

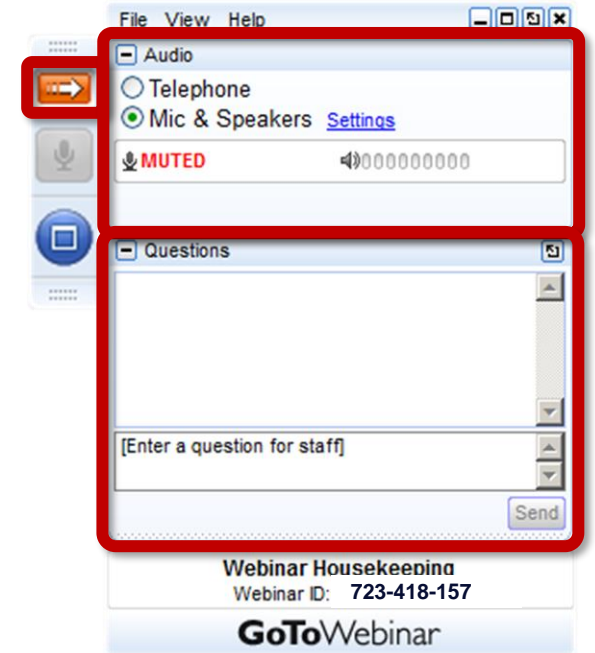
# All Participant Call

March 2025



# Housekeeping Items

- All lines have been muted.
- Issues with audio?
  - Dial in using: 631-992-3221
  - Access Code: 723-418-157
- Type questions in Q&A section at any time. We'll open for questions after each agenda topic.
- This meeting is being recorded, and the recording will be shared in our next newsletter.



## Your Participation

Open and close your control panel

Join audio:

- Choose "Mic & Speakers" to use VoIP
- Choose "Telephone" and dial using the information provided

Submit questions and comments via the Questions panel

**Note:** Today's presentation is being recorded and will be provided within 48 hrs

# Today's Topics

---

Employee Spotlight	Dennis Sherba
New Participants	Ashley Green Michael McCune
Phenotype Validation Studies	Hussein Ezzeldin, PhD Francis X. Campion, MD, FACP
Hub Network Maintenance	Mike Yackanich
My Directory Portal	Tiffanie Hickman
Marketing Update	Tina Feldmann
Information & Resources	Ashley Green
Q&A	Anyone

# Employee Spotlight



# Employee Spotlight

Dennis Sherba  
Vice President of Operations and Staff

[Connect with Dennis on LinkedIn](#)



# Participant Update

# Congratulations to our newest Participants!



THE UNIVERSITY  
*of* NORTH CAROLINA  
*at* CHAPEL HILL

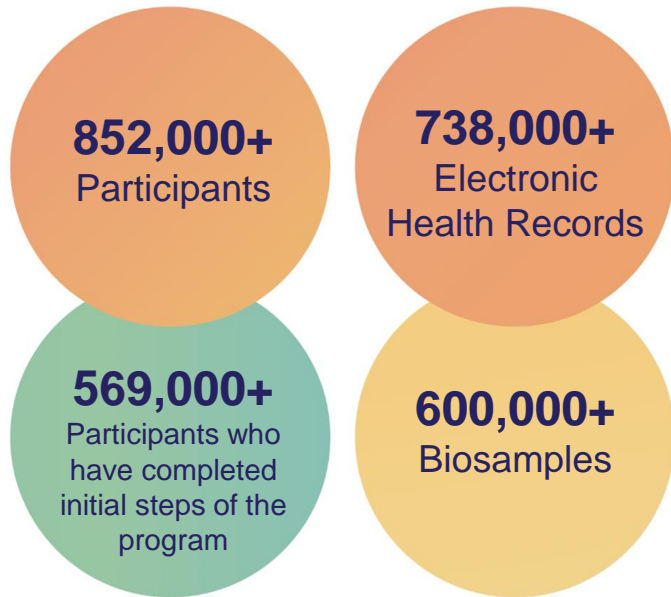
The University of North Carolina at Chapel Hill is the nation's first public university at the heart of what's next, preparing a diverse student body to become creators, explorers, innovators and leaders in North Carolina and throughout the world.

The University of North Carolina at Chapel Hill is part of All Of Us, an NIH-supported program to test individually authorized data sharing for its database of 850K+ participants who voluntarily provide their data for research.

