# Health Insurance Claims–Immunization Information System (IIS) Data Linkage for Post-Vaccination Surveillance

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# Disclosure Statement

I do not have any financial conflicts of interest to disclose.

# Outline


**CBER Active Surveillance Program**

**IIS-Claims Data Linkage**

**Regulatory and Public Health Impact**

**Barriers to Data Linkage**

**Conclusion**

# 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.*

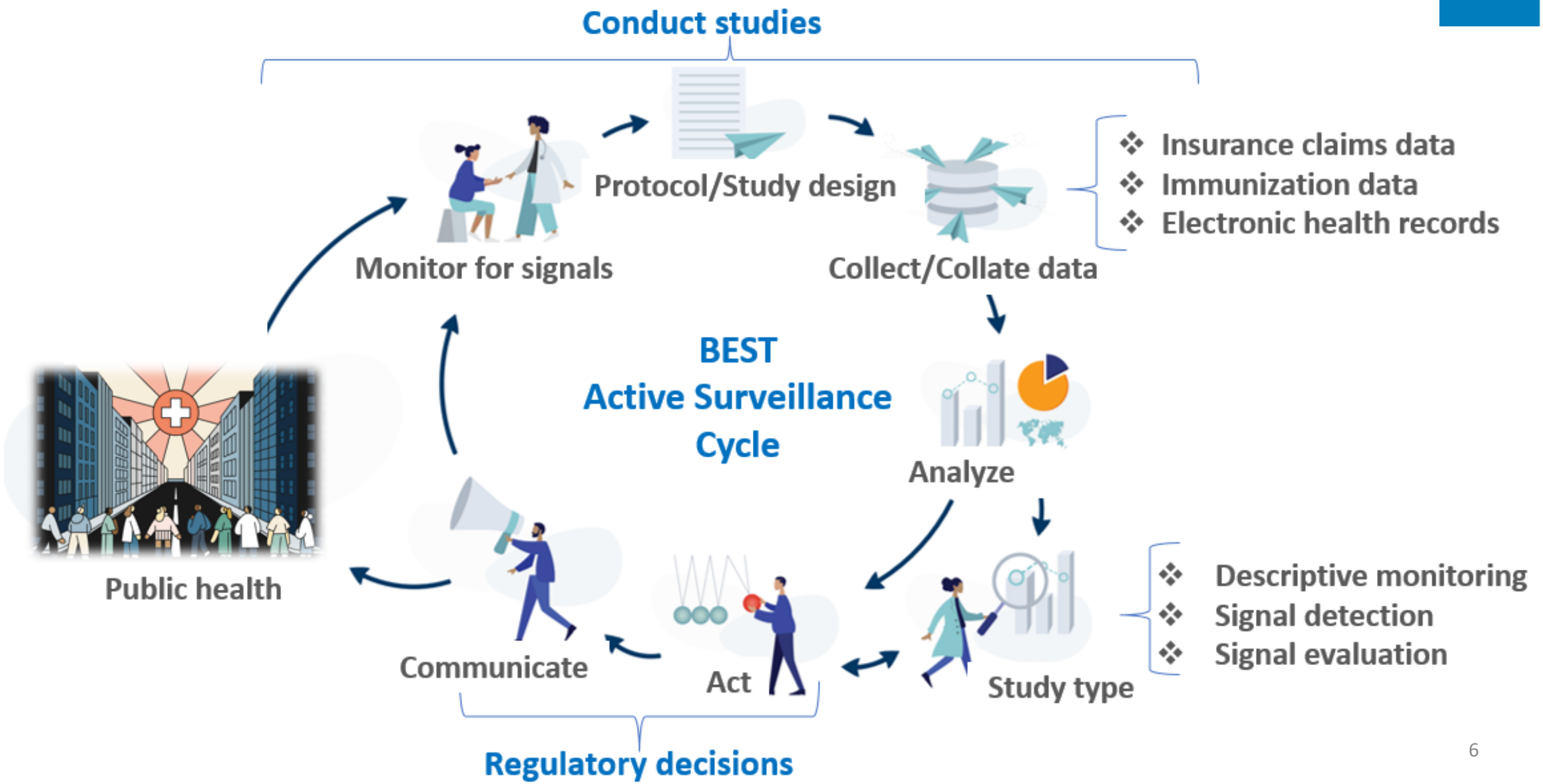
BEST: Biologics Effectiveness and Safety

