



Analyzing IIS Supplementation Rates for COVID-19 Vaccination Surveillance

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CVS Health

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Disclosures

- All views expressed in this presentation belong to authors, not CVS Health or the Food and Drug Administration, Center for Biologics Evaluation and Research (FDA CBER).

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Acumen

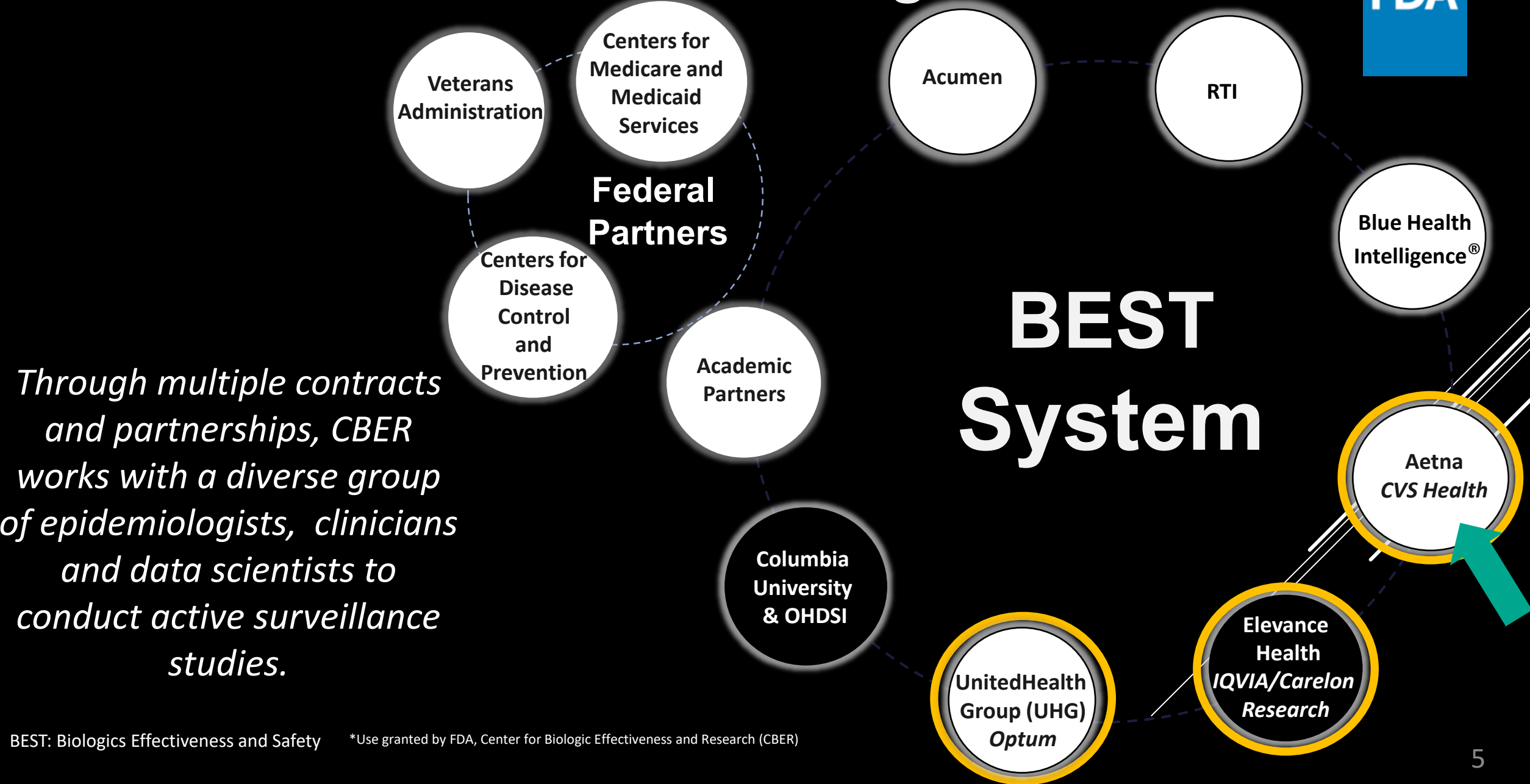
IIS Collaborators:

