

Centering the Patient in HIV Care with LA CAB + RPV

Suppression and Additional Treatment Goals

We will begin shortly...



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ViiV Faculty



Mark Lewandowski, PharmD

Medical Director, LAIs for Treatment
ViiV Healthcare

Moderator



Elizabeth Moore, PhD

Medical Manager- LAIs for Treatment
ViiV Healthcare

Presenter

Centering the Patient in HIV Care with LA CAB + RPV: Suppression and Additional Treatment Goals



Daniela Chiriboga, MD

Physician
Midway Specialty Care



Gary Sinclair, MD

Medical Director of Clinical Research
Prism Health North Texas

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



Agenda

September 9 • 7:00 – 8:15 PM ET



Centering the Patient
in HIV Care



with CAB+RPV LA

Overview of CAB + RPV LA

Beyond Suppression

Bringing it all Together

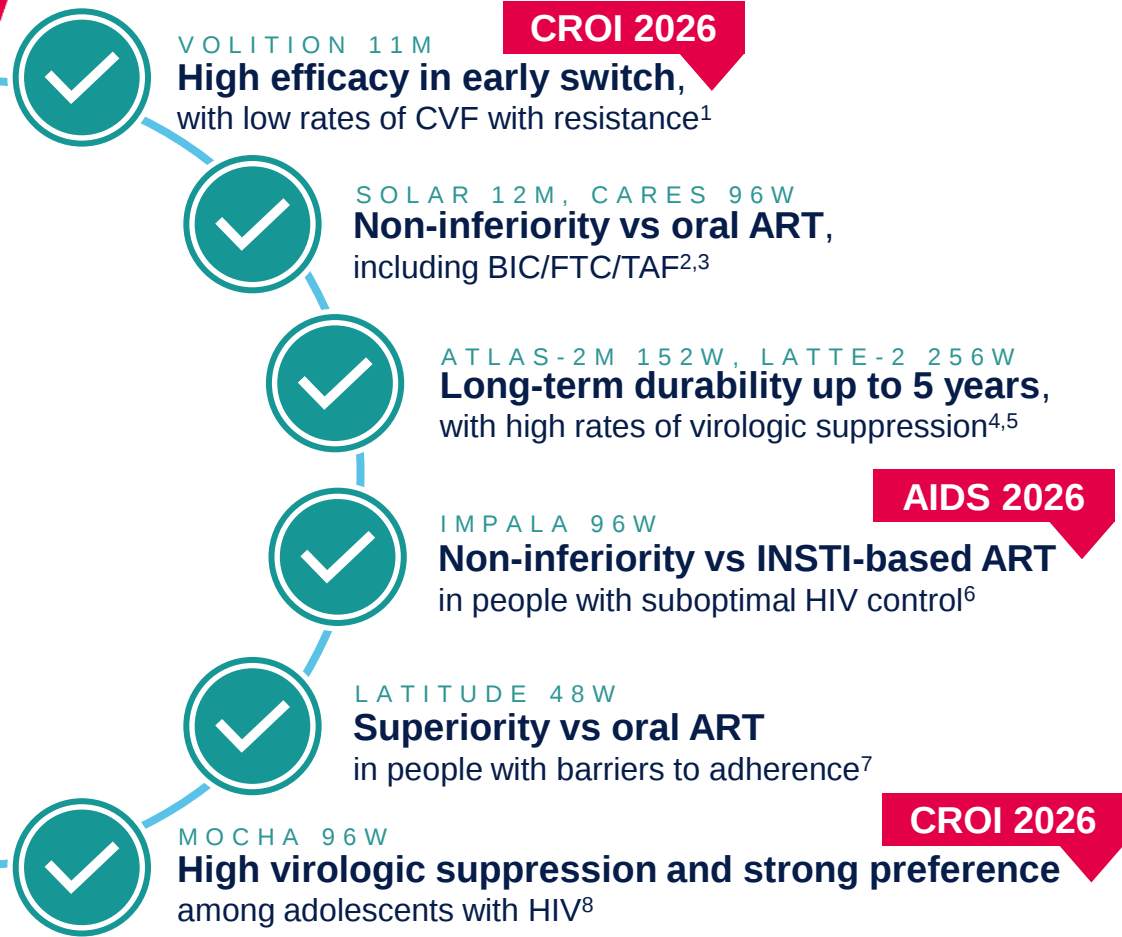
Q&A

Please use the Q&A function to submit comments and questions throughout the Webinar

CAB + RPV LA: Highly efficacious with long-term durability in people with HIV, including under-represented populations

ROBUST CLINICAL DEVELOPMENT AND PH III/IV PROGRAM

CONSISTENT EFFECTIVENESS IN REAL-WORLD EVIDENCE



Meta-analysis of published RWE at Month 12*⁹

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**, bicitegravir; **CAB**, cabotegravir; **CI**, confidence interval; **CVF**, confirmed virologic failure; **FTC**, emtricitabine; **M**, month; **RPV**, rilpivirine; **RWE**, real-world evidence; **TAF**, tenofovir alafenamide; **VL**, viral load; **W**, week

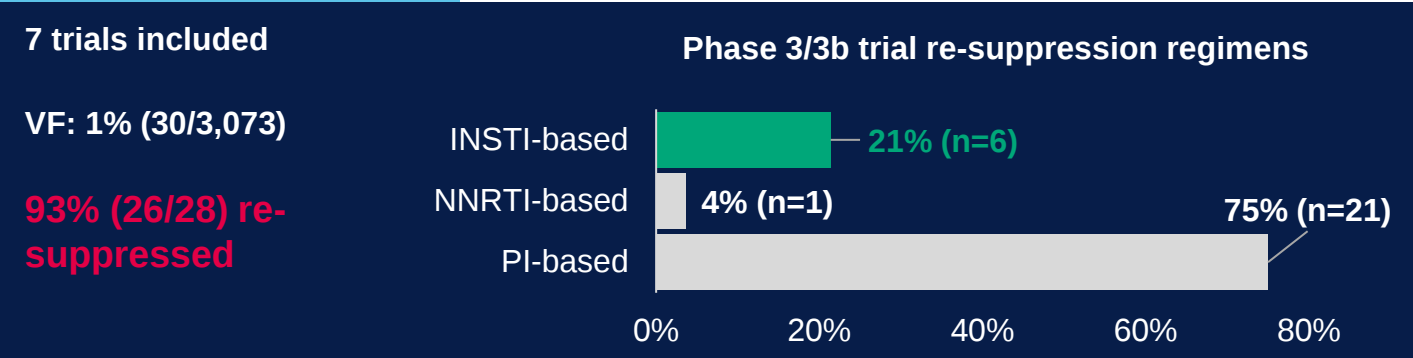
1. Cordova E, et al. Open Forum Infect Dis. 2026; ofag383.; 2. Ramgopal MN, et al. Lancet HIV 2023;10:e566–77
3. Kityo C, et al. Nat Med 2026;32:168–77; 4. Overton ET, et al. Clin Infect Dis 2023;76:1646–54
5. Smith G, et al. Open Forum Infect Dis 2021;8:ofab439; 6. Ruzagira E, et al. AIDS 2026. Poster LB24;
7. Rana AI, et al. N Engl J Med 2026 Feb 26;394(9):858-871; 8. Gaur A, et al. CROI 2026. Oral 155
9. Orkin C, et al. EACS 2025. Poster eP103

Re-Suppression on INSTI-based Regimens After VF in RCTs and RWE in Studies Evaluating CAB+RPV LA

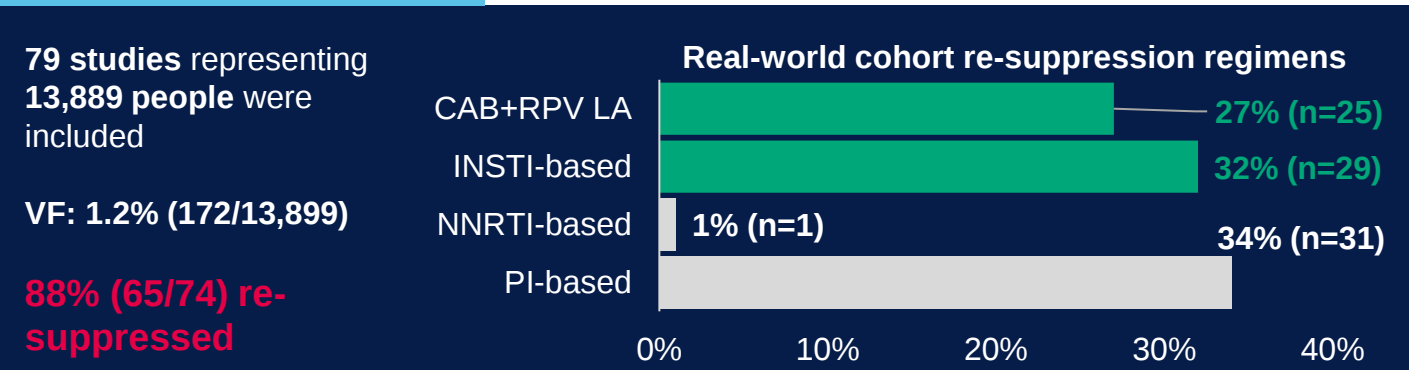
Systematic literature review (SLR)*

Phase 3/3b trials and real-world cohorts (N>10) that reported post-VF regimens and re-suppression outcomes.

Phase 3/3b trials^{1,2}



Real-world cohorts³



Additional studies reporting re-suppression post VF on CAB+RPV LA with INSTI-based regimens[†]

- Multi-country RCT in Uganda, Kenya, and South Africa⁴
- VF: 2.6% (7/268) at Week 96
- n=5 resuppressed on **INSTI-based regimen (TLD)**, n=1 on LPV/r +TDF/FTC, n=1 on ATZ/r/AZT/3TC

- Single-center case series of 6 patients who experienced VF on CAB + RPV LA in Ontario, Canada⁵
- n=5 resuppressed on **INSTI-based regimen (BIC/F/TAF)****

INSTI: integrase inhibitor; NNRTI: non-nucleoside reuptake inhibitors; PI: protease inhibitors; VF: virologic failure; TLD: tenofovir alafenamide, lamivudine, dolutegravir
*SLR used Pubmed, Embase, Cochrane and 23 HIV-related conferences through March 2024. Post-VF regimens and re-suppression outcomes among PWH who were virologically suppressed at CAB+RPV LA initiation. Includes 115 participants from CUSTOMIZE with no VF; **6th VF data not available; † studies not included in SLR

1. Elias et al. HIV Glasgow 2024; Glasgow, Scotland. Poster P062. 2. Sinclair et al. IAS 2021; Virtual. Poster PED416; 3. Ring K et al HIV Med 2025; 26(8) 1267-88; 4 Ruzagira E, et al. AIDS 2026. Poster LB24.; 5. Giguere al. IAS 2025; Kigali, Rwanda. Poster LB10

OPERA: High, comparable effectiveness of CAB + RPV LA vs BIC/FTC/TAF



Adults who were virologically suppressed on ART switching to CAB + RPV LA or BIC/FTC/TAF in the US between February 2022 and March 2025

> OPERA

- / Prospectively captured, routine clinical data from electronic health records
- / BL characteristics, persistence and virologic effectiveness were compared across regimens

BL characteristics (N=4,090)



Age
Median: 38 years



Female
14%



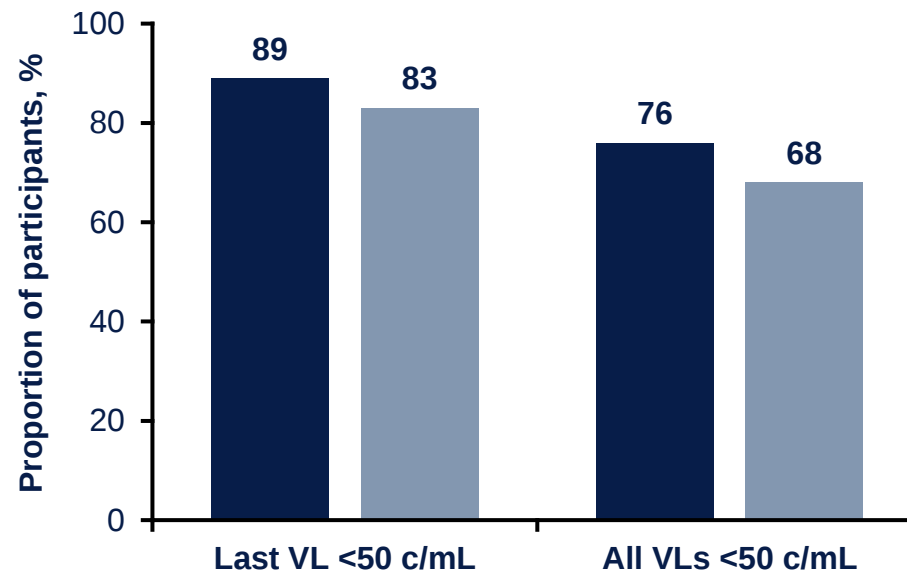
Black
42%*



IDU
6%

Virologic outcomes

■ CAB + RPV LA (n=4,090) ■ BIC/FTC/TAF (n=2,699)
Median (IQR) follow-up: 15 (8–25) vs 22 (14–31) months



