Conflicts of Interest

- Cindy Garris, Ronald D'Amico, Marybeth Dalessandro, and Maggie Czarnogorski are employees of ViiV Healthcare and own stock in GlaxoSmithKline
- Nisha Tanda is a contract employee working for GlaxoSmithKline
- Jane Fricker is an employee of and owns stock in GlaxoSmithKline
- Sonal G. Mansukhani is an employee of Evidera, which receives funding from ViiV Healthcare for their work
- Paul Benson has nothing to disclose
- Blair Thedinger owns stock in ViiV Healthcare
- Daniela Chiriboga-Salazar has served as a principal investigator for ViiV Healthcare and her institution has received grants and non-financial support from ViiV Healthcare
- Jason Flamm has served as a principal investigator for ViiV Healthcare

PATIENT PERSPECTIVES ON IMPLEMENTATION OF A LONG-ACTING INJECTABLE ANTIRETROVIRAL THERAPY REGIMEN IN HIV US HEALTHCARE SETTINGS: FINAL MONTH 12 RESULTS FROM THE CUSTOMIZE STUDY

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Background

- Cabotegravir (CAB), an INSTI, and rilpivirine (RPV), an NNRTI, have been approved in the United States, Canada, Australia, and Europe as the first complete long-acting (LA) injectable regimen indicated for the maintenance of virologic suppression in people living with HIV-1 (PLHIV)[1,2]
- CAB + RPV LA administered monthly[3,4] or every 2 months[5] may address challenges associated with daily oral ART, such as stigma, pill burden/fatigue, drug/food interactions, and adherence
- CAB + RPV LA provides PLHIV with a less frequent dosing alternative to daily oral ART but requires regular clinic visits to receive injections from a healthcare provider
- It is important to understand how to optimize administration of CAB + RPV LA in routine care from the perspective of PLHIV
- The CUSTOMIZE study reports patient participant perspectives after 12 months of CAB + RPV LA implementation in US healthcare settings

ART, antiretroviral therapy; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor.

1. Cabenuva [prescribing information]. ViiV Healthcare; 2021. **2.** Vocabria [prescribing information]. ViiV Healthcare; 2021. **3.** Swindells et al. *N Engl J Med*. 2020;382:1112-1123. **4.** Orkin et al. *N Engl J Med*. 2020;382:1124-1135. **5.** Overton et al. *Lancet*. 2020;396:1994-2005.

CUSTOMIZE study sites



Clinic Types

- Private Practice
- University hospital
- Federally Qualified Health Center (FQHC)
- AIDS Healthcare Foundation
- Integrated Managed Care Consortium

CUSTOMIZE: Single-Arm, Multicenter, Hybrid III Implementation-Effectiveness Study

- CUSTOMIZE assessed patient participant perspectives during a 12-month period to identify barriers and facilitators of and effective strategies for successful implementation of the CAB + RPV LA injectable regimen in clinical practice settings
- Virologically suppressed participants were enrolled across 8 US clinics to receive monthly CAB + RPV LA injections after a 1-month oral lead-in of CAB and RPV
- Participants completed surveys at baseline/Month 1, Month 4, and Month 12 (before the first, fourth, and twelfth injections, respectively)
  - Surveys assessed attitudes, expectations, and experiences of participants regarding the CAB + RPV LA regimen, including HIV treatment preference
  - Treatment satisfaction was assessed by the 12-item version of the HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs)
  - Univariate distribution of every survey item was tabulated and summarized using standard distributional statistics

CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

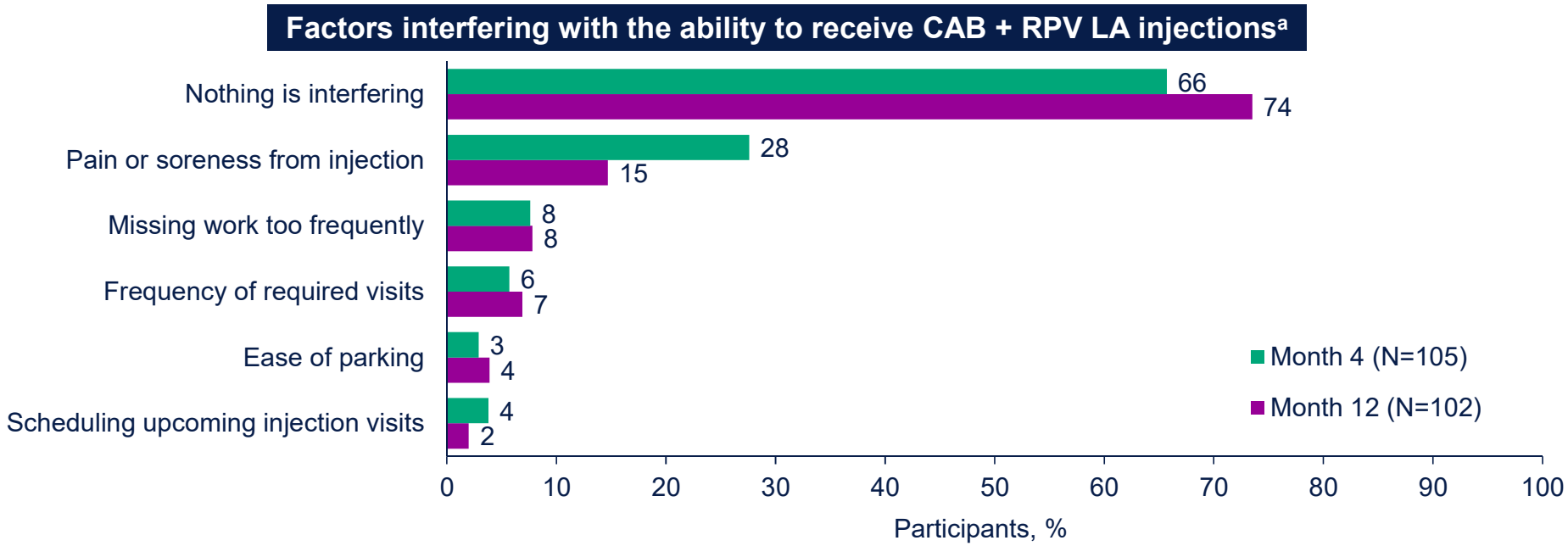
Participant Characteristics

Parameter	Participants (N=109)[a]
Age, mean (range), y	39 (20-65)
<35, n (%)	52 (48)
35-49, n (%)	31 (28)
≥50, n (%)	26 (24)
Male, n (%)	95 (87)
Race, n (%)	
White or Caucasian or European heritage	64 (59)
Black or African American	38 (35)
American Indian or Alaskan Native	5 (5)
Multiple	2 (2)
Ethnicity, n (%)	
Hispanic or Latino	29 (27)
Body mass index, median (range), kg/m^2	27 (17-54)

CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

[a]Baseline characteristics are not included for 6 additional participants who enrolled in CUSTOMIZE but discontinued before receiving their first CAB + RPV LA injection.

Most Participants Had No Challenges Receiving CAB + RPV LA Injections



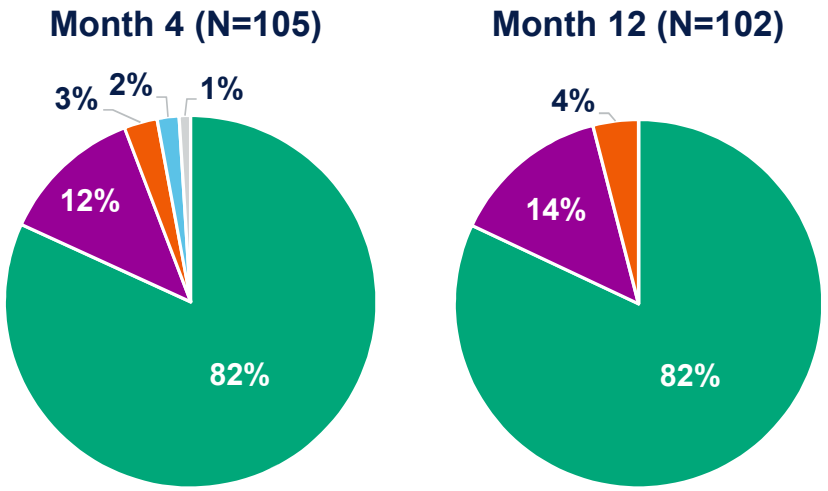
- The most common concern at baseline was injection pain or soreness (58%); by Month 12, 15% of participants reported this concern
- At Month 12, 83% of participants indicated appointments available outside of traditional work time would be extremely or very helpful

CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

[a]Participants were asked to report any factors that interfered with their ability to receive monthly CAB + RPV LA injections.

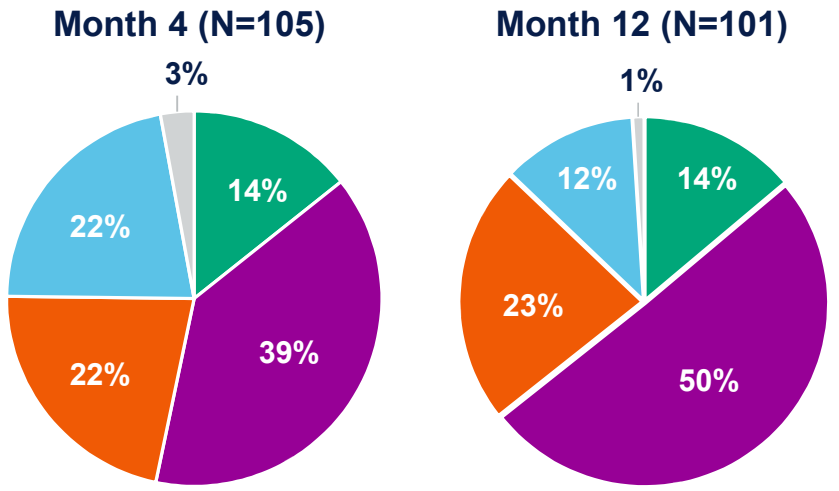
Time Spent in the Clinic Decreased Between Months 4 and 12

Average exam room waiting time[a]



Exam room waiting time was consistent between Months 4 and 12: majority reported 15 mins or less

Average total clinic time[a]



The proportion of participants spending ≤30 minutes in the clinic increased between Months 4 (53%) and 12 (64%)

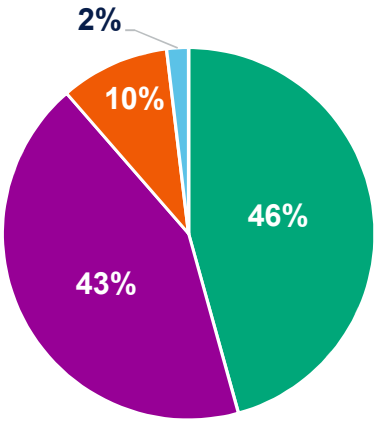
1-15 min | 16-30 min | 31-45 min | 46-60 min | >60 min

[a]Participant-reported time spent in an exam room waiting and total time spent in the clinic were assessed in separate survey questions.

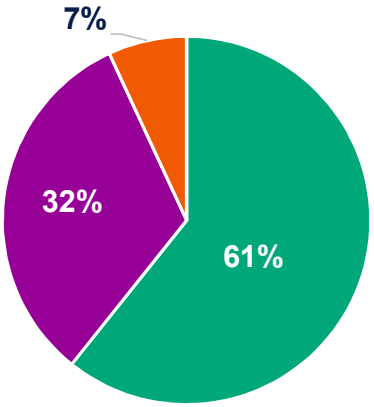
Monthly Clinic Visits and Time Spent in the Clinic Were Highly Acceptable After 4 and 12 Months

Acceptability of time spent in the clinic/practice[a]

Month 4 (N=105)