# FDA CBER Active Surveillance Data Sources

| Data Source* | Database Type | No. Patients Covered (Millions) | Time Period Covered |
|---|---|---|---|
| MarketScan Commercial and Medicare Supplemental | Claims | 254 | 1999 - 2019 |
| MarketScan Medicaid | Claims | 48 | 1999 - 2019 |
| Blue Health Intelligence® | Claims | 33.6 | 2012 - present |
| Optum | Claims | 66 | 1993 - present |
| Carelon Research | Claims | 70.6 | 2010 - present |
| CVS Health | Claims | 41.6 | 2018 - present |
| OneFlorida Clinical Research Consortium – Medicaid | Claims | 6.7 | 2012 - present |
| OneFlorida Clinical Research Consortium - EHR | EHR | 5.6 | 2012 – present |
| Optum EHR | EHR | 102 | 2007 - 2020 |
| MedStar Health Research Institute | EHR | 6 | 2009 - present |
| PEDSnet | EHR | 6.2 | 2009 - present |
| IBM CED | Linked EHR Claims | 5.4 | 2000 - present |
| Optum Integrated Claims – EHR | Linked EHR Claims | 25 | 2007 - 2020 |
| OneFlorida Clinical Research Consortium – Linked EHR Claims | Linked EHR Claims | 1.5 | 2012 - present |

*Data lag varies for different databases from a few days to a few months.

# Active Surveillance cycle



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# IIS-Claims Data Linkage

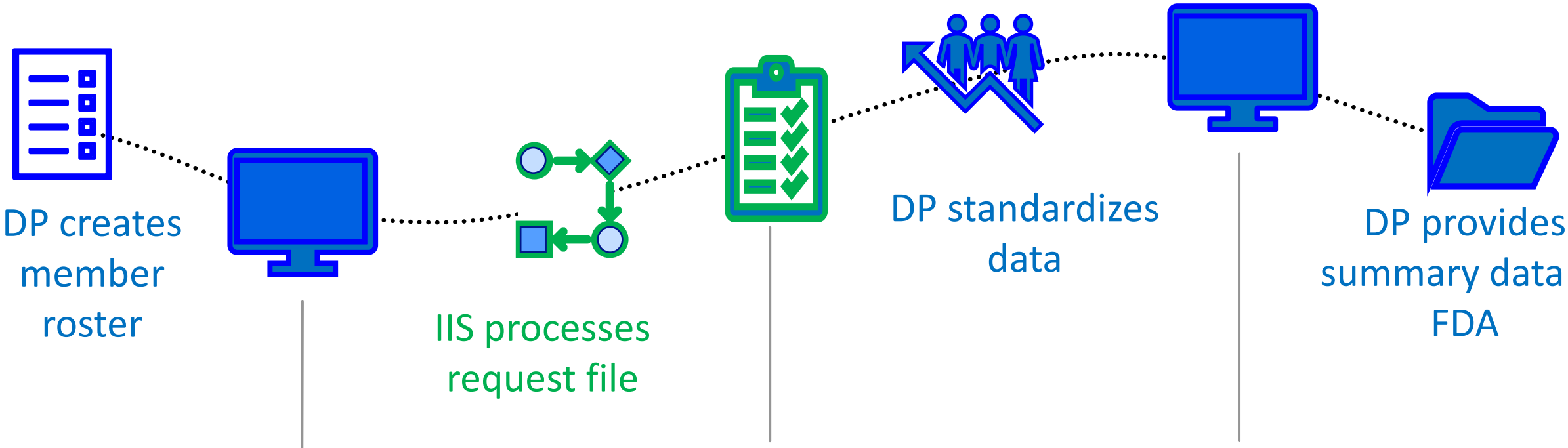
## FILE EXCHANGE METHODS

- Box Storage
- Health Level Seven International (HL7)
- Secure Email
- Secure File Transfer Protocol (SFTP)
- SOAP Web Service
- Secure Web Server

## GENERAL LINKAGE PROCESS

- BEST data partners (DPs) provide a set of PII from claims data to be used for file linkage
- Each IIS jurisdiction links individuals to immunization records through PII, using their preferred method
- IIS returns immunization data with unique ID for rematching. Some IIS return PII.

