



AIRA
AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

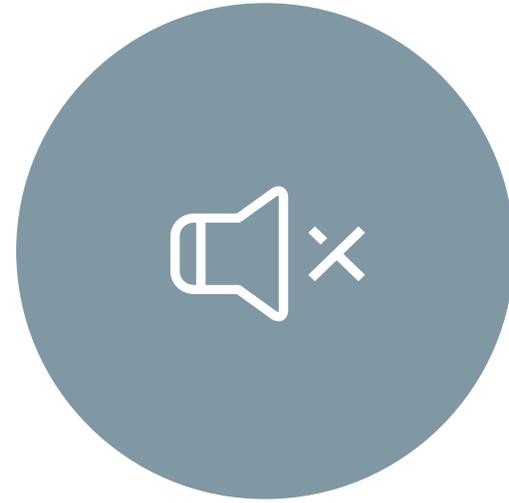
Discovery Session: AIRA 2023 National Meeting Highlights

AIRA Discovery Session
May 22, 2023
4 PM EST

AIRA Discovery Session



This meeting is being recorded
and will be posted in the
AIRA repository

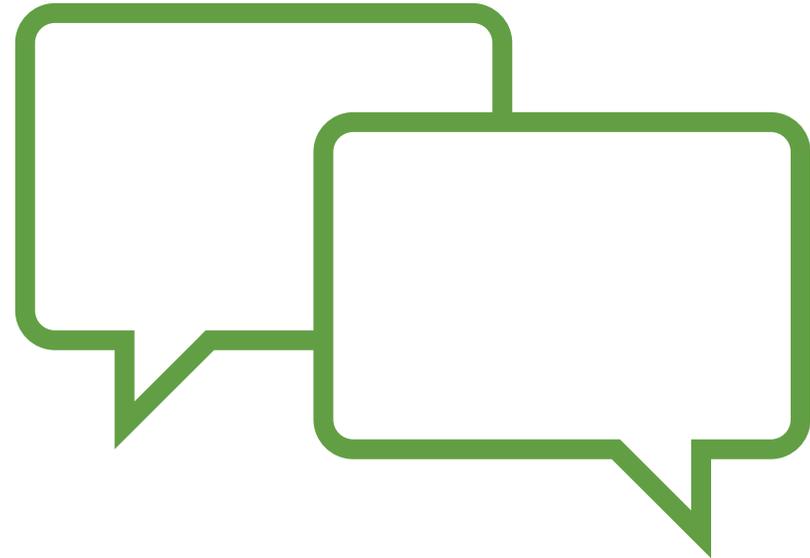


All phone lines
are muted



Technical Support

If you experience any technical issues during the meeting, please contact **Kim Rutland** via direct message in the Chat.



Questions

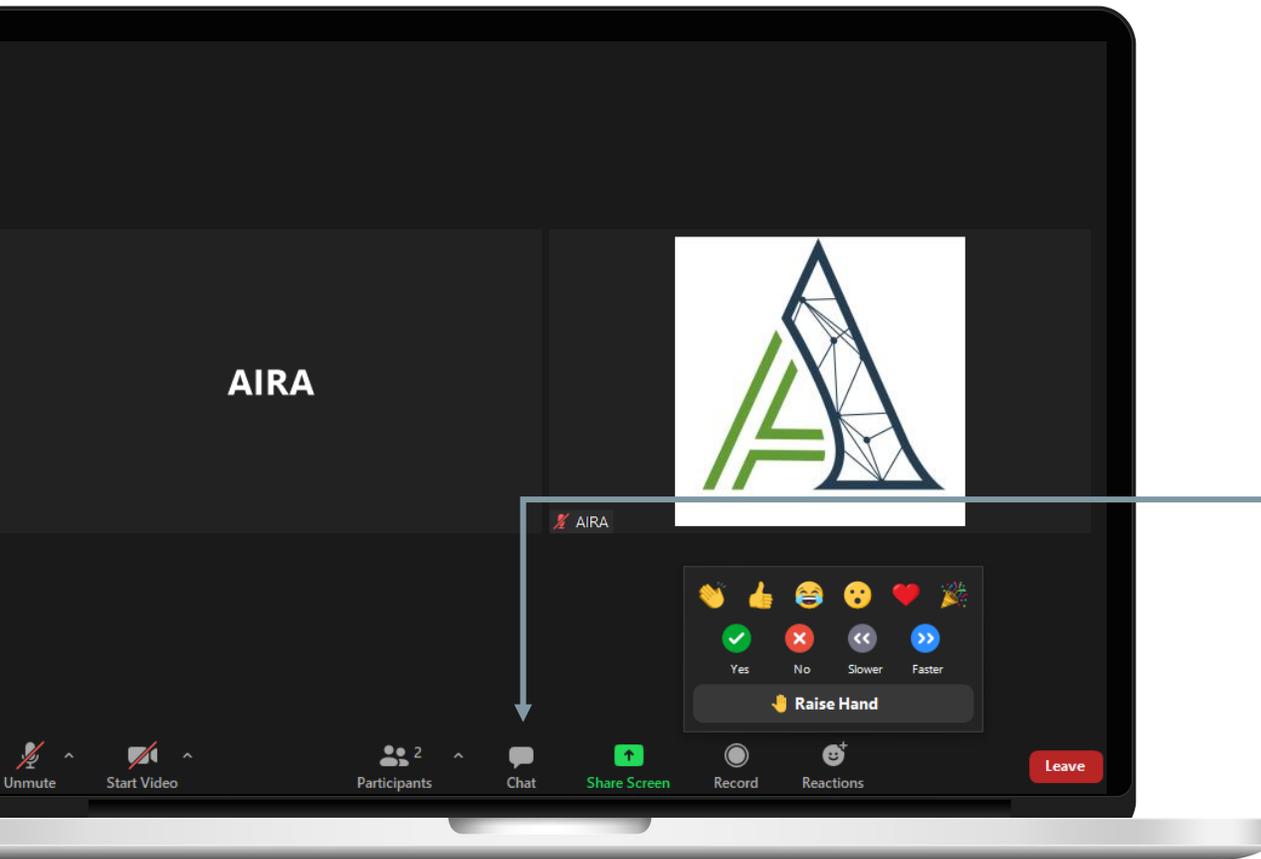
How do I ask a question?

There will be time allotted for Q&A following the presentations.

If you think of a question during the presentations:



Select the chat icon and type your question into the chat box.



National Meeting Recap

Courtney Londo, AIRA





Keynote Speaker

Dr. Saundra Dalton-Smith

Founding Physician and CEO

Restorasis Workplace Wellbeing
Consulting Agency

CDC's Vision for IISs

IISs support the standardized capture and exchange of high-quality, individual-level immunization data for all doses of ACIP*-recommended vaccines

These data are linked across jurisdictions, providers, and partners, and to other individual-level data sources to inform public health action

* ACIP: Advisory Committee on Immunization Practices



Policy Plenary

MODERATOR

Rebecca Coyle, MEd, Executive Director,
AIRA

PANELISTS

Abby Bownas, AVAC Manager, Principal,
NVG LLC

Claire Hannan, MPH, Executive Director, AIM

"The policy session was so helpful. I feel like I know what steps to take to work on legislating effective policies. Great resources, too!"



Measurement & Improvement Plenary

MODERATOR

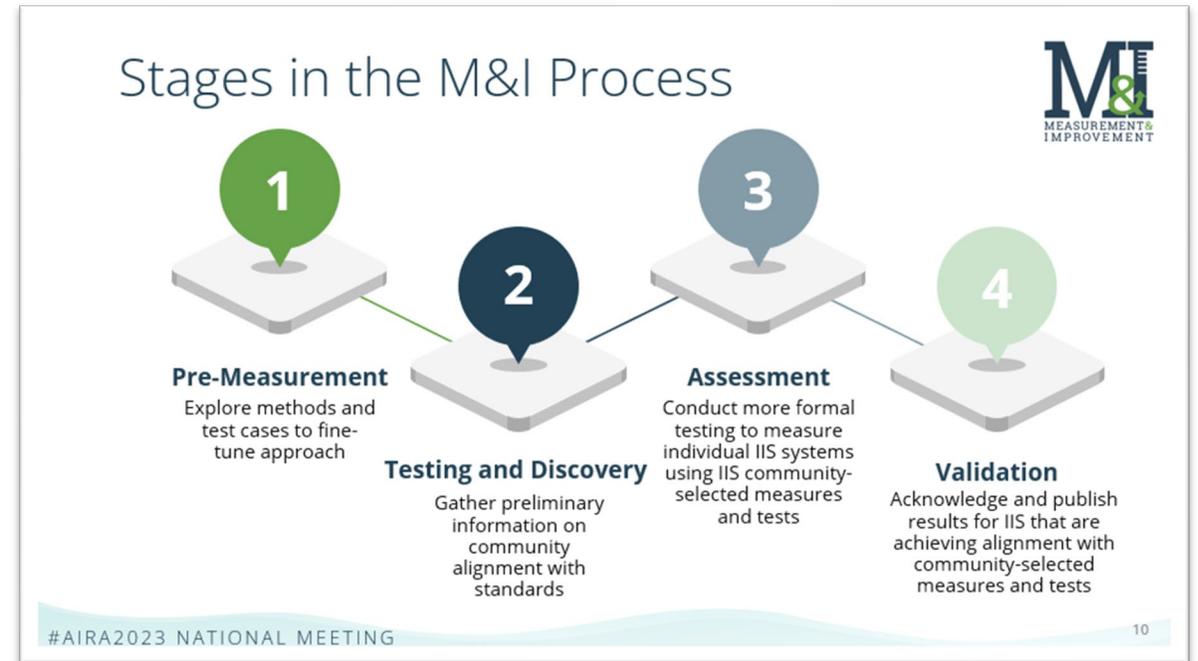
Rebecca Coyle, MEd, Executive Director,
AIRA

PANELISTS

Valentin Sostaric, Immunization Data
Systems Chief, Arizona Department of Health
Services

Assiatou Diallo, MPH, Senior Technical
Analyst, AIRA

Mary Beth Kurilo, MPH, MSW, Senior Director
of Health Informatics, AIRA



Crowdsourcing Session

“ What is the #1 issue facing IIS today?
—

- Data quality
- Funding
- Sufficient workforce
- Provider compliance hurdles
- Data modernization
- Disconnect between federal, state, and end consumer

A stylized globe in shades of blue and teal is centered in the background. Overlaid on the globe are several white curved lines representing flight paths or race routes. In the top-left and bottom-left corners, there are small white silhouettes of airplanes. In the top-right and bottom-right corners, there are white curved arrows pointing upwards and outwards, suggesting a circular or global path.

