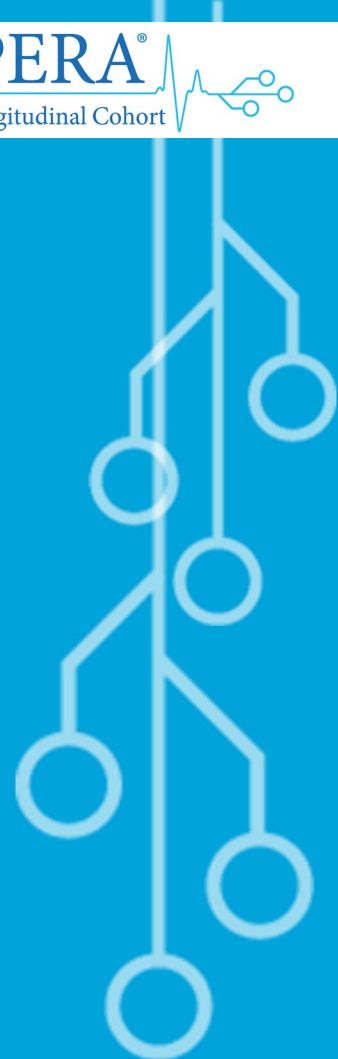


# Real-World Use of Long-Acting Cabotegravir + Rilpivirine in the US: Effectiveness in the First Year

Michael G Sension

CAN Community Health, Fort Lauderdale, FL, USA

Friday, October 21, 2022





# Disclosures

Speakers Bureaus: ViiV Healthcare and Gilead Sciences

Advisory Boards: ViiV Healthcare, Gilead Sciences, and Epividian

# Cabotegravir + Rilpivirine (CAB+RPV)



1<sup>st</sup> long-acting (LA) ART regimen



Intramuscular gluteal injections administered by HCP



Approved for people with HIV-1 (PWH) :

- On a stable ART regimen
- Virologically suppressed (HIV-1 RNA < 50 copies/mL)
- No history of treatment failure
- No known or suspected resistance to either CAB or RPV

FDA Approval Dates

Jan 21, 2021:

Monthly injections

Feb 1, 2022

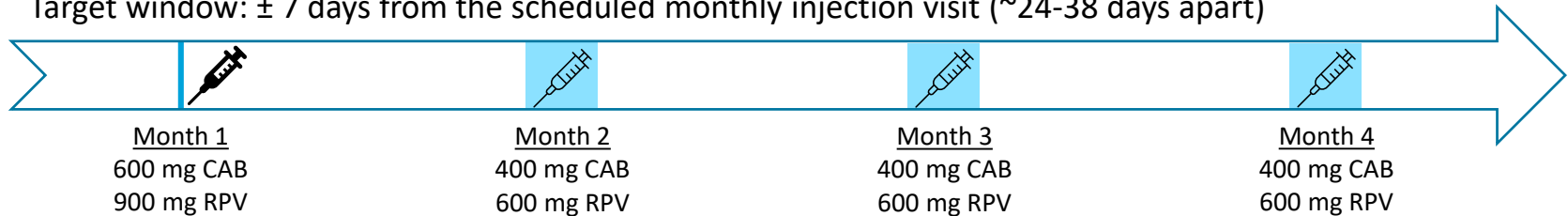
Every-2-month injections  
(every other month)

