ViiV Healthcare Scientific Interactive Webinar

VOLITION:

The Choice, The Decision & The Primary Outcome

Early Switch to Long-acting Injectables

Thursday 26th February

16:00–17:00 CET

15:00–16:00 GMT

08:00–09:00 MST

VOLITION
Protocol 219700

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Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.

Welcome and introduction

Dr Samia Dakhia

Senior Medical Affairs Director and
Head of Medical Operations for Europe and International Region

ViiV Healthcare, Rueil-Malmaison, France

Expert panel and disclosures

Dr Samia Dakhia (Moderator)

ViiV Healthcare, Rueil-Malmaison, France

Full-time employee of ViiV Healthcare

Dr Pedro Cahn

Fundación Huésped, Buenos Aires, Argentina

Speaker fees: ViiV Healthcare
Advisory boards: ViiV Healthcare and Gilead Sciences
Funding to institution: Merck Sharp & Dohme
Data Safety Monitoring Board: Moderna

Dr Charlotte-Paige Rolle

Orlando Immunology Center, Orlando, Florida, USA

Research funding: Gilead Sciences
Honoraria and advisory boards: ViiV Healthcare
Funding to institution: Gilead Sciences, Merck Sharp & Dohme, and ViiV Healthcare

Dr William Short

University of Pennsylvania, Philadelphia, Pennsylvania, USA

Consultant: ViiV Healthcare, Gilead Sciences
Funding to institution: Gilead Sciences

Objective and agenda

Explore and discuss the latest results from the VOLITION study, including the primary endpoint data presented at CROI, and consider their implications for clinical practice

Duration	Session title	Speaker(s)/Moderator
10 mins	**Welcome and introduction**	Dr Samia Dakhia
10 mins	**VOLITION: Key insights from 2025** / *The power of choice: Preference following suppression in people with HIV* / *The power of choice: HCP perspectives on early switch*	Dr Pedro Cahn
15 mins	**VOLITION: Primary co-endpoint data**	Dr Charlotte-Paige Rolle
20 mins	**Panel discussion and Q&A**	Dr Pedro Cahn and Dr William Short, moderated by Dr Samia Dakhia
5 mins	**Summary and close**	Dr Samia Dakhia

HCP, healthcare professional

The VOLITION study addresses key unmet needs in people with HIV

VOLITION Protocol 219700

VOLITION is the first study to evaluate the efficacy of **early switch to CAB + RPV LA immediately after attaining virologic suppression** with DTG/3TC in ART-naïve adults with HIV

VOLITION assesses the outcome of the **choice to switch** to CAB + RPV LA after achieving virologic suppression, and are the closest data to treatment-naïve yet

VOLITION evaluates the empowerment of **shared decision making,** and how treatment preference can drive **persistence** of virologic suppression and **treatment satisfaction**

3TC, lamivudine; **ART**, antiretroviral treatment; **DTG**, dolutegravir; **CAB**, cabotegravir; **RPV**, rilpivirine; **LA** long-acting

Rolle C-P, et al. CROI 2026. Poster 525

CAB + RPV LA at CROI: Continues to support high efficacy with long-term durability in people with HIV

ROBUST CLINICAL DEVELOPMENT AND PHASE IIIB/IV PROGRAMME

VOLITION 11M

CROI 2026

High efficacy in early switch, with low rates of CVF with resistance[1]

SOLAR 12M, CARES 96W

Non-inferiority vs oral ART, including BIC/FTC/TAF[2,3]

ATLAS-2M 152W, LATTE-2 256W

Long-term durability up to 5 years, with high rates of virologic suppression[4,5]

IMPALA 48W

Non-inferiority vs INSTI-based ART in people with suboptimal HIV control[6]

MOCHA 96W

CROI 2026

High virologic suppression and strong preference among adolescents with HIV[7]

CONSISTENT EFFECTIVENESS IN REAL-WORLD EVIDENCE

Meta-analysis of published RWE at Month 12[8]

27 studies, encompassing 7,687 virologically suppressed (VL <50 c/mL) people with HIV receiving CAB + RPV LA for 12 months

93% virologic suppression
maintained after switching to CAB + RPV LA
(N=1,708 people with HIV across six studies; 95% CI: 88.7, 96.9)

0.3% resistance at failure
with overall low virologic failure rate
(N=1,003 people with HIV across five studies; 95% CI: 0.0, 1.2)

Results presented in the meta-analysis reflect estimates calculated using a random-effects model, and number of studies included for each endpoint varied due to differing timepoints and endpoint definitions. **BIC**, bictegravir; **CI**, confidence interval; **CVF**, confirmed virologic failure; **FTC**, emtricitabine; **INSTI**, integrase strand transfer inhibitor; **M,** months; **RWE**, real-world evidence; **TAF**, tenofovir alafenamide; **VL,** viral load; **W,** week

1. Rolle C-P, et al. CROI 2026. Poster 525; **2**. Ramgopal MN, et al. Lancet HIV 2023;10:e566–77 **3.** Kityo C et al. Nat Med 2026;32:168–77; **4.** Overton ET, et al. Clin Infect Dis 2023;76:1646–54; **5.** Smith G, et al. Open Forum Infect Dis 2021;8:ofab439; **6.** Cresswell FV, et al. IAS 2025. Oral OAB0106LB; **7.** Gaur A, et al. CROI 2026. Abstract 155 **8.** Orkin C, et al. EACS 2025. Poster eP103

CAB + RPV LA at CROI: Continues to support low viral failure and good tolerability in real world studies of people with HIV

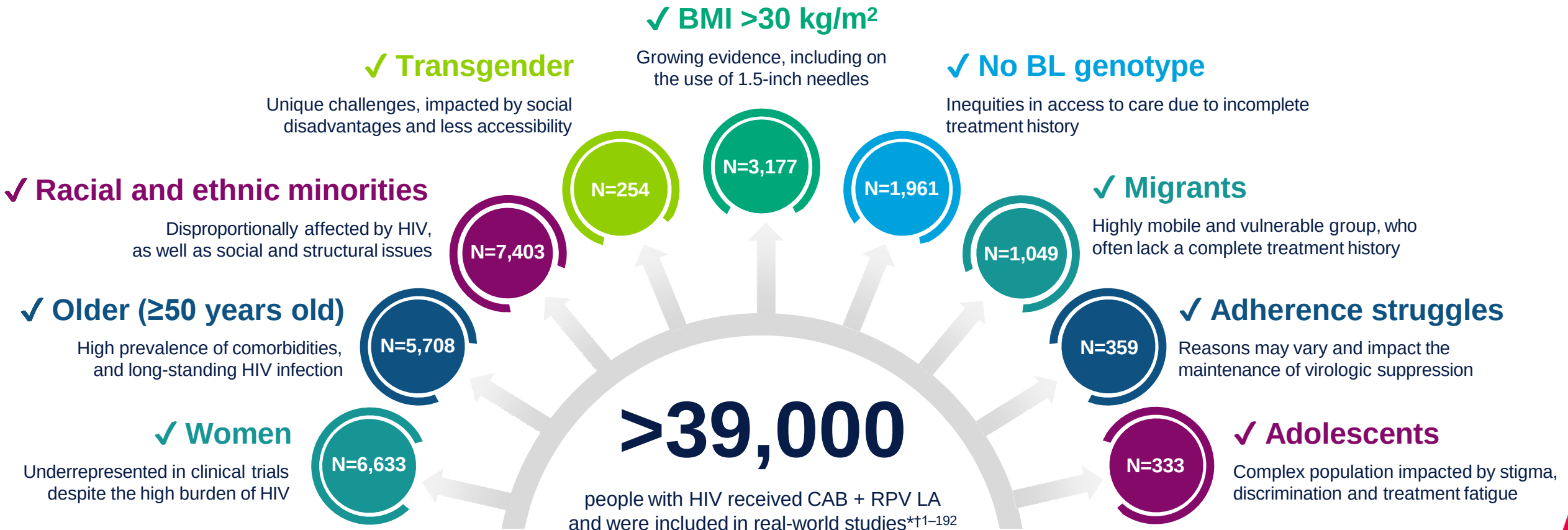
CROI 2026

	OPERA[1] >1 YEAR	RELATIVITY[2] >1 YEAR	COMBINE-2 C2C[3]	SCohoLART[4] 2 YEARS
	N=4,000 Median (IQR) follow-up: 16 (9–26) months* On-treatment analysis	N=3,146 Median (IQR) follow-up: 13.8 (9–19) months On-treatment analysis	N=937 Median (IQR) follow-up: 10.2 (7.1–16.6) months* On-treatment analysis	N=549 Median (IQR) follow-up: 24 (17.0–26.8) months On-treatment analysis
Virologically suppressed†	**95%**	**≥96%** Throughout follow-up	**99%**	**98.6%**
Virological failure‡	**1%** (n=43)	**0.6%** (n=20)	**0.5%** (n=5)	**1.1%** (n=6)
VF with INSTI resistance	**NR**	**0.9%** (n=3)	**0.4%** (n=12)	**0.5%** (n=3)