Alaska, Arizona, California CAIR, California San Diego, California San Joaquin, Colorado, Delaware, Georgia, Illinois, Indiana, Iowa, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Montana, North Carolina, Nebraska, Nevada, New Jersey, New Mexico, New York, New York City, Oklahoma, Pennsylvania, Puerto Rico, Texas, Utah, Vermont, Virginia, Washington, Wisconsin

Agenda

- **Background**
- **Objectives**
- **Research Methods**
- **Results**
- **Conclusions**

FDA CBER Active Surveillance Program



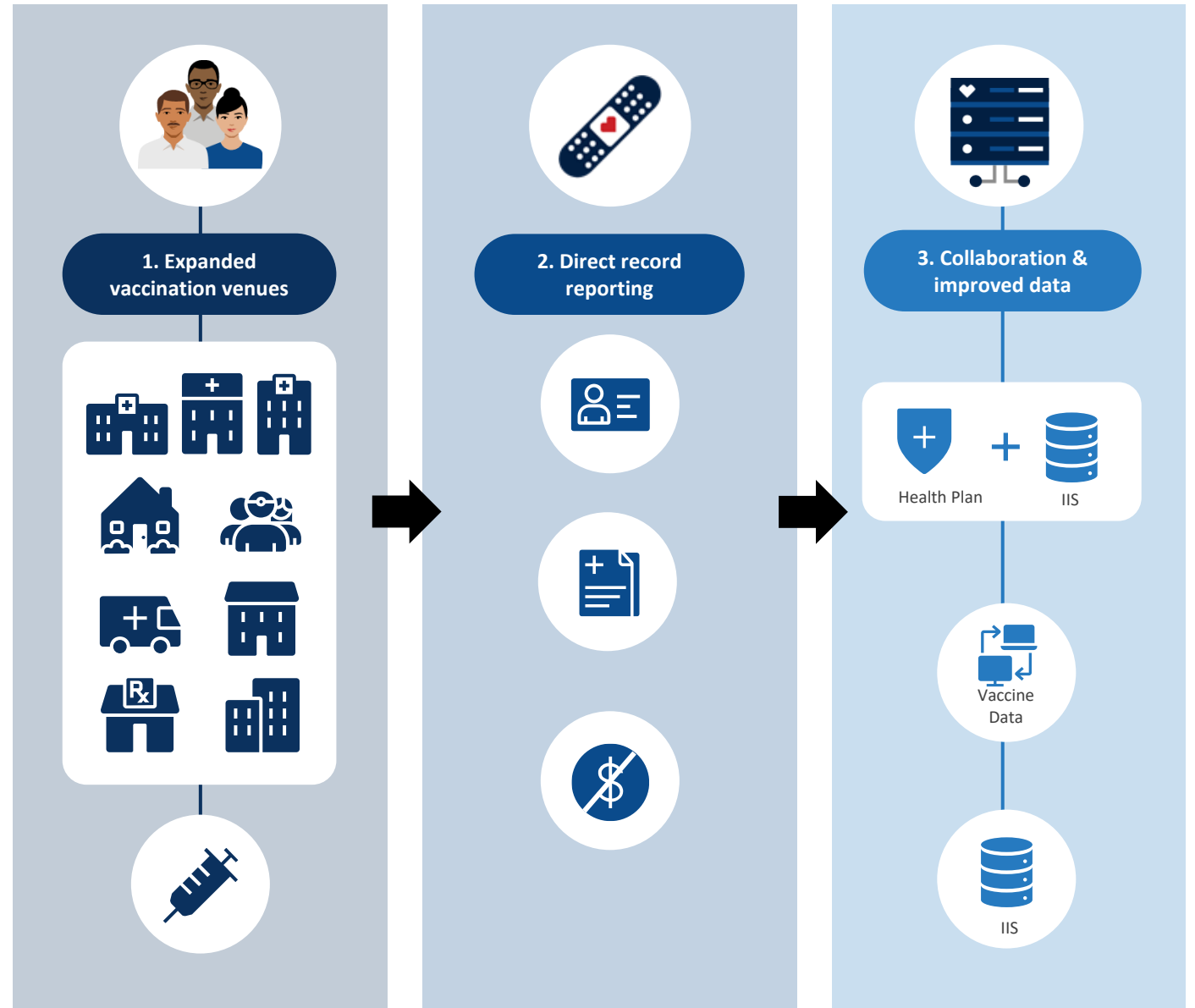
Through multiple contracts and partnerships, CBER works with a diverse group of epidemiologists, clinicians and data scientists to conduct active surveillance studies.