# CAB+RPV LA Injection schedule

## Monthly dosing schedule

Target date: same date every month

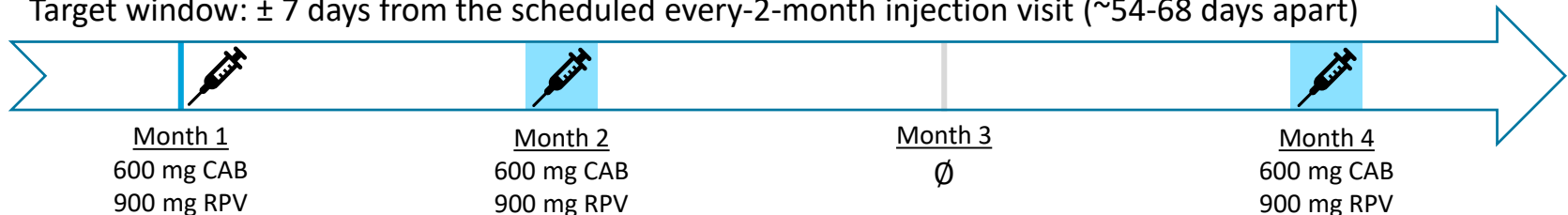
Target window:  $\pm 7$  days from the scheduled monthly injection visit (~24-38 days apart)



## Every-2-month dosing schedule

Target date: same date every other month

Target window:  $\pm 7$  days from the scheduled every-2-month injection visit (~54-68 days apart)





# Study objectives

In the first year of CAB+RPV LA use in the US:



Characterize the population who received CAB+RPV LA injections



Describe the CAB+RPV LA regimens durability and patterns of use



Assess the virologic effectiveness of CAB+RPV LA

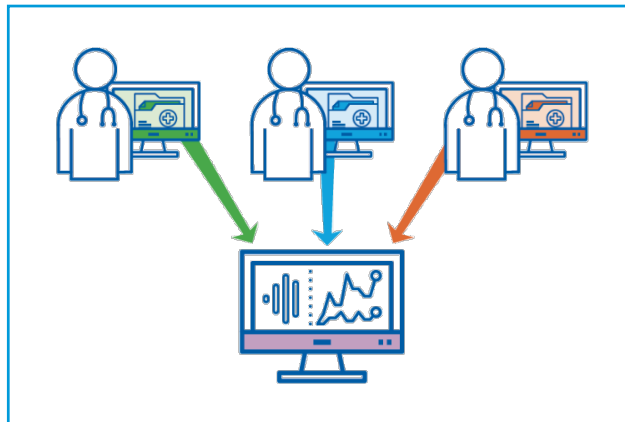
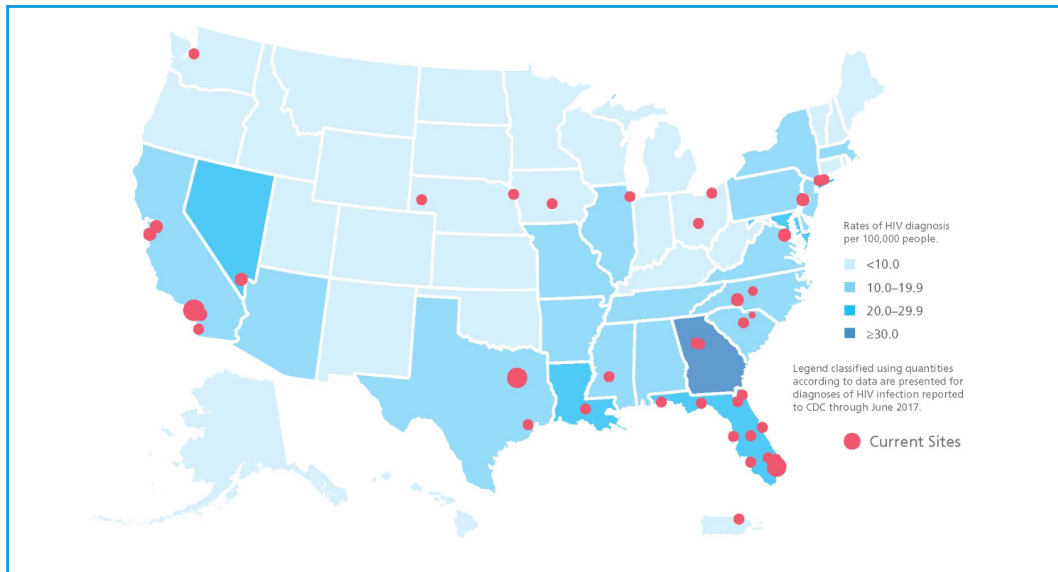
# Methods



