Real-World Use of *Cabenuva* in Virologically Suppressed People Living With HIV

Summary

- Overall, the real-world evidence (RWE) presented to date shows that the rate of maintaining virologic suppression with *Cabenuva* (long-acting cabotegravir plus rilpivirine [CAB + RPV LA]) is similar to what has been reported in phase 3 clinical trials.
- Below please find a summary of the data available to date from OPERA, the Trio Cohort Study, BEYOND, CARLOS, COMBINE-2, and SCohoLART.
  - Other RWE citations can be found in the reference list below.
- Important Safety Information can be found in the Prescribing Information and can also be accessed from Our HIV Medicines.

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A growing body of RWE has been presented/published with data in > 15,600 virologically suppressed people with HIV (PWH) treated with CAB + RPV LA that shows results consistent with the phase 3 clinical trials conducted to date. Potential overlap between patient cohorts presented below cannot be ruled out.

OPERA

OPERA includes routine clinical data from electronic health records from 101 sites across 23 US states and territories.[1] This analysis includes data collected for virologically suppressed PWH who switched to CAB + RPV LA or a new oral antiretroviral therapy (ART) regimen between January 21, 2021 and December 31, 2022. The OPERA cohort includes ~14% of PLHIV.

Through June 2023, 1362 PLHIV switched to CAB + RPV LA and 2783 switched to a new oral ART regimen.[1] The median (interquartile range [IQR]) duration of follow-up was 11 (7.6-14.3) months for CAB + RPV LA-treated patients and 17.1 (11.6-23.5) months for oral ART-treated patients.

Baseline demographics and characteristics can be found below in Table 1.

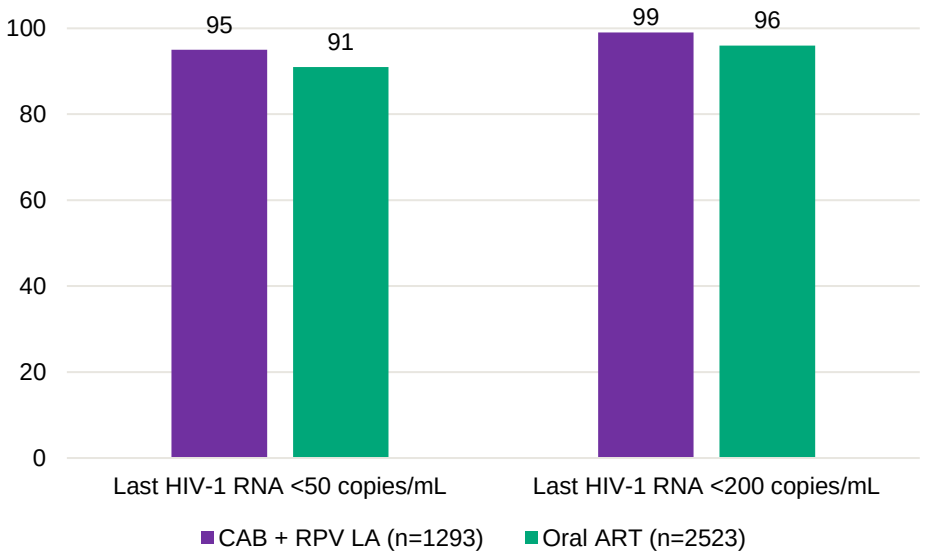
Table 1. Baseline Demographics and Characteristics from OPERA[1]

	CAB + RPV LA N = 1362	Oral ART N = 2783
Age, median (IQR), years	39 (32-52)	45 (34-56)
Female sex, %	17	18
Black race, %	41	43
Hispanic ethnicity, %	29	24
Prior third-agent class, %		
INSTI	74	68
NNRTI	8	17
PI	3	7
> 1 third-agent class	16	8
Months of prior ART, median (IQR)	20 (7-38)	37 (20-55)

ART = antiretroviral therapy; CAB + RPV LA = long-acting cabotegravir plus rilpivirine; INSTI = integrase strand-transfer inhibitor; IQR = interquartile range; NNRTI = non-nucleoside reverse transcriptase inhibitor; PI = protease inhibitor

Virologic outcomes (at least 1 HIV-1 RNA after the first injections) are available for 1293 (95%) of patients treated with CAB + RPV LA and 2523 (91%) treated with oral ART.[1] See Figure 1 below.