BEST: Biologics Effectiveness and Safety *Use granted by FDA, Center for Biologic Effectiveness and Research (CBER)

Vaccines, Healthcare System & Data

The post-COVID era underscored the flexibility, innovation, and collaboration between healthcare providers, government agencies, and health plans.

- 1. Expanded vaccination venues:** Vaccinations available in non-traditional outpatient venues -- religious centers, libraries, retailers, and stadiums-- further increasing accessibility and convenience.
- 2. Direct record reporting:** With vaccines provided at no cost to patients, the usual claim filing process for health plans was disrupted, complicating the traditional data flow.
- 3. Collaboration & improved data:** Health plans access and integrate IIS vaccination data with existing health data for comprehensive health profiles, facilitating more accurate and enhanced analytics for public health studies and safety surveillance.

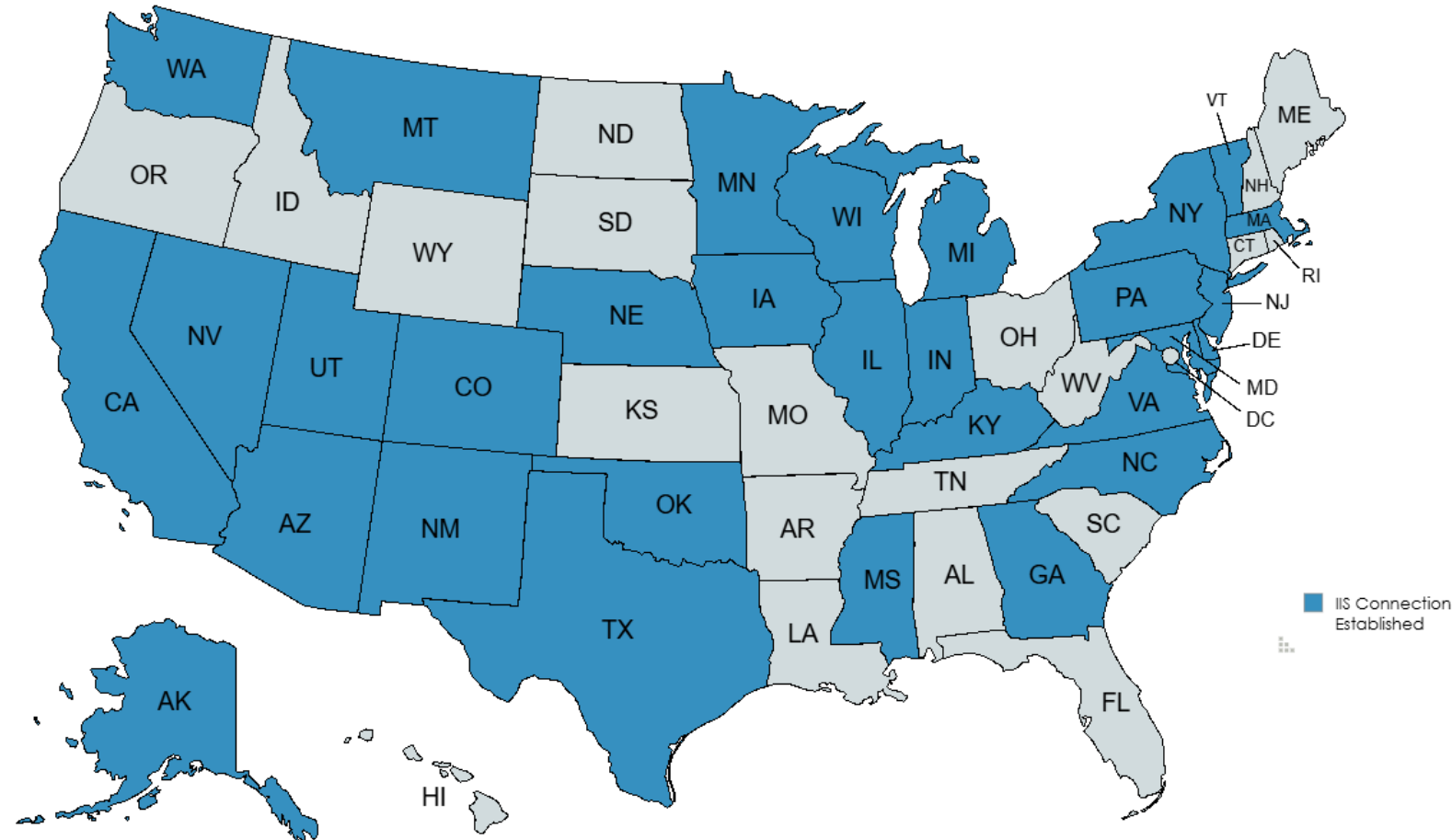


IIS and Aetna Collaboration

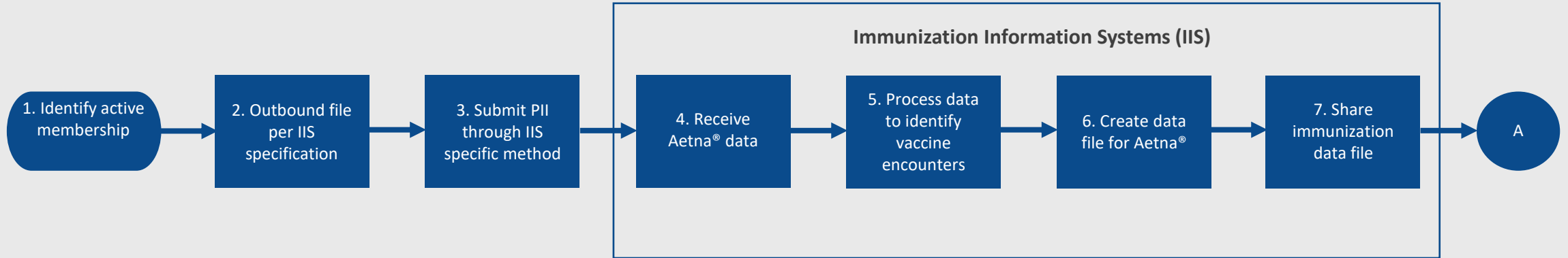
Agreements included:

- Use for public health
 - not for commercial use or general health insurance operations except with permission
- Daily, Monthly, Every Six-Months, or one time
- Data transactions to not interfere with clinical practice data transactions
- Legal, privacy and regulatory data protection and security measures

IIS agreed to collaborate with Aetna®, a CVS Health® company



Data Exchange Process



Aetna®

1. Identifies active members on a periodic basis¹
2. Prepares Personally Identifiable Information (PII) files per IIS specifications
3. Submits PII through IIS preferred data exchange method²

IIS

4. Receives Aetna® data and preforms QA
5. Processes data file to identify Aetna® member vaccine encounters
6. Creates data file for Aetna®
7. Submits vaccine file to Aetna® through IIS preferred method