# Detailed Example of IIS-Claims Data Linkage




[a] Common fields included in request file specifications across IIS include member number, first name, middle name, last name, birth date, mother's first name, and mother's maiden last name.

[b] For IIS with HL7 connections, Query By Parameter (QBP) messages are submitted and the IIS returns Responses (RSP) with relevant members' immunization history.

[c] Common fields included in response files include CPT code, CVX code, vaccine administration date, vaccine manufacturer, etc.

# IIS Partnership with FDA: Flow of Data

IIS

Data Partners

FDA/CBER BEST System

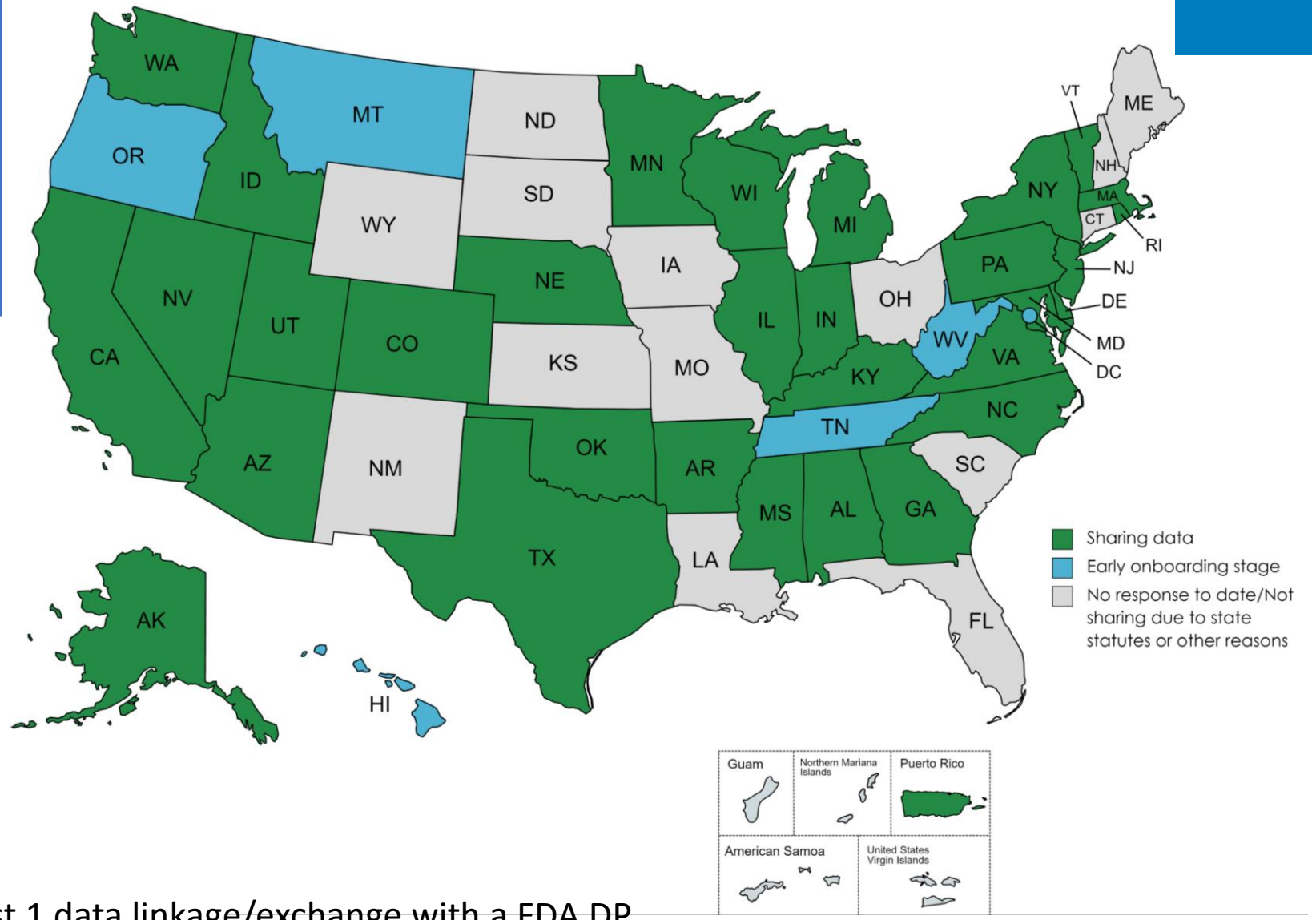


**IIS** share vaccination data on health plan members with **BEST health plan data partners**

**Data partners** clean, validate, aggregate and analyze linked vaccination and claims data per FDA protocols

**Data Partners** provide aggregated summary data to **FDA/CBER**, to monitor vaccine safety and effectiveness.

# Status of CBER-BEST and Data Partners IIS Jurisdiction Outreach




Note: Sharing data means made at least 1 data linkage/exchange with a FDA DP

Last updated April, 2023

# IIS COVID-19 Data Linkage Feasibility Study (Single DP)

| | Total study population (Age <64) | At least one dose | | Completed series | |
|---|---|---|---|---|---|
| | | Claims[a] | Combined IIS/Claims[b] | Claims[a] | Combined IIS/Claims[b] |
| | | No. (%) | No. (%) | No. (%) | No. (%) |
| **Total (12/2020-12/2021)** | 5,112,722 | 1,676,235 (32.8%) | 2,458,231 (48.1%) | 1,248,637 (24.4%) | 2,143,556 (41.9%) |