# OPERA<sup>®</sup>

The Longitudinal Cohort

>145K PWH (96 clinics, 22 states, 1 US territory)<sup>a</sup>  
~ 14% of people diagnosed with HIV in the US



Prospectively captured,  
routine clinical data from  
electronic health records

87 publications

<sup>a</sup> As of February 2022

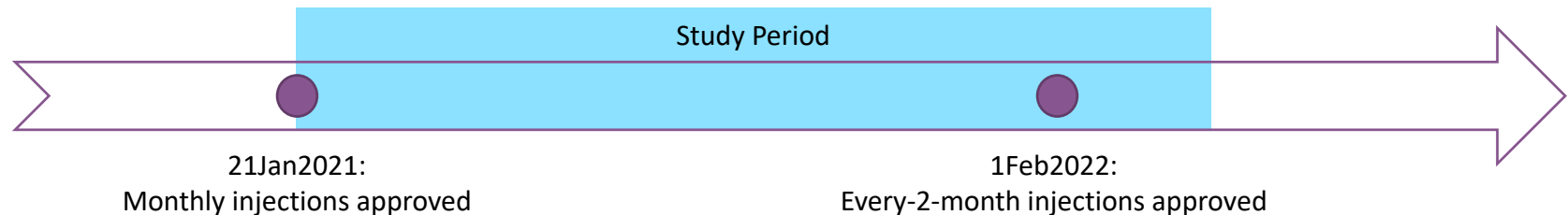
# Study design

## Inclusion Criteria

- ◆ HIV-positive
- ◆ ≥18 years old
- ◆ Active in care
- ◆ Never participated in a CAB+RPV trial
- ◆ Received ≥1 CAB+RPV LA injection

## Study Period

- ◆ 1<sup>st</sup> CAB+RPV LA injection between 21Jan2021 and 28Feb2022
- ◆ Follow-up through 15Mar2022
- ◆ Baseline: first CAB+RPV injections





# Definitions



- ◆ Confirmed virologic failure
  - 2 consecutive VLs  $\geq 200$  copies/mL
  - or
  - 1 VL  $\geq 200$  copies/mL + discontinuation



- ◆ Discontinuation
  - $>2$  consecutive missed doses
    - Monthly dosing:  $>69$  days without an injection
    - Bi-monthly dosing:  $>127$  days without an injection

