation: PLWHIV = participants living with human immunodeficiency virus

2.1.1 Feasibility of Intervention Measure

The FIM (four items) is employed to evaluate the feasibility of an implementation strategy and assess perceived intervention feasibility. Items are measured on a five-point rating scale (1=CCI [redacted], 2=CCI [redacted], 3=CCI [redacted], 4=CCI [redacted], 5=CCI [redacted]). The FIM was validated with other implementation outcome measures.[1] Higher scores indicate greater feasibility. There are no reverse-scored items on the FIM, and the mean score for feasibility of the intervention is calculated by averaging the responses from the four items.

2.1.2 Acceptability of Intervention Measure

The AIM (four items) is employed to evaluate the acceptability of an implementation strategy and assesses perceived intervention acceptability. The items are measured on a five-point rating scale (1=CCI [redacted], 2=CCI [redacted], 3=CCI [redacted], 4=CCI [redacted], 5=CCI [redacted]). The AIM was validated with a suite of implementation outcome measures.[1] Higher scores indicate greater acceptability. There are no reverse-scored items on the AIM, and the mean score for acceptability of the intervention is calculated by averaging the responses from the four items.

2.1.3 PLWHIV Additional Questionnaire

The tailored PLWHIV questionnaire was developed specifically for this study and contains items regarding the reasons for switching to CABENUVA, adherence to their previous oral HIV medication, preferences and attitudes regarding their medication regimen, and perceived advantages and disadvantages of receiving injections at the IC/ASA. The Baseline/ Month 1 PLWHIV questionnaire has 34 items (including the FIM and AIM), and the Month 3 and Month 8 questionnaires have 39 items, will be a hybrid of paper and CRF (Medidata).

2.1.4 Data Management

The Baseline/ Month 1 PLWHIV questionnaires will be collected by electronic data capture (EDC) via MediData rave using tablets at the study sites. Subsequent questionnaires will also be collected by EDC. Any questionnaires completed on paper, due to issues with EDC devices for example, will be entered into the EDC at the sites by clinical staff. Queries will focus on issues of missing data. Missing surveys will be queried (by e-mail) to the IC/ASA staff member, to verify that surveys were completed. If data are still missing, follow-up queries will be initiated by the study team with respective IC/ASA staff. Queries remaining open from unresponsive IC/ASA staff may be closed with GSK/ViiV review and approval.

2.2 Windows for Questionnaire Completion

Baseline/Month 1 is defined as the date when a participant signs the Informed Consent Form (ICF) and completes Baseline/Month 1 protocol procedures prior to receiving the first study related CABENUVA injections at the IC/ASA

All additional study visits, including those where questionnaires and/or interviews are administered at Months 3 and 8 will be anchored off of each participant's Month 1 visit, so it will reflect the months on study, regardless of what dosing regimen the participant is on (e.g., monthly or every 2 months) and regardless of whether they have missed any injections and received oral bridging.

At Month 1, questionnaires should be completed after signing the ICF and before receiving CABENUVA intramuscular (IM) injections or within 14 days following the Month 1 visit. Questionnaires should be completed before receiving CABENUVA IM injections or +/- 14 days following the last visit.

2.3 Conditions for Inclusion in Analytic Dataset

Duplicate Questionnaires

In the instance that duplicate questionnaires are present for the same participant at the same visit, the temporally first-administered questionnaire will be included in the analytical dataset if it is fully completed. If the first questionnaire is not fully completed and the temporally second-administered questionnaire is fully completed, then the second questionnaire will be included in the analytical dataset. If neither questionnaire is fully completed, the temporally first-administered questionnaire will be included in the analytical dataset.

Out-of-Window Questionnaires

Questionnaires will not be excluded for being out of temporal window (see Section 2). A sensitivity analysis will be performed for all analyses described in the current SAP that pertain to FIM or AIM items, with all out-of-window questionnaires removed. Results of these analyses will be compared to the main analyses, and the magnitude of differences will be summarized descriptively.

2.4 Implementation Science-Related Protocol Deviations

Implementation science-related protocol deviations will be reported, where numerators equal the number of PLWHIV experiencing the respective deviation type, and denominators equal the number of PLWHIV in analytic dataset. Deviations reported will include, but are not limited to, the following:

questionnaires with missing data, questionnaires completed but not required at respective time point, questionnaires completed out of window (early), questionnaire completed out of window (late), and duplicate questionnaire completed. Missing data is considered a deviation if any item is missing, and the participant has not dropped out of the study. See section 2.3 and 3.1 for how deviations affect inclusion in analytic dataset.

3 Statistical Methods

This SAP has been developed to guide the analyses for the data collected and assumes that all data will be collected in adherence to the protocol developed by GSK/ViiV. The analysis population is all PLWHIV who complete any portion of any questionnaire at any point in the study. As the data are analyzed, some deviation from expectations may occur. In instances where these deviations would make the proposed analyzes inappropriate, modifications to the SAP—along with justifications for these changes—will be made and noted in the final report.

Continuous and interval-like variables will be summarized using descriptive statistics (e.g., n, mean, standard deviation [SD], median, minimum, maximum, first and third quartiles, and confidence intervals [CIs]). Data in tables will be tabulated relative to the source data. Mean, median, and quartiles will be tabulated to one more decimal place than the source data; minimum/maximum values will have the same decimal places as source data; percentages will be rounded to one decimal place after calculation. SD and CIs will be tabulated to two more decimal places than the source data. Categorical variables will be reported as frequency counts, the percentage of PLWHIV in corresponding categories, and 95% CIs.

Subgroup analysis will be performed to evaluate the effect of contextual factors on the variability of responses to feasibility and acceptability. These factors may include, but are not limited to, demographic, baseline characteristics, prior clinical experience, initiation method (oral lead in or direct to injection or receiving continuation dose), the number of injections received prior to enrollment and injection option (monthly or every two months) for PLWHIV. Once specified these will be added to this SAP.

For the analyses of the proportion of PLWHIV responding agree or completely agree on all FIM items, this will include the PLWHIV who select response option 4 (CCI [redacted]) or 5 CCI [redacted] for all four FIM items at a given time point, out of all PLWHIV who completed all four FIM items at that respective timepoint. The same definition applies to the analogous analysis for the AIM.

3.1 Missing Data Handling Scheme

Missing data at the multi-item scale level for standardized scales (FIM and AIM) will be addressed with standard proration rules[2]: if at least 50% of the items are completed the scale will be scored by taking the mean of the completed items, unless otherwise specified for a particular outcome. Following this, partially completed FIM and AIM administrations will be scored if two, three, or four items are completed, and will not be scored if only one item is completed. Items not completed will be logged as

missing data. No missing data will be imputed. Table shells for missing data from FIM and AIM scales can be found in Appendix A.

3.2 Cross-sectional Univariate Distributions of Study Variables and Features of Score Distributions

For questions with ordinal responses, a univariate distribution of every item will be tabulated. Standard distributional statistics will be tabulated for interval-like (ordinal) variables, including mean, SD, median, percentage missing, range (minimum and maximum of responses), percentage of the sample at the ceiling (highest possible score) and floor (lowest possible score), first and third quartiles, and 95% CIs. For questions with descriptive responses, a frequency distribution of all responses will be presented with n (%).

3.3 Distributions of Study Variables and Features of Score Distributions, Change from Baseline/ Month 1 for FIM and AIM

The univariate distribution of item change scores (Month 3 minus Baseline/ Month 1, Month 8 minus Baseline/ Month 1, and Month 8 minus Month 3) will be tabulated for the FIM and AIM, both in terms of distributional characteristics of change and frequency of responses. Distributional characteristic tables will include the SD of the change distribution, median change, first and third quartiles, and 95% CIs. Change analyses will be limited to those PLWHIV completing questionnaires at Baseline/ Month 1 and each respective timepoint. Categorical data for the FIM and AIM will be presented in shift analyses showing the frequency of change by the degree of shift across response categories and will be presented for Baseline/ Month 1 to Month 3, Baseline/ Month 1 to Month 8, and Month 3 to Month 8.

4 Fidelity to Treatment in Dosing Window

The fidelity to treatment in dosing window will be described in terms of the number and percentage of participants with CABENUVA injections not completed within the +/-7 day window of target dosing date, grouped by the number of missed injections. The distributional characteristics (mean, standard deviation, median, first and third quartiles minimum, and maximum) of the number of days from the target dosing date will also be summarized by visit. Fidelity to treatment in dosing window will be described separately for participants receiving monthly and bi-monthly injections.

5 Qualitative Analysis

Qualitative analyses will be described in the Qualitative Analysis Plan.

5 References

1. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci.* 2017;12(1):108.
2. Cella D. *Manual of the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System—Version 4.* Evanston, IL: Center on Outcomes, Research & Education (CORE), Evanston Northwestern Healthcare and Northwestern University; 1997.

6 Table Shells: Baseline, Month 3, Month 8, and Change

Table 1. PLWHIV Characteristics Baseline (N=XX)

Question	Number of Participants at Baseline	Response / Statistic	Value
1. What is your age?	XX	Mean (SD)	XX.X (X.X)
		Median (Q1-Q3)	XX (XX-XX)
		Range (–Min, Max)	(XX, XX)
		Missing	X
2. I consider my current state of health to be … [1]	XX	Excellent	n (%)
		Very Good	n (%)
		Good	n (%)
		Fair	n (%)
		Poor	n (%)
		Missing	n (%)
3. What is the highest level of education you have completed (select one response)?[1]	XX	Less than high school	n (%)
		High School or equivalent	n (%)
		Bachelor's degree	n (%)
		Master's degree	n (%)
		Doctoral degree	n (%)
		Other	n (%)
		Prefer not to answer	n (%)
		Missing	n (%)
4. What is your employment status?[2,3]	XX	Employed full-time	n (%)
		Employed part-time	n (%)
		Student	n (%)
		Not currently employed	n (%)
		Retired	n (%)
		Not working due to my health	n (%)
		Other*	n (%)
		Missing	n (%)

[1] Select one response
[2] Select all that apply
[3] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents.
Abbreviation: PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation
NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing.

* "Other" responses and open-ended text responses will be presented in an appendix

Table 1.2.1. PLWHIV Medication Regimen: Experience, Practices, and Views, Baseline (N=XX)

Question	Number of Participants at Baseline	Response	n (%)
1. How often do you typically see your HIV doctor?[1]	XX	Once every 3 months	n (%)
		Once every 4 months	n (%)
		Once every 6 months	n (%)
		Once every 12 months	n (%)
		Other*	n (%)
		Missing	n (%)
2. Have you received CABENUVA injections before today?[1]	XX	No, I have not received CABENUVA injections prior to today. (Go to Q4)	n (%)
		Yes, I've received CABEUNVA injections prior to today. (provide Q3 as pop-up)	n (%)
		I am not sure. (Go to Q3)	n (%)
		Missing	n (%)
3. How many CABENUVA injections have you had in the past?[1]	XX	1 injection	n (%)
		2 injections	n (%)
		3 or more injections	n (%)
		Missing	n (%)
4. What is the primary reason why you decided to switch your ART regimen to CABENUVA?[1,2]	XX	It was difficult for me to remember to take my previous HIV medications everyday	n (%)
		I was concerned about the long-term side effects of my previous HIV medications	n (%)
		I was not tolerating my prior HIV medications well because of side effects	n (%)
		I was tired of taking my medication every day	n (%)
		I experience(d) anxiety or stress about others seeing my daily pills and finding out that I have HIV	n (%)
		I do not want my HIV treatment to remind me of my HIV status every day	n (%)
		I experience(d) anxiety or stress about missing a dose of my HIV medications	n (%)
		I wanted a treatment option that is more convenient for my life	n (%)
		My HIV doctor suggested that I switch	n (%)
		I worried that my viral load was not suppressed with my prior oral HIV medications	n (%)
		I had difficulty swallowing my oral HIV treatment	n (%)
		Other*	n (%)
		Missing	n (%)

Question	Number of Participants at Baseline	Response	n (%)
5. What other reason(s) did you have for switching your ART regimen to CABENUVA?[2,3]	XX	It was difficult for me to remember to take my previous HIV medications everyday	n (%)
		I was concerned about the long-term side effects of my previous HIV medications	n (%)
		I was not tolerating my prior HIV medications well because of side effects	n (%)
		I was tired of taking my medication every day	n (%)
		I experience(d) anxiety or stress about others seeing my daily pills and finding out that I have HIV	n (%)
		I do not want my HIV treatment to remind me of my HIV status every day	n (%)
		I experience(d) anxiety or stress about missing a dose of my HIV medications	n (%)
		I wanted a treatment option that is more convenient for my life	n (%)
		My HIV doctor suggested that I switch	n (%)
		I worried that my viral load was not suppressed with my prior oral HIV medications	n (%)
		I had difficulty swallowing my oral HIV treatment	n (%)
		Other*	n (%)
		Missing	n (%)
6. Prior to deciding to switch to CABENUVA, did you have any problems with taking your daily oral HIV medications?[2,3]	XX	I experienced side effects with my daily HIV medications	n (%)
		I had problems remembering to take my daily HIV medications	n (%)
		I was concerned about running out of my daily HIV medications	n (%)
		I take too many oral medications and would prefer to take fewer all together	n (%)
		I had anxiety about taking my daily HIV medications	n (%)
		I felt that I had to hide my daily HIV medications from others	n (%)
		My daily HIV medications reminded me of my HIV status	n (%)
		My daily HIV medication routine was not convenient for me	n (%)
		I had difficulty with paying for my daily HIV medications	n (%)
		I had difficulty swallowing my daily pills (for any reason)	n (%)
		I worried about potential interaction with other treatments	n (%)
		I worried about the food requirement when taking my daily HIV medication	n (%)
		I had difficulty/worry about getting to the pharmacy to get my daily HIV medications	n (%)
		I had difficulty/worry about wait times at the pharmacy to get my daily HIV medications	n (%)
		I had difficulty/worry about the pharmacy not having my daily HIV medications in stock	n (%)
		Other*	n (%)

Question	Number of Participants at Baseline	Response	n (%)
		I did not have any problems with my prior daily HIV medications	n (%)
		Missing	n (%)

Question	Number of Participants at Baseline	Response	n (%)
7. When you were taking daily oral HIV medication, how often did you not take your HIV medicine during a typical week?[1]	XX	Never	n (%)
		Less than once per week	n (%)
		Once or twice per week	n (%)
		Three or four times per week	n (%)
		More than five times per week	n (%)
		Missing	n (%)
8. What were your reasons for not taking your daily oral HIV medicine?[2,3]	XX	Forgot	n (%)
		Social plans interfered with usual dosing time	n (%)
		Work schedule interfered with usual dosing time	n (%)
		Travel/vacation (either work or pleasure)	n (%)
		To avoid side effects	n (%)
		Did not feel well	n (%)
		Ran out of medication	n (%)
		Changed medication	n (%)
		I never forgot to take my daily oral meds	n (%)
		Other*	n (%)
		Missing	n (%)
9.What are/were your biggest concerns about receiving CABENUVA at an infusion center?[2,3]	XX	The infusion center managing my pain or soreness from CABENUVA	n (%)
		The infusion center managing the side effects from CABENUVA	n (%)
		My doctor not knowing if I have a bad reaction	n (%)
		The infusion center not aware of my other medical history	n (%)
		Infusion center not aware of my other medications and possible interactions	n (%)
		Scheduling upcoming CABENUVA visits	n (%)
		Rescheduling missed CABENUVA visits	n (%)
		Forgetting my appointments for the CABENUVA visits	n (%)
		Frequency of the required visits to the infusion center clinic as well as my primary HIV doctor	n (%)
		Transportation to the infusion center for the CABENUVA visits	n (%)
		Parking at the infusion center for CABENUVA visits	n (%)
		The infusion center hours for CABENUVA visits	n (%)
		Childcare during CABENUVA visits	n (%)
		Infusion Center not being an HIV-specific clinic	n (%)
		Others at the clinic may find out that I am HIV positive	n (%)
		Other*	n (%)
		No current worries about receiving CABENUVA at an infusion center	n (%)
		Missing	n (%)

Question	Number of Participants at Baseline	Response	n (%)
10. Where would you prefer to receive CABENUVA?[1,2]	XX	At my HIV doctor's clinic	n (%)
		At an infusion center	n (%)
		At home	n (%)
		At a pharmacy	n (%)
		Other*	n (%)
		Missing	n (%)
11. How interested would you be in these other ways of receiving your CABENUVA injections, if available in the future?			
11a. At home, administered by a partner as two injections in your gluteal (buttocks) muscle (same type of injections you have been/will be receiving in this study)[1]	XX	Very interested	n (%)
		Moderately interested	n (%)
		Somewhat interested	n (%)
		A little interested	n (%)
		Not at all interested	n (%)
		Missing	n (%)
11b. At home, administered by a partner as two injections in your thigh[1]	XX	Very interested	n (%)
		Moderately interested	n (%)
		Somewhat interested	n (%)
		A little interested	n (%)
		Not at all interested	n (%)
		Missing	n (%)
11c. At home, self-administered by you as two injections in your thigh[1]	XX	Very interested	n (%)
		Moderately interested	n (%)
		Somewhat interested	n (%)
		A little interested	n (%)
		Not at all interested	n (%)
		Missing	n (%)

[1] Select one response
[2] Within each question, response choices will be ordered by percent endorsing descending, ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.
[3] Select all that apply
Abbreviations: ART = antiretroviral therapy; HIV = human immunodeficiency virus; PLWHIV = participants living with human immunodeficiency virus.
NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.
Cell percentages do not include missing. Cell percentages do not include missing.
* "Other" responses and open-ended text responses will be presented in an appendix

Table 1.2.2. PLWHIV Medication Regimen: Experience, Practices, and Views, Month 3 (N=XX)

Question	Number of Participants at Month 3	Response	n (%)
1. Do you have any concerns about continuing to receive CABENUVA at an infusion center?[1]	XX	Yes (go to Q2)	n (%)
		No (go to Q3)	n (%)
		Missing	n (%)
2. What are your biggest concerns about continuing to receive CABENUVA at an infusion center?[2,3]	XX	The infusion center managing my pain or soreness from CABENUVA	n (%)
		The infusion center managing the side effects from CABENUVA	n (%)
		My doctor not knowing if I have a bad reaction	n (%)
		The infusion center not aware of my other medical history	n (%)
		Infusion center not aware of my other medications and possible interactions	n (%)
		Scheduling upcoming CABENUVA visits	n (%)
		Rescheduling missed CABENUVA visits	n (%)
		Forgetting my appointments for the CABENUVA visits	n (%)
		Frequency of the required visits to the infusion center clinic as well as my primary HIV provider	n (%)
		Transportation to the infusion center for the CABENUVA visits	n (%)
		Parking at the infusion center for CABENUVA visits	n (%)
		The infusion center hours for CABENUVA visits	n (%)
		Childcare during CABENUVA visits	n (%)
		Infusion center not being an HIV-specific clinic	n (%)

		Others at the infusion center may find out that I am HIV positive	n (%)
		Other*	n (%)
		Missing	n (%)
3. Where would you prefer to receive CABENUVA?[1,3]	XX	At my HIV provider's clinic	n (%)
		At an infusion center	n (%)
		At home	n (%)
		At a pharmacy	n (%)
		Other*	n (%)
		Missing	n (%)
4. How interested would you be in these other ways of receiving your CABENUVA injections, if available in the future?			
4a. At home, administered by a partner as two injections in your gluteal (buttocks) muscle (same type of injections you have been receiving in this study)[1]	XX	Very interested	n (%)
		Moderately interested	n (%)
		Somewhat interested	n (%)
		A little interested	n (%)
		Not at all interested	n (%)
		Missing	n (%)
4b. At home, administered by a partner as two injections in your thigh[1]	XX	Very interested	n (%)
		Moderately interested	n (%)
		Somewhat interested	n (%)
		A little interested	n (%)
		Not at all interested	n (%)
		Missing	n (%)
4c. At home, self-administered by you as two injections in your thigh[1]	XXX	Very interested	n (%)
		Moderately interested	n (%)
		Somewhat interested	n (%)
		A little interested	n (%)
		Not at all interested	n (%)

		Missing	n (%)

[1] Select one response

[2] Select all that apply

[3] Within each question, response choices will be ordered by percent endorsing, descending, ties will go in order presented to respondents. or items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviation: HIV = human immunodeficiency virus; PLWHIV = participants living with human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing and responses from participants who completed items which violated the prescribed skip pattern were omitted*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.2.3. PLWHIV Medication Regimen: Experience, Practices, and Views, Month 8

Table 1.3.1. PLWHIV Views on IC Administration Model, Baseline (N=XX)

Question	Number of Participants at Baseline	Response	n (%)
1. How acceptable is it to you to come to the infusion center for CABENUVA?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
2. What are the advantages of going to the infusion center to receive CABENUVA?[2,3]	XX	Convenient location of the infusion center	n (%)
		Ease of parking at the infusion center	n (%)
		Convenient hours for the infusion center	n (%)
		More privacy at the infusion center	n (%)
		I like that people do not know what medication I am there to receive	n (%)
		Reduced stigma	n (%)

Question	Number of Participants at Baseline	Response	n (%)
		Injections are not available at my provider's office	n (%)
		Other*	n (%)
		No advantages of receiving CABENUVA at the infusion center	n (%)
		Missing	n (%)
3. What are the disadvantages of going to the infusion center to receive CABENUVA?[2,3]	XX	Inconvenient location of the infusion center	n (%)
		Unfamiliar with routine at the infusion center	n (%)
		Unfamiliar with the infusion center staff	n (%)
		Inconvenient hours for the infusion center	n (%)
		Less privacy at the infusion center	n (%)
		Decreased contact with my HIV provider	n (%)
		Difficulty scheduling and rescheduling appointments	n (%)
		Too many appointments between the IC and the HIV doctors	n (%)
		Too many lab draws	n (%)
		Infusion center doesn't know how to manage the pain or side effects of CABENUVA	n (%)
		I don't want other people at the infusion center to know I have HIV	n (%)
		Other*	n (%)
		No disadvantages of receiving CABENUVA at the infusion center	n (%)
		Missing	n (%)
4.How convenient is it for you to get to the infusion center for your CABENUVA visits?[1]	XX	Very Convenient	n (%)
		Somewhat convenient	n (%)
		A little convenient	n (%)
		Neutral	n (%)
		A little inconvenient	n (%)

Question	Number of Participants at Baseline	Response	n (%)
		Somewhat inconvenient	n (%)
		Very inconvenient	n (%)
		Missing	n (%)
5. How long does it typically take you to get to the infusion center?[1]	XX	1-15 minutes	n (%)
		16-30 minutes	n (%)
		31-45 minutes	n (%)
		46-60 minutes	n (%)
		More than 60 minutes	n (%)
		Missing	n (%)
6. How acceptable to you is the time it typically takes you to get to the infusion center?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
7. How much time do you *expect* to spend in the infusion center for each CABENUVA visit?[1]	XX	1-15 minutes	n (%)
		16-30 minutes	n (%)
		31-45 minutes	n (%)
		46-60 minutes	n (%)
		More than 60 minutes	n (%)
		Missing	n (%)
8. How concerned are you about unwanted disclosure of your HIV status when attending	XX	Very concerned	n (%)
		Moderately concerned	n (%)

Question	Number of Participants at Baseline	Response	n (%)
appointments at your HIV providers office?[1]		Somewhat concerned	n (%)
		A little concerned	n (%)
		Not at all concerned	n (%)
		Missing	n (%)
9. How concerned are you about unwanted disclosure of your HIV status when attending appointments at the infusion center?[1]	XX	Very concerned	n (%)
		Moderately concerned	n (%)
		Somewhat concerned	n (%)
		A little concerned	n (%)
		Not at all concerned	n (%)
		Missing	n (%)
10. How acceptable is it to go to two separate places for your care (that is, the infusion center for CABENUVA and to your clinic for your regular HIV appointments)?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
11. How acceptable is it for you to get labs drawn at the infusion center?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)

Question	Number of Participants at Baseline	Response	n (%)
		Missing	n (%)
12. How acceptable was the insurance verification process at the infusion center?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
13. What is your overall opinion about going to an infusion center to receive CABENUVA?[1]	XX	Very positive	n (%)
		Somewhat positive	n (%)
		A little positive	n (%)
		Neutral	n (%)
		A little negative	n (%)
		Somewhat negative	n (%)
		Very negative	n (%)
		Missing	n (%)

[1] Select one response

[2] Select all that apply

[3]Within each question, response choices will be ordered by percent endorsing, descending, ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviation: HIV = human immunodeficiency virus; PLWHIV = participants living with human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing and responses from participants who completed items which violated the prescribed skip pattern were omitted.

*"Other" responses and open-ended text responses will be presented in an appendix.

