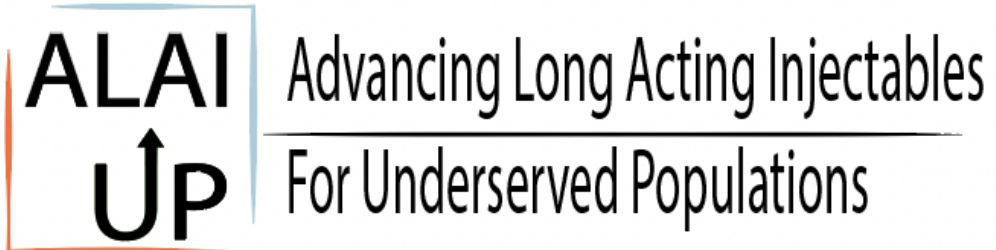


# Early implementation and clinical outcomes from real-world use of injectable cabotegravir/rilpivirine (iCAB/RPV) at 8 US clinics participating in the ALAI UP Project

Nadia Nguyen, PhD, MSPH

On behalf of the ALAI UP team

IAPAC Continuum Conference 2024, Puerto Rico



# ALAI UP Team

Columbia University Irving Medical Center /  
NewYork Presbyterian



Kerri Carnevale



Delivette Castor



Jenna Eldib



Charlie Ferrusi

Southeast AIDS  
Education Training Center



Jenn Burdge

Albert Einstein  
College of Medicine



Bryan Kutner

New York City  
Department of  
Health and Mental Hygiene



Marilyn Blasingame

City University  
Of New York  
Hunter College



Liz Furuya



Esther Huang



Ben Lane



Kathrine Meyers



Nadia Nguyen



Cody Chastain



Mamta Karani



Sarit Golub



Coco Ni



Sarah Wiant



Jason Zucker



Ana Muscarella