THE AMAZING IIS RACE

Thanks to our participants!

Congratulations to our winners!

AIRA Award Ceremony

REOCCURRING THEMES

2023



Persevering through obstacles with enormous fortitude and dedication



Innovative problem-solving in the face of evolving program challenges



Steadfastness in completing the work that needed to be done

Thank you to our sponsors!

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2023 – Another Record Setting Year

2019: Indianapolis, IN

- 425 attendees

2021: Portland, OR (Hybrid)

- 462 attendees
 - 278 virtual
 - 184 in-person

2022: Virtual

- 660 attendees

2023: San Diego, CA

- **545** attendees!

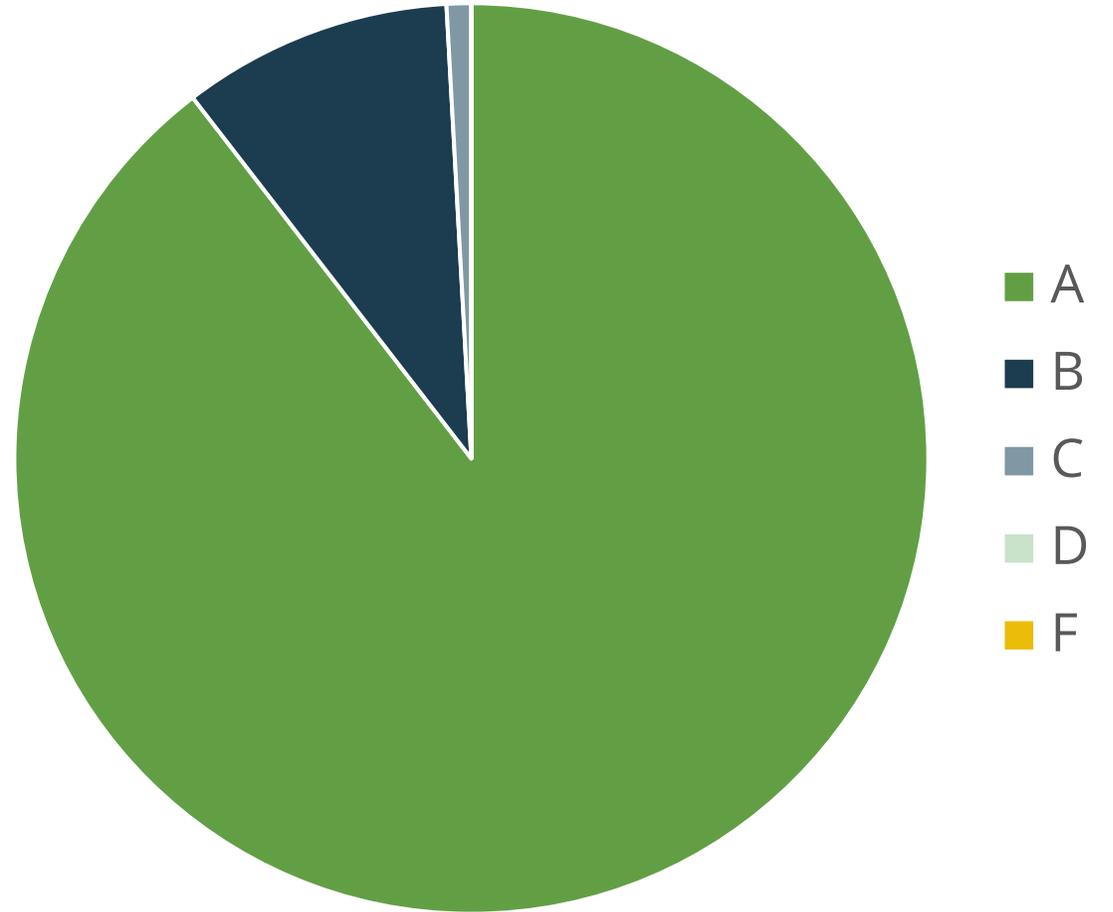


Who Attended

Position Classification	#	%
CDC Staff	20	3.7
IIS Implementers	34	6.3
IIS Managers	51	9.4
Immunization Program Managers	46	8.5
Other IIS Staff	79	14.5
Other Immunization Program Staff	93	17.1
Presidents or CEOs	10	1.8
Technical Staff (e.g. IT)	42	7.7
Other	169	31.1



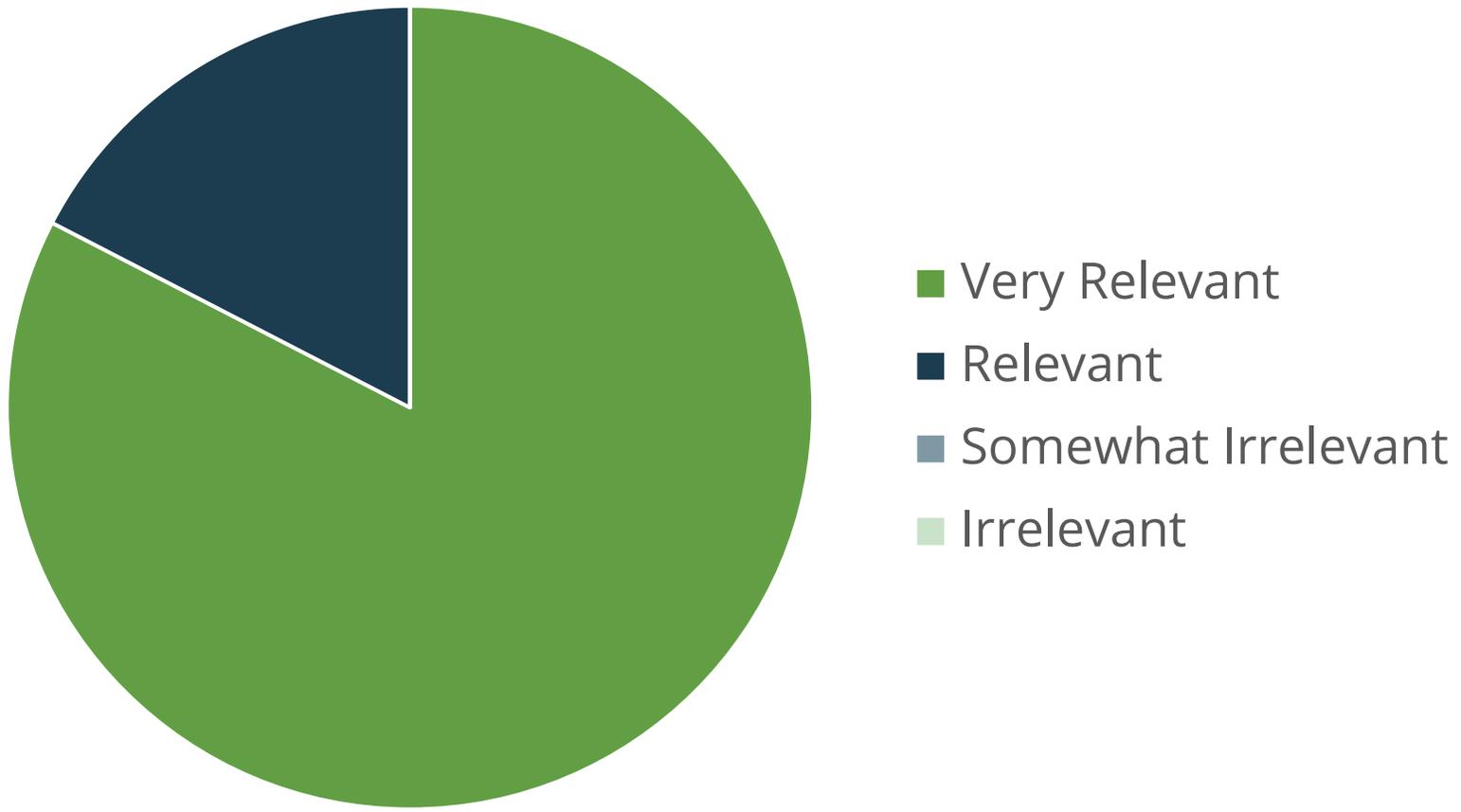
What is your overall grade for the AIRA 2023 National Meeting?



Answered: 115
Skipped: 2



How relevant was this meeting's content to the work that you do?



Some takeaways

...the future is bright!
So many young,
talented people.

Data modernization
(and data quality) are
critical for jurisdictions
to meet evolving
national standards.

Renewed passion for
my work - new ideas
to try to implement -
new partnerships



Additional comments, compliments, and constructive feedback

Great info and connections made.
Fantastic experience.

Volume of people made it challenging with the space

Want to go back next year, want to present next year, very laid back, was expecting it to be much stuffier

We are better together and community matters.

Another great AIRA National Meeting organized by the always awesome and fun dedicated AIRA team!



