

# Cabotegravir Long-Acting for PrEP

## Real World Data on On-Time Dosing, HIV Testing and HIV Acquisition from the OPERA Cohort

**Ricky K Hsu, MD**

AIDS Healthcare Foundation, NYU Langone Medical Center

Anthony M Mills, Laurence Brunet, Kevin R Frost, Ricky K Hsu,  
Gerald Pierone Jr, Michael Sension, Philip C Lackey, Karam Mounzer,  
Michael B Wohlfeiler, Jennifer S Fusco, Carolyn Brown, Vani Vannappagari,  
Michael Aboud, Piotr Budnik, Gregory P Fusco



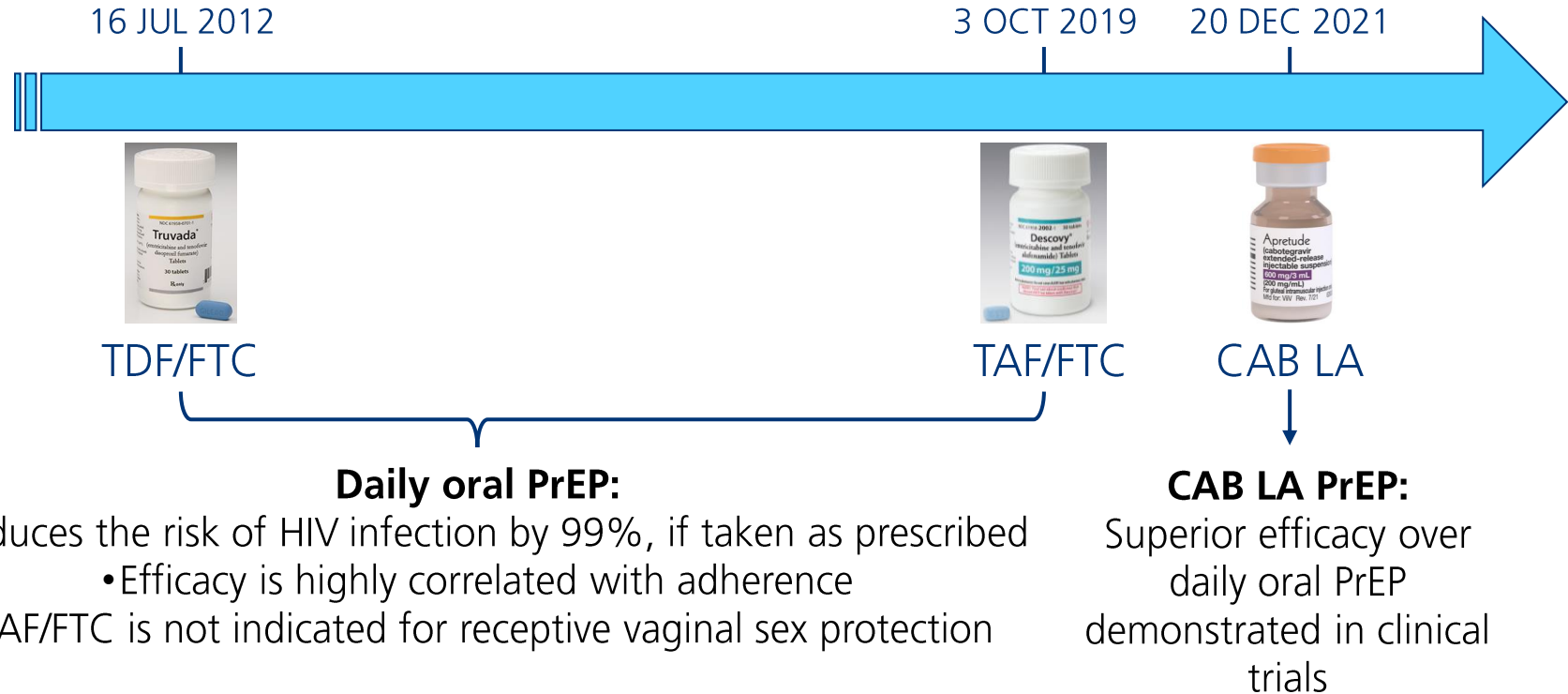
# Disclosures

- ◆ All relevant financial disclosures have been mitigated
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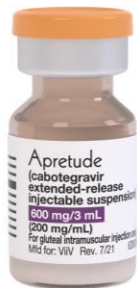
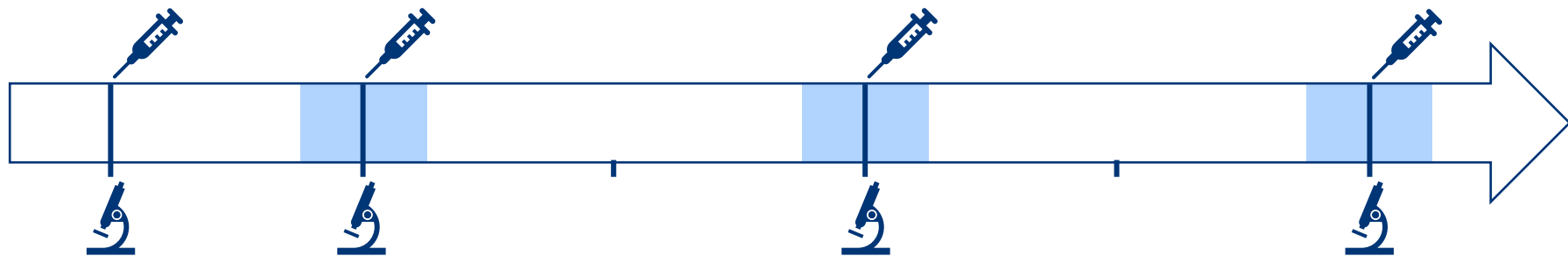
# Background & Objectives