Moya Brown-Lopez

**No disclosures to report**



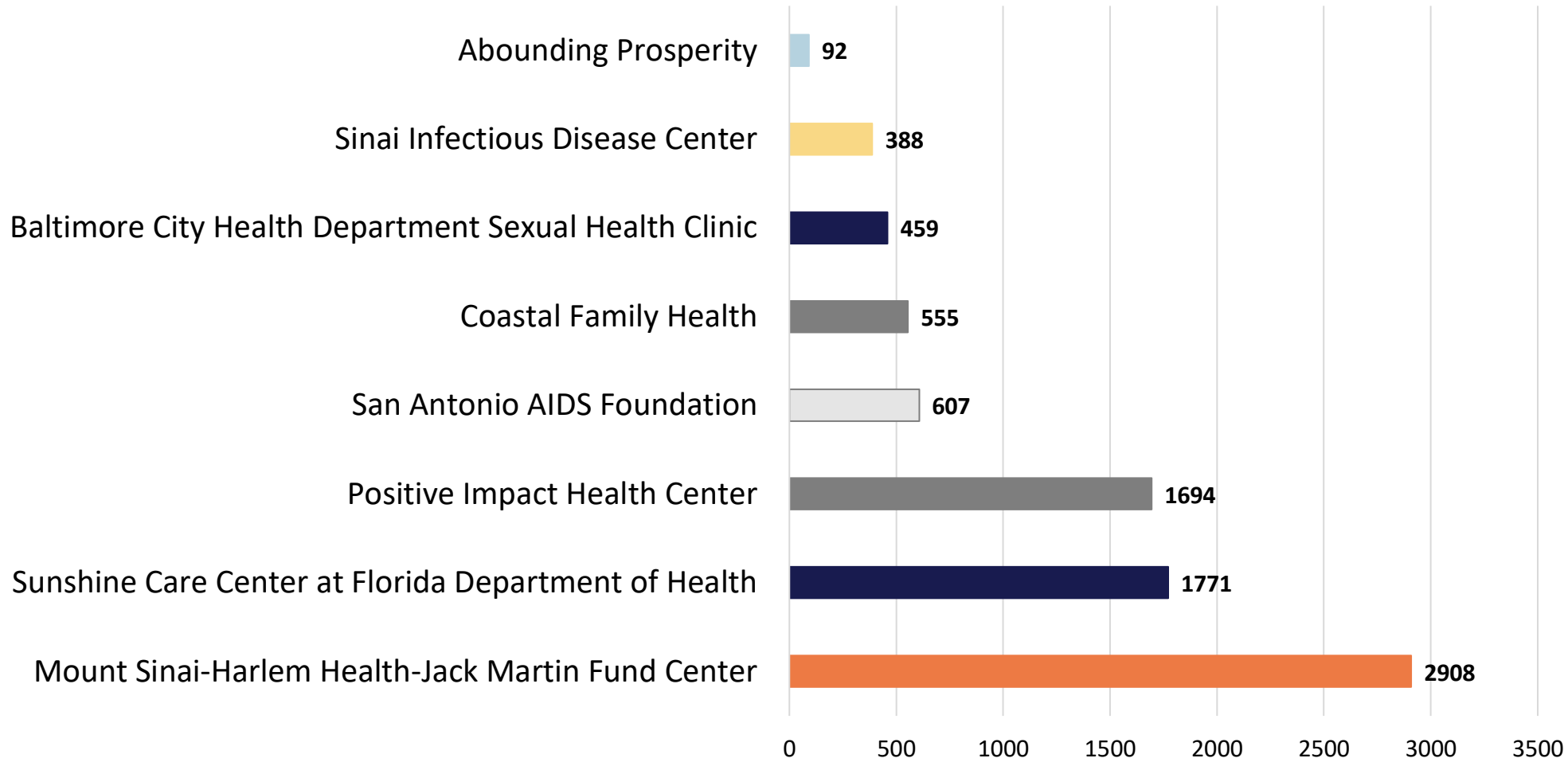
# Background

- The first long-acting injectable antiretroviral therapy (LAI ART), injectable cabotegravir/rilpivirine (iCAB/RPV), was approved by the FDA in 2021.
- Yet data from real-world use remains scarce and little is known about equity in access and use
- ALAI UP is a HRSA-funded SPNS project to accelerate the equitable implementation of LAI ARTs, starting with iCAB/RPV
- ALAI UP selected 8 diverse clinical sites and began supporting clinics in March 2023



# ALAI UP Sites

**~8500**  
clients with  
HIV across  
ALAI UP  
sites



Number of Clients with HIV served March 2023-February 2024

## ALAI UP Clinic Types

- Health Department
- Academic Medical Center
- Hospital-Based Infectious Disease Clinic
- AIDS Service Organization
- Community Based Organization
- Federally Qualified Health Center