FROM THE
CALI SUN TO
THE
SUNSHINE
STATE



AIRA
2024
National
Meeting

AIRA 2024

National Meeting

May 7-9, 2024



ORLANDO, FL





Today's Speakers

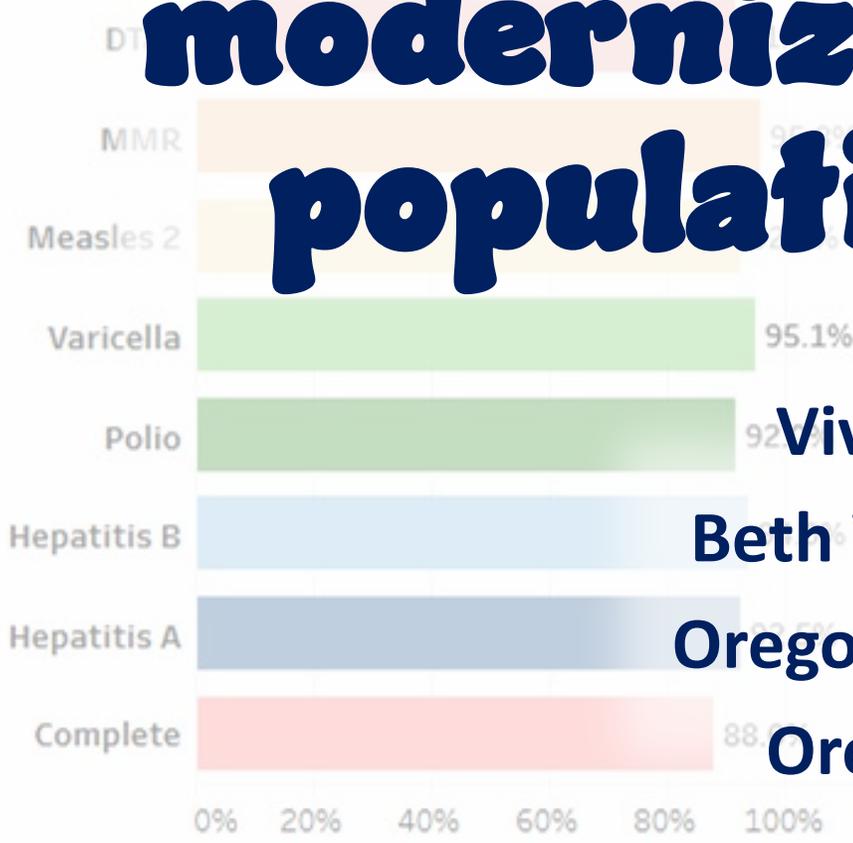
- **Vivian Larson, PhD, MPH**, Oregon Health Authority
- **Tainya Clarke, PhD, MPH, MSc**, Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER)



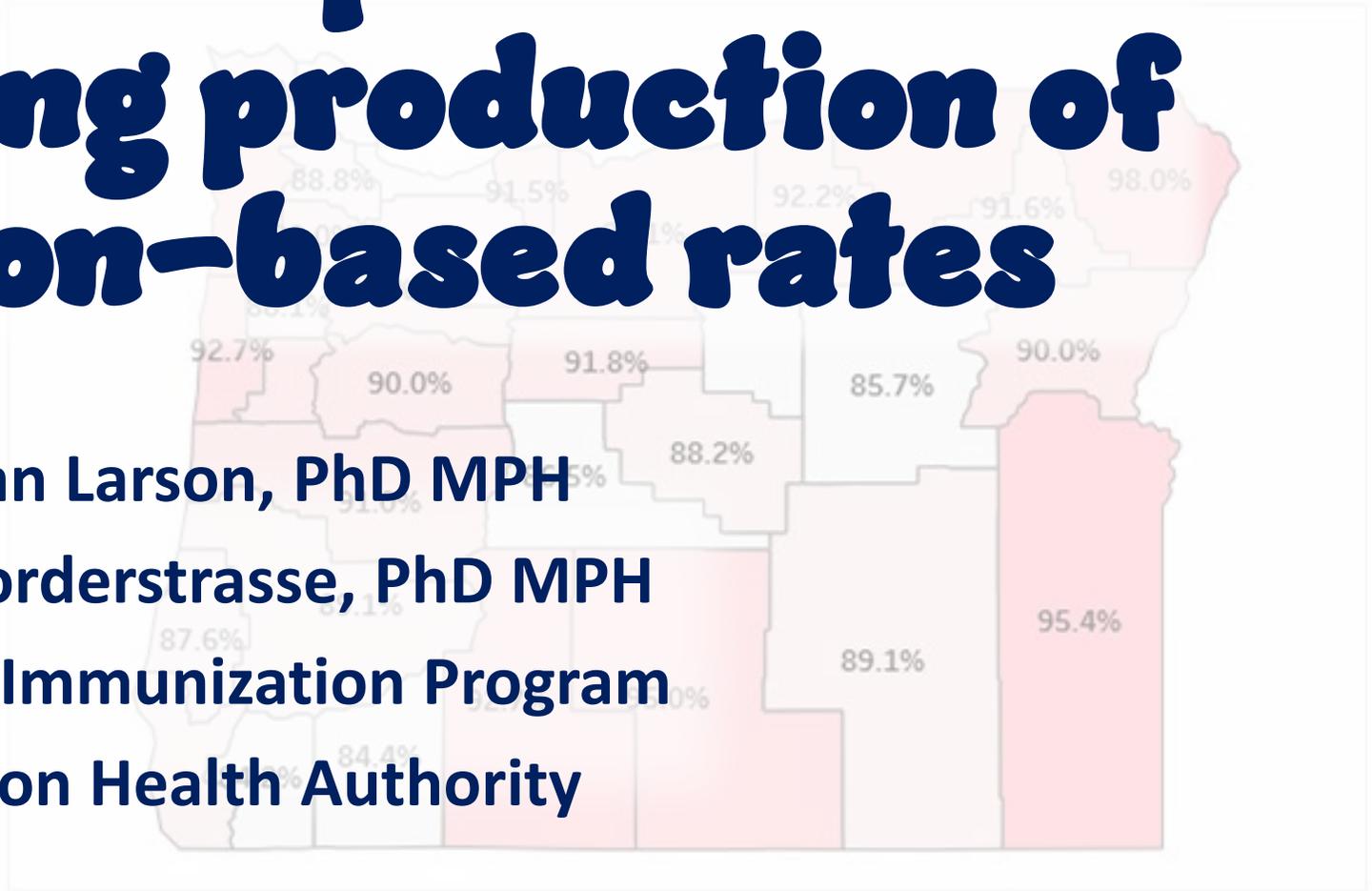
Statewide, over 88% of kindergarten students completed all school-required vaccines in 2022. From 92% to 95% of kindergartners completed each individual required vaccine. Use the year and county selection tools to change the displays of vaccination rates. *Note: county-specific immunization rates are missing for 1992 and 1996.*

Year
Select county

Oregon's experience modernizing production of population-based rates



Vivian Larson, PhD MPH
Beth Vorderstrasse, PhD MPH
Oregon Immunization Program
Oregon Health Authority



Kindergarten vaccination rates for DTaP (Diphtheria, Tetanus and Pertussis), Hepatitis A, Hepatitis B, MMR (1st dose of Measles, Mumps and Rubella), 2nd dose of Measles, Polio, and Varicella are shown from 1983 to 2022. To look at one vaccine at a time click on the vaccine of interest. Dip in immunization rates in 1990, 2001, and 2006 occurred when new vaccine requirements were added for kindergartners, with increases seen

Outline

(1) Background and context

(2) OIP's data modernization goals

(3) CDC DMI Overview

(4) Oregon's interpretation of DMI priorities with examples

Background

2019

2020

- Annual process
- Siloed approach to processing population-based rates (PBR)
 - Child, adolescent, adults
 - Different packages/programs to process and output data
- Data products:
 - Static tables
 - Preliminary Tableau dashboards released
 - Anticipated versioning, no data viz plan

Background

2019

2020

- Central COVID-19 SAS reporting database (daily data extracts)
- First viz released within days of vaccine in arms
 - Daily refresh
 - Data viz plan developed detailing phases/dashboards
- Bolus of personnel support
 - OIP staff pulled from regular duties to support COVID-specific work

Background

2019

2020+

- Heightened expectations of data sharing



Transparency

Quantity of products produced

Timeliness of data

Granularity of data released

OIP's Data Modernization Goals



Reduce time burden



Increase transparency & access to PBR data



Ensure consistency & reliability



Increase cadence of reporting*



Improve data products

CDC DMI Priorities

Build the right
foundation

Manage change
and governance

Accelerate data
into action

Support and
extend external
partnerships

Develop state-
of-the-art
workforce

*“How our nation will move from siloed and brittle public health data systems to **connected, resilient, adaptable** and **sustainable ‘response-ready’** systems that can help us solve problems before they happen and reduce the harm caused by the problems that do happen”*

Priority 1: Build the right foundation

CDC

- Scalable foundation
- Appropriate automated data sources
- Enable timely and complete data sharing
- Break down silos that keep critical data disconnected

OIP

- PBRs moved to modernization team
- Data processing via centralized SAS program
- Creation and maintenance of databases for populations of interest
- Protocols created for
 - County assignment and PO Box handling
 - CVX review and inclusion



- Time intensive process to validate code and output with previous methods
- Process changes require extensive approvals
- Breaking down silos within Surveillance & Quality Team

CVX Code Database Development

- Ex: DTaP-Tdap-TD for 2-year-olds and teens
- Allows for:
 - Review of what is already included in current databases
 - CVX codes included in definitions of up-to-date
 - Review of new CVX codes with each new data pull