Proportion of participants with CVF[†]

1% (n=46/4,090) **vs** **2%** (n=46/2,699)
CAB + RPV LA **BIC/FTC/TAF**



After experiencing CVF on CAB + RPV LA, 46% (n=21/46) of participants remained on CAB + RPV LA or switched to BIC/FTC/TAF[‡]

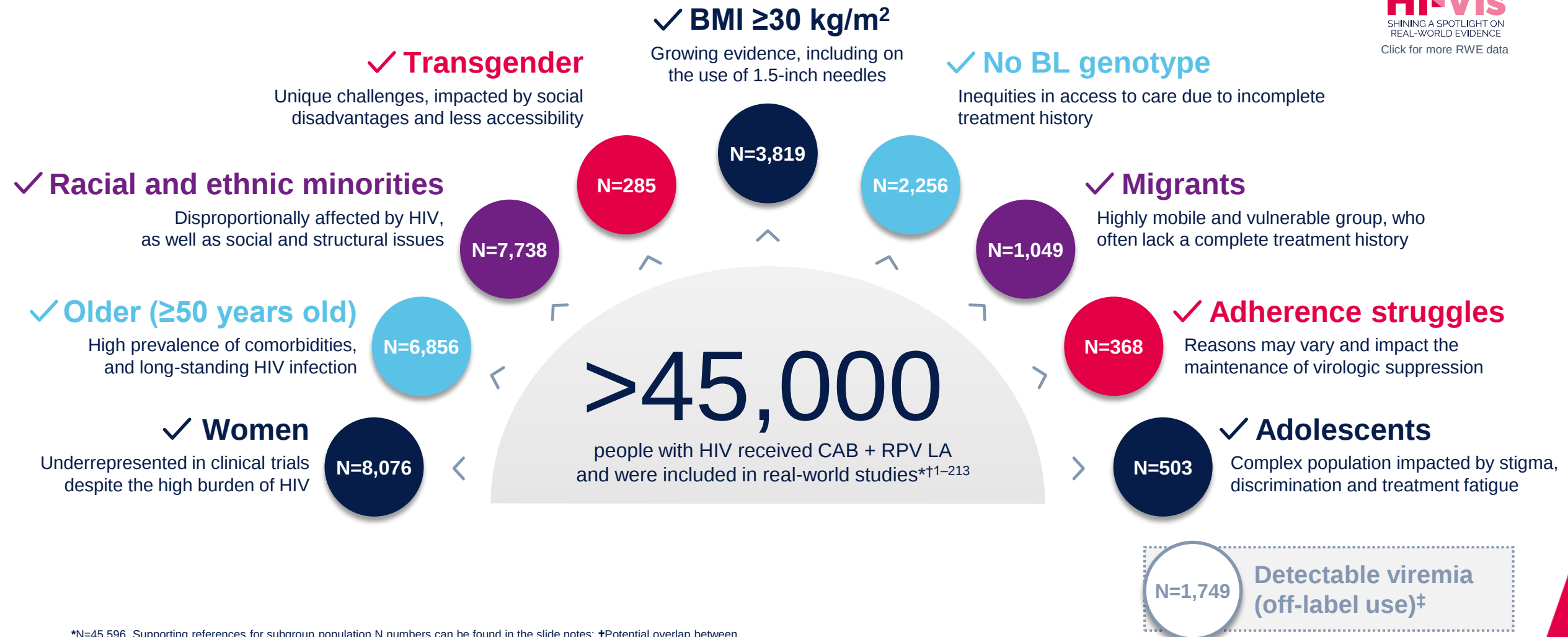


Resuppression to <50 c/mL following CVF[§]

68% (n=15/22) **CAB + RPV LA**
(vs 69% [n=20/29] BIC/FTC/TAF)

*Data missing for 322 individuals; [†]Two consecutive VLs ≥200 c/mL or one VL ≥200 c/mL followed by discontinuation within 4 months. After adjusting for BL characteristics, difference was not statistically significant; [‡]Switched to BIC/FTC/TAF (n=13), remained on CAB + RPV LA (n=8), switched to DRV/c/FTC/TAF (n=8), switched to a regimen with ≥2 core agents, excluding CAB + RPV LA and DTG/RPV (n=8), Other (n=6), Unknown (n=3); [§]In participants with post-CVF VL available. See slide notes for abbreviations

CAB + RPV LA: Real-world use in broad and diverse populations with unmet needs



*N=45,596. Supporting references for subgroup population N numbers can be found in the slide notes; †Potential overlap between real-world cohorts cannot be ruled out; ‡Use of CAB + RPV LA in people with detectable viremia is outside of the labelled indication
BMI, body mass index

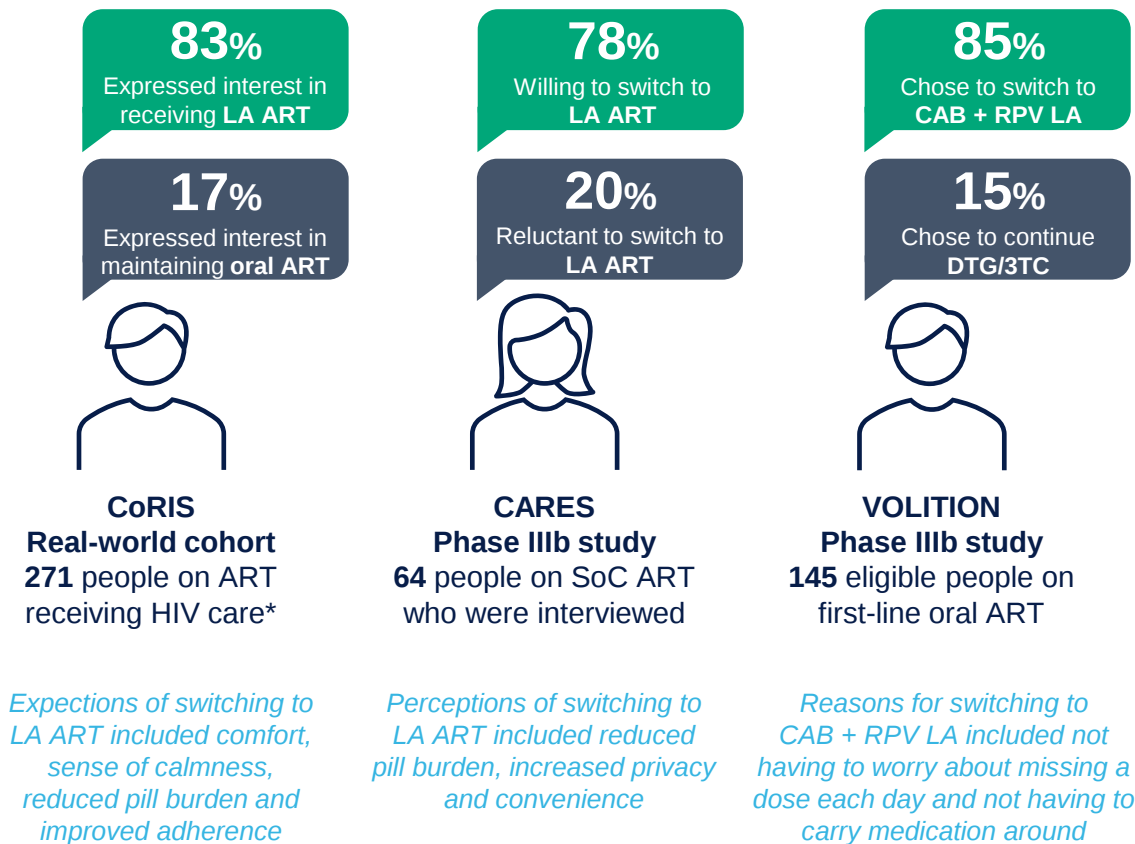
CAB + RPV LA: Additional benefits beyond virologic suppression are consistently reported in RCTs and RWE



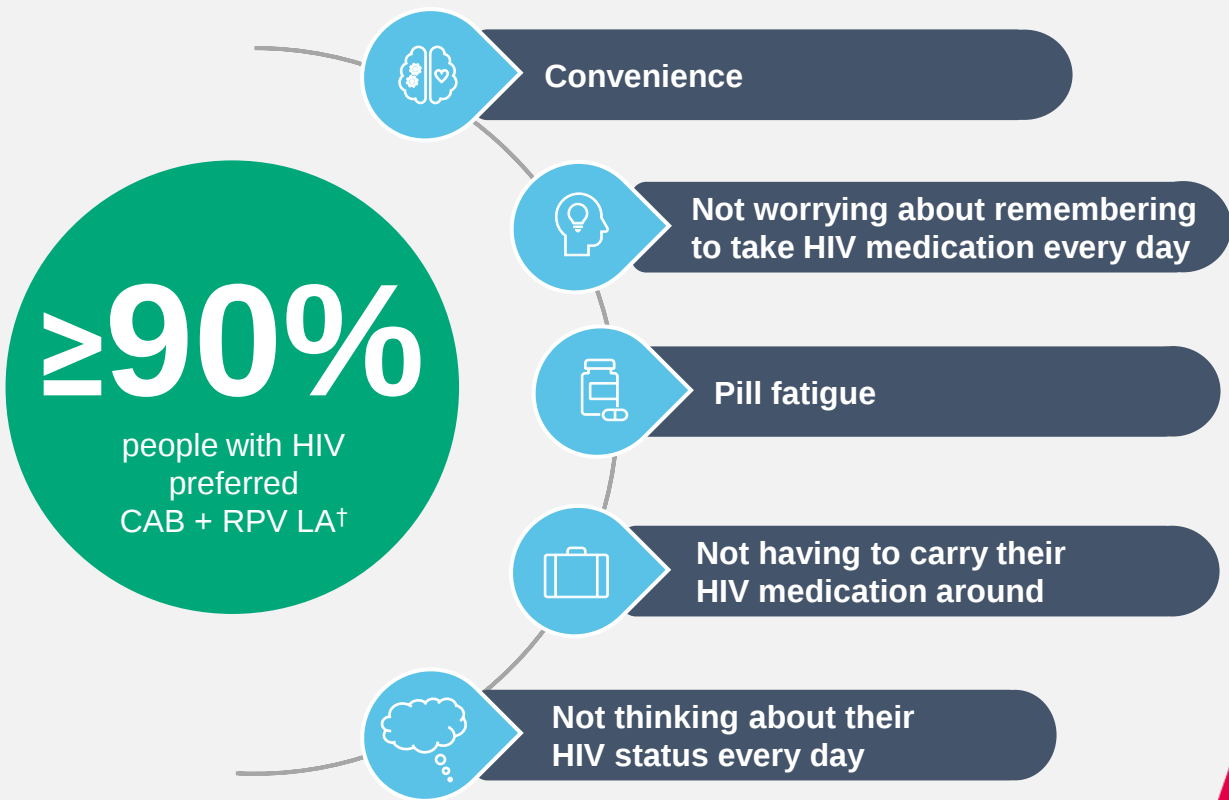
*RCTs: ATLAS-2M Week 48 HCP-reported adherence: 98% (n=3,719);¹ SOLAR Month 12 HCP-reported adherence: 93% (n=2,527);² CARISEL Month 12 HCP-reported adherence: 93% (n=2,376);³ CARES Week 96 HCP-reported adherence: 96% (n=1,039).⁴ RWE: CARLOS Month 24 HCP-reported adherence: 94% (n=3,676);⁵ BEYOND Month 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.⁷ ‡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.⁹ ¶HIVTSQs: Increased scores in all items, with therapy satisfaction reaching 5.9/6.0 at Month 13.¹⁰ §§Switching to CAB + RPV LA helps reduce barriers to keep HIV status disclosed; HSS score at BL vs Month 6: 67.5% vs 33% (p=0.009), respectively.¹¹
CrCl, creatinine clearance; DDI, drug–drug interaction; HIVDQoL, HIV dependent quality of life; HIVTSQs, HIV treatment satisfaction survey status version; HSS, HIV stigma scale; IQR, interquartile range.
See slide notes for references.