| **Deidentified States** | | | | | |
| **State 1** | 643,602 | 201,474 (31.3%) | 316,177 (49.1%) | 145,137 (22.6%) | 287,198 (44.6%) |
| **State 2** | 158,385 | 47,831 (30.2%) | 76,820 (48.5%) | 38,294 (24.2%) | 68,478 (43.2%) |
| **State 3** | 1,143,375 | 422,934 (37.0%) | 520,249 (45.5%) | 310,479 (27.2%) | 404,913 (35.4%) |
| **State 4** | 696,305 | 184,312 (26.5%) | 265,936 (38.2%) | 135,725 (19.5%) | 228,643 (32.8%) |
| **State 5** | 786,234 | 255,544 (32.5%) | 401,634 (51.1%) | 193,105 (24.6%) | 366,046 (46.6%) |
| **State 6** | 318,060 | 136,090 (42.8%) | 167,745 (52.7%) | 102,514 (32.2%) | 144,224 (45.3%) |
| **State 7** | 330,165 | 124,739 (37.8%) | 191,327 (58.0%) | 101,157 (30.6%) | 180,397 (54.6%) |
| **State 8** | 360,267 | 110,016 (30.5%) | 179,787 (49.9%) | 83,987 (23.3%) | 159,617 (44.3%) |
| **State 9** | 87,663 | 18,927 (21.6%) | 40,901 (46.7%) | 12,709 (14.5%) | 36,876 (42.1%) |
| **State 10** | 219,939 | 54,303 (24.7%) | 105,376 (47.9%) | 39,386 (17.9%) | 95,468 (43.4%) |
| **State 11** | 254,098 | 76,424 (30.1%) | 133,781 (52.7%) | 54,735 (21.5%) | 122,816 (48.3%) |
| **Multiple states[c]** | 114,629 | 43,641 (38.1%) | 58,498 (51.0%) | 31,409 (27.4%) | 48,880 (42.6%) |

[a] Prior to hierarchical deduplication of vaccine records across IIS and claims.
[b] After hierarchical deduplication of vaccine records across IIS and claims.
[c] There were multiple states listed for a patient, among the eleven states of interest.