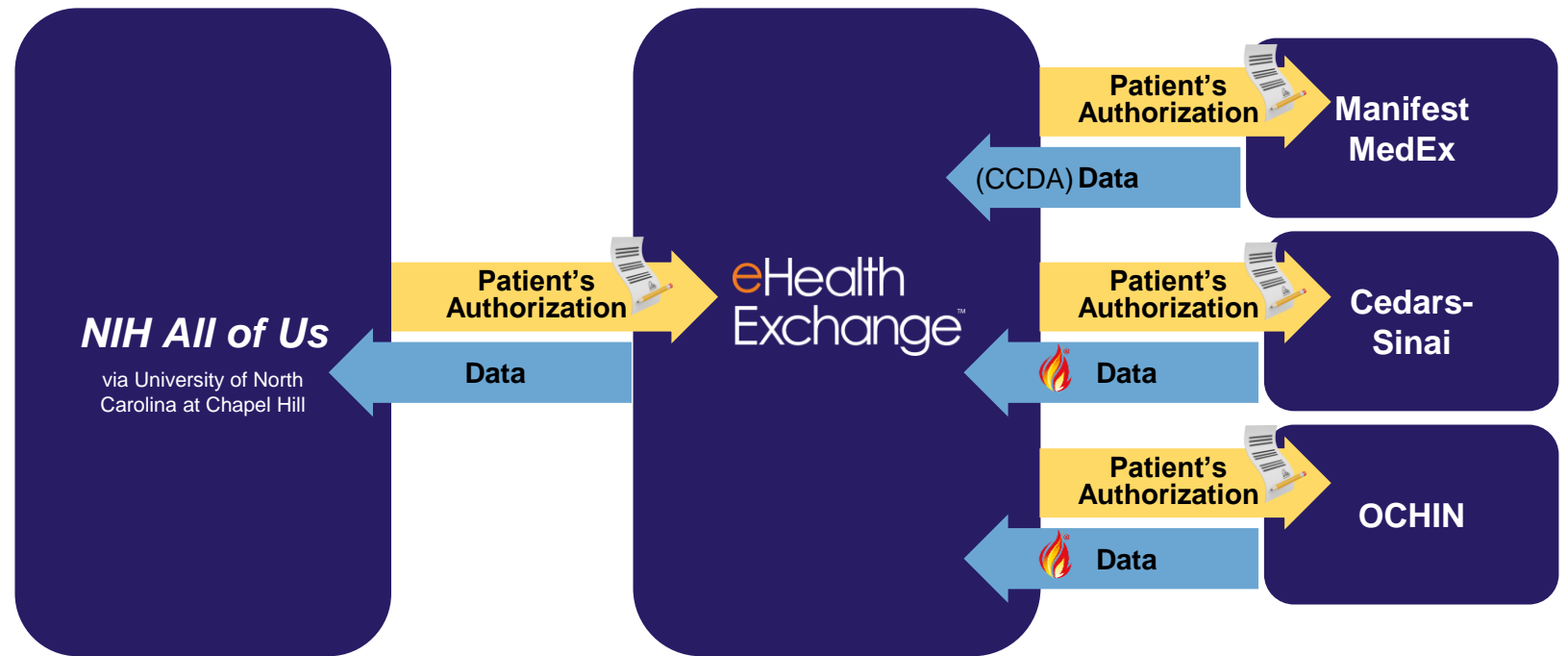
Committed to Improving Patient Care via Data Exchange

# First Research Exchange

## National Institute of Health (NIH) All of Us



*Accelerating health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us.*





# FDA BEST Program: Accelerating the Automation of Adverse Event Reporting

Hussein Ezzeldin, PhD

Office of Biostatistics and Pharmacovigilance (OBPV)

Center for Biologics Evaluation and Research (CBER)