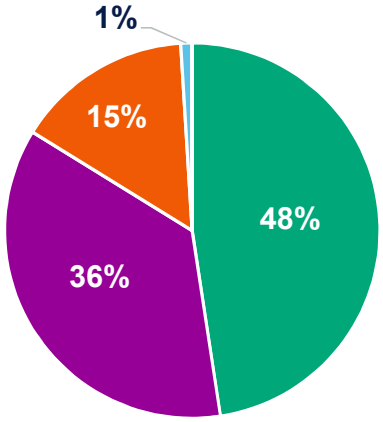
Month 12 (N=102)



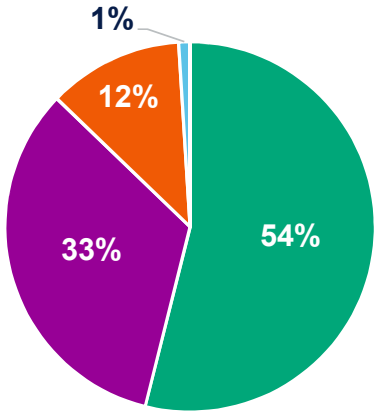
At Month 12, 93% thought time in the clinic was extremely or very acceptable

Acceptability of coming to the clinic/practice[a]

Month 4 (N=105)



Month 12 (N=102)



At Month 12, 87% thought coming to the clinic was extremely or very acceptable

Extremely acceptable | Very acceptable | Somewhat acceptable | A little acceptable | Not at all acceptable

[a]Participant-reported acceptability of time spent in the clinic/practice and of coming to the clinic/practice on a monthly basis were assessed in separate survey questions.

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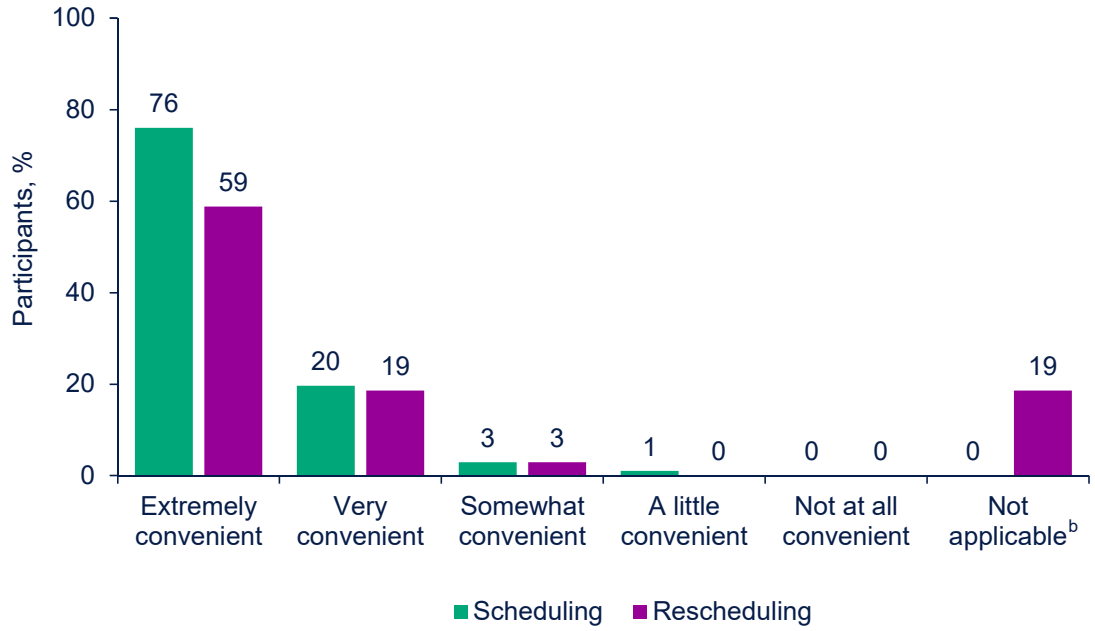
Flamm et al. Virtual ISPOR 2021. Slides.