Presented data include real-world cohorts that included virologically suppressed people with HIV (OPERA, RELATIVITY, COMBINE-2 C2C and SCohoLART) reporting both virologic suppression and VF, with the highest number of people with HIV and longest follow-up (≥10 months) as of February 2026 or presented at CROI 2026
IQR, interquartile range; **NR**, not reported; **VF**, virologic failure
Footnotes available upon request

1. Hsu R, et al. CROI 2026. Poster 527; **2.** Buzón-Martín L, et al. J Antimicrob Chemother 2025: 2025;80(12):3438-51
3. Pozniak A, et al. IAS 2025. Poster EP0171; **4.** Muccini C, et al. EACS 2025. Poster eP121

CAB + RPV LA: Continues to support effectiveness in broad and diverse groups of people with HIV



*N=39,434. Supporting references for subgroup population N numbers can be found in the slide notes; †Potential overlap between real-world cohorts cannot be ruled out

BL, baseline; **BMI,** body mass index

References available upon request

CAB + RPV LA: Continues to support additional benefits beyond virologic suppression are consistently reported in RCTs and RWE

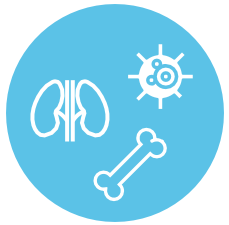
ADHERENCE

High, directly observed adherence to injections,* [1–7] and **higher adherence** and **persistence vs daily oral ART** (including BIC/FTC/TAF) [8,9]

DDIs

Low risk of DDIs and **can bypass the gut**, avoiding further DDIs related to oral absorption [10]

METABOLIC, RENAL, BONE AND IMMUNE



Neutral impact on **insulin resistance, metabolic syndrome, renal and bone biomarkers,** and increased **CD4/CD8 ratio** after switching from oral ART† [11–20]

ENGAGEMENT IN CARE

High retention in care with **benefits** of **increased HCP touchpoints,** including feeling **more engaged in managing HIV** and **broader health** [8,21–23]

QUALITY OF LIFE

Strong preference vs prior oral ART,‡ [2,4,5] and **high and improved QoL,**‡ [8,24–30] including **alleviation** of **psychological challenges** and **stigma**§ [24,27,31]

*RCTs: ATLAS-2M Week 48 HCP-reported adherence: 98% (n=3,719);[1] SOLAR Month 12 HCP-reported adherence: 93% (n=2,527);[2] CARISEL Month 12 HCP-reported adherence: 93% (n=2,376);[3] CARES Week 48 HCP-reported adherence: 96% (n=1,758);[4] RWE: CARLOS Month 24 HCP-reported adherence: 94% (n=3,676);[5] BEYOND Month 24 HCP-reported adherence: 89% (n=2,509);[6] †BL vs 7 months: CrCl (Cockcroft-Gault) [90.9 mL/min (IQR: 78.2–101.6) vs 99.1 mL/min (IQR: 85.1–110.3); p=0.0001, respectively;[16] ‡HIV-specific PozQoL [score range 13–65], and EQ-5D-5L-US [score range 0–1])[8]; perception of own quality of life changes (greater or better) at Month 6 vs BL after switching to CAB + RPV LA; HIVDQoL score 88% vs 33% (p=0.01), respectively;[26] HIVTSQs: Increased scores in all items, with therapy satisfaction reaching 5.9/6.0 at Month 13[26] §Switching to CAB + RPV LA helps reduce efforts to keep HIV status disclosed; HSS score at BL vs Month 6: 87.5% vs 33% (p=0.009), respectively[26]

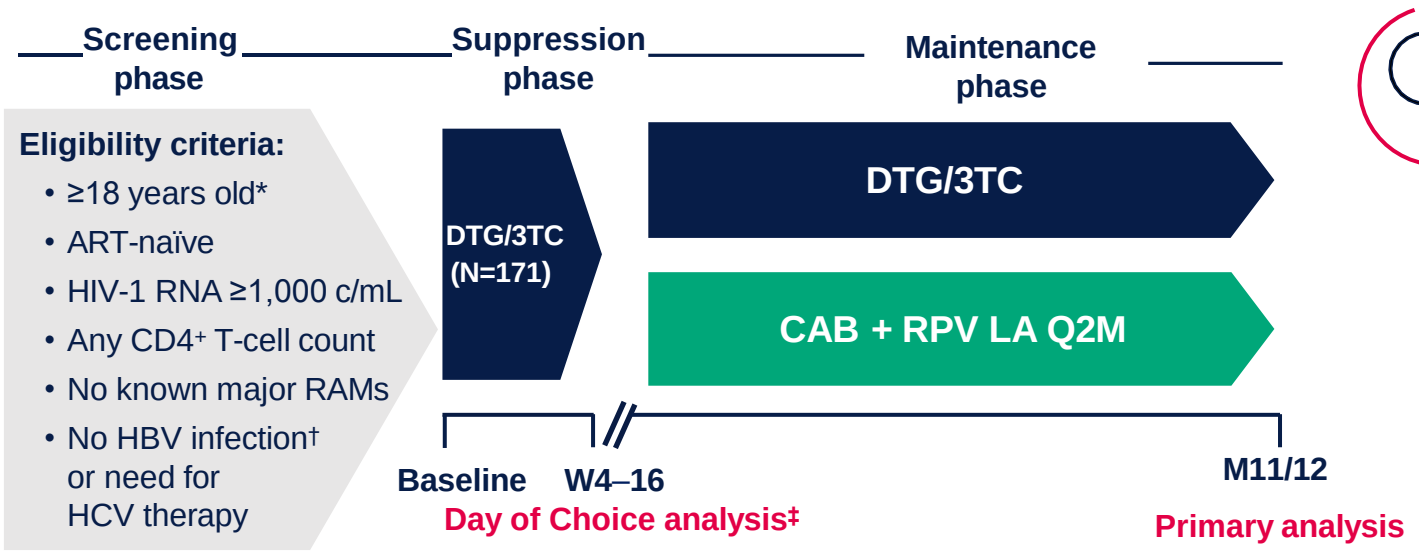
CrCl, creatinine clearance; **DDI,** drug–drug interaction; **EQ-5D-5L-US,** EuroQol 5-Dimension, 5 level United States; **HIVDQoL,** HIV dependent quality of life; **HIVTSQs,** HIV treatment satisfaction survey status version **HSS,** HIV stigma scale; **QoL**, quality of life

References available upon request

VOLITION: A Phase IIIb study to evaluate switch to CAB + RPV LA after rapid virologic suppression on DTG/3TC

VOLITION Protocol 219700

Phase IIIb, multicenter, non-randomized, parallel-group, open-label study evaluating the efficacy, safety and patient-reported outcomes following the option to switch from DTG/3TC to CAB + RPV LA after attaining viral suppression



Co-primary endpoints

- Time to virologic suppression (HIV-1 RNA <50 c/mL) from baseline
- The proportion of participants with HIV-1 RNA <50 c/mL per FDA Snapshot algorithm at Month 11 (CAB + RPV LA)

*≥18 years (or older, if required by local regulations); †Participants positive for HBsAg were excluded. Participants negative for anti-HBs but positive for anti-HBc were excluded only if HBV DNA was detected; ‡Participants proceeded to DoC at their next study visit following the first plasma HIV-1 RNA result <50 c/mL (Week 4 at the earliest but no later than Week 16). Participants had to be suppressed to <50 c/mL in order to qualify for the option to switch to CAB + RPV LA. Exclusion criteria for switch included: treatment-emergent ALT ≥5×ULN; or ALT ≥3×ULN and bilirubin ≥1.5×ULN (with >35% direct bilirubin) and pregnancy

ALT, alanine aminotransferase; **anti-HBc**, hepatitis B core antibody; **anti-HBs**, hepatitis B surface antibody; **DoC**, Day of Choice; **FDA**, Food and Drug Administration; **HBV**, hepatitis B virus **HBsAg**, hepatitis B surface antigen; **HCV**, hepatitis C virus; **Q2M,** every 2 months; **RAM**, resistance-associated mutation; **ULN**, upper limit of normal

A diverse population of treatment-naïve adults with HIV were enrolled in the study and chose to switch to CAB + RPV LA at DoC