CVX	DTaP-Tdap 2YO	DTaP-Tdap TEEN	DTaP-Tdap-TD TEEN
1	1	1	1
9			1
20	1	1	1
22	1	1	1
50	1	1	1
102	1	1	1
106	1	1	1
107	1	1	1
110	1	1	1
113	1		1
115	1	1	1
120	1	1	1
130	1	1	1
132	1	1	1
138			1
139	1		1

Priority 2: Accelerate data into action

CDC

- Advance use of analytics for efficient and effective decision-making
- Identify health inequities and promote equitable health outcomes

OIP

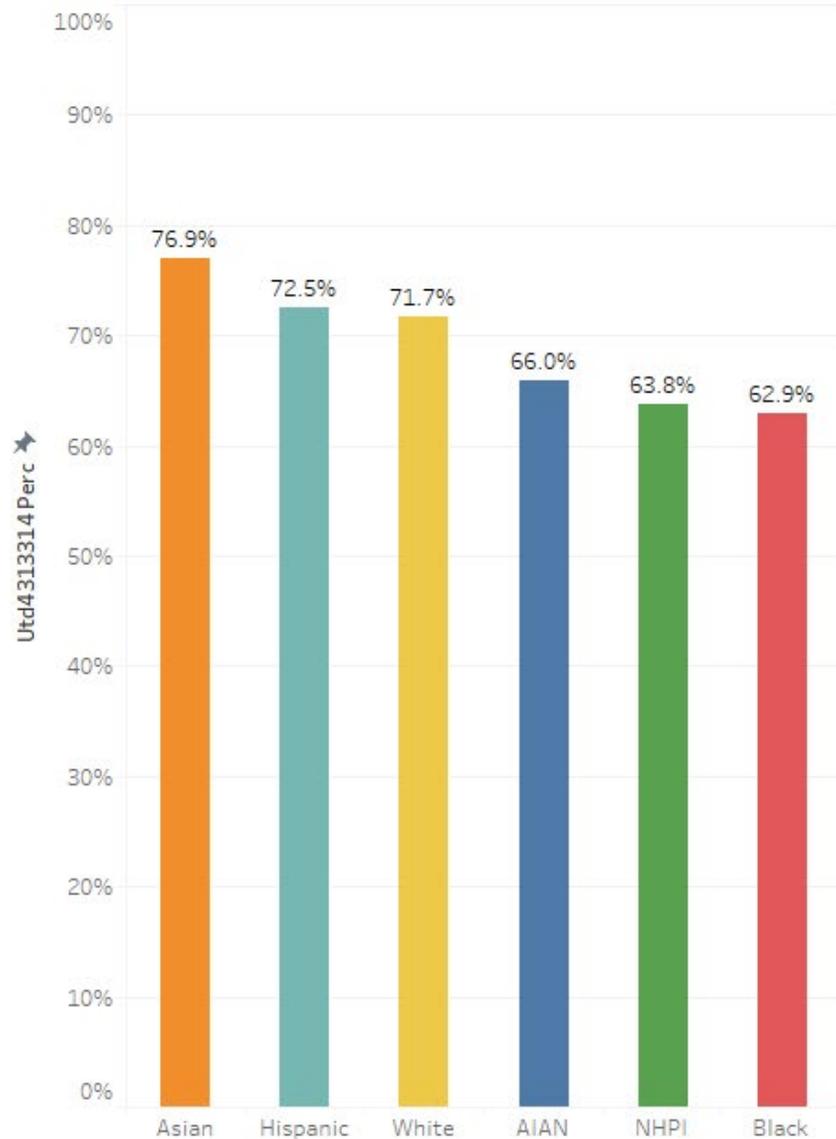
- More thoughtful data visualizations
 - Data viz plans with phased rollout
 - Elicit partner/public feedback
 - Exploration of new and modern chart/graphs/tables
- Update suppression threshold for population subgroups



- Process changes require extensive approvals
- Partner feedback- Who to ask? What to do with conflicting suggestions?
- Planning and creating data visualization requires learning and time

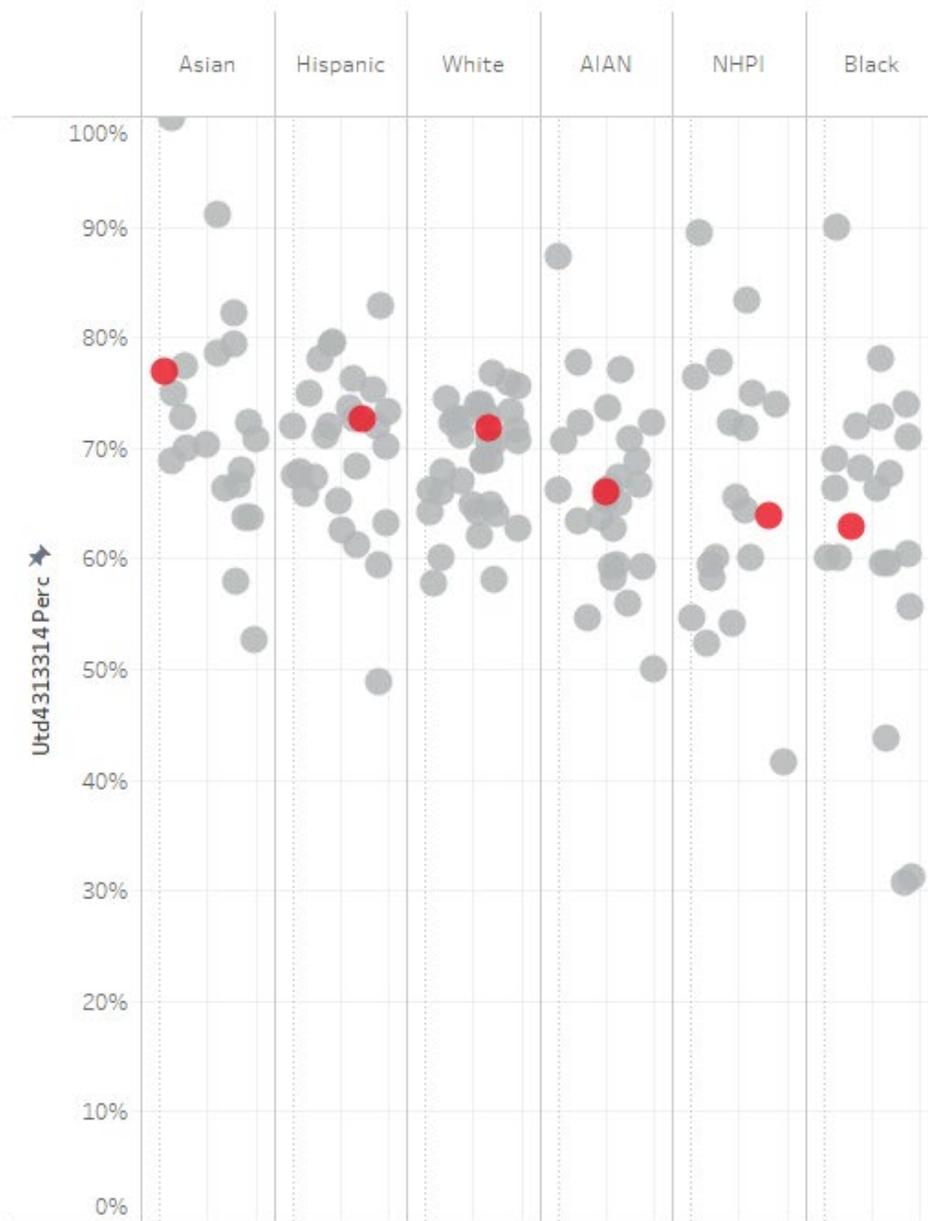
Bar Graph

Geographic region:



Jitter Plot

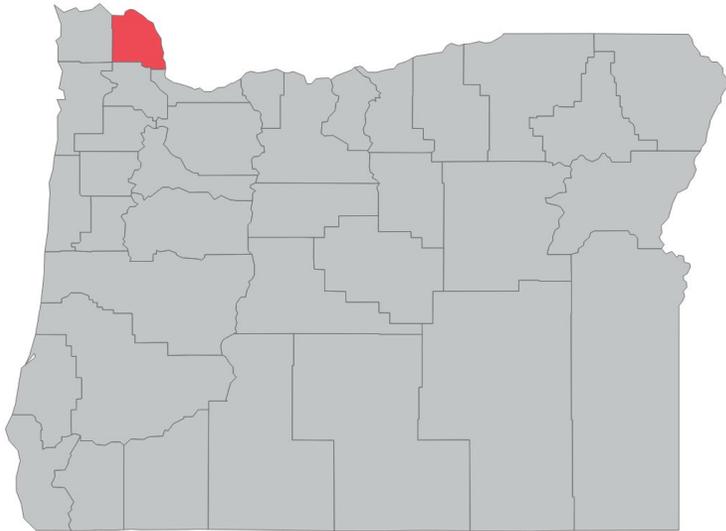
Statewide County



**Viz
Revamp:
Trial and
error**

Suppression threshold impact

Columbia County



2019 2020 2021 2022

Hispanic ^{c,e}	*	*	*	*
White ^{c,e}	63%	66%	64%	66%
African American ^{c,e}	*	*	*	*
Asian ^{c,e}	*	*	*	*
American Indian and Alaskan Native ^{c,e}	*	*	*	*
Hawaiian/Pacific Islander ^{c,e}	*	*	*	*

Hispanic ^{c,e}	79% [#]	77% [#]	58% [#]	63% [#]
White ^{c,e}	63%	66%	64%	66%
African American ^{c,e}	67% [#]	50% [#]	*	73% [#]
Asian ^{c,e}	71% [#]	54% [#]	60% [#]	72% [#]
American Indian and Alaskan Native ^{c,e}	57% [#]	61% [#]	48% [#]	61% [#]
Hawaiian/Pacific Islander ^{c,e}	*	*	*	45% [#]