# Pre-exposure prophylaxis (PrEP) landscape



# Cabotegravir long-acting (CAB LA) PrEP dosing schedule



2 initiation injections given 1 month apart, followed by a continuation injection every 2 months, within a 2-week target window



HIV testing should be performed with each injection, per CDC guidelines and US prescribing information

# Objectives and Methods





# Study objectives



Compare baseline characteristics of CAB LA PrEP and oral PrEP users



Describe timeliness of CAB LA PrEP dosing



Describe patterns of HIV testing during CAB LA PrEP use

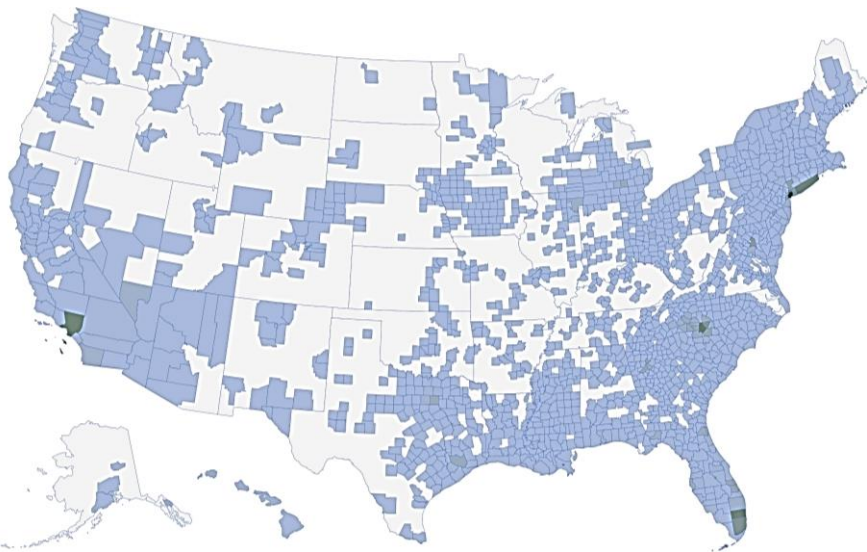


Identify cases of HIV acquisition among CAB LA PrEP users



# OPERA<sup>®</sup>

The Longitudinal Cohort



**O**bservational **P**harmaco-  
**E**pidemiology **R**esearch & **A**nalysis

> 849,000 people without HIV

> 53,000 people ever received PrEP





# Study population



## **CAB LA PrEP users**

- $\geq 1$  CAB LA PrEP injection between 21DEC2021 and 30JUN2023
- $\geq 18$  years old at first CAB LA injection
- Follow-up through study end (31DEC2023), loss to follow-up, death, or HIV acquisition



## **Oral PrEP users**

- New oral PrEP regimen (TDF/FTC or TAF/FTC) between 21DEC2021 and 30JUN2023
- $\geq 18$  years old at start of new oral PrEP regimen
- No CAB LA injection during the study period

# Results





# Baseline characteristics of CAB LA PrEP and oral PrEP users (1)

	<b>CAB LA PrEP Users N = 764</b>	<b>Oral PrEP Users N = 18,507</b>
Age, median years (IQR)	32 (26, 40)	31 (25, 38)
Women, n (%)	97 (13)	1,569 (9)
Black race, n (%)	223 (29)	4,498 (24)
Hispanic ethnicity, n (%)	223 (29)	6,344 (34)
US Region, n (%)		
Northeast	341 (45)	2,180 (12)
South	254 (33)	9,294 (50)
Midwest	11 (1)	916 (5)
West	158 (21)	6,061 (33)
US Territories	0	56 (< 1)



# Baseline characteristics of CAB LA and oral PrEP users (2)

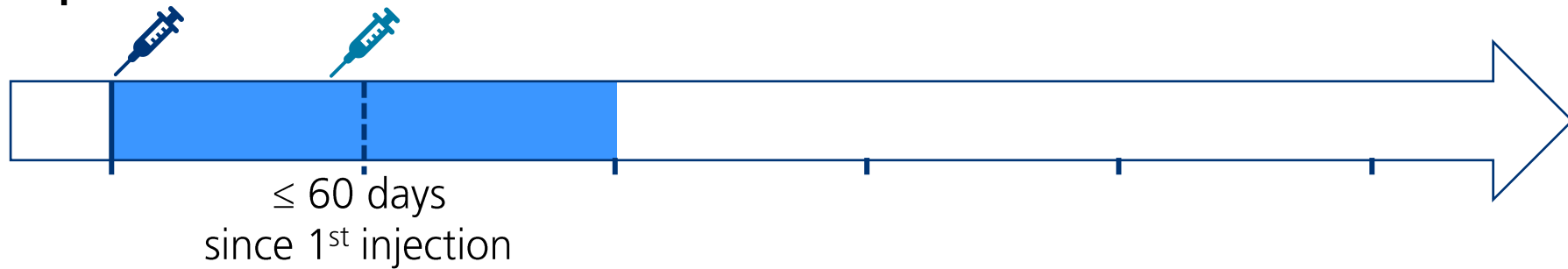
	<b>CAB LA PrEP Users N = 764</b>	<b>Oral PrEP Users N = 18,507</b>
Payer, n (%) <sup>a</sup>		
Medicaid	243 (32)	1,173 (6)
Medicare	46 (6)	260 (1)
Commercial Insurance	574 (75)	8,078 (44)
Other	179 (23)	10,124 (55)
Unknown	54 (7)	1,383 (8)
Median months in care at the clinic before PrEP start (IQR)	18 (4, 43)	2 (0, 25)
Median number of visits in the 12 months before PrEP start (IQR)	6 (3, 11)	2 (1, 3)