Parameter	DTG/3TC (Suppression phase) (N=171)[1]	Switched to CAB + RPV LA (n=129/151)*[2]
Median age, years (range)	31 (18–70)	31 (18–67)
≥50 years, n (%)	18 (11)	13 (10)
Women (self-identified gender), n (%)	45 (26)	34 (26)
Race, n (%)		
Black or African American	51 (30)	42 (33)
White	106 (62)	77 (60)
Other races	7 (4)†	5 (4)‡
Not reported or unknown	7 (4)	5 (4)
Hispanic/Latinx ethnicity, n (%)	88 (51)	66 (51)
Region, n (%)§		
North America	78 (46)	63 (49)
Europe	47 (27)	30 (23)
South America	46 (27)	36 (28)
CD4+ T cells/mm^3, median (IQR)	396 (252–543)	555 (427–668)
Median BMI, kg/m^2 (IQR)	24.4 (21.7–29.1)	25.5 (22.4–29.4)
≥30 kg/m^2, n (%)	34 (20)	27 (21)

*n=151/171 participants who initiated DTG/3TC were eligible for choice to switch to CAB + RPV LA; †Other races, detail: Multiple, n=3; Asian, n=4; ‡Other races, detail: Multiple, n=3; Asian, n=2; §Regions of participants in the DTG/3TC pre-switch population include: Argentina (n=28), Canada, (n=9), Chile (n=18), France (n=9), Germany (n=5), Italy (n=16), Spain (n=17), United States (including Puerto Rico; n=69), In those who chose to switch to CAB + RPV LA regions were North America which includes United States (including Puerto Rico, n=54) and Canada (n=9); Europe includes France (n=6), Germany (n=4), Italy (n=9), and Spain (n=11); South America includes Argentina (n=20) and Chile (n=16)

1. Felizarta F, et al. IAS 2025. Poster EP0170; **2.** Rolle C-P, et al. CROI 2026. Poster 525

VOLITION: Key insights from 2025

Dr Pedro Cahn

Fundación Huésped, Buenos Aires, Argentina

The power of choice: Preference following suppression in people with HIV

Felizarta F, et al. IAS 2025. Poster EP0170

Methods

- We present participant experience data which were evaluated at baseline and Day of Choice using questionnaires
- Outcomes included:
  - Choice of regimen and reasons for switching
  - Psychological challenges related to HIV treatment (DoC only)
  - Perceptions, barriers and facilitators of switching treatment
  - Acceptability and feasibility of switching (Acceptability of Intervention Measure [AIM] and Feasibility of Intervention Measure [FIM]; DoC only)*
  - Emotions and feelings relating to HIV diagnosis and status

*AIM and FIM are rated on a 1–5 Likert scale: 1 = “completely disagree”; 2 = “disagree”; 3 = “neither agree nor disagree”; 4 = “agree”; 5 = “completely agree”

The proportion of participants who reported worry about their HIV diagnosis decreased by DoC

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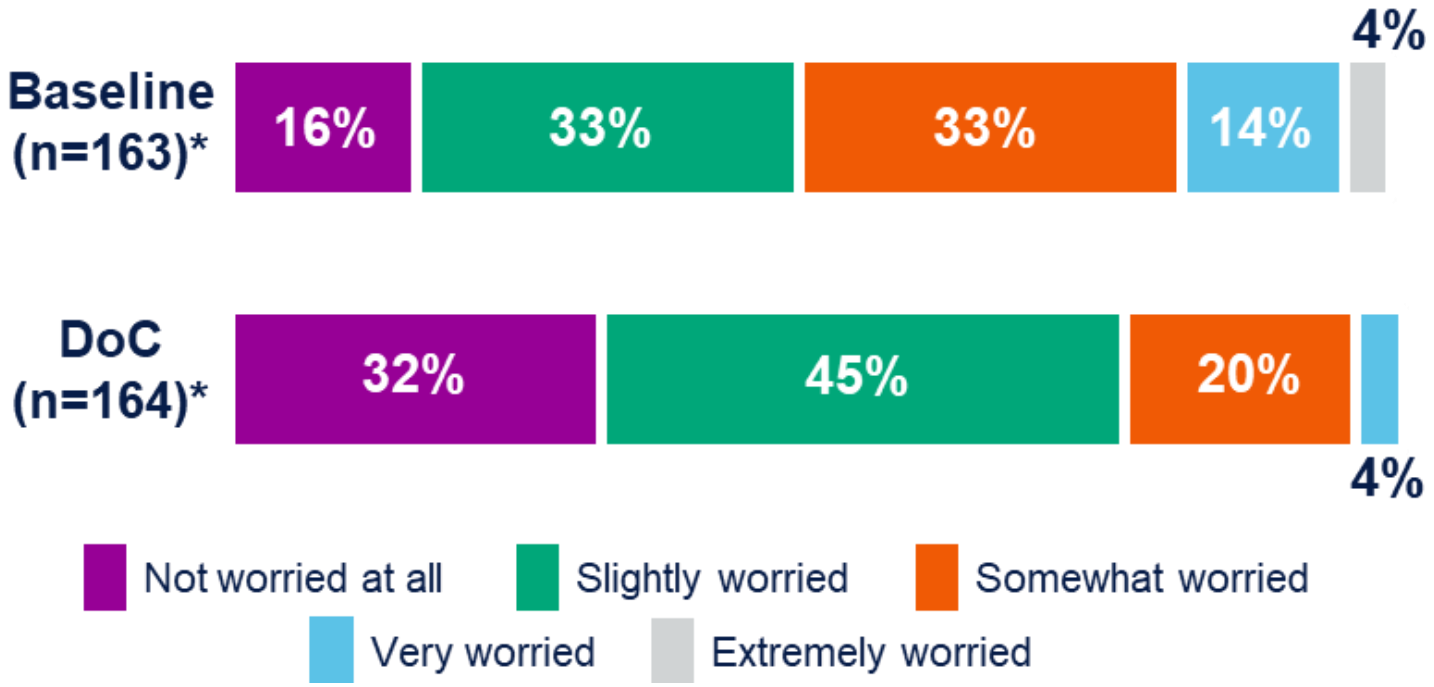
"How do you feel about your HIV diagnosis?"



*Includes all participants who completed questionnaires within the window at each timepoint (n=8 and n=7 participants had missing data at baseline and DoC, respectively)

Felizarta F, et al. IAS 2025. Poster EP0170

Fewer participants reported experiencing negative emotions or feelings due to their HIV status at DoC versus baseline

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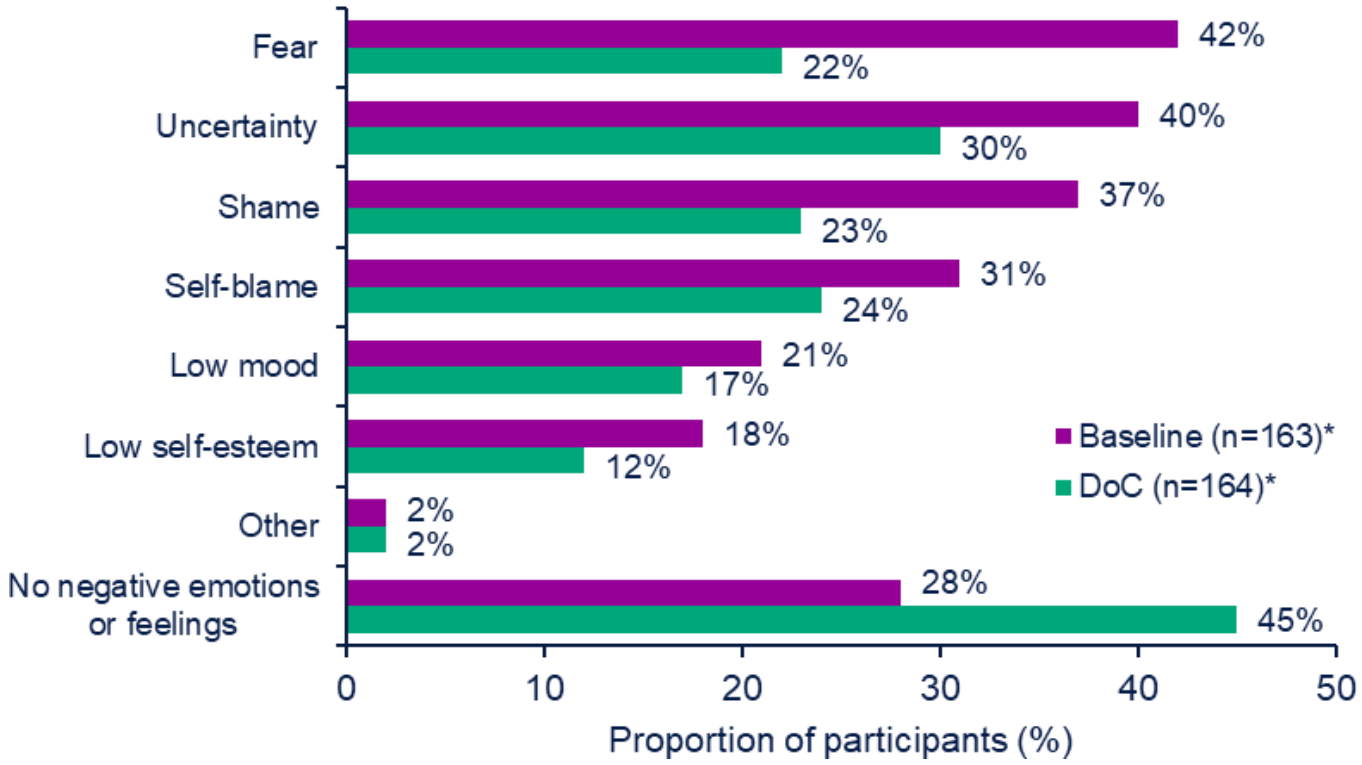
"Are you experiencing any of the following negative emotions or feelings due to your HIV status?"