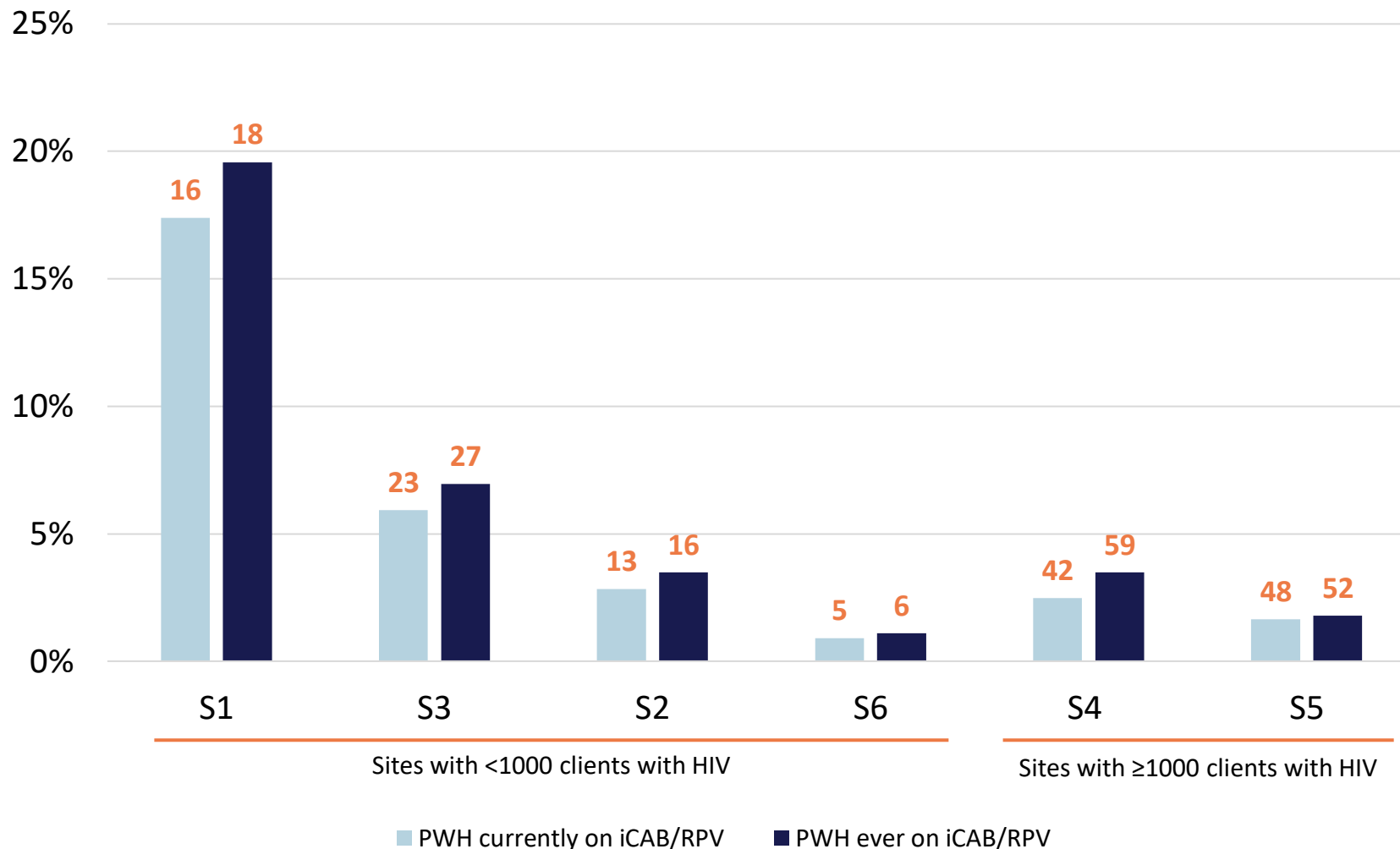
# Methods

- ALAI UP and clinics co-developed a clinical monitoring process to measure reach, equity, fidelity, and safety
- Using client-level data, we report on the first 12 months of monitoring iCAB/RPV use at clinics participating in ALAI UP (March 2023-February 2024)

Domain	Question	Indicators
Reach	How many clients have initiated iCAB/RPV?	<ul style="list-style-type: none"><li>• Number and proportion of clients with HIV who have been initiated on iCAB/RPV</li></ul>
Equity	Which clients have initiated iCAB/RPV? Which clients have not?	<ul style="list-style-type: none"><li>• The extent to which a clients' race, ethnicity, gender, and age are not associated initiation of iCAB/RPV</li></ul>
Fidelity	Is iCAB/RPV being delivered according to protocol?	<ul style="list-style-type: none"><li>• Number and proportion of iCAB/RPV injections within 7 days of injection window</li></ul>
Safety	What are clients' outcomes after they initiate iCAB/RPV?	<ul style="list-style-type: none"><li>• Number and proportion of clients with (1) VL&lt;50 copies/mL, (2) 2 consecutive VL 50-200 copies, or (3) VL&gt;200 copies/mL after initiating iCAB/RPV</li><li>• Number and proportion of clients discontinue iCAB/RPV for (1) non-clinical reasons, (2) clinical reasons, or are (3) lost to follow up</li></ul>

# Reach: Proportion of Clients with HIV currently on and ever initiated on iCAB/RPV at end of Year 1 (Feb 29, 2024)

Percent of clients with HIV on iCAB/RPV



**6088**

Clients with HIV across 6/8 ALAI UP sites

**178**

**(2.9%)**  
Clients with HIV ever initiated on iCAB/RPV





## Reach: Clients ever initiated on iCAB/RPV

- Race: 73% Black, 13% White
- Ethnicity: 21% Hispanic/Latinx
- Gender: 71% Cisgender men, 21% Cisgender women, 5% Transgender
- Age: 84% age 30-65



# **Equity: Clients ever vs never initiated on iCAB/RPV by race, ethnicity, gender, and age**

- Within clinics, race, ethnicity, gender or age were not associated with iCAB/RPV initiation
- Caveat 1: Other social determinants of health are important but not always measured in routine practice
- Caveat 2: Lower or higher iCAB/RPV initiation proportions in specific populations may reflect client preference not inequity