# Results



# Study population



People with HIV (PWH) in OPERA  
N = 145,398



PWH in care 1/21/21 to 2/28/22  
N = 105,833



Adult PWH who ever received CAB+RPV injections  
N = 421



1<sup>st</sup> CAB+RPV injections between 1/21/21 and 2/28/22  
N = **383**

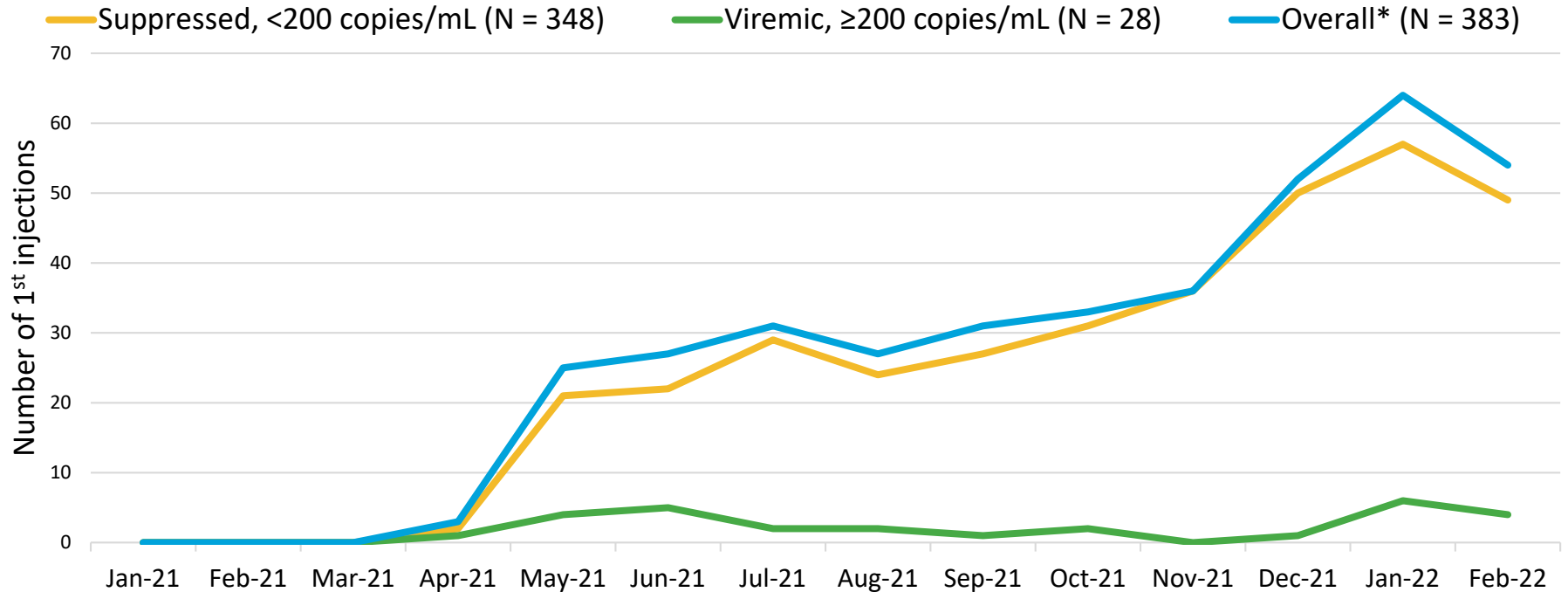


# ART experience and baseline viral load\* at first CAB+RPV LA injections

	n (%)
Treatment-naïve	0 (0%)
Treatment-experienced, VL <50 copies/mL	321 (84%)
Treatment-experienced, VL ≥50 to <200 copies/mL	27 (7%)
Treatment-experienced VL ≥200 copies/mL	28 (7%)
No baseline VL	7 (2%)
<b>Total</b>	<b>383 (100%)</b>

\*Baseline viral load defined as last viral load at or prior to first CAB+RPV injections

# Date of 1<sup>st</sup> CAB+RPV LA injections



\*7 individuals had no baseline viral load recorded prior to their first injections

# Demographic characteristics at first CAB+RPV LA injections



	Suppressed (<200 copies/mL) N = 348	Viremic (≥200 copies/mL) N = 28	Undetectable (<50 copies/mL) N = 321	Detectable (≥50 copies/mL) N = 55
Age, median (IQR)	40 (32, 52)	36 (29, 44)	40 (32, 52)	38 (31, 45)
18-25, n (%)	14 (4)	≤5*	13 (4)	≤5*
26-49, n (%)	235 (68)	24 (86)	217 (68)	42 (76)
50+, n (%)	99 (28)	≤5*	91 (28)	10 (18)
Female sex, n (%)	49 (14)	15 (54)	45 (14)	19 (34)
Race, n (%)				
Black	128 (37)	22 (79)	117 (36)	33 (60)
White	185 (53)	6 (21)	171 (53)	20 (36)
Other/unknown race	35 (10)	0 (0)	33 (10)	≤5*
Hispanic ethnicity, n (%)	100 (29)	≤5*	95 (30)	8 (14)