*Participants could select more than one response. Includes all participants who completed questionnaires within the window at each timepoint (n=8 and n=7 participants had missing data at baseline and DoC, respectively)

Felizarta F, et al. IAS 2025. Poster EP0170

Participants valued being empowered with the choice to switch and its associated advantages

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- At DoC, participants found the option of switching to CAB + RPV LA highly acceptable (mean [SD] AIM: 4.4 [0.78])
- Participants found the act of switching feasible (mean [SD] FIM: 4.3 [0.89])

"How does it feel to be given a choice about your future HIV treatment?" (n=155)*

- **72%** "I am happy to know there are options for future treatment to match my lifestyle"
- **55%** "It provides me with an option to suit my needs and daily life"
- **53%** "It gives me hope for the future"

"What are the advantages of having the option of switching from a daily pill for HIV treatment to a LA HIV injection treatment to keep your HIV undetectable (virally suppressed)?" (n=155)*

- **70%** "The option to switch fits my life better"
- **67%** "Freedom to travel without concern about keeping my HIV undetectable"
- **58%** "I get more of a say/more autonomy in my treatment"

*Includes all participants who were eligible for choice to switch from DTG/3TC to CAB + RPV LA. Participants could select more than one response. The three most commonly-reported answers are provided
SD, standard deviation

CAB + RPV LA was the preferred treatment at DoC for a variety of reasons

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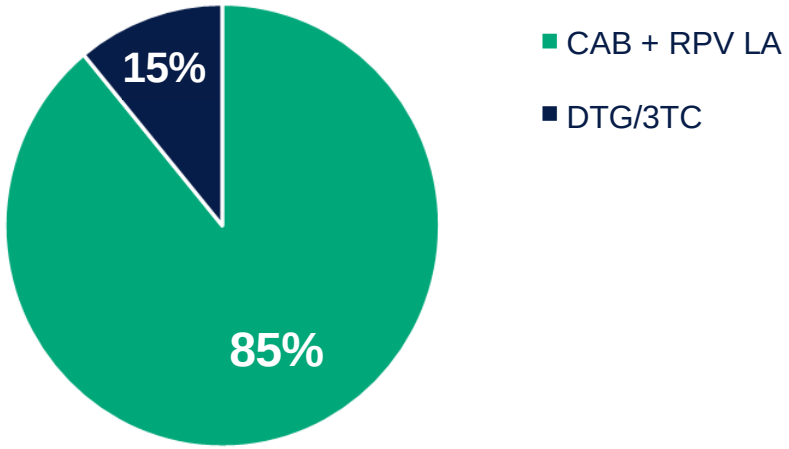
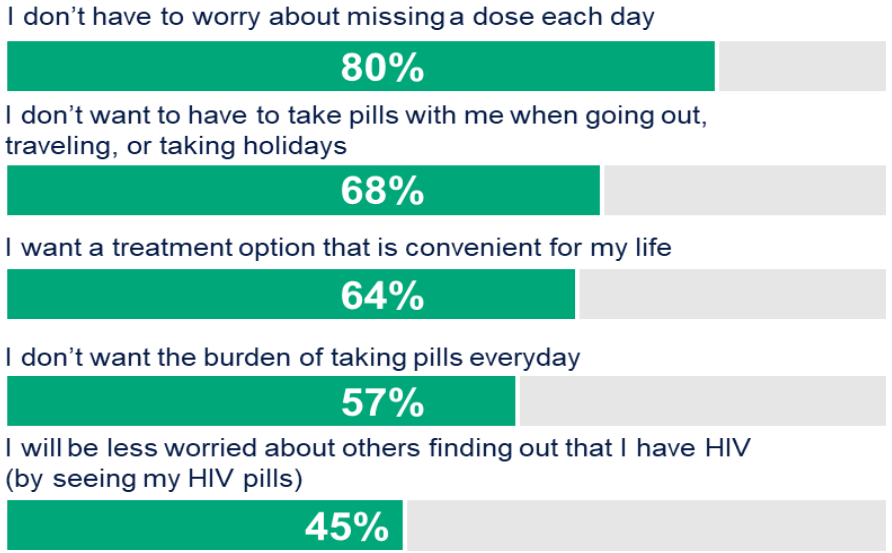
- Overall, 129 participants (85%; n=129/151) switched to CAB + RPV LA at DoC:[1,2]
  - Median age (range) was 31 (18–67), and 10% were ≥50 years
  - 26% were female, 33% were Black or African American, and 51% were Hispanic/Latinx
  - 21% had a BMI ≥30 kg/m^2

Proportion of participants who chose to switch to CAB + RPV LA or continue DTG/3TC (n=151)*



Top five participant-reported reasons for switching to CAB + RPV LA (n=129)†[1]



*Four participants withdrew from the study prior to DoC; adverse event (n=1), lost to follow-up (n=1), physician decision (n=2); 22 were ineligible to switch: HIV-1 RNA not suppressed (n=15), HIV subtype A1/A6 (n=1), other (n=6). †Responses are not mutually exclusive. The most common reasons why participants chose to remain on DTG/3TC included: believing that remembering to take the pill daily was easy, or it will be easy to take their daily pill for HIV treatment daily (31%, n=13/42) and not liking injections (17%, n=7/42)

1. Felizarta F, et al. IAS 2025. Poster EP0170; **2**. Rolle C-P, et al. CROI 2026. Poster 525

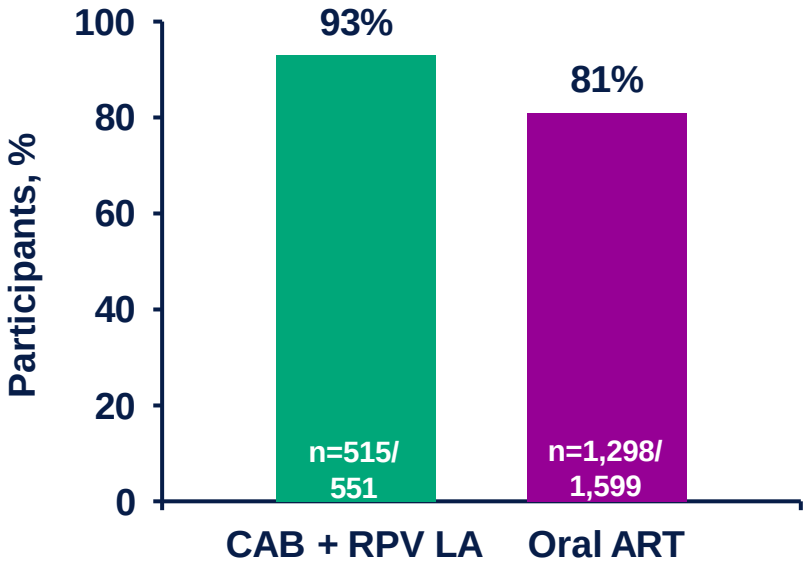
CAB + RPV LA is associated with greater engagement and retention in care compared with daily oral ART

- As CAB + RPV LA is administered Q2M by a HCP,[1] this provides the opportunity for **additional healthcare touchpoints** and potential **supplementary benefits**, including better retention and engagement in care[2]

- The real-world **OPERA** study reported a higher proportion of **retention in care** versus oral ART after ≥12 months following switch to CAB + RPV LA*[2]
  - An increase in HCP touchpoints gave **additional opportunities for early detection** of HIV progression, STIs and chronic diseases[2,3]

- The real-world **BEYOND** study reported 55% (n=125/227) of people with HIV who switched to CAB + RPV LA felt **more engaged in managing their HIV**[4]