Priority 5: Manage change and governance to support new ways of thinking

CDC

- Aid adoption of unified technology
- Become a culture of learning and collaboration
- Support new ideas, learn from failures, and encourage risk-taking

OIP

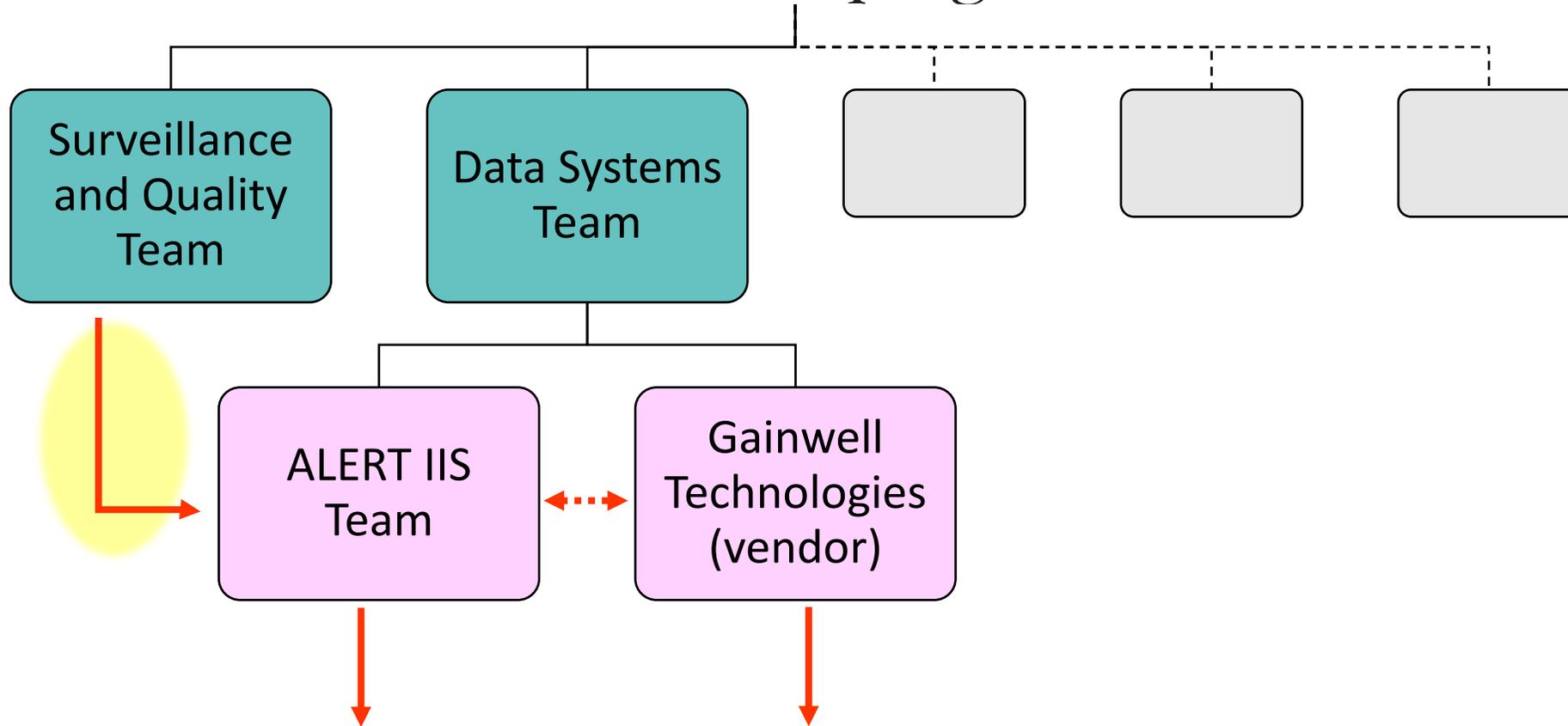
- Creation of a community of practice
- Buy-in and support from management
 - Coordination and collaboration Epi/Analyst and ALERT IIS teams



- Carving out time and the resources for learning
- Critical evaluation of current processes- difficulty embracing change
- Breaking down silos across OIP



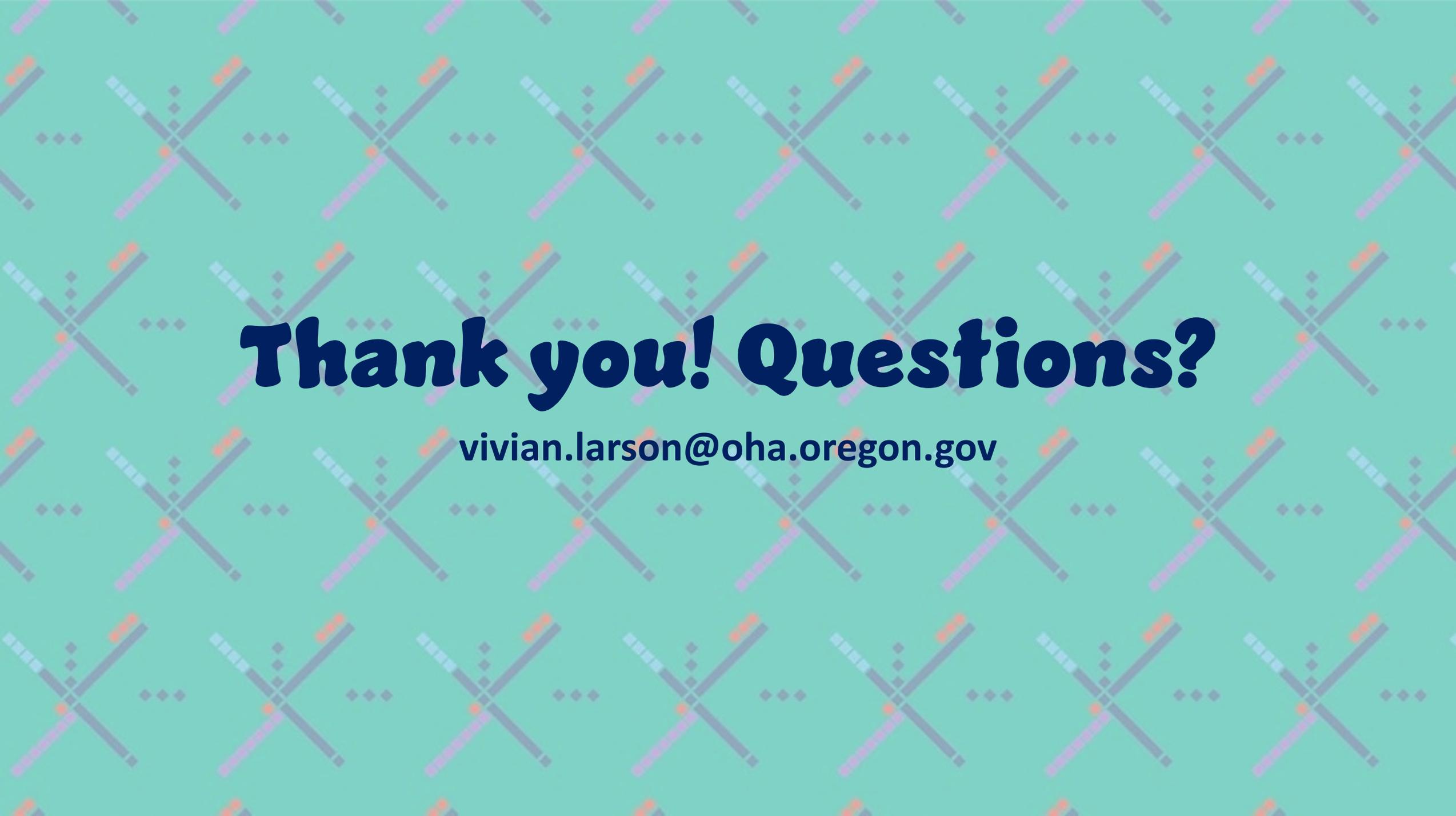
oregon
immunization
program



OIP's Data Modernization Goals

Goals	Plan
Reduce time burden	<ul style="list-style-type: none">• Transfer PBRs to modernization team• Central processing programs in SAS
Increase transparency & access to PBR data	<ul style="list-style-type: none">• Maintain databases in central location for analysts/epis to access• Lower denominator threshold for suppression
Ensure consistency & reliability	<ul style="list-style-type: none">• Uniform data pulls out of ALERT IIS• Documentation and Read Me's for scripts• Establish protocols for major processing steps common across PBRs
Increase cadence of reporting*	<ul style="list-style-type: none">• Continue collaboration with ALERT IIS Team and future work with vendor for automated data extracts (move cadence to quarterly)
Improve data products	<ul style="list-style-type: none">• Shift from static tables to interactive vizzes• Create data viz plans and phased roll-out for all data vizzes• More thoughtful visualizations that reflect feedback

**anticipated start date mid-late 2023*



Thank you! Questions?