<sup>a</sup> Payer categories are not mutually exclusive

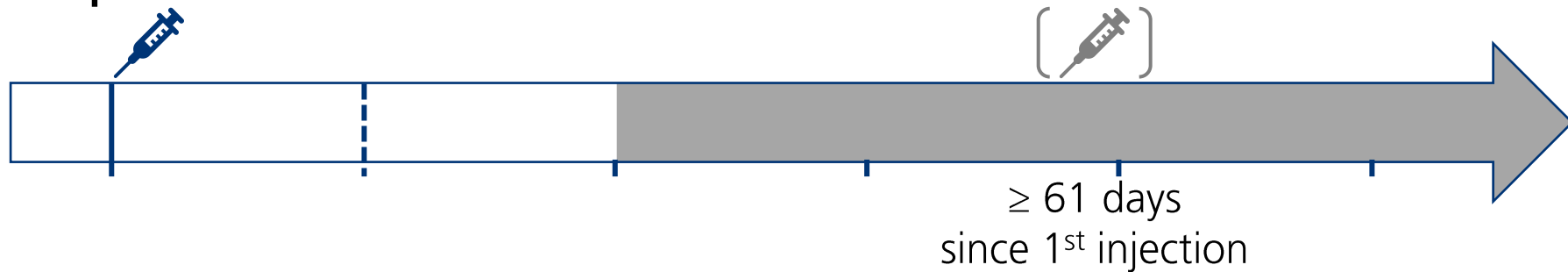


# Complete vs. incomplete initiation among all CAB LA PrEP users (N = 764)

## Complete initiation

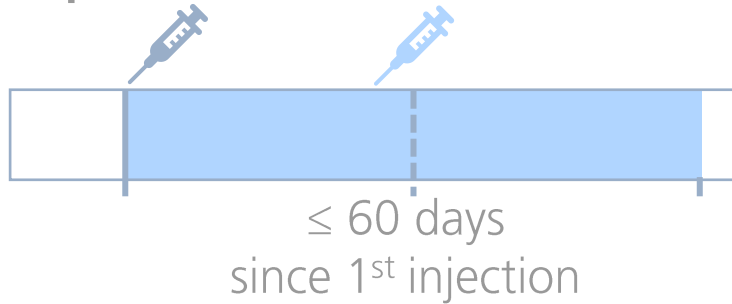


## Incomplete initiation



# Complete vs. incomplete initiation among all CAB LA PrEP users (N = 764)

Complete



646 (85%) complete initiators

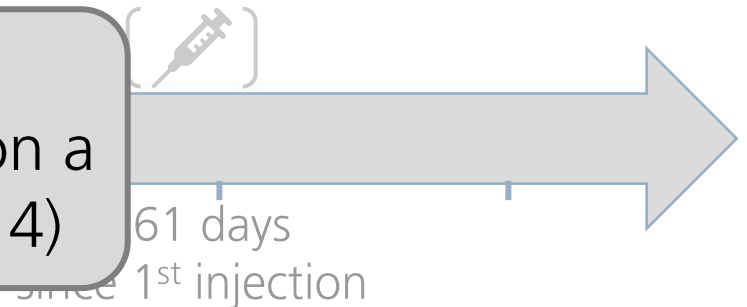
↳ Median 10 months of follow-up (IQR: 7, 13)

↳ Median 5 injections/person (IQR: 3, 7)

Incomplete

118 (15%) incomplete initiators

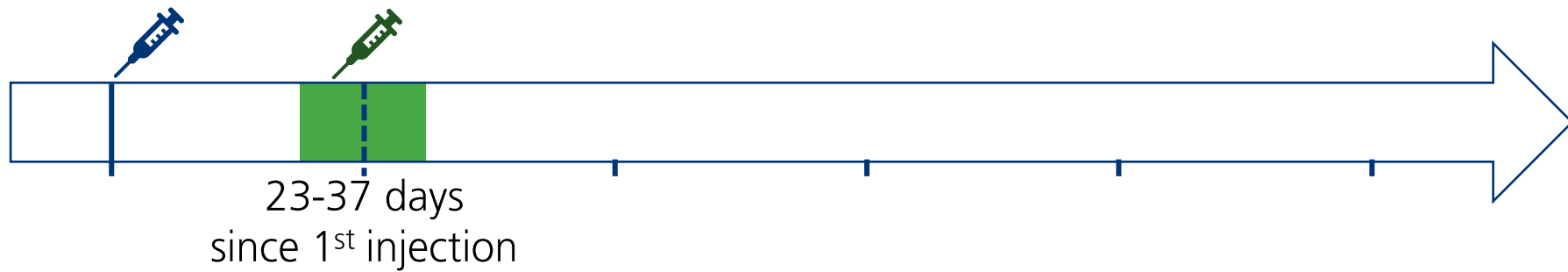
↳ 66 (56%) had an additional injection a median of 11 weeks later (IQR: 9, 14)