Proportion of participants retained in care in the OPERA study[2]



1. Cabenuva US PI. November 2025; **2.** Lackey PC, et al. AIDS 2024. Poster; **3.** Lackey PC, et al. IDWeek 2024. Poster 577; **4.** Valenti W, et al. AIDS 2024. Poster TUPEB116

***CDC definition of retention in care: two or more VL or CD4 tests per year, ≥3 months apart[5]
CDC, Centers for Disease Control and Prevention; **STI,** sexually transmitted infection

People with HIV preferred CAB + RPV LA to daily oral therapy in real-world studies

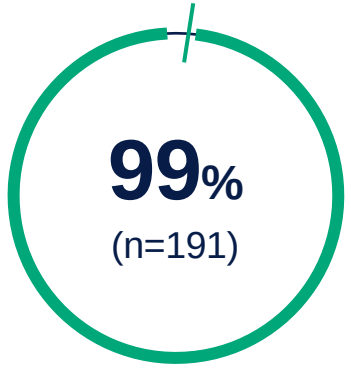
Participant preference for CAB + RPV LA versus previous daily oral ART:

Hospital Ramón y Cajal[1]
Median (IQR) follow-up: 15 (9–22) months
(Spain; Q2M*)

CARLOS‡[2]
Month 24
(Germany; Q2M)

BEYOND§[3]
Month 24
(US; Q1M/Q2M)

Hospital Clínic Barcelona[4]
Week 52
(Spain; Q2M*)



PREFER-LA[5]
Median (IQR) follow-up: 12 (9–15) months
(US)

Includes the largest discrete cohorts reporting treatment preference outcomes. Potential overlap between cohorts cannot be ruled out
*This is an assumption as only Q2M dosing is available in Europe; †Participants wanting to continue on CAB + RPV LA
‡People with HIV switched from suppressive daily oral therapy to CAB + RPV LA Q2M in accordance with the label[6]
§People with HIV switched from suppressive daily oral therapy to CAB + RPV LA Q1M (52%) or Q2M (48%) and could be consistent (76%) or inconsistent with the label (24%)[7]

1. Rosas-Cancio M, et al. IAS 2025. Poster EP0184
2. Wyen C, et al. AIDS 2026 Jan 20. Online ahead of print; **3.** Felizarta F, et al. IAS 2025. Poster THPEB036
4. González-Cordón A, et al. GeSIDA 2024. Poster PT-10
5. Henry Z, et al. IDWeek 2025. Poster P-396; **6.** Borch J, et al. HIV Glasgow 2022. Oral O43
7. Sinclair G, et al. IDWeek 2023. Poster 1607

The power of choice:
HCP perspectives on early switch

Jonsson-Oldenbüttel C, et al. EACS 2025. Oral RO2.5

Provider perceptions of choice, and impact of shared decision making, on newly suppressed people living with HIV were assessed

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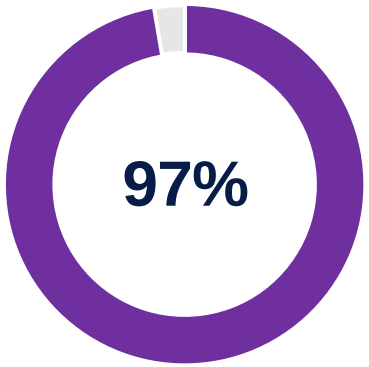
- Providers completed electronic **quantitative questionnaires** (n=101) at baseline and at DoC, **and qualitative interviews** (n=80) at DoC
- This mixed method approach was used to assess the acceptability, feasibility, perceptions, barriers to, and facilitators of, providing the **option to switch to CAB + RPV LA**
  - The acceptability and feasibility of the option to switch to CAB + RPV LA were assessed using the 4-item Acceptability of Intervention (AIM) and Feasibility of Intervention (FIM) measures rated on a Likert scale (1=completely disagree and 5=completely agree)
  - Qualitative data were analysed using a framework analysis approach

Locations of the providers (n=101)

Provider role (n=80, qualitative interviews):*
- Principal investigator: n=15
- Site coordinator: n=39
- Other (including nurse or sub-investigator): n=26

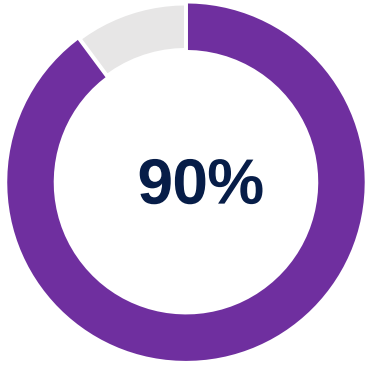
*Locations for providers who participated in qualitative interviews at DoC. North America (n=36/80): United States (30), Canada (4), Puerto Rico (2); South America (n=11/80): Argentina (8), Chile (3). Europe (n=33/80): Spain (15), France (10), Italy (6), Germany (2)

Results: Providers indicated confidence and satisfaction with CAB + RPV LA



Providers shared positive perspectives of CAB + RPV LA (n=71/73*)

- 28% (n=20/71) of providers with positive perspectives stated that CAB + RPV LA fits lifestyles/increases autonomy of people living with HIV



Providers reported confidence in CAB + RPV LA efficacy and satisfaction with the treatment (n=53/59*)

- 81% (n=43/53) cited prior clinical experience as the main reason for confidence and satisfaction with CAB + RPV LA

*73/80 HCP discussed their own perceptions of CAB + RPV LA in their qualitative interview; 59/80 HCPs discussed their confidence or satisfaction with the efficacy and safety of CAB + RPV LA in their qualitative interview

Jonsson-Oldenbüttel C, et al. EACS 2025. Oral presentation RO2.5

Offering the choice to switch immediately after virologic suppression has more perceived advantages than disadvantages to HCPs

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Advantages of switching to CAB + RPV LA*

The option helps people living with HIV who are tired of taking pills every day	**73%** (n=69/101)
The option reduces stress or anxiety over daily adherence	**73%** (n=69/101)
The option helps people living with HIV who are concerned about disclosure of their HIV status/others finding their pills	**72%** (n=68/101)

Disadvantages of switching to CAB + RPV LA*

Healthcare teams may not have systems in place to adequately track changes between DTG/3TC and CAB + RPV LA	**35%** (n=33/101)
The flexibility provided may prevent people living with HIV from forming a routine with their treatment	**27%** (n=26/101)
There are no disadvantages	**27%** (n=26/101)

- At DoC, offering the choice to switch shortly after suppression was highly feasible and acceptable (FIM: 4.3 [0.84], n=74; AIM: 4.4 [0.79], n=74)†

*Responses are not mutually exclusive; †Mean [SD]; 1 = completely disagree and 5 = completely agree

Jonsson-Oldenbüttel C, et al. EACS 2025. Oral presentation RO2.5

VOLITION 2025 data: Summary

In VOLITION, most participants felt that being given the **choice** to switch to CAB + RPV LA provided greater freedom to travel and more autonomy in their treatment[1]

Most eligible participants chose to switch to CAB + RPV LA at DoC (85%)[2] and found switching **highly acceptable and feasible**[1]

HCPs reported that offering the choice of treatments as part of **shared decision making** had more advantages than disadvantages in the clinical management of their patients[3]

1. Felizarta F, et al. IAS 2025. Poster EP0170; **2.** Rolle C-P, et al. CROI 2026. Poster 525; **3.** Jonsson-Oldenbüttel et al. EACS 2025. Oral presentation RO2.5

Early Switch to CAB+RPV LA in Treatment-Naive Adults With HIV-1: Month 11 Outcomes From VOLITION