CAB + RPV LA: High interest and preference reinforces the importance of choice and partnered treatment decisions

Are people with HIV interested in switching to LA ART?¹⁻³



People with HIV showed high preference for CAB + RPV LA vs oral ART in RCTs and RWE⁴⁻¹⁴



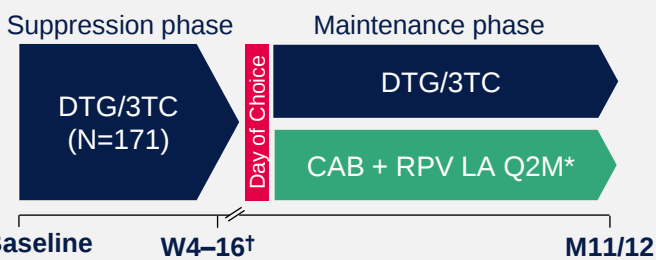
See slide notes for footnotes and abbreviations

References available upon request

VOLITION: High efficacy in early switch to CAB + RPV LA, empowering ART-naïve people with HIV to choose their preferred treatment

Importance of choice

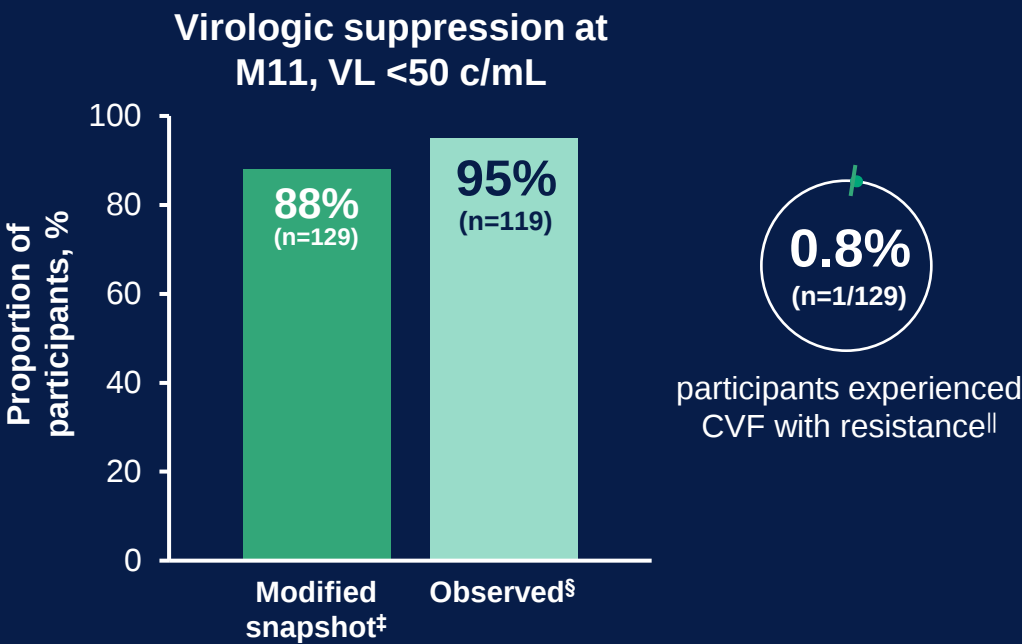
Phase IIIb, multicenter, non-randomized, parallel-group, open-label study



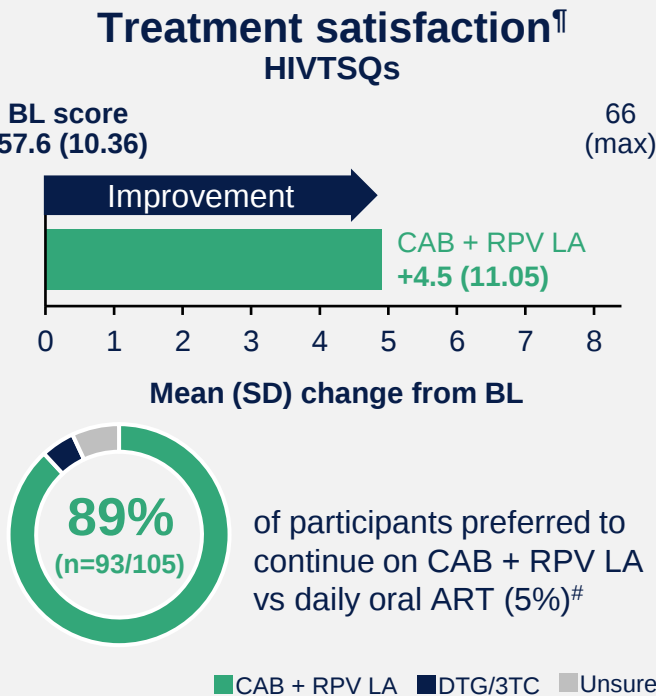
At Day of Choice, **85%** (n=129/151) of eligible participants **chose to switch to CAB + RPV LA** vs continuing daily oral ART

CROI 2026

High efficacy and rare CVF with resistance



High treatment satisfaction

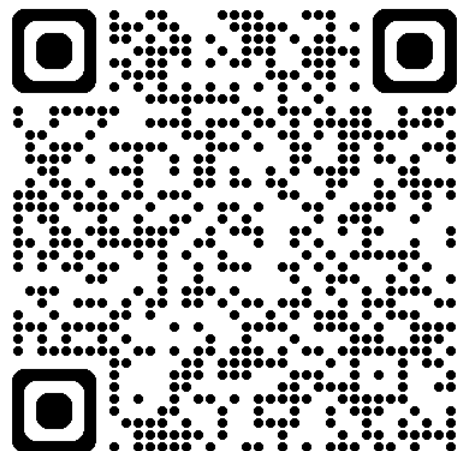


CAB + RPV LA was well tolerated through Month 11, with most DRAEs being ISRs. No new safety signals were identified and no AEs led to withdrawal

*A diverse population of participants was represented (n=129): 26% women, 33% Black or African American, 51% Hispanic/Latine, 21% with BMI ≥30 kg/m², 22% with CD4⁺ <350 cells/mm³; †Median time to virologic suppression (<50 c/mL) on DTG/3TC: 4.1 weeks (95% CI: 4.1, 4.3); ‡Modified snapshot: RealTime HIV-1 RNA results were prioritised over the cobas® 6800 assay when available and within the Snapshot window; §Includes only participants with available virologic data in-window; ¶Three additional participants met CVF criteria and were withdrawn, however retrospective retesting did not confirm CVF, and no RAMs were detected; ¶¶Mean (SD) BL HIVTSQs total score (n=127), mean (SD) change from BL to Month 11 HIVTSQs total score (n=114); #Includes 105 participants who responded to the preference questionnaire, with remaining 7% unsure. After rounding proportions total 101%
3TC, lamivudine; BL, baseline; BMI, body mass index; DRAE, drug-related adverse event; DTG, dolutegravir; HIVTSQs, HIV Treatment Satisfaction Questionnaire status version; M, Month; Q2M, every 2 months
RAM, resistance-associated mutation; SD, standard deviation; W, Week

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<https://doi.org/10.1093/ofid/ofag383>



Open Forum Infectious Diseases

MAJOR ARTICLE

Rapid Virologic Suppression With DTG/3TC Facilitates Early Switch to CAB+RPV LA for Treatment-Naïve People With HIV-1: Month 11/12 Outcomes From the Phase 3b VOLITION Study

Ezequiel Córdova¹, Charlotte-Paige Rolle², Kai Hove³, Franco Felizarta⁴, Marc Johnson⁵, Guillermo Cuevas Tascón⁶, Jean-Michel Molina^{7,8}, Joaquin Bravo Urbieto^{9,10,11}, Laurent Hocqueloux¹², Sergio Lupo¹³, Carlos M. Perez¹⁴, Björn-Erik Ole Jensen¹⁵, Celia Jonsson-Oldenbüttel¹⁶, Francisco Xavier Zamora Vargas¹⁷, János Szabó¹⁸, Pedro Cahn¹⁹, Andrea Antinori²⁰, Juan Carlos López Bernaldo de Quirós²¹, Antonella Castagna²², Monika Bui²³, Richard Grove²³, Kehui Wang²⁴, Marty St. Clair²⁵, Riya Moodley³, Jacob Radford³, Julie Priest²⁵, Cassidy A. Gutner²⁵, Ian Jacob³, Avishek Chatterjee²⁶, Suryakant Somvanshi²⁷, Irina Kolobova²⁵, Rekha Trehan³, Christopher Polk²⁵, Parul Patel²⁵, Patricia de los Rios²⁵, Paul DiMondi²⁸, Lori A. Gordon²⁵, Kimberley Brown²⁵, Harmony P. Garges²⁵, Bryn Jones³, Jean van Wyk³

¹IDEAA Foundation, Buenos Aires, Argentina; ²Orlando Immunology Center, Orlando, Florida, USA; ³ViiV Healthcare, London, United Kingdom; ⁴Private Practice, Bakersfield, California, USA; ⁵Atrium Health Carolinas Medical Center, Charlotte, North Carolina, USA; ⁶Department of Internal Medicine, Hospital Universitario Infanta Leonor, Madrid, Spain; ⁷Paris Cité University, Paris, France; ⁸Department of Infectious Diseases, St-Louis and Lariboisière Hospitals, Assistance Publique Hôpitaux de Paris, Paris, France; ⁹Infectious Diseases Unit,

Corresponding Author: Bryn Jones **Institutional address:** 79, New Oxford Street, London, WC1A 1DG, United Kingdom **Phone number:** +44 7341079814/+44 2080479844 **Email:** bryn.c.jones@viiVhealthcare.com

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DOI: 10.1093/ofid/ofag383

CAB + RPV LA: People with HIV report strong preference, improved treatment satisfaction

Preference



across RCTs^{1–7} and RWE^{8–11}

Treatment satisfaction

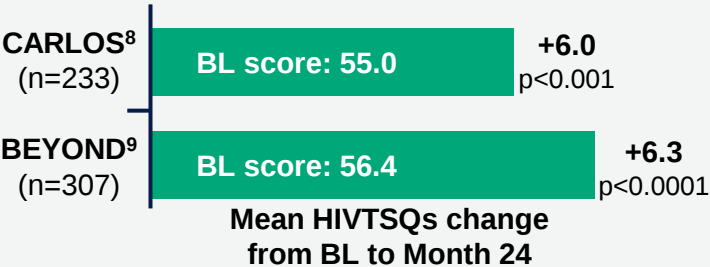
Switching to CAB + RPV LA was associated with significant improvement in treatment satisfaction versus previous oral ART^{1,8,9}



In SOLAR, treatment satisfaction significantly improved in people switching to CAB + RPV LA versus continuing BIC/FTC/TAF, through Month 12 (Mean change in adjusted HIVTSQ score from BL: +3.4 vs -1.6, p<0.001)^{†1}



Statistically significant improvement in treatment satisfaction after switching to CAB + RPV LA in real-world clinical practice



*Outcomes reported at Month 12 in SOLAR (90%, n=425), CARISEL (99%, n=277), CUSTOMIZE (92%, n=102), CARLOS (99%, n=257), BEYOND (97%, n=229) and ILANA (97%, n=95). Outcomes reported at Week 48 in ATLAS-2M (98%, n=306), ATLAS + FLAIR pooled data (98%, n=532) and MOCHA (100%, n=140). Outcomes reported at Week 96 in CARES (>99%, n=244). Outcomes reported at median (IQR) CAB + RPV LA duration of 1.0 (0.5, 1.7) years in ADELPHI (93%, n=28)
[†]Adjusted mean difference between study arms for the mean change in total HIVTSQs scores from BL to Month 12. CAB + RPV LA BL score: 57.88; BIC/FTC/TAF BL score: 58.38; Adjusted treatment difference 95% CI 4.95 (3.59, 6.31, p<0.0001)
HIVTSQs, HIV Treatment Satisfaction Questionnaire status version

CAB + RPV LA: Additional benefits beyond virologic suppression are consistently reported in RCTs and RWE

PREFERENCE / CHOICE

OBSERVED ADHERENCE

QUALITY OF LIFE / STIGMA

ENGAGEMENT IN CARE

OVERALL HEALTH



- ✓ **High preference** vs. daily oral ART and switching to CAB + RPV LA associated with **significant improvement in treatment satisfaction** vs oral ART^{1,2, 20, 21, 24}
- ✓ **CAB+RPV consistently chosen** when given the opportunity to select preferred treatment option^{1,2,21,24,25}

*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 96 HCP-reported adherence: 96% (n=1,039);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;⁷ ‡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; HIVTSQs: Increased scores in all items, with therapy satisfaction reaching 5.9/6.0 at Month 13
§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;
HIVDQoL, HIV dependent quality of life; HIVTSQs, HIV treatment satisfaction survey status version; HSS, HIV stigma scale; IQR, interquartile range

Suboptimal adherence can lead to an increased risk of viral transmission and resistance

It is estimated that **38% of people with HIV** have **suboptimal adherence** to oral ART due to factors including:^{1–3}



Pill fatigue



Stigma



Complexity of dosing schedule



Emotional challenges



Busy lifestyle



DHHS guidelines emphasize the importance of **regular assessment** of **barriers** faced by people with HIV to ensure **tailored care** to meet their needs and preferences⁴

1. Ortego C et al AIDS Behav. 2011 Oct;15(7):1381-96.
 2. Nachega JB, et al. Lancet HIV 2023;10:e332–42
 3. Akinwunmi B, et al. Eur J Public Health 2021;31:567–75; 4. DHHS. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV, Sep 2025

High, long-term efficacy observed with CAB + RPV LA vs INSTI-based daily oral ART among key populations who may face challenges with adherence to oral ART and retention in care

AIDS 2026

LATA: Superior efficacy vs DTG-based ART at Week 96

Adolescents (12–19 years) suppressed on ART for ≥12 months with no prior treatment failure (N=235)

> LATA

Primary endpoint

Confirmed viral rebound (≥50 c/mL) by Week 96
(ITT-adjusted Kaplan-Meier estimated proportion)



CAB + RPV LA
0.9%



DTG/3TC/TDF
6.4%

Difference:
-5.5% (95% CI: -9.1, -2.4)
p=0.001

15 events observed

2 events observed

Cumulative incidence at Week 96



Low emergent resistance by Week 96*

INSTI/NNRTI RAMs were present in **1 participant** on CAB + RPV LA
NNRTI RAMs were present in **2 participants** on DTG/3TC/TDF