Figure 1. Virologic Outcomes from OPERA[1]

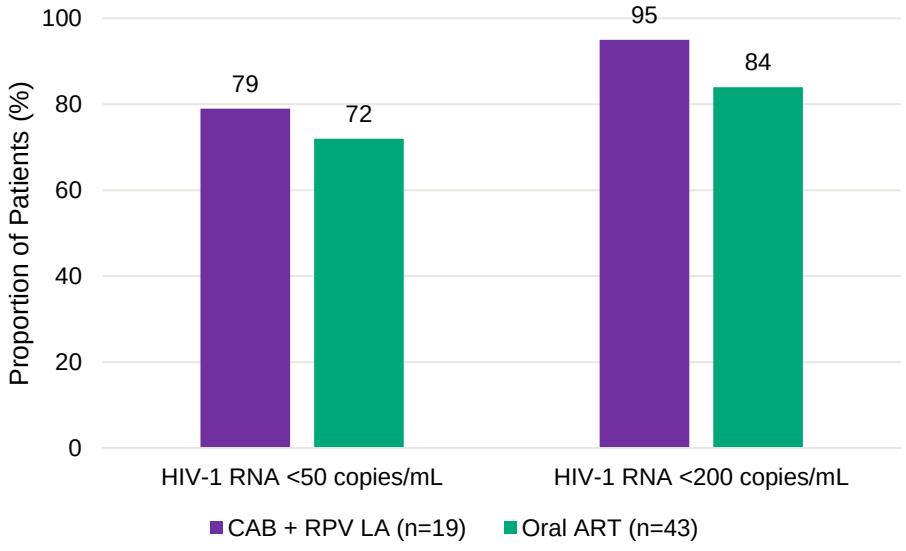


ART = antiretroviral therapy; CAB + RPV LA = long-acting cabotegravir plus rilpivirine

CVF, defined as 2 consecutive HIV-1 RNA ≥ 200 copies/mL or 1 HIV-1 RNA ≥ 200 copies/mL followed by discontinuation, was reported in 2% (25/1293) of patients who received CAB + RPV LA and 3% (78/2523) who received oral ART (adjusted odds ratio = 0.64, 95% CI 0.4-1.02).[1]

Among those with CVF, the rate of subsequent virologic suppression was high.[1] See Figure 2 below.

Figure 2. Virologic Suppression Following CVF[1]*



*Among those with HIV-1 RNA available post-CVF

ART = antiretroviral therapy; CAB + RPV LA = long-acting cabotegravir plus rilpivirine; CVF = confirmed virologic failure

A logistic regression model was fit to evaluate age, sex, race, US region, injection drug use, history of AIDS-defining illness, CD4+ T-cell count, comorbid conditions, prior regimen class, and body mass index (BMI) as predictors of CVF.[1] Only baseline CD4+ T-cell count was associated with CVF; every 100 cell/μL increase was associated with a 15% lower risk of CVF.

A subsequent analysis of additional data from OPERA is available from a total of 2858 virologically suppressed patients who received CAB + RPV LA between January 21, 2021 and December 31, 2023.[2]

The median (IQR) time of follow-up among complete initiators (those who received 2 initiation injections within 67 days; n = 2618) was 11 months (6, 18). Patient demographics were similar to what has been reported previously.

Virologic outcomes were available for 2485 patients who had at least 1 viral load available during follow up.[2] The last HIV-1 RNA assessed was < 50 copies/mL among 95% (2355/2485) of patients overall and in 94% (700/743) of patients with a BMI ≥ 30 kg/m^2.

In this analysis the rate of CVF during follow up was 1% overall (n=21) and 1% (n=8) among those with a BMI ≥ 30 kg/m^2.[2] Most CVFs (12/21) occurred during the first 6 months of follow up.

An analysis of 415 virologically suppressed women has been presented.[3] Among the 372 women with complete initiation and at least 1 HIV-1 RNA assessment available, 94% (349/372) had HIV-1 RNA < 50 copies/mL at their last follow up. CVF occurred in ≤ 5 patients (HIPAA regulations require masking values of 1 to 5 individuals).

No safety data or whether resistance occurred at virologic failure is available from OPERA currently.