Francis X. Champion, MD, FACP

Principal Lead, Digital Health

MITRE

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eHealth Exchange™

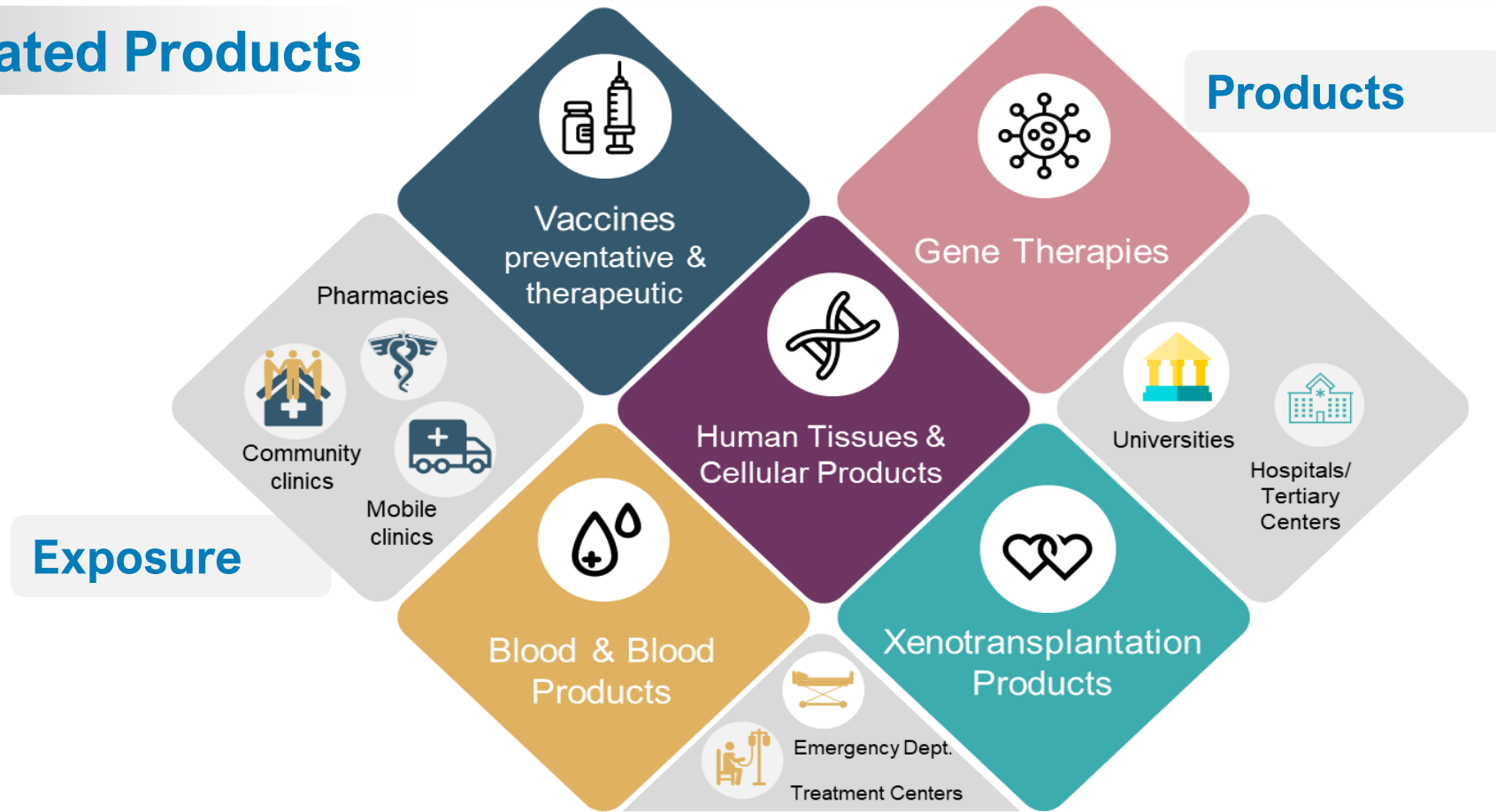
# Agenda

- 1. Background: FDA Biologics Effectiveness and Safety Innovative Methods (BEST IM)**
- 2. Opportunities for Health Systems**
  - Level of effort by health systems
  - Support for execution
- 3. Invitation to Join**

# BEST IM Goal

Modernize the safety surveillance of vaccines, blood, and biologic therapeutics used to care for patients.

## CBER-Regulated Products



# Challenges and Opportunities

\*Assuming a clinical **exposure** and potential **outcome**



Existing manual process **creates burden, under/over reporting, and unstandardized quality**



**BEST** uses **innovative methods to reduce burden, while increasing quantity and quality of AE reports**

## Current



### Manual Detection

- **Individual flagging** of potential AEs
- **Under-recognition/under-counting** of outcomes



### Manual Validation

- **Time-intensive** to review dispersed data
- Potential AEs **not always communicated**
- Separate **and** unstandardized **case definitions**



### Manual Reporting

- **Data re-entry** to report externally
- **Lack of granularity** in report evidence

vs.

## Future



### Automated Detection

- **Batch detection**, more focus on patient care
- **AI algorithm** scores potential cases



### Semi-Automated Validation

- **Evidence integration** reduces burden
- **Flagged and prioritized** cases sent for review
- Standardized and integrated **case definition**



### Semi-Automated Reporting

- **Auto-population** of granular ICSR evidence
- **Generation** of evidence-based ICSR narrative

ICSR, individual case safety report

# Current Safety Surveillance Tools

## Vaccine Adverse Event Reporting System (VAERS) Form

**VAERS** Vaccine Adverse Event Reporting System  
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18** and **21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

---

**INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE** (Use **Continuation Page** if needed)

<p>1. Patient name: (first) _____ (last) _____ Street address: _____ City: _____ State: _____ County: _____ ZIP code: _____ Phone: ( ) _____ Email: _____</p> <p>2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown</p> <p>4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm _____ <input type="checkbox"/> AM <input type="checkbox"/> PM</p> <p>5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm _____ <input type="checkbox"/> AM <input type="checkbox"/> PM</p> <p>6. Age at vaccination: _____ Years 7. Today's date: (mm/dd/yyyy) _____</p> <p>8. Pregnant at time of vaccination?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)</p>	<p>9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:</p> <p>10. Allergies to medications, food, or other products:</p> <p>11. Other illnesses at the time of vaccination and up to one month prior:</p> <p>12. Chronic or long-standing health conditions:</p>
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INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN
<p>13. Form completed by: (name) _____ Relation to patient: <input type="checkbox"/> Healthcare professional/staff <input type="checkbox"/> Patient (yourself) <input type="checkbox"/> Parent/guardian/caregiver <input type="checkbox"/> Other: _____ Street address: _____ <input type="checkbox"/> Check if same as item 1 City: _____ State: _____ ZIP code: _____ Phone: ( ) _____ Email: _____ 14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____</p>	<p>15. Facility/clinic name: _____ Fax: ( ) _____ Street address: _____ <input type="checkbox"/> Check if same as item 13 City: _____ State: _____ ZIP code: _____ Phone: ( ) _____</p> <p>16. Type of facility: (Check one) <input type="checkbox"/> Doctor's office, urgent care, or hospital <input type="checkbox"/> Pharmacy or store <input type="checkbox"/> Workplace clinic <input type="checkbox"/> Public health clinic <input type="checkbox"/> Nursing home or senior living facility <input type="checkbox"/> School or student health clinic <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unknown</p>

---

**WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?**

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given)						
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	
select	select	select	select	select	select	
select	select	select	select	select	select	
select	select	select	select	select	select	
select	select	select	select	select	select	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) \_\_\_\_\_

21. Result or outcome of adverse event(s): (Check all that apply)  
 Doctor or other healthcare professional office/clinic visit  
 Emergency room/department or urgent care  
 Hospitalization Number of days: \_\_\_\_\_

## MedWatch Form (Biologics & Blood)

Reset Form

**FDA** DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**MEDWATCH**  
The FDA Safety Information and Adverse Event Reporting Program  
Form FDA 3500

Form Approved: OMB No. 0910-0291, Expires: 06-30-2025  
See PRA statement on page 6.

**FDA USE ONLY**

Triage unit sequence # \_\_\_\_\_  
FDA Rec. Date \_\_\_\_\_

For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

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**Note:** For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jan-1900.