Viral suppression (VL <50 c/mL)

94.9% (n=223/235) CAB + RPV LA
(vs 93.8% [n=226/241] DTG/3TC/TDF)



Discontinuations due to drug-related AEs†

0.9% (n=2/235) CAB + RPV LA (vs 0% [n=0/241] DTG/3TC/TDF)
There were no discontinuations due to ISRs

94%
N=235‡

of participants receiving CAB + RPV LA
reported that **taking LAIs was a lot easier** than taking daily treatment

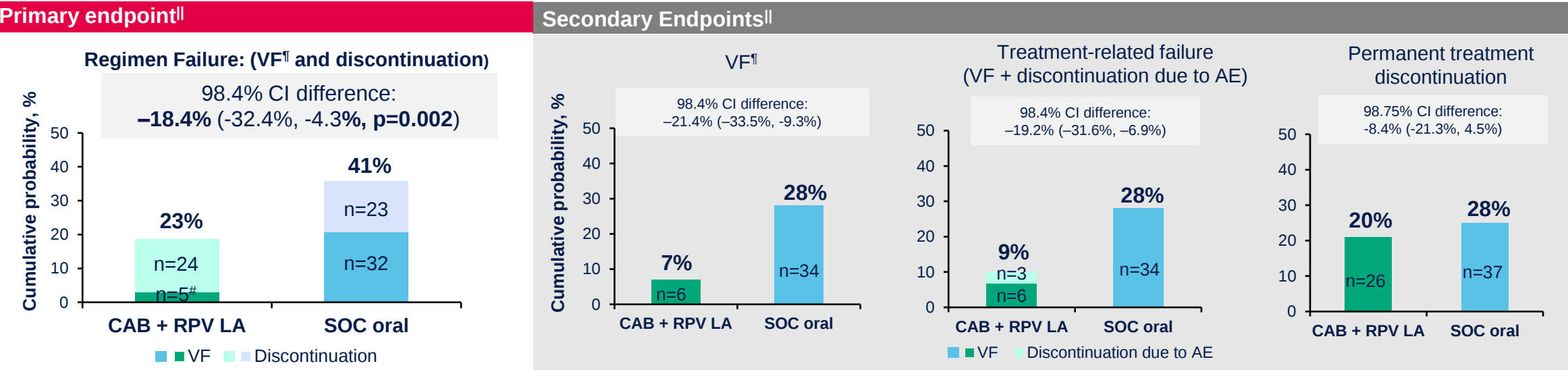
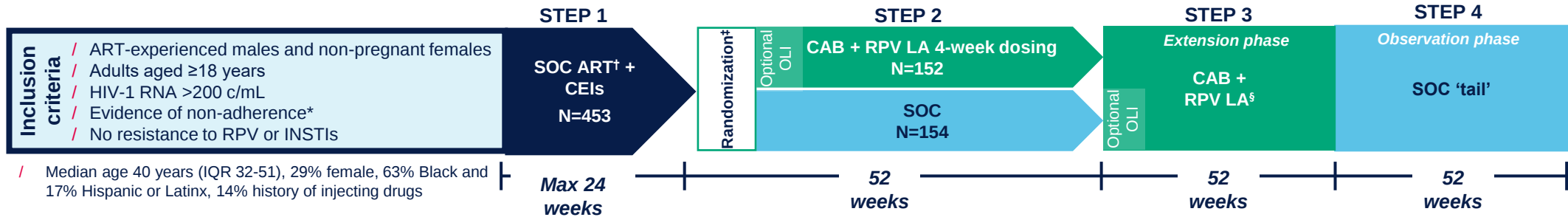
*At confirmed viral rebound (n=2 events with CAB + RPV LA; n=15 events with DTG/3TC/TDF [data missing for n=7]). No INSTI RAMs were observed with DTG/3TC/TDF

†No discontinuations due to ISRs were reported; ‡It was assumed data were for all participants receiving CAB + RPV LA as it was not reported otherwise.

It was not possible to calculate the exact number (n) of participants who reported that taking LAIs was a lot easier than taking daily treatment due to rounding

LATITUDE: Superior efficacy of CAB + RPV LA compared to daily oral SOC in PWH with adherence challenges

A Phase III prospective, randomized, open-label study to evaluate LA ART in PWH with adherence challenges in ACTG US sites (including Puerto Rico)



Week 48, cumulative incidence of a serious AE was 19.3% in CAB+RPV LA group and 14.5% in SOC group (between group difference, -4.8%, 95% CI, -5.6 to 15.2)

CAB + RPV LA superior to oral ART in reducing the risk of regimen failure among PWH with adherence challenges

*Poor viral response despite oral ART for ≥6 months or loss to clinical follow-up with ART non-adherence for ≥6 months; [†]Consisting of a ≥3-drug ART regimen with ≥2 drugs predicted to be fully active including a boosted protease inhibitor (PI/cobi) and/or an integrase strand transfer inhibitor for up to 24 weeks; [‡]Participants who achieve viral suppression criteria at or after Step 1, Week 4, defined as: a) HIV-1 RNA ≤200 c/mL or b) HIV-1 RNA 201-399 c/mL followed by HIV-1 RNA ≤200 c/mL by Step 1 Week 24 will be eligible to enter Step 2. Participants with confirmed VF in Step 2; CAB + RPV LA (n=6), 2 with emergent RAMS (i) Week 18 E138EK; G140GS; Q148K; K103R (ii) Week 49 E138K; Q148K; K20KR; M230M; Oral SOC ART (n=28), 2 with emergent RAMS (i) Week 37, A71V; V77I; V106I (ii) Week 48, M184I; [§]There is an optional oral lead-in for SOC arm moving to step 3; ^{||}Pre-planned interim review by an independent DSMB; [¶]VF, confirmed HIV-1 RNA >200 c/mL; [#]One participant assigned to LAI had treatment discontinuation as the primary endpoint but subsequently experienced VF, contributing to the total number of VFs; **ACTG**, AIDS Clinical Trial Group; **AE**, adverse event **CEIs**, conditional economic incentives; **cobi**, cobicistat; **DSMB**, data safety monitoring board; **LAI**, long-acting injectable; **PI**, protease inhibitor; **RAM**, resistance-associated mutation; **SOC**, standard of care; **US**, United States

Evaluating CAB + RPV LA in people with adherence challenges to oral ART

Study design:

Retrospective observational study at the UCSD Owen Clinic



Study participants

- People with HIV-1 with adherence challenges to oral ART defined as having HIV-1 viral load ≥ 200 c/mL in the prior 12 months and either
- Poor response to oral therapy*
- Lost to follow-up†

Initiated
CAB +
RPV LA

Primary Outcome:

Discontinuation or virologic failure (VF)[¶]

48 weeks

96 weeks

Demographics and characteristics:

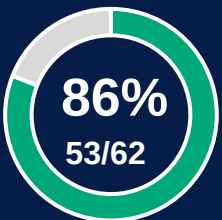
Key demographics	Parameter, n (%) [‡]	N=62
	White race	28 (45.2)
	Hispanic ethnicity	22 (35.5)
Clinical characteristics	Male gender identity	44 (71.0)
	Any active substance use	25 (40.3)
	Any neuropsychiatric disorder	35 (56.5)
	Years since HIV diagnosis, median	13.3
	Viral load ≥ 50 c/mL at LAI initiation	27 (43.5)
	Viral load $>10,000$ c/mL at LAI initiation	7 (11.3)
	Q2M dosing at initiation	59 (95.2)
	Q1M then Q2M	3 (4.8)
	Other ART [†] at initiation	13 (21)

Results:

48 weeks

96 weeks

Proportion of participants who were virally suppressed (<200 c/mL)

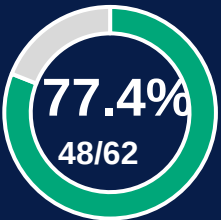


Primary outcome:
17.7% (n=11)²

Discontinuation reasons

- ✓ VF with resistance (n=3)²
- ✓ Preference (n=2), lost to follow up (n=3), death (n=1), VF** (n=2)²

Methamphetamine use significantly associated with VF or loss to follow up (OR=12.5, p=0.026) in univariate analysis



Primary outcome:
22.6% (n=14)¹

- ✓ No additional VFs between week 48 and 96¹
- ✓ Adverse events (n=3)¹

A high proportion of PWH with adherence challenges maintained viral suppression with CAB + RPV LA through week 96 with no failures occurring beyond week 48

UCSD, University of California San Diego; PWH, people with HIV; VL, viral load.

*HIV VLs ≥ 200 copies/mL separated by ≥ 4 weeks in the prior 18 months despite being prescribed oral ART. †No contact with an HIV provider for ≥ 6 months and non-adherence to ART for ≥ 7 days. ‡Unless otherwise indicated. ¶Other ART at the 96-week analysis included: TAF/FTC (n=3), Lenacapavir SQ injection (n=9), Fostemsavir (n=1); **VF then resuppressed without ART change; † At week 48 VF defined as VL ≥ 200 c/mL > 30 days after CAB+RPV LA initiation. ‡At week 96, VF defined as 2 consecutive VLs ≥ 200 c/mL, one VL ≥ 1000 c/mL or one VL ≥ 200 c/mL with evidence of resistance associated mutations to CAB or RPV.

1. Ostrer et al. AIDS 2026; Rio de Janeiro, Brazil. Poster TUPEB106.
2. Hastie et al. IAS 2025; Kigali, Rwanda. Poster EP0180.

Treatment guidelines: CAB + RPV LA can achieve virologic suppression in people with detectable viremia (off-label use)



Data for CAB + RPV LA in people with viremia are emerging (off-label use), and the IAS–USA and DHHS guidelines have been updated to reflect growing interest in its use in this population^{1,2}

IAS–USA guidelines¹

May be considered for people with viremia who are **unable to take oral ART consistently**, are at **high risk of HIV disease progression** and have **no resistance to CAB or RPV**

DHHS guidelines²

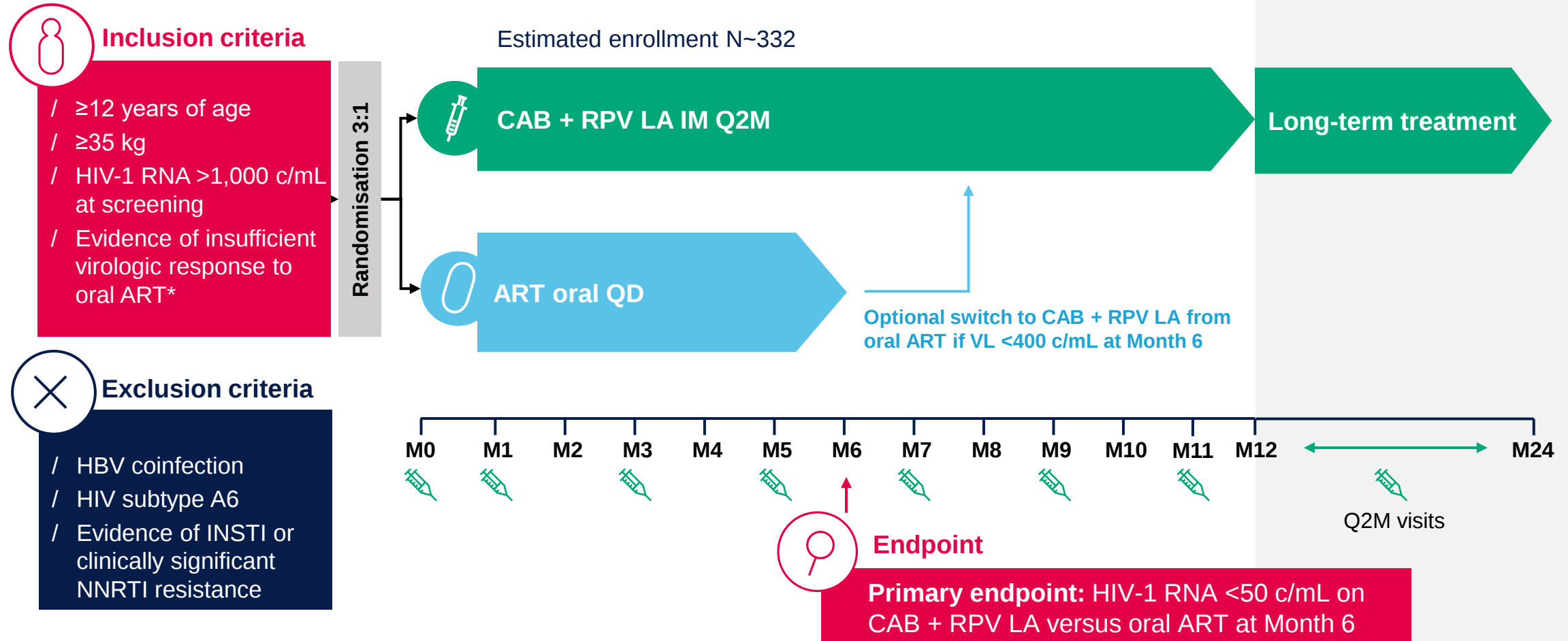
On a **case-by-case basis** in select individuals with **persistent VF** despite intensive adherence support on oral ART, who have **no evidence of resistance to RPV or CAB**, and with **shared decision-making** between providers and people with HIV