Abbreviations: No. = number

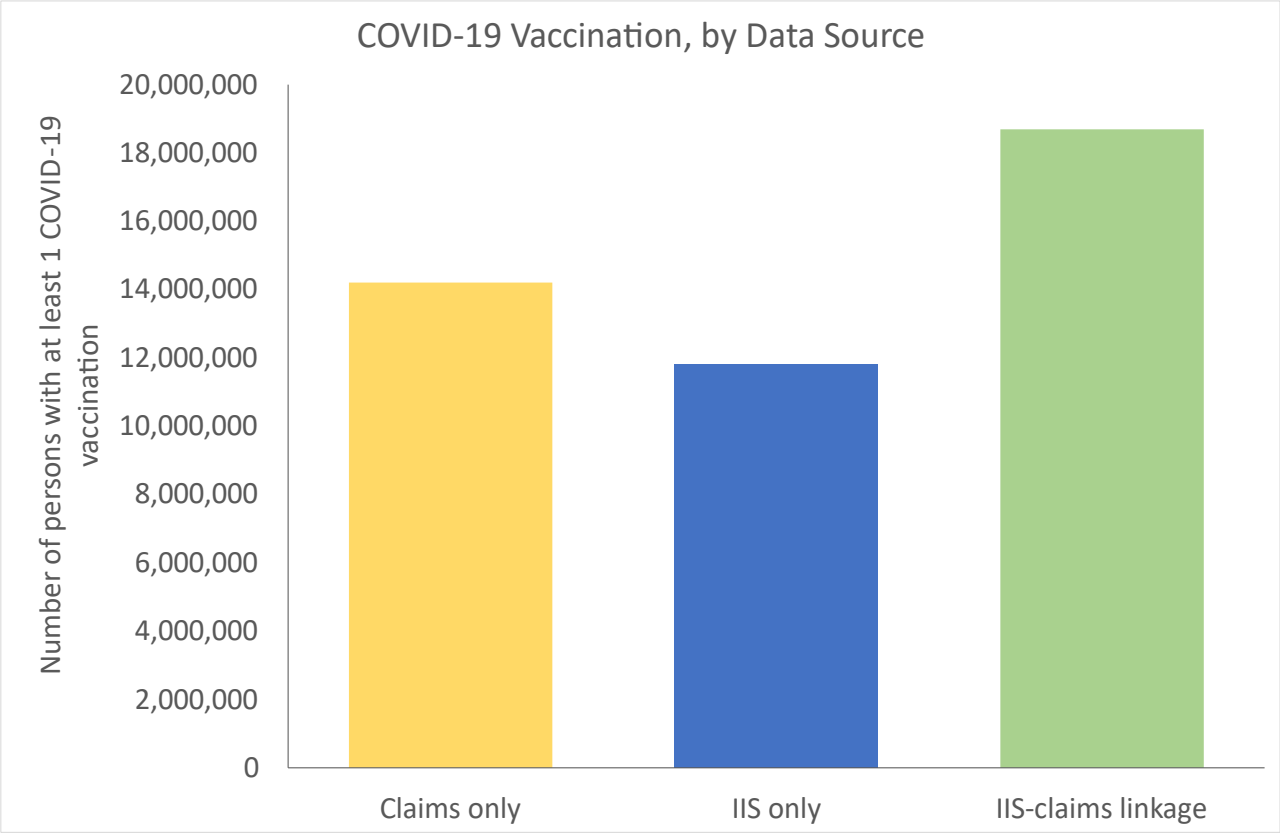
# IIS COVID-19 Data Linkage Feasibility Study (All DPs)

Vaccinated rates

- Claims data alone: 13.5–46.4%
- IIS—claims linkage: 22.5–65.5%

Some linkages contributed to as much as 50% increase in immunization data.

Linkage to IIS decreases COVID-19 vaccine misclassification in studies that rely on claims.




NOTE: Data current as of September 30, 2022
Vaccine totals represent at least 1 COVID-19 vaccination in IIS jurisdictions exchanging data with any BEST DP