Study oversight

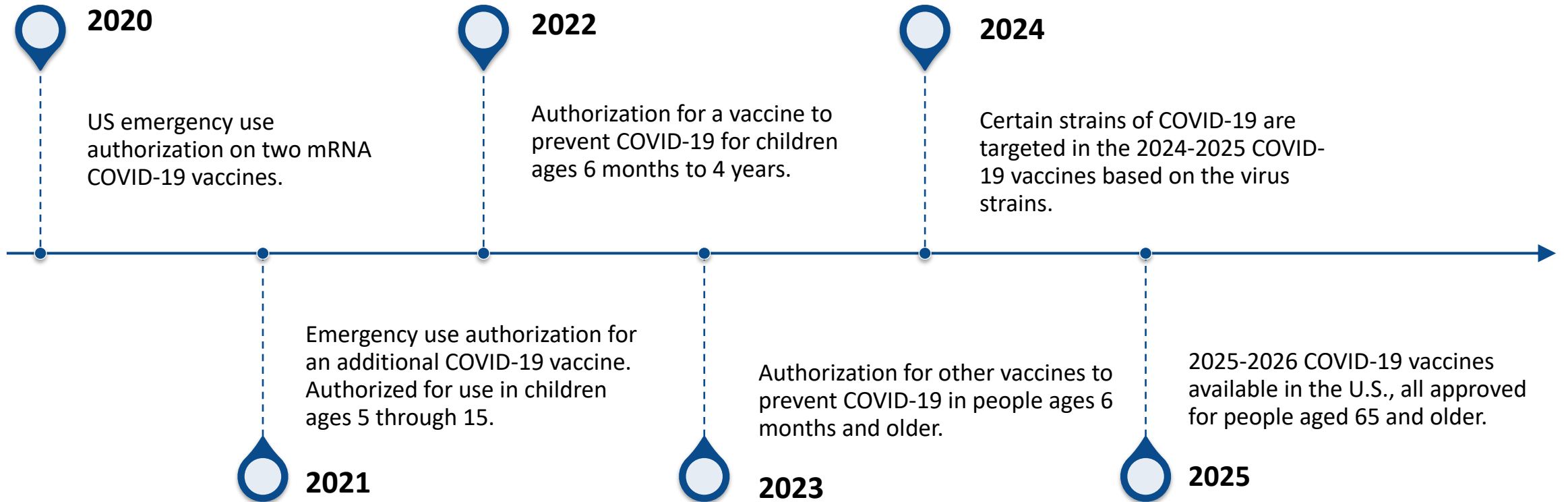
8. Receives IIS encounter data with PII and performs QA
9. Adds study-id and removes PII
10. Stacks IIS vaccine encounters in Aetna® Safety Surveillance Common Data Model³

¹Timeframe is IIS determination: 1 is Daily, 24 are monthly, 1 is 6 months & 2 are one-time

²Data exchange methods: Web server, sftp, hl7, client/HMO query method, email & box storage

³Observational Medical Outcomes Partnership (OMOP) Common Data Model

Background: COVID-19 Vaccination Surveillance



Study Objectives



To evaluate IIS supplementation rates for COVID-19 vaccinations across demographic subgroups, including age, sex and geographic location among commercially insured individuals.



Assess the IIS contributions to comprehensive vaccination surveillance and calculated the proportion of claims-documented vaccinations also captured in IIS.

Populations of interest

COVID-19

- Individuals aged 6 months through 64 years
- Enrolled in a commercial health plan with both medical and pharmacy benefit
- At least one dose between August 2023 – September 2024

Data were stratified by:

- Age groups at vaccine administration
 - Sex (female/male)
 - Geographic location (urban/rural)
- Health and Human Services (HHS) region

Data sources

IIS data, which were regularly exchanged between jurisdictions and CVS Health.

Medical and pharmacy claims of commercially fully insured plan of CVS Health (Aetna) in states with IIS data exchanges.

OMOP Common Data Model, which combined IIS and insurance claims data together through a standardized process.

Analysis

Vaccinations identified using:

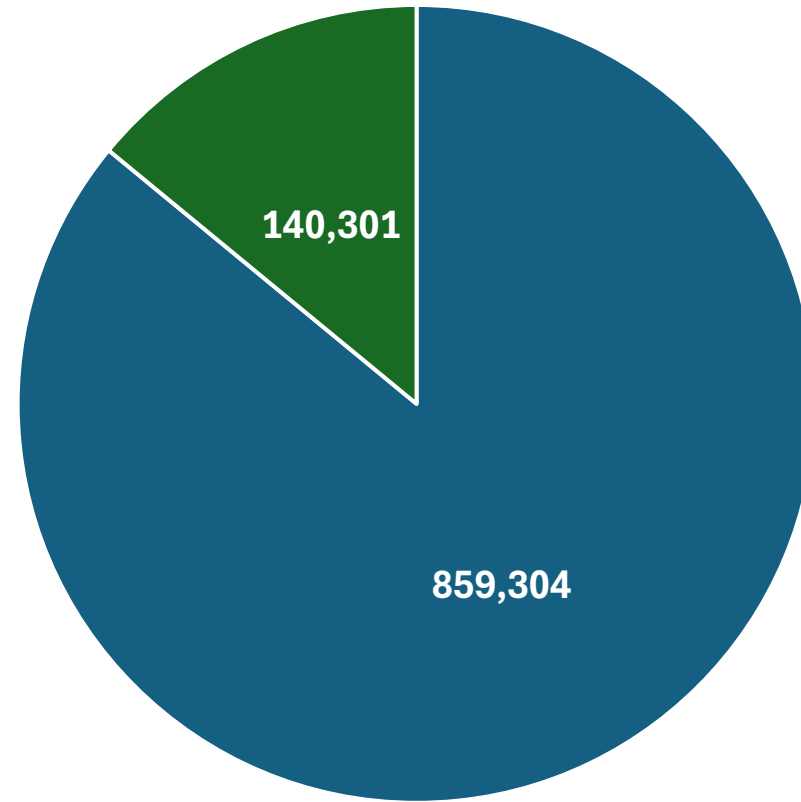
- National Drug Code (NDC)
- Current Procedural Terminology (CPT)
- Healthcare Common Procedure Coding System (HCPCS)
- Vaccine administration (CVX) codes