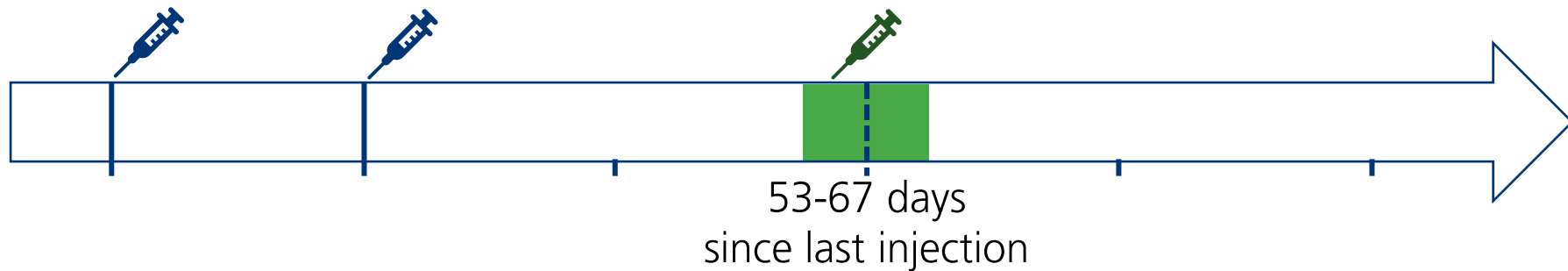


# On-time injections among complete initiators (N = 646)

## Initiation



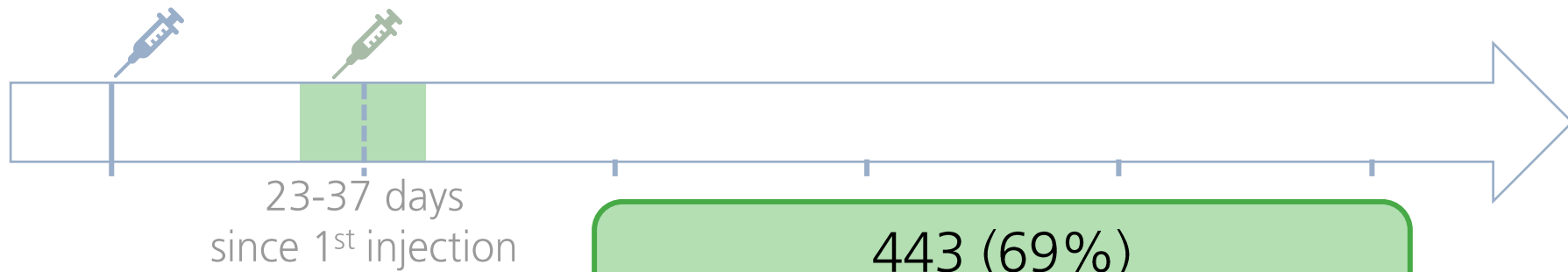
## Continuation



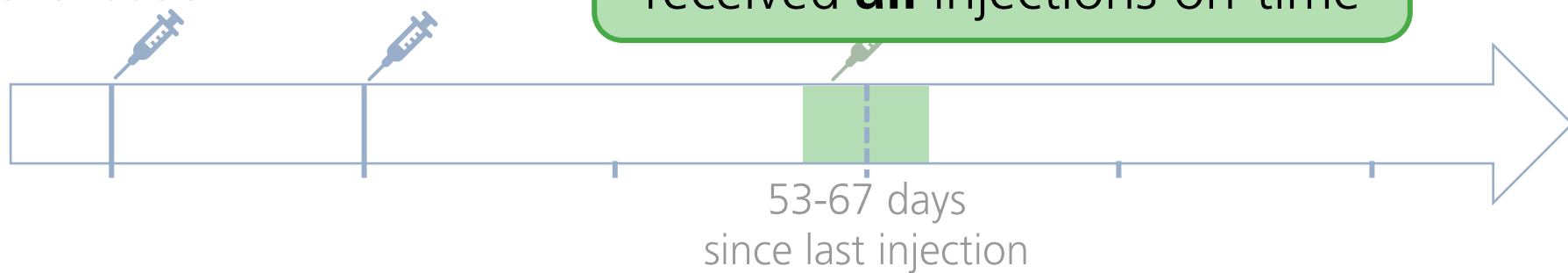


# On-time injections among complete initiators (N = 646)

Initiation



Continuation







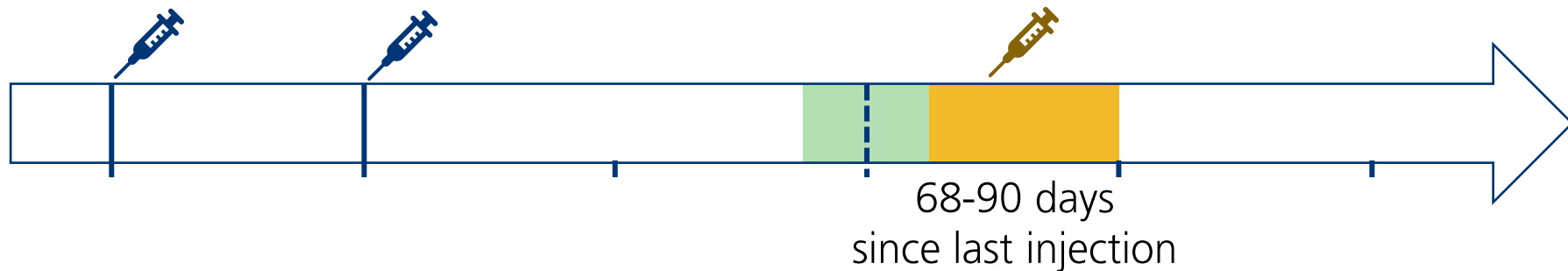