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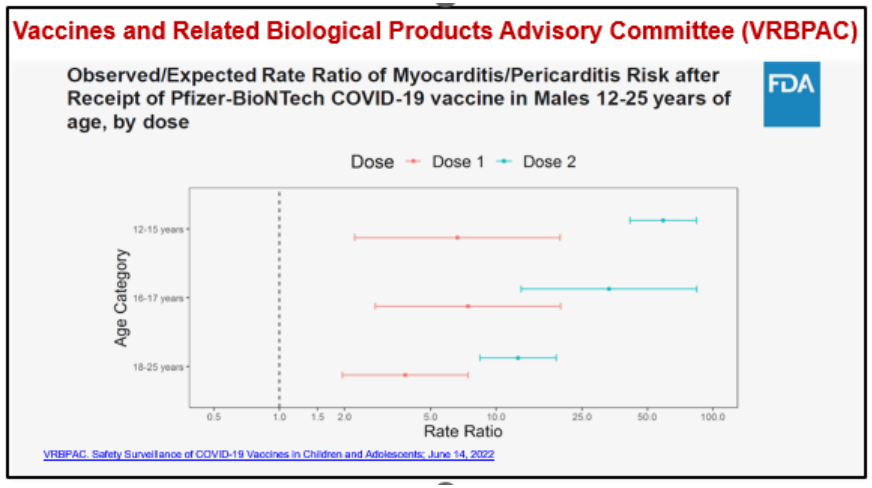
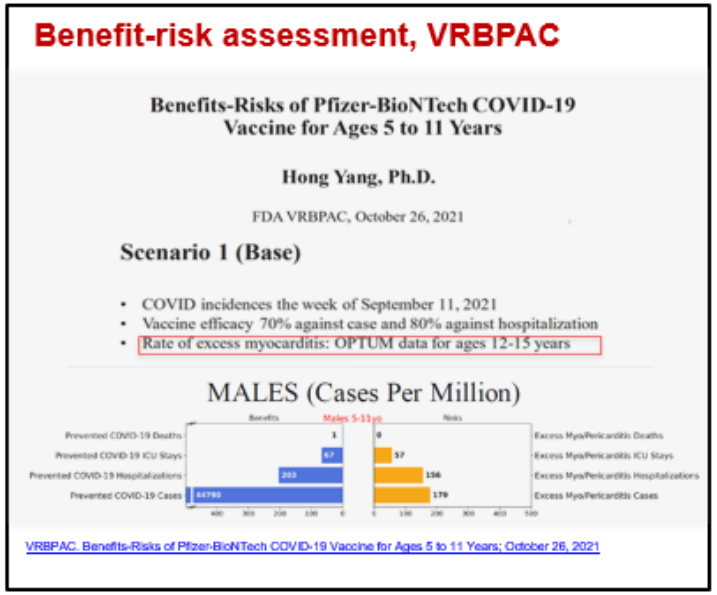
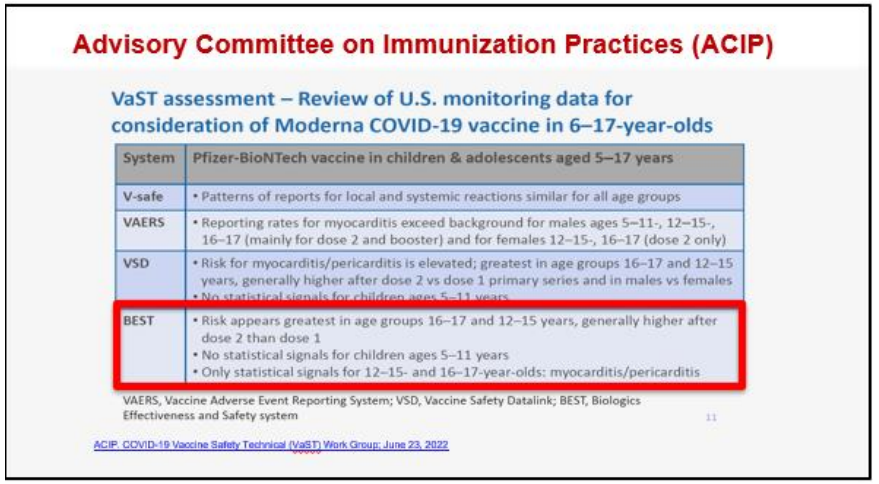
# Regulatory and Public Health Impact