Table 1.3.2. PLWHIV Views on IC Administration Model, Month 3 (N=XX)

Question	Number of Participants at Month 3	Response	n (%)
1. How acceptable is it to you to come to the infusion center for CABENUVA?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
2. What are the advantages of going to the infusion center to receive CABENUVA?[2,3]	XX	Convenient location of the infusion center	n (%)
		Ease of parking at the infusion center	n (%)
		Convenient hours for the infusion center	n (%)
		Ease of scheduling and rescheduling appointments at the infusion center	n (%)
		More privacy at the infusion center	n (%)
		I like that people do not know what medication I am there to receive	n (%)
		Reduced stigma at the infusion center	n (%)
		Injections are not available at my provider's office	n (%)
		No advantages of receiving CABENUVA at the infusion center	n (%)
		Other*	n (%)
		Missing	n (%)
3. What are the disadvantages of going to the infusion center to receive CABENUVA?[2,3]	XX	Inconvenient location of the infusion center	n (%)
		Difficulty of parking at the infusion center	n (%)
		Unfamiliar with routine at the infusion center	n (%)
		Unfamiliar with the infusion center staff	n (%)
		Inconvenient hours for the infusion center	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		Less privacy at the infusion center	n (%)
		More stigma at the infusion center	n (%)
		Decreased contact with my HIV provider	n (%)
		Difficulty scheduling and rescheduling appointments at the infusion center	n (%)
		Too many appointments between the infusion center and my HIV providers	n (%)
		Too many lab draws	n (%)
		Infusion center doesn't know how to manage the pain or side effects of CABENUVA	n (%)
		I don't want other people at the infusion center to know I have HIV	n (%)
		No disadvantages of receiving CABENUVA at the infusion center	n (%)
		Other*	n (%)
		Missing	n (%)
4. How convenient is it for you to get to the infusion center for your CABENUVA visits?[1]	XX	Very convenient	n (%)
		Somewhat convenient	n (%)
		A little convenient	n (%)
		Neutral	n (%)
		A little inconvenient	n (%)
		Somewhat inconvenient	n (%)
		Very inconvenient	n (%)
		Missing	n (%)
5. How long does it typically take you to get to the infusion center?[1]	XX	1-15 minutes	n (%)
		16-30 minutes	n (%)
		31-45 minutes	n (%)
		46-60 minutes	n (%)
		More than 60 minutes	n (%)
		Missing	n (%)

Question	Number of Participants at Month 3	Response	n (%)
6. How acceptable is the time it typically takes you to get to the infusion center?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
7. Not including your first visit, how much time have you been spending at the infusion center for your CABENUVA visits?[1]	XX	1-15 minutes	n (%)
		16-30 minutes	n (%)
		31-45 minutes	n (%)
		46-60 minutes	n (%)
		More than 60 minutes	n (%)
		Missing	n (%)
8. How acceptable is the amount of time you spend at the infusion center for your CABENUVA visits?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
9. How easy or difficult was it to schedule your monthly injection visits at the infusion center?[1]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neutral	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		Somewhat difficult	n (%)
		Very difficult	n (%)
		Extremely difficult	n (%)
		Missing	n (%)
10. How easy or difficult was it to reschedule your injection visits at the infusion center, if needed?[1]	XX	Extremely easy	n (%)
		Very easy	n (%)
		Somewhat easy	n (%)
		Neutral	n (%)
		Somewhat difficult	n (%)
		Very difficult	n (%)
		Extremely difficult	n (%)
		I have not had to reschedule any visits yet	n (%)
		Missing	n (%)
11. How satisfied are you with the appointment reminders you receive from the infusion center?[1]	XX	Extremely satisfied	n (%)
		Very satisfied	n (%)
		Somewhat satisfied	n (%)
		Neutral	n (%)
		Somewhat dissatisfied	n (%)
		Very dissatisfied	n (%)
		Extremely dissatisfied	n (%)
		Missing	n (%)
12. How satisfied are you with the convenience of the infusion center hours available for your injection appointments?[1]	XX	Extremely satisfied	n (%)
		Very satisfied	n (%)
		Somewhat satisfied	n (%)
		Neutral	n (%)
		Somewhat dissatisfied	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		Very dissatisfied	n (%)
		Extremely dissatisfied	n (%)
		Missing	n (%)
13. Which appointment times would be most helpful to you for getting the CABENUVA treatment at the infusion center?[2,3]	XX	Standard business hours during weekdays (e.g., 8am – 5pm)	n (%)
		Early morning during weekdays (e.g., before 8am)	n (%)
		Evenings during weekdays (e.g., after 5pm)	n (%)
		Weekend mornings	n (%)
		Weekend afternoons	n (%)
		Weekend evenings	n (%)
		Missing	n (%)
14. If you had questions about CABENUVA treatment in-between appointments (other than appointment scheduling or rescheduling), who did you reach out to for answers to your question(s)?[2,3]	XX	Staff at the infusion center	n (%)
		My regular HIV provider	n (%)
		Other staff at my regular HIV provider's office	n (%)
		Other people with HIV	n (%)
		Social media	n (%)
		No questions to date	n (%)
		Missing	n (%)
14a. If "staff at the infusion center" selected, how satisfied were you with the infusion center staff's ability to answer your question(s)?[1]	XX	Extremely satisfied	n (%)
		Very satisfied	n (%)
		Somewhat satisfied	n (%)
		Neutral	n (%)
		Somewhat dissatisfied	n (%)
		Very dissatisfied	n (%)
		Extremely dissatisfied	n (%)
		Missing	n (%)

Question	Number of Participants at Month 3	Response	n (%)
15. How acceptable is it for you to get labs drawn at the infusion center?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
16. How acceptable is it to go to two separate places for your care (that is, the infusion center for CABENUVA and to your clinic for your regular HIV appointments)?[1]	XX	Very acceptable	n (%)
		Somewhat acceptable	n (%)
		A little acceptable	n (%)
		Neutral	n (%)
		A little unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Missing	n (%)
17. We know that people can be treated differently due to factors including, but not limited to, HIV status, gender, and race. Have you been treated differently, or experienced stigma or discrimination at the infusion center?[1]	XX	Yes	n (%)
		No (skip to question #30)	n (%)
		Prefer not to answer	n (%)
		Missing	n (%)
17a. If yes, how has your experience at the infusion center compared to your experience at your HIV provider's office/clinic?[1]	XX	A lot worse	n (%)
		Somewhat worse	n (%)
		A little worse	n (%)
		About the same	n (%)
		A little better	n (%)
		Somewhat better	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		A lot better	n (%)
		Missing	n (%)
18. Do you believe you have been treated differently based on any of the following factors:[2,3]	XX	Age	n (%)
		Race/ethnicity	n (%)
		Sex	n (%)
		Gender identity	n (%)
		Sexual preference	n (%)
		HIV status	n (%)
		Religion	n (%)
		Physical appearance	n (%)
		Housing status	n (%)
		Due to pregnancy/being pregnant	n (%)
		Other*	n (%)
		None of the above	n (%)
		Extremely comfortable	n (%)
		Missing	n (%)
19. How comfortable are you with the infusion center managing your CABENUVA injections?[1]	XX	Very comfortable	n (%)
		Somewhat comfortable	n (%)
		Neutral	n (%)
		Somewhat uncomfortable	n (%)
		Very uncomfortable	n (%)
		Extremely uncomfortable	n (%)
		Extremely welcome	n (%)
		Missing	n (%)
20. How welcome do you feel at the infusion center?[1]	XX	Very welcome	n (%)
		Somewhat welcome	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		Neutral	n (%)
		Somewhat unwelcome	n (%)
		Very unwelcome	n (%)
		Extremely unwelcome	n (%)
		Extremely respectful	n (%)
		Missing	n (%)
21. How respectful are the infusion center staff when you are there for your injections?[1]	XX	Very respectful	n (%)
		Somewhat respectful	n (%)
		Neutral	n (%)
		Somewhat disrespectful	n (%)
		Very disrespectful	n (%)
		Extremely disrespectful	n (%)
		Missing	n (%)
22. How satisfied are you with the level of privacy at the infusion center for receiving your injections?[1]	XX	Extremely satisfied	n (%)
		Very satisfied	n (%)
		Somewhat satisfied	n (%)
		Neutral	n (%)
		Somewhat dissatisfied	n (%)
		Very dissatisfied	n (%)
		Extremely dissatisfied	n (%)
		Missing	n (%)
23. How concerned are you about unwanted disclosure of your HIV status when attending appointments at your HIV provider's office?[1]	XX	Very concerned	n (%)
		Moderately concerned	n (%)
		Somewhat concerned	n (%)
		A little concerned	n (%)
		Not at all concerned	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		Missing	n (%)
24. How concerned are you about unwanted disclosure of your HIV status when attending appointments at the infusion center? [1]	XX	Very concerned	n (%)
		Moderately concerned	n (%)
		Somewhat concerned	n (%)
		A little concerned	n (%)
		Not at all concerned	n (%)
		Extremely satisfied	n (%)
		Missing	n (%)
25. How satisfied are you with the level of care you are receiving at the infusion center? [1]	XX	Very satisfied	n (%)
		Somewhat satisfied	n (%)
		Neutral	n (%)
		Somewhat dissatisfied	n (%)
		Very dissatisfied	n (%)
		Extremely dissatisfied	n (%)
		Missing	n (%)
26. What is your overall opinion about going to an infusion center to receive CABENUVA? [1]	XX	Extremely positive	n (%)
		Somewhat positive	n (%)
		A little positive	n (%)
		Neutral	n (%)
		A little negative	n (%)
		Somewhat negative	n (%)
		Very negative	n (%)
		Missing	n (%)
27. How does your total monthly out of pocket cost for CABENUVA (how much you have to pay) compare with how much you paid	XX	Significantly more cost now	n (%)
		Somewhat more cost now	n (%)
		About the same cost now	n (%)

Question	Number of Participants at Month 3	Response	n (%)
monthly for your previous oral HIV medication?[1] If you are receiving CABENUVA injections every 2 months: Divide your out of pocket cost for CABENUVA in half to obtain your monthly out of pocket cost for comparison to your monthly cost for oral HIV medication.		A little less cost now	n (%)
		A lot less cost now	n (%)
		Don't know/Unsure/Not applicable	n (%)
		Missing	n (%)
28. How satisfied are you with how much you are paying (out of pocket cost) for your CABENUVA injections?[1]	XX	Extremely satisfied	n (%)
		Very satisfied	n (%)
		Somewhat satisfied	n (%)
		Neutral	n (%)
		Somewhat dissatisfied	n (%)
		Very dissatisfied	n (%)
		Extremely dissatisfied	n (%)
		Missing	n (%)

[1] Select one response

[2] Select all that apply

[3]Within each question, response choices will be ordered by percent endorsing, descending, ties will go in order presented to respondents. or items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviations: HIV = human immunodeficiency virus; PLWHIV = participants living with human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing and responses from participants who completed items which violated the prescribed skip pattern were omitted.

*"Other" responses and open-ended text responses will be presented in an appendix.

Table 1.3.3. PLWHIV Views on IC Administration Model, Month 8

Table 2.1. PLWHIV Responding "Agree" or "Completely Agree" On All FIM Items at Baseline, Month 3, and Month 8: Proportions and Change

	Number completing all 4 FIM items	Number endorsing 4 or 5 on all FIM Items	% endorsing all FIM Items	% Point Change
Baseline[1]	XX	XX	XX%	-
Month 3[1]	XX	XX	XX%	-
Month 8[1]	XX	XX	XX%	-
Baseline to Month 3[2]	XX	BL=XX; M3=XX	BL=XX%; M3=XX%	XX%
Baseline to Month 8[2]	XX	BL=XX; M8=XX	BL=XX%; M8=XX%	XX%
Month 3 to Month 8[2]	XX	M3=XX; M8=XX	M3=XX%; M8=XX%	XX%

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items

[2]Each change row is limited to those completing all 4 items at both respective timepoints, which may differ from reporting at each individual timepoint: numerator = number responding '4' or '5', denominator = number completing all 4 items.

Abbreviations: PLWHIV = Participants living with human immunodeficiency virus; BL = Baseline; FIM = Feasibility of Intervention Measure; M3 = Month 3; M8 = Month 8

Responses: 4=CCI 5=CCI .

Table 2.2. PLWHIV Responding "Agree" or "Completely Agree" On All AIM Items at Baseline, Month 3, and Month 8: Proportions and Change

	Number completing all 4 AIM items	Number endorsing 4 or 5 on all AIM Items	% endorsing all AIM Items	% Point Change
Baseline[1]	XX	XX	XX%	-
Month 3[1]	XX	XX	XX%	-
Month 8[1]	XX	XX	XX%	-
Baseline to Month 3[2]	XX	BL=XX; M3=XX	BL=XX%; M3=XX%	XX%
Baseline to Month 8[2]	XX	BL=XX; M8=XX	BL=XX%; M8=XX%	XX%
Month 3 to Month 8[2]	XX	M3=XX; M8=XX	M3=XX%; M8=XX%	XX%

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items

[2]Each change row is limited to those completing all 4 items at both respective timepoints, which may differ from reporting at each individual timepoint; numerator = number responding '4' or '5', denominator = number completing all 4 items

Abbreviations: PLWHIV = Participants living with human immunodeficiency virus; AIM = Acceptability of Intervention Measure; BL = Baseline; M3 = Month 3; M8 = Month 8

Responses: 4=CCI 5=CCI

Table 3.1. PLWHIV, Distributional Characteristics of Feasibility of Intervention Measure (FIM), N=XX

Item/ Scale	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (–Min, Max)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
FIM Mean Score	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X,X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
1. Administering CABENUVA seems implementable in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
2. Administering CABENUVA seems possible in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
3. Administering CABENUVA seems doable in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
4. Administering CABENUVA seems easy to implement in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)

Abbreviations: BL = Baseline; CI = confidence interval; FIM = Feasibility of Intervention Measure; M3 = Month 3; M8 = Month 8; PLWHIV = Participants living with human immunodeficiency virus; SD = standard deviation.
Percent Floor for the mean score is the percent of respondents with a score of 1 (CCI [redacted]) out of all respondents replying to at least two FIM items at a given time point.
Percent Ceiling for the mean score is the percent of respondents with a score of 5 (CCI [redacted]) out of all respondents replying to at least two FIM items at a given time point.
NOTE: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who filled out any portion of a survey the respective timepoint. Missing for the mean score counts any instance where a respondent completed one FIM item, not reaching the minimum of 2 items required to calculate a mean FIM score.

Cell percentages do not include missing.

Table 3.2. PLWHIV, Distributional Characteristics of Acceptability of Intervention Measure (AIM), N=XX

Item/ Scale	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (–Min, Max)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
AIM Mean Score	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X,X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
1. The idea of providing CABENUVA at my infusion center meets my approval.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
2. The idea of providing CABENUVA at my infusion center is appealing to me.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.	BL	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)
	M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.X, X.X)

Abbreviations: AIM = Acceptability of Intervention Measure; BL = Baseline; CI = confidence interval; M3 = Month 3; M8 = Month 8; PLWHIV = Participants living with human immunodeficiency virus; SD = standard deviation.
Percent Floor for the mean score is the percent of respondents with a score of 1 [redacted] out of all respondents replying to at least two AIM items at a given time point.
Percent Ceiling for the mean score is the percent of respondents with a score of 5 [redacted] out of all respondents replying to at least two AIM items at a given time point.
NOTE: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who filled out any portion of a survey the respective timepoint. Missing for the mean score counts any instance where a respondent completed one AIM item, not reaching the minimum of 2 items required to calculate a mean AIM score.

Cell percentages do not include missing.

Table 4.1. PLWHIV, Univariate Distribution of Feasibility of Intervention Measure (FIM), N=XX

Items	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Administering CABENUVA seems implementable in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Administering CABENUVA seems possible in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. Administering CABENUVA seems doable in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Administering CABENUVA seems easy to implement in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; M3 = Month 3; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus.

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing.

Table 4.2. PLWHIV, Univariate Distribution of Acceptability of Intervention Measure (AIM), N=XX

Items	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The idea of providing CABENUVA at my infusion center meets my approval.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. The idea of providing CABENUVA at my infusion center is appealing to me.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; M3 = Month 3; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus.

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing.

Table 5.1. PLWHIV, Distributional Characteristics of Change in Feasibility of Intervention Measure (FIM), N=XX

Item/Scale	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (Min, Max)	95% CI (Lower, Upper)
FIM Mean Score	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
1. Administering CABENUVA seems implementable in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
2. Administering CABENUVA seems possible in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
3. Administering CABENUVA seems doable in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
4. Administering CABENUVA seems easy to implement in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)

[1] Only includes PLWHIV who completed surveys at respective months

Abbreviations: BL = Baseline; CI = confidence interval; FIM = Feasibility of Intervention Measure; M3 = Month 3; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing.

Table 5.2. PLWHIV, Distributional Characteristics of Change in Acceptability of Intervention Measure (AIM)

Item/Scale	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (–Min, Max)	95% CI (Lower, Upper)
AIM Mean Score	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X,X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
1. The idea of providing CABENUVA at my infusion center meets my approval.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
2. The idea of providing CABENUVA at my infusion center is appealing to me.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.	BL to M3	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	BL to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)
	M3 to M8	XX	XX	XX	XX	XX (X.X, X.X)	(X.X, X.X)	(X.X, X.X)

[1] Only includes PLWHIV who completed surveys at respective months

Abbreviations: AIM = Acceptability of Intervention Measure; BL = Baseline; CI = confidence interval; M3 = Month 3; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing.

Table 6.1. PLWHIV, Shift of Feasibility of Intervention Measure (FIM) Response Frequency by Item, N=XX

1.Administering CABENUVA seems implementable in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

2. Administering CABENUVA seems possible in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
3. Administering CABENUVA seems doable in my infusion center.							
		Baseline					

		Completely Disagree N=(XX)	Disagree N=(XX)	Neither agree nor disagree N=(XX)	Agree (N=XX)	Completely Agree (N=XX)	Missing[1] (N=XX)
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 3					
		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

4. Administering CABENUVA seems easy to implement in my infusion center.

		Baseline					
		Completely Disagree	Disagree N=(XX)	Neither agree nor	Agree (N=XX)	Completely Agree	Missing[1] (N=XX)

		N=(XX)		disagree N=(XX)		(N=XX)	
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 3					
		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

[1]Missing at T1, completed at T2

[2]Missing at T2, completed at T1

Abbreviations: PLWHIV = participants living with human immunodeficiency virus; BL = baseline; FIM = Feasibility of Intervention Measure;
Percentage calculations:

Non-missing cell %:

numerator = number selecting respective combination of Time 1 and Time 2 responses

denominator = number of participants responding within Time 1 response category at Time 1

Table 6.2. PLWHIV, Shift of Acceptability of Intervention Measure (AIM) Response Frequency by Item, N=XX

1. The idea of providing CABENUVA at my infusion center meets my approval.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

2. The idea of providing CABENUVA at my infusion center is appealing to me.

		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.							
		Baseline					
		Completely Disagree N=(XX)	Disagree N=(XX)	Neither agree nor disagree N=(XX)	Agree (N=XX)	Completely Agree (N=XX)	Missing[1] (N=XX)
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.							
		Baseline					

		Completely Disagree N=(XX)	Disagree N=(XX)	Neither agree nor disagree N=(XX)	Agree (N=XX)	Completely Agree (N=XX)	Missing[1] (N=XX)
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 3					
		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

[1]Missing at T1, completed at T2

[2]Missing at T2, completed at T1

Abbreviations: PLWHIV = participants living with human immunodeficiency virus; AIM = Acceptability of Intervention Measure
Percentage calculations:

Non-missing cell %:

numerator = number selecting respective combination of Time 1 and Time 2 responses

denominator = number of participants responding within Time 1 response category at Time 1

Table 7. Implementation Science-Related Protocol Deviations, N=XX

Protocol Deviation	IS-related Protocol Deviations For PLWHIV (N= XX) n(%)
Total Sample IS-related Protocol Deviations	xx (xx.x)
Questionnaire incomplete[1]	xx (xx.x)
Questionnaire completed but not required	xx (xx.x)
Questionnaire completed out of window (early)	xx (xx.x)
Questionnaire completed out of window (late)	xx (xx.x)
Duplicate questionnaire completed	xx (xx.x)
Placeholder, other possible deviation	xx (xx.x)

Abbreviations: PLWHIV = Participants living with human immunodeficiency virus

[1]Deviations associated with incomplete IS questionnaires are for those initiated but not completed

Note: Numerators equal the number of PLWHIV experiencing respective deviation type, denominators equal the number of PLWHIV in analytic dataset

7 Table Shells: Adherence

Table 8. CABENUVA Adherence, Safety Set

		CABENUVA Monthly Injection (N=XX) n (%)	CABENUVA Bi-monthly Injection (N=XX) n (%)
Number of participants with the following number of CABENUVA injections NOT completed within +/-7 day windows of scheduled dates.	0	xx (xx.x)	xx (xx.x)
	1	xx (xx.x)	xx (xx.x)
	2	xx (xx.x)	xx (xx.x)
	3	xx (xx.x)	xx (xx.x)
	4	xx (xx.x)	xx (xx.x)
	5	xx (xx.x)	xx (xx.x)
	6	xx (xx.x)	xx (xx.x)

	7	xx (xx.x)	xx (xx.x)

If a participant switches between monthly and bi-monthly injection groups during the study, the participant will be summarized under the treatment group within which they began the study

Baseline target dosing date was determined as follows:

The last date of VOCABRIA + ENDURANT for patients on oral lead-in.

Previous injection date + 1 month for participants on monthly CABENUVA regimen prior to the study.

Previous injection date + 2 months for participants on a bi-monthly CABENUVA regimen prior to the study. For participants on a planned bi-monthly CABENUVA regimen prior to the study receiving their first dose (loading dose), target date was injection date + 1 month.

Date of first injection for participants on neither oral lead-in nor previously using CABENUVA.

Target dosing date for follow-up visits were determined as follows:

Day of the month of baseline injection + 1 month for participants on monthly CABENUVA regimen.

Day of the month of baseline injection + 2 months for participants on a bi-monthly CABENUVA regimen.

For target injection dates occurring on the 29, 30th, or 31st in months without that day, the last day of the month was used.

As fidelity is to be determined based on total number of injections given during the course of the study, injections not occurring due to participant withdrawal, loss-to-follow-up or missed injections prior to study discontinuation were set to missing.

Table 9. CABENUVA Adherence: days from the target dosing date at each study visit, Safety Set

		CABENUVA Monthly Injection (N=XX)	CABENUVA Bi-monthly Injection (N=XX)
Month 1 (days)	n	XX	XX
	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX
Month 2 (days)	n	XX	XX
	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX
Month 3 (days)	n	XX	XX
	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX
Month 4 (days)	n	XX	XX
	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX
	n	XX	XX

Month 5 (days)	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX
Month 6 (days)	n	XX	XX
	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX
Month 7 (days)	N	XX	XX
	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX
Month 8 (days)	N	XX	XX
	Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)
	Median (Q1, Q3)	XX.XX (XX, XX)	XX.XX (XX, XX)
	Min, Max	XX.XX, XX.XX	XX.XX, XX.XX

If a participant switches between monthly and bi-monthly injection groups during the study, the participant will be summarized under the treatment group within which they began the study

Baseline target dosing date was determined as follows:

- The last date of VOCABRIA + ENDURANT for patients on oral lead-in.
- Previous injection date + 1 month for participants on monthly CABENUVA regimen prior to the study.
- Previous injection date + 2 months for participants on a bi-monthly CABENUVA regimen prior to the study. For participants on a planned bi-monthly CABENUVA regimen prior to the study receiving their first dose (loading dose), target date was injection date + 1 month.
- Date of first injection for participants on neither oral lead-in nor previously using CABENUVA.

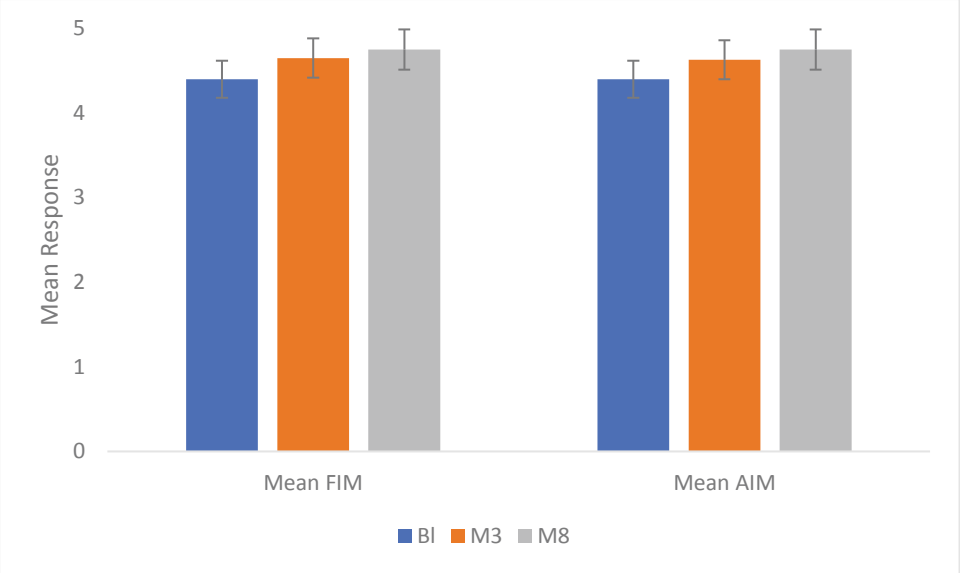
Target dosing date for follow-up visits were determined as follows:

- Day of the month of baseline injection + 1 month for participants on monthly CABENUVA regimen.
- Day of the month of baseline injection + 2 months for participants on a bi-monthly CABENUVA regimen.
- For target injection dates occurring on the 29, 30th, or 31st in months without that day, the last day of the month was used.

As fidelity is to be determined based on total number of injections given during the course of the study, injections not occurring due to participant withdrawal, loss-to-follow-up or missed injections prior to study discontinuation were set to missing.

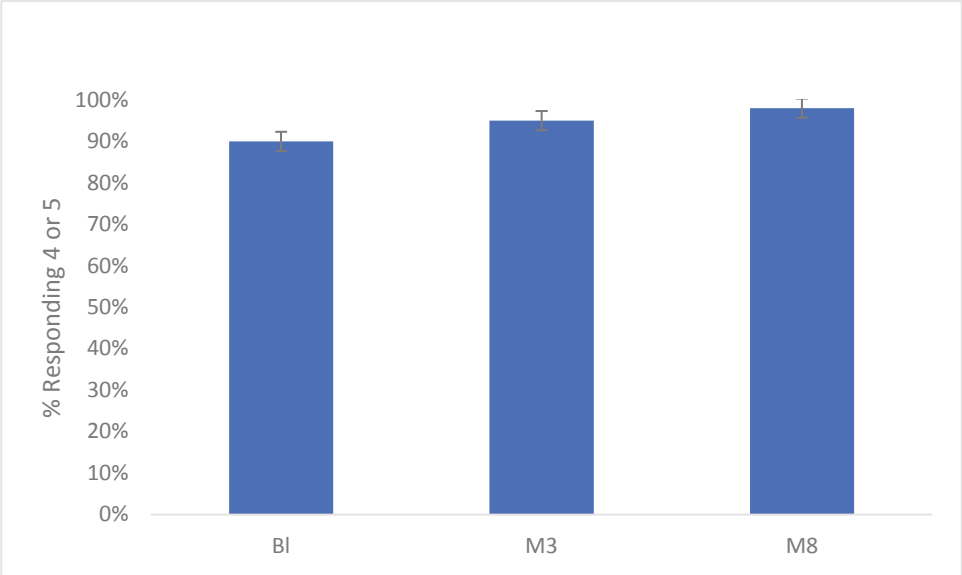
8 Figures

Figure 1. Bar Chart Showing Mean PLWHIV FIM and AIM Responses at Baseline, Month 3, and Month 8



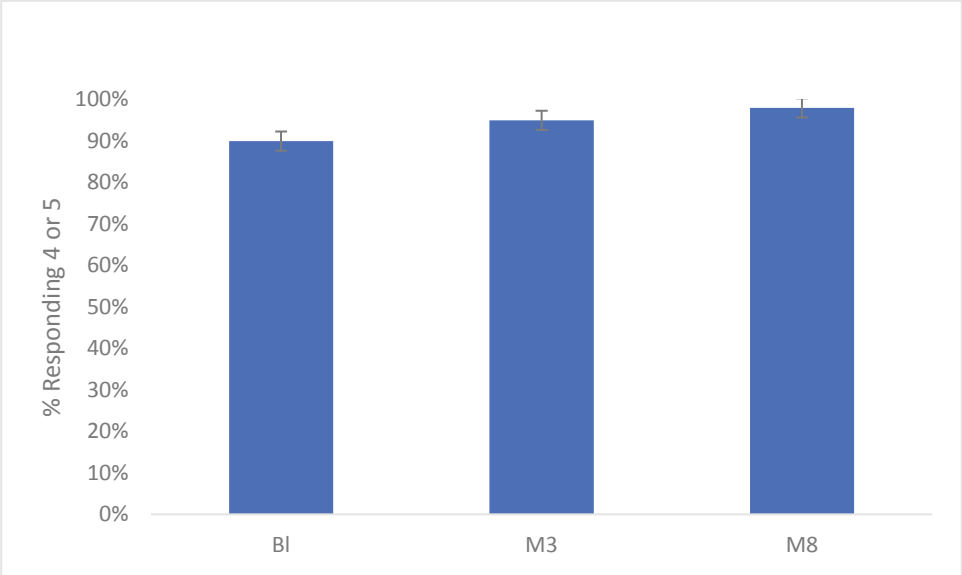
Abbreviations: PLWHIV = Participants living with human immunodeficiency virus; FIM = Feasibility of Intervention Measure; AIM = Acceptability of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Error Bars = Standard error

Figure 2. Bar Chart Showing Proportion of PLWHIV Responding "Agree" or Completely Agree" on All FIM Items at Baseline, Month 3, and Month 8



Abbreviations: PLWHIV = Participants living with human immunodeficiency virus; FIM = Feasibility of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Responses: 4=CCI 5=CCI
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