\*HIPAA privacy requirements preclude the reporting of 5 or fewer observations in any cell 14

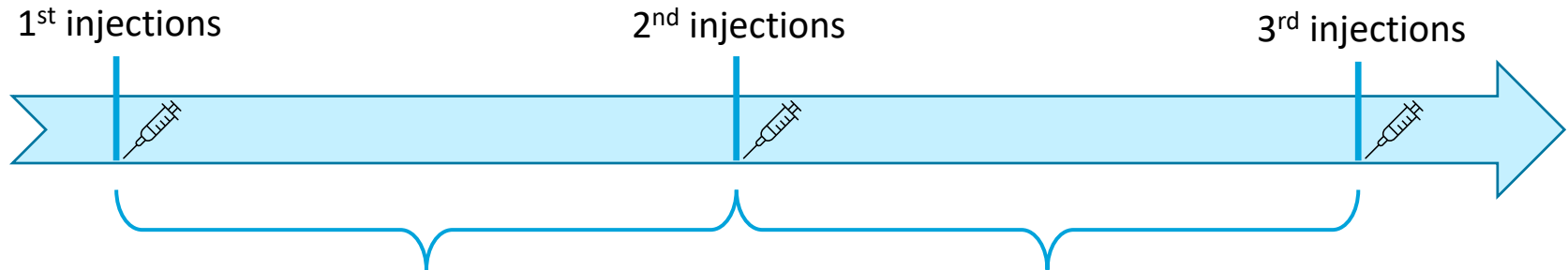
# Clinical characteristics at first CAB+RPV LA injections



	<b>Suppressed (<math>&lt;200</math> copies/mL) N = 348</b>	<b>Viremic (<math>\geq 200</math> copies/mL) N = 28</b>	<b>Undetectable (<math>&lt;50</math> copies/mL) N = 321</b>	<b>Detectable (<math>\geq 50</math> copies/mL) N = 55</b>
Years from HIV Dx, median (IQR)	7 (4, 14)	10 (5, 16)	7 (4, 14)	8 (4, 17)
Year of ART Initiation, n (%)				
Before or during 2015	121 (35)	8 (29)	113 (35)	16 (29)
2016 to 2018	109 (31)	11 (39)	97 (30)	23 (42)
During or after 2019	118 (34)	9 (32)	111 (35)	16 (29)
AIDS Defining Illness, n (%)	76 (22)	6 (21)	64 (20)	18 (33)
Log Viral Load, median (IQR)	1.3 (1.3, 1.3)	4.2 (3.1, 4.8)	1.3 (1.3, 1.3)	2.3 (1.9, 4.2)
CD4 Cell Count, cells/mm <sup>3</sup> , median (IQR)	651 (471, 865)	477 (260,689)	658 (480, 871)	539 (333, 696)
BMI, median (IQR)	27 (24, 31)	27 (22, 29)	28 (24, 31)	27 (22, 30)

# Time between first three injections

Target (monthly): ~ 24 to 38 days apart



## Days from 1<sup>st</sup> to 2<sup>nd</sup> injections:

- N = 326
- Median: 31 (IQR: 28, 34)
- ≤23 days: <1%
- ≥39 days: 9%

## Days from 2<sup>nd</sup> to 3<sup>rd</sup> injections\*:

- N = 249
- Median: 30 (IQR: 28, 33)
- ≤23 days: 1%
- ≥39 days: 10%

\*2 individuals transitioned to every-2-month during this period



# Oral bridging



## Multiple types of bridging regimens/prescriptions

- Maintain prior ART prescription
- New prescription at CAB+RPV LA start
- New prescription before a gap