**A. PATIENT INFORMATION**

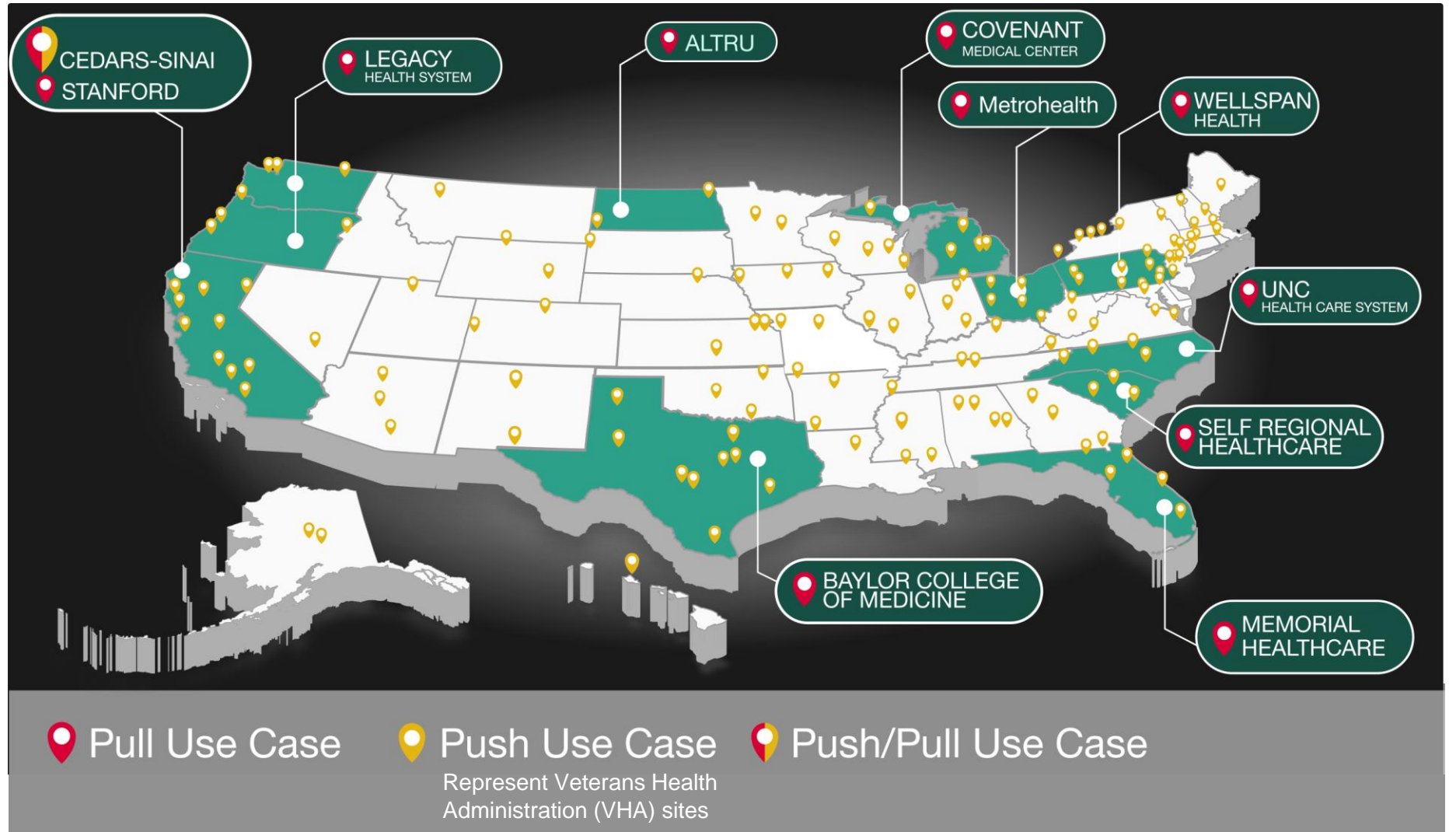
<p>1. Patient Identifier (In confidence) _____</p>	<p>2. Age _____ or Date of Birth (e.g., 01-Jan-1900)  <input type="checkbox"/> Year(s) <input type="checkbox"/> Week(s)  <input type="checkbox"/> Month(s) <input type="checkbox"/> Day(s)</p>
<p>3a. Sex: Enter the patient's sex at birth (the sex that a person has or was assigned to at birth).  <input type="checkbox"/> Male <input type="checkbox"/> Undifferentiated  <input type="checkbox"/> Female <input type="checkbox"/> Decline to answer</p>	<p>3b. Gender: Enter the patient's current gender (how the patient thinks of themself).  <input type="checkbox"/> Cisgender man/boy (gender corresponds with birth sex)  <input type="checkbox"/> Cisgender woman/girl (gender corresponds with birth sex)  <input type="checkbox"/> Transgender man/trans man/ female-to-male (FTM)  <input type="checkbox"/> Transgender woman/trans woman/ male-to-female (MTF)  <input type="checkbox"/> Other gender category; please specify: _____  <input type="checkbox"/> Decline to answer</p>
<p>4. Weight _____  <input type="checkbox"/> lb <input type="checkbox"/> kg</p>	<p>5. Ethnicity (Check one)  <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino</p>
<p>6. Race (check all that apply)  <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Native Hawaiian/ Other Pacific Islander  <input type="checkbox"/> Asian  <input type="checkbox"/> Black or African American <input type="checkbox"/> White</p>	