Local guideline example: New York State DOH

1. Gandhi RT, et al. JAMA 2025;333:609–28
2. DHHS. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV, Sep 2025
3. BHIVA. Guidelines on antiretroviral treatment for adults living with HIV-1, 2022 (2025 interim update)
4. WHO. Overview of WHO recommendations on HIV and sexually transmitted infection testing, prevention, treatment, care and service delivery. 2025
5. WHO. WHO recommends injectable lenacapavir for HIV prevention.
Available at: <https://www.who.int/news/item/14-07-2025-who-recommends-injectable-lenacapavir-for-hiv-prevention>. Accessed Feb 2026

CROWN: Study design

Phase IIIb, open-label, randomised, multicenter superiority study of CAB + RPV LA in viremic participants



*At least one of the following: a) $< 1 \log_{10}$ decrease in HIV-1 RNA or HIV-1 RNA > 200 c/mL at two time points at least 4 weeks apart in individuals who have been prescribed oral ART for at least 3 consecutive months, b) a documented lapse in current oral ART regimen usage expected to result in HIV-1 viraemia (defined as at least a 30-day consecutive period of non-use of oral ART), c) a documented need for change from oral ART regimen that the investigator attributes as the primary reason for insufficient virologic response (e.g. safety findings and/or limited tolerability, clinically relevant DDIs)
DDI, drug–drug interaction; IM, intramuscular; M, Month

**Adherence sufficient
to achieve and
maintain viral
suppression**

**Adherence required for
optimal long-term
health outcomes**

Suboptimal adherence can lead to an increased risk of viral transmission and resistance

It is estimated that **38% of people with HIV** have **suboptimal adherence** to oral ART due to factors including:^{1–3}

- Pill fatigue
- Emotional challenges
- Stigma
- Busy lifestyle
- Complexity of dosing schedule

DHHS guidelines emphasize the importance of **regular assessment of barriers** faced by people with HIV to ensure **tailored care** to meet their needs and preferences⁴

HCP, healthcare professional

Non-adherence to oral ART is associated with:^{1,5–8}

- A lower CD4 count
- AIDS-related mortality
- Increased risk of transmission
- Higher healthcare costs
- Emerging resistance
- Comorbidities
- Inflammation

LAIs like CAB + RPV LA could help to overcome some of these adherence challenges, and this directly-observed therapy removes the need for adherence to daily dosing while allowing HCPs to track doses received⁹

1. Ortego C et al AIDS Behav. 2011 Oct;15(7):1381-96.
 2. Nachega JB, et al. Lancet HIV 2023;10:e332–42
 3. Akinwunmi B, et al. Eur J Public Health 2021;31:567–75; 4. DHHS. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV, Sep 2025
 5. Byrd KK, et al. J Acquir Immune Defic Syndr 2019;82:245–51
 6. van Rensburg R, et al. CROI 2026. Poster 657; 7. Castillo-Mancilla JR, et al. Open Forum Infect Dis 2023;10:ofad230
 8. Castillo-Mancilla JR, et al. J Int AIDS Soc 2019;22:e25297; 9. Davis JM, et al. Clin Infect Dis 2024:ciae557

Virally suppressed individuals with suboptimal adherence at increased risk of negative clinical outcomes

Open Forum Infectious Diseases

MAJOR ARTICLE



Association of Incomplete Adherence to Antiretroviral Therapy With Cardiovascular Events and Mortality in Virologically Suppressed Persons With HIV: The Swiss HIV Cohort Study

Jose R. Castillo-Mancilla,¹ Matthias Cavassini,^{2,3} Marie Paule Schneider,⁴ Hansjakob Furrer,⁴ Alexandra Calmy,⁵ Manuel Battegay,^{6,7} Giulia Scaferla,⁸ Enos Bernasconi,⁹ Huldrych F. Günthard,^{10,11} and Tracy R. Glass,^{4,12} for the Swiss HIV Cohort Study

¹University of Colorado-AMC, Aurora, Colorado, USA, ²Infectious Diseases Service, Lausanne University Hospital, Lausanne, Switzerland, ³School of Pharmaceutical Sciences and Institute of Pharmaceutical Sciences of Western Switzerland, University of Geneva, Geneva, Switzerland, ⁴Department of Infectious Diseases, Bern University Hospital, Inselspital, University of Bern, Bern, Switzerland, ⁵Division of Infectious Diseases, HIV/AIDS Unit, Geneva University Hospitals, Geneva, Switzerland, ⁶University of Basel, Basel, Switzerland, ⁷Division of Infectious Diseases, University Hospital Basel, Basel, Switzerland, ⁸Division of Infectious Diseases, Kantonsspital St. Gallen, St. Gallen, Switzerland, ⁹Division of Infectious Diseases, Ospedale Regionale di Lugano, Lugano, Switzerland, ¹⁰Division of Infectious Diseases and Hospital Epidemiology, University Hospital Zurich, Zurich, Switzerland, ¹¹Institute of Medical Virology, University of Zurich, Zurich, Switzerland, and ¹²Department of Medicine, Swiss Tropical and Public Health Institute, Basel, Switzerland

Background. Incomplete antiretroviral therapy (ART) adherence, even if sufficient to maintain viral suppression, is associated with enhanced inflammation in persons with HIV (PWH). However, its clinical implications remain unknown.

Methods. PWH enrolled in the Swiss HIV Cohort Study without a history of cardiovascular disease (CVD) who initiated ART between 2003 and 2018 and had viral suppression (<50 copies/mL) for ≥6 months were evaluated. The association between incomplete self-reported ART adherence (≥1 or ≥2 missed doses in the last month) and (1) any CVD event (myocardial infarction, revascularization, cerebral hemorrhage, stroke, and/or death due to CVD event) or (2) non-CVD-related death was evaluated using adjusted Cox proportional hazards models.

Results. A total of 6971 PWH (74% male) were included in the analysis (median age [interquartile range (IQR)], 39 [32–47] years). The median (IQR) follow-up was 8 (4–11) years, with 14 (8–23) adherence questionnaires collected per participant. In total, 205 (3%) participants experienced a CVD event, and 186 (3%) died a non-CVD-related death. In an adjusted competing risk model where missing data were imputed, missing ≥1 ART dose showed an increased, but not statistically significant, risk for CVD events (hazard ratio [HR], 1.23; 95% CI, 0.85–1.79; *P* = .28). Non-CVD-related mortality showed a statistically significantly increased risk with missing ≥1 ART dose (HR, 1.44; 95% CI, 1.00–2.07; *P* = .05) and missing ≥2 ART doses (HR, 2.21; 95% CI, 1.37–3.57; *P* = .001).

Conclusions. Incomplete ART adherence was significantly associated with an increased risk for non-CVD-related mortality in PWH with virologic suppression. This highlights the potential role of nonadherence to ART as a driver of non-AIDS clinical outcomes.

Keywords. adherence; antiretroviral therapy; cardiovascular disease; viral suppression.

Despite achieving suppressed viral replication by conventional assays, persons with HIV (PWH) taking antiretroviral therapy (ART) have residual systemic inflammation that has been associated with the development of serious non-AIDS events and increased all-cause mortality [1, 2]. While the underlying causes of this residual inflammation and immune activation are

not completely understood, they are likely to be multifactorial, requiring a multitargeted approach to reduce the inflammation [3]. Recently, ART nonadherence has been evaluated as a potential driver of the chronic inflammation observed in this population. Recent data have demonstrated that incomplete ART adherence is associated with increased levels of systemic inflammation, immune activation, and coagulopathy in virologically suppressed individuals [4–8] and that optimal adherence may lead to levels of inflammation similar to those observed in persons without HIV [9]. Several potential mechanisms to explain this association have been proposed, in particular that incomplete adherence could result in intermittent low-level HIV replication (ie, below the limit of detection by clinically available assays) [10–12], resulting in enhanced inflammation and immune activation [13, 14]. However, despite being identified in several studies, the association of incomplete adherence with

- 6971 PWH (74% male) from the Swiss HIV Cohort were included in the analysis (median age [interquartile range (IQR)], 39 [32–47] years).
- The median (IQR) follow-up was 8 (4–11) years, with 14 (8–23) adherence questionnaires collected per participant

Independent associations between incomplete adherence with non-CVD-related mortality in virally suppressed individuals¹⁴

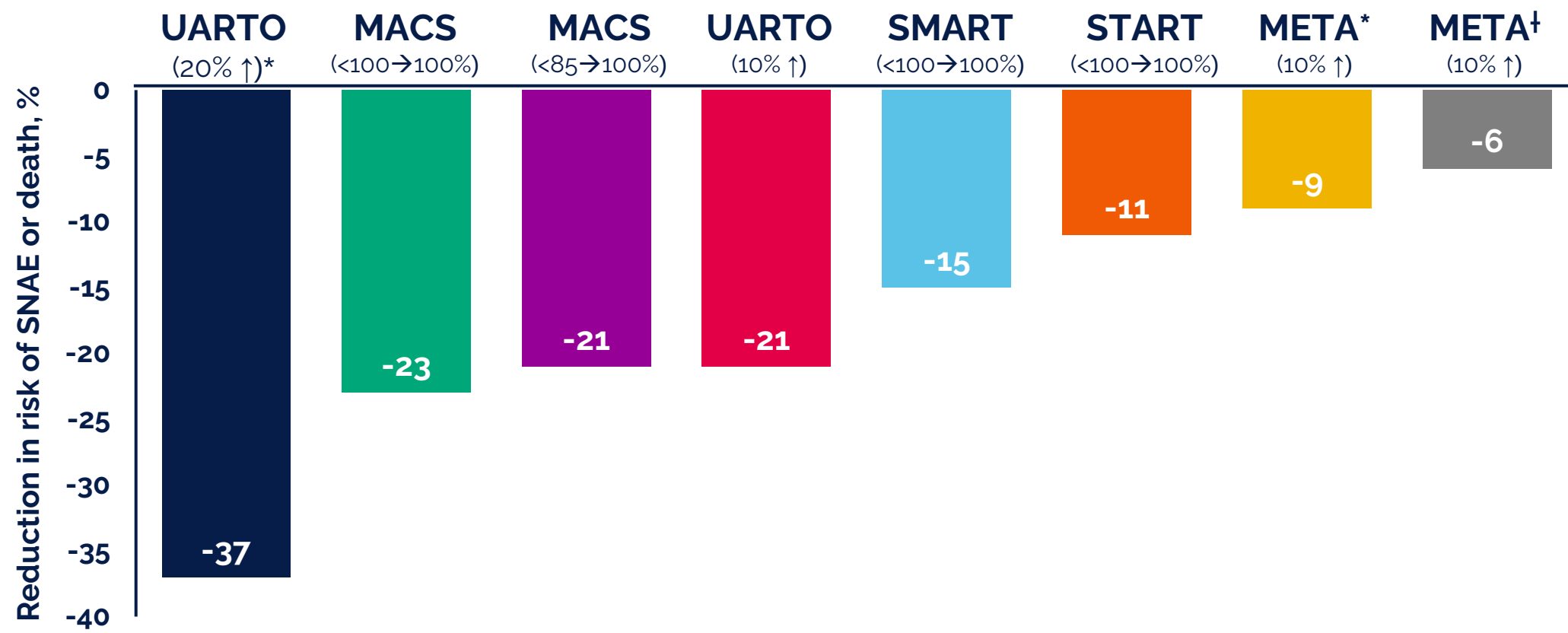
Characteristic	Non-CVD-Related Mortality ^b Univariate/Multivariate	<i>P</i> Value
Incomplete ART adherence ^c		
Missed ≥2 doses of ART in the last 4 wk		
Model 2b: Competing risk models with non-CVD-related death as a competing event with missing data imputed	186/186	
Univariate, n = 6971	2.21 (1.38–3.56)	.001
Multivariate, n = 6971	2.21 (1.37–3.57)	.001

- Missing ≥1 ART dose showed an increased, but not statistically significant, risk for CVD events (hazard ratio [HR], 1.23; 95% CI, 0.85–1.79; *P* = .28)

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Correspondence: Jose R. Castillo-Mancilla, MD, Division of Infectious Diseases, Department of Medicine, University of Colorado Anschutz Medical Campus, 12700 E. 19th Ave., B180, Aurora, CO 80045 (jose.castillo-mancilla@ucdenver.edu).
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DOI: 10.1093/ofid/ofab032