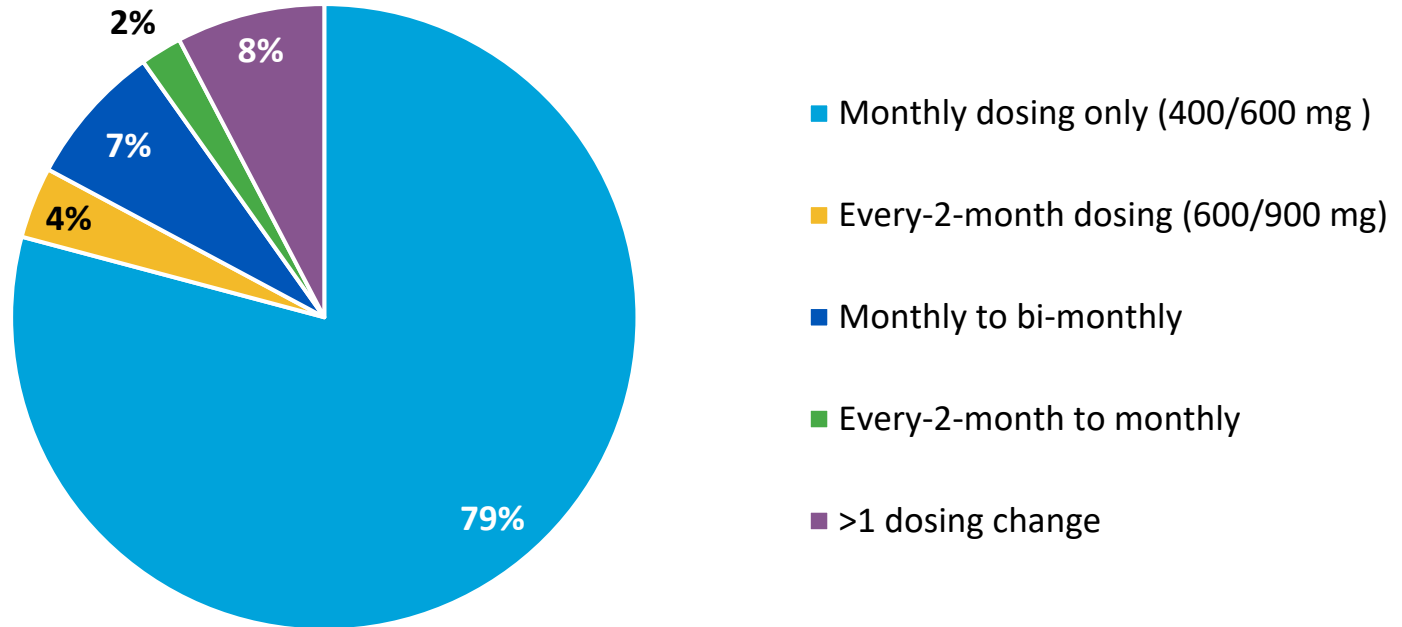
## Oral bridging poorly documented in EHR

- No notes indicating if oral bridging was taken
- Cannot determine if missed injections were covered by oral bridging or not