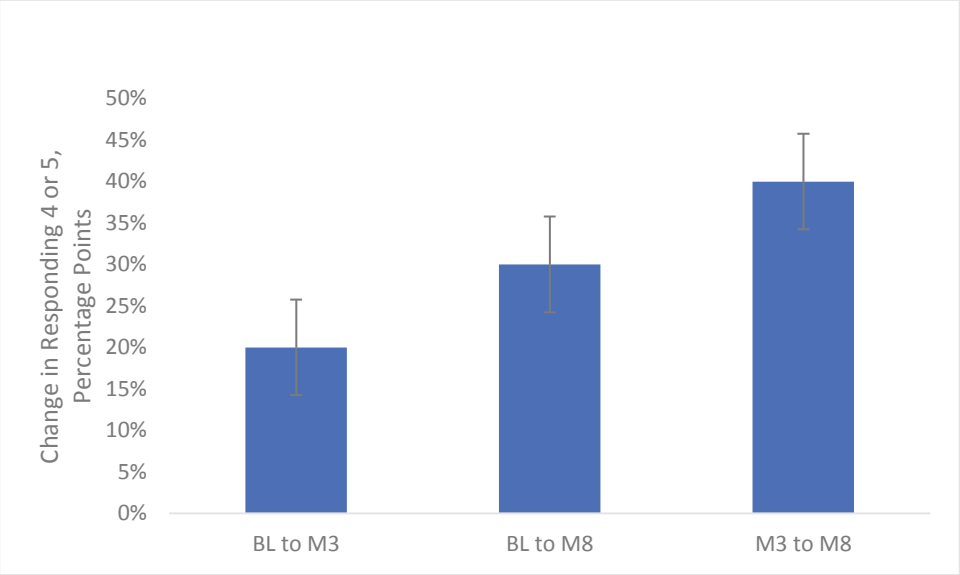
Figure 3. Bar Chart Showing Proportion of PLWHIV Responding "Agree" or Completely Agree" on All AIM Items at Baseline, Month 3, and Month 8



Abbreviations: PLWHIV = Participants living with human immunodeficiency virus; AIM = Acceptability of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Responses: 4=CCI 5=CCI
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items

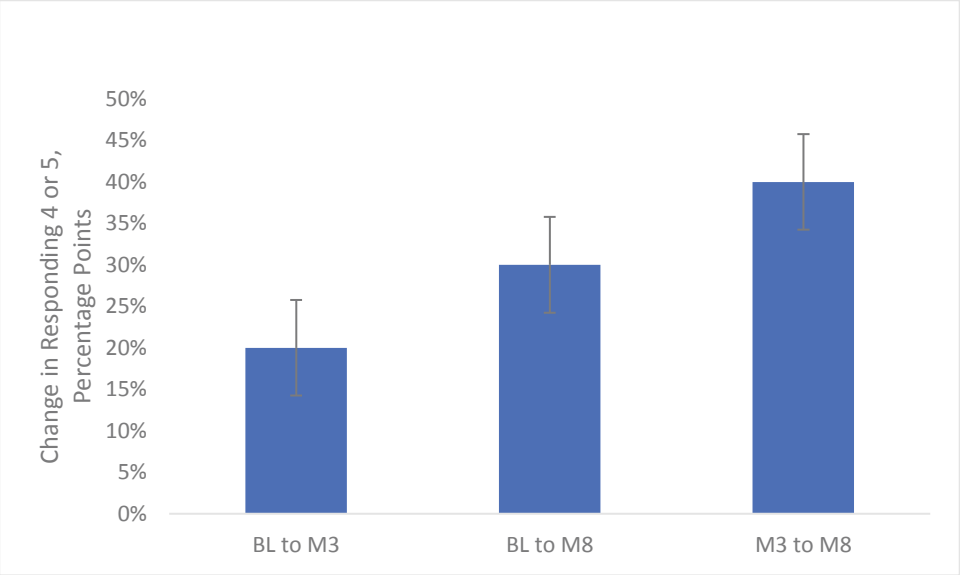
Error Bars = Standard error

Figure 4. Bar Chart Showing Change in Proportion of PLWHIV Responding "Agree" or Completely Agree" on All FIM Items, Baseline to Month 3, Baseline to Month 8, and Month 3 to Month 8



Abbreviations: PLWHIV = Participants living with human immunodeficiency virus; FIM = Feasibility of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Responses: 4=CCI 5=CCI
Note: Each bar is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 5. Bar Chart Showing Change in Proportion of PLWHIV Responding "Agree" or Completely Agree" on All AIM Items, Baseline to Month 3, Baseline to Month 8, and Month 3 to Month 8



Abbreviations: PLWHIV = Participants living with human immunodeficiency virus; AIM = Acceptability of Intervention Measure; BL=Baseline; M3 = Month 3; M8 = Month 8
Responses: 4=CCI 5=CCI
Note: Each bar is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Appendix A. Missing Data

Table A1. Summary of Missing Data

Timepoint	Item	Completed n(%)	Missing n(%)
Baseline N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 3 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 8 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)

Abbreviations: AIM = Acceptability of Intervention Measure; FIM = Feasibility of Intervention Measure

Table A2. Summary of Free-text Responses

A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or other Alternate Sites of Administration

Statistical Analysis Plan: HIV Care Providers and Key Personal Involved in the Patients' Care (Clinical Staff) and Expert Panel

EVA-30466 | March 4, 2024 | Version 3.0

Prepared For:

PPD , GSK

PPD , PhD | PPD , Global Implementation Research, ViiV Healthcare

Prepared By:

PPD PhD

PPD , PhD MPH

PPD , PhD MPH

Project Contact:

PPD

Statistical Analysis Plan (SAP) Signature Page

SAP Title: A Phase 4, Open-label, Single-arm Study to Optimize Implementation of CABENUVA for the Treatment of HIV-1, for Administration in US Community-based Infusion Centers or other Alternate Sites of Administration.
Statistical Analysis Plan: HIV Care Providers and Key Personal Involved in the Patients' Care (Clinical Staff) and Expert Panel

SAP Date and Version: March 4th, 2024; Version 3.0

This SAP with the title, number, and version indicated above has been reviewed and approved by the Evidera Principal Investigators and Project Managers.

PPD

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Date

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Date

_____
Date

_____
Date

Table of Contents

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List of Abbreviations

Abbreviation	Definition
AE	Adverse event
AIDS	Acquired immunodeficiency syndrome
AIM	Acceptability of Intervention Measure
ART	Antiretroviral therapy
ASA	Alternative site of administration
BL	Baseline
CI	Confidence interval
eCRF	Electronic case report form
FDA	Food and Drug Administration
FIM	Feasibility of Intervention Measure
FPFV	First participant first visit
HIV	Human immunodeficiency virus
HMO	Health Maintenance Organization
IC	Infusion center
IM	Intramuscular
M3	Month 3
M4	Month 4
M6	Month 6
M8	Month 8
OCR	Optical character recognition
PDF	Portable document format
PLWHIV	Participants living with human immunodeficiency virus
POT	Plan of treatment
QAP	Qualitative analysis plan
SAP	Statistical analysis plan
SD	Standard deviation
SoA	Schedule of Activities

1 Introduction

CABENUVA is a two-drug, co-packaged product of cabotegravir plus rilpivirine, both administered as long-acting, intramuscular (IM) injections once-monthly or every two months; it is an approved treatment for human immunodeficiency virus (HIV). Clinical trial results have shown that CABENUVA administered once-monthly or every two months is non-inferior to daily oral treatment for HIV.

Long-acting injectable treatments require changes in how HIV care is delivered. People living with HIV must attend appointments for their injections once a month or every two months, rather than seeing their providers several times per year for a prescription refill and monitoring visits. This poses new healthcare delivery challenges, including a shift in resources to this alternative means of delivering and receiving treatment —thus requiring the expansion of alternative injection facilities to include infusion centers (ICs) or alternate sites of administration (ASA). This has the potential to impact workload capacity for these facilities, though it also has the potential to positively impact treatment engagement and retention for people living with HIV.

ICs/ASA are an appealing option that can ease the burden of additional appointments, administrative work, and drug ordering in HIV specialty clinics, as well as provide people living with HIV with greater flexibility in where they receive their once monthly or every two monthly injections. In this study, the intervention itself is the process of using an IC/ASA as the location to receive the CABENUVA IM injections. Specifically, the acceptability and feasibility of injection delivery at ICs/ASAs will be assessed from the perspectives of the participants living with HIV (PLWHIV), HIV care providers/clinical staff, and IC/ASA staff.

This statistical analysis plan (SAP) describes analyses for the acceptability and feasibility of an IC/ASA to deliver CABENUVA IM injections, as reported by HIV care providers/clinical staff, as well as a tailored questionnaire that asks HIV care providers/clinical staff about their general practice history as well as their experience, attitudes, and expectations regarding the IC model of administration of CABENUVA.

This SAP will also evaluate the feasibility, acceptability, and the process of CABENUVA administrations at ICs from the Expert Panel. The Expert Panel will generate an implementation blueprint and consist of HIV care providers referring patients living with HIV to an IC/ASA, IC staff members involved in decision-making and/or oversight of daily operations, and ViiV.

This is one of four SAPs for the following protocol: *Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based infusion centers or alternate sites of administration*. The three additional SAPs are:

(1) analyses for the IC staff questionnaires, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based infusion centers or alternate sites of administration, Statistical Analysis Plan: IC Staff*;

(2) analyses of questionnaires for PLWHIV, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based*

infusion centers or alternate sites of administration, Statistical Analysis Plan: Participants living with HIV for Implementation Science Questionnaires; and

(3) analyses for clinical data for PLWHIV, *A Phase 4, open-label, single arm study to optimize implementation of CABENUVA for the treatment of HIV-1, for administration in US community-based infusion centers or alternate sites of administration: Statistical Analysis Plan for Clinical Analyses.*

While there are no primary objectives involving HIV care providers/clinical staff or the Expert Panel for this study, this SAP will describe the planned secondary quantitative objectives related to HIV care providers/Expert Panel as outlined in Table A. Additionally, this plan does not incorporate the qualitative interview analyses at the end of study. These analyses will be detailed in a separate qualitative analysis plan (QAP) (currently under development).

Table A. Objectives and Endpoints for HIV Care Providers/Clinical Staff and the Expert Panel

Objectives	Endpoints
To evaluate feasibility of CABENUVA administration at infusion centers or alternate sites of administration HIV care providers/ clinical staff	Proportion of HIV care providers/clinical staff that agree or completely agree (a score of 4 or higher) across all items on the FIM at Month 1, Month 4 and at Month 8
	Change over time in the FIM at Month 4 and Month 8 with HIV care providers/clinical staff
	Summary of other quantitative questionnaires assessed with HIV care providers/ clinical staff at Month 1, Month 4 and Month 8
	Qualitative interviews assessed at Month 8 with HIV care providers/ clinical staff (QAP)
To evaluate acceptability of CABENUVA administration at infusion centers or alternate sites of administration from HIV care providers/clinical staff	Proportion of HIV care providers/clinical staff that agree or completely agree (a score of 4 or higher) across all items on the AIM at Month 1, Month 4 and Month 8
	Change of HIV care providers/clinical staff over time in the AIM at Month 4 and Month 8
	Summary of other quantitative questionnaires assessed with HIV care providers/clinical staff at Month 1, Month 4 and Month 8
	Qualitative interviews assessed at Month 8 with HIV care providers/clinical staff (QAP)
To evaluate feasibility, acceptability and the process of CABENUVA administration at infusion centers or alternate sites of administration from the Expert Panel	Proportion of Expert Panel that agree or completely agree (a score of 4 or higher) across all items on the FIM and AIM respectively prior to FPFV, and at Month 3 and Month 6
	Change of Expert Panel over time in FIM and AIM respectively through Month 6
	Summary of other quantitative questionnaires assessed with Expert Panel prior to FPFV, and at Month 3 and Month 6
	Qualitative interviews assessed with Expert Panel prior to FPFV and at Month 6 (QAP)
To evaluate perceptions, facilitators, and barriers/concerns by HIV care providers/clinical staff	Qualitative interviews assessed at Month 8 with HIV care providers/clinical staff (QAP) Summary of HIV care provider/clinical staff other quantitative questionnaires at Month 1, Month 4, and Month 8
To assess the advantages to receive or refer participants to receive CABENUVA at the infusion center or alternate sites of administration or	Qualitative interviews assessed at Month 8 with HIV care providers/clinical staff (QAP) Summary of advantage to referring participants to the IC/ASA to receive CABENUVA at Month 1, Month 4, and Month 8 assessed by HIV care provider other quantitative questionnaires

Objectives	Endpoints
alternate site of administration from HIV care providers/clinical staff	
To assess the disadvantages about receiving CABENUVA at the infusion center or alternate sites of administration or alternate site of administration from HIV care providers/clinical staff	Summary of disadvantage of referring participants to IC/ASA for CABENUVA injections from HIV care providers/clinical staff other quantitative questionnaires at Month 1, Month 4 and Month 8
	Qualitative interviews assessed at Month 8 with HIV care providers/clinical staff (QAP)
To evaluate the acceptability of receiving and referring participants for CABENUVA injections at infusion centers or alternate sites of administration from HIV care providers/clinical staff	Summary of acceptability of the process of referring participants to the infusion center or alternate sites of administration for CABENUVA by HIV care providers/clinical staff other quantitative questionnaires at Month 1, Month 4, and Month 8
	Qualitative interviews assessed at Month 8 with HIV care providers/clinical staff (QAP)
To evaluate the usefulness of the POT for HIV care providers/clinical staff	Summary of usefulness of the POT by HIV care providers/ clinical staff other quantitative questionnaires at Month 4 and Month 8
	Qualitative interviews assessed at Month 8 with HIV care providers/clinical staff (QAP)
To evaluate overall opinion of receiving and administering the injection at an infusion center or alternate sites of administration by HIV care providers/clinical staff	Qualitative interviews at Month 8 with 00000HIV care providers/clinical staff (QAP) Summary of overall opinion of referring patients to an IC center for CABENUVA injections by HIV care provider/clinical staff via other quantitative questionnaires at Month 1, Month 4 and Month 8

Abbreviations: AIM = Acceptability of Intervention Measure; ASA=Alternative Site of Administration; FIM = Feasibility of Intervention Measure; FPFV = first participant first visit; HIV = human immunodeficiency virus; IC = infusion center; POT = plan of treatment; QAP = qualitative analysis plan

2 Study Design

This is a Phase 4, single arm, open-label, multi-center study examining the administration of CABENUVA IM in IC/ASAs in the United States. This study is being conducted following Food and Drug Administration (FDA) approval and commercial availability of CABENUVA. Eligible and consenting participants will be followed for eight months to evaluate an implementation blueprint for IM administration of CABENUVA for HIV-1 treatment at ICs/ASAs. The total duration for study participants is approximately eight months from the time of enrollment and receipt of the first administration of CABENUVA IM injections at the ICs/ASA.

Relevant to this SAP, approximately 20 HIV care providers/clinical staff who refer their patients living with HIV to a study ICs/ASA to receive CABENUVA will be asked to complete questionnaires per the Schedule of Activities (SoA, see ANNEX 1 in protocol) after the HIV care provider's first referred patient is enrolled into the study. This study also has an Expert Panel, consisting of approximately 10 members, which will consist of key ICs/ASA staff members involved in decision making and/or oversee daily operations at the ICs/ASA, selected HIV care providers that may refer PLWHIV, and ViiV. Panel members will meet prior to Baseline/Month 1 to design the Blueprint.

The duration of study participation for each HIV care provider/clinical staff is approximately 8 months after their last PLWHIV has their first visit (last participant first visit) and receives CABENUVA IM injections at a participating ICs/ASA. HIV care provider/clinical staff and Expert Panel questionnaires consist of the Feasibility of Intervention Measure (FIM) and the Acceptability of Intervention Measure (AIM) and additional tailored questions. HIV care providers/clinical staff will be asked to complete the Baseline/Month 1 questionnaire within four weeks of their first referred participant's first visit (FPFV) in the study at any study site. Month 4 and Month 8 assessments are to be completed when the HIV care provider's/clinical staff first referred patient completes the Month 4 or Month 8 study visits, respectively. Questionnaires can be completed up to two weeks before or after the Month 4 or Month 8 study visits. The Expert Panel will be asked to complete the Baseline/Month 1 questionnaire prior to the FPFV, defined as the date when a participant signs the informed consent form, completes protocol procedures, and receives the first CABENUVA injections at any IC/ASA. Month 3 and Month 6 assessments are to be completed after approximately 10 participants (across all ICs/ASAs) have completed their Month 3 and Month 6 study visits at any IC/ASA site.

2.1 Description of the HIV Care Provider/Clinical Staff and Expert Panel Questionnaire and Schedule for Completion

The HIV care provider/clinical staff questionnaire consists of two validated instruments and tailored items written for this study. The validated instruments are the FIM and AIM, described below. The tailored items ask HIV care providers/clinical staff about several topics including, but not limited to, their practice, experience, and views on the CABENUVA / long-acting injectable model, as well as using ICs/ASAs to implement that model. The Expert Panel questionnaire also consists of the FIM and AIM and tailored items. Two different versions of the FIM and AIM will be used for the Expert Panel: one for HIV care providers/clinical staff and one for IC/ASA staff. Across FIM and AIM versions, the stem of each item has slightly different wording, reflecting the different roles of HIV care providers/clinical staff and IC/ASA staff. Response options are the same across versions. Due to the small numbers on the Expert Panel, the FIM and AIM will be summarized in all tables together, though the differences in the wording for underlying groups, due to their different roles, should be noted. The tailored items will ask the Expert Panel about the specifics of the implementation of the study.

A feasibility composite score for HIV care providers/clinical staff and Expert Panel, to be determined, will be added to this SAP. The exact components of the feasibility composite score will be informed by the Expert Panel process to ensure it matches the critical variables identified by all members of the panel.

Table B. Questionnaire Administration for HIV Care Provider/Clinical Staff and Expert Panel

Questionnaire	Baseline	Month 3	Month 4	Month 6	Month 8
HIV Care Provider Tailored Items, HIV Care Provider/ Clinical Staff	x		x		x*
Feasibility of Intervention Measure, HIV Care Provider/ Clinical Staff	x		x		x
Acceptability of Intervention Measure, HIV Care Provider/ Clinical Staff	x		x		x
Feasibility of Intervention Measure, Expert Panel	x	x		x	

Questionnaire	Baseline	Month 3	Month 4	Month 6	Month 8
Acceptability of Intervention Measure, Expert Panel	x	x		x	

Abbreviation: HIV = human immunodeficiency virus

2.1.1 Feasibility of Intervention Measure

The FIM is employed to evaluate the feasibility of an implementation strategy. This four-item measure assesses perceived intervention feasibility. The items are measured on a five-point rating scale (1=CCI [redacted], 2=CCI [redacted] 3=CCI [redacted], 4=CCI [redacted] and 5=CCI [redacted]. The FIM was validated with other implementation outcome measures.[1] Higher scores indicate greater feasibility. There are no reverse-scored items on the FIM, and the mean score for feasibility of the intervention is calculated by averaging the responses from four items.

2.1.2 Acceptability of Intervention Measure

The AIM is employed to evaluate the acceptability of an implementation strategy. This four-item measure assesses perceived intervention acceptability. The items are measured on a five-point rating scale (1=CCI [redacted], 2=CCI [redacted] 3=CCI [redacted], 4=CCI [redacted] and 5=CCI [redacted]). The AIM was validated with a suite of implementation outcome measures.[1] Higher scores indicate greater acceptability. There are no reverse-scored items on the AIM, and the mean score for acceptability of the intervention is calculated by averaging the responses from four items.

2.1.3 HIV Care Provider/Clinical Staff Additional Questionnaire

The tailored HIV care provider/clinical staff questionnaire was developed specifically for this study and contains items regarding the provider's practice and experience, as well as their attitudes, expectations, and concerns regarding the use of CABENUVA/long-acting injectable administered by ICs/ASAs. The baseline HIV care provider/clinical staff questionnaire has 38 items (including the FIM and AIM) using several different response scales.

2.1.4 Expert Panel Additional Questionnaire

The tailored Expert Panel questionnaire items were developed specifically for this study and contain items regarding the Expert Panel's preferences and assessment for CABENUVA administration. The baseline questionnaire has 18 items using several different response scales.

3 Statistical Methods

This SAP has been developed to guide the analyses for the data collected and assumes that all data will be collected in adherence to the protocol developed by GSK/ViiV. There are two analysis populations discussed in this SAP: (1) all responding HIV care providers/clinical staff who complete any portion of any questionnaire at any point in the study and (2) all responding members of the Expert Panel comprised of key IC/ASA staff members involved in decision making and/or oversee daily operations at the IC/ASA, selected HIV care providers, and ViiV members who complete any portion of any questionnaire at any point in the study. As the data are analyzed, some deviation from expectations may occur. In instances where these deviations would make the proposed analyses inappropriate, modifications to the analysis

plan, along with justifications for these changes, will be made and noted in the final report. Given the small sample size of HIV care providers/clinical staff and the Expert Panel, the planned analyses will be descriptive.

Continuous and interval-like variables will be summarized using descriptive statistics (e.g., n, mean, standard deviation [SD], median, minimum, maximum, first and third quartiles, and 95% confidence intervals [CI]). Data in tables will be tabulated relative to the source data. Mean, median, quartiles, and percentages will be tabulated to one more decimal place than the source data; minimum/maximum values will have the same decimal places as source data; percentages will be rounded to one decimal place after calculation. SD and CIs will be tabulated to two more decimal places than the source data. Categorical variables will be reported as frequency counts, the percentage of HIV care providers/clinical staff and Expert Panel in corresponding categories, and 95% CIs.

Subgroup analysis will be performed to evaluate the effect of contextual factors on the variability of responses to feasibility, and acceptability. These factors will include, but are not limited to, affiliation for HIV care providers. Once specified these will be added to this SAP. No subgroup analyses will be performed for the Expert Panel due to insufficient sample size.

For the analyses of the proportion of HIV care providers/clinical staff and Expert Panel members responding agree or completely agree on all FIM items, this will include the HIV care providers/clinical staff and Expert Panel members who select response option 4 CCI [redacted] or 5 CCI [redacted] for all four FIM items at a given time point, out of all HIV care providers/clinical staff and Expert Panel members who completed all four FIM items at that respective timepoint. The same definition applies to the analogous analysis for the AIM.

Table shells for analyses of HIV care providers/clinical staff can be found in Section 6, and for the Expert Panel can be found in Section 7.

3.1 Missing Data Handling Scheme

HIV care provider/clinical staff and Expert Panel member questionnaires will be completed in a hybrid, eCRF (Medidata) and on paper, converted to portable document format (PDF), and sent to Evidera via DataFax. Forms received will be quality checked for missing data and illegible responses by the study team. Queries will focus on issues with optical character recognition (OCR; legibility), missing data, or DataFax form elements required to include the data. Missing pages will be queried by e-mail to the HIV care provider/clinical staff and Expert Panel member to verify that all pages were scanned. If data are still missing, follow-up queries will be initiated by the study team with respective HIV care providers/clinical staff and Expert Panel member. Queries remaining open from unresponsive HIV care providers/clinical staff or Expert Panel members may be closed with GSK/ViiV review and approval. Missing data at the multi-item scale level for standardized scales (FIM and AIM) will be addressed with standard proration rules[2]: if at least 50% of the items are completed the scale will be scored by taking the mean of the completed items, unless otherwise specified for a particular outcome. Following this, partially completed FIM and AIM administrations will be scored if two, three, or four items are completed, and will not be scored if only one item is completed. Items not completed will be logged as missing data. Summaries will

be produced on all available data, no missing data will be imputed. Table shells for missing data from FIM and AIM scales can be found in Appendix A.

3.2 Cross-sectional Univariate Distributions of Study Variables and Features of Score Distributions

For questions with ordinal responses, a univariate distribution of every item will be tabulated. Standard distributional statistics will be tabulated for interval-like (ordinal) variables, including mean, SD, median, percentage missing, range (minimum and maximum of responses), percentage of the sample at the ceiling (highest possible score) and floor (lowest possible score), first and third quartiles, and 95% CIs. For questions with descriptive responses, a frequency distribution of all responses will be presented with n(%).

3.3 Distributions of Study Variables and Features of Score Distributions, Change from Baseline for FIM and AIM

The univariate distribution of item change scores for HIV care providers/clinical staff (Month 4 minus Baseline, Month 8 minus Baseline, and Month 8 minus Month 4) and the Expert Panel (Month 3 minus Baseline, Month 6 minus baseline, and Month 6 minus Month 3) will be tabulated for the FIM and the AIM, both in terms of distributional characteristics of change and in terms of frequency of responses. Distributional characteristic tables will include the SD of the change distribution, median change, first and third quartiles, and 95% CIs. Change analyses will be limited to those HIV care providers/clinical staff completing questionnaires at baseline and respective timepoints. Categorical data for the FIM and AIM from the HIV care provider/clinical staff and Expert Panel member questionnaires will be presented in shift analyses showing the frequency of change by the degree of shift across response categories, and will be presented for Baseline to Month 4, Baseline to Month 8, and Month 4 to Month 8 for HIV care providers/clinical staff and Baseline to Month 3, Baseline to Month 6 and Month 3 to Month 6 for the Expert Panel.

4 Qualitative Analysis

Qualitative analyses will be described in a separate qualitative analysis plan.

5 References

1. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci.* 2017;12(1):108.
2. Cella D. *Manual of the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System—Version 4.* Evanston, IL: Center on Outcomes, Research & Education (CORE), Evanston Northwestern Healthcare and Northwestern University; 1997.

6 Table Shells, HIV Care Providers/Clinical Staff: Baseline, Month 4, Month 8, and Change

Table 1. HIV Care Provider, Practice and Experience- Baseline (N= XX)

Question	Number of Participants at Baseline	Response/Statistic	Value
1. What type of clinic/practice do you work in (select the answer that is most fitting)?[1,2]	XX	Hospital-based setting, non-university affiliated	n (%)
		University or Medical School Based Hospital (employed by or primarily affiliated with an academic institution)	n (%)
		Federally Qualified Health Center	n (%)
		Private Practice/Solo or Group Practice	n (%)
		General Class HMO/Integrated Network (e.g., Kaiser Permanente, Geisinger)	n (%)
		AIDS Health Care Foundation	n (%)
		VA Medical Center or other VA facility (e.g., outpatient clinic)	n (%)
		AIDS Service Organization with Clinical Services	n (%)
		Other*	n (%)
		Missing	n (%)
2. How many patients are served by your clinic/practice?[1]	XX	<200 PLWHIV	n (%)
		201-500 PLWHIV	n (%)
		501-1000 PLWHIV	n (%)
		1001-2000 PLWHIV	n (%)
		2001-3000 PLWHIV	n (%)
		3001-4000 PLWHIV	n (%)
		More than 4000 PLWHIV	n (%)
		Missing	n (%)
2a. How many patients in your practice are currently on CABENUVA?[1]	XX	1-10 PLWHIV	n (%)
		11-25 PLWHIV	n (%)
		26-50 PLWHIV	n (%)
		51-100 PLWHIV	n (%)
		More than 100	n (%)
		Missing	n (%)

[1] Select one response

[2]Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents.

Abbreviations: AIDS = acquired immunodeficiency syndrome; HIV = human immunodeficiency virus; HMO = health maintenance organization; PLWHIV = participants living with human immunodeficiency virus; VA = Veteran's Affairs

NOTE: Missing = the number of participants who completed any portion of a survey at any time but did not complete respective item; Missing % = the number of participants who filled out any portion of a survey at any time but did NOT complete the respective item / the number of people who filled out any portion of a survey at any time.