TRIO COHORT STUDY[4]

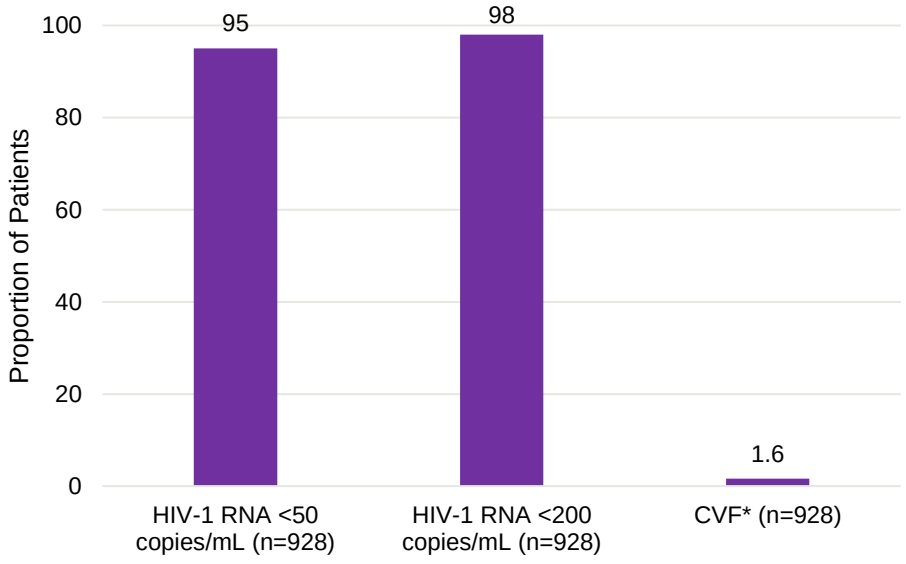
The Trio Health Cohort is an observational study that utilizes electronic medical records to prospectively collect longitudinal data. Data are available for 1198 patients who were virologically suppressed at the time of switching to CAB + RPV LA and received injections between February 2021 and March 2024. The median (IQR) length of follow up was 11 (5, 18) months.

At baseline, patients were mostly male (77%) and Black/African American (48%) or White (42%). The median (IQR) BMI at baseline was 28 kg/m^2 (24, 32) and a BMI 30-39 or ≥ 40 kg/m^2 was reported in 30% and 6% of patients, respectively. Among the 314 patients with HIV genotype data available prior to initiation, 2% (6/314) had INSTI resistance reported but < 1% (2/314) had resistance to cabotegravir. Non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance was reported in 19% (61/314) of patients but resistance to rilpivirine was reported in 5% (15/214).

Among the 928 patients with at least 1 follow up HIV-1 RNA available, 95% (n = 882) were < 50 copies/mL (see Figure 3).

There were 6934 follow up injections administered and 89% (6176/6934) were on time (delayed injections defined as > 7 days after target). Sixty-nine percent (n = 1123) of individuals included had no delayed injections.

Figure 3. Virologic Outcomes from the Trio Cohort Study[4]



*CVF was defined as 2 consecutive VLs ≥ 200 copies/mL or 1 VL ≥ 200 copies/mL with discontinuation within 4 months of the last recorded injection.

CVF = confirmed virologic failure

CVF among those with post-baseline HIV-1 RNA data available was observed in 15 patients (1.6%) after a median (IQR) of 7 (3, 12) months. An HIV genotype after CVF was available for 5 patients; cabotegravir resistance was reported in 1 patient (S147G + N155H) and rilpivirine resistance was reported in 3 (Y181C + G190S; K101E; Y181C). Only 8/15 patients had > 2 months of follow up on a subsequent regimen and 6 re-suppressed.

No safety data is available from the Trio Cohort Study.