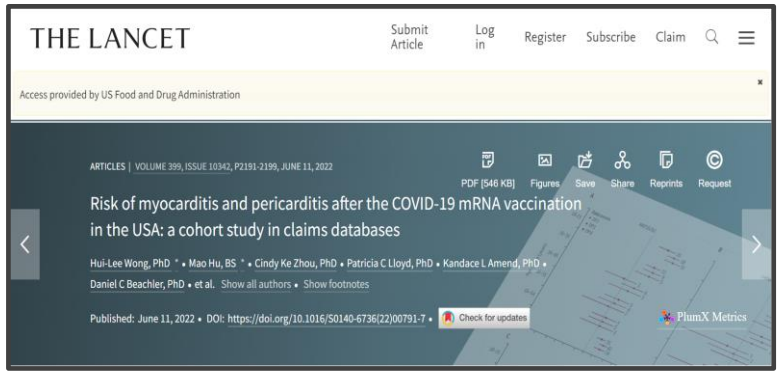


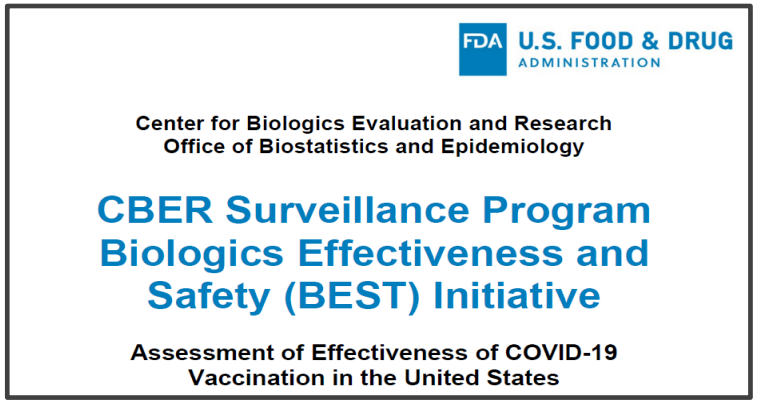

- BEST studies have contributed to EUA and approvals during numerous FDA advisory panels.
- BEST studies provided risk estimates for input in benefit–risk assessment for regulatory decision making.
- As part of the both passive and active US surveillance system, BEST studies contribute to the advisory committee that determines the public health policies regarding vaccines in the US.

# Regulatory and Public Health Impact contd.



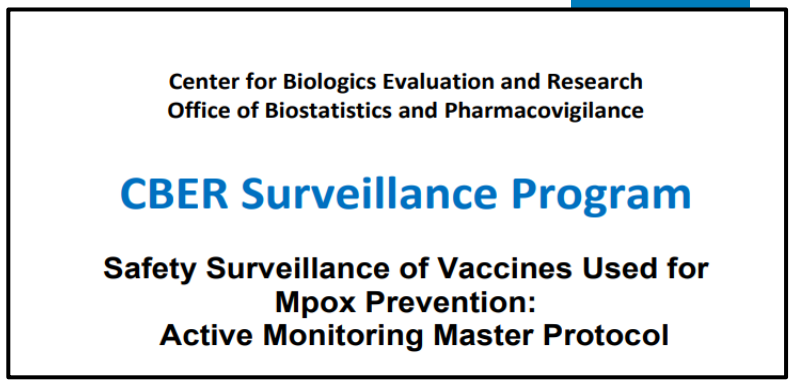

- IIS data are crucial to FDA safety assessment/surveillance, e.g. defining the risk of Myocarditis/pericarditis after mRNA vaccines in young males.

**Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases - The Lancet**




- IIS data provide more power to detect any potential rare safety outcomes after vaccine receipt.
- IIS data are crucial for absolute vaccine effectiveness (VE) studies.

**Vaccines & Allergenics – BEST Initiative**




- IIS data were essential to measure exposure for JYNNEOS and ACAM2000.
- Vaccinated in Claims Only ~10% Vaccinated in IIS ~90%
- IIS data were critical to give us the ability to do monitoring.

**Vaccines & Allergenics – BEST Initiative**

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# Barriers to Data Linkage

- Within-state data sharing only
- No data sharing for public health purposes
- Share with insurance payors, but not government agencies
- No data sharing with health insurance payors
- No clear statute, but no data sharing


- Cost per person too high for routine data exchange


- Jurisdiction has few to no personnel to facilitate routine exchange
- Old or insufficient infrastructure for data exchange with insurance payors

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- BEST Initiative contributes to FDA CBER's mission to ensure biologic products safety and effectiveness through active surveillance.

- IIS data complements COVID-19 claims data adding up to 50% more immunization information for timely, evidence-based regulatory decision making.

- IIS mpox data captured nine times as many vaccine administrations as claims data.

- Continued and expanded IIS data linkage is needed for BEST to continue generating rapid and comprehensive response to the COVID-19 pandemic, mpox, seasonal influenza, and future outbreaks that require vaccine administration.

# BEST Post-market Surveillance Activity

## Biologics Effectiveness and Safety (BEST) Initiative

- **ABOUT**
  - BACKGROUND
  - COLLABORATORS
  - PRIVACY & SECURITY
- **DATA & SURVEILLANCE ACTIVITIES**
  - DISTRIBUTED NETWORK AND COMMON DATA MODEL
  - ARTIFICIAL INTELLIGENCE AND NATURAL LANGUAGE PROCESSING
- **COMMUNICATIONS & OUTREACH**
  - ENGAGING STAKEHOLDERS
  - EVENTS
  - PUBLICATIONS & PRESENTATIONS

# Study Team

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