vivian.larson@oha.oregon.gov

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

Tainya Clarke, PhD MPH

**Biologics Effectiveness and Safety (BEST) Initiative
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)**

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

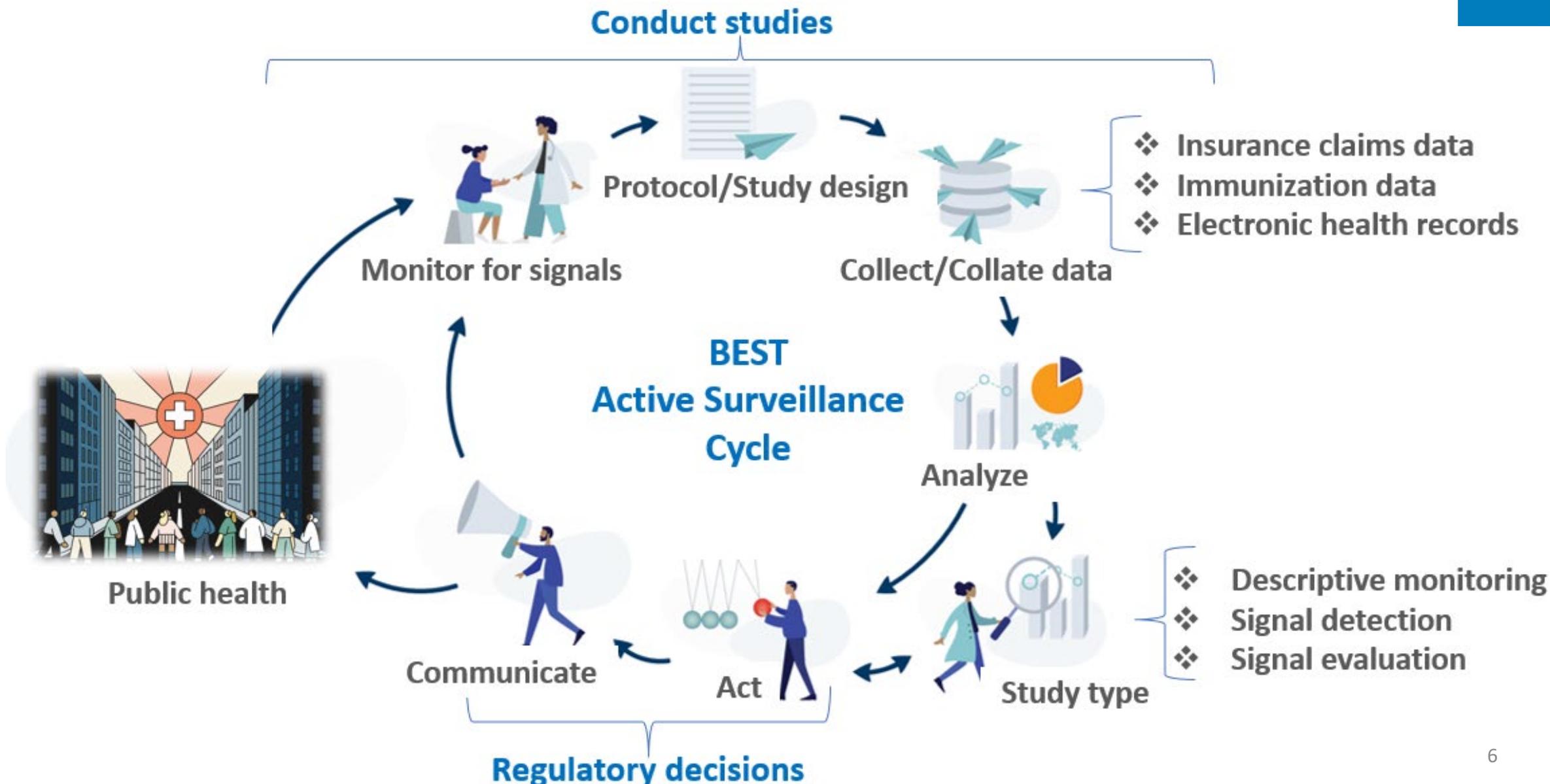
FDA CBER Active Surveillance Data Sources



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



Outline

CBER Active Surveillance Program

IIS-Claims Data Linkage

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Conclusion



IIS-Claims Data Linkage



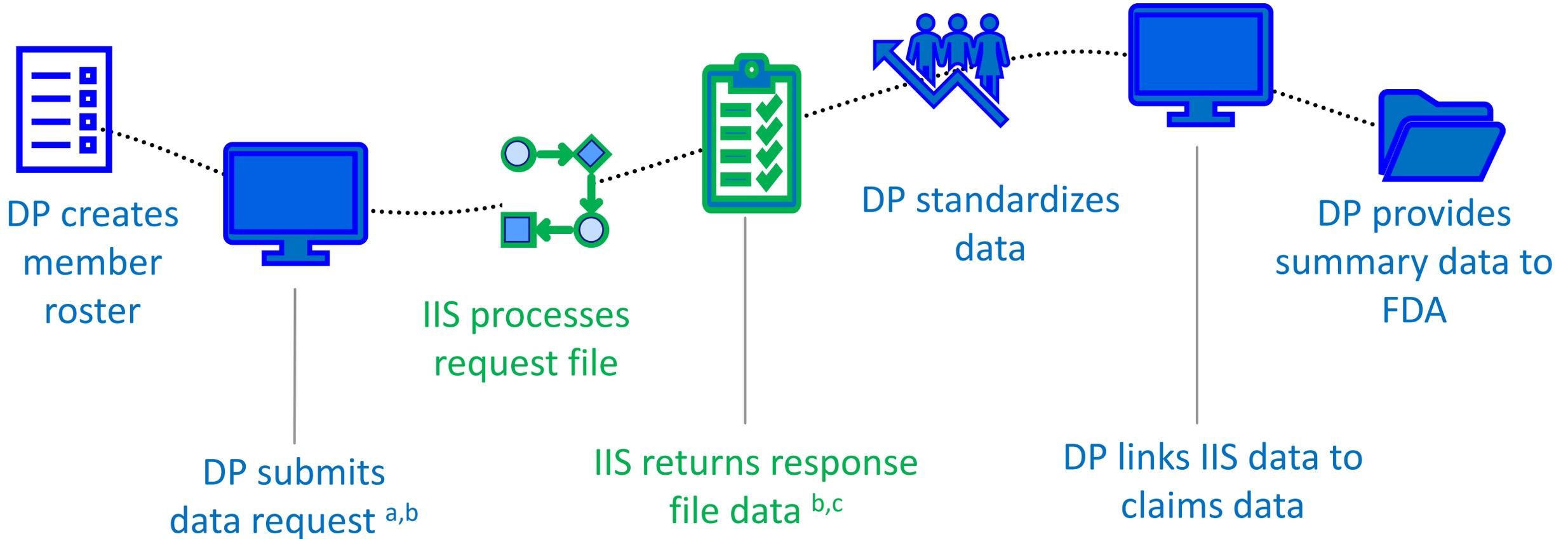
FILE EXCHANGE METHODS

- ❖ 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

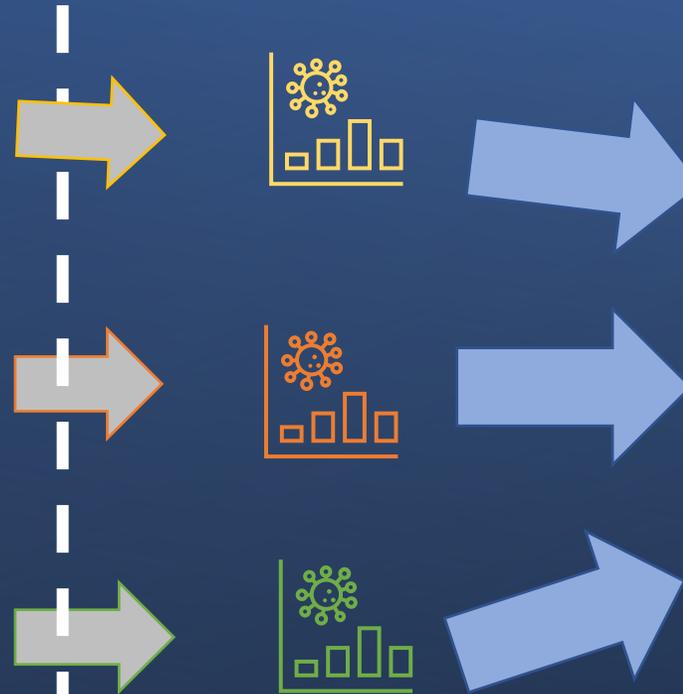
FDA/CBER
BEST System



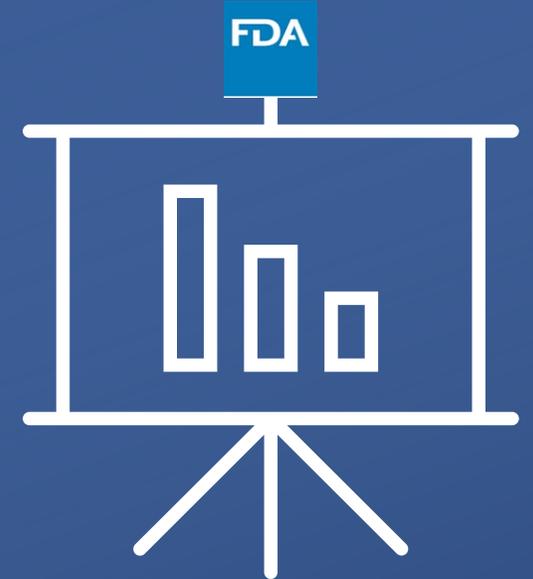
IIS share vaccination data on health plan members with **BEST health plan data partners**