BEYOND[5]

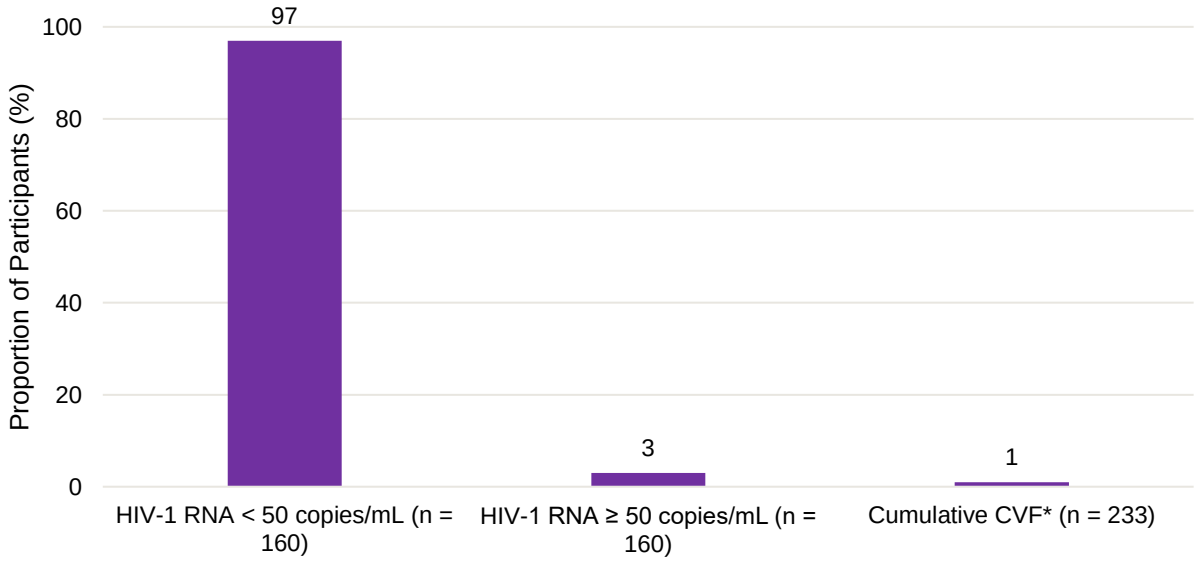
BEYOND was a 2-year prospective, observational real-world study of the use of CAB + RPV LA across 27 sites in the US. Data for the consistent-with-label (CWL) population (n = 233) through Month 24 are included here.

The mean (standard deviation [SD]) age was 46 (13) years. Patients included were mostly male (88%) and White (49%) or Black or African American (39%). The median (range) BMI was 28 (17-58) kg/m^2. Half of patients included were initiated on every-2-month CAB + RPV LA; by Month 24, 98% of participants received every-2-month dosing. The most common prior regimen was bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF, 37%). The median (range) duration of prior treatment was 10.3 (0.1-35.7) years.

The rate of adherence to the dosing schedule (±7 days) was dependent on the definition used. When assessed relative to the date of the initial injection, 59% of injections were administered on time. When assessed relative to the date of the previous injection, 89% of injections were administered on time.

Virologic data was available at both baseline and Month 12 through 24 for 160 participants. See Figure 4 below. Through this analysis there were a total of 2 CVFs reported; no new CVFs occurred after Month 6.

Figure 4. Virologic Outcomes from BEYOND through Month 24[5]



*includes patients with at least 1 HIV-1 RNA available (n = 233).

CVF = confirmed virologic failure (defined as 2 consecutive HIV-1 RNA ≥ 200 copies/mL or 1 HIV-1 RNA ≥ 200 copies/mL followed by discontinuation with 3 months

Of the 308 participants included in the Month 24 analysis (includes both the CWL and inconsistent with label populations), 28% (n = 87) had an adverse event. Five percent (n = 14) reported a drug-related adverse event (excluding injection site reactions [ISRs]). ISRs were reported by 10% (n = 31) of participants. It is important to note that BEYOND was not designed to collect adverse event information. If adverse events were reported, sites were instructed to capture them on the case report form. There was no prospective monitoring of adverse events beyond what is normally done in clinical practice.

Through Month 24, 44 patients from the CWL population discontinued CAB + RPV LA. The most common reasons cited patient preference 20% (both populations), medication cost/access issues (20%; both populations), and ISRs/injection pain (9% [all from CWL group).