# Delayed injections

## among complete initiators (N = 646)

### Initiation

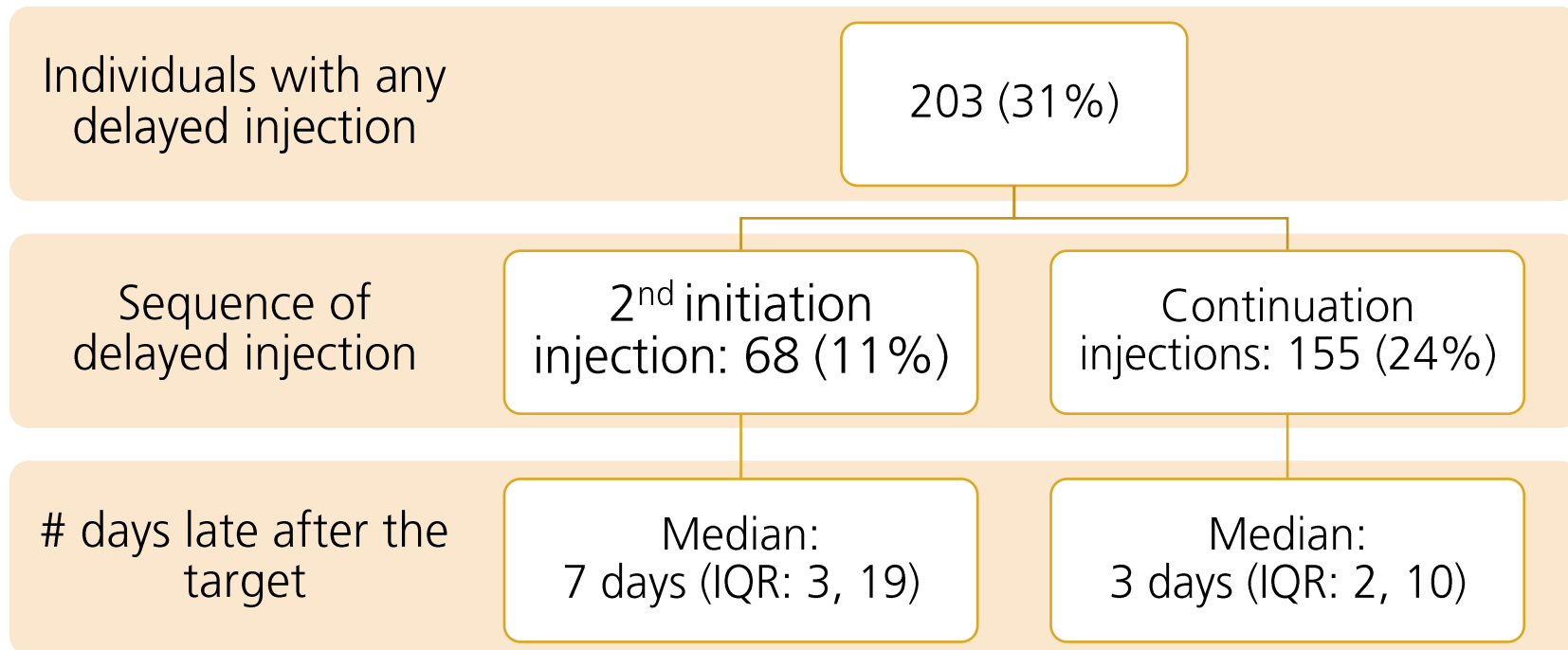


### Continuation



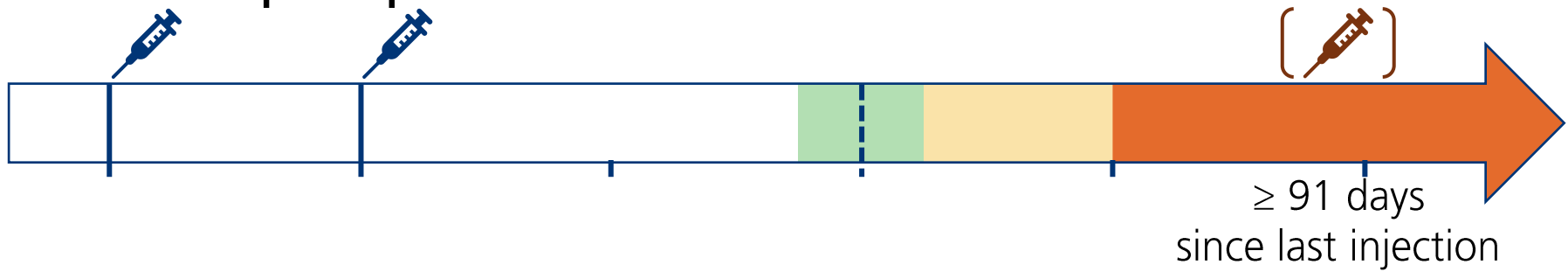


# Delayed injections among complete initiators (N = 646)

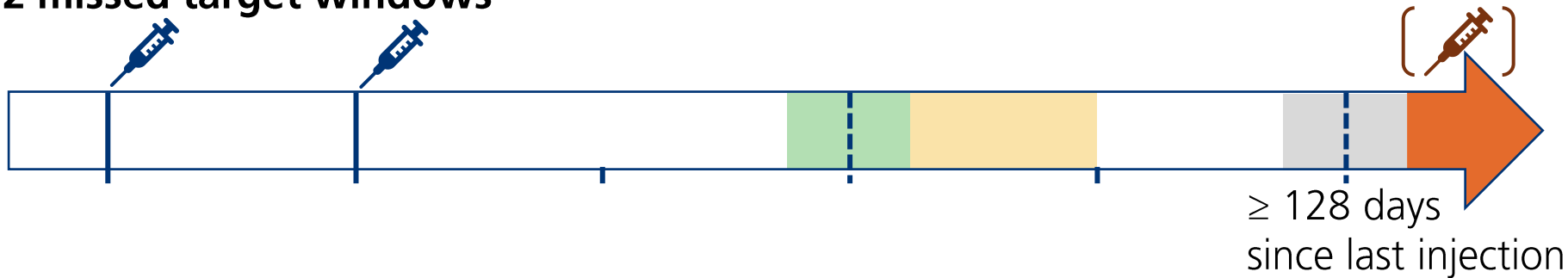


# Missed continuation injections among complete initiators (N = 646)

Reinitiation required per label



≥ 2 missed target windows





