Clinical Monitoring for Real-World Delivery of Long-Acting Injectable Antiretroviral Therapy (LAI ART)

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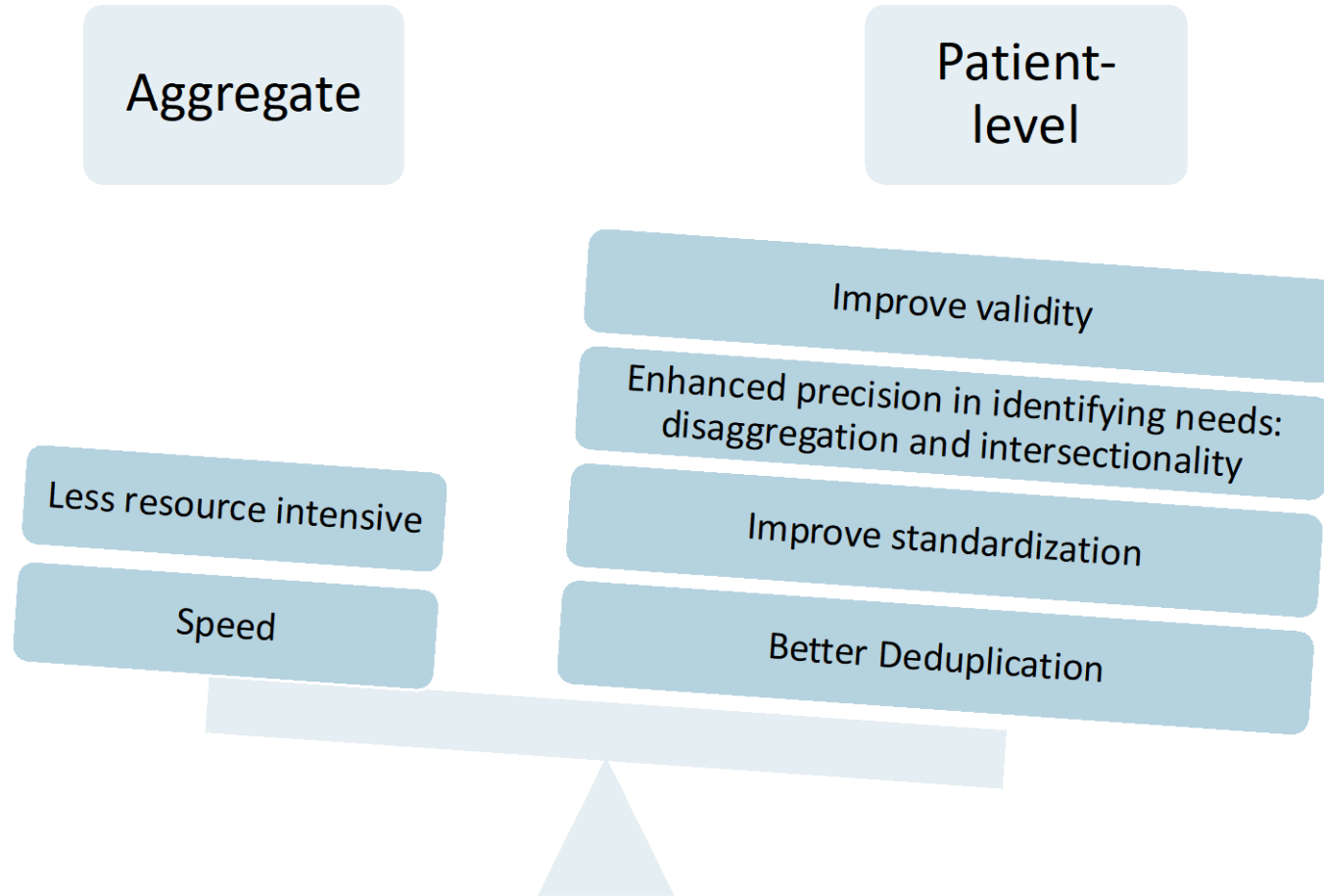
Background

- The first long-acting injectable antiretroviral therapy (LAI ART), Injectable cabotegravir/rilpivirine (iCAB/RPV), was approved by the FDA in 2021.
- iCAB/RPV can contribute to ending the HIV epidemic if factors influencing implementation and equitable outcomes are identified and addressed. These include:
    - Clinical, socioeconomic, or logistical factors for clients or
    - Health system factors may influence the implementation of iCAB/RPV.
    - Assessing contextual variation
- ALAI UP, a HRSA-funded special project of national significance (SPNS) project, aims to accelerate the equitable implementation of LAI ARTs, starting with iCAB/RPV.
    - Since March 2023, ALAI UP has supported 8 diverse clinical sites.