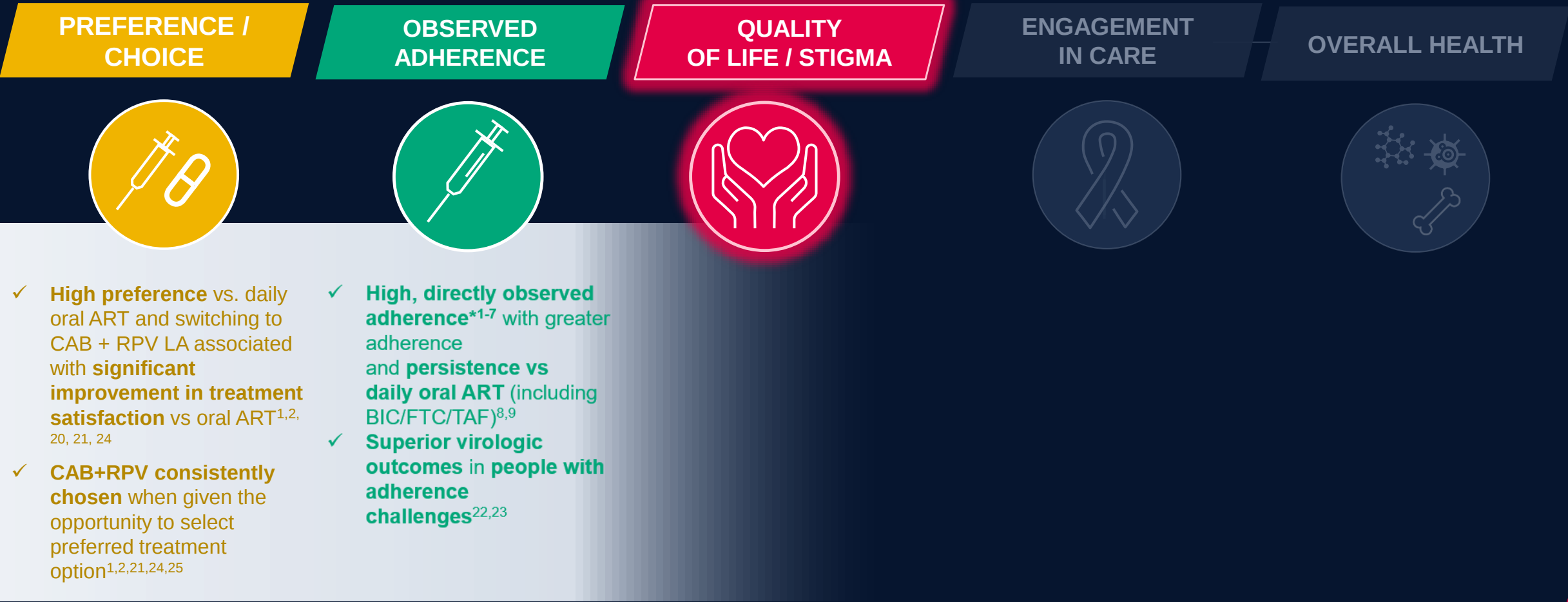
Estimating the reduction in risk of serious non-AIDS events (SNAEs) or death associated with increasing ART adherence

Modelled reduction in the risk of SNAE and/or death based on changes in IL-6 and D-dimer for virally suppressed PWH who increase their ART adherence



*Modeled increases in ART adherence

CAB + RPV LA: Additional benefits beyond virologic suppression are consistently reported in RCTs and RWE



*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 96 HCP-reported adherence: 96% (n=1,039);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;⁷ ‡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; HIVTSQs: Increased scores in all items, with therapy satisfaction reaching 5.9/6.0 at Month 13 §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; HIVDQoL, HIV dependent quality of life; HIVTSQs, HIV treatment satisfaction survey status version; HSS, HIV stigma scale; IQR, interquartile range

A high proportion of people with HIV experience poor QoL



Despite the availability of highly effective, well tolerated daily oral ART, **many people with HIV experience poorer QoL than the general population**^{1,2}



Factors negatively affecting HRQoL of people with HIV include **stigma, difficulties disclosing HIV status and multimorbidity**³

In addition to the UNAIDS targets for people with HIV in 2025, there is a proposed “fourth 90”:^{3–5}



by addressing multimorbidity, HRQoL, stigma and discrimination



Addressing key unmet needs and improving HRQoL supports UNAIDS overall targets

An integrated, person-centred approach is likely to enhance the HRQoL of people with HIV, reinforcing the importance of involving them in treatment discussions and shared decision making^{3,5,6}

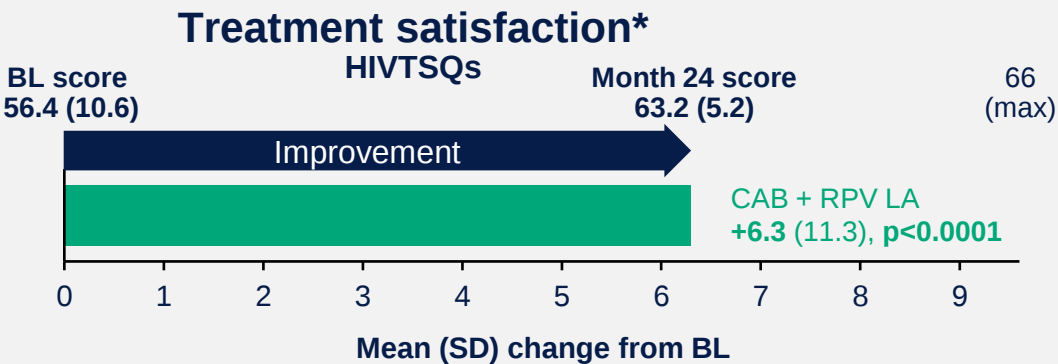
BEYOND: Improved PROs with CAB + RPV LA vs prior daily oral ART continues to be demonstrated after 2 years

Preference and treatment satisfaction



preferred CAB + RPV LA vs daily oral ART

mainly due to not worrying about remembering to take HIV-1 medication every day (85%) and being more convenient (84%)

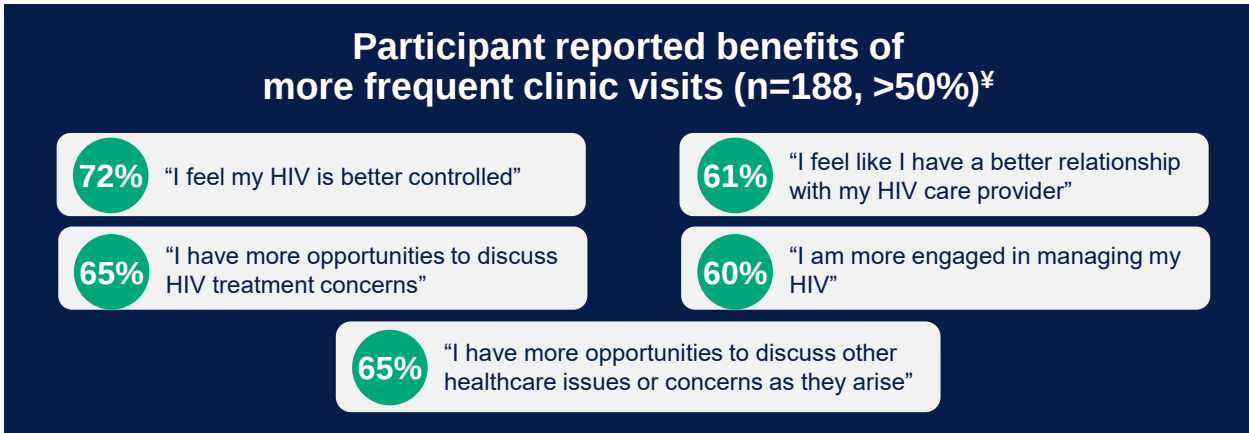


Psychological challenges, concerns, and benefits of more frequent clinic visits

Proportion of people with HIV reporting psychological challenges and feeling stigmatized by HIV-1 treatment decreased from BL (40%, n=308) to Month 24 (7%, n=192)

Concerns about CAB + RPV LA, e.g. effectiveness, tolerability, and administration logistics, decreased from BL to Month 24[†]

People with HIV found more frequent clinic visits to be beneficial to their care after 24 months on CAB + RPV LA[‡]



Footnotes available upon request
SD, standard deviation

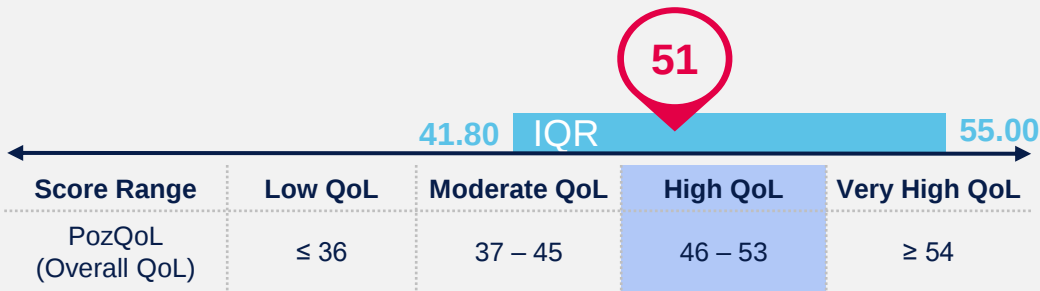
CAB + RPV LA: High and improved QoL in people switching from oral ART



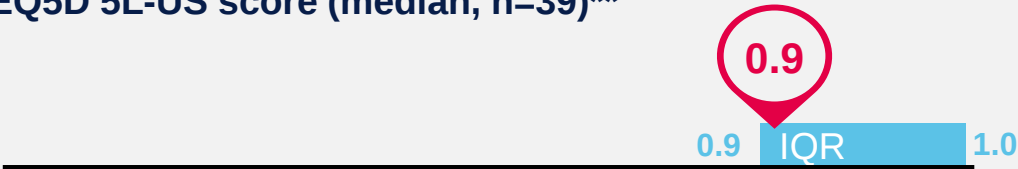
ADELPHI study showed high health-related quality of life (HRQoL) and EQ-5D-5L-US* scores in a cross-sectional survey of those switching to CAB + RPV LA¹

PWH-Reported HRQoL Summary Scores

Overall PozQoL score (median, n=38)*

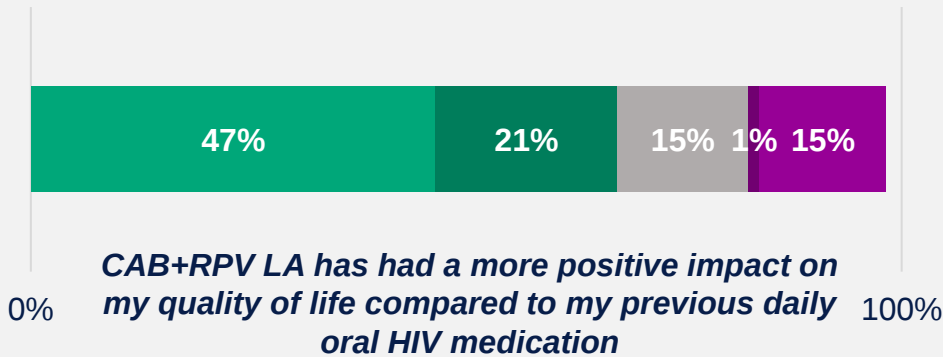


EQ5D 5L-US score (median, n=39)**



PREFER-LA study showed self-reported improvement in quality of life in participants who switched from daily oral ART to CAB+RPV LA²

Quality of Life Impact (n=159)



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

*HIV-specific PozQoL score range 13-65; **EQ-5D-5L-US score range 0-1 where 1.0 represents best possible health state
PWH, people with HIV

1. Brogan et al. IDWeek 2024 Poster P-538;
2. Henry Z, et al. IDWeek 2025. Poster P-396

CAB + RPV LA: Additional benefits beyond virologic suppression are consistently reported in RCTs and RWE

PREFERENCE / CHOICE



- ✓ **High preference** vs. daily oral ART and switching to CAB + RPV LA associated with **significant improvement in treatment satisfaction** vs oral ART^{1,2, 20, 21, 24}
- ✓ **CAB+RPV consistently chosen** when given the opportunity to select preferred treatment option^{1,2,21,24,25}

OBSERVED ADHERENCE



- ✓ **High, directly observed adherence**^{*1-7} with greater adherence and **persistence vs daily oral ART** (including BIC/FTC/TAF)^{8,9}
- ✓ **Superior virologic outcomes in people with adherence challenges**^{22,23}

QUALITY OF LIFE / STIGMA



- ✓ **High and improved quality of life**,^{†8,13-19} including **alleviation of psychological challenges and reduced stigma**^{§13,16,20}