# Missed continuation injections among complete initiators (N = 646)

## Reinitiation required per label

( $\geq 91$  days without injection)

205 individuals (32%)

87 (42%) received an additional injection

Median 53 days after the target  
(IQR: 42, 58)

## $\geq 2$ missed target windows

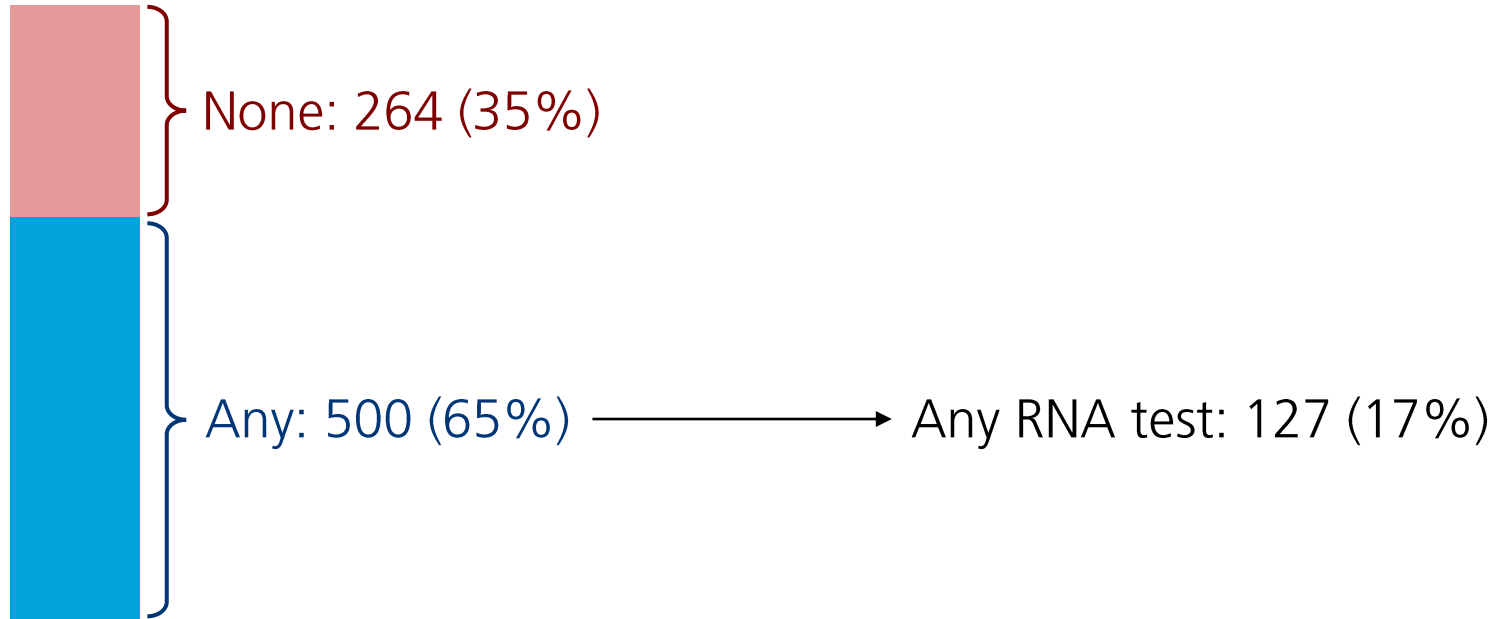
( $\geq 128$  days without injection)

124 individuals (19%)