Rationale

- As iCAB/RPV is introduced into routine care, it is critical to define and operationalize: a) clinical monitoring and evaluation (M&E) metrics of iCAB/RPV delivery; b) context-specific indicators of health inequity; and c) feasibility of measuring these equity indicators to inform learning.

- Individual- rather than aggregate - level M&E data can better inform inequity in health outcomes, and describing the strengths and challenges with collecting and utilizing these data within electronic medical records is critical

In the early stage of introduction, client-level monitoring and evaluation data may provide advantages over aggregate monitoring.

Approach: Client-Level Monitoring

Aggregate

Patient-level

Improve validity

Enhanced precision in identifying needs: disaggregation and intersectionality

Less resource intensive

Improve standardization

Speed

Better Deduplication

Objectives

- Client-level clinical monitoring evaluation and learning aims to:
  - Assess whether ALAI UP is achieving its goal of supporting the equitable introduction and scale-up of LAI ART.
  - Build capacity of sites to collect, report, and utilize clinical monitoring data.

Approach: Clinical Monitoring

- ALAI UP program team and sites co-developed a clinical monitoring process to measure reach, equity, fidelity, and safety across based on the clinical cascade.

- Sites reported quarterly during Year 1 – initially in aggregate & then transitioning to client-level once infrastructure was developed.

iCAB/RPV Clinical Cascade
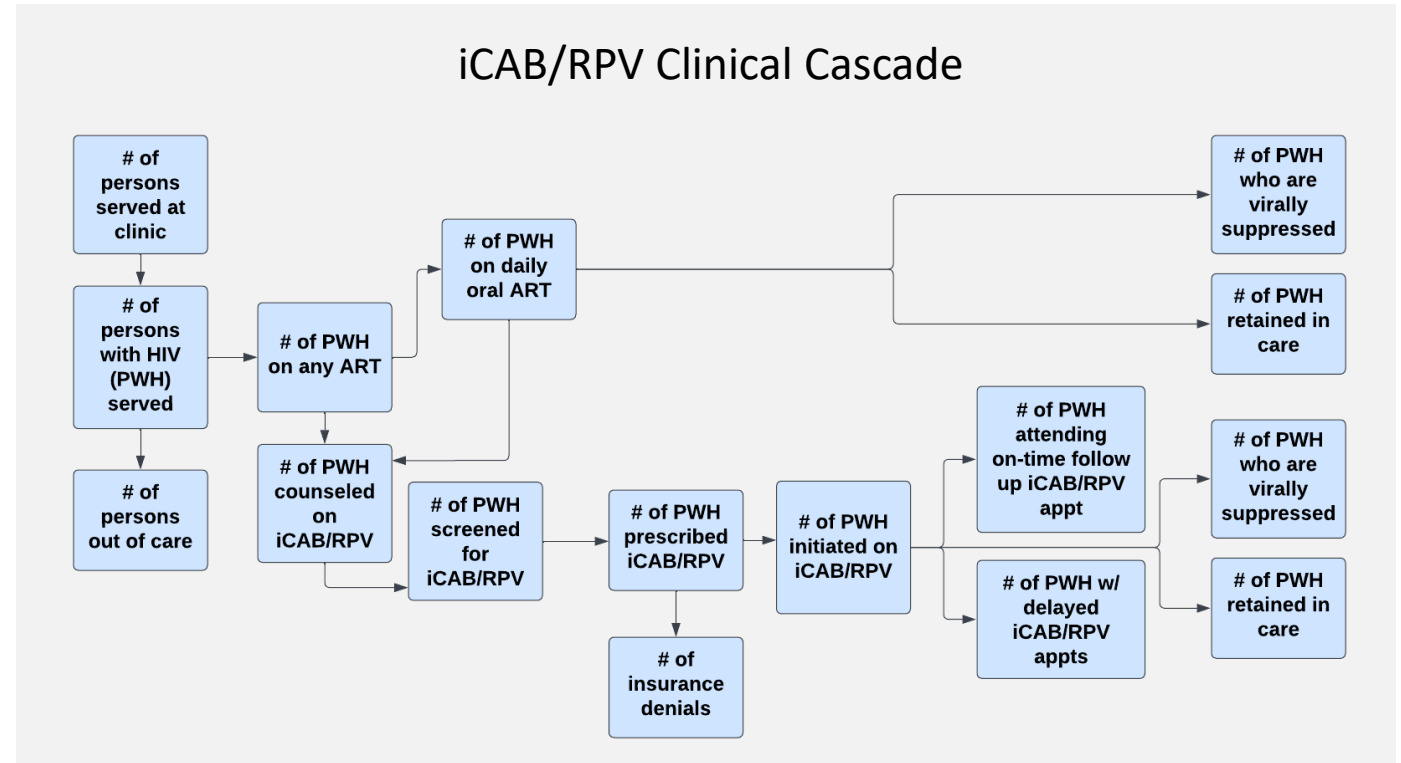
Approach: Evaluation
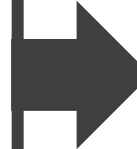