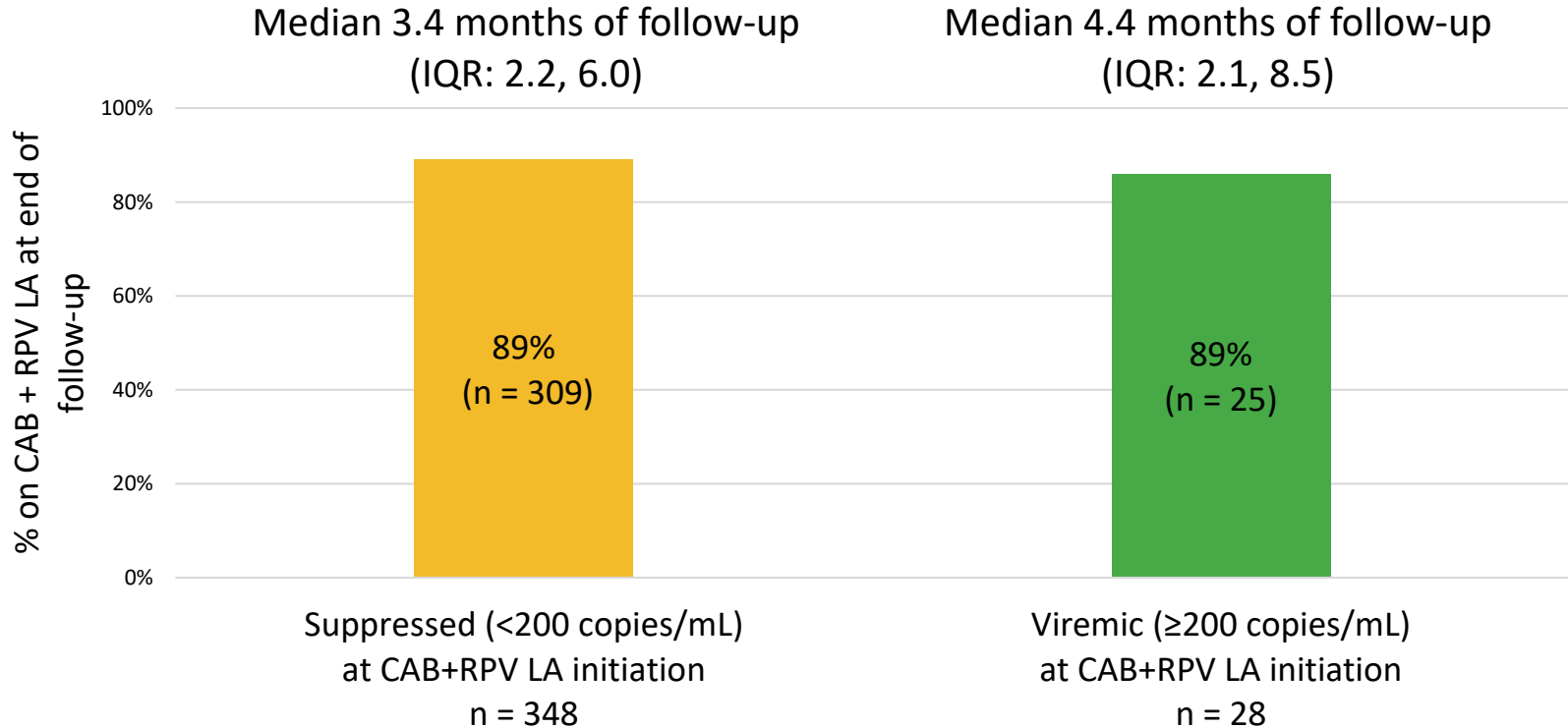


# Dosing frequency over follow-up

(N = 326 with >1 injections)