Cell percentages do not include missing

*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.2.1. HIV Care Provider/Clinical Staff, Experience with CABENUVA - Baseline, (N= XX)

Question	Number of Participants at Baseline	Response	n (%)
1. How acceptable was the overall process of interacting with the infusion center so far?[1]	N=XX	Very acceptable	XX (XX.X%)
		Somewhat acceptable	XX (XX.X%)
		A little acceptable	XX (XX.X%)
		Neutral	XX (XX.X%)
		A little unacceptable	XX (XX.X%)
		Somewhat unacceptable	XX (XX.X%)
		Very unacceptable	XX (XX.X%)
		I have not interacted with the infusion center yet.	XX (XX.X%)
		Missing	XX (XX.X%)
2. How acceptable was the process of obtaining or dispensing oral lead in medication?[1]	N=XX	Very acceptable	XX (XX.X%)
		Somewhat acceptable	XX (XX.X%)
		A little acceptable	XX (XX.X%)
		Neutral	XX (XX.X%)
		A little unacceptable	XX (XX.X%)
		Somewhat unacceptable	XX (XX.X%)
		Very unacceptable	XX (XX.X%)
		Missing	XX (XX.X%)
3. How do you prefer to be notified if a patient	N=XX	Email	XX (XX.X%)
		Fax	XX (XX.X%)

receives CABENUVA on time?[1,3]		Phone call	XX (XX.X%)
		Postal Letter	XX (XX.X%)
		Secure electronic medical record (EMR) message	XX (XX.X%)
		No communication necessary	XX (XX.X%)
		Missing	XX (XX.X%)
4. How do you prefer to be notified if a patient misses or receives CABENUVA out of window at the infusion center?[1,3]	N=XX	Email	XX (XX.X%)
		Secure electronic medical record (EMR) message	XX (XX.X%)
		Phone call	XX (XX.X%)
		Fax	XX (XX.X%)
		Postal Letter	XX (XX.X%)
		No communication necessary	XX (XX.X%)
		Missing	XX (XX.X%)
5. Where do you expect that patients in your care will receive CABENUVA?[2,3]	N=XX	In my clinic, by my healthcare staff	XX (XX.X%)
		Infusion Center	XX (XX.X%)
		Home-nursing visits	XX (XX.X%)
		At a pharmacy	XX (XX.X%)
		Through a mobile van service	XX (XX.X%)
		Other*	XX (XX.X%)
		Missing	XX (XX.X%)
6. How often do you/your clinic buy and bill any other medications?[1]	N=XX	Always	XX (XX.X%)
		Often	XX (XX.X%)
		Occasionally	XX (XX.X%)

		Rarely	XX (XX.X%)
		Never	XX (XX.X%)
		Missing	XX (XX.X%)
7. How often have you referred your patients to an infusion center before for any reason?[1]	N=XX	Always	XX (XX.X%)
		Often	XX (XX.X%)
		Occasionally	XX (XX.X%)
		Rarely	XX (XX.X%)
		Never	XX (XX.X%)
		Missing	XX (XX.X%)

[1] Select one response

[2] Select all that apply

[3] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviations: HIV = Human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing

Table 1.2.2. HIV Care Provider/Clinical Staff Experience with CABENUVA – Month 4 (N=XX)

Question	Number of Participants at Month 4	Response	n (%)
1. How acceptable was the overall process of interacting with	N=XX	Very acceptable	XX (XX.X%)
		Somewhat acceptable	XX (XX.X%)
		A little acceptable	XX (XX.X%)

the infusion center so far?[1]		Neutral	XX (XX.X%)
		A little unacceptable	XX (XX.X%)
		Somewhat unacceptable	XX (XX.X%)
		Very unacceptable	XX (XX.X%)
		I have not interacted with the infusion center yet.	XX (XX.X%)
		Missing	XX (XX.X%)
2. How acceptable was the process of obtaining or dispensing oral lead in medication?[1]	N=XX	Very acceptable	XX (XX.X%)
		Somewhat acceptable	XX (XX.X%)
		A little acceptable	XX (XX.X%)
		Neutral	XX (XX.X%)
		A little unacceptable	XX (XX.X%)
		Somewhat unacceptable	XX (XX.X%)
		Very unacceptable	XX (XX.X%)
		I was not involved in this process	XX (XX.X%)
		Missing	XX (XX.X%)
3. How are you notified if a patient receives CABENUVA on time?[2,3]	N=XX	Email	XX (XX.X%)
		Fax	XX (XX.X%)
		Phone call	XX (XX.X%)
		Postal Letter	XX (XX.X%)
		Secure electronic medical record (EMR) message	XX (XX.X%)
		No communication necessary	XX (XX.X%)
		Missing	XX (XX.X%)

4. How are you notified if a patient misses or receives CABENUVA out of window at the infusion center?[2,3]	N=XX	Email	XX (XX.X%)
		Phone call	XX (XX.X%)
		Fax	XX (XX.X%)
		No communication necessary	XX (XX.X%)
		Postal Letter	XX (XX.X%)
		Secure electronic medical record (EMR) message	XX (XX.X%)
		Missing	XX (XX.X%)
5. Where do patients in your care receive CABENUVA?[2,3]	N=XX	In my clinic, by my healthcare staff	XX (XX.X%)
		Infusion Center	XX (XX.X%)
		Home-nursing visits	XX (XX.X%)
		At a pharmacy	XX (XX.X%)
		Through a mobile van service	XX (XX.X%)
		Other*	XX (XX.X%)
		Missing	XX (XX.X%)
6. Do you recall seeing or completing the plan of treatment (POT)? [1]	N=XX	No or not sure (skip all remaining questions)	XX (XX.X%)
		Yes	XX (XX.X%)
		Missing	XX (XX.X%)
7. The information included in the plan of treatment (POT) is comprehensive enough for the infusion center to administer	N=XX	Strongly Agree	XX (XX.X%)
		Agree	XX (XX.X%)
		Occasionally	XX (XX.X%)
		Neither agree nor disagree	XX (XX.X%)
		Disagree	XX (XX.X%)

CABENUVA to patients.[1]		Strongly disagree	XX (XX.X%)
		Missing	XX (XX.X%)
8. The plan of treatment (POT) has all of the information I think it should have for the infusion center to administer CABENUVA.[1]	N=XX	Strongly Agree	XX (XX.X%)
		Agree	XX (XX.X%)
		Occasionally	XX (XX.X%)
		Neither agree nor disagree	XX (XX.X%)
		Disagree	XX (XX.X%)
		Strongly disagree	XX (XX.X%)
		Missing	XX (XX.X%)
9. What do you think is missing from or could be improved about the plan of treatment (POT)? [1]	N=XX	Open-ended text*	XX (XX.X%)

[1] Select one response

[2] Select all that apply

[3] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviations: HIV = Human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing

* Responses and open-ended text responses will be presented in an appendix

Table 1.2.3. HIV Care Provider/Clinical Staff Experience with CABENUVA – Month 8 (N=XX)

Question	Number of Participants at Month 4	Response	n (%)
1. How acceptable was the overall process of interacting with the infusion center so far?[1]	N=XX	Very acceptable	XX (XX.X%)
		Somewhat acceptable	XX (XX.X%)
		A little acceptable	XX (XX.X%)
		Neutral	XX (XX.X%)
		A little unacceptable	XX (XX.X%)
		Somewhat unacceptable	XX (XX.X%)
		Very unacceptable	XX (XX.X%)
		I have not interacted with the infusion center yet.	XX (XX.X%)
		Missing	XX (XX.X%)
2. How acceptable was the process of obtaining or dispensing oral lead in medication?[1]	N=XX	Very acceptable	XX (XX.X%)
		Somewhat acceptable	XX (XX.X%)
		A little acceptable	XX (XX.X%)
		Neutral	XX (XX.X%)
		A little unacceptable	XX (XX.X%)
		Somewhat unacceptable	XX (XX.X%)
		Very unacceptable	XX (XX.X%)
		I was not involved in this process	XX (XX.X%)
		Missing	XX (XX.X%)
	N=XX	Email	XX (XX.X%)

3. How are you notified if a patient receives CABENUVA on time?[2,3]		Fax	XX (XX.X%)
		Phone call	XX (XX.X%)
		Postal Letter	XX (XX.X%)
		Secure electronic medical record (EMR) message	XX (XX.X%)
		No communication necessary	XX (XX.X%)
		Missing	XX (XX.X%)
4. How are you notified if a patient misses or receives CABENUVA out of window at the infusion center?[2,3]	N=XX	Email	XX (XX.X%)
		Phone call	XX (XX.X%)
		Fax	XX (XX.X%)
		No communication necessary	XX (XX.X%)
		Postal Letter	XX (XX.X%)
		Secure electronic medical record (EMR) message	XX (XX.X%)
		Missing	XX (XX.X%)
5. Where do patients in your care receive CABENUVA?[2,3]	N=XX	In my clinic, by my healthcare staff	XX (XX.X%)
		Infusion Center	XX (XX.X%)
		Home-nursing visits	XX (XX.X%)
		At a pharmacy	XX (XX.X%)
		Through a mobile van service	XX (XX.X%)
		Other*	XX (XX.X%)
		Missing	XX (XX.X%)
6. Do you recall seeing or completing the	N=XX	No or not sure (skip all remaining questions)	XX (XX.X%)
		Yes	XX (XX.X%)

plan of treatment (POT)? [1]		Missing	XX (XX.X%)
7. The information included in the plan of treatment (POT) is comprehensive enough for the infusion center to administer CABENUVA to patients.[1]	N=XX	Strongly Agree	XX (XX.X%)
		Agree	XX (XX.X%)
		Occasionally	XX (XX.X%)
		Neither agree nor disagree	XX (XX.X%)
		Disagree	XX (XX.X%)
		Strongly disagree	XX (XX.X%)
		Missing	XX (XX.X%)
8. The plan of treatment (POT) has all of the information I think it should have for the infusion center to administer CABENUVA.[1]	N=XX	Strongly Agree	XX (XX.X%)
		Agree	XX (XX.X%)
		Occasionally	XX (XX.X%)
		Neither agree nor disagree	XX (XX.X%)
		Disagree	XX (XX.X%)
		Strongly disagree	XX (XX.X%)
		Missing	XX (XX.X%)
9. What do you think is missing from or could be improved about the plan of treatment (POT)? [1]	N=XX	Open-ended text*	XX (XX.X%)

[1] Select one response

[2] Select all that apply

[3] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviations: HIV = Human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing

*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.3.1. HIV Care Provider/Clinical Staff Prospective Preferences with CABENUVA – Baseline (N=XX)

Item	Number of Participants at Baseline	Response	n (%)
1. What types of patients do you plan to refer to an infusion center to receive CABENUVA?[1,2]	XX	All patients	n (%)
		Patients who want to start CABENUVA but prefer not to come to the HIV clinic for each injection visit	n (%)
		Patients who have had difficulty maintaining their daily oral treatment regimen	n (%)
		Patients who have concerns about disclosure of their HIV status to others	n (%)
		Patients who feel stigmatized by their HIV	n (%)
		Patients with more chaotic lifestyles (variable work schedules, frequent travel, balancing work and school)	n (%)
		Patients with more structured lifestyles	n (%)
		Newly diagnosed (<2 years since diagnosis)	n (%)
		Treatment experienced	n (%)
		Patients already receiving CABENUVA	n (%)
		Younger patients (<35 years old)	n (%)
		Older patients (>50 years old)	n (%)
		Other*	n (%)
		Missing	n (%)
2. What are the potential advantages of referring patients to an infusion center for CABENUVA from your perspective?[1,2]	XX	Infusions centers have more clinic space	n (%)
		Infusion centers have more time to add visits to their schedules	n (%)
		Infusion centers have more staff to manage scheduling/rescheduling appointments	n (%)
		Infusion centers have more staff to administer it	n (%)
		Infusion centers have the space to store the medication	n (%)
		Infusion centers manage acquisition of the medication	n (%)
		Infusion center handles the logistics of administration	n (%)
		Infusion centers manage the insurance verification process	n (%)
		Infusion centers manage the insurance reimbursement	n (%)
		Convenience for the patient	n (%)
		Financial considerations for my clinic	n (%)
		Financial considerations for my clinic	n (%)
		Missing	n (%)
3. What are the potential disadvantages of referring patients to an infusion center	XX	Concern I won't be aware when my patient receives CABENUVA	n (%)
		Concern I won't be aware if my patient does not receive CABENUVA on time	n (%)
		Concern about adverse event management	n (%)
		Concern about management of injection site reactions	n (%)

Item	Number of Participants at Baseline	Response	n (%)
for CABENUVA from your perspective?[1,2]		Concern about reduced involvement in management of HIV-related care	n (%)
		Inconvenience for patients; having to go to two locations (clinic for routine visits, infusion center for injections)	n (%)
		Concern patient won't want to go to infusion center	n (%)
		Concern about stigma patient may experience receiving an CABENUVA at infusion center	n (%)
		Missed opportunity for revenue for my HIV clinic	n (%)
		Issues with infusion centers handling the logistics associated with insurance verification and approval	n (%)
		Issues with infusion centers handling the logistics associated with insurance reimbursement	n (%)
		Fear of losing my patient to another provider	n (%)
		Other*	n (%)
		Missing	n (%)
4. If your patient is receiving CABENUVA at an infusion center, how often do you want to see them in your clinic for follow-up?[3]	XX	Once every month	n (%)
		Once after the first injection at the infusion center, then every 3 months	n (%)
		Once after the first injection at the infusion center, then every 6 months	n (%)
		Once every 3 months	n (%)
		Once every 6 months	n (%)
		Once a year	n (%)
		Other*	n (%)
		Missing	n (%)
5. If your patient is receiving CABENUVA at an infusion center, how often do you want to them to get routine labs?[3]	XX	Once every month	n (%)
		Once after the first injection at the infusion center, then every 3 months	n (%)
		Once after the first injection at the infusion center, then every 6 months	n (%)
		Once every 3 months	n (%)
		Once every 6 months	n (%)
		Once a year	n (%)
		Other*	n (%)
		Missing	n (%)

[1] Select all that apply

[2] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviation: HIV = human immunodeficiency virus

[3] Select one response

NOTE: Missing = the number of participants who completed any portion of a survey at any time but did not complete respective item; Missing % = the number of participants who filled out any portion of a survey at any time but did NOT complete the respective item / the number of people who filled out any portion of a survey at any time.

Cell percentages do not include missing

*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.3.2. HIV Care Provider/Clinical Staff Preferences with CABENUVA – Month 4

Question	Number of Participants at Month 4	Response	n (%)
1. How many patients have you referred to a Palmetto infusion center to receive CABENUVA injections?	XX	1 patient	n (%)
		2 patients	n (%)
		3 patients	n (%)
		4 patients	n (%)
		5 or more patients	n (%)
		Missing	n (%)
2. How many patients in your care have received at least one CABENUVA injection at a Palmetto infusion center?	XX	0 patients	n (%)
		1 patient	n (%)
		2 patients	n (%)
		3 patients	n (%)
		4 patients	n (%)
		5 or more patients	n (%)
		Missing	n (%)
3. How many patients in your care have ever received at least one CABENUVA injection outside of a research study at your clinic/practice?	XX	0 patients	n (%)
		1 patient	n (%)
		2 patients	n (%)
		3 patients	n (%)
		4 patients	n (%)
		5 patients	n (%)
		6 patients	n (%)
		7 patients	n (%)

		8 patients	n (%)
		9 patients	n (%)
		10 or more patients	n (%)
		Missing	n (%)
4. What types of patients have you referred to an infusion center to receive CABENUVA?[1,2]	XX	All patients	n (%)
		Patients who want to start CABENUVA but prefer not to come to the HIV clinic for each injection visits	n (%)
		Patients who have had difficulty maintaining their daily oral treatment regimen	n (%)
		Patients who have concerns about disclosure of their HIV status to others	n (%)
		Patients who feel stigmatized by their HIV	n (%)
		Patients with more chaotic lifestyles (variable work schedules, frequent travel, balancing work and school)	n (%)
		Patients with more structured lifestyles	n (%)
		Newly diagnosed (<2 years since diagnosis)	n (%)
		Treatment experienced	n (%)
		Patients already receiving CABENUVA	n (%)
		Younger patients (<35 years old)	n (%)
		Older patients (>50 years old)	n (%)
		Other*	n (%)
		Missing	n (%)
5. What are the advantages of referring patients to an infusion center for CABENUVA from your perspective?[1,2]	XX	Infusions centers have more clinic space	n (%)
		Infusion centers have more time to add visits to their schedules	n (%)

		Infusion centers have more staff to manage scheduling/rescheduling appointments	n (%)
		Infusion centers have more staff to administer it	n (%)
		Infusion centers have the space to store the medication	n (%)
		Infusion centers manage acquisition of the medication	n (%)
		Infusion center handles the logistics of administration	n (%)
		Infusion centers manage the insurance verification process	n (%)
		Infusion centers manage the insurance reimbursement	n (%)
		Convenience for the patient	n (%)
		Financial considerations for my clinic	n (%)
		Other	n (%)
		Missing	n (%)
6. What are the disadvantages of referring patients to an infusion center for CABENUVA from your perspective?[1,2]	XX	Concern I won't be aware when my patient receives CABENUVA	n (%)
		Concern I won't be aware if my patient does not receive CABENUVA on time	n (%)
		Concern about adverse event management	n (%)
		Concern about management of injection site reactions	n (%)
		Concern about reduced involvement in management of HIV-related care	n (%)
		Inconvenience for patients; having to go to two locations (clinic for routine visits, infusion center for injections)	n (%)
		Concern patient won't want to go to infusion center	n (%)

		Concern about stigma patient may experience receiving an CABENUVA at infusion center	n (%)
		Missed opportunity for revenue for my HIV clinic	n (%)
		Issues with infusion centers handling the logistics associated with insurance verification and approval	n (%)
		Issues with infusion centers handling the logistics associated with insurance reimbursement	n (%)
		Fear of losing my patient to another provider	n (%)
		Other*	n (%)
		Missing	n (%)
7. If a patient in your care is receiving CABENUVA at an infusion center, how often do you see them/expect to see them in your clinic for follow-up?[3]	XX	Once every month	n (%)
		Once after the first injection at the infusion center, then every 3 months	n (%)
		Once after the first injection at the infusion center, then every 6 months	n (%)
		Once every 3 months	n (%)
		Once every 6 months	n (%)
		Once a year	n (%)
		Other*	n (%)
		Missing	n (%)
8. If a patient in your care is receiving CABENUVA at an infusion center, how often do they get/expect to get routine labs?[3]	XX	Once every month	n (%)
		Once after the first injection at the infusion center, then every 3 months	n (%)
		Once after the first injection at the infusion center, then every 6 months	n (%)

		Once every 3 months	n (%)
		Once every 6 months	n (%)
		Once a year	n (%)
		Other*	n (%)
		Missing	n (%)

[1] Select one response

[2] Select all that apply

[3] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviations: HIV = Human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing

*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.3.3. HIV Care Provider/Clinical Staff Preferences with CABENUVA – Month 8

Question	Number of Participants at Month 8	Response	n (%)
1. How many patients have you referred to a Palmetto infusion center to receive CABENUVA injections?	XX	1 patient	n (%)
		2 patients	n (%)
		3 patients	n (%)
		4 patients	n (%)
		5 or more patients	n (%)
		Missing	n (%)
2. How many patients in your care have received at least one CABENUVA injection at a Palmetto infusion center?	XX	0 patients	n (%)
		1 patient	n (%)
		2 patients	n (%)
		3 patients	n (%)

		4 patients	n (%)
		5 or more patients	n (%)
		Missing	n (%)
3. How many patients in your care have ever received at least one CABENUVA injection outside of a research study at your clinic/practice?	XX	0 patients	n (%)
		1 patient	n (%)
		2 patients	n (%)
		3 patients	n (%)
		4 patients	n (%)
		5 patients	n (%)
		6 patients	n (%)
		7 patients	n (%)
		8 patients	n (%)
		9 patients	n (%)
		10 or more patients	n (%)
		Missing	n (%)
4. What types of patients have you referred to an infusion center to receive CABENUVA?[1,2]	XX	All patients	n (%)
		Patients who want to start CABENUVA but prefer not to come to the HIV clinic	n (%)
		Patients who have had difficulty maintaining their daily oral treatment regimen	n (%)
		Patients who have concerns about disclosure of their HIV status to others	n (%)
		Patients who feel stigmatized by their HIV	n (%)
		Patients with more chaotic lifestyles (variable work schedules, frequent travel, balancing work and school)	n (%)
		Patients with more structured lifestyles	n (%)
		Newly diagnosed (<2 years since diagnosis)	n (%)
		Treatment experienced	n (%)

		Patients already receiving CABENUVA	n (%)
		Younger patients (<35 years old)	n (%)
		Older patients (>50 years old)	n (%)
		Other*	n (%)
		Missing	n (%)
5. What are the advantages of referring patients to an infusion center for CABENUVA from your perspective?[1,2]	XX	Infusions centers have more clinic space	n (%)
		Infusion centers have more time to add visits to their schedules	n (%)
		Infusion centers have more staff to manage scheduling/rescheduling appointments	n (%)
		Infusion centers have more staff to administer it	n (%)
		Infusion centers have the space to store the medication	n (%)
		Infusion centers manage acquisition of the medication	n (%)
		Infusion center handles the logistics of administration	n (%)
		Infusion centers manage the insurance verification process	n (%)
		Infusion centers manage the insurance reimbursement	n (%)
		Convenience for the patient	n (%)
		Financial considerations for my clinic	n (%)
		Other	n (%)
		Missing	n (%)

6. What are the disadvantages of referring patients to an infusion center for CABENUVA from your perspective?[1,2]	XX	Concern I won't be aware when my patient receives CABENUVA	n (%)
		Concern I won't be aware if my patient does not receive CABENUVA on time	n (%)
		Concern about adverse event management	n (%)
		Concern about management of injection site reactions	n (%)
		Concern about reduced involvement in management of HIV-related care	n (%)
		Inconvenience for patients; having to go to two locations (clinic for routine visits, infusion center for injections)	n (%)
		Concern patient won't want to go to infusion center	n (%)
		Concern about stigma patient may experience receiving an CABENUVA at infusion center	n (%)
		Missed opportunity for revenue for my HIV clinic	n (%)
		Issues with infusion centers handling the logistics associated with insurance verification and approval	n (%)
		Issues with infusion centers handling the logistics associated with insurance reimbursement	n (%)
		Fear of losing my patient to another provider	n (%)
		Other*	n (%)
		Missing	n (%)
7. If a patient in your care is receiving CABENUVA at an infusion center, how often do you see them/expect to see them in your clinic for follow-up?[3]	XX	Once every month	n (%)
		Once after the first injection at the infusion center, then every 3 months	n (%)
		Once after the first injection at the infusion center, then every 6 months	n (%)
		Once every 3 months	n (%)

		Once every 6 months	n (%)
		Once a year	n (%)
		Other*	n (%)
		Missing	n (%)
8. If a patient in your care is receiving CABENUVA at an infusion center, how often do they get/expect to get routine labs?[3]	XX	Once every month	n (%)
		Once after the first injection at the infusion center, then every 3 months	n (%)
		Once after the first injection at the infusion center, then every 6 months	n (%)
		Once every 3 months	n (%)
		Once every 6 months	n (%)
		Once a year	n (%)
		Other*	n (%)
		Missing	n (%)
9. Overall, how satisfied are you with the experience of referring patients to receive CABENUVA at an infusion center?	XX	Extremely satisfied	n (%)
		Very satisfied	n (%)
		Somewhat satisfied	n (%)
		Neutral	n (%)
		Somewhat dissatisfied	n (%)
		Very dissatisfied	n (%)
		Extremely dissatisfied	n (%)
		I was not involved in this process	n (%)
		Missing	n (%)
10. How likely are you to continue to refer patients to receive CABENUVA at an infusion center moving forward?	XX	Extremely likely	n (%)
		Very likely	n (%)
		Somewhat likely	n (%)
		Neutral	n (%)
		Somewhat unlikely	n (%)

		Very unlikely	n (%)
		Extremely unlikely	n (%)
		I was not involved in this process	n (%)
		Missing	n (%)

[1] Select one response

[2] Select all that apply

[3] Within each question, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints.

Abbreviations: HIV = Human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing

*"Other" responses and open-ended text responses will be presented in an appendix

Table 1.4.1. HIV Care Provider/Clinical Staff Concerns about CABENUVA Administration - Baseline (N=XX)

Items	Number of Participants at Baseline	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
1. Managing the oral lead-in phase of CABENUVA treatment before starting injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Being informed (in a timely manner) when a patient receives CABENUVA	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. Infusion center managing post-injection reactions appropriately	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Infusion center's ability to manage patients presenting to CABENUVA appointments with other care needs that need to be addressed	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
5. Infusion center's ability to schedule/reschedule missed CABENUVA visits within correct treatment window	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
6. Being informed (in a timely manner) when a patient needs oral therapy for planned missed CABENUVA visits	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
7. Being informed (in a timely manner) when a patient misses a CABENUVA visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
8. Infusion Center's (lack of) persistence to follow up with	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Items	Number of Participants at Baseline	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
patients on missed appointments							
9. Patients not being virologically suppressed due to missed injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
10. Risk of drug resistance for patients not adherent to injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
11. Being informed (in a timely manner) of adverse events	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
12. Being informed of laboratory results (e.g., CD4, VL, LFTs)	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
13. Infusion Center not taking adequate steps to address privacy concerns for PLWHIV	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
14. Worried that my patient will feel stigmatized at the infusion center	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
15. Patients' willingness to travel to an infusion for each injection visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
16. Patient reluctance to receive care at infusion center due to perception of severity of illness	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

NOTE: all items are 'select one response'; Table will be sorted from highest to lowest percentage of providers indicating extremely concerned, followed by moderately concerned, somewhat concerned, slightly concerned, and not at all concerned.

NOTE: Missing = the number of participants who completed any portion of a survey at any time but did not complete respective item; Missing % = the number of participants who filled out any portion of a survey at any time but did NOT complete the respective item / the number of people who filled out any portion of a survey at any time.

Cell percentages do not include missing

Instructions to respondents:

Survey Completion Instructions: "We want to understand any concerns or barriers to successful administration of long-acting CABENUVA injections at an infusion center. For each item, please indicate how concerned you would be about each of the following challenges potentially being a barrier based on your current expectations and knowledge."

Table 1.4.2. HIV Care Provider/Clinical Staff Concerns about CABENUVA Administration – Month 4 (N=XX)

Items	Number of Participants at Month 4	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
1. Managing the oral lead-in phase of CABENUVA treatment before starting injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Being informed (in a timely manner) when a patient receives CABENUVA	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. Infusion center managing post-injection reactions appropriately	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Infusion center's ability to manage patients presenting to CABENUVA appointments with other care needs that need to be addressed	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
5. Infusion center's ability to schedule/reschedule missed CABENUVA visits within correct treatment window	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
6. Being informed (in a timely manner) when a patient needs oral therapy for planned missed CABENUVA visits	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
7. Being informed (in a timely manner) when a patient misses a CABENUVA visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

8. Infusion Center's (lack of) persistence to follow up with patients on missed appointments	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
9. Patients not being virologically suppressed due to missed injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
10. Risk of drug resistance for patients not adherent to injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
11. Being informed (in a timely manner) of adverse events	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
12. Being informed of laboratory results (e.g., CD4, VL, LFTs, etc.)	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
13. Infusion Center not taking adequate steps to address privacy concerns for PLWHIV	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
14. Worried that my patient will feel stigmatized at the infusion center	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
15. Patients' willingness to travel to an infusion center for each injection visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
16. Patient reluctance to receive care at infusion center due to perception of severity of illness	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

NOTE: all items are 'select one response'; Table will be sorted from highest to lowest percentage, at baseline, of providers indicating extremely concerned, followed by moderately concerned, somewhat concerned, slightly concerned and not at all concerned. The top 5 items in terms of percent indicating extremely concerned at baseline will be **bolded** at all subsequent time points

NOTE: Missing = the number of participants who completed any portion of a survey at any time but did not complete respective item; Missing % = the number of participants who filled out any portion of a survey at any time but did NOT complete the respective item / the number of people who filled out any portion of a survey at any time.