---

**B. ADVERSE EVENT, PRODUCT PROBLEM**

<p>1. Type of Report (check all that apply)  <input type="checkbox"/> Adverse Event  <input type="checkbox"/> Product Use/Medication Error  <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)  <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine</p>	<p>2. Outcome Attributed to Adverse Event (check all that apply)  <input type="checkbox"/> Death – Date of death (e.g., 01-Jan-1900): _____  <input type="checkbox"/> Life-threatening <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage  <input type="checkbox"/> Hospitalization (initial or prolonged) <input type="checkbox"/> Disability or Permanent Damage  <input type="checkbox"/> Other Serious or Important Medical Events <input type="checkbox"/> Congenital Anomaly/Birth Defects</p>
<p>3. Date of Event (e.g., 01-Jan-1900) _____</p>	<p>4. Date of this Report (e.g., 01-Jan-1900) _____</p>
<p>5. Describe Event, Problem or Product Use/Medication Error _____                  Characters Remaining (max. 4,000): _____</p>	

# First Pilot



Source: [https://ehealthexchange.org/participants/?participant\\_type=fda-pilot](https://ehealthexchange.org/participants/?participant_type=fda-pilot)

# Accomplishments

The first group of 11 pilot health systems demonstrated the value of using data interoperability standards for public health.

## Papers Published:

frontiers | Public Health | Sections | Articles | Research Topics | Editorial board

Front. Public Health, 07 July 2024

JMIR Public Health and Surveillance

JMIR Publications  
Advancing Digital Health & Open Science

Articles | Search articles

Journal of Medical Internet Research

Published on 25.11.2024 in Vol 26 (2024)

Preprints (earlier versions) of this paper are available at <https://preprints.jmir.org/preprint/54597>, first published November 15, 2023.

### A Computable Phenotype Algorithm for Postvaccination Myocarditis/Pericarditis Detection Using Real-World Data: Validation Study

Matthew Deady<sup>1</sup> ; Raymond Duncan<sup>2</sup> ; Matthew Sonesen<sup>3</sup> ; Renier Estiandan<sup>3</sup> ; Kelly Stimpert<sup>4</sup> ; Sylvia Cho<sup>5</sup> ; Jeffrey Beers<sup>1</sup> ; Brian Goodness<sup>1</sup> ; Lance Daniel Jones<sup>1</sup> ; Richard Forshee<sup>5</sup> ; Steven A Anderson<sup>5</sup> ; Hussein Ezzeldin<sup>5</sup>

## Award Received:

Use of FHIR® for innovative electronic exchange of clinical data for validation of adverse events.