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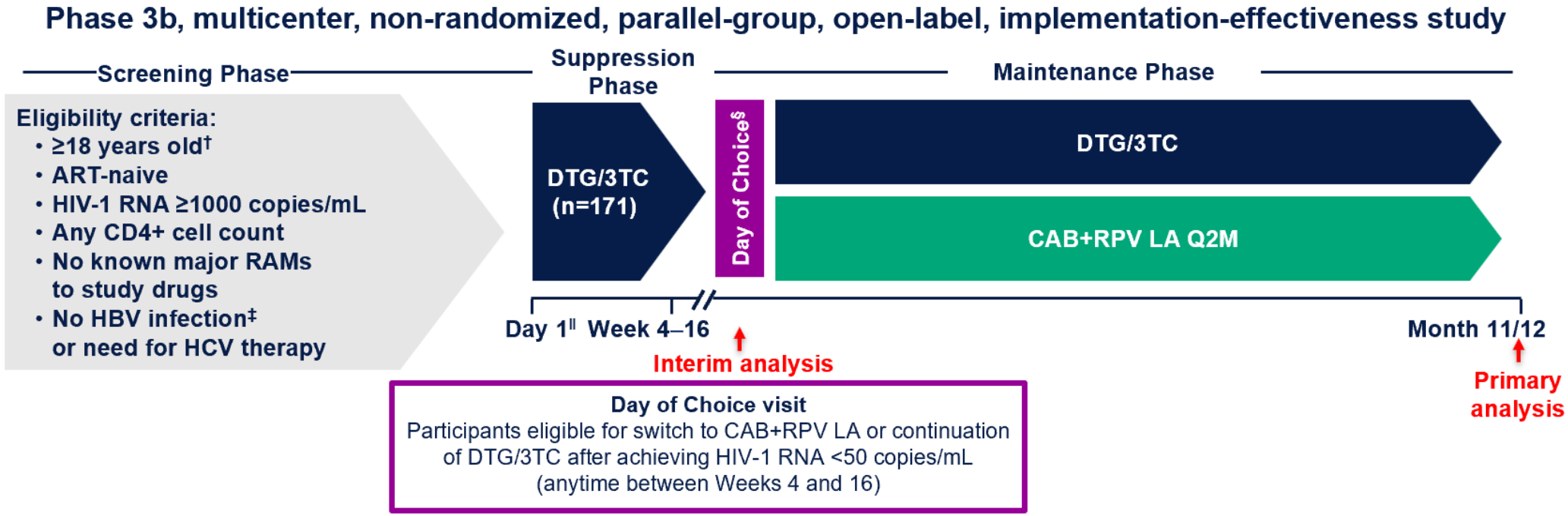
Introduction

- CAB+RPV LA is the first and only complete LA injectable regimen dosed every 2 months (Q2M), and is recommended for the treatment of virologically suppressed people with HIV (PWH)[1]
- In real-world and clinical studies, CAB+RPV LA has demonstrated durable efficacy and a low virologic failure rate,[2-9] with greater treatment satisfaction and preference over daily oral therapy[10-12]
- CAB+RPV LA and dolutegravir and lamivudine (DTG/3TC) are integrase strand transfer inhibitor-based, HIV antiretroviral therapy (ART) regimens with different modalities and dosing frequencies, allowing for greater patient choice and selection of regimens according to lifestyle considerations
- VOLITION (NCT05917509) is the first study to evaluate optional early switch to CAB+RPV LA, through shared decision-making, immediately after attaining virologic suppression with DTG/3TC in ART-naive adults with HIV-1
  - Time to virologic suppression (HIV-1 RNA <50 copies/mL) from Day 1 was a co-primary endpoint; DTG/3TC enabled rapid virologic suppression with median time to suppression of 4.1 weeks (95% CI: 4.1–4.3)[13]
  - On Day 1, 85% (n=101/119) of participants who had considered what treatment they would choose at Day of Choice (DoC) expressed an interest in switching to CAB+RPV LA therapy[13]
- Here, we present VOLITION Month 11 outcomes for participants choosing to switch to CAB+RPV LA

1. US Department of Health and Human Services. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed January 2026. **2.** Kityo et al. *Nat Med*. 2026;32:168-177. **3.** Orkin et al. *N Engl J Med*. 2020;382:1124-1135. **4.** Overton et al. *Lancet*. 2021;396:1994-2005. **5.** Ramgopal et al. *Lancet HIV*. 2023;10:e566-e577. **6.** Swindells et al. *N Engl J Med*. 2020;382:1112-1123. **7.** John et al. *HIV Med*. 2024;25:935-945. **8.** Wyen et al. *AIDS*. 2026 [Epub ahead of print]. **9.** Sension et al. IDWeek 2025; Atlanta, GA. Poster P-371. **10.** Mussini et al. *AIDS Behav*. 2025;29:64-76. **11.** Chounta et al. *Patient*. 2021;14:849-862. **12.** Murray et al. *AIDS Behav*. 2020;24:3533-3544. **13.** Córdova et al. IAS 2025; Kigali, Rwanda. Poster WEPEB033.

VOLITION Study Design*



*VOLITION was conducted at 45 sites across the United States (n=15), Spain (n=8), France (n=5), Italy (n=4), Argentina (n=4), Chile (n=4), Germany (n=3), and Canada (n=2). †≥18 years (or older, if required by local regulations). ‡Participants positive for HBsAg were excluded. Participants negative for anti-HBs but positive for anti-HBc were excluded only if HBV DNA was detected. §Participants proceeded to DoC at their next study visit following the first plasma HIV-1 RNA result <50 copies/mL (Week 4 at the earliest but no later than Week 16). Participants had to be suppressed <50 copies/mL in order to qualify for option switch to CAB+RPV LA. Exclusion criteria for switch included: treatment-emergent ALT ≥5×ULN; or ALT ≥3×ULN and bilirubin ≥1.5×ULN (with >35% direct bilirubin) and pregnancy. DoC is used as baseline for CAB+RPV LA switch participants in the Maintenance Phase. ‖Day 1 is used as baseline for full study population at Suppression Phase and for participants continuing DTG/3TC into the Maintenance Phase.
3TC, lamivudine; ALT, alanine aminotransferase; anti-HBc, hepatitis B core antigen antibody; anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; CAB, cabotegravir; DoC, Day of Choice; DTG, dolutegravir; HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; LA, long-acting; Q2M, every 2 months; RAM, resistance-associated mutation; RPV, rilpivirine; ULN, upper limit of normal.

Methods

- The VOLITION study evaluated initial virologic suppression with DTG/3TC up to ~16 weeks followed by participant-determined optional switch to CAB+RPV LA dosed Q2M or continuation of DTG/3TC through Month 11/12
- A co-primary endpoint was the proportion of participants with HIV-1 RNA <50 copies/mL per Snapshot algorithm at Month 11 with CAB+RPV LA
  - Observed data, comprising only participants with available virologic data in-window, are also presented
- Secondary outcomes assessed included:
  - The proportion of participants with confirmed virologic failure (CVF; defined as two consecutive plasma HIV-1 RNA values ≥200 copies/mL after prior suppression to <50 copies/mL)
  - Safety and tolerability
  - Patient experience outcomes: Reasons for switch; advantages of having the option to switch to CAB+RPV LA; treatment satisfaction (12-item HIV Treatment Satisfaction Questionnaire status version [HIVTSQs]); treatment preference (preference questionnaire [single question])

Methods (cont)

- HIV-1 RNA was measured using the Roche cobas 6800 assay (F. Hoffmann-La Roche) for participant virologic management. Prior studies in the clinical development program have used the RealTime HIV-1 assay (Abbott)
- During the study, it was noted in contemporaneous trials, including VOLITION, that central lab viral load results were inconsistent with local lab findings, prompting additional testing using the RealTime assay
- Virologic efficacy analyses presented here are based on the results from the RealTime assay (modified Snapshot algorithm)

Results

- Overall, 171 participants enrolled in the study and initiated DTG/3TC, 151 (88%) of whom were eligible and were offered the choice to switch to CAB+RPV LA at DoC*
- Of those offered the choice, 129 (85%) participants chose to switch to CAB+RPV LA
- A diverse population of participants was represented, comprising 51% Hispanic/Latinx, 33% Black or African American, and 26% women

*Four participants withdrew during the suppression phase; reasons for ineligibility for switch were: did not achieve virologic suppression (defined as HIV-1 RNA <50 copies/mL; n=15); and baseline resistance to NNRTI [E138A] (n=1).