Scheduling and Rescheduling CAB + RPV LA Injections Was Convenient Through 12 Months of Treatment

- 96% (98/102) of participants found scheduling injections to be extremely or very convenient
- Of participants needing to reschedule injections, 96% (79/82) found rescheduling to be extremely or very convenient

Convenience of scheduling and rescheduling injection visits (N=102)[a]

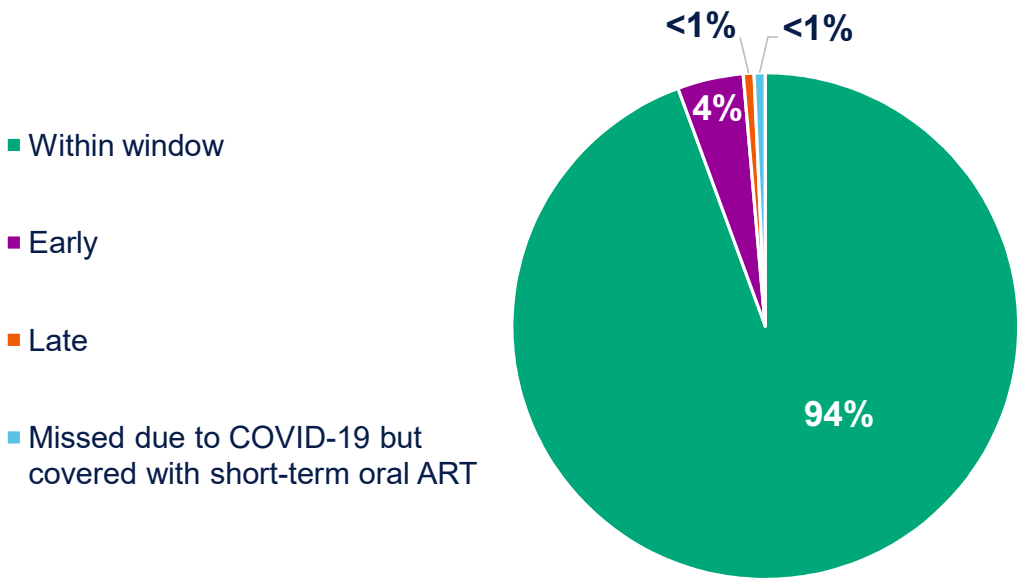


CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

[a]Participant-reported convenience of their clinics' procedures for scheduling and rescheduling injection visits was assessed at Month 12. [b]Participants did not have to schedule/reschedule injections.

Most Injections Occurred Within the ±7-Day Dosing Window Through Month 12

Adherence to treatment window through Month 12



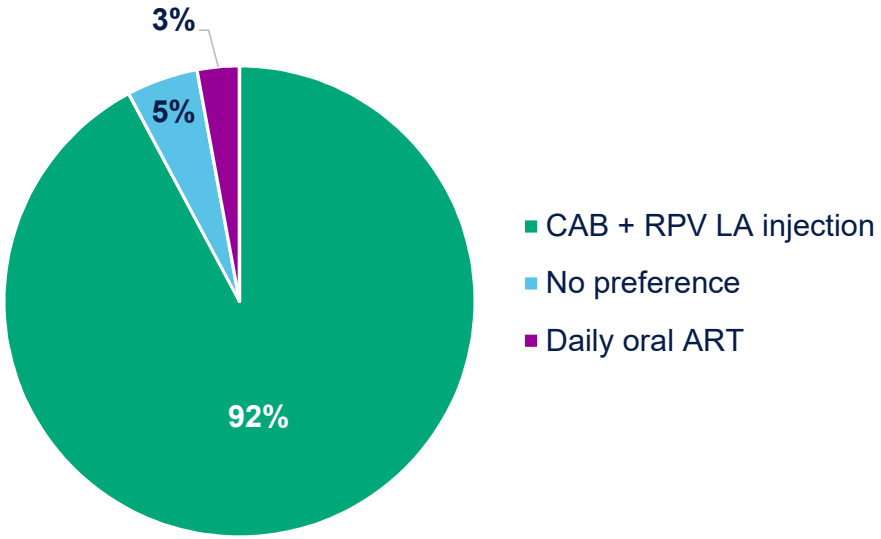
	Number of injections (N=1140)
Within window, n (%)	1076 (94)
Early out of window (>7 days before target treatment date), n (%)	48 (4)
8 to 14 days early	40 (4)
>14 days early	8 (<1)
Late out of window (>7 days after target treatment date), n (%)	8 (<1)
Mean, days	9.6
Median (range), days	10.0 (8.0-11.0)
Missed due to COVID-19, n (%)	8 (<1)