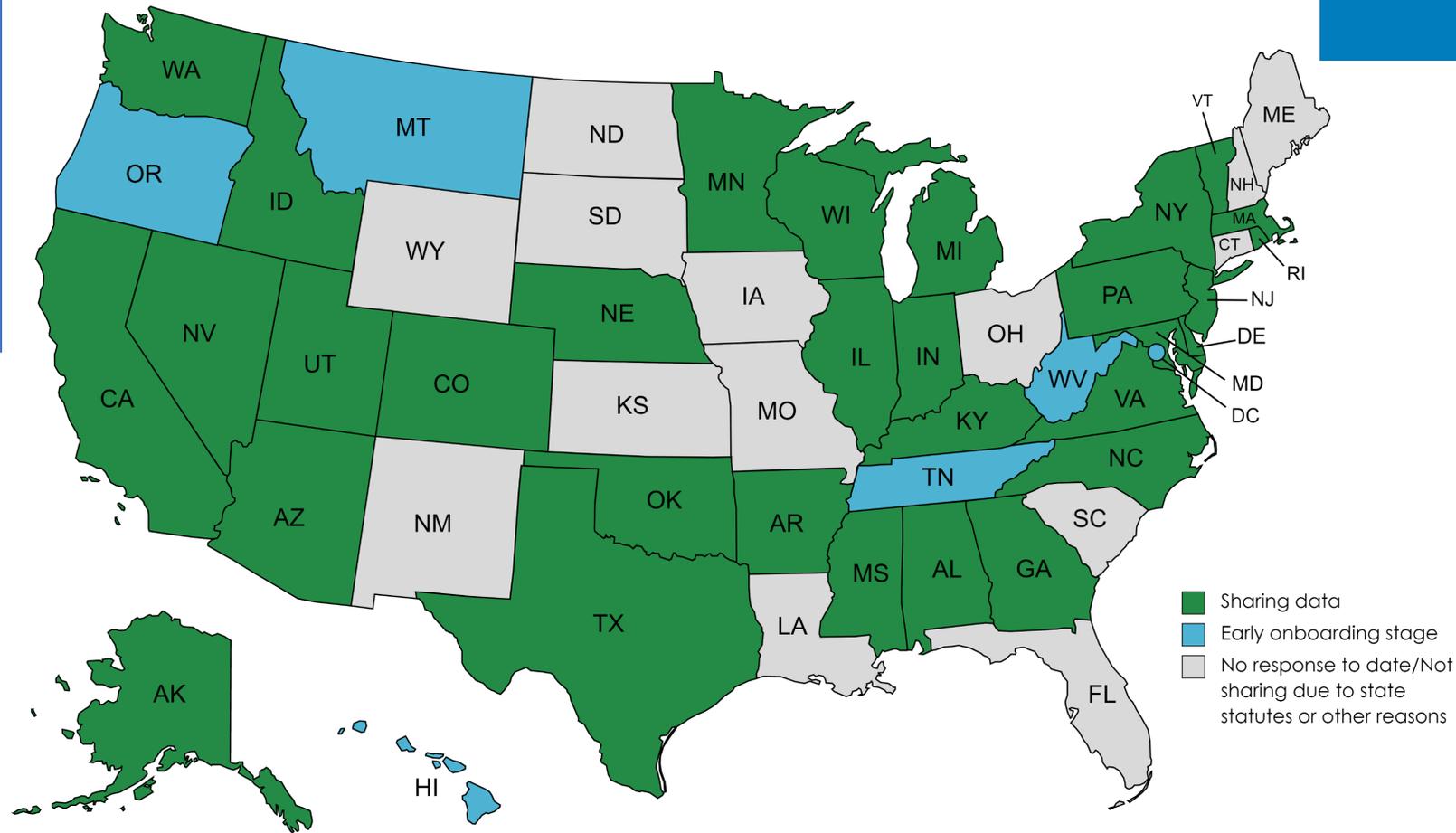
Data partners clean, validate, aggregate and analyze linked vaccination and claims data per FDA protocols



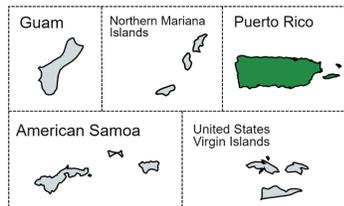
Data Partners provide aggregated summary data to **FDA/CBER**, to monitor vaccine safety and effectiveness.



Status of CBER-BEST and Data Partners IIS Jurisdiction Outreach



- Sharing data
- Early onboarding stage
- No response to date/Not sharing due to state statutes or other reasons



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)

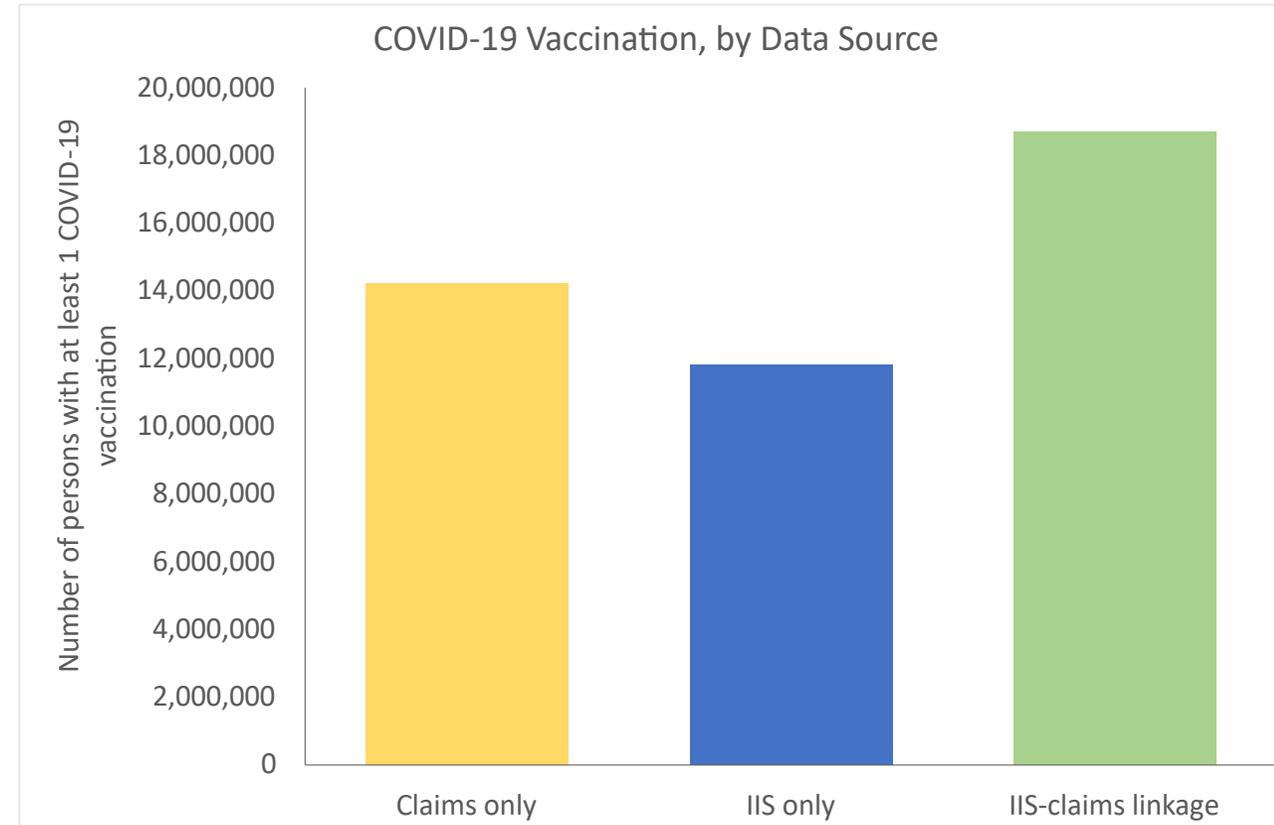


Vaccinated rates

- 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

Outline

CBER Active Surveillance Program

IIS-Claims Data Linkage

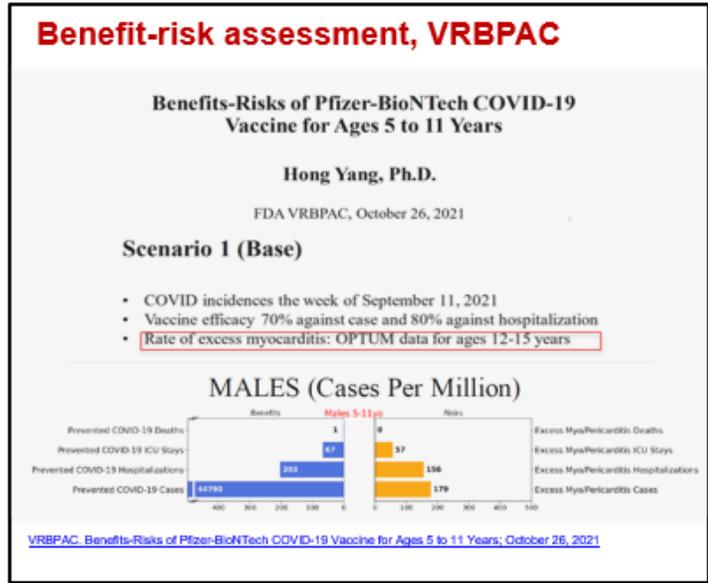
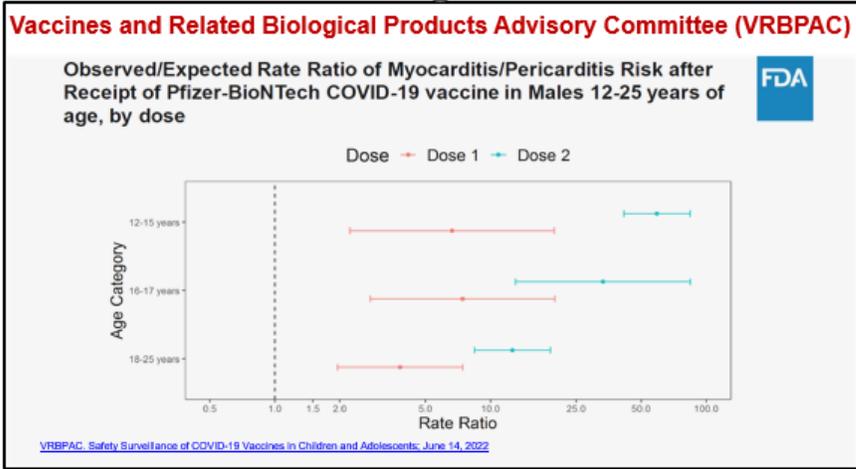
Regulatory and Public Health Impact