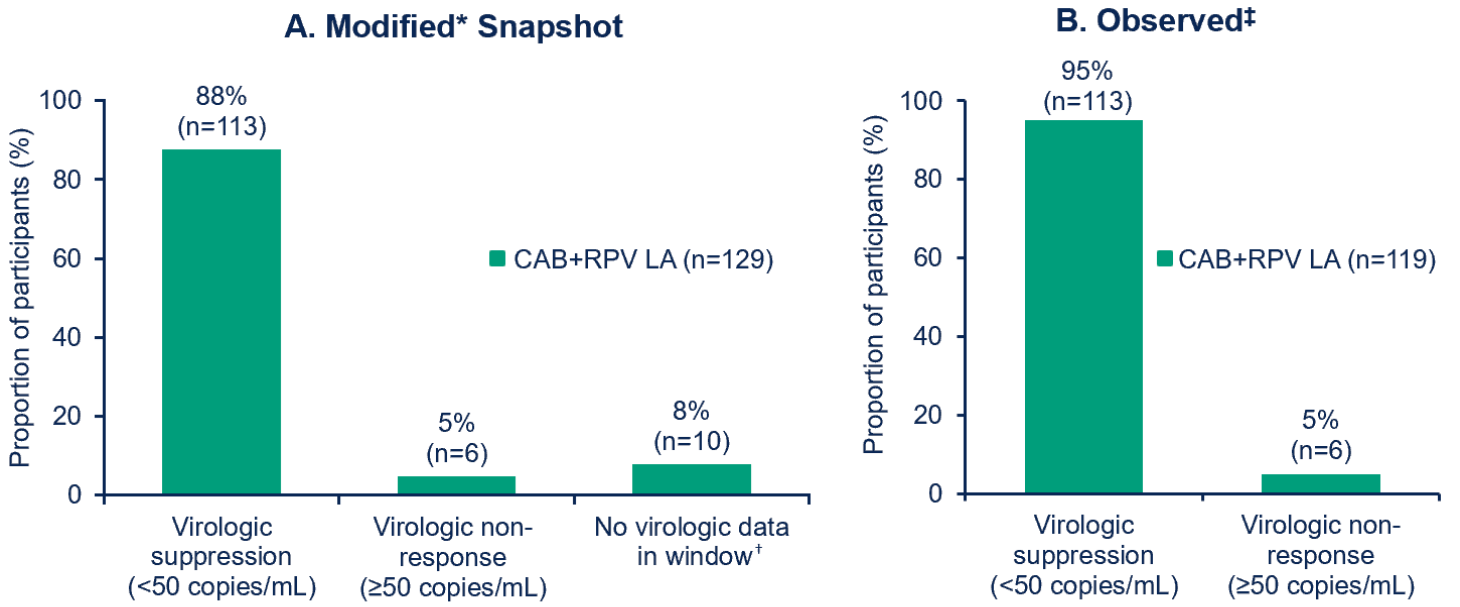
A Diverse Population of Participants Chose to Switch to CAB+RPV LA at DoC

Parameter	CAB+RPV LA (n=129)
Median years (range)	31 (18–67)
<35 years, n (%)	79 (61)
35–<50 years, n (%)	37 (29)
≥50 years, n (%)	13 (10)
Women (self-reported gender), n (%)	34 (26)
Race, n (%)	
Black or African American	42 (33)
White	77 (60)
Other races*	5 (4)
Not reported or unknown	5 (4)
Hispanic/Latinx ethnicity, n (%)	66 (51)
Region, n† (%)	
North America	63 (49)
Europe	30 (23)
South America	36 (28)
Median (IQR) weight (kg)	77.7 (65.3, 86.0)
Median (IQR) BMI (kg/m^2)	25.5 (22.4, 29.4)
BMI (kg/m^2) category, n (%)	
Overweight (25 to <30)	47 (36)
Obesity (≥30)	27 (21)
Median (IQR) CD4+ cell (cells/mm^3)	555 (427, 668)
CD4+ cell (cells/mm^3) category, n (%)‡	
<100	1 (<1)
100 to <200	7 (6)
200 to <350	20 (16)
≥350	98 (78)

*Other race participants: Multiple, n=3; Asian, n=2. †North America includes United States (including Puerto Rico; n=54) and Canada (n=9); Europe includes France (n=6), Germany (n=4), Italy (n=9), and Spain (n=11); South America includes Argentina (n=20) and Chile (n=16). ‡n=126.
3TC, lamivudine; BMI, body mass index; CAB, cabotegravir; DoC, Day of Choice; DTG, dolutegravir; IQR, interquartile range; LA, long-acting; NNRTI, non-nucleoside reverse transcriptase inhibitor; RPV, rilpivirine.

High Rate of Virologic Suppression at Month 11

- At Month 11, high rates of virologic suppression were observed following early switch to CAB+RPV LA, with 88% (n=113/129) of participants maintaining virologic suppression, per the modified Snapshot. The observed virologic suppression rate at Month 11 was 95% (n=113/119 with available virologic data in-window)
- Of the 729 injection visits in the maintenance phase, 661 (91%) were administered within the dosing window (89% [652/729]) or earlier (1% [9/729]; >7 days before the target injection date); the median (IQR) delay for late injections was 9 (8–10) days



*In the modified Snapshot algorithm, RealTime HIV-1 RNA results were prioritized over the cobas 6800 assay when available and within the Snapshot window. †n=10 discontinued study for other reasons. ‡Includes only participants with available virologic data in-window.
CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

CD4+ Cell Counts Improved From DoC to Month 11 with CAB+RPV LA

- Median (interquartile range [IQR]) CD4+ cell counts increased from DoC to Month 11 by 78 (–10, 182) cells/mm3 (n=118/129) following early switch to CAB+RPV LA, with an absolute (median [IQR]) CD4+ count of 624 (431, 826) cells/mm3 at Month 11

One Participant Met CVF Criteria With Emergent Resistance

	Participant*
Sex at birth, age range (years)	Male, 20–29
BMI (kg/m^2)†	≥30
HIV-1 subtype	B
Viral load at Day 1 (copies/mL; cobas 6800)	55,700
RAMs at DoC (proviral DNA)	None
Time to virologic failure (months)	9
Viral load at SVF/CVF (copies/mL; cobas 6800)	405/1410
Viral load at SVF/CVF (copies/mL; RealTime)	285/1213
RAMs at failure	NNRTI: M230L INSTI: E138K, Q148K
ART following CAB+RPV LA discontinuation	DRV/COBI/FTC/TAF‡

- One (<1%) participant met CVF criteria with emergent INSTI and NNRTI resistance
- Three additional participants were withdrawn from the study after meeting CVF criteria with the cobas 6800 assay; these participants did not meet CVF criteria based on retrospective retesting with the RealTime assay
  - None of these participants had treatment-emergent resistance mutations

*CAB+RPV LA injections were administered with 1.5-inch needles, and all injections were received on time. †BMI at DoC. ‡Participant resuppressed within ~6 months.
ART, antiretroviral therapy; BMI, body mass index; CAB, cabotegravir; COBI, cobicistat; CVF, confirmed virologic failure; DoC, Day of Choice; DRV, darunavir; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; RAM, resistance-associated mutation; SVF, suspected virologic failure; TAF, tenofovir alafenamide fumarate; TDF, tenofovir disoproxil fumarate.

CAB+RPV LA Was Well Tolerated Through Month 11

Parameter, n (%)	CAB + RPV LA (n=129)
Any AE	97 (75)
Drug-related AE*	66 (51)
Injection site pain	55 (43)
Injection site discomfort	9 (7)
Injection site nodule	5 (4)
Injection site bruising	4 (3)
Drug-related AEs excluding ISRs	13 (10)†
Grade 3 to 4 AEs	17 (13)
Drug-related Grade 3 to 4 AEs	3 (2)‡
AEs leading to withdrawal	0
Any SAEs	12 (9)§
Drug-related SAEs	0
Fatal AEs	0

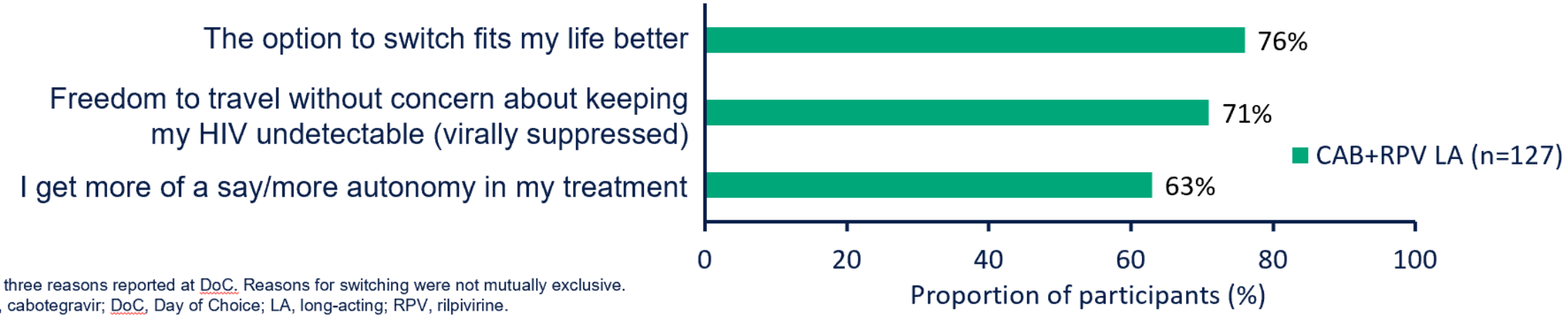
*AEs occurring in more than 2% of participants are shown. †Drug-related, non-ISR AEs occurring in >1 participant: pyrexia (n=3), back pain (n=2), myalgia (n=2), pain in extremity (n=2), dizziness (n=2), headache (n=2), and nausea (n=2). ‡Three participants had drug-related Grade 3 events: injection site pain (n=2) and injection pain swelling (n=1 [participant had two instances of this AE])
§SAEs included (all n=1) spontaneous abortion, oral abscess, acute kidney injury, burn infection, cardiac failure, cellulitis, facial paralysis, erosive gastritis, herpes zoster, latent tuberculosis, metastatic malignant melanoma, pancreatitis acute, pneumonia, and suicidal ideation.
AE, adverse event; CAB, cabotegravir; ISR, injection site reaction; LA, long-acting; RPV, rilpivirine; SAE, serious adverse event.