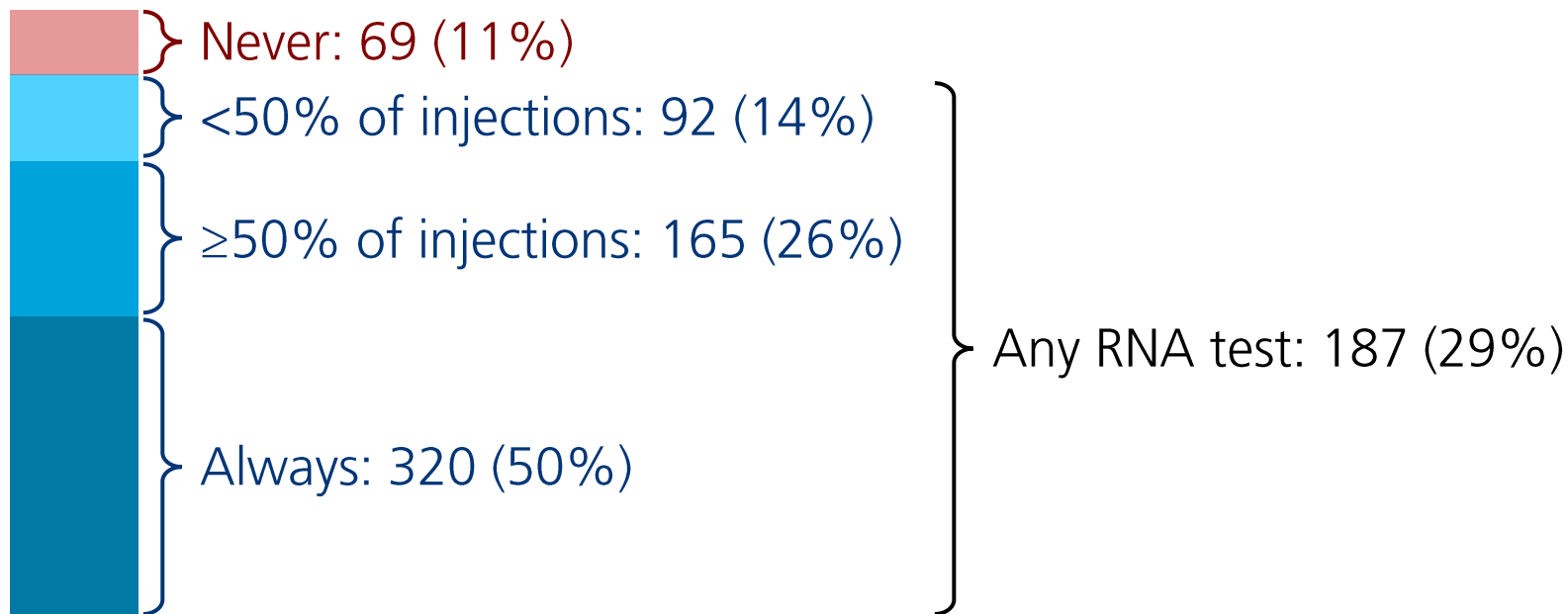
18 (14%) received an additional injection

Median 100 days after the target  
(IQR: 73, 143)

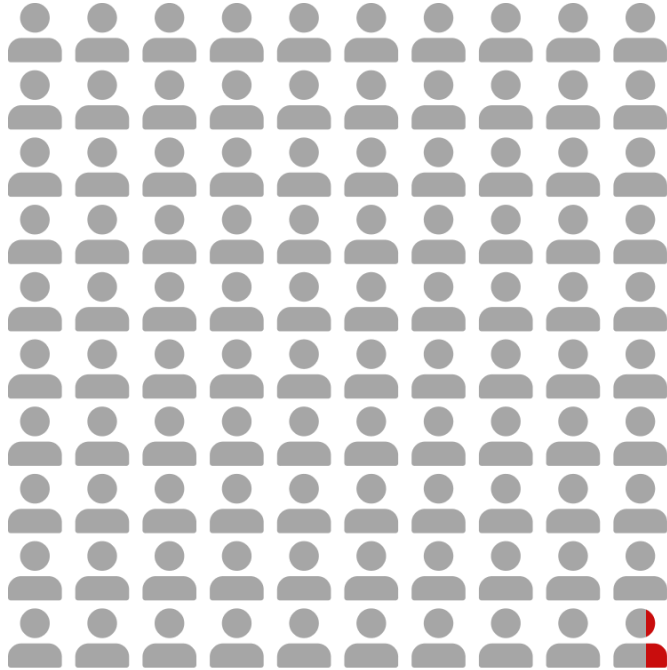
# HIV testing within 1 week before/at 1<sup>st</sup> CAB LA PrEP injection (N = 764)



# HIV testing within 1 week before/at subsequent CAB LA PrEP injection (N = 646)



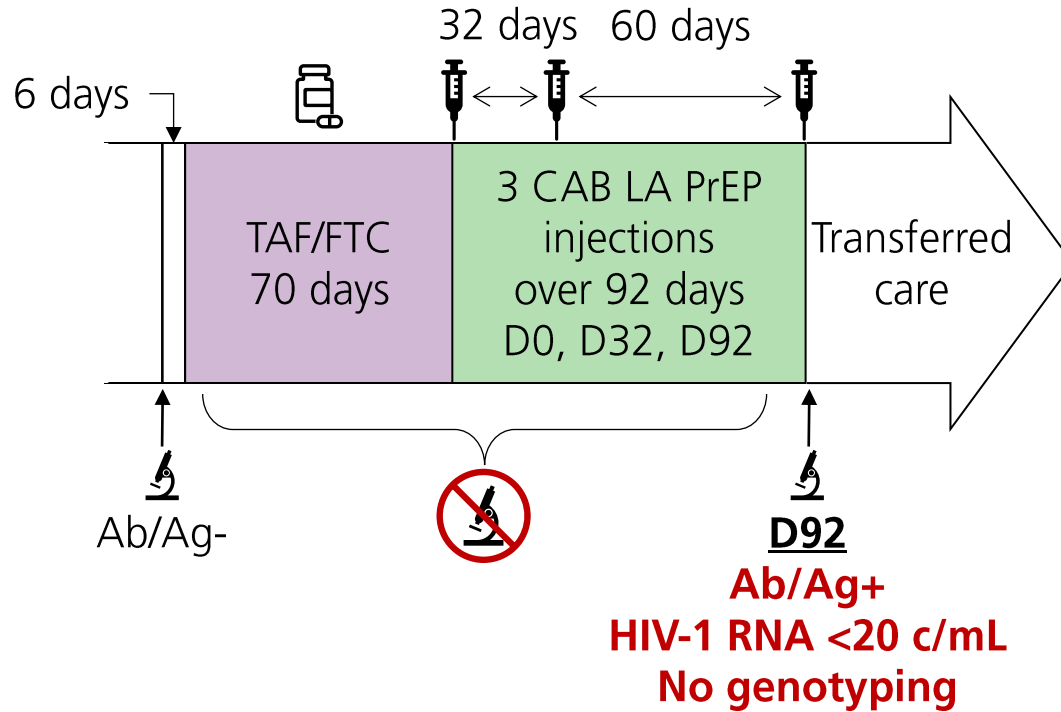
# HIV acquisition among CAB LA PrEP users