# Fidelity: On-time injections among clients ever on iCAB/RPB at end of Year 1 (Feb 29, 2024)

614

iCAB/RPV maintenance injections delivered as of February 29, 2024

Monthly Dosing



Bi-Monthly Dosing



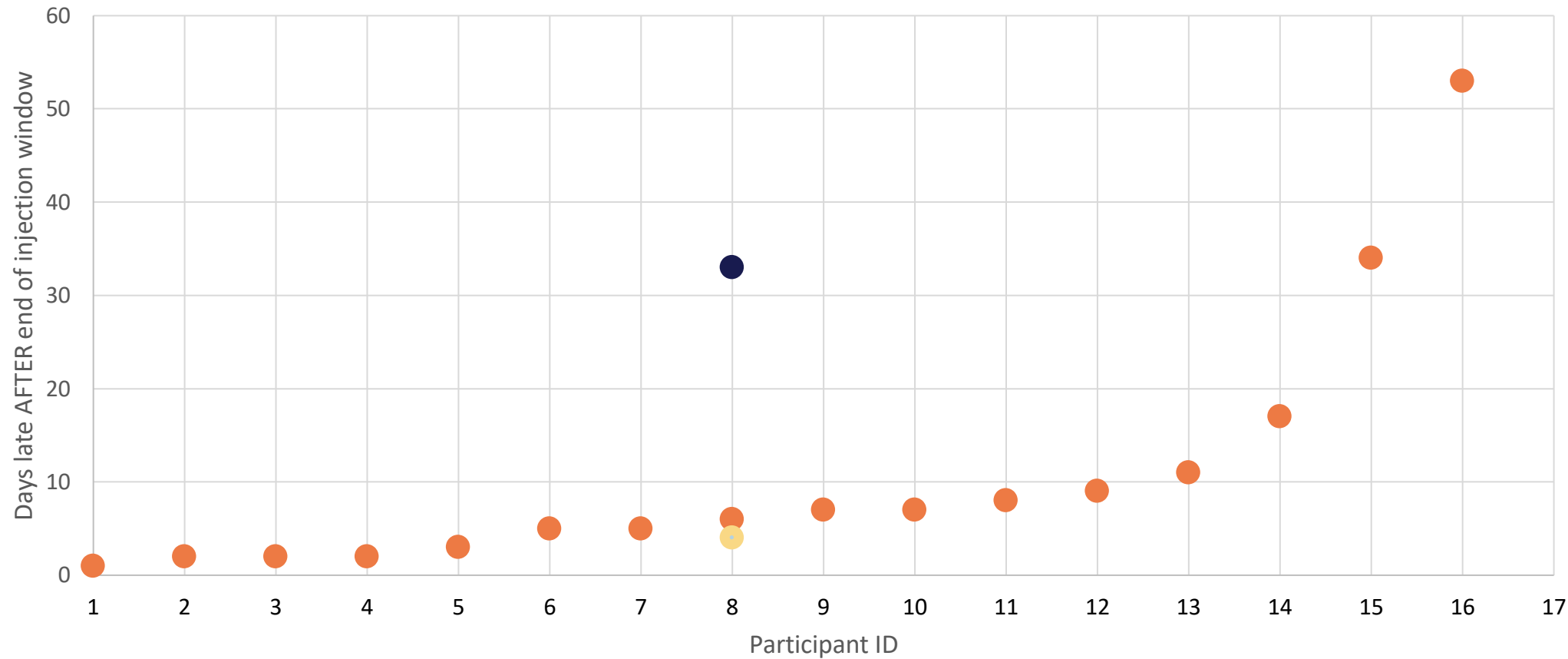
EARLY  
3%

ON TIME  
94%

LATE  
3%



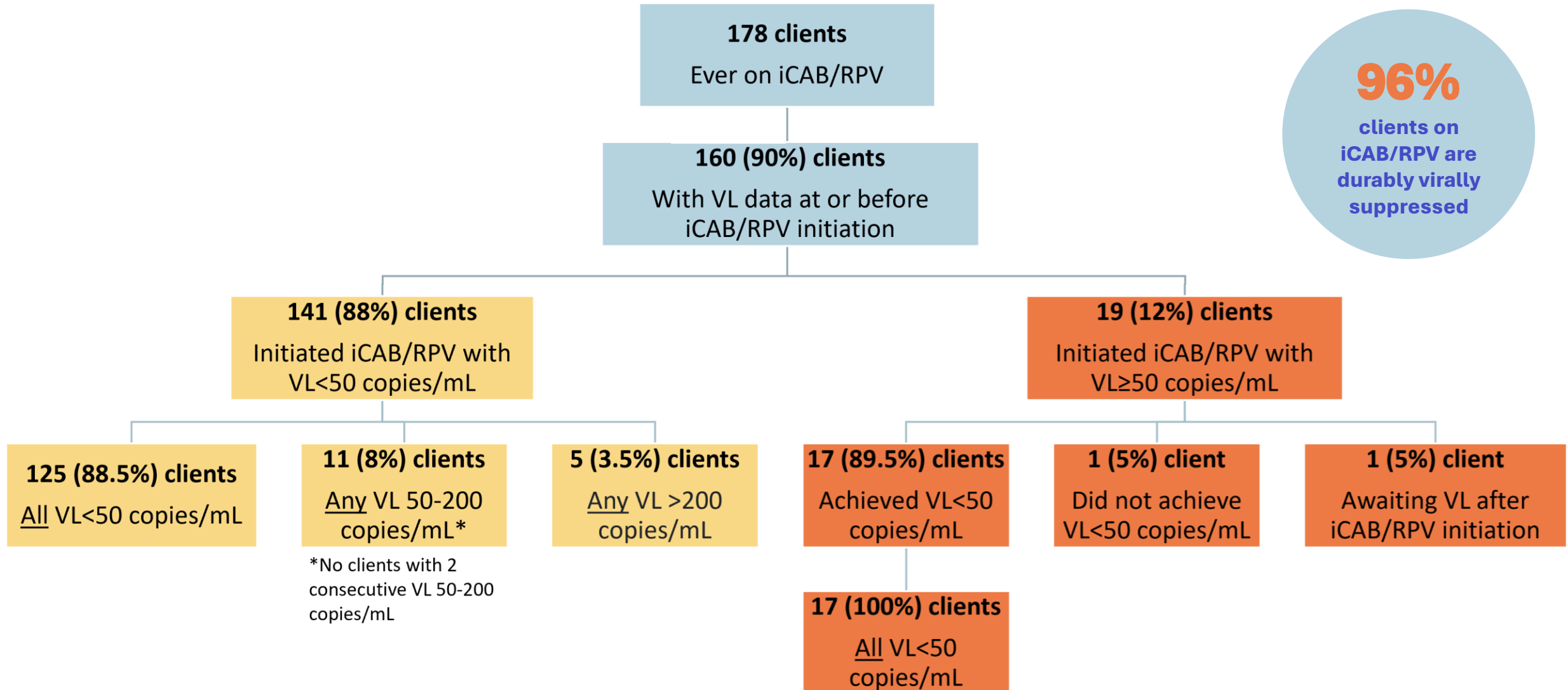
# Fidelity: Late injections among clients ever on iCAB/RPB at end of Year 1 (Feb 29, 2024)