Results (cont)

- Overall, 51% of participants had a drug-related AE, the majority of which were ISRs
- ISRs were reported in 49% (n=63/129) of participants, most of which were Grade 1 or 2 (98%), with a median (IQR) duration of 3 days (2–6)
- There were no AEs leading to withdrawal and no participant had drug-related SAEs; no deaths occurred

Top Advantages of Having the Option to Switch to CAB+RPV LA Centered Around Lifestyle Fit, Greater Freedom, and More Autonomy*

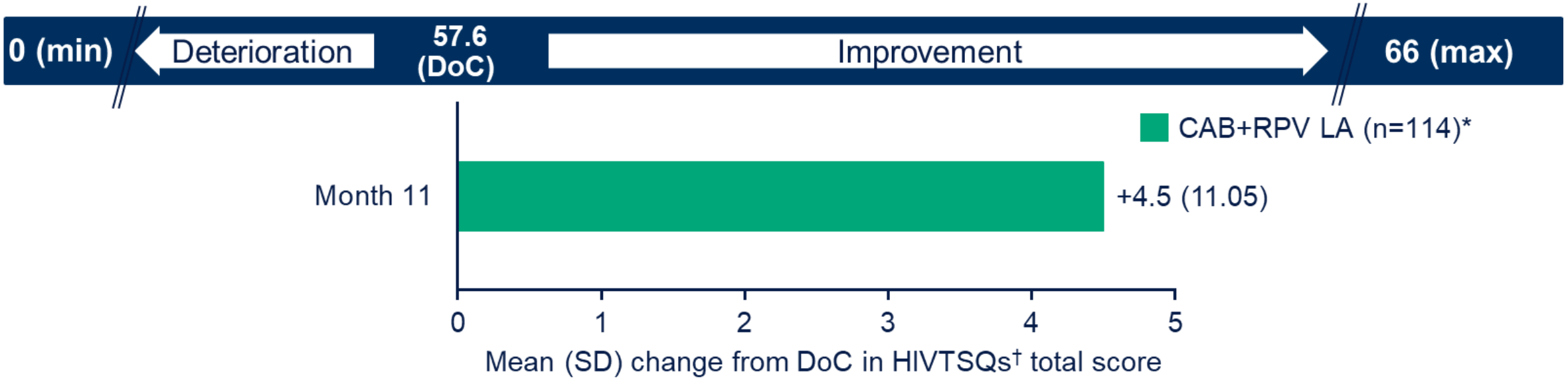
- When asked about the perceived advantages of having the option to switch to CAB+RPV LA at DoC, participants most frequently cited better fit with life (n=96/127, 76%), freedom to travel, (n=90/127, 71%), and more autonomy in their treatment (n=80/127, 63%)
- At DoC, the most common reasons for switching to CAB+RPV LA were to avoid worrying about missed daily doses (n=103/129, 80%), travel convenience (n=88/129, 68%) and lifestyle fit (n=82/129, 64%)



*Top three reasons reported at DoC. Reasons for switching were not mutually exclusive.
CAB, cabotegravir; DoC, Day of Choice; LA, long-acting; RPV, rilpivirine.

Treatment Satisfaction Improved After DoC and Remained High Through Month 11 With CAB+RPV LA

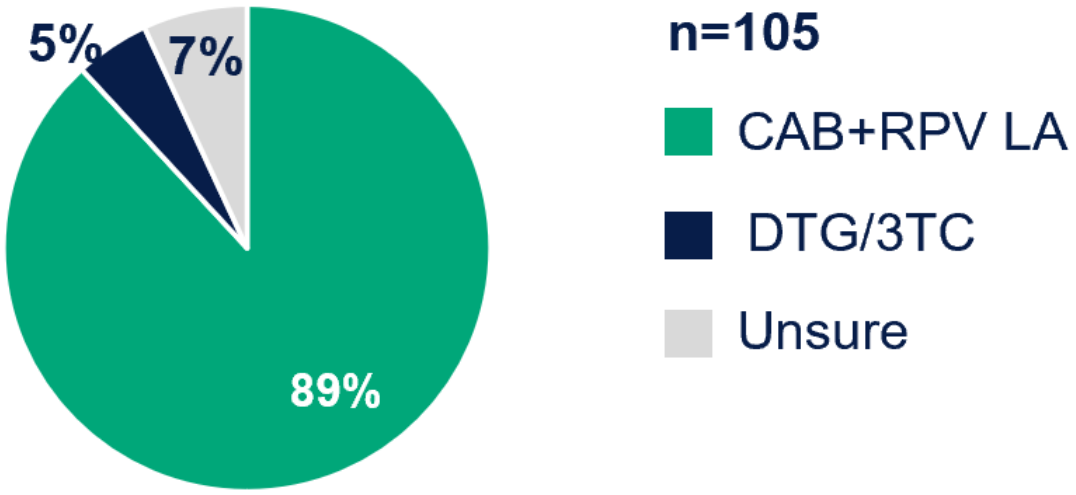
- Participants reported high levels of treatment satisfaction at DoC (mean [standard deviation; SD] total score, 57.6 [10.36]; n=127) which improved to Month 11



*DoC, n=127; Month 11; n=114. †HIVTSQs: 12-item version; range per item 0–6, where 0 = "very dissatisfied" and 6 = "very satisfied." Total score = sum of item 1–11.
CAB, cabotegravir; DoC, Day of Choice; HIVTSQs, HIV Treatment Satisfaction Questionnaire status version; LA, long-acting; RPV, rilpivirine; SD, standard deviation.

The Majority of Participants Planned to Continue CAB+RPV LA After the Study

Participant-reported, post-study treatment plans*



- At Month 11, 89% (n=93/105) of participants receiving CAB+RPV LA who responded to the preference questionnaire stated that they planned to continue CAB+RPV LA after the study

*Includes only participants who received CAB+RPV LA and responded to the questionnaire. The question asked was “”What are your plans for your treatment after the study ends?”. Options selected were “I will continue with CAB+RPV LA (injection)”, “I am currently on CAB+RPV LA (injection) but I am not sure if I will continue with it”, and “I am currently on CAB+RPV LA (injection) but I will switch back to DTG/3TC (pill)”. Where percentages do not sum to 100%, this is due to rounding.
3TC, lamivudine; CAB, cabotegravir; DTG, dolutegravir; LA, long-acting; RPV, rilpivirine.

Conclusions

- In VOLITION, providing ART-naive individuals with the option for early switch to CAB+RPV LA immediately following virologic suppression with daily oral therapy, allowed them to choose a treatment to meet their individualized needs, which is essential for long-term treatment success and optimized quality of life
- Early switch to CAB+RPV LA demonstrated:
  - High rates of virologic suppression
  - Low rates (<1%) of CVF with resistance
  - High treatment satisfaction with CAB+RPV LA at Month 11
  - High rates of preference for continuing CAB+RPV LA after the study
- CAB+RPV LA was well tolerated, with no new safety signals identified
- The VOLITION study integrates shared decision-making into treatment selection by empowering people to choose their preferred treatment, which can facilitate better alignment with individual preferences and support treatment success

Empowering people with the option for early switch to CAB+RPV LA immediately following virologic suppression through shared decision-making can enable treatment success, as shown by high rates of virologic suppression, low rates of CVF with resistance, and high treatment satisfaction and preference at Month 11.

VOLITION: Key takeaways

In the VOLITION study, **most eligible ART-naïve individuals chose to switch to CAB + RPV LA** after achieving rapid virologic suppression with DTG/3TC

Offering CAB + RPV LA immediately after suppression in **early switch** resulted in:

- **High rates of virologic suppression** for those on CAB + RPV LA (**95%,** n=113/119)
- Low rates of CVF with resistance (<1%, n=1/129)
- Good tolerability profile from well established classes of ART

Choice of treatment with CAB + RPV LA showed **no withdrawals due to AEs or ISRs**

CAB + RPV LA showed **high treatment satisfaction** and **ongoing preference** after 11 months

AE, adverse event; **ISR**, injection-site reaction

Rolle C-P, et al. CROI 2026. Poster 525