FORUM  
Innovation  
Awards  
2024 WINNER

Congratulations to

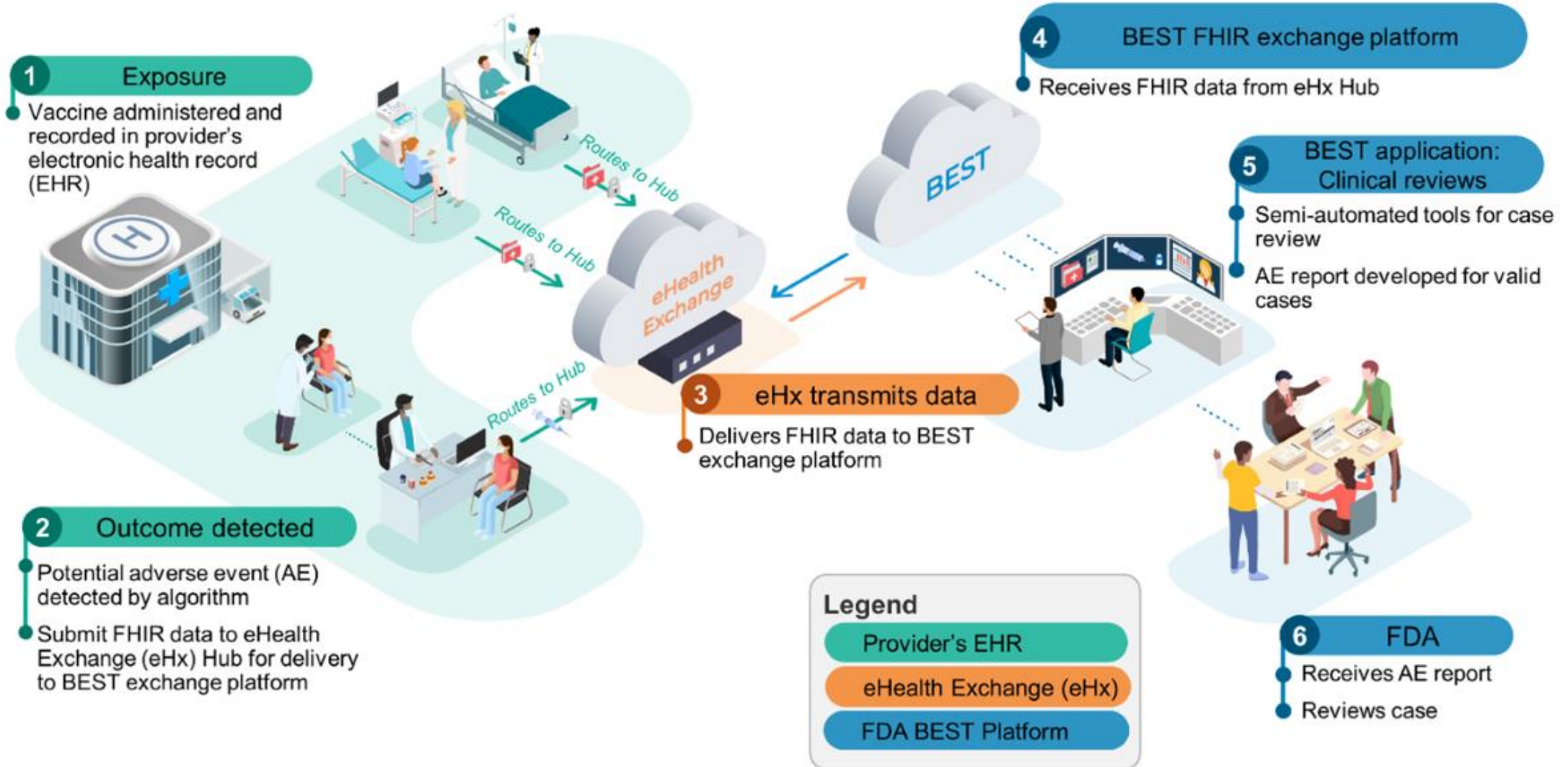
FDA U.S. FOOD & DRUG  
ADMINISTRATION

FORUM Innovation Award Winner!

eHealth Exchange™

See the [poster](#) describing this work.

# Postvaccination AE Detection and Validation





## CALL TO ACTION: Opportunity for Health System Participation



**Join BEST IM  
in 2025**

### **Upcoming Studies**

FDA will run several studies using EHR data for the evaluation of vaccines and biologics-related adverse events.

- Your health system can opt into any, or all, of the FDA studies.
- Use existing connectivity established through the eHealth Exchange.

### **Public Health**

Use existing public health exchange purpose allowed under the eHealth Exchange Data Use and Reciprocal Support Agreement (DURSA) that participants have already signed.

- Participants do NOT need additional data use agreements.

# Benefits to Health Systems



## **Innovate to Improve Patient Safety**

- Demonstrate public health leadership and community benefit by enhancing innovative safety surveillance.



## **Reduce Provider Burden**

- Replace current manual reporting.



## **Collaborate with Interoperability Pioneers**

- Use FHIR for semi-automated detection of biologics-related adverse events, and advance interoperability in your health system.



## **Publish Findings**

- Pursue an opportunity to author a white paper or journal article.

# Level of Effort by Health Systems



**Initial eHealth Exchange configuration:**  $\leq 8$  hours

**For each FDA Study:** ~20 hours (depends on health system readiness)

**Step 1:** Health System identifies patients of interest.

- a) Identify exposed patients (e.g., those who received mRNA vaccine).
- b) Identify patients with the outcome of interest (e.g., those patients diagnosed with myocarditis).
- c) Identify the subset of patients in whom the outcome could plausibly be related to the exposure (e.g., those who received an mRNA vaccine then were diagnosed with myocarditis 1-42 days following vaccination).

**Step 2:** Health System sends spreadsheets with FHIR patient identifiers + all dates of exposure and dates of outcome diagnosis for patients of interest to the FDA via secure email.

**Analysis:** FDA pulls all the needed resources from eHx (e.g., condition, document reference, observation, immunization, encounters) for a subset of patients of interest. FDA performs electronic phenotyping using CQL, adjudication of cases by clinician experts, and data analysis.

# Learn more about Joining the FDA BEST IM Network!

Send an email to [CBER-BESTIM@FDA.HHS.GOV](mailto:CBER-BESTIM@FDA.HHS.GOV)



[CBER-BESTIM@fda.hhs.gov](mailto:CBER-BESTIM@fda.hhs.gov)



<https://bestinitiative.org/>

# Hub Network Maintenance



# Network Maintenance – Core Switches

**Sunday February 16<sup>th</sup>, 2025**  
**6:00pm to 10:00pm EST**

**The eHealth Exchange Hub environments were migrated to new core switches**

## What is a “Core Switch”?

- Network switches connect devices to allow them to communicate with each other within a network.
- Switch upgrades typically result in improved performance, stability, and scalability.

## Key Points regarding the migration

- The migration did NOT result in a service interruption.
- The migration occurred within the predefined 4-hour maintenance window on the evening before a federal holiday - which is a period of lowest network volume.
- No changes were required by our participants (e.g., public IP addresses did not change).



# Network Maintenance - Firewall

Thursday February 27<sup>th</sup>, 2025  
8:00pm to 1:30am EST

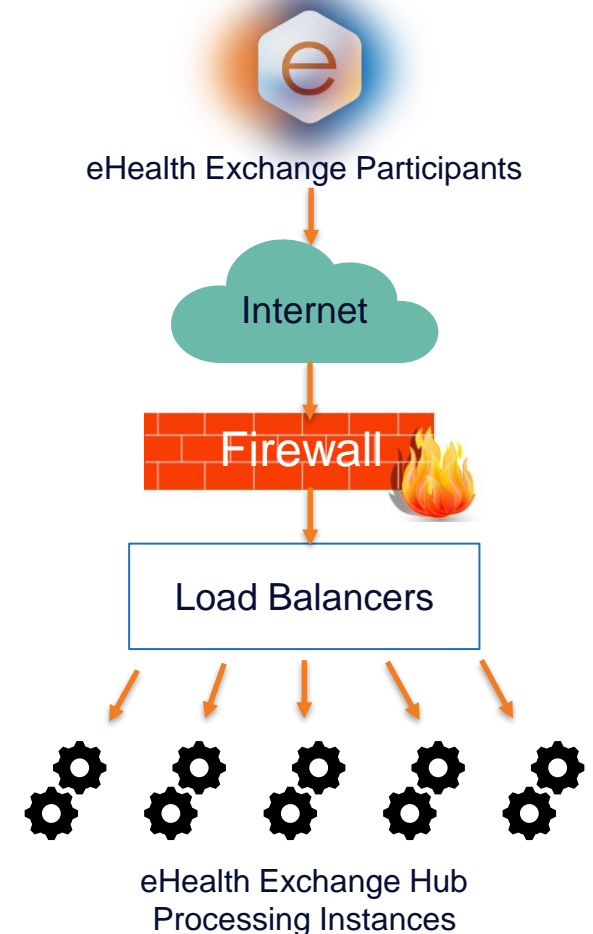
The eHealth Exchange Hub environments were migrated to new firewall devices