# Duration of CAB+RPV LA use



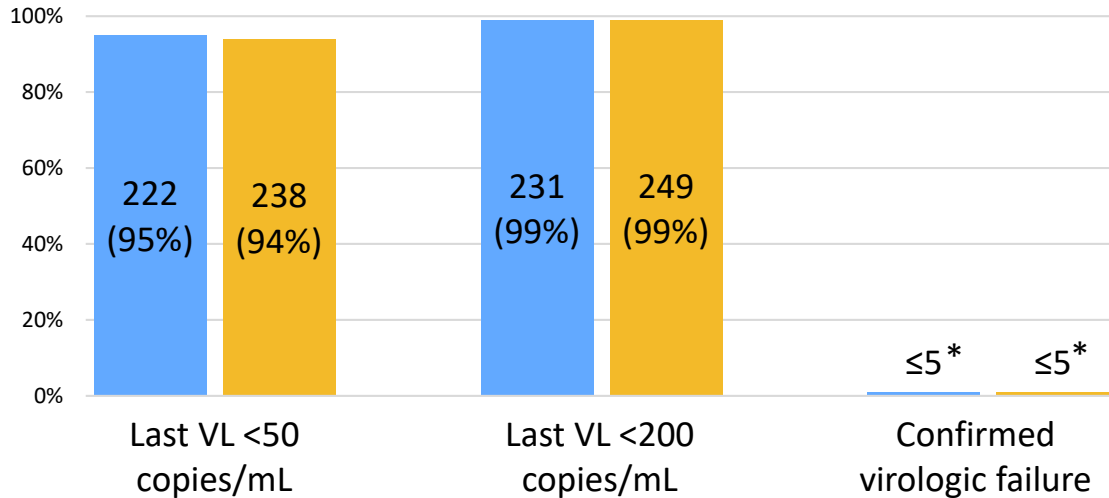


# Virologic outcomes

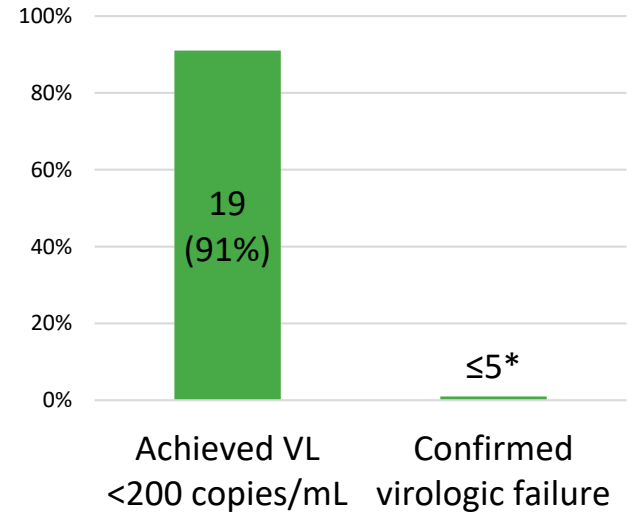
## Among those with $\geq 1$ VL after first injections

■ Undetectable ( $<50$  copies/mL) at CAB+RPV LA initiation (n = 234)

■ Suppressed ( $<200$  copies/mL) at CAB+RPV LA initiation (n = 252)




■ Viremic ( $\geq 200$  copies/mL) at CAB+RPV LA initiation (n = 21)




# Discussion






High levels of virologic control with few virologic failures were observed in the early months of use, suggesting that CAB+RPV LA is effective among virologically suppressed individuals



High levels of virologic control with few virologic failures were observed in the early months of use, suggesting that CAB+RPV LA is effective among virologically suppressed individuals

10% of early initiation injections were administered outside of the target window, which could impede the establishment of a pattern of adherence and achievement of optimal effectiveness



High levels of virologic control with few virologic failures were observed in the early months of use, suggesting that CAB+RPV LA is effective among virologically suppressed individuals

10% of early initiation injections were administered outside of the target window, which could impede the establishment of a pattern of adherence and achievement of optimal effectiveness

Oral bridging needs to be documented consistently in the EHR to create an accurate depiction of the patient's use to help guide decisions on continued use of long-acting injectable ART



# Acknowledgments

## Co-authors

- ◆ Ricky K Hsu
- ◆ Jennifer S Fusco
- ◆ Laurence Brunet
- ◆ Quateka Cochran
- ◆ Christine Uranaka
- ◆ Gayathri Sridhar
- ◆ Vani Vannappagari
- ◆ Andrew R Zolopa
- ◆ Jean Van Wyk
- ◆ Lewis McCurdy
- ◆ Michael B Wohlfeiler
- ◆ Gregory P Fusco

This research would not be possible without the generosity of people living with HIV and their OPERA<sup>®</sup> caregivers.

Additionally, we are grateful for the following individuals: Lito Torres (SAS analyst), Kelly Oh (SAS QA), Bernie Stooks (IT/Data Management), Lisa Lutzi (Database Architecture) & Judy Johnson (Medical Terminology Classification).



This research was supported by ViiV Healthcare