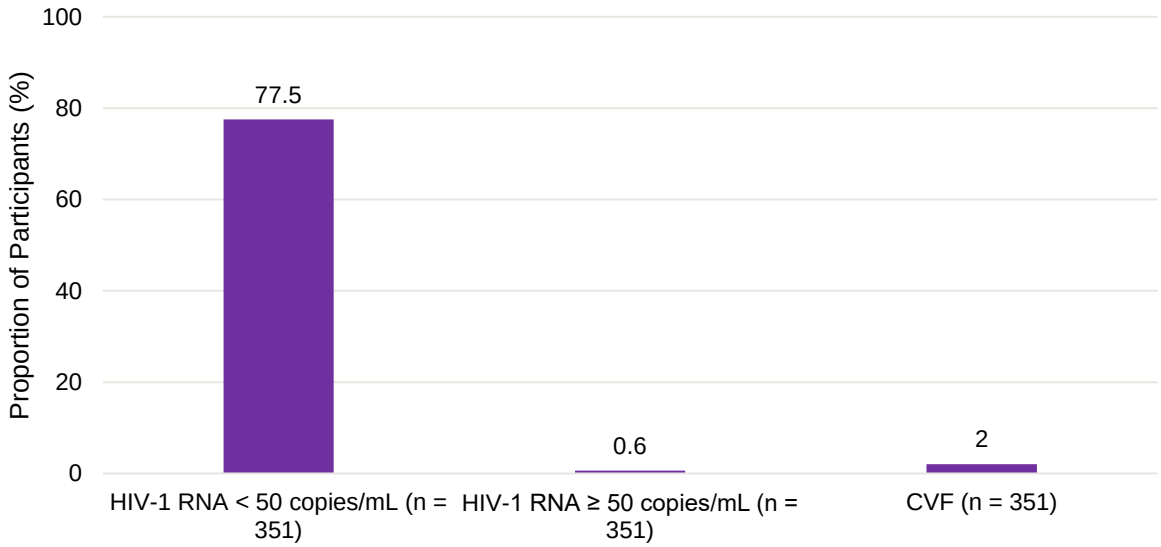
CARLOS[6]

CARLOS is a non-interventional, 3-year, multicenter, prospective German cohort study of virologically suppressed PWH who switched to CAB + RPV LA administered every 2 months. The analysis population included participants who reached the Month 24 window, as well as those who discontinued treatment but would have reached Month 24 at the time of data cut-off (November 4, 2024).

The median (IQR) age was 42 (35, 50) years and 74% were < 50 years of age. Patients included were predominantly male (95%). BMI was ≥ 30 kg/m^2 in 13% of patients. The most common oral ART used prior to CAB + RPV LA was BIC/FTC/TAF (23%). The median (IQR) duration of prior treatment was 7.9 (4.3, 11.4) years.

Virologic outcomes were available for 351 participants who received at least 1 dose of CAB + RPV LA. See Figure 5 below. When analyzing the last known viral load at Month 24 or at discontinuation (last observation carried forward), 98% (n = 343/351) of participants maintained virologic suppression. There were 5 CVFs reported through Month 12 with 3 having NNRTI and/or integrase strand-transfer inhibitor (INSTI) resistance detected at failure (E138K and Q148R [n=1]; Y181C, T97A, E138K, Q148R and N155H [n=1]; K101E [n=1]). Between Months 12 and 24, two additional participants met CVF criteria. One participant met criteria based on two viral loads 2 days apart at their 10th injection and resuppressed on CAB + RPV LA. The second participant had NNRTI (K101P) and INSTI (E138K, Q148R) mutations at failure.

Figure 5. Virologic Outcomes from CARLOS through Month 24[6]



*CVF defined as confirmed HIV-1 RNA ≥ 200 copies/mL or a single HIV-1 RNA ≥ 200 copies/mL followed by treatment discontinuation for any reason

CVF = confirmed virologic failure

Adherence to the dosing schedule (±7 days) was reported in 88% (n = 3231/3676) of maintenance injection visits.

Excluding ISRs, 54 drug-related adverse events were reported amongst the 351 participants. One serious drug-related adverse event was reported (anxiety disorder). Of 4027 injections administered, 370 (9%) resulted in an ISR; pain was the most common (8%) ISR reported. There were 18 (5%) discontinuations due to ISRs/other tolerability reasons and 34 (10%) for other reasons including a preference for oral ART (n = 16) and other (n = 9). Additionally, 18 participants were missing data or lost to follow-up.