## What is a “Firewall”?

- A firewall is a network security device that monitors and controls incoming and outgoing network traffic based on predetermined security rules.
- Firewall upgrades typically result in enhanced security, improved performance, and future-proofing against evolving threats.

## Key Points regarding the migration

- The migration required periodic service interruptions during the event.
- The equipment upgrade resulted in significant performance improvements (lower resource utilization, reduction in error counts, etc.)
- No changes were required by our participants (e.g., public IP addresses did not change).



# Network Maintenance – Load Balancers

**Saturday March 8<sup>th</sup>, 2025**  
**5:00am to 9:00am EST**

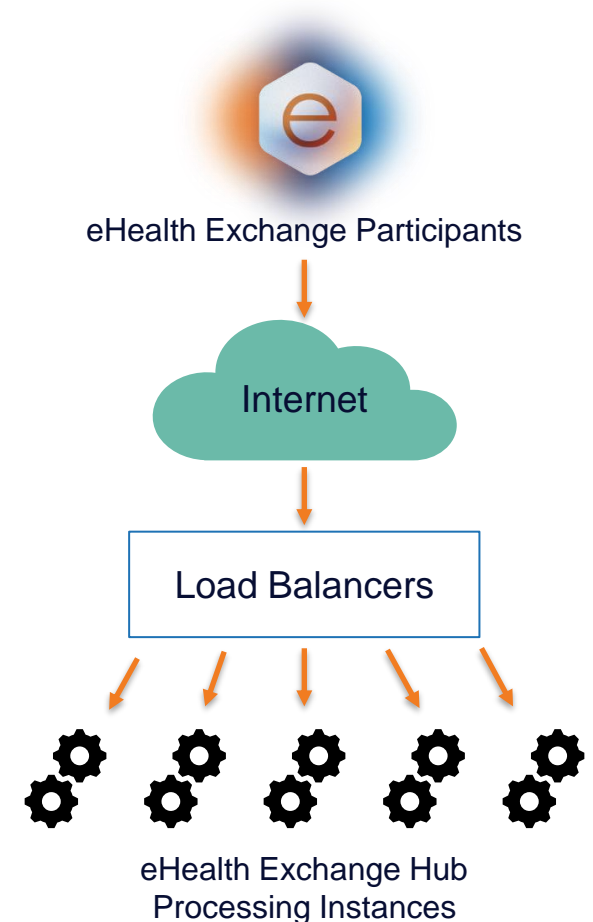
**The eHealth Exchange Hub environments were migrated to new network load balancers**

## What is a “Load Balancer”?

- Load Balancers allow us to distribute requests equally across multiple processing instances (aka “scale out” architecture).
- By taking advantage of multiple processing instances, we can address volume increases quickly and efficiently.

## Key Points regarding the migration

- The migration did NOT require a service interruption.
- The migration occurred on a Saturday morning - which is period of lowest network volume.
- No changes were required by our participants (e.g., public IP addresses did not change).





Week of March 3<sup>rd</sup>

# Network Maintenance – Processing Instances

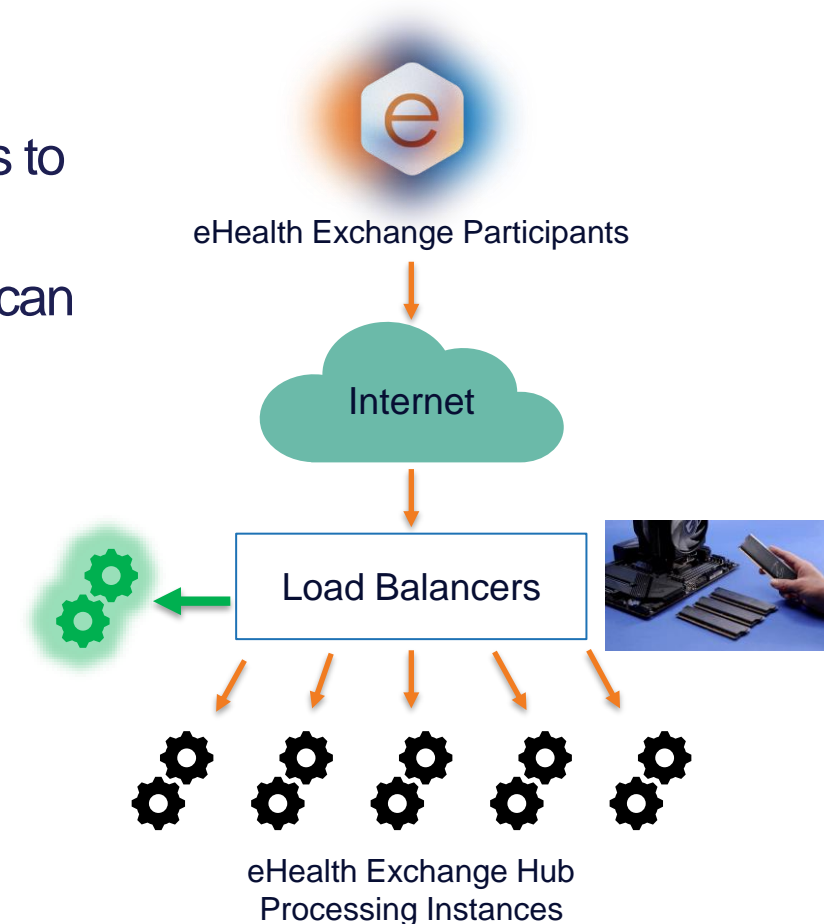
## The eHealth Exchange Hub scale-out processing instances – increased RAM/Count