Data Quality Standards

Timeliness in submitting reports

Completeness of reported indicators overall and by disaggregations

Accuracy Valid Consistent Error pattern
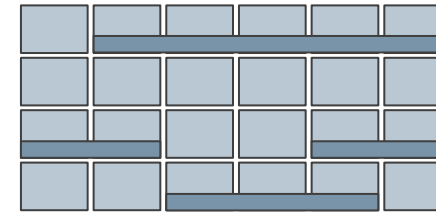
Summary of reported data and quality assurance

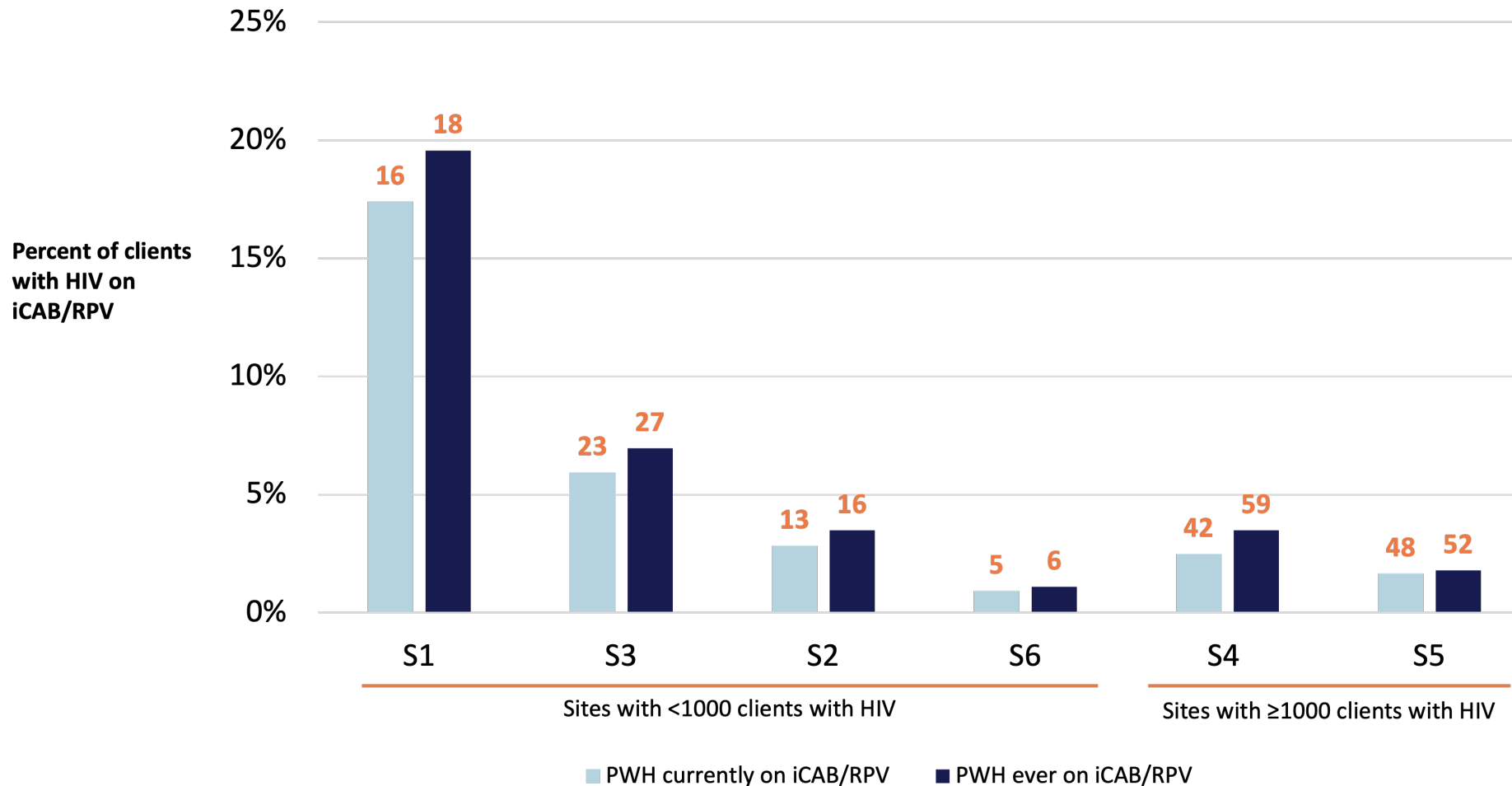**Plans to remediate quality gaps/opportunities**