Cell percentages do not include missing

Instructions to respondents:

Survey Completion Instructions: "We want to understand any concerns or barriers to successful administration of long-acting CABENUVA injections at an infusion center. For each item, please indicate how concerned you would be about each of the following challenges potentially being a barrier based on your current expectations and knowledge."

Table 1.4.3. HIV Care Provider/Clinical Staff Concerns about CABENUVA Administration - Month 8 (N=XX)

Items	Number of Participants at Month 4	Missing	Extremely concerned	Moderately concerned	Somewhat concerned	Slightly concerned	Not at all concerned
1. Managing the oral lead-in phase of CABENUVA treatment before starting injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Being informed (in a timely manner) when a patient receives CABENUVA	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. Infusion center managing post-injection reactions appropriately	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Infusion center's ability to manage patients presenting to CABENUVA appointments with other care needs that need to be addressed	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
5. Infusion center's ability to schedule/reschedule missed CABENUVA visits within correct treatment window	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
6. Being informed (in a timely manner) when a patient needs oral therapy for planned missed CABENUVA visits	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

7. Being informed (in a timely manner) when a patient misses a CABENUVA visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
8. Infusion Center's (lack of) persistence to follow up with patients on missed appointments	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
9. Patients not being virologically suppressed due to missed injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
10. Risk of drug resistance for patients not adherent to injections	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
11. Being informed (in a timely manner) of adverse events	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
12. Being informed of laboratory results (e.g., CD4, VL, LFTs, etc.)	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
13. Infusion Center not taking adequate steps to address privacy concerns for PLWHIV	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
14. Worried that my patient will feel stigmatized at the infusion center	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
15. Patients' willingness to travel to an infusion center for each injection visit	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
16. Patient reluctance to receive care at infusion center due to perception of severity of illness	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

NOTE: all items are 'select one response'; Table will be sorted from highest to lowest percentage, at baseline, of providers indicating extremely concerned, followed by moderately concerned, somewhat concerned, slightly concerned and not at all

concerned. The top 5 items in terms of percent indicating extremely concerned at baseline will be **bolded** at all subsequent time points

NOTE: Missing = the number of participants who completed any portion of a survey at any time but did not complete respective item; Missing % = the number of participants who filled out any portion of a survey at any time but did NOT complete the respective item / the number of people who filled out any portion of a survey at any time.

Cell percentages do not include missing

Instructions to respondents:

Survey Completion Instructions: "We want to understand any concerns or barriers to successful administration of long-acting CABENUVA injections at an infusion center. For each item, please indicate how concerned you would be about each of the following challenges potentially being a barrier based on your current expectations and knowledge."

Table 2.1. HIV Care Providers/Clinical Staff Responding "Agree" or Completely Agree" On All FIM Items at Baseline, Month 4, and Month 8: Proportions and Change

	Number completing all 4 FIM items	Number endorsing '4' or '5' on all FIM Items	% endorsing all FIM Items	Percentage Point Change
Baseline[1]	XX	XX	XX%	-
Month 4[1]	XX	XX	XX%	-
Month 8[1]	XX	XX	XX%	-
Baseline to Month 4[2]	XX	BL=XX; M4=XX	BL=XX%; M4=XX%	XX%
Baseline to Month 8[2]	XX	BL=XX; M8=XX	BL=XX%; M8=XX%	XX%
Month 4 to Month 8[2]	XX	M4=XX; M8=XX	M4=XX%; M8=XX%	XX%

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items

[2]Each change row is limited to those completing all 4 items at both respective timepoints: numerator = number responding '4' or '5', denominator = number completing all 4 items

Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M4 = Month 4; M8 = Month 8

Responses: 4=CCI 5=CCI

Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint

Table 2.2. HIV Care Providers/Clinical Staff Responding "Agree" or Completely Agree" On All AIM Items at Baseline, Month 4, and Month 8: Proportions and Change

	Number completing all 4 AIM items	Number endorsing '4' or '5' on all AIM Items	% endorsing all AIM Items[1]	Percentage Point Change[2]
Baseline[1]	XX	XX	XX%	-
Month 4[1]	XX	XX	XX%	-
Month 8[1]	XX	XX	XX%	-
Baseline to Month 4[2]	XX	BL=XX; M4=XX	BL=XX%; M4=XX%	XX%
Baseline to Month 8[2]	XX	BL=XX; M8=XX	BL=XX%; M8=XX%	XX%
Month 4 to Month 8[2]	XX	M4=XX; M8=XX	M4=XX%; M8=XX%	XX%

Responses: 4=CCI 5=CCI

Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items

[2]Each change row is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items

Abbreviations: AIM = Acceptability of Intervention Measure; BL=baseline; M4 = Month 4; M8 = Month 8

Table 3.1. HIV Care Provider/Clinical Staff, Distributional Characteristics of Feasibility of Intervention Measure (FIM), N=XX

Item/ Scale	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (Max ,Min)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
FIM Mean Score	BL	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M4	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M8	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
1. Infusion Center administered CABENUVA seems implementable for the patients in our clinic/practice.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
2. Infusion Center administered CABENUVA seems possible for the patients in our clinic/practice.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
3. Infusion Center administered CABENUVA seems doable for the patients in our clinic/practice.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
4. Infusion Center administered CABENUVA seems easy to implement for the patients in our clinic/practice.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)

Abbreviations: BL = Baseline; CI = confidence interval; FIM = Feasibility of Intervention Measure; M4 = Month 4; M8 = Month 8; SD = standard deviation; BL = Baseline; M4 = Month 4; M8 = Month 8.

Percent Floor for the mean score is the percent of respondents with a score of 1 [redacted] out of all respondents replying to at least two FIM item at a given time point.

Percent Ceiling for the mean score is the percent of respondents with a score of 5 [redacted] out of all respondents replying to at least two FIM item at a given time point.

NOTE: Missing for individual item counts = the number of participants who completed any portion of a survey at any time but did not complete respective item; Missing % = the number of participants who filled out any portion of a survey at any time but did NOT complete the respective item / the number of people who filled out any portion of a survey at any time. Missing for the mean score counts any instance where a respondent completed one FIM item, not reaching the minimum of 2 items required to calculate a mean FIM score.

Cell percentages do not include missing

Table 3.2. HIV Care Provider/Clinical Staff, Distributional Characteristics of Acceptability of Intervention Measure (AIM), N=XX

Item/ Scale	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (Max ,Min)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
AIM Mean Score	BL	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M4	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M8	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
1. The idea of providing CABENUVA at my infusion center meets my approval.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
2. The idea of providing CABENUVA at my infusion center is appealing to me.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
3. I like the idea of providing CABENUVA for PLWHIV in my infusion center.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
4. I welcome providing CABENUVA for PLWHIV in my infusion center.	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)

Abbreviations: AIM = Acceptability of Intervention Measure; BL = Baseline; CI = confidence interval; M4 = Month 4; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation; BL = Baseline; M3 = Month 3; M8 = Month 8.
Percent Floor for the mean score is the percent of respondents with a score of 1 CCI out of all respondents replying to at least two AIM item at a given time point.
Percent Ceiling for the mean score is the percent of respondents with a score of 5 CCI out of all respondents replying to at least two AIM item at a given time point.
NOTE: Missing for individual item counts = the number of participants who completed any portion of a survey at any time but did not complete respective item; Missing % = the number of participants who filled out any portion of a survey at any time but did NOT complete the respective item / the number of people who filled out any portion of a survey at any time. Missing for the mean score counts any instance where a respondent completed one AIM item, not reaching the minimum of 2 items required to calculate a mean AIM score.
Cell percentages do not include missing

Table 4.1. HIV Care Provider/Clinical Staff, Univariate Distribution of Feasibility of Intervention Measure (FIM), N=XX

Item	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Infusion Center administered CABENUVA seems implementable for the patients in our clinic/practice.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. Infusion Center administered CABENUVA seems possible for the patients in our clinic/practice.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. Infusion Center administered CABENUVA seems doable for the patients in our clinic/practice.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. Infusion Center administered CABENUVA seems easy to implement for the patients in our clinic/practice.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; HIV = human immunodeficiency virus; M4 = Month 4; M8 = Month 8

NOTE: NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint..

Cell percentages do not include missing

Table 4.2. HIV Care Provide/ Clinical Staff, Univariate Distribution of Acceptability of Intervention Measure (AIM), N=XX

Items	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The idea of an infusion center providing CABENUVA meets my approval.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2. The idea of an infusion center providing CABENUVA is appealing to me.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3. I like the idea of an infusion center providing CABENUVA for PLWHIV in our clinic/practice.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
4. I welcome an infusion center providing CABENUVA for PLWHIV in our clinic/practice.	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M4	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M8	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; HIV = human immunodeficiency virus; M4 = Month 4; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint..

Cell percentages do not include missing

Table 5.1. HIV Care Provider/Clinical Staff, Distributional Characteristics of Change in Feasibility of Intervention Measure (FIM), N=XX

Item/ Scale	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (Max - Min)	95% CI Lower-Upper
FIM Mean Score	BL to M4	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX - X.XXX)
	BL to M8	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX - X.XXX)
	M4 to M8	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX - X.XXX)
1. Infusion Center administered CABENUVA seems implementable for the patients in our clinic/practice.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
2. Infusion Center administered CABENUVA seems possible for the patients in our clinic/practice.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
3. Infusion Center administered CABENUVA seems doable for the patients in our clinic/practice.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
4. Infusion Center administered CABENUVA seems easy to implement for the patients in our clinic/practice.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)

[1] Only includes Providers who completed surveys at respective months

Abbreviations: BL = Baseline; CI = confidence interval; FIM = Feasibility of Intervention Measure; M4 = Month 4; M8 = Month 8; SD = standard deviation

NOTE: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to complete a survey at the respective timepoint. Missing for the mean score counts any instance where a respondent completed one FIM item, not reaching the minimum of 2 items required to calculate a mean FIM score.

Cell percentages do not include missing

Table 5.2. HIV Care Provider/Clinical Staff, Distributional Characteristics of Change in Acceptability of Intervention Measure (AIM), N=XX

Item/ Scale	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (Max - Min)	95% CI Lower-Upper
AIM Mean Score	BL to M4	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX - X.XXX)
	BL to M8	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX - X.XXX)
	M4 to M8	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX - X.XXX)
1. The idea of an infusion center providing CABENUVA meets my approval.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
2. The idea of an infusion center providing CABENUVA is appealing to me.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
3. I like the idea of an infusion center providing CABENUVA for PLWHIV in our clinic/practice.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
4. I welcome an infusion center providing CABENUVA for PLWHIV in our clinic/practice.	BL to M4	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	BL to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)
	M4 to M8	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	(X.XX - X.XX)

[1] Only includes Providers who completed surveys at respective months

Abbreviations: AIM = Acceptability of Intervention Measure; BL = Baseline; CI = confidence interval; M4 = Month 4; M8 = Month 8; PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation

NOTE: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to complete a survey at the respective timepoint. Missing for the mean score counts any instance where a respondent completed one AIM item, not reaching the minimum of 2 items required to calculate a mean AIM score.

Cell percentages do not include missing

Table 6.1. HIV Care Provider/Clinical Staff, Shift of Feasibility of Intervention Measure (FIM) Response Frequency by item, N=XX

1.Infusion Center administered CABENUVA seems implementable for the patients in our clinic/practice.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 4	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 4					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
2. Infusion Center administered CABENUVA seems possible for the patients in our clinic/practice.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

Month 4	**Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 4					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

3. Infusion Center administered CABENUVA seems doable for the patients in our clinic/practice.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 4	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 4					

		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

4. Infusion Center administered CABENUVA seems easy to implement for the patients in our clinic/practice.

		Baseline					
		Completely Disagree N=(XX)	Disagree N=(XX)	Neither agree nor disagree N=(XX)	Agree (N=XX)	Completely Agree (N=XX)	Missing[1] (N=XX)
Month 4	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 4					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

[1]Missing at T1, completed at T2

[2]Missing at T2, completed at T1

Abbreviations: HIV = Human immunodeficiency virus; FIM = Feasibility of Intervention Measure

Percentage calculations:

Non-missing cell %:

numerator = number selecting respective combination of Time 1 and Time 2 responses

denominator = number of participants responding within Time 1 response category at Time 1

Table 6.2. HIV Care Provider, Shift of Acceptability of Intervention Measure (AIM) Response Frequency by item, N=XX

1. The idea of an infusion center providing CABENUVA meets my approval.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 4	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 4					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
2. The idea of an infusion center providing CABENUVA is appealing to me.							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**

Month 4	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 4					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

3. I like the idea of an infusion center providing CABENUVA for PLWHIV in our clinic/practice.

		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 4	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 4					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

4. I welcome an infusion center providing CABENUVA for patients in our clinic/practice.

		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 4	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 4					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 8	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

[1]Missing at T1, completed at T2

[2]Missing at T2, completed at T1

Abbreviations: HIV = Human immunodeficiency virus; AIM = Acceptability of Intervention Measure; PLWHIV = participants living with human immunodeficiency virus

Percentage calculations:

Non-missing cell %:

numerator = number selecting respective combination of Time 1 and Time 2 responses

denominator = number of participants responding within Time 1 response category at Time 1

Table 7. Implementation Science-Related Protocol Deviations, HIV Care Provider/Clinical Staff N=XX

Protocol Deviation	IS-related Protocol Deviations Reported for HIV Care Provider/Clinical Staff n (%)
IS-related Protocol Deviations	
Placeholder sub-category 1	
Placeholder sub-category 2	
Placeholder sub-category 3	

7 Table Shells, Expert Panel: Baseline, Month 3, Month 6, and Change

Table 8.1. Expert Panel, Preferences for CABENUVA Administration Moving to Infusion Center, HIV Care Providers and IC Staff - Baseline, (N= XX)

Question	Number of Participants at Baseline	Response	n (%)
1. What is the preferred method for HIV providers/clinic staff to refer patients to receive CABENUVA at an infusion Center?[1,3]	N=XX	Phone call	n (%)
		Email	n (%)
		Fax	n (%)
		Secure Electronic Medical Record message	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
2. What details should be included on the referral form?[2,3]	N=XX	Patient age	n (%)
		Patient insurance details	n (%)
		Current/most recent viral load	n (%)
		Prior ART regimen	n (%)
		Duration of Prior ART regimen	n (%)
		History of prior ART failure	n (%)
		Allergies	n (%)
		Relevant medical conditions	n (%)
		Relevant concomitant medications	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
3. What is your preference for who will conduct the insurance benefit verification?[1,3]	N=XX	HIV Provider/ Clinic Staff	n (%)
		Infusion Center Staff	n (%)
		ViiV Connect (reimbursement hub)	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
4. What is the expectation for an acceptable amount of time for the insurance benefit verification process (e.g. total time from patient referral to infusion center to notification of insurance coverage to patient)?[1]	N=XX	<1 business day	n (%)
		1–2 business days	n (%)
		3–4 business days	n (%)
		5–6 business days	n (%)
		>6 business days	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)

Question	Number of Participants at Baseline	Response	n (%)
5. What is your preference for who notifies the patient about insurance coverage? [1,3]	N=XX	HIV provider/ Clinic Staff	n (%)
		Infusion Center Staff	n (%)
		Missing	n (%)
6. What is the preferred method for contacting patients to relay insurance coverage information? [1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Secure Electronic Medical Record message	n (%)
		In person discussion	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
7. What are the expected modes of communication to patients for appointment reminders for their CABENUVA injections? [2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Secure Electronic Medical Record message	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
8. What is your preferred mode of communication from infusion center to HIV provider/ clinic staff about completed CABENUVA injection visits? [1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure Electronic Medical Record message	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
9. What is your preferred mode of communication from infusion center to HIV provider/clinic staff about missed CABENUVA injection visits? [1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure Electronic Medical Record message	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
10. What is the preferred process for providing oral ART therapy when a patient will miss one or more	N=XX	Infusion center staff contacts referring HIV provider to manage	n (%)
		Infusion center staff notifies referring HIV provider, and IC manages the process of acquiring or helping the patient to acquire oral therapy	n (%)

Question	Number of Participants at Baseline	Response	n (%)
CABENUVA injection visits due to planned travel or other reasons? [1,3]		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
11. What is your preferred mode of communication between HIV provider/clinic staff and infusion center when a patient decides to discontinue CABENUVA or discontinue receiving injections at the infusion center? [1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure Electronic Medical Record message	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
12. What is your preferred mode of communication about adverse events from infusion center to HIV provider/clinic staff (either due to CABENUVA injections or other events)? [1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure Electronic Medical Record message	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
13. What is the preferred process for managing mild adverse events (i.e., Grade 1-2 injection site reactions) [1,3]	N=XX	Infusion center manages the event and notifies referring HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then manages the event in collaboration with HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
14. What is the preferred process for managing severe or serious adverse events (i.e., a vasovagal reaction)? [1,3]	N=XX	Infusion center manages the event and notifies referring HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then manages the event in collaboration with HIV provider	n (%)
		Infusion center notifies referring HIV provider Reimmediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)

Question	Number of Participants at Baseline	Response	n (%)
15. How often do you think it is appropriate to do routine labs at the infusion center? [2]	N=XX	Never/ not needed	n (%)
		Every month / at each injection	n (%)
		Every 2 months	n (%)
		Every 3 months	n (%)
		Every 4 months	n (%)
		Every 6 months	n (%)
		Yearly	n (%)
		As needed (i.e., when an adverse event occurs)	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
16. If ad-hoc labs are needed (e.g., in the case of an adverse event), where should they be done? [1,3]	N=XX	HIV provider's office	n (%)
		Infusion Center	n (%)
		External lab	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
17. How do you prefer that ad hoc labs be communicated between HIV provider/clinic staff and infusion center? [1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure Electronic Medical Record message	n (%)
		Other*	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)
18. For patients receiving CABENUVA injections at the infusion center, what is the preferred interval of time for patients to be seen by their HIV provider? [2]	N=XX	Never/ not needed	n (%)
		Every month	n (%)
		Every 2 months	n (%)
		Every 3 months	n (%)
		Every 4 months	n (%)
		Every 6 months	n (%)
		Yearly	n (%)
		As needed (i.e., when an adverse event occurs)	n (%)
		Other	n (%)
		Unsure/ Not applicable to role	n (%)
		Missing	n (%)

[1] Select one response

[2] Select all that apply

[3] Within each question, where appropriate, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents.

Abbreviations: ART = antiretroviral therapy; HIV = human immunodeficiency virus; IC = infusion center
NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.
Cell percentages do not include missingCell percentages do not include missing
*"Other" responses and open-ended text responses will be presented in an appendix

Table 8.2.1. Expert Panel, Assessment of CABENUVA Administration Moving to Infusion Center, HIV Care Providers – Month 3, (N= XX)

Question	Number of Participants at Month 3	Response	n (%)
9. Have you submitted a referral to the infusion center?[1]	N=XX		n (%)
			n (%)
		Missing	n (%)
9a. If yes, how acceptable has the referral process been?[1,2]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
9b. If yes, what challenges, if any, have you or your staff encountered with the referral process?[2,3,4]	N=XX	I/my staff have not encountered any challenges with the referral process. [If selecting this option please do not select any others and proceed to 9c.]	n (%)
		It was unclear how to initiate the referral.	n (%)
		It was unclear when to initiate the referral.	n (%)
		I/my staff did not know where to find the plan of treatment (POT) to initiate the referral process.	n (%)
		I /my staff was not clear on how to complete the plan of treatment (POT) as part of the referral process.	n (%)
		The plan of treatment (POT) does not provide enough information for a referral.	n (%)
		The plan of treatment (POT) required too much information for a referral.	n (%)
		The process of transferring the information to the infusion center was difficult due to technology limitations (e.g., too much paperwork to fax).	n (%)
		I did not know to whom to send the plan of treatment (POT) and supporting documentation.	n (%)
		I was not comfortable faxing the documentation required for the referral process.	n (%)

		I was never informed whether or not my patient was eligible to receive CABENUVA injections at the infusion center.	n (%)
		The process to initiate oral cabotegravir and rilpivirine was not clear	n (%)
		Other*	n (%)
		Missing	n (%)
9c. If no, what are the reason(s) you have not yet referred a patient to the infusion center to receive CABENUVA? (Only complete this question if you have not submitted a referral to the infusion center.)[2,3,4]	N=XX	I am not recommending CABENUVA as a treatment option for my patients at this time.	n (%)
		I have not identified a patient that is appropriate for receipt of CABENUVA.	n (%)
		I prefer to administer CABENUVA at my own clinic at this time.	n (%)
		I prefer to administer CABENUVA at my own clinic for patients new to CABENUVA prior to referring them to the infusion center.	n (%)
		My patient(s) do not want to receive CABENUVA at an infusion center at this time.	n (%)
		I do not have enough information about the infusion centers to recommend it for my patients.	n (%)
		It was unclear how to initiate the referral.	n (%)
		It was unclear when to initiate the referral.	n (%)
		I/my staff did not know where to find the plan of treatment (POT) to initiate the referral process.	n (%)
		I/my staff was not clear on how to complete the plan of treatment (POT) as part of the referral process.	n (%)
		The plan of treatment (POT) does not provide enough information for a referral.	n (%)
		The plan of treatment (POT) required too much information for a referral.	n (%)
		Other*	n (%)
		Missing	n (%)
9d. How likely are you to refer (or to continue to refer) patients to infusion centers to receive CABENUVA?[1]	N=XX	Extremely likely	n (%)
		Very likely	n (%)
		Somewhat likely	n (%)
		Neither likely nor unlikely	n (%)
		Somewhat unlikely	n (%)
		Very unlikely	n (%)
		Extremely unlikely	n (%)
		Missing	n (%)
10. Have you seen the plan of treatment (POT) or referral form?[1,5]	N=XX	Yes (Go to Q11a.)	n (%)
		No (Go to Q12.)	n (%)
		Missing	n (%)
	N=XX	Yes (Go to Q11b.)	n (%)

10a. Is there anything missing from the plan of treatment (POT) or referral form?[1]		No (Go to Q11c.)	n (%)
		Missing	n (%)
10b. If yes, what is missing from the plan of treatment (POT) or referral form?[3,4]	N=XX	Place to provide comments to infusion center	n (%)
		Documentation of my preferences regarding modality of urgent communications	n (%)
		Documentation of my preferences regarding modality of non-urgent communications	n (%)
		Other*	n (%)
		Missing	n (%)
10c. Is there anything on the plan of treatment (POT) or referral form that you feel should not be included (or is not needed) as part of the referral process?[3,4]	N=XX	I think that all of the information on the plan of treatment (POT) or referral form is needed or should be included as part of a referral. [If selecting this option please do not select any others.]	n (%)
		Patient demographic information	n (%)
		Patient height	n (%)
		Patient weight	n (%)
		Allergies	n (%)
		Patient diagnosis Z21 asymptomatic human immunodeficiency virus (HIV) infection status	n (%)
		Patient diagnosis B230 HIV disease	n (%)
		Dose frequency initiation	n (%)
		Dose frequency continuation	n (%)
		Lab orders	n (%)
		End date of oral lead-in drug	n (%)
		Date of previous injection	n (%)
		Physician preferred method of contact	n (%)
		Patient insurance details	n (%)
		Prior antiretroviral therapy (ART) regimen	n (%)
		Duration of prior ART regimen	n (%)
		History of prior ART failure	n (%)
		Relevant medical conditions	n (%)
		Current medication list	n (%)
		Relevant concomitant medications	n (%)
		Affirmation of HIV diagnosis	n (%)
		Other*	n (%)
		Missing	n (%)
11. Who has conducted the insurance verification/confirmation process?[1,4]	N=XX	Myself or my office	n (%)
		Infusion center	n (%)
		Both myself or my office and the infusion center	n (%)
		ViiV Connect (reimbursement hub)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)

		I have not referred a patient to the infusion center at this time and unable to reflect on the processes involved. (Go to Q39.)	n (%)
		Missing	n (%)
12. Have there been any challenges with the insurance verification/ confirmation process for your patients referred to the infusion center?[1,6]	N=XX	Yes (Go to Q13a.)	n (%)
		No (Go to Q14.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)
		Missing	n (%)
12a. If yes, what have the challenges been with the insurance verification/confirmation process?[3,4]	N=XX	The insurance verification process has been difficult for my office and my staff to manage ourselves.	n (%)
		The insurance verification process has been difficult for my office and my staff to coordinate with the infusion center.	n (%)
		The amount of patient information required by insurance plans is burdensome.	n (%)
		The time required to complete the insurance verification process is burdensome.	n (%)
		I did not receive a communication regarding the status of the insurance verification/confirmation process being conducted by the infusion center.	n (%)
		Other*	n (%)
		Missing	n (%)
13. On average, how long has the insurance verification/confirmation process been taking for your patients referred to the infusion center?[1]	N=XX	<1 business day	n (%)
		1–2 business days	n (%)
		3–4 business days	n (%)
		5–6 business days	n (%)
		7-10 business days	n (%)
		11-14 business days	n (%)
		>14 business days	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
14. How acceptable has the insurance verification/confirmation process been overall for your patients referred to the infusion center?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
15. Who has been notifying patients about the status of	N=XX	Myself or my office	n (%)
		Infusion center (Go to Q19.)	n (%)

their insurance confirmation/verification?[1,4]		Both myself/ my office and the infusion center	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)
		Missing	n (%)
16. How have patients been contacted to relay insurance coverage information?[3,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Secure electronic medical record message	n (%)
		In-person discussion	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)
		Missing	n (%)
17. How acceptable has the process been for relaying insurance coverage information to patients?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
18. How acceptable has the communication been between yourself (or your office) and the infusion center during the oral lead-in phase?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Not applicable/none of my patients were on oral lead-in	n (%)
		Missing	n (%)
19. How acceptable has the communication via FastFax been following the completion of a patient appointment?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)

20. How have you requested to be notified about non-urgent communications?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested a specific method for non-urgent communications.	n (%)
		I have not had any non-urgent communications. (Go to Q22.)	n (%)
		Other*	n (%)
		Missing	n (%)
20a. How acceptable has the communication been regarding non-urgent communications?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
21. Have you had a situation that required an urgent communication to you or your office from the infusion center?[1]		Yes	n (%)
		No (Go to Q23.)	n (%)
		I don't know (Go to Q23.)	n (%)
		Missing	n (%)
21a. How have you requested to be notified about urgent communications?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested a specific method for urgent communications.	n (%)
		Other*	n (%)
		Missing	n (%)
21b. How acceptable has the communication been regarding urgent communications?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)

		Missing	n (%)
22. Have you had any referred patients with an unplanned missed CABENUVA injection visit?[1]	N=XX	Yes	n (%)
		No (Go to Q24.)	n (%)
		I don't know (Go to Q24.)	n (%)
		Missing	n (%)
22a. How have you requested to be notified about unplanned missed CABENUVA injection visits?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about missed injection visits.	n (%)
		Other*	n (%)
		Missing	n (%)
22b. How acceptable has the communication been regarding unplanned missed CABENUVA injection visits?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
23. Have you had any referred patients with a planned missed CABENUVA injection visit?[1]	N=XX	Yes	n (%)
		No (Go to Q25.)	n (%)
		I don't know (Go to Q25.)	n (%)
		Missing	n (%)
23. How have you requested to be notified about planned missed CABENUVA injection visits?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about planned missed injection visits.	n (%)
		Other*	n (%)
		Missing	n (%)
23b. How acceptable has the communication been regarding planned missed CABENUVA injection visits?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)