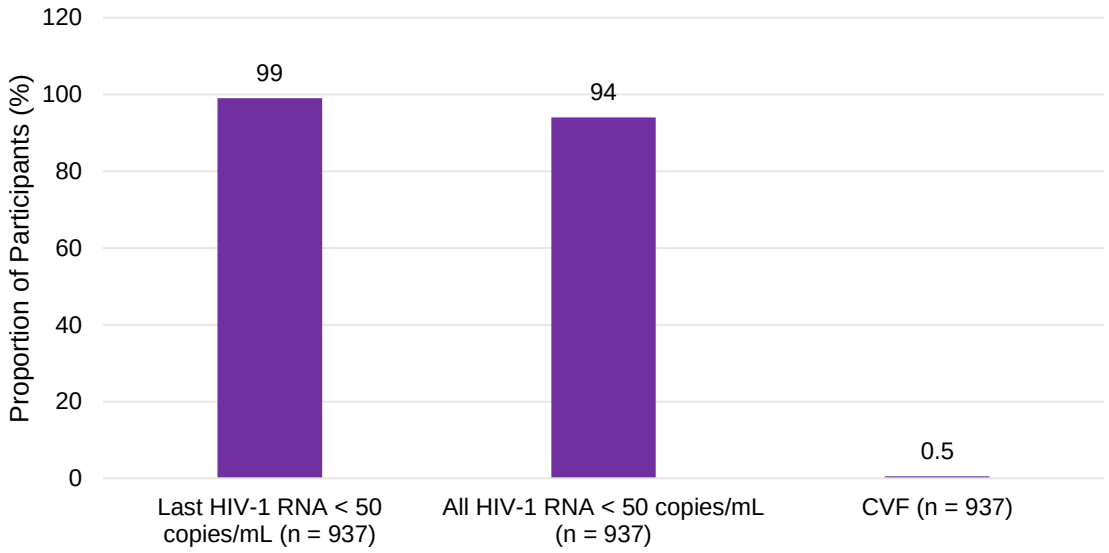
COMBINE-2[7]

COMBINE-2 includes virologically suppressed patients with no history of resistance or virologic failure with NNRTI and INSTI classes enrolled at NEAT ID Network across 7 Europe countries from December 2020 through May 2024.

The median (IQR) age was 45 (37, 53) years and 36% were > 50 years of age. Patients included were predominantly male (85%) and White (64%). The median (IQR) BMI was 25 kg/m² (23, 28). The median (IQR) duration of prior treatment was 9 (6, 14) years.

Of the 956 patients included, 882 (92%) remained on CAB + RPV LA at the time of analysis with a median (IQR) duration of follow-up was 10 (7, 17) months and 937 patients had follow-up viral loads available. Virologic outcomes are summarized in Figure 6. Additional information regarding the 5 patients with CVF is summarized in Table 2. Virologic outcomes were similar in those with BMI < 30 kg/m² and ≥ 30 kg/m² (last VL < 50 copies/mL, 99% [both groups]; all VL < 50 copies/mL, 94% and 97%, respectively).

Figure 6. Virologic Outcomes from COMBINE-2[7]



*CVF was defined as 2 consecutive VLs ≥ 200 copies/mL or 1 VL ≥ 200 copies/mL followed by discontinuation

CVF = confirmed virologic failure

Table 2. COMBINE-2 CVF Summary[a,7]

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Sex	Male	Female	Male	Male	Male
BMI, kg/m^2	25.3	23.5	25.1	29	Unknown
HIV-1 sub-type	B	D	B	H	01_AE
Time to CVF after CAB + RPV LA Initiation, days	35	96	402	120	582
Baseline RAMs	NA	NA	NA	NA	NA
RAMs at Failure	NNRTI: V179I, E138A INSTI: none	None detected	None detected	NNRTI: K101E, E138G, G190S); INSTI: L74M, Q148R, T97A)	NNRTI: E138K; INSTI: N155H
ART after Failure	DRV/c/FTC/TAF	DRV/r + ABC/3TC, then BIC/FTC/TAF, then DTG/3TC	DRV/c/FTC/TAF, then DOR/3TC/TDF	DRV/r, FTC/TDF	DRV/c/FTC/TAF
Follow-up VL after switch, copies/mL	< 20	109 (DRV/r regimen), then 30 (both INSTI-based regimens)	1 (both regimens)	20	NA

[a] All patients with CVF had no missed or delayed injections.