Data quality assessment is a standardized review of data quality by the ALAI UP M&E team to support sites in achieving data quality standards of timeliness, completeness, and accuracy in reported data. ALAI UP will coordinate with each site's M&E point of contact(s) to verify, recount reported data, and if necessary, identify and address any data quality issues within or between sites.

Summary of one year of clinical monitoring
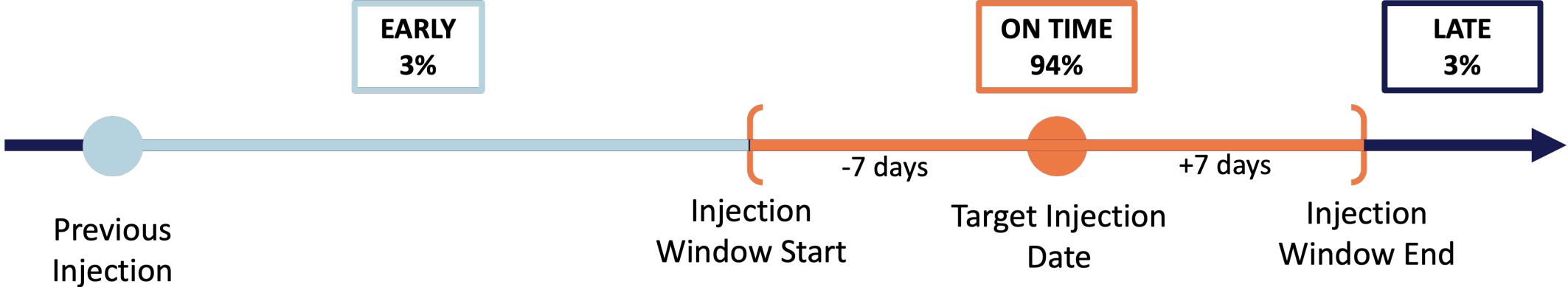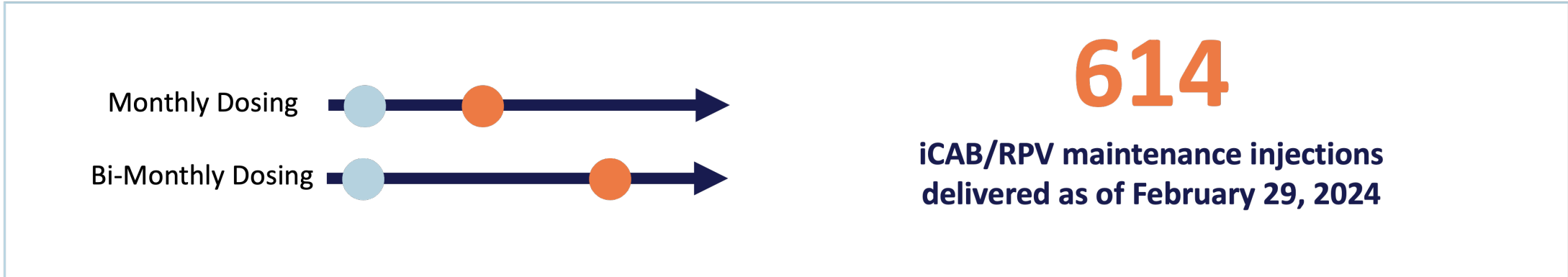
March 1, 2023 – February 29, 2024