		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
24. Have you had a patient that required oral therapy to cover missed doses of CABENUVA?[1]	N=XX	Yes	n (%)
		No (Go to Q26.)	n (%)
		I don't know (Go to Q26.)	n (%)
		Missing	n (%)
24a. How acceptable has the communication been regarding oral therapy to cover missed doses of CABENUVA?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
24b. How acceptable has the process been coordinating oral therapy between your office and the infusion center?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
25. Have you had a patient experience an adverse event (AE) while receiving CABENUVA injections at the infusion center?[1]	N=XX	Yes	n (%)
		No (Go to Q27.)	n (%)
		I don't know (Go to Q27.)	n (%)
		Missing	n (%)
25a. How have you requested to be notified about communications regarding AEs?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about AEs.	n (%)
		Other*	n (%)
		Missing	n (%)
25b. How acceptable has the communication been regarding AEs?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)

		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
26. What is your preferred process for managing each of the following adverse event situations (select one response per column): 26a. Managing mild adverse events (i.e., Grade 1-2 injection site reactions)[1,4]	N=XX	Infusion center manages the event and notifies referring HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then manages the event in collaboration with HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		Missing	n (%)
26. What is your preferred process for managing each of the following adverse event situations (select one response per column): 26b. Managing severe or serious adverse events (i.e., a vasovagal reaction)[1,4]	N=XX	Infusion center manages the event and notifies referring HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then manages the event in collaboration with HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		Missing	n (%)
27. Have you had a patient discontinue CABENUVA injections at the infusion center?[1]	N=XX	Yes	n (%)
		No (Go to Q29.)	n (%)
		I don't know (Go to Q29.)	n (%)
		Missing	n (%)
27a. How have you requested to be notified about communications regarding patient discontinuation of CABENUVA?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about patient discontinuation of CABENUVA.	n (%)
		Other*	n (%)
		Missing	n (%)
27b. How acceptable has the communication been regarding patient discontinuation of CABENUVA?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)

		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
28. Have you requested labs to be conducted at the infusion center on the plan of treatment (POT)?[1]	N=XX N=XX	Yes	n (%)
		No (Go to Q30.)	n (%)
		I don't know (Go to Q30.)	n (%)
		Missing	n (%)
28a. What timepoints have you requested that labs be done at the infusion center?[1]	N=XX	Every month / at each injection	n (%)
		Every 2 months	n (%)
		Every 3 months	n (%)
		Every 4 months	n (%)
		Every 6 months	n (%)
		Yearly	n (%)
		As needed (i.e., when an adverse event occurs)	n (%)
		Other*	n (%)
		Missing	n (%)
28b. How have you requested to be notified about communications regarding labs you may have requested via the plan of treatment (POT)?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about labs.	n (%)
		Other*	n (%)
		Missing	n (%)
28c. How acceptable has the communication been regarding labs you may have requested via the plan of treatment (POT)?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
29. If ad-hoc labs are needed (e.g., in the case of an adverse event), where do you prefer they be done?[1,4]	N=XX	My office or lab affiliated with my office	n (%)
		Infusion center	n (%)
		External lab	n (%)
		Other*	n (%)
	N=XX	Yes	n (%)
		No (Go to Q32.)	n (%)

30. Have you requested ad-hoc labs to be conducted via the infusion center?[1]		I don't know (Go to Q32.)	n (%)
		Missing	n (%)
30a. How have you requested to be notified about communications regarding ad-hoc labs you may have requested?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about ad-hoc labs.	n (%)
		Other*	n (%)
		Missing	n (%)
30b. How acceptable has the communication been regarding ad-hoc labs you might have requested?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
31. How often are you typically seeing or expect to see your patients who are receiving CABENUVA at an infusion center?[1]	N=XX	Never/not needed	n (%)
		Every month	n (%)
		Every 2 months	n (%)
		Every 3 months	n (%)
		Every 4 months	n (%)
		Every 6 months	n (%)
		Yearly	n (%)
		As needed (i.e., when an adverse event occurs)	n (%)
		Missing	n (%)
32. On average, how does this compare with the frequency of visits for these patients prior to starting CABENUVA at an infusion center?[1]	N=XX	Much more frequently than before	n (%)
		More frequently than before	n (%)
		About the same as before	n (%)
		Less frequently than before	n (%)
		Much less frequently than before	n (%)
		Missing	n (%)
33. Overall, how have your patients described their experiences of receiving injections at the infusion center?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)

		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I don't know/haven't talked to a patient about their experiences.	n (%)
		Missing	n (%)
34. Have your patients expressed any concerns about stigma at the infusion center?[1]	N=XX	Yes	n (%)
		No	n (%)
		Missing	n (%)
35. Have your patients expressed any concerns about privacy at the infusion center?[1]	N=XX	Yes	n (%)
		No	n (%)
		Missing	n (%)
36. Do you have any other thoughts or comments about your experiences that you'd like to share? Please write in your response below.	N=XX	Open-ended text*	-
		Missing	n (%)

[1] Select one response
[2] Select all that apply
[3] Within each question, where appropriate, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints
Abbreviations: AE = adverse event; ART = antiretroviral therapy; HIV = human immunodeficiency virus; POT = plan of treatment
NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.
Cell percentages do not include missing
*"Other" responses and open-ended text responses will be presented in an appendix

Table 8.2.2. Expert Panel, Assessment of CABENUVA Administration Moving to Infusion Center, HIV Care Providers – Month 6, (N= XX)

Question	Number of Participants at Month 6	Response	n (%)
9. Have you submitted a referral to the infusion center?[1]	N=XX	Yes (Go Q9a and Q9b.)	n (%)
		No (Go to Q9c.)	n (%)
		Missing	n (%)
9a. If yes, how acceptable has the referral process been?[1,2]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Missing	n (%)
9b. If yes, what challenges, if any, have you or your staff encountered with the referral process?[2,3,4]	N=XX N=XX	I/my staff have not encountered any challenges with the referral process. [If selecting this option please do not select any others and proceed to 9c.]	n (%)
		It was unclear how to initiate the referral.	n (%)
		It was unclear when to initiate the referral.	n (%)
		I/my staff did not know where to find the plan of treatment (POT) to initiate the referral process.	n (%)
		I /my staff was not clear on how to complete the plan of treatment (POT) as part of the referral process.	n (%)
		The plan of treatment (POT) does not provide enough information for a referral.	n (%)
		The plan of treatment (POT) required too much information for a referral.	n (%)
		The process of transferring the information to the infusion center was difficult due to technology limitations (e.g., too much paperwork to fax).	n (%)
		I did not know to whom to send the plan of treatment (POT) and supporting documentation.	n (%)
		I was not comfortable faxing the documentation required for the referral process.	n (%)
		I was never informed whether or not my patient was eligible to receive CABENUVA injections at the infusion center.	n (%)
		The process to initiate oral cabotegravir and rilpivirine was not clear	n (%)
		Other*	n (%)
		Missing	n (%)
9c. If no, what are the reason(s) you have not yet referred a patient to the infusion center to receive CABENUVA? (Only complete this question if you have not submitted a referral to the infusion center.)[2,3,4]	N=XX	I am not recommending CABENUVA as a treatment option for my patients at this time.	n (%)
		I have not identified a patient that is appropriate for receipt of CABENUVA.	n (%)
		I prefer to administer CABENUVA at my own clinic at this time.	n (%)
		I prefer to administer CABENUVA at my own clinic for patients new to CABENUVA prior to referring them to the infusion center.	n (%)
		My patient(s) do not want to receive CABENUVA at an infusion center at this time.	n (%)
		I do not have enough information about the infusion centers to recommend it for my patients.	n (%)
		It was unclear how to initiate the referral.	n (%)
		It was unclear when to initiate the referral.	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		I/my staff did not know where to find the plan of treatment (POT) to initiate the referral process.	n (%)
		I/my staff was not clear on how to complete the plan of treatment (POT) as part of the referral process.	n (%)
		The plan of treatment (POT) does not provide enough information for a referral.	n (%)
		The plan of treatment (POT) required too much information for a referral.	n (%)
		Other*	n (%)
		Missing	n (%)
10. How likely are you to refer (or to continue to refer) patients to infusion centers to receive CABENUVA?[1]	N=XX	Extremely likely	n (%)
		Very likely	n (%)
		Somewhat likely	n (%)
		Neither likely nor unlikely	n (%)
		Somewhat unlikely	n (%)
		Very unlikely	n (%)
		Extremely unlikely	n (%)
		Missing	n (%)
11. Have you seen the plan of treatment (POT) or referral form?[1,5]	N=XX	Yes (Go to Q11a.)	n (%)
		No (Go to Q12.)	n (%)
		Missing	n (%)
11a. Is there anything missing from the plan of treatment (POT) or referral form?[1]	N=XX	Yes (Go to Q11b.)	n (%)
		No (Go to Q11c.)	n (%)
		Missing	n (%)
11b. If yes, what is missing from the plan of treatment (POT) or referral form?[3,4]	N=XX	Place to provide comments to infusion center	n (%)
		Documentation of my preferences regarding modality of urgent communications	n (%)
		Documentation of my preferences regarding modality of non-urgent communications	n (%)
		Other*	n (%)
		Missing	n (%)
11c. Is there anything on the plan of treatment (POT) or referral form that you feel should not be included (or is not needed) as part of the referral process?[3,4]	N=XX	I think that all of the information on the plan of treatment (POT) or referral form is needed or should be included as part of a referral. [If selecting this option please do not select any others.]	n (%)
		Patient demographic information	n (%)
		Patient height	n (%)
		Patient weight	n (%)
		Allergies	n (%)
		Patient diagnosis Z21 asymptomatic human immunodeficiency virus (HIV) infection status	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Patient diagnosis B230 HIV disease	n (%)
		Dose frequency initiation	n (%)
		Dose frequency continuation	n (%)
		Lab orders	n (%)
		End date of oral lead-in drug	n (%)
		Date of previous injection	n (%)
		Physician preferred method of contact	n (%)
		Patient insurance details	n (%)
		Prior antiretroviral therapy (ART) regimen	n (%)
		Duration of prior ART regimen	n (%)
		History of prior ART failure	n (%)
		Relevant medical conditions	n (%)
		Current medication list	n (%)
		Relevant concomitant medications	n (%)
		Affirmation of HIV diagnosis	n (%)
		Other*	n (%)
		Missing	n (%)
12. Who has conducted the insurance verification/confirmation process?[1,4]	N=XX	Myself or my office	n (%)
		Infusion center	n (%)
		Both myself or my office and the infusion center	n (%)
		ViiV Connect (reimbursement hub)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)
		I have not referred a patient to the infusion center at this time and unable to reflect on the processes involved. (Go to Q39.)	n (%)
		Missing	n (%)
13. Have there been any challenges with the insurance verification/ confirmation process for your patients referred to the infusion center?[1,6]	N=XX	Yes (Go to Q13a.)	n (%)
		No (Go to Q14.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)
		Missing	n (%)
13a. If yes, what have the challenges been with the insurance verification/confirmation process?[3,4]	N=XX	The insurance verification process has been difficult for my office and my staff to manage ourselves.	n (%)
		The insurance verification process has been difficult for my office and my staff to coordinate with the infusion center.	n (%)
		The amount of patient information required by insurance plans is burdensome.	n (%)
		The time required to complete the insurance verification process is burdensome.	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		I did not receive a communication regarding the status of the insurance verification/confirmation process being conducted by the infusion center.	n (%)
		Other*	n (%)
		Missing	n (%)
14. On average, how long has the insurance verification/confirmation process been taking for your patients referred to the infusion center?[1]	N=XX	<1 business day	n (%)
		1–2 business days	n (%)
		3–4 business days	n (%)
		5–6 business days	n (%)
		7-10 business days	n (%)
		11-14 business days	n (%)
		>14 business days	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
15. How acceptable has the insurance verification/confirmation process been overall for your patients referred to the infusion center?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
16. Who has been notifying patients about the status of their insurance confirmation/verification?[1,4]	N=XX	Myself or my office	n (%)
		Infusion center (Go to Q19.)	n (%)
		Both myself/ my office and the infusion center	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)
		Missing	n (%)
17. How have patients been contacted to relay insurance coverage information?[3,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Secure electronic medical record message	n (%)
		In-person discussion	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q19.)	n (%)
		Missing	n (%)

Question	Number of Participants at Month 6	Response	n (%)
18. How acceptable has the process been for relaying insurance coverage information to patients?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
19. How acceptable has the communication been between yourself (or your office) and the infusion center during the oral lead-in phase?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Not applicable/none of my patients were on oral lead-in	n (%)
		Missing	n (%)
20. How acceptable has the communication via FastFax been following the completion of a patient appointment?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
21. How have you requested to be notified about non-urgent communications?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		I haven't requested a specific method for non-urgent communications.	n (%)
		I have not had any non-urgent communications. (Go to Q22.)	n (%)
		Other*	n (%)
		Missing	n (%)
21a. How acceptable has the communication been regarding non-urgent communications?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
22. Have you had a situation that required an urgent communication to you or your office from the infusion center?[1]	N=XX	Yes	n (%)
		No (Go to Q23.)	n (%)
		I don't know (Go to Q23.)	n (%)
		Missing	n (%)
22a. How have you requested to be notified about urgent communications?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested a specific method for urgent communications.	n (%)
		Other*	n (%)
		Missing	n (%)
22b. How acceptable has the communication been regarding urgent communications?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
23. Have you had any referred patients with an unplanned	N=XX	Yes	n (%)
		No (Go to Q24.)	n (%)
		I don't know (Go to Q24.)	n (%)

Question	Number of Participants at Month 6	Response	n (%)
missed CABENUVA injection visit?[1]		Missing	n (%)
23a. How have you requested to be notified about unplanned missed CABENUVA injection visits?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about missed injection visits.	n (%)
		Other*	n (%)
		Missing	n (%)
23b. How acceptable has the communication been regarding unplanned missed CABENUVA injection visits?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
24. Have you had any referred patients with a planned missed CABENUVA injection visit?[1]	N=XX	Yes	n (%)
		No (Go to Q25.)	n (%)
		I don't know (Go to Q25.)	n (%)
		Missing	n (%)
24a. How have you requested to be notified about planned missed CABENUVA injection visits?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about planned missed injection visits.	n (%)
		Other*	n (%)
		Missing	n (%)
24b. How acceptable has the communication been regarding planned missed CABENUVA injection visits?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
25. Have you had a patient that required oral therapy to cover missed doses of CABENUVA?[1]	N=XX	Yes	n (%)
		No (Go to Q26.)	n (%)
		I don't know (Go to Q26.)	n (%)
		Missing	n (%)
25a. How acceptable has the communication been regarding oral therapy to cover missed doses of CABENUVA?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
25b. How acceptable has the process been coordinating oral therapy between your office and the infusion center?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
26. Have you had a patient experience an adverse event (AE) while receiving CABENUVA injections at the infusion center?[1]	N=XX	Yes	n (%)
		No (Go to Q27.)	n (%)
		I don't know (Go to Q27.)	n (%)
		Missing	n (%)
26a. How have you requested to be notified about communications regarding AEs?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about AEs.	n (%)
		Other*	n (%)
		Missing	n (%)
	N=XX	Extremely acceptable	n (%)

Question	Number of Participants at Month 6	Response	n (%)
26b. How acceptable has the communication been regarding AEs?[1]		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
27. What is your preferred process for managing each of the following adverse event situations (select one response per column): 27a. Managing mild adverse events (i.e., Grade 1-2 injection site reactions)[1,4]	N=XX	Infusion center manages the event and notifies referring HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then manages the event in collaboration with HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		Missing	n (%)
27. What is your preferred process for managing each of the following adverse event situations (select one response per column): 27b. Managing severe or serious adverse events (i.e., a vasovagal reaction)[1,4]	N=XX	Infusion center manages the event and notifies referring HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then manages the event in collaboration with HIV provider	n (%)
		Infusion center notifies referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		Missing	n (%)
28. Have you had a patient discontinue CABENUVA injections at the infusion center?[1]	N=XX	Yes	n (%)
		No (Go to Q29.)	n (%)
		I don't know (Go to Q29.)	n (%)
		Missing	n (%)
28a. How have you requested to be notified about communications regarding patient discontinuation of CABENUVA?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about patient discontinuation of CABENUVA.	n (%)
		Other*	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Missing	n (%)
28b. How acceptable has the communication been regarding patient discontinuation of CABENUVA?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
29. Have you requested labs to be conducted at the infusion center on the plan of treatment (POT)?[1]	N=XX	Yes	n (%)
		No (Go to Q30.)	n (%)
		I don't know (Go to Q30.)	n (%)
		Missing	n (%)
29a. What timepoints have you requested that labs be done at the infusion center?[1]	N=XX	Every month / at each injection	n (%)
		Every 2 months	n (%)
		Every 3 months	n (%)
		Every 4 months	n (%)
		Every 6 months	n (%)
		Yearly	n (%)
		As needed (i.e., when an adverse event occurs)	n (%)
		Other*	n (%)
		Missing	n (%)
29b. How have you requested to be notified about communications regarding labs you may have requested via the plan of treatment (POT)?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about labs.	n (%)
		Other*	n (%)
		Missing	n (%)
29c. How acceptable has the communication been regarding labs you may have requested via the plan of treatment (POT)?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
30. If ad-hoc labs are needed (e.g., in the case of an adverse event), where do you prefer they be done?[1,4]	N=XX	My office or lab affiliated with my office	n (%)
		Infusion center	n (%)
		External lab	n (%)
		Other*	n (%)
31. Have you requested ad-hoc labs to be conducted via the infusion center?[1]	N=XX	Yes	n (%)
		No (Go to Q32.)	n (%)
		I don't know (Go to Q32.)	n (%)
		Missing	n (%)
31a. How have you requested to be notified about communications regarding ad-hoc labs you may have requested?[1,4]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		I don't remember	n (%)
		I haven't requested specific communication about ad-hoc labs.	n (%)
		Other*	n (%)
		Missing	n (%)
31b. How acceptable has the communication been regarding ad-hoc labs you might have requested?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
32. How often are you typically seeing or expect to see your patients who are receiving CABENUVA at an infusion center?[1]	N=XX	Never/not needed	n (%)
		Every month	n (%)
		Every 2 months	n (%)
		Every 3 months	n (%)
		Every 4 months	n (%)
		Every 6 months	n (%)
		Yearly	n (%)
		As needed (i.e., when an adverse event occurs)	n (%)
		Missing	n (%)
	N=XX	Much more frequently than before	n (%)

Question	Number of Participants at Month 6	Response	n (%)
33. On average, how does this compare with the frequency of visits for these patients prior to starting CABENUVA at an infusion center?[1]		More frequently than before	n (%)
		About the same as before	n (%)
		Less frequently than before	n (%)
		Much less frequently than before	n (%)
		Missing	n (%)
34. More frequent clinic visits due to CABENUVA administration (at the infusion center) will provide a benefit to my patients on this regimen in terms of improved medical, psychological, and/or social health.[1]	N=XX	Strongly disagree	n (%)
		Disagree	n (%)
		Somewhat disagree	n (%)
		Neither agree nor disagree	n (%)
		Somewhat agree	n (%)
		Agree	n (%)
		Strongly agree	n (%)
		Missing	n (%)
35. How much has your ability to manage your patients' health changed since they started receiving CABENUVA at an infusion center?[1]	N=XX	Extremely improved	n (%)
		Very improved	n (%)
		Somewhat improved	n (%)
		No change	n (%)
		Somewhat worsened	n (%)
		Very worsened	n (%)
		Extremely worsened	n (%)
		Missing	n (%)
36. Overall, how have your patients described their experiences of receiving injections at the infusion center?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I don't know/haven't talked to a patient about their experiences.	n (%)
		Missing	n (%)
37. Have your patients expressed any concerns about stigma at the infusion center?[1]	N=XX	Yes	n (%)
		No	n (%)
		Missing	n (%)
38. Have your patients expressed any concerns about privacy at the infusion center?[1]	N=XX	Yes	n (%)
		No	n (%)
		Missing	n (%)
	N=XX	Open-ended text*	-

Question	Number of Participants at Month 6	Response	n (%)
37a/38a. Please explain the situation that led to your concerns and any changes you made to this patient's care as a result.		Missing	n (%)
44. Do you have any other thoughts or comments about your experiences that you'd like to share? Please write in your response below.	N=XX	Open-ended text*	-
		Missing	n (%)

[1] Select one response
[2] Select all that apply
[3] Within each question, where appropriate, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints
Abbreviations: AE = adverse event; ART = antiretroviral therapy; HIV = human immunodeficiency virus; POT = plan of treatment
NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.
Cell percentages do not include missing
*"Other" responses and open-ended text responses will be presented in an appendix

Table 8.2.3. Expert Panel, Impact of CABENUVA Administration Moving to Infusion Center, HIV Care Providers – Month 6, (N= XX)

	Number of Participants at Month 6	Missing	Negative impact	No impact	Positive impact	Unknown/too early to tell
39. Current impact to clinic/ healthcare organization resourcing and capacity	XX	n (%)	n (%)	n (%)	n (%)	n (%)
40. Expected future impact to clinic/ healthcare organization resourcing and capacity	XX	n (%)	n (%)	n (%)	n (%)	n (%)
41. Current financial impact to clinic/ healthcare organization	XX	n (%)	n (%)	n (%)	n (%)	n (%)
42. Expected future financial impact to clinic/ healthcare organization	XX	n (%)	n (%)	n (%)	n (%)	n (%)
43. If you selected negative or positive impact in questions 39 through 42, please explain the impact below.	Open-ended text*					

Abbreviation: HIV = human immunodeficiency virus

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.
*Responses will be presented in an appendixCell percentages do not include missing
*Responses will be presented in an appendix

Table 8.3.1. Expert Panel, Assessment of CABENUVA Administration Moving to Infusion Center, IC Staff – Month 3, (N= XX)

Question	Number of Participants at Month 3	Response	n (%)
9. How acceptable has the referral process been?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q10.)	n (%)
		Missing	n (%)
9a. What challenges have you or your staff encountered with the referral process?[2,3]	N=XX	I have not encountered any challenges with the referral process. [If selecting this option please do not select any others and proceed to 10.]	n (%)
		It was unclear how to handle the referral.	n (%)
		The plan of treatment (POT) submitted to initiate the referral process was incomplete.	n (%)
		The process of transferring the information from the HIV providers tone of our infusion centers was difficult due to technology limitations (e.g., too much paperwork to fax).	n (%)
		It was difficult to reach the HIV provider to follow-up on missing or incomplete information on the plan of treatment (POT).	n (%)
		The process of initiating oral cabotegravir and rilpivirine has been unclear.	n (%)
		Other*	n (%)
		Missing	n (%)
10. Is there anything missing from the plan of treatment (POT)/referral form?[1]	N=XX	Yes (Go to Q10a.)	n (%)
		No (Go to Q10b.)	n (%)
		I have not seen the plan of treatment/referral form. (Go to Q11.)	n (%)
		Missing	n (%)
10a. If yes, what is missing from the POT/referral form?[2,3]	N=XX	Place to provide comments to infusion center	n (%)
		Documentation of HIV provider preferences regarding modality of urgent communications	n (%)
		Documentation of HIV provider preferences regarding modality of non-urgent communications	n (%)
		Other*	n (%)
		Missing	n (%)
10b. Is there anything on the plan of treatment (POT) or referral for that you feel	N=XX	I think that all of the information on the plan of treatment (POT) or referral form is needed or should be included as part of a referral.	n (%)

Question	Number of Participants at Month 3	Response	n (%)
should not be included (or is not needed) as part of the referral process?[2,3]		[If selecting this option please do not select any others.]	n (%)
		Patient demographic information	n (%)
		Patient height	n (%)
		Patient weight	n (%)
		Allergies	n (%)
		Patient diagnosis Z21 asymptomatic human immunodeficiency virus (HIV) infection status	n (%)
		Patient diagnosis B230 HIV disease	n (%)
		Dose frequency initiation	n (%)
		Dose frequency continuation	n (%)
		Lab orders	n (%)
		End date of oral lead-in drug	n (%)
		Date of previous injection	n (%)
		Physician preferred method of contact	n (%)
		Patient insurance details	n (%)
		Prior antiretroviral therapy (ART) regimen	n (%)
		Duration of prior ART regimen	n (%)
		History of prior ART failure	n (%)
		Relevant medical conditions	n (%)
		Current medication list	n (%)
		Relevant concomitant medications	n (%)
		Affirmation of HIV diagnosis	n (%)
		Other*	n (%)
		Missing	n (%)
11. Who has conducted the insurance verification/confirmation process?[1,3]	N=XX	Patient's HIV provider	n (%)
		Infusion centers	n (%)
		Both the infusion centers and the HIV provider	n (%)
		ViiV Connect (reimbursement hub)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)
12. Have there been any challenges with the insurance verification/confirmation process?[1]	N=XX	Yes (Go to Q12a.)	n (%)
		No (Go to Q13.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)
12a. If yes, what have the challenges been with the	N=XX	The insurance verification process has been difficult for our infusion centers to manage.	n (%)

Question	Number of Participants at Month 3	Response	n (%)
insurance verification/confirmation process?[2,3]		The insurance verification process has been difficult for our infusion centers to coordinate with the HIV provider's office and/or their staff.	n (%)
		The amount of patient information required by insurance plans is burdensome.	n (%)
		The time required to complete the insurance verification process is burdensome.	n (%)
		Other*	n (%)
		Missing	n (%)
13. On average, how long has the insurance verification/confirmation process been taking for patients referred to receive CABENUVA?[1]	N=XX	<1 business day	n (%)
		1–2 business days	n (%)
		3–4 business days	n (%)
		5–6 business days	n (%)
		7-10 business days	n (%)
		11-14 business days	n (%)
		>14 business days	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
14. How acceptable has the insurance verification/confirmation process been overall?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
15. Who has been notifying patients about the status of their insurance confirmation/verification?[1,3]	N=XX	Patient's HIV provider (Go to Q18.)	n (%)
		Infusion centers	n (%)
		Both the infusion centers and the HIV provider	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)
16. How have patients been contacted to relay insurance coverage information?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Secure electronic medical record message	n (%)
		In-person discussion	n (%)
		Other*	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)
17. How acceptable has the process been for relaying insurance coverage information to patients?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
18. How acceptable has the communication been between your infusion centers and the HIV providers during the oral lead-in phase?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
19. How receptive have HIV providers been to communications via FastFax for sharing information following th19completion of a patient appointment?[1]	N=XX	Extremely receptive	n (%)
		Very receptive	n (%)
		Somewhat receptive	n (%)
		Neither receptive nor unreceptive	n (%)
		Somewhat unreceptive	n (%)
		Very unreceptive	n (%)
		Extremely unreceptive	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q20.)	n (%)
		Missing	n (%)
19a. Other than FastFax, what other communication strategies have your infusion centers used to share information following the completion of a patient appointment?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Combination of methods (e.g., phone, text, and/or email)	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)

Question	Number of Participants at Month 3	Response	n (%)
20. What are the communication preferences for HIV providers for non-urgent communications?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q21.)	n (%)
		Missing	n (%)
20a. How acceptable has the communication been regarding non-urgent communications with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
21. Have there been any situations that required an urgent communication to an HIV provider from one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q22.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q22.)	n (%)
		Missing	n (%)
21a. What are the communication preferences for HIV providers for urgent communications?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q22.)	n (%)
		Missing	n (%)
21b. How acceptable has the communication been regarding urgent communications with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)

Question	Number of Participants at Month 3	Response	n (%)
22. Have there been any patients with an unplanned missed CABENUVA injection visit at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q23.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q23.)	n (%)
		Missing	n (%)
22a. What are the communication preferences for HIV providers for unplanned missed CABENUVA injection visits?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q23.)	n (%)
		Missing	n (%)
22b. How acceptable has the communication been regarding unplanned missed CABENUVA injection visits with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
23. Have there been any patients with a planned missed CABENUVA injection visit at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q24.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q24.)	n (%)
		Missing	n (%)
23a. What are the communication preferences for HIV providers about planned missed CABENUVA injection visits?[1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q24.)	n (%)
		Missing	n (%)
23b. How acceptable has the communication been regarding planned missed CABENUVA	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)