ENGAGEMENT IN CARE

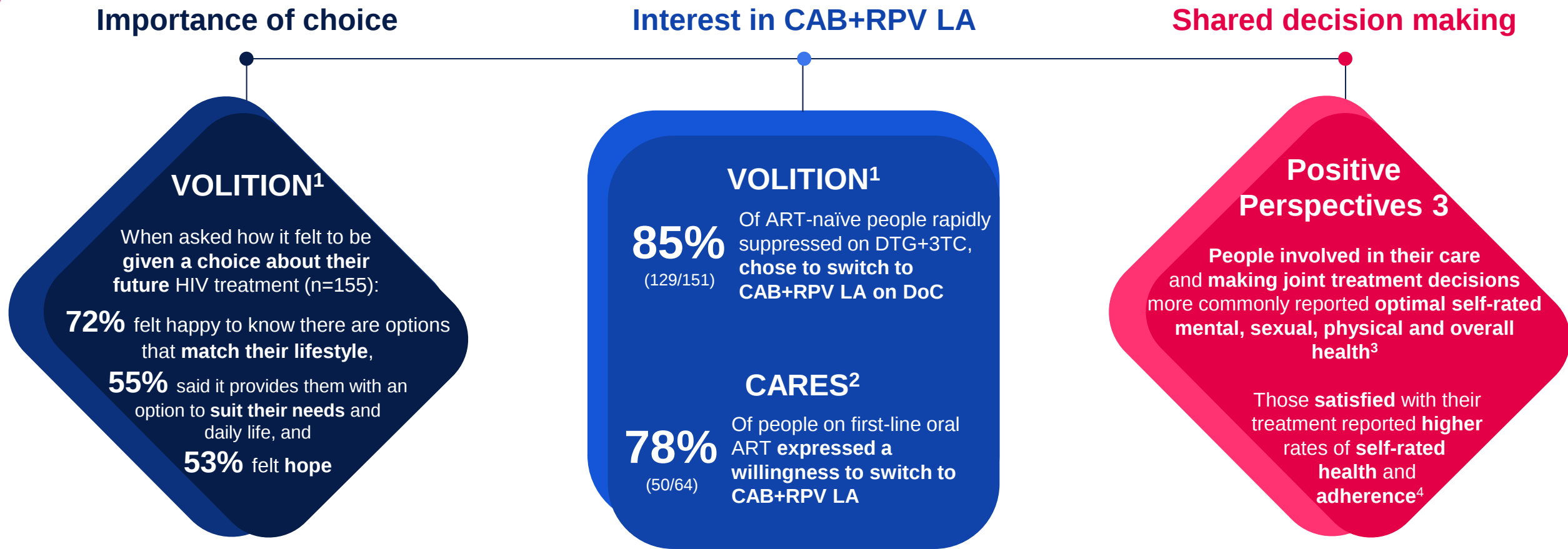


OVERALL HEALTH



*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 96 HCP-reported adherence: 96% (n=1,039);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;⁷ ‡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; HIVTSQs: Increased scores in all items, with therapy satisfaction reaching 5.9/6.0 at Month 13
§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;
HIVDQoL, HIV dependent quality of life; HIVTSQs, HIV treatment satisfaction survey status version; HSS, HIV stigma scale; IQR, interquartile range

CAB + RPV LA: Strong interest and willingness to switch to LA reinforces the importance of choice and shared decision making



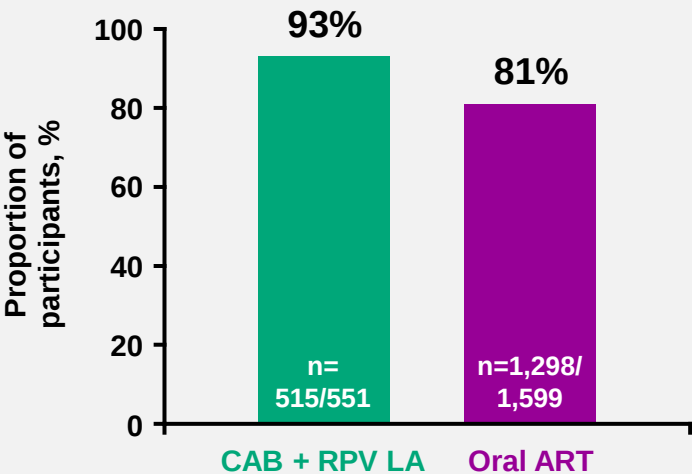
VOLITION: Participant-experience data at BL and DoC using questionnaires; CARES: In-depth interviews conducted with 69 participants on CAB+RPV LA and 64 on oral ART (only data for oral ART shown); PP3: Cross-sectional survey of people living with HIV on ART (n=698)

1. Cordova E, et al. Open Forum Infect Dis. 2026; ofag383;
2. Durden E, et al. IAS 2025. Kigali, Rwanda. Poster LB38;
3. Patel et al. IAS 2025. Kigali, Rwanda. Poster EP0608
4. Patel et al. IAS 2025. Kigali, Rwanda. Poster WEPED080

CAB + RPV LA: Greater engagement and retention in care compared with daily oral ART

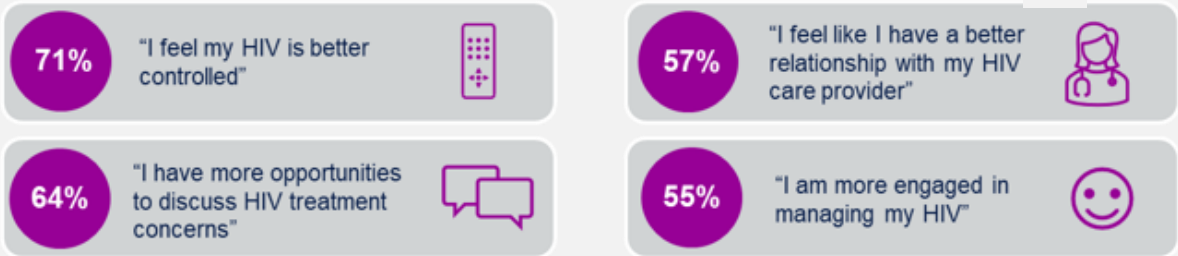


The real-world OPERA study found that a **higher proportion** of people with HIV who switched to CAB + RPV LA were **retained in care** versus oral ART after ≥12 months of follow up*¹



The real-world BEYOND study found people with HIV who switched to CAB + RPV LA **reported greater engagement in care, more chances to discuss treatment, stronger relationships with providers, and increased involvement in managing their HIV.**²

Participant-reported benefits of more frequent clinic visits (n=227, >50%)*



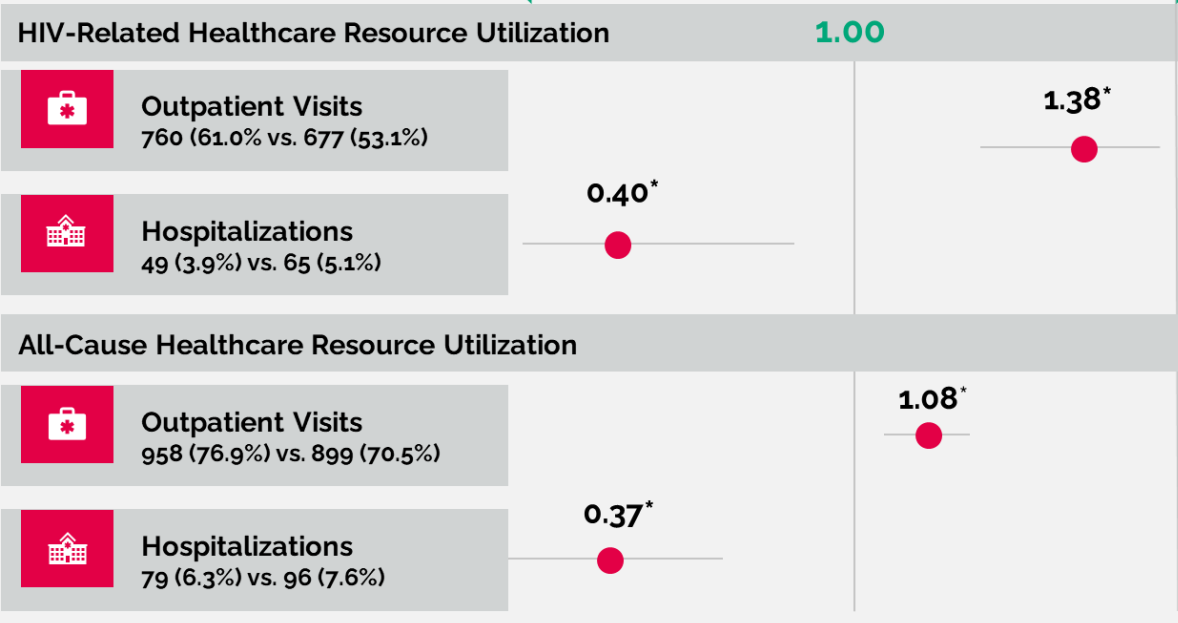
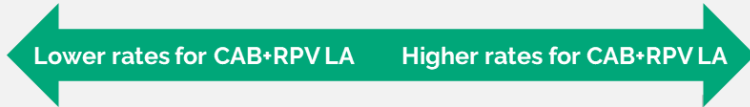
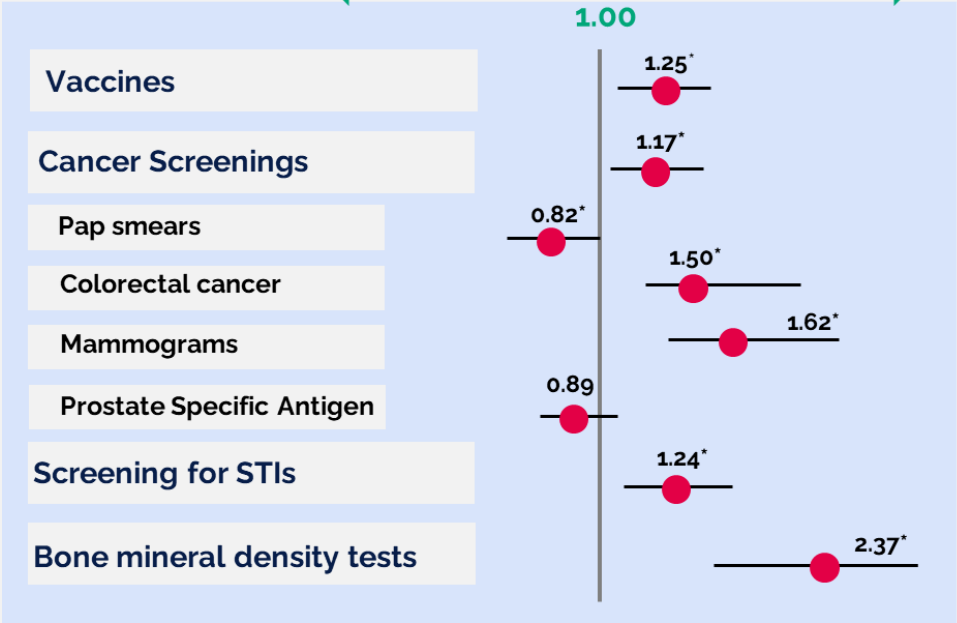
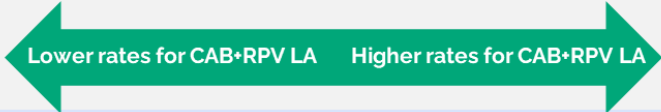
*CDC's definition of retention in care: two or more VL or CD4 tests per year, ≥3 months apart⁴
 **Responses were not mutually exclusive.
 CDC, Centers for Disease Control and Prevention; **STI**, sexually transmitted infections

1. Lackey PC, et al. AIDS 2024. Poster WEPEC319
 2. Valenti W, et al. AIDS 2024. Poster TUPEB116

CAB + RPV LA: Provides the opportunity for additional healthcare touchpoints and potential ancillary benefits



ABOVE showed that those switching to CAB + RPV LA had higher rates of vaccinations, cancer screenings, and bone density testing. In the CAB+RPV LA cohort, hospitalization rates were lower, suggesting that **more healthcare interactions could improve outcomes for PWH³**



OPERA also showed that an **increase in HCP touchpoints** gave additional opportunities for more STI testing and vaccine administration.^{1,2}

^{*}CDC's definition of retention in care: two or more VL or CD4 tests per year, ≥3 months apart⁴
CDC, Centers for Disease Control and Prevention; **STI**, sexually transmitted infections

¹. Lackey PC, et al. AIDS 2024. Poster WEPEC319
². Lackey PC, et al. IDWeek 2024. Poster 577; ³. Garriss et al; AMCP 2025, Houston, TX. Poster B6

Setting

Sana Clinic, a harm-reduction clinic at Prevention Point in Philadelphia, PA



Study and population

Retrospective cohort of **40 PWH with history of IDU** who initiated CAB+RPV LA between Feb 2022 and June 2025 with at least 6 months of follow up

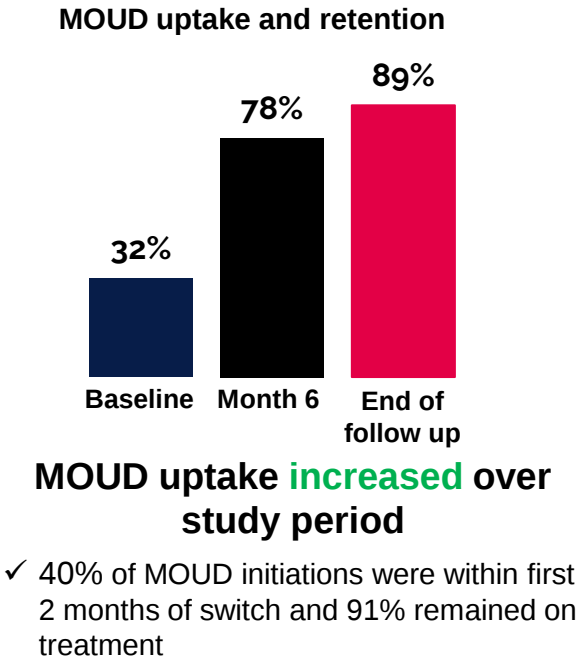
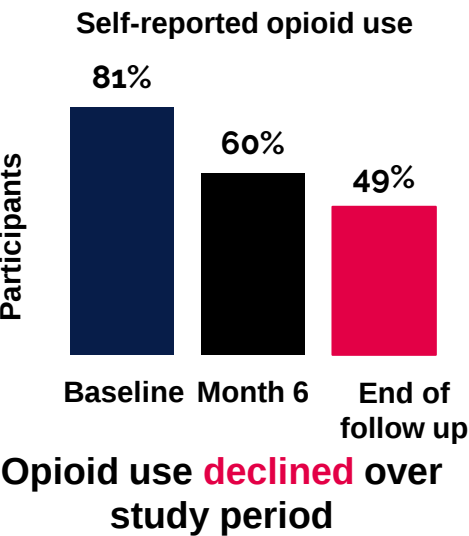