- COVID-19 vaccinations were categorized by source:
 - Claims only
 - IIS only
 - Claims and IIS
- Assess the IIS contributions to comprehensive vaccination surveillance
- Calculate the proportion of claims-documented vaccinations also captured in IIS

Results: COVID-19 vaccinations by source

140K

of COVID-19 vaccine recipients
with ≥ 1 dose were identified from
IIS data



- Vaccinations Identified from Health Insurance Claims Only
- Vaccinations Identified From IIS Data

Figure 1. Distribution of COVID-19 Vaccinations by data source

Results: COVID-19 Vaccinations Demographics

67K+
of the vaccinated adults were
older than 45 years

45%
of vaccinees were male

95%+
of the vaccinees resided in an
urban area

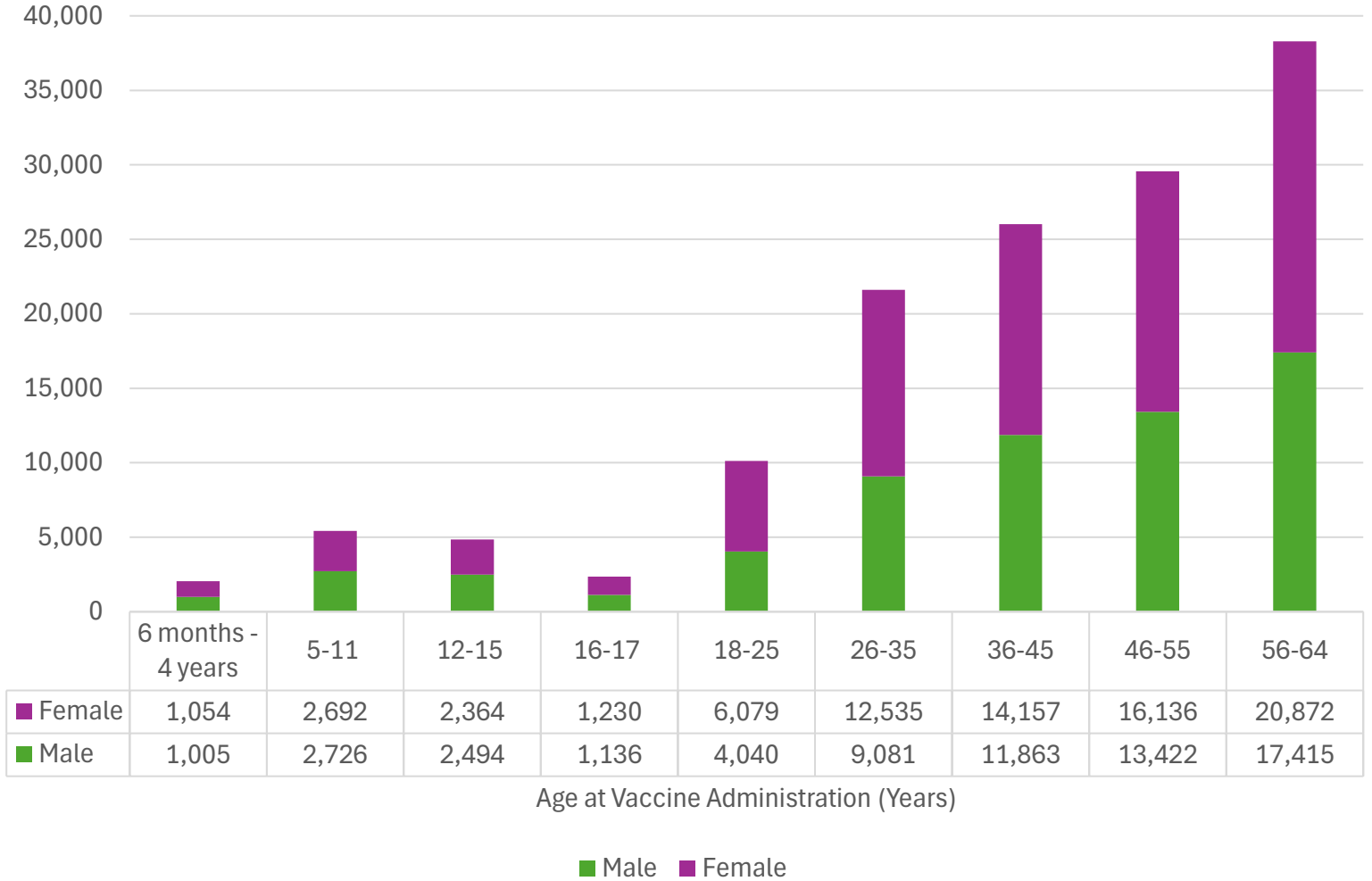


Figure 2. Age and Sex at administration for COVID-19 Vaccinations Identified From IIS Data

Results: COVID-19 Vaccination by HHS Region

Health and Human Services (HHS) Region	Counts
Region 1	5,059
Region 2	43,381
Region 3	25,096
Region 4	712
Region 5	6,033
Region 6	6,386
Region 8	6,396
Region 9	47,238

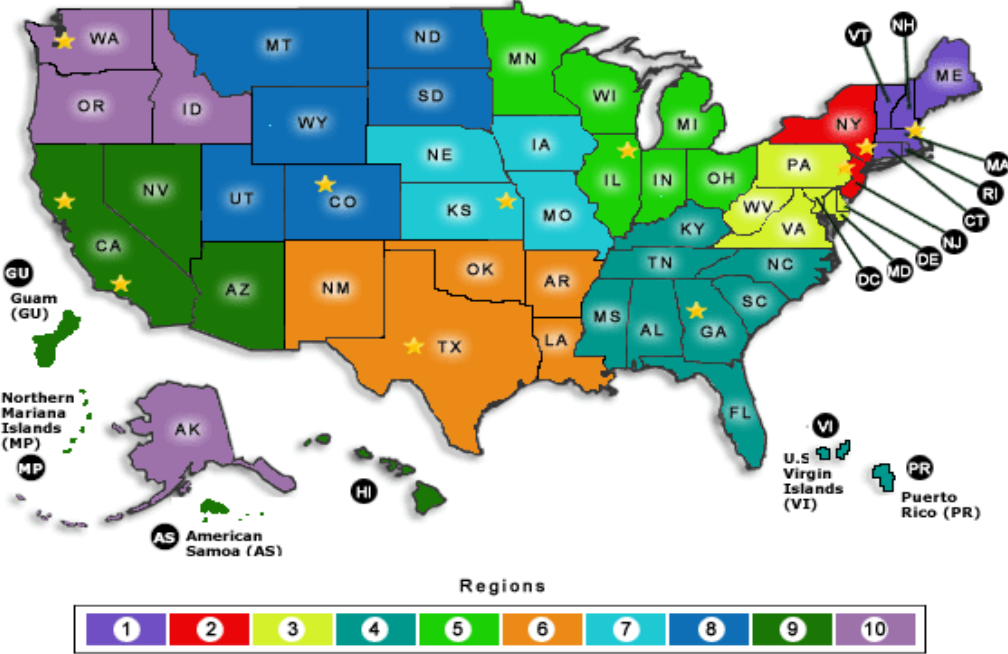


Table 1. HHS Regional Distribution of COVID-19 Vaccinations Identified From IIS Data

Results: COVID-19 Vaccinations Dose Comparison

999,605

received at least one COVID-19 vaccine dose

861,088

of individuals vaccinated with COVID-19 vaccines were identified from Claims only