$$\frac{2 \text{ HIV cases}}{764 \text{ CAB LA PrEP users}} = 0.3\%$$

**BUT...**

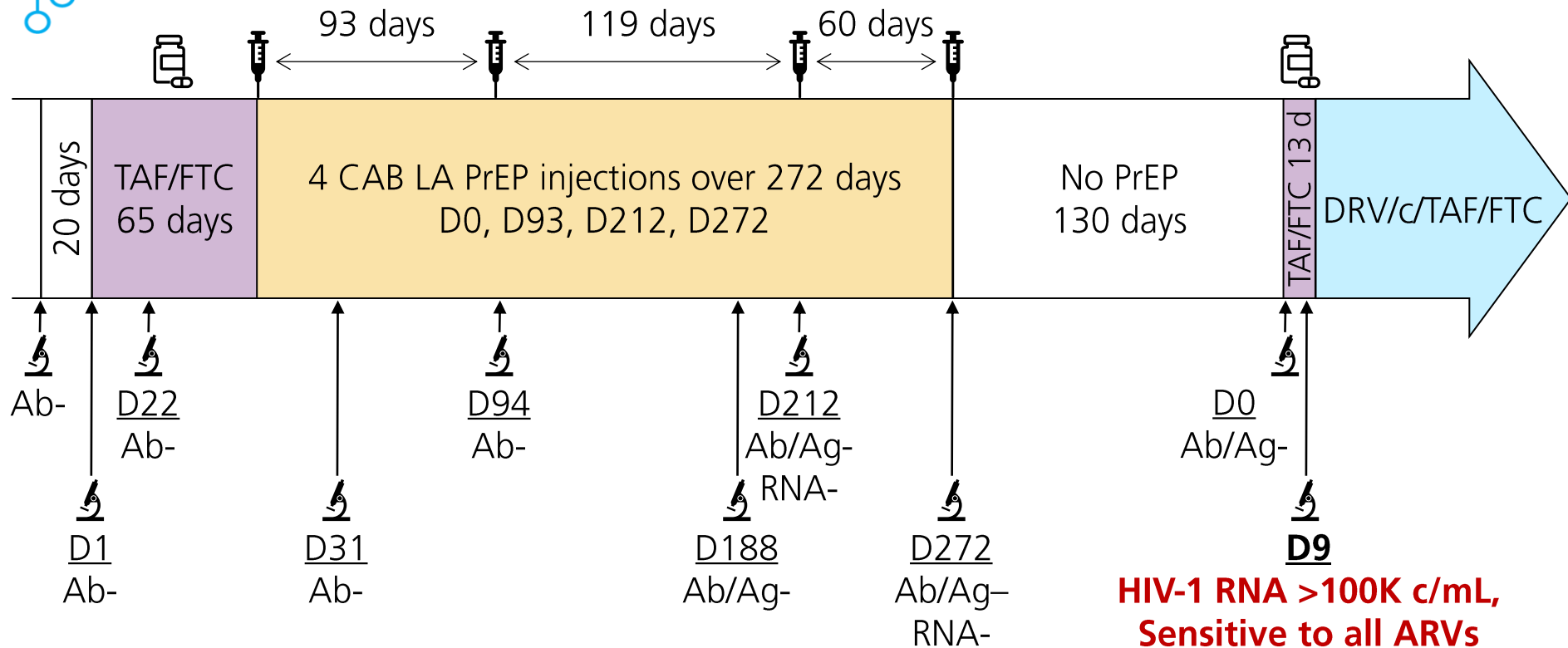
# Case #1\*



\* Case #1 was presented at CROI 2024 (poster #1109)



# Case #2



# Discussion





# Key findings (1)



Compared to oral PrEP, a higher proportion of CAB LA PrEP users were women, Black, insured or on Medicaid, and had a longer history of care at the clinic



- 764 individuals received CAB LA PrEP in the OPERA cohort
- ◆ 85% completed the initiation sequence
  - ◆ 69% of complete initiators received all injections on-time
  - ◆ Most injection delays were short (< 1 week)



## Key findings (2)



HIV testing before and during CAB LA PrEP use often did not conform to the product label or CDC guidelines prevention

- ◆ 65% were tested at 1<sup>st</sup> injection and 50% were tested at all subsequent injections



CAB LA PrEP was at least 99.7% effective for HIV prevention

- ◆ Only 2 cases of HIV acquisition were observed, but could not be directly linked to lack of CAB LA PrEP effectiveness
  - Inconsistent testing, no HIV confirmatory test (Case #1)
  - CAB LA PrEP discontinuation, seroconversion on TAF/FTC (Case #2)



# Strengths & limitations



The OPERA cohort is the largest cohort of CAB LA PrEP use in routine clinical care in the US to date



EHR data provided detailed information on individuals' CAB LA PrEP experience, including the administration of each injection (directly observed prevention)



Documentation of oral bridging was inconsistent, which may have resulted in the misclassification of injections as delayed or missed

# Acknowledgements

This research would not be possible without the generosity of people on PrEP and their OPERA caregivers.

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