3TC= lamivudine; ABC = abacavir; ART = antiretroviral therapy; BIC = bictegravir; BMI = body mass index; CAB + RPV LA = long-acting cabotegravir plus rilpivirine; c = cobicistat; CVF = confirmed virologic failure; DTG = dolutegravir; DOR = doravirine; DRV = darunavir; INSTI = integrase strand-transfer inhibitor; NA = not available; NNRTI = non-nucleoside reverse transcriptase inhibitor; r = ritonavir; RAMs = resistance associated mutations; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; VL = viral load

Overall, 919 (96%) patients had on-time injections; 25 (3%) had delayed doses and 7 (1%) had missed doses.

Treatment discontinuation was reported in 74 patients (8%); 48 patients continued to be followed in the study.

No safety data is available from COMBINE-2.

SCOHOLART[8]

SCohoLART is prospective, single-center, cohort study of virologically suppressed adults (N = 549; HIV-1 RNA < 50 copies/mL) treated with CAB + RPV LA in Milan, Italy; enrolment started in July 2022. Patients included were mostly male (91%) with a median (IQR) age of 49 (40-56) years. The median (IQR) time since diagnosis was 13.8 (8.7-20.4) years and duration of prior ART was 11.3 (7.9-17.3).

At Months 12 and 24, 99% (95% CI 98.2% to 99.9%) and 98.6% (95% CI 97.5% to 99.6%) of participants had HIV-1 RNA < 50 copies/mL, respectively.

Treatment discontinuation occurred in 16% of participants by Month 24. Reasons for treatment discontinuation included: injection site reaction (n = 37), other causes (n = 22), toxicity (central nervous system, n= 4; gastrointestinal, n = 2; other, n = 12), virologic failure (n = 6; see Table 2 for additional details), hypersensitivity/allergy (n = 4), and death (n = 2).

Table 2. Virologic Failures Reported in SCohoLART[8]

Participant (sex, age)	BMI (kg/m^2)	Regimen prior to CAB + RPV LA	HIV-1 RNA at VF (copies/mL)	Regimen after VF	HIV-1 RNA after switch (copies/mL)	RAMs at VF[a]
Participant 1 (Male, 50)	22.2	DTG/ABC/3TC	371; 436	DRV/c/FTC/TAF	< 50 (after 4 weeks)	NRTI: E138A[b] INSTI: E138E/K[c], Q148R[b]
Participant 2 (Male, 41)	25.7	DTG/RPV	34,300	DRV/c/FTC/TAF	< 50 (after 32 weeks)	NNRTI[c]: K101P/Q, E138A; INSTI[c]: E138K, Q148R
Participant 3 (Male, 56)	24.6	BIC/FTC/TAF	636; 66,500	DRV/c/FTC/TAF	< 50 (after 14 weeks)	NNRTI[b]: K101E, E138A; INSTI: G157Q[b]
Participant 4 (Male, 57)	25.3	BIC/FTC/TAF	276; 55	BIC/FTC/TAF	< 50 (after 1 week)	WT
Participant 5 (Male, 30)	28.3	BIC/FTC/TAF	55; 55	BIC/FTC/TAF	< 50 (after 24 weeks)	WT
Participant 6 (Male, 40)	30.8	DTG/RPV	72; 58	CAB + RPV	< 50 (after 4 weeks)	Not amplifiable

[a] Pre-ART resistance tests not available for Participants 1, 2 and 3; WT for Participants 4, 5, and 6; [b] DNA and RNA testing; [c] RNA testing only

3TC = lamivudine; ABC = abacavir; BIC = bictegravir; BMI = body mass index; CAB = cabotegravir; DRV/c = darunavir/cobicistat; FTC = emtricitabine; INSTI = integrase strand transfer inhibitor; LA = long-acting NNRTI = non-nucleoside reverse transcriptase inhibitor; VF = virologic failure; WT = wild type

Through the follow-up period, 98.1% (n = 5276/5376) of scheduled injections were administered within the ±7 day dosing window.

OTHER STUDIES REPORTING REAL WORLD EVIDENCE

Please see the reference list below for other RWE presentations or publications (not all inclusive).[9-54]

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

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