ART, antiretroviral therapy.

Most Participants Preferred CAB + RPV LA Injections to Daily Oral ART

- At Month 12, 92% of participants preferred CAB + RPV LA injections to daily oral ART (3%)
- Attributes of the HIV therapy that most supported participant preference[a] were
  - Frequency of administration (44%)
  - Mode of administration (40%)

HIV treatment preference at Month 12 (N=102)



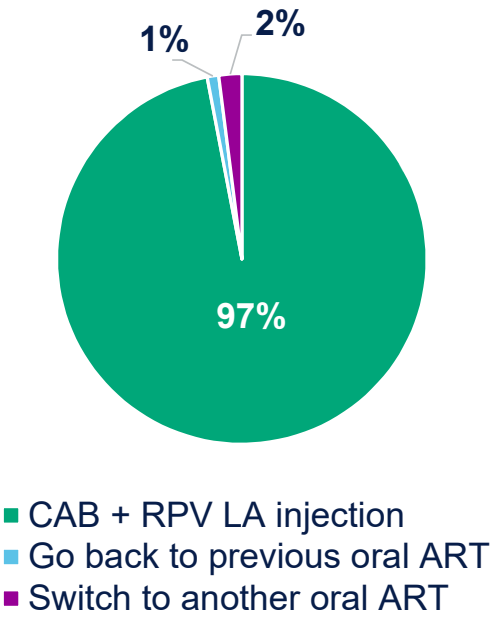
ART, antiretroviral therapy; CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.

[a]Additional question asked for participants selecting daily oral ART or CAB + RPV LA as their preferred HIV therapy.

Treatment Satisfaction Was High, and Most Participants Plan to Continue CAB + RPV LA Treatment Going Forward

- Treatment satisfaction increased from baseline at Months 4 and 12, with mean (SD) change from baseline in HIVTSQs scores of +1.50 (6.59) and +2.56 (6.18), respectively[a]
  - Mean HIVTSQs scores[a] were
    - 60.7 at baseline
    - 62.1 at Month 4
    - 63.3 at Month 12
- At Month 12, 99 (97%) of 102 participants reported that they will continue using CAB + RPV LA for HIV treatment going forward

Which treatment will you use going forward? (N=102)[b]



ART, antiretroviral therapy; CAB, cabotegravir; HIVTSQs, HIV Treatment Satisfaction Questionnaire, status version; LA, long-acting; RPV, rilpivirine.

[a]0- to 66-point scale, where higher values represent higher treatment satisfaction. [b]Assessed at Month 12.

Conclusions

- Final implementation data from CUSTOMIZE suggest that CAB + RPV LA, the first complete long-acting ART, is a convenient, acceptable, and feasible treatment option
- Most participants had no challenges receiving monthly CAB + RPV LA injections
- Time spent in the clinic and coming to the clinic for monthly injection visits was highly acceptable after 12 months for most participants
- Scheduling was extremely or very convenient for 96% of participants
- Most injections (94%) occurred within the ±7-day dosing window through 12 months of treatment, with <1% of injection visits impacted by COVID-19
- After 12 months, 92% of participants preferred CAB + RPV LA to daily oral ART, and 97% reported that they will continue CAB + RPV LA for treatment going forward, indicating this regimen is an appealing treatment for PLHIV.

ART, antiretroviral therapy; CAB, cabotegravir; LA, long-acting; PLHIV, people living with HIV-1; RPV, rilpivirine.

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