Question	Number of Participants at Month 3	Response	n (%)
injection visits with HIV providers?[1]		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
24. Have any patients required oral therapy to cover missed doses of CABENUVA?[1]	N=XX	Yes	n (%)
		No (Go to Q25)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q25.)	n (%)
		Missing	n (%)
24a. How acceptable has the communication been regarding oral therapy to cover missed doses of CABENUVA between the infusion center and the HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
24b. How acceptable has the process been coordinating oral therapy between the infusion centers and HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
25. Have any patients experienced an adverse event (AE) while receiving CABENUVA injections at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q26.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q26.)	n (%)
25a. What are the communication preferences for HIV providers to be notified about regarding AEs?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q26.)	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		Missing	n (%)
25b. How acceptable has the communication been regarding AEs with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
26. What is your preferred process for managing each of the following adverse event situations (select one response per column): 26a. Managing mild adverse events (i.e., Grade 1-2 injection site reactions)[1,3]	N=XX	Infusion centers manage the event and notify referring HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then manage the event in collaboration with HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
26. What is your preferred process for managing each of the following adverse event situations (select one response per column): 26b. Managing severe or serious adverse events (i.e., a vasovagal reaction)[1,3]	N=XX	Infusion centers manage the event and notify referring HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then manage the event in collaboration with HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
27. Have any patients discontinued CABENUVA injections at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q28.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q28.)	n (%)
		Missing	n (%)
27a. What are the communication preferences for HIV providers regarding patient discontinuation of CABENUVA?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q28.)	n (%)
		Missing	n (%)
27b. How acceptable has the communication been regarding patient discontinuation of CABENUVA with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
28. Have HIV providers requested labs to be conducted via the infusion centers on the plan of treatment (POT)?[1]	N=XX	Yes	n (%)
		No (Go to Q29.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q29.)	n (%)
		Missing	n (%)
28a. What are the communication preferences for HIV providers regarding labs they may have requested via the plan of treatment (POT)?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q29.)	n (%)
		Missing	n (%)
28b. How acceptable has the communication been regarding labs the HIV provider may have requested via the plan of treatment (POT)?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
29. If ad-hoc labs are needed (e.g., in the case of an adverse event), where do the infusion centers prefer they are done?[1,3]	N=XX	HIV provider's office	n (%)
		Infusion centers	n (%)
		External lab	n (%)
		Other*	n (%)
		Missing	n (%)
	N=XX	Yes	n (%)

Question	Number of Participants at Month 3	Response	n (%)
30. Have HIV providers requested ad-hoc labs to be conducted at the infusion centers?[1]		No (Go to Q31.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q31.)	n (%)
		Missing	n (%)
30a. What are the communication preferences for HIV providers regarding ad-hoc labs they may have requested?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q31.)	n (%)
		Missing	n (%)
30b. How acceptable has the communication been regarding ad-hoc labs requested by HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
31. Which format do you prefer for the blueprint?[2,3]	N=XX	PowerPoint	n (%)
		Word document or PDF	n (%)
		Either format	n (%)
		Missing	n (%)
32. In which format did you receive the blueprint?[2,3]	N=XX	PowerPoint	n (%)
		Either Format	n (%)
		Word document or PDF	n (%)
		Missing	n (%)
33. How often do you use or refer to the blueprint?[1]	N=XX	Extremely often	n (%)
		Very often	n (%)
		Somewhat often	n (%)
		Seldom	n (%)
		I have never used or referred to the blueprint (skip remaining)	n (%)
		Missing	n (%)
34. How useful is the blueprint?[1]	N=XX	Extremely useful	n (%)
		Very useful	n (%)
		Somewhat useful	n (%)

Question	Number of Participants at Month 3	Response	n (%)
		Neutral	n (%)
		Not very useful	n (%)
		Not useful at all	n (%)
35. The blueprint contains the information I need to administer CABENUVA at my infusion center.[1]	N=XX	Strongly agree	n (%)
		Agree	n (%)
		Neither agree nor disagree	n (%)
		Disagree	n (%)
		Strongly disagree	n (%)
		Missing	n (%)
36. There is information I need for administering CABENUVA in my infusion center that is missing from the blueprint.[1]	N=XX	Strongly agree (go to 36a)	n (%)
		Agree (go to 36a)	n (%)
		Neither agree nor disagree	n (%)
		Disagree	n (%)
		Strongly disagree	n (%)
		Missing	n (%)
36a. What do you think is missing from the blueprint?[1]	N=XX	Open-ended text*	n (%)
		Missing	n (%)
37. What is your overall opinion of the blueprint?[1]		Extremely positive	n (%)
		Very positive	n (%)
		Somewhat positive	n (%)
		Neutral	n (%)
		Somewhat negative	n (%)
		Very negative	n (%)
		Extremely negative	n (%)
		Missing	n (%)
38. Do you have any other thoughts or comments about your experiences that you'd like to share? Please write in your response below.	N=XX	Open-ended text*	n (%)
		Missing	n (%)

1 Select one response

2 Select all that apply

3 Within each question, where appropriate, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints

Abbreviations: AE = adverse event; ART = antiretroviral therapy; HIV = human immunodeficiency virus; POT = plan of treatment

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint. Cell percentages do not include missing

*"Other" responses and open-ended text responses will be presented in an appendix

Table 8.3.2. Expert Panel, Assessment of CABENUVA Administration Moving to Infusion Center, IC Staff – Month 6, (N= XX)

Question	Number of Participants at Month 6	Response	n (%)
9. How acceptable has the referral process been?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q10.)	n (%)
		Missing	n (%)
9a. What challenges have you or your staff encountered with the referral process?[2,3]	N=XX	I have not encountered any challenges with the referral process. [If selecting this option please do not select any others and proceed to 10.]	n (%)
		It was unclear how to handle the referral.	n (%)
		The plan of treatment (POT) submitted to initiate the referral process was incomplete.	n (%)
		The process of transferring the information from the HIV providers tone of our infusion centers was difficult due to technology limitations (e.g., too much paperwork to fax).	n (%)
		It was difficult to reach the HIV provider to follow-up on missing or incomplete information on the plan of treatment (POT).	n (%)
		The process of initiating oral cabotegravir and rilpivirine has been unclear.	n (%)
		Other*	n (%)
		Missing	n (%)
10. Is there anything missing from the plan of treatment (POT)/referral form?[1]	N=XX	Yes (Go to Q10a.)	n (%)
		No (Go to Q10b.)	n (%)
		I have not seen the plan of treatment/referral form. (Go to Q11.)	n (%)
		Missing	n (%)
10a. If yes, what is missing from the POT/referral form?[2,3]	N=XX	Place to provide comments to infusion center	n (%)
		Documentation of HIV provider preferences regarding modality of urgent communications	n (%)
		Documentation of HIV provider preferences regarding modality of non-urgent communications	n (%)
		Other*	n (%)
		Missing	n (%)

Question	Number of Participants at Month 6	Response	n (%)
10b. Is there anything on the plan of treatment (POT) or referral for that you feel should not be included (or is not needed) as part of the referral process?[2,3]	N=XX	I think that all of the information on the plan of treatment (POT) or referral form is needed or should be included as part of a referral.	n (%)
		[If selecting this option please do not select any others.]	n (%)
		Patient demographic information	n (%)
		Patient height	n (%)
		Patient weight	n (%)
		Allergies	n (%)
		Patient diagnosis Z21 asymptomatic human immunodeficiency virus (HIV) infection status	n (%)
		Patient diagnosis B230 HIV disease	n (%)
		Dose frequency initiation	n (%)
		Dose frequency continuation	n (%)
		Lab orders	n (%)
		End date of oral lead-in drug	n (%)
		Date of previous injection	n (%)
		Physician preferred method of contact	n (%)
		Patient insurance details	n (%)
		Prior antiretroviral therapy (ART) regimen	n (%)
		Duration of prior ART regimen	n (%)
		History of prior ART failure	n (%)
		Relevant medical conditions	n (%)
		Current medication list	n (%)
		Relevant concomitant medications	n (%)
		Affirmation of HIV diagnosis	n (%)
		Other*	n (%)
		Missing	n (%)
11. Who has conducted the insurance verification/confirmation process?[1,3]	N=XX	Patient's HIV provider	n (%)
		Infusion centers	n (%)
		Both the infusion centers and the HIV provider	n (%)
		ViiV Connect (reimbursement hub)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)
12. Have there been any challenges with the insurance verification/confirmation process?[1]	N=XX	Yes (Go to Q12a.)	n (%)
		No (Go to Q13.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)

Question	Number of Participants at Month 6	Response	n (%)
12a. If yes, what have the challenges been with the insurance verification/confirmation process?[2,3]	N=XX	The insurance verification process has been difficult for our infusion centers to manage.	n (%)
		The insurance verification process has been difficult for our infusion centers to coordinate with the HIV provider's office and/or their staff.	n (%)
		The amount of patient information required by insurance plans is burdensome.	n (%)
		The time required to complete the insurance verification process is burdensome.	n (%)
		Other*	n (%)
		Missing	n (%)
13. On average, how long has the insurance verification/confirmation process been taking for patients referred to receive CABENUVA?[1]	N=XX	<1 business day	n (%)
		1–2 business days	n (%)
		3–4 business days	n (%)
		5–6 business days	n (%)
		7-10 business days	n (%)
		11-14 business days	n (%)
		>14 business days	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
14. How acceptable has the insurance verification/confirmation process been overall?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
15. Who has been notifying patients about the status of their insurance confirmation/verification?[1,3]	N=XX	Patient's HIV provider (Go to Q18.)	n (%)
		Infusion centers	n (%)
		Both the infusion centers and the HIV provider	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)
16. How have patients been contacted to relay insurance coverage information?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Secure electronic medical record message	n (%)
		In-person discussion	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q18.)	n (%)
		Missing	n (%)
17. How acceptable has the process been for relaying insurance coverage information to patients?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
18. How acceptable has the communication been between your infusion centers and the HIV providers during the oral lead-in phase?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
19. How receptive have HIV providers been to communications via FastFax for sharing information following th19completion of a patient appointment?[1]	N=XX	Extremely receptive	n (%)
		Very receptive	n (%)
		Somewhat receptive	n (%)
		Neither receptive nor unreceptive	n (%)
		Somewhat unreceptive	n (%)
		Very unreceptive	n (%)
		Extremely unreceptive	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q20.)	n (%)
		Missing	n (%)
19a. Other than FastFax, what other communication strategies have your infusion centers used to share information following the completion of a patient appointment?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Combination of methods (e.g., phone, text, and/or email)	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process.	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Missing	n (%)
20. What are the communication preferences for HIV providers for non-urgent communications?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q21.)	n (%)
		Missing	n (%)
20a. How acceptable has the communication been regarding non-urgent communications with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
21. Have there been any situations that required an urgent communication to an HIV provider from one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q22.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q22.)	n (%)
		Missing	n (%)
21a. What are the communication preferences for HIV providers for urgent communications?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q22.)	n (%)
		Missing	n (%)
21b. How acceptable has the communication been regarding urgent communications with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Missing	n (%)
22. Have there been any patients with an unplanned missed CABENUVA injection visit at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q23.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q23.)	n (%)
		Missing	n (%)
22a. What are the communication preferences for HIV providers for unplanned missed CABENUVA injection visits?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q23.)	n (%)
		Missing	n (%)
22b. How acceptable has the communication been regarding unplanned missed CABENUVA injection visits with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
23. Have there been any patients with a planned missed CABENUVA injection visit at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q24.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q24.)	n (%)
		Missing	n (%)
23a. What are the communication preferences for HIV providers about planned missed CABENUVA injection visits?[1,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q24.)	n (%)
		Missing	n (%)
23b. How acceptable has the communication been regarding	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)

Question	Number of Participants at Month 6	Response	n (%)
planned missed CABENUVA injection visits with HIV providers?[1]		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
24. Have any patients required oral therapy to cover missed doses of CABENUVA?[1]	N=XX	Yes	n (%)
		No (Go to Q25)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q25.)	n (%)
		Missing	n (%)
24a. How acceptable has the communication been regarding oral therapy to cover missed doses of CABENUVA between the infusion center and the HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
24b. How acceptable has the process been coordinating oral therapy between the infusion centers and HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
25. Have any patients experienced an adverse event (AE) while receiving CABENUVA injections at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q26.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q26.)	n (%)
25a. What are the communication preferences for HIV providers to be notified about regarding AEs?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q26.)	n (%)
		Missing	n (%)
25b. How acceptable has the communication been regarding AEs with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
26. What is your preferred process for managing each of the following adverse event situations (select one response per column): 26a. Managing mild adverse events (i.e., Grade 1-2 injection site reactions)[1,3]	N=XX	Infusion centers manage the event and notify referring HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then manage the event in collaboration with HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
26. What is your preferred process for managing each of the following adverse event situations (select one response per column): 26b. Managing severe or serious adverse events (i.e., a vasovagal reaction)[1,3]	N=XX	Infusion centers manage the event and notify referring HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then manage the event in collaboration with HIV provider	n (%)
		Infusion centers notify referring HIV provider immediately, then HIV provider manages the event	n (%)
		Process may vary depending on the event	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process.	n (%)
		Missing	n (%)
27. Have any patients discontinued CABENUVA injections at one of your infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q28.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q28.)	n (%)
		Missing	n (%)
27a. What are the communication preferences for HIV providers regarding patient discontinuation of CABENUVA?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q28.)	n (%)
		Missing	n (%)
27b. How acceptable has the communication been regarding patient discontinuation of CABENUVA with HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
28. Have HIV providers requested labs to be conducted via the infusion centers on the plan of treatment (POT)?[1]	N=XX	Yes	n (%)
		No (Go to Q29.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q29.)	n (%)
		Missing	n (%)
28a. What are the communication preferences for HIV providers regarding labs they may have requested via the plan of treatment (POT)?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q29.)	n (%)
		Missing	n (%)
28b. How acceptable has the communication been regarding labs the HIV provider may have requested via the plan of treatment (POT)?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
29. If ad-hoc labs are needed (e.g., in the case of an adverse event), where do the infusion centers prefer they are done?[1,3]	N=XX	HIV provider's office	n (%)
		Infusion centers	n (%)
		External lab	n (%)
		Other*	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Missing	n (%)
30. Have HIV providers requested ad-hoc labs to be conducted at the infusion centers?[1]	N=XX	Yes	n (%)
		No (Go to Q31.)	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q31.)	n (%)
		Missing	n (%)
30a. What are the communication preferences for HIV providers regarding ad-hoc labs they may have requested?[2,3]	N=XX	Phone call	n (%)
		Text	n (%)
		Email	n (%)
		Fax	n (%)
		Secure electronic medical record message	n (%)
		Other*	n (%)
		I do not have knowledge of/not involved in this process. (Go to Q31.)	n (%)
		Missing	n (%)
30b. How acceptable has the communication been regarding ad-hoc labs requested by HIV providers?[1]	N=XX	Extremely acceptable	n (%)
		Very acceptable	n (%)
		Somewhat acceptable	n (%)
		Neither acceptable nor unacceptable	n (%)
		Somewhat unacceptable	n (%)
		Very unacceptable	n (%)
		Extremely unacceptable	n (%)
		Missing	n (%)
31. Which format do you prefer for the blueprint?[2,3]	N=XX	PowerPoint	n (%)
		Word document or PDF	n (%)
		Either format	n (%)
		Missing	n (%)
32. How often do you use or refer to the blueprint?[1]	N=XX	Extremely often	n (%)
		Very often	n (%)
		Somewhat often	n (%)
		Seldom	n (%)
		I have never used or referred to the blueprint (skip all remaining questions).	n (%)
		Missing	n (%)
33. How useful is the blueprint?[1]	N=XX	Extremely useful	n (%)
		Very useful	n (%)
		Somewhat useful	n (%)
		Neutral	n (%)
		Not very useful	n (%)

Question	Number of Participants at Month 6	Response	n (%)
		Not at all useful	n (%)
		Missing	n (%)
34. The blueprint contains the information I need to administer CABENUVA at our infusion centers.[1]	N=XX	Strongly agree	n (%)
		Agree	n (%)
		Neither agree nor disagree	n (%)
		Disagree	n (%)
		Strongly disagree	n (%)
		Missing	n (%)
35. There is information I need for administering CABENUVA in our infusion centers that should be included in the blueprint.[1]	N=XX	Strongly agree (Go to Q36a.)	n (%)
		Agree (Go to Q36a.)	n (%)
		Neither agree nor disagree	n (%)
		Disagree	n (%)
		Strongly disagree	n (%)
		Missing	n (%)
35a. What do you think is missing from the blueprint?	N=XX	Open-ended text*	-
		Missing	n (%)
36. Are there any process details in the blueprint you think should be changed?[1]	N=XX	Yes (Go to Q37a)	n (%)
		No (Go to Q38)	n (%)
		Missing	n (%)
36a. What details do you think should be changed?	N=XX	Open-ended text*	-
		Missing	n (%)
37. What is your overall opinion of the blueprint?[1]	N=XX	Extremely positive	n (%)
		Very positive	n (%)
		Somewhat positive	n (%)
		Neutral	n (%)
		Somewhat negative	n (%)
		Very negative	n (%)
		Extremely negative	n (%)
		Missing	n (%)
38. Do you have any other thoughts or comments about your experiences that you'd like to share? Please write in your response below.	N=XX	Open-ended text*	-
		Missing	n (%)

[1] Select one response
[2] Select all that apply
[3] Within each question, where appropriate, response choices will be ordered by percent endorsing, descending, and ties will go in order presented to respondents. For items with more than 5 response options, the top 5 selected response options within each item at baseline will be bolded in tables for subsequent timepoints
Abbreviations: AE = adverse event; ART = antiretroviral therapy; HIV = human immunodeficiency virus; POT = plan of treatment

NOTE: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.
Cell percentages do not include missing
*"Other" responses and open-ended text responses will be presented in an appendix

Table 9.1. Expert Panel Responding "Agree" or Completely Agree" On All FIM Items at Baseline, Month 3, and Month 6: Proportions and Change

	Number completing all 4 FIM items	Number endorsing '4' or '5' on all FIM Items	% endorsing all FIM Items[1]	Percentage Point Change[2]
Baseline[1]	XX	XX	XX%	-
Month 3[1]	XX	XX	XX%	-
Month 6[1]	XX	XX	XX%	-
Baseline to Month 3[2]	XX	BL=XX; M3=XX	BL=XX%; M3=XX%	XX%
Baseline to Month 6[2]	XX	BL=XX; M6=XX	BL=XX%; M6=XX%	XX%
Month 3 to Month 6[2]	XX	M3=XX; M6=XX	M3=XX%; M6=XX%	XX%

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items
[2]Each change row is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Abbreviations: FIM = Feasibility of Intervention Measure; BL= baseline; M3 = Month 3; M6 = Month 6
Responses: 4=CCI 5=CCI .
Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint

Table 9.2. Expert Panel Responding "Agree" or Completely Agree" On All AIM Items at Baseline, Month 3, and Month 6: Proportions and Change

	Number completing all 4 AIM items	Number endorsing '4' or '5' on all AIM Items	% endorsing all AIM Items[1]	Percentage Point Change[2]
Baseline[1]	XX	XX	XX%	-
Month 3[1]	XX	XX	XX%	-
Month 6[1]	XX	XX	XX%	-
Baseline to Month 3[2]	XX	BL=XX; M3=XX	BL=XX%; M3=XX%	XX%
Baseline to Month 6[2]	XX	BL=XX; M6=XX	BL=XX%; M6=XX%	XX%
Month 3 to Month 6[2]	XX	M3=XX; M6=XX	M3=XX%; M6=XX%	XX%

[1]For each cross-sectional time point row, numerator = number responding '4' or '5', denominator = number completing all 4 items
[2]Each change row is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Abbreviations: AIM = Acceptability of Intervention Measure; BL=baseline; M3 = Month 3; M6 = Month 6
Responses: 4=CCI 5=CCI
Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint

Table 10.1. Expert Panel, Distributional Characteristics of Feasibility of Intervention Measure (FIM), N=XX

Item	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (Max ,Min)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
FIM Mean Score	BL	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M3	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M6	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
FIM Q1	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
FIM Q2	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
FIM Q3	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
FIM Q4	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)

Abbreviations: BL= Baseline; CI = confidence interval; FIM = Feasibility of Intervention Measure; M3 = Month 3; M6 = Month 6; SD = standard deviation

Percent Floor for the mean score is the percent of respondents with a score of 1 CCI [redacted] out of all respondents replying to at least two FIM items at a given time point.

Percent Ceiling for the mean score is the percent of respondents with a score of 5 CCI [redacted] out of all respondents replying to at least two FIM items at a given time point.

NOTE 1: FIM item wording differed by the position of the expert panel member. The FIM items presented to HIV care providers/ clinical staff were as follows: 1. Infusion Center administered CABENUVA seems implementable for the patients in our clinic/practice; 2. Infusion Center administered CABENUVA seems possible for the patients in our clinic/practice; 3. Infusion Center administered CABENUVA seems doable for the patients in our clinic/practice; 4. Infusion Center administered CABENUVA seems easy to implement for the patients in our clinic/practice. The FIM items presented to IC Staff were as follows: 1. Administering CABENUVA seems implementable in my infusion center; 2. Administering CABENUVA seems possible in my infusion center; 3. Administering CABENUVA seems doable in my infusion center; 4. Administering CABENUVA seems easy to implement in my infusion center.

NOTE 2: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item. Missing for the mean score counts any instance where a respondent completed one FIM item, not reaching the minimum of 2 items required to calculate a mean FIM score
Cell percentages do not include missing

Table 10.2. Expert Panel, Distributional Characteristics of Acceptability of Intervention Measure (AIM), N=XX

Item	Time Point	Number of Participants	Missing	Mean	SD	Median (Q1, Q3)	Range (Max ,Min)	Percent Missing	Percent Floor	Percent Ceiling	95% CI (Lower, Upper)
AIM Mean Score	BL	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M3	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
	M6	XX	XX	X.XX	X.XXX	X.XX (X.XX, X.X)	(X.X, X.X)	XX%	XX%	XX%	(X.XXX, X.XXX)
AIM Q1	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
AIM Q2	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
AIM Q3	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
AIM Q4	BL	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M3	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)
	M6	XX	XX	X.X	X.XX	X.X (X.X, X.X)	(X, X)	XX%	XX%	XX%	(X.XX, X.XX)

Abbreviations: BL= Baseline; CI = confidence interval; AIM = Acceptability of Intervention Measure; M3 = Month 3; M6 = Month 6; SD = standard deviation

Percent Floor for the mean score is the percent of respondents with a score of 1 CCI out of all respondents replying to at least two AIM items at a given time point.

Percent Ceiling for the mean score is the percent of respondents with a score of 5 CCI out of all respondents replying to at least two AIM items at a given time point.

NOTE 1: NOTE: AIM item wording differed by the position of the expert panel member. The AIM items presented to HIV care providers/ clinical staff were as follows: 1. The idea of an infusion center providing CABENUVA meets my approval; 2. The idea of an infusion center providing CABENUVA is appealing to me; 3. I like the idea of an infusion center providing CABENUVA for PLWHIV in our clinic/practice; 4. I welcome an infusion center providing CABENUVA for patients in our clinic/practice. The AIM items presented to IC Staff were as follows: 1. The idea of providing CABENUVA at my infusion center meets my approval; 2. The idea of providing CABENUVA at my infusion center is appealing to me; 3. I like the idea of providing CABENUVA for PLWHIV in my infusion center; 4. I welcome providing CABENUVA for PLWHIV in my infusion center.

NOTE 2: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item

Cell percentages do not include missing

Table 11.1. Expert Panel, Univariate Distribution of Feasibility of Intervention Measure (FIM), N=XX

Items	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
FIM Q1	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
FIM Q2	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
FIM Q3	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
FIM Q4	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; M3 = Month 3; M6 = Month 6

NOTE 1: FIM item wording differed by the position of the expert panel member. The FIM items presented to HIV care providers/ clinical staff were as follows: 1. Infusion Center administered CABENUVA seems implementable for the patients in our clinic/practice; 2. Infusion Center administered CABENUVA seems possible for the patients in our clinic/practice; 3. Infusion Center administered CABENUVA seems doable for the patients in our clinic/practice; 4. Infusion Center administered CABENUVA seems easy to implement for the patients in our clinic/practice. The FIM items presented to IC Staff were as follows: 1. Administering CABENUVA seems implementable in my infusion center; 2. Administering CABENUVA seems possible in my infusion center; 3. Administering CABENUVA seems doable in my infusion center; 4. Administering CABENUVA seems easy to implement in my infusion center.

NOTE 2: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item

Cell percentages do not include missing

Table 11.2. Expert Panel, Univariate Distribution of Acceptability of Intervention Measure (AIM), N=XX

Items	Time Point	Number of Participants	Missing	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
AIM Q1	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
AIM Q2	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
AIM Q3	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
AIM Q4	BL	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M3	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	M6	XX	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Abbreviations: BL = Baseline; M3 = Month 3; M6 = Month 6; PLWHIV = participants living with human immunodeficiency virus

NOTE 1: AIM item wording differed by the position of the expert panel member. The AIM items presented to HIV care providers/ clinical staff were as follows: 1. The idea of an infusion center providing CABENUVA meets my approval; 2. The idea of an infusion center providing CABENUVA is appealing to me; 3. I like the idea of an infusion center providing CABENUVA for PLWHIV in our clinic/practice; 4. I welcome an infusion center providing CABENUVA for patients in our clinic/practice. The AIM items presented to IC Staff were as follows: 1. The idea of providing CABENUVA at my infusion center meets my approval; 2. The idea of providing CABENUVA at my infusion center is appealing to me; 3. I like the idea of providing CABENUVA for PLWHIV in my infusion center; 4. I welcome providing CABENUVA for PLWHIV in my infusion center.

NOTE 2: Missing = the number of participants who are eligible to complete a survey at the respective timepoint but did not complete respective item; Missing % = the number of participants who were eligible to complete a survey at the respective timepoint but did NOT complete the respective item / the number of people who were eligible to fill out a survey at the respective timepoint.

Cell percentages do not include missing

Table 12.1. Expert Panel, Distributional Characteristics of Change in Feasibility of Intervention Measure (FIM), N=XX

Item	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (Min, Max)	95% CI (Lower, Upper)
FIM Mean Score	BL to M3	XX	XX	X.XXX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX, X.XXX)
	BL to M6	XX	XX	X.XXX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX, X.XXX)
	M3 to M6	XX	XX	X.XXX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX, X.XXX)
FIM Q1	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
FIM Q2	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
FIM Q3	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
FIM Q4	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)

[1]Only includes Expert Panel who completed surveys at respective months

Abbreviations: FIM = Feasibility of Intervention Measure; BL= Baseline; CI = confidence interval; M3 = Month 3; M6 = Month 6; PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation

NOTE 1: FIM item wording differed by the position of the expert panel member. The FIM items presented to HIV care providers/ clinical staff were as follows: 1. Infusion Center administered CABENUVA seems implementable for the patients in our clinic/practice; 2. Infusion Center administered CABENUVA seems possible for the patients in our clinic/practice; 3. Infusion Center administered CABENUVA seems doable for the patients in our clinic/practice; 4. Infusion Center administered CABENUVA seems easy to implement for the patients in our clinic/practice. The FIM items presented to IC Staff were as follows: 1. Administering CABENUVA seems implementable in my infusion center; 2. Administering CABENUVA seems possible in my infusion center; 3. Administering CABENUVA seems doable in my infusion center; 4. Administering CABENUVA seems easy to implement in my infusion center.