141,344

of individuals vaccinated with COVID-19 vaccines were identified from IIS data

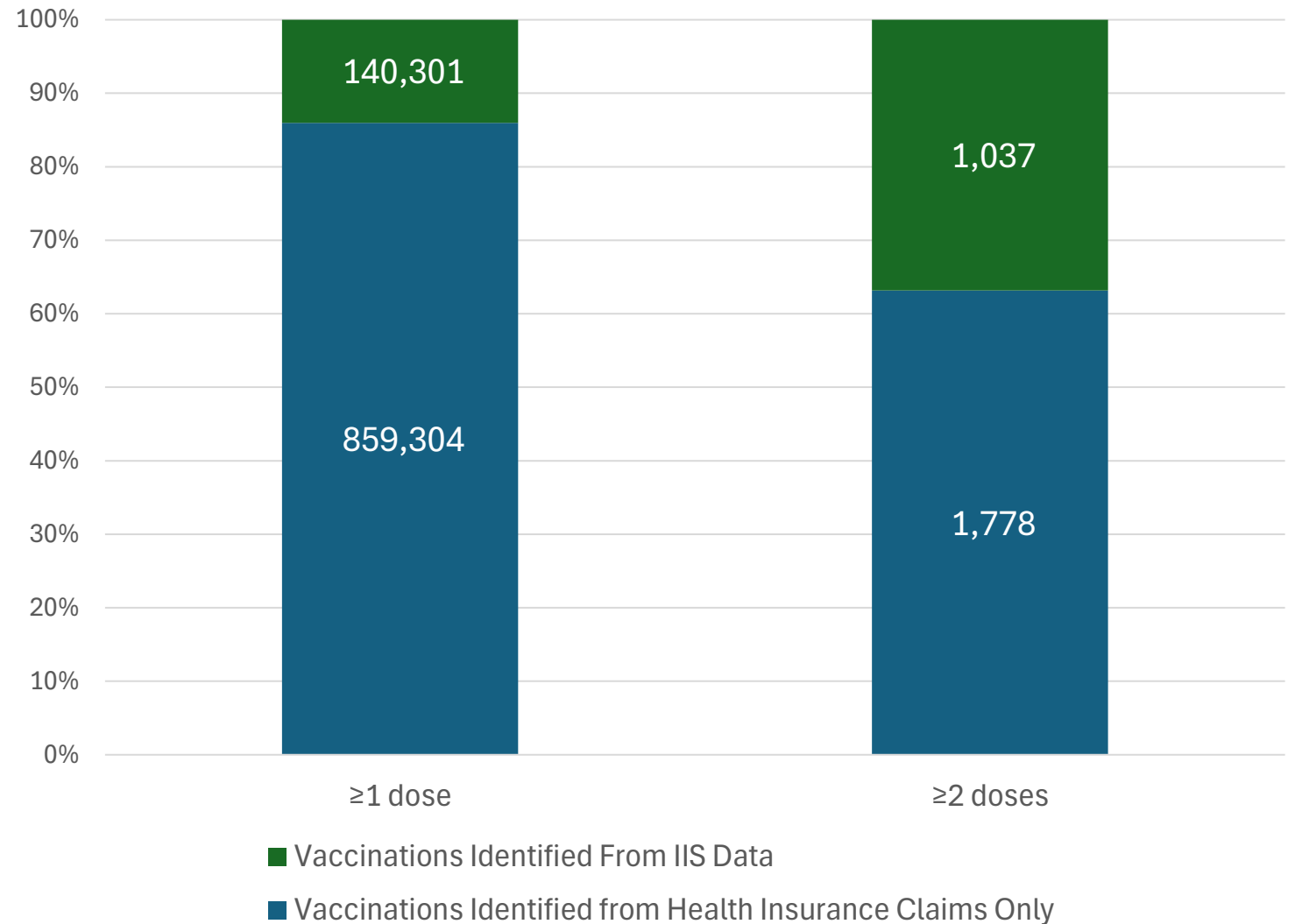


Figure 3. Number of COVID-19 doses among Vaccine Recipients

Conclusions

1.

IIS data was able to identify additional vaccinations among commercially insured adults.

2.

IIS data augmented with insurance claims data significantly enhances the robustness of vaccine safety surveillance of COVID-19 among commercially insured adults.

3.

Observed patterns suggest areas where strengthening the data exchange partnership could maximize public health value of IIS.

**Thank you for the
collaboration!**

Questions?