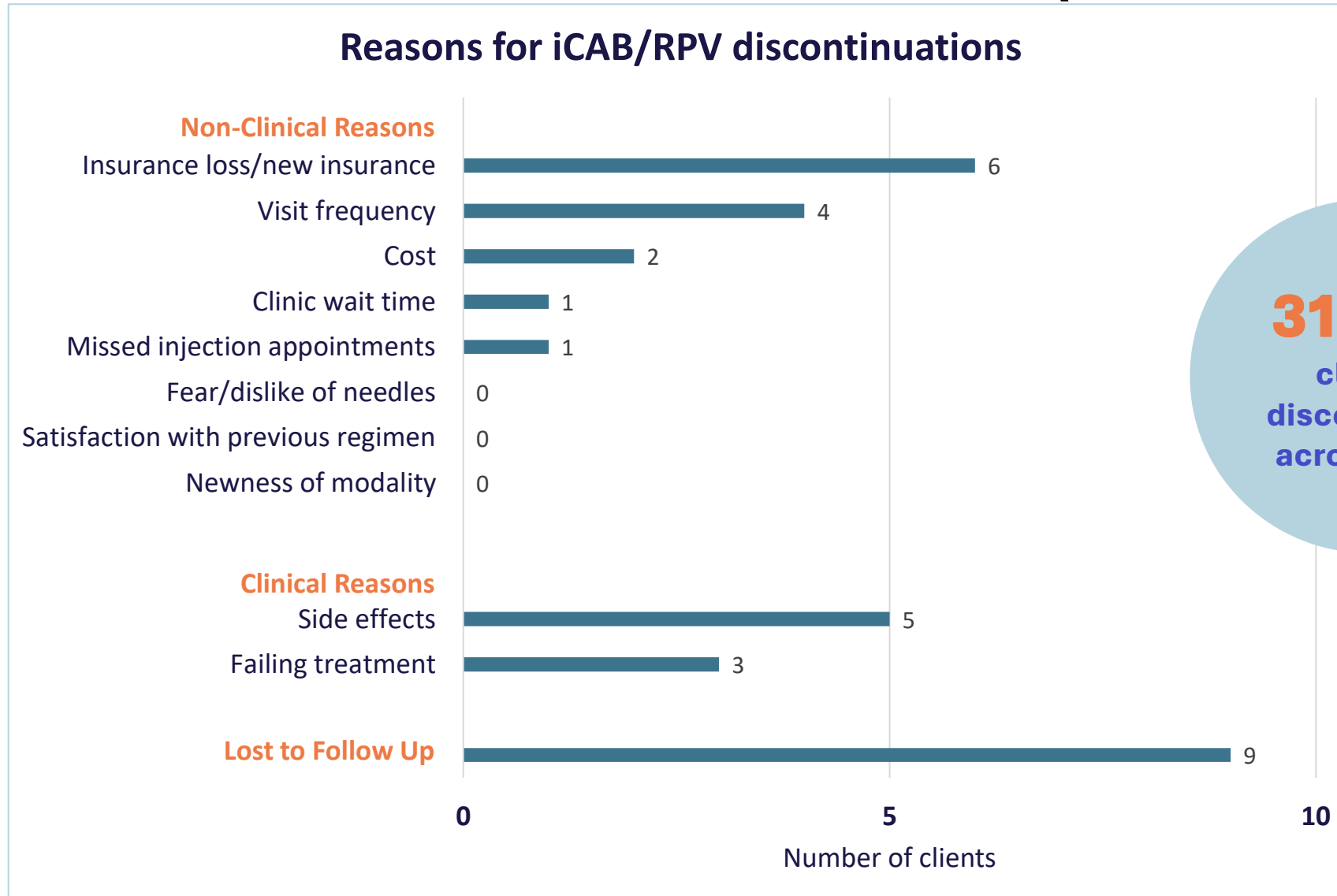
**9%**  
clients ever  
had a late  
injection

● First late injection    ● Second late injection    ● Third late injection

# Safety: Viral suppression among clients ever on iCAB/RPV at end of Year 1 (Feb 29, 2024)



# Safety: iCAB/RPV discontinuation among clients ever on iCAB/RPB at end of Year 1 (Feb 29, 2024)



**31/178**  
clients  
discontinued  
across sites



# Conclusions

- iCAB/RPV reach after 1 year of ALAI UP support has been modest but matches early industry predictions. This may reflect significant, outer-context implementation barriers not addressed by ALAI UP.
- Among the clients who have initiated iCAB/RPV, the majority of injections were delivered on time.
- Nearly all clients on iCAB/RPV were virally suppressed, including clients who were initiated with VL  $\geq 50$  copies/mL.
- Loss of insurance coverage, visit frequency, and side effects were the most common reasons for planned discontinuation.
- The iCAB/RPV clients with low-level viremia, side effects, treatment failure, and clients who were lost to follow up warrant closer monitoring and investigation.

# Acknowledgement

This program is supported by the Health Resources and Services Administration (HRSA) and the Minority HIV/AIDS Fund of the U.S. Department of Health and Human Services (HHS) as part of an award totalling \$7,000,000. We appreciate the support of our HRSA Program Officer Marlene Matosky and Clinical Advisor Britt Gayle.

The contents are those of the presenters and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit [HRSA.gov](https://www.hrsa.gov).



**For ALAI UP resources and  
publications**



**Visit: [targethiv.org/spns/alai-up](https://targethiv.org/spns/alai-up)**