Patient Characteristics

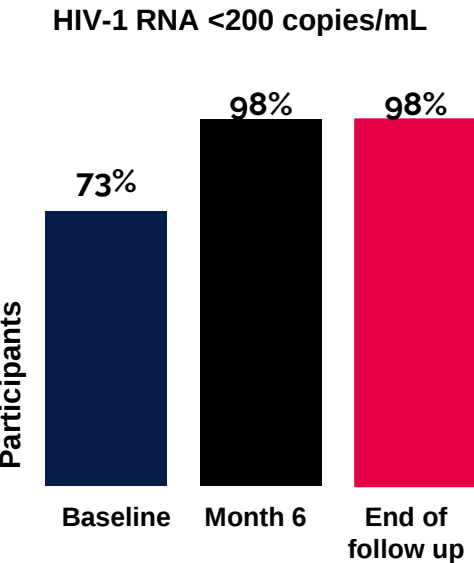
- 65% male; 95% cisgender;
- 57.5% White; 25% Black; 17.5% Latinx
- 57.5% Unstably housed
- 92.5% reported history of OUD



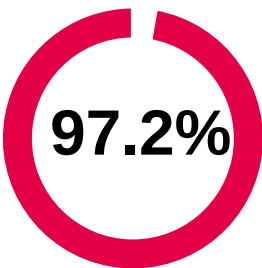
Opioid Use Disorder Outcomes



HIV Outcomes

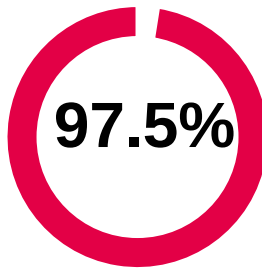


Retention among survivors



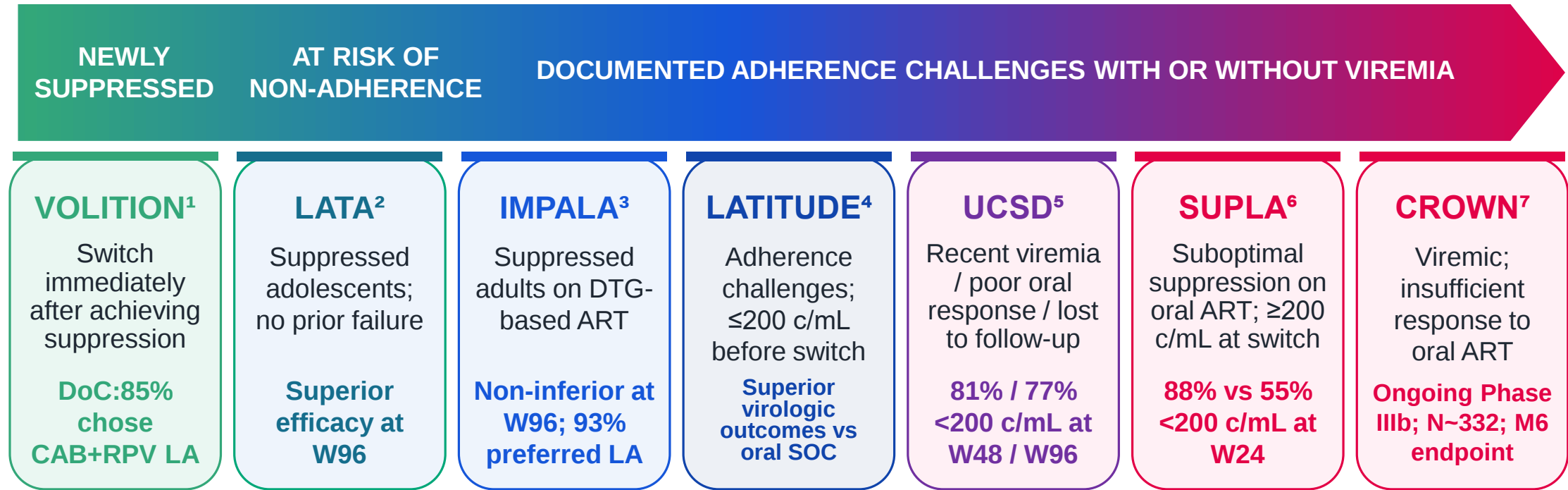
- ✓ **32.5%** received doses at alternative sites
- ✓ **22.5%** received doses incarcerated

Participants with no missed doses



Switching to CAB+RPV LA was associated with improved viral suppression and engagement in Opioid Use Disorder Treatment among

CAB + RPV LA evidence spans a broad spectrum of PLWH—from newly suppressed people to adherence challenges, with or without viremia



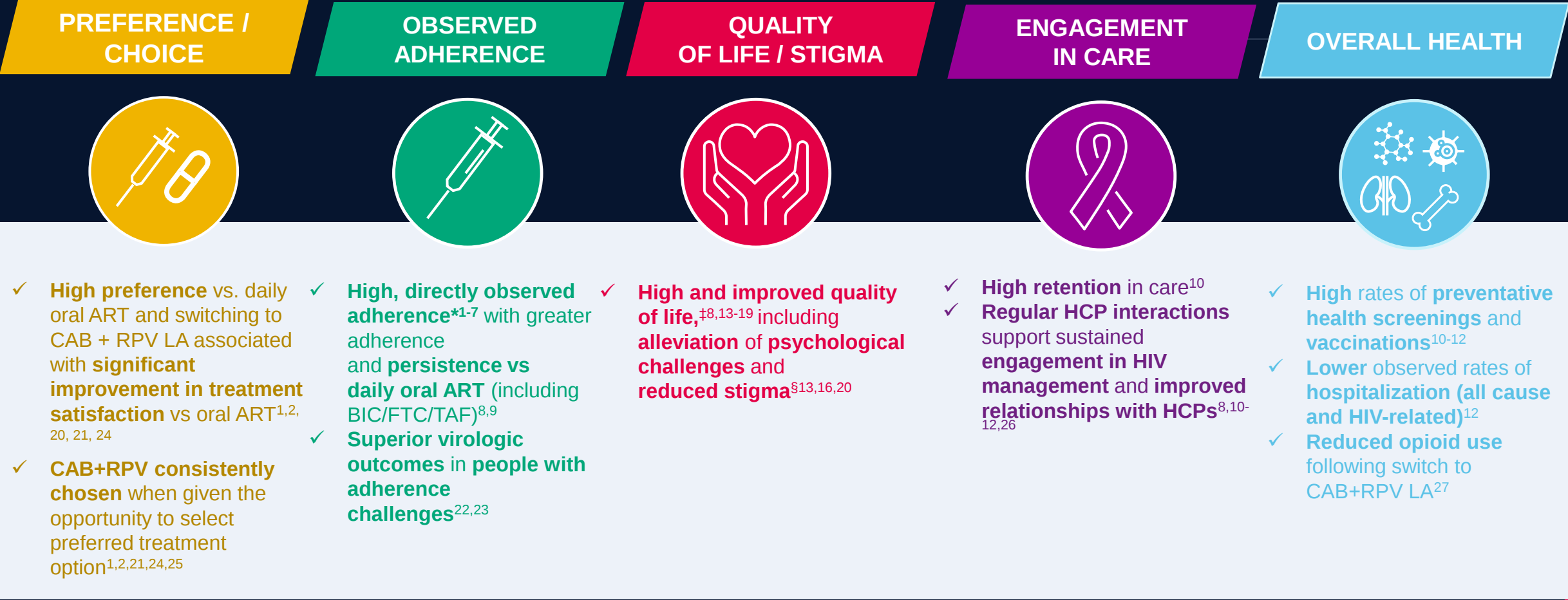
✓Most common Grades 1 to 4 AEs in ≥2% participants in label: ISRs, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash
✓ISRs through Week 48: FLAIR and ATLAS, 83% reported ISR, 1% discontinued due to ISRs; ATLAS-2M, 75% reported any ISR, <1% discontinued due to ISRs

Together, the program evaluates CAB + RPV LA from choice-led early switch through increasingly complex adherence challenges—with and without viremia.

CAB, cabotegravir; DoC: Day of Choice; ISR, injection site reactions; LA, long-acting; PLWH, people living with HIV; RPV, rilpivirine; SOC, standard of care

1. Cordova E, et al. Open Forum Infect Dis. 2026; ofag383. 2. Dangarembizi M, et al. AIDS 2026. Abstract OAX1105LB. 3. Ruzagira E, et al. AIDS 2026. Poster LB24. 4. Rana A, et al. NEJM 2026, 394(9): 858-871. 5. Ostrer L et al AIDS 2026. Poster TUPEB106. 6. Chen NY, et al. CROI 2026. Poster 530. 7. CROWN (NCT06694805). Available at: <https://clinicaltrials.gov/study/NCT06694805> (accessed Mar 2026)

CAB + RPV LA: Additional benefits beyond virologic suppression are consistently reported in RCTs and RWE



*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 96 HCP-reported adherence: 96% (n=1,039);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;⁷ ‡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; HIVTSQs: Increased scores in all items, with therapy satisfaction reaching 5.9/6.0 at Month 13
§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;
HIVDQoL, HIV dependent quality of life; HIVTSQs, HIV treatment satisfaction survey status version; HSS, HIV stigma scale; IQR, interquartile range

Q & A

- Please use the Q&A function to submit comments and questions
- If we are unable to get to your question, we will ensure to follow up with you!

FEEDBACK



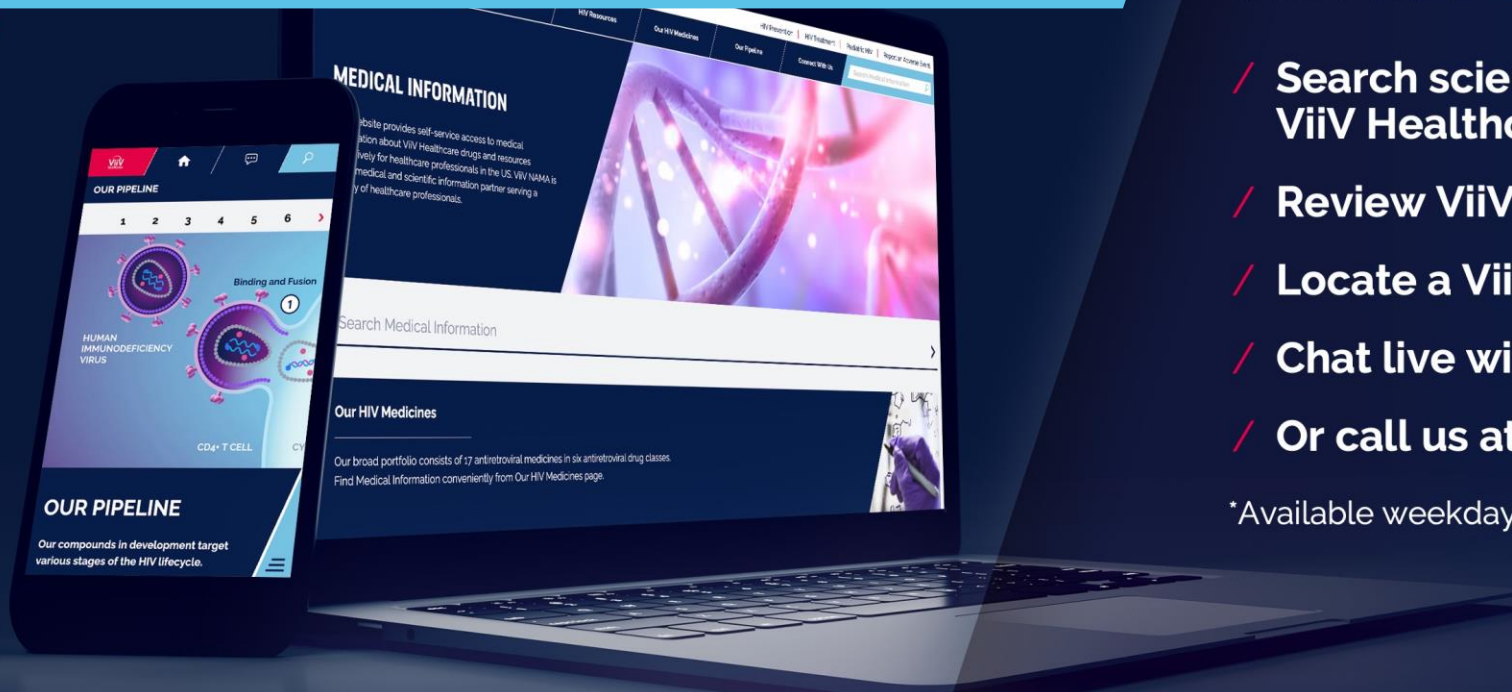
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