Barriers to Data Linkage

Conclusion



Regulatory and Public Health Impact



Advisory Committee on Immunization Practices (ACIP)

VaST assessment – Review of U.S. monitoring data for consideration of Moderna COVID-19 vaccine in 6–17-year-olds

System	Pfizer-BioNTech vaccine in children & adolescents aged 5–17 years
V-safe	• Patterns of reports for local and systemic reactions similar for all age groups
VAERS	• Reporting rates for myocarditis exceed background for males ages 5–11-, 12–15-, 16–17 (mainly for dose 2 and booster) and for females 12–15-, 16–17 (dose 2 only)
VSD	• Risk for myocarditis/pericarditis is elevated; greatest in age groups 16–17 and 12–15 years, generally higher after dose 2 vs dose 1 primary series and in males vs females • No statistical signals for children ages 5–11 years
BEST	• Risk appears greatest in age groups 16–17 and 12–15 years, generally higher after dose 2 than dose 1 • No statistical signals for children ages 5–11 years • Only statistical signals for 12–15- and 16–17-year-olds: myocarditis/pericarditis

VAERS, Vaccine Adverse Event Reporting System; VSD, Vaccine Safety Datalink; BEST, Biologics Effectiveness and Safety system

ACIP, COVID-19 Vaccine Safety Technical (VaST) Work Group, June 23, 2022

- 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.

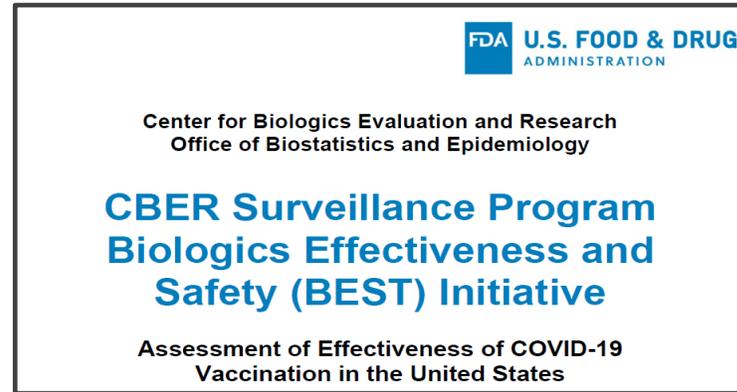
- As part of the both passive and active US surveillance system, BEST studies contribute to the advisory committee that determines the public health policies regarding vaccines in the US.

Regulatory and Public Health Impact contd.



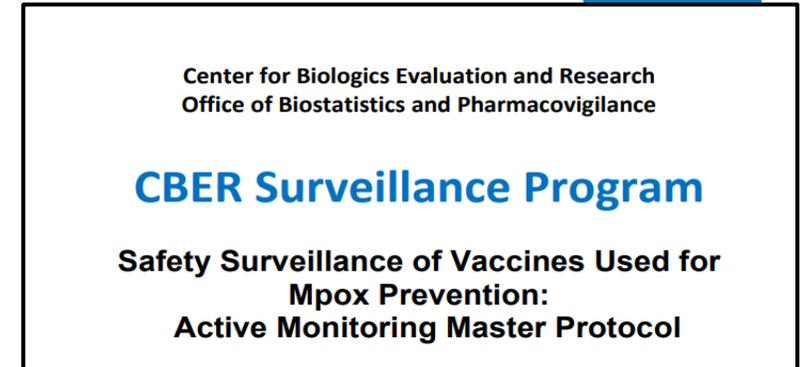
- IIS data are crucial to FDA safety assessment/surveillance, e.g. defining the risk of Myocarditis/pericarditis after mRNA vaccines in young males.

[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 & Allergens – 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 & Allergens – BEST Initiative](#)

Outline

CBER Active Surveillance Program

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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

Outline

CBER Active Surveillance Program

IIS-Claims Data Linkage

Regulatory and Public Health Impact

Barriers to Data Linkage

Conclusion





- ❑ 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.

BES Post-market Surveillance Activity

Biologics Effectiveness and Safety (BEST) Initiative



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Study Team

Tainya C. Clarke¹, Patricia C. Lloyd¹, Yixin Jiao², Sandia Akhtar², Kathryn Federici³, Grace Yang³, Daniel Beachler⁴, Smita Bhatia⁵, Grace Stockbower⁴, Alex Secora⁶, Cheryl N. McMahon-Walraven⁵, Lauren Peetluk⁷, An-chi Lo², Katie Matuska², Yoganand Chillarige², Vaibhav Sharma⁵, Gyanada Acharya², Ramin Riahi⁴, Christian Reich⁶, Richard Forshee¹, Azadeh Shoaibi¹, Steven A. Anderson¹, Hui Lee Wong¹

¹United States Food and Drug Administration, Center for Biologics Evaluation and Research, Silver Spring, MD;

²Acumen, LLC, Burlingame, CA;

³OptumServe, Falls Church, VA;

⁴Carelon Research, Inc., Wilmington, DE;

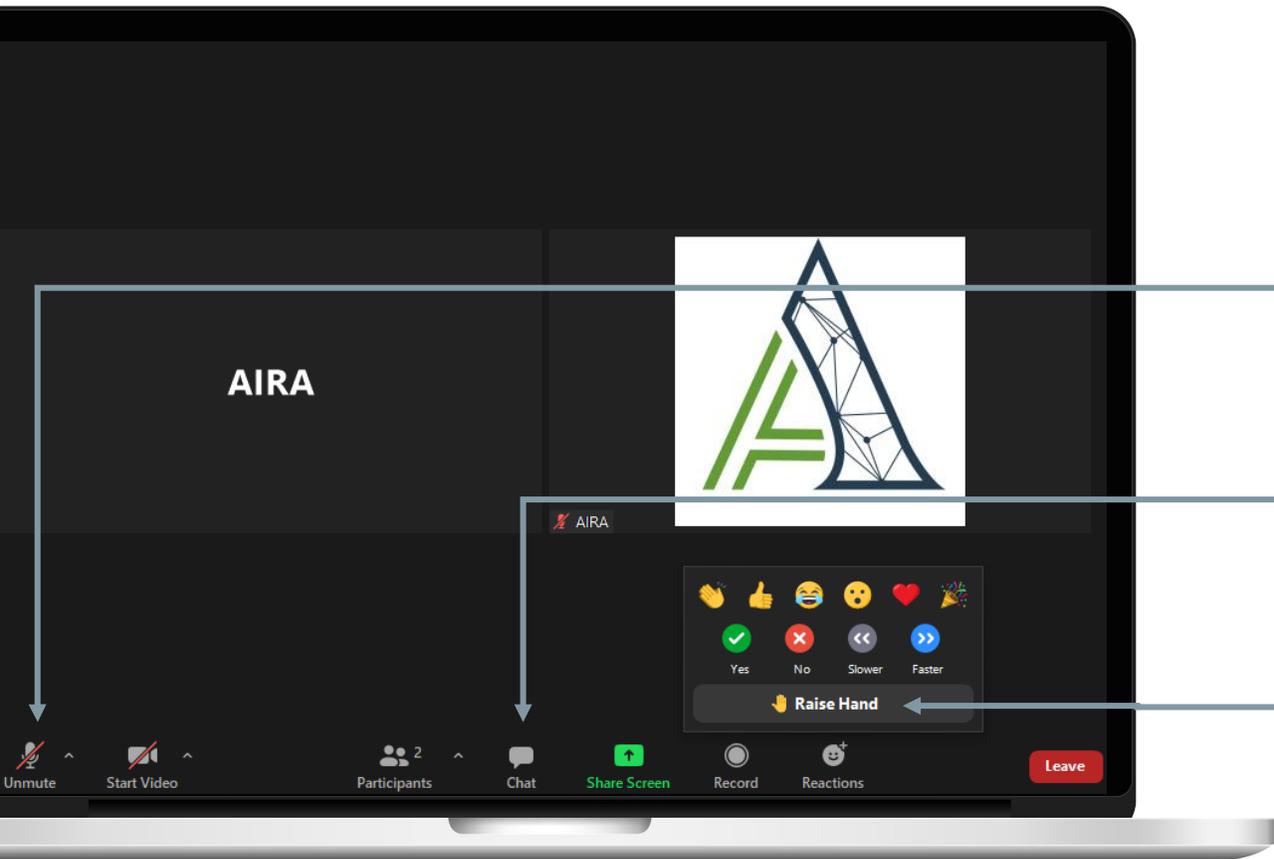
⁵CVS Health Clinical Trial Services, Blue Bell, PA;

⁶IQVIA, Falls Church, VA;

⁷Optum Epidemiology, Boston, MA.



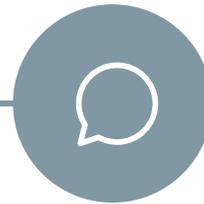
Question & Answer



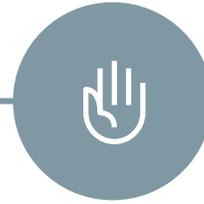
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Select the unmute icon and ask your question verbally.



Select the chat icon and type your question into the chat box.



Select the reactions icon, select "Raise Hand," and you will be called on.





Thank you to our presenters,
and thanks to all of you for
joining us!

Please complete a brief evaluation survey.

The next Discovery Session
will be on **June 26, 2023**