NOTE 2: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item. Cell percentages do not include missing

Table 12.2. Expert Panel, Distributional Characteristics of Change in Acceptability of Intervention Measure (AIM), N=XX

Item	Time Point	Number of Participants[1]	Missing	Mean Change	SD	Median (Q1, Q3)	Range (Max - Min)	95% CI Lower-Upper
AIM Mean Score	BL to M3	XX	XX	X.XXX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX, X.XXX)
	BL to M6	XX	XX	X.XXX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX, X.XXX)
	M3 to M6	XX	XX	X.XXX	X.XXX	X.XX (X.XX, X.XX)	(X.X, X.X)	(X.XXX, X.XXX)
AIM Q1	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
AIM Q2	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
AIM Q3	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
AIM Q4	BL to M3	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	BL to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)
	M3 to M6	XX	XX	X.XX	X.XX	XX (X.X, X.X)	(X, X)	(X.XX, X.XX)

[1]Only includes Expert Panel who completed surveys at respective months

Abbreviations: AIM = Acceptability of Intervention Measure; BL= Baseline; CI = confidence interval; M3 = Month 3; M6 = Month 6; PLWHIV = participants living with human immunodeficiency virus; SD = standard deviation

NOTE 1: AIM item wording differed by the position of the expert panel member. The AIM items presented to HIV care providers/ clinical staff were as follows: 1. The idea of an infusion center providing CABENUVA meets my approval; 2. The idea of an infusion center providing CABENUVA is appealing to me; 3. I like the idea of an infusion center providing CABENUVA for PLWHIV in our clinic/practice; 4. I welcome an infusion center providing CABENUVA for patients in our clinic/practice. The AIM items presented to IC Staff were as follows: 1. The idea of providing CABENUVA at my infusion center meets my approval; 2. The idea of providing CABENUVA at my infusion center is appealing to me; 3. I like the idea of providing CABENUVA for PLWHIV in my infusion center; 4. I welcome providing CABENUVA for PLWHIV in my infusion center.

NOTE 2: Missing for individual item counts = the number of participants who were eligible to complete a survey at the respective timepoint but did not complete respective item.

Cell percentages do not include missing

Table 13.1. Expert Panel, Shift of Feasibility of Intervention Measure (FIM) Response Frequency by item, N=XX

1.FIM Q1							
		Baseline					
		Completely Disagree N=(XX)	Disagree N=(XX)	Neither agree nor disagree N=(XX)	Agree (N=XX)	Completely Agree (N=XX)	Missing[1] (N=XX)
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 6	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 6	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
2.FIM Q2							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
3.FIM Q3							

		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
4.FIM Q4							
		Baseline					
		Completely	**Disagree**	**Neither**	**Agree**	**Completely**	

		Disagree N=(XX)	N=(XX)	agree nor disagree N=(XX)	(N=XX)	Agree (N=XX)	Missing[1] (N=XX)
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 6	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 3					
		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 6	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

[1]Missing at T1, completed at T2
[2]Missing at T2, completed at T1
Abbreviations: FIM = Feasibility of Intervention Measure
Percentage calculations:
Non-missing cell %:
numerator = number selecting respective combination of Time 1 and Time 2 responses
denominator = number of participants responding within Time 1 response category at Time 1 at T1

Table 13.2. Expert Panel, Shift of Acceptability of Intervention Measure (AIM) Response

1.AIM Q1							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
2.AIM Q2							
		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
3.AIM Q3							

		Baseline					
		Completely Disagree N=(XX)	**Disagree N=(XX)**	**Neither agree nor disagree N=(XX)**	**Agree (N=XX)**	**Completely Agree (N=XX)**	**Missing[1] (N=XX)**
Month 3	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
		Month 3					
		Completely Disagree N=(xx)	**Disagree N=(xx)**	**Neither agree nor disagree N=(xx)**	**Agree (N=xx)**	**Completely Agree (N=xx)**	**Missing (N=XX)**
Month 6	**Completely Disagree (N=XX)**	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
4.AIM Q4							
		Baseline					
		Completely	**Disagree**	**Neither**	**Agree**	**Completely**	

		Disagree N=(XX)	N=(XX)	agree nor disagree N=(XX)	(N=XX)	Agree (N=XX)	Missing[1] (N=XX)
Month 3	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Month 6	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

		Month 4					
		Completely Disagree N=(xx)	Disagree N=(xx)	Neither agree nor disagree N=(xx)	Agree (N=xx)	Completely Agree (N=xx)	Missing (N=XX)
Month 8	Completely Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Neither agree nor disagree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Completely Agree (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
	Missing[2] (N=XX)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)

[1]Missing at T1, completed at T2
[2]Missing at T2, completed at T1
Abbreviations: FIM = Feasibility of Intervention Measure
Percentage calculations:
Non-missing cell %:
numerator = number selecting respective combination of Time 1 and Time 2 responses
denominator = number of participants responding within Time 1 response category at Time 1

Table 14. Implementation Science-Related Protocol Deviations

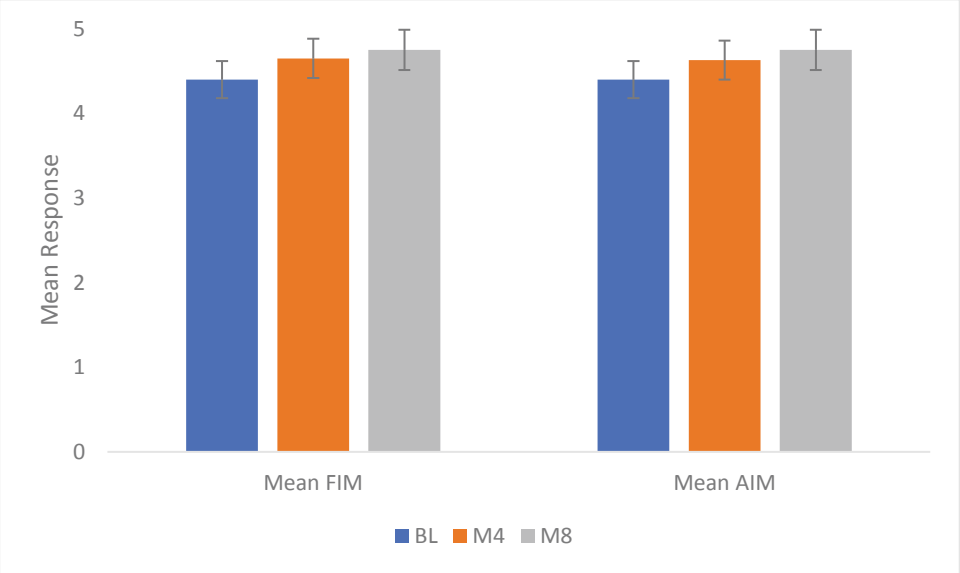
Protocol Deviation	IS-related Protocol Deviations Reported for Expert Panel n(%)
IS-related Protocol Deviations	
Placeholder sub-category 1	
Placeholder sub-category 2	
Placeholder sub-category 3	

[1] Deviations associated with incomplete IS questionnaires are for those initiated but not completed

Note: Numerators equal the number of expert panel members experiencing respective deviation type, denominators equal the number of expert panel members in ana

8 Figures

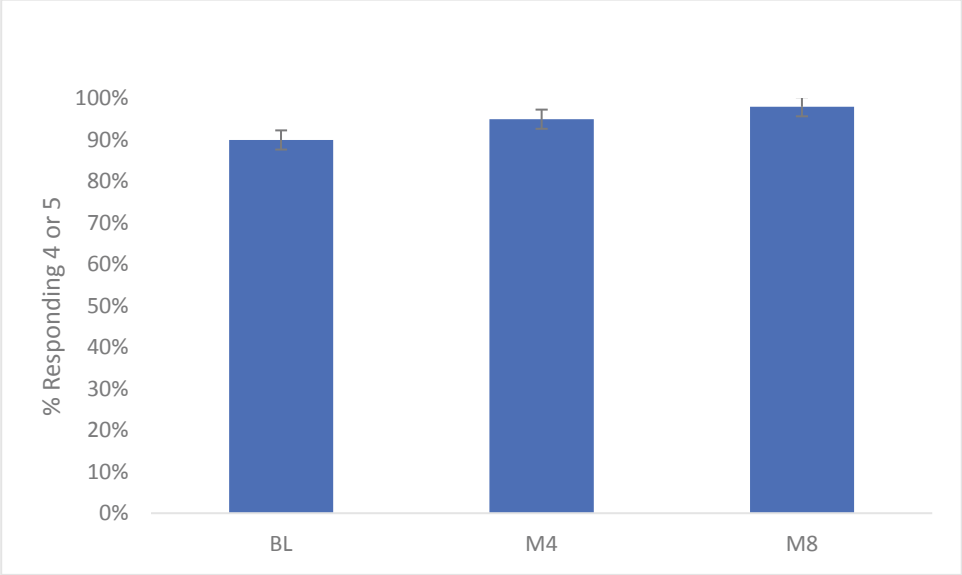
Figure 1. Bar Chart Showing Mean HIV Care Providers/Clinical Staff FIM and AIM Responses at Baseline, Month 4 and Month 8



Abbreviations: FIM = Feasibility of Intervention Measure; AIM = Acceptability of Intervention Measure; BL=baseline; M4 = Month 4; M8 = Month 8

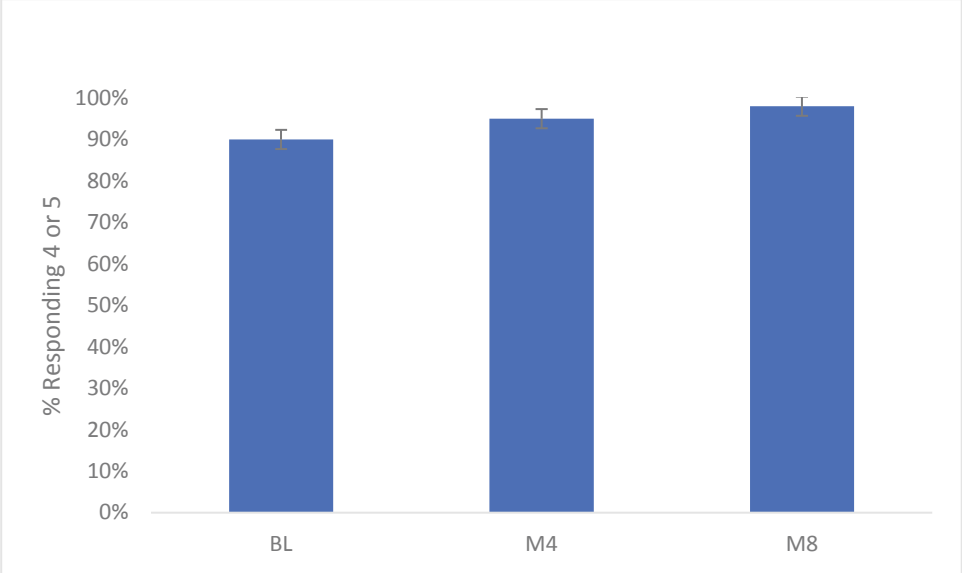
Error Bars = Standard error

Figure 2. Bar chart showing proportion of HIV Care Providers/Clinical Staff Responding "Agree" or Completely Agree" On All FIM Items at Baseline, Month 4, and Month 8



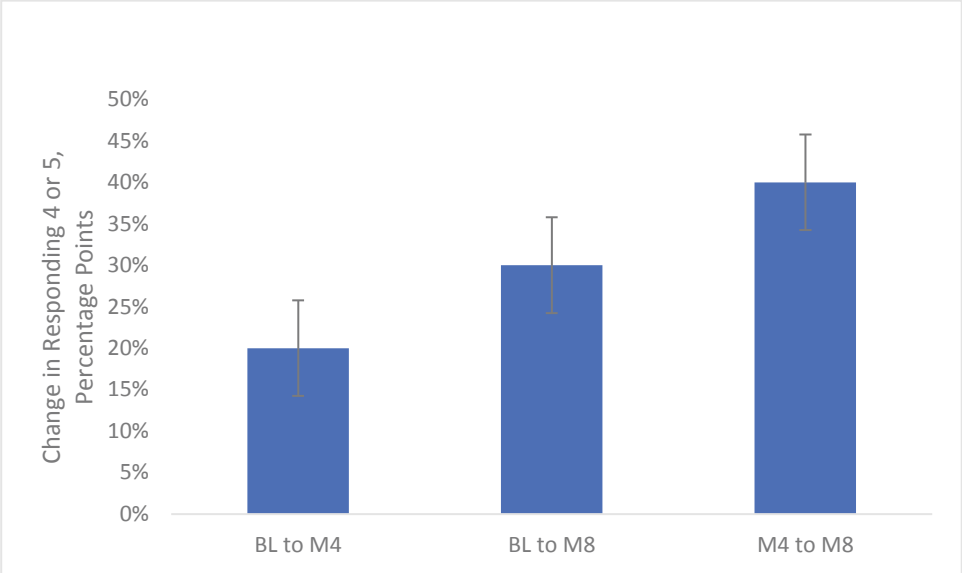
Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M4 = Month 4; M8 = Month 8
Responses: 4=CCI 5=CCI
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 3. Bar chart showing proportion of HIV Care Providers/Clinical Staff Responding "Agree" or Completely Agree" On All AIM Items at Baseline, Month 4, and Month 8



Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M4 = Month 4; M8 = Month 8
Responses: 4=CCI 5=CCI
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

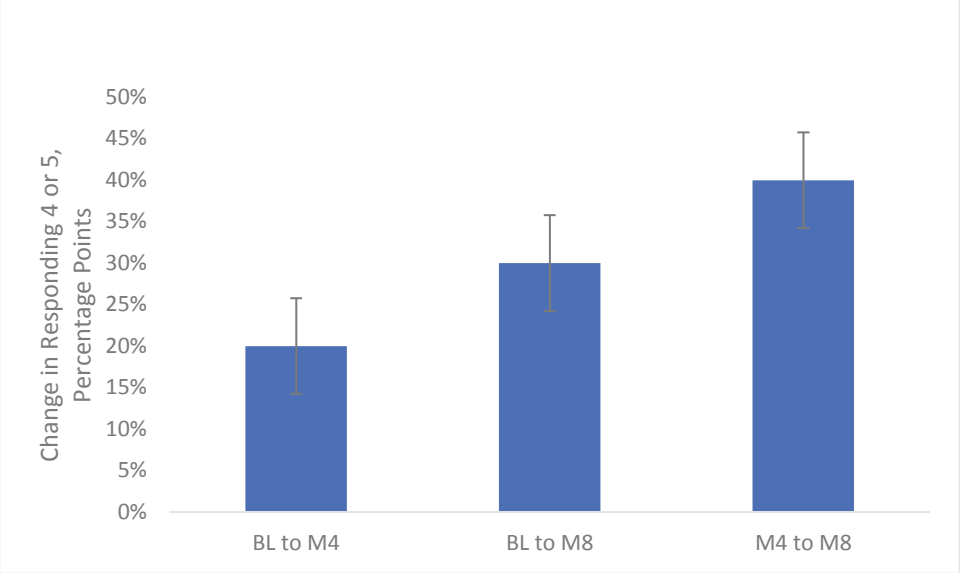
Figure 4. Bar chart showing change in Proportion of HIV Care Providers/Clinical Staff Responding "Agree" or Completely Agree" On All FIM Items, Baseline to Month 4, Baseline to Month 8, and Month 4 to Month 8



Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M4 = Month 4; M8 = Month 8
Responses: 4=CCI 5=CCI

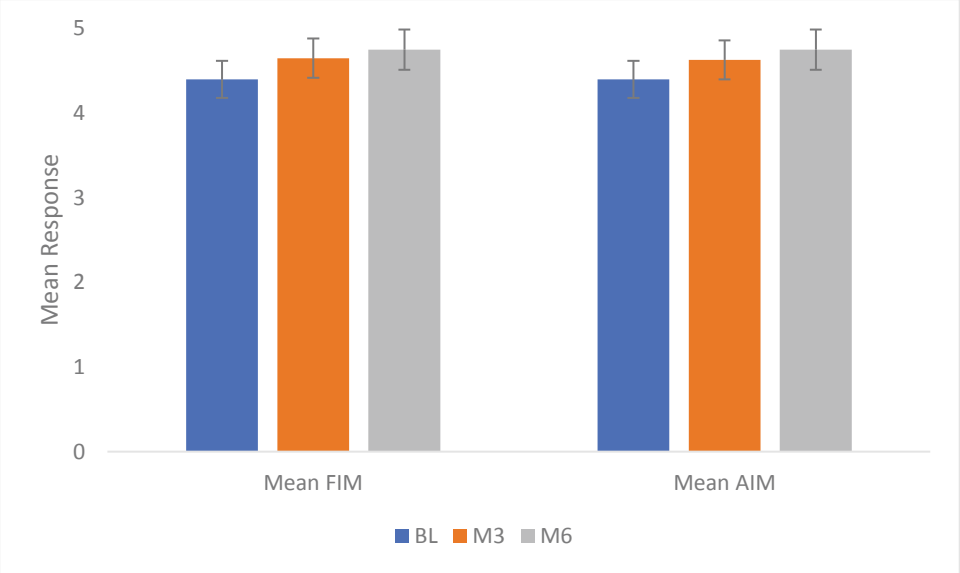
Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint. Each change row is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 5. Bar chart showing change in Proportion of HIV Care Providers/Clinical Staff Responding "Agree" or Completely Agree" On All AIM Items, Baseline to Month 4, Baseline to Month 8, and Month 4 to Month 8



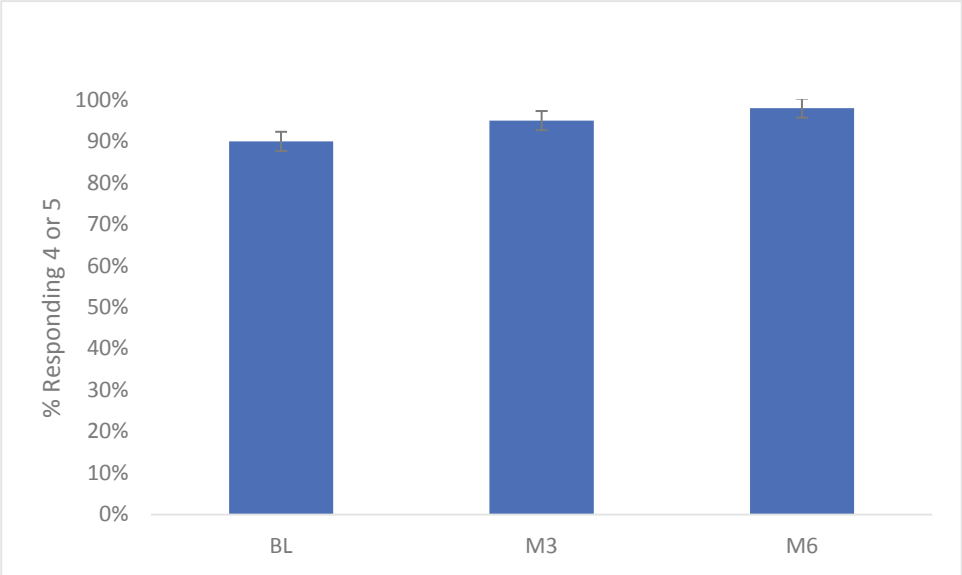
Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M4 = Month 4; M8 = Month 8
Responses: 4=CCI , 5=CCI
Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint. Each change row is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 6. Bar Chart Showing Mean Expert Panel FIM and AIM Responses at Baseline, Month 3, and Month 6



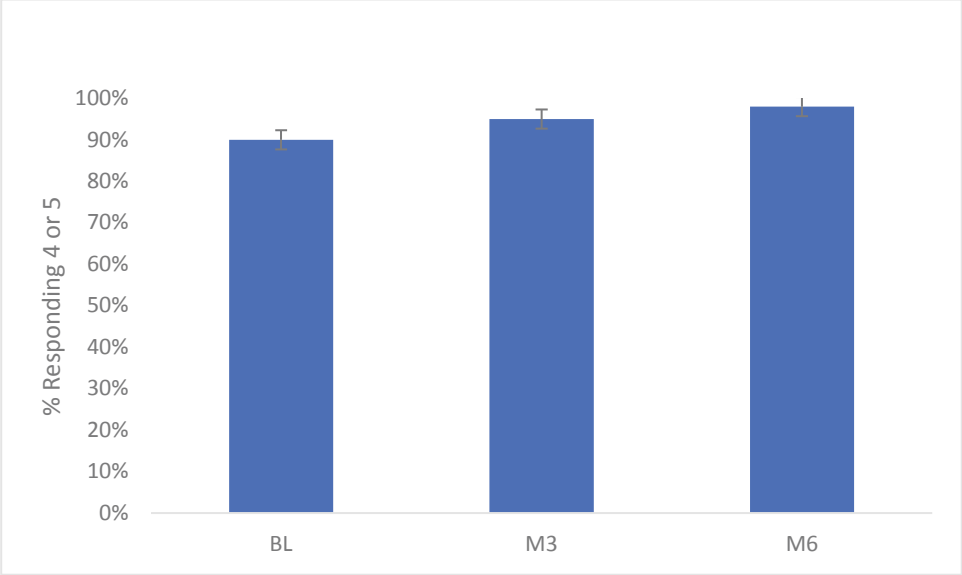
Abbreviations: FIM = Feasibility of Intervention Measure; AIM = Acceptability of Intervention Measure; BL=baseline; M3 = Month 3; M6 = Month 6
Error Bars = Standard error

Figure 7. Bar chart showing proportion of Expert Panel Responding "Agree" or Completely Agree" On All FIM Items at Baseline, Month 3, and Month 6



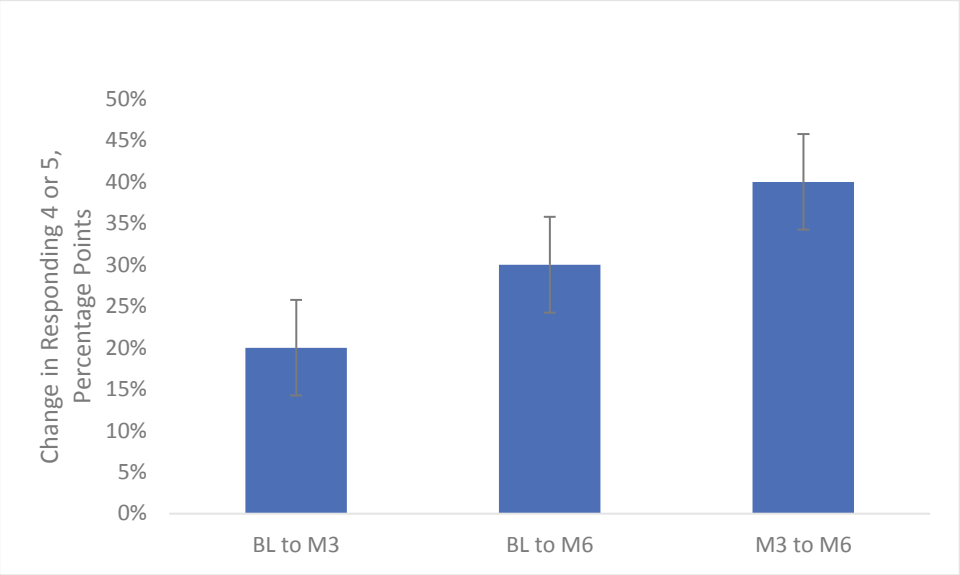
Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M3 = Month 3; M6 = Month 6
Responses: 4=CCI , 5=CCI
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 8. Bar chart showing proportion of Expert Panel Responding "Agree" or Completely Agree" On All AIM Items at Baseline, Month 3, and Month 6



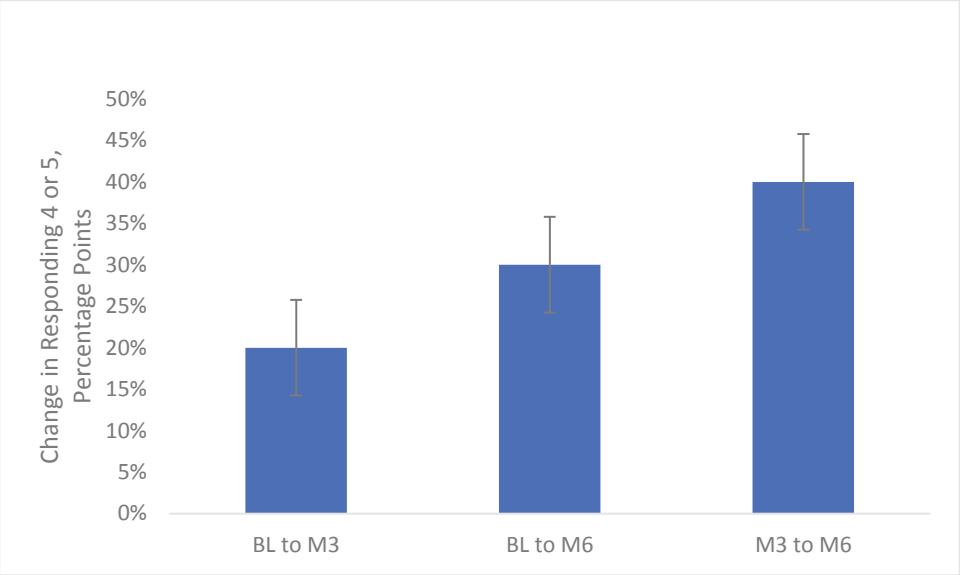
Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M3 = Month 3; M6 = Month 6
Responses: 4=CCI , 5=CCI
For each time point, numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 9. Bar chart showing change in Proportion of Expert Panel Responding "Agree" or Completely Agree" On All FIM Items, Baseline to Month 3, Baseline to Month 6, and Month 3 to Month 6



Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M3 = Month 3; M6 = Month 6
Responses: 4=CCI 5=CCI
Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint. Each change row is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Figure 10. Bar chart showing change in Proportion of Expert Panel Responding "Agree" or Completely Agree" On All AIM Items, Baseline to Month 3, Baseline to Month 6, and Month 3 to Month 6



Abbreviations: FIM = Feasibility of Intervention Measure; BL=baseline; M3 = Month 3; M6 = Month 6
Responses: 4=CCI 5=CCI
Note: Reporting for change includes only those who completed surveys at both respective time points, which may differ from reporting at each individual timepoint. Each change row is limited to those completing all 4 items at both respective timepoints; numerator = number responding '4' or '5', denominator = number completing all 4 items
Error Bars = Standard error

Appendix A. Missing Data

Table A1. Summary of Missing Data, HCP Providers/Clinical Staff

Timepoint	Item	Completed n(%)	Missing n(%)
Baseline N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 4 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 8 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)

Abbreviations: AIM = Acceptability of Intervention Measure; FIM = Feasibility of Intervention Measure

Table A2. Summary of Free-text Responses, HIV Care Provider/Clinical Staff

Table A3. Summary of Missing Data, Expert Panel

	Item	Completed n(%)	Missing n(%)
Baseline N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 3 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)
Month 6 N=XX	FIM Item 1	n (%)	n (%)
	FIM Item 2	n (%)	n (%)
	FIM Item 3	n (%)	n (%)
	FIM Item 4	n (%)	n (%)
	AIM Item 1	n (%)	n (%)
	AIM Item 2	n (%)	n (%)
	AIM Item 3	n (%)	n (%)
	AIM Item 4	n (%)	n (%)

Abbreviations: AIM = Acceptability of Intervention Measure; FIM = Feasibility of Intervention Measure

Table A4. Summary of Free-text Responses, Expert Panel