Reach: Proportion of Clients with HIV who ever initiated iCAB/RPV or during Year 1 of ALAI UP

Percent of clients with HIV on iCAB/RPV

Sites with <1000 clients with HIV: S1, S3, S2, S6
Sites with ≥1000 clients with HIV: S4, S5

- PWH currently on iCAB/RPV
- PWH ever on iCAB/RPV

Site	PWH currently on iCAB/RPV	PWH ever on iCAB/RPV
S1	16	18
S3	23	27
S2	13	16
S6	5	6
S4	42	59
S5	48	52

6088 Clients with HIV across 6/8 ALAI UP sites

178 (2.9%) Clients with HIV ever initiated on iCAB/RPV

Fidelity: On-time injections among clients ever on iCAB/RPB at end of Year 1

Monthly Dosing

Bi-Monthly Dosing

614
iCAB/RPV maintenance injections delivered as of February 29, 2024

EARLY
3%

ON TIME
94%

LATE
3%

-7 days

+7 days

Previous Injection

Injection Window Start

Target Injection Date

Injection Window End

Other Social Determinants to inform equitable delivery

Variable	S1	S2	S3*	S4*	S5	S6	S7	S8
Employment	yellow	red	yellow	yellow	red	green	green	yellow
Housing status	yellow	yellow	green	yellow	yellow	green	green	red
Poverty level	yellow	yellow	green	green	red	green	green	red
Immigration status	yellow	red	green	green	yellow	green	green	red
Primary language	green	yellow	green	green	green	green	green	green
History of incarceration	yellow	red	green	red	green	yellow	green	red
Other HIV-related SDoH reported quantitatively	yellow	red	red	red	yellow	green	green	red

Legend:
- red: No data available
- orange: Collected but not accessible
- yellow: Some data available, with varying completeness or data issues
- green: Data available for almost all

* Data availability reflects that of people on iCAB/RPV.

Discussion Questions: MEL Context

1. How did you predict iCAB/RPV delivery would affect inequity – creating, exaggerating and/or reducing?

2. Outside of ALAI UP, how did you invest in/utilize monitoring and evaluation activities to support HIV care? To what extent were data reviews of all patients a part of your site data workflow?

Discussion Questions: ALAI-UP Data Reporting Process

1. What benefits and challenges has your site faced with the implementation of client-level monitoring with your data system and staffing support?

   A. We know the process was time-consuming, can you discuss the time and resources invested in collecting, and cleaning client-level data on clinical performance measures on long-acting injectable ARTs (LAI ART) like injectable cabotegravir/rilpivirine (iCAB/RPV) in the context of your site and the ALAI UP program (across sites)?

   B. What value, if any, have you found in collecting, reporting and reviewing the client-level data?

Discussion Questions: Learning and Data Use

1. As part of ALAI UP, to what extent did you assess and aim to address inequity in the HIV care continuum?

2. Has your site utilized any of the results from the client-level monitoring, evaluation, and learning to better understand clinical performance in LAI ART delivery and equity in delivery? If so, what lessons have been learned?

3. Can you elaborate on the importance of client-level monitoring in assessing and ensuring equitable service delivery within the project context?

Thank you!

If you have any questions, please contact Delivette Castor (dc2022@cumc.columbia.edu).

ALAI UP
Advancing Long Acting Injectables
For Underserved Populations