### What is a “Processing Instance”?

- eHx leverages a scale-out architecture that utilizes multiple servers to support the network’s real-time transaction processing.
- As transaction volume increases, additional processing instances can be added quickly and efficiently.

### Key Points regarding the updates

- The updates did NOT require a service interruption.
- Two additional processing instances were added.
- Additional RAM was added to all processing instances.



# My Directory Portal

## My Directory Portal

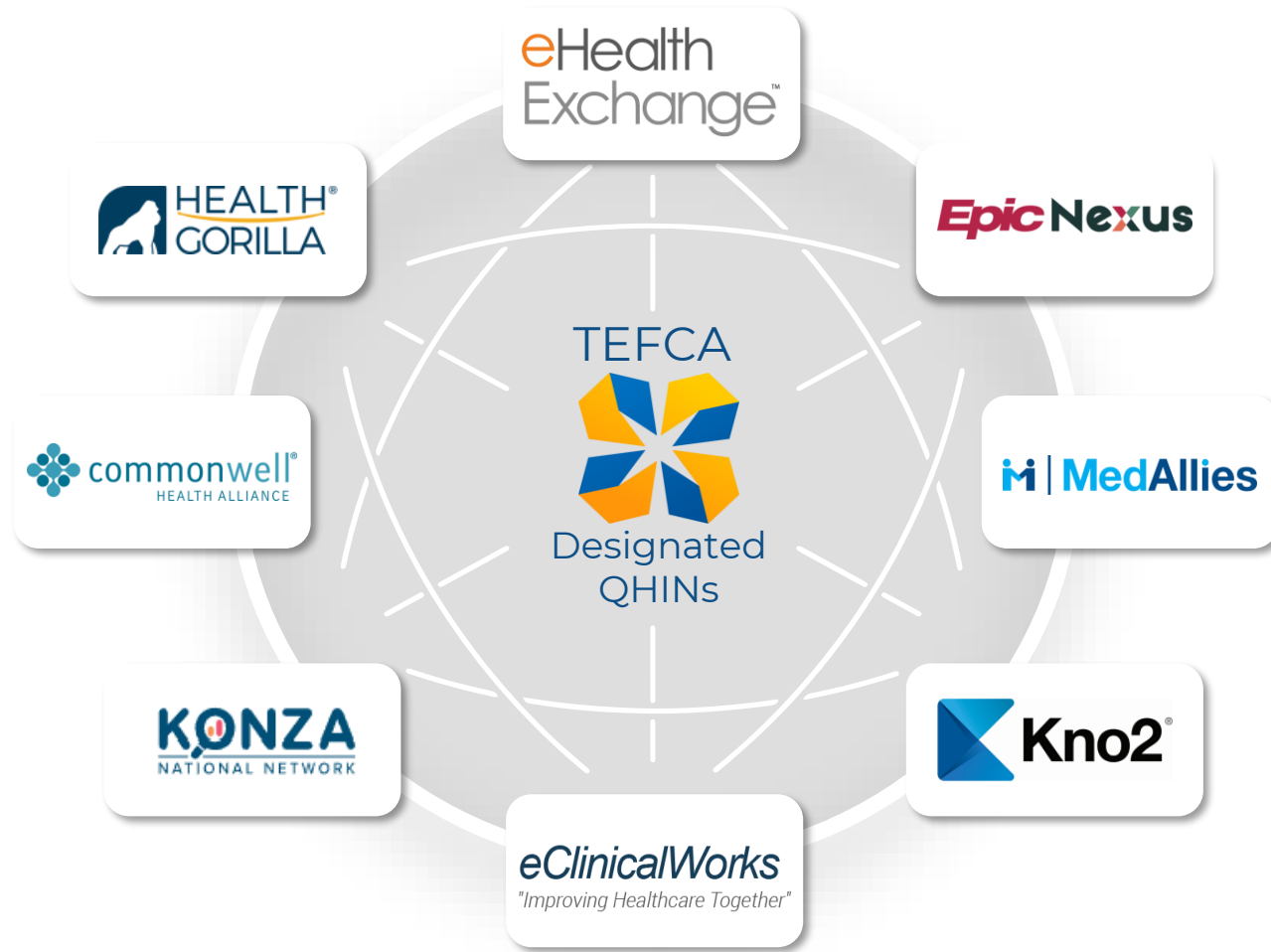
The Directory Portal is a user Interface that helps eHealth Exchange manage the directory for the eHealth Exchange network and eHealth Exchange QHIN directory for the TEFCA network. It is a means of conveying the technical information needed to make connections to eHealth Exchange participants. It is currently in use by eHealth Exchange staff in Production.

The pilots have completed testing in validation and will complete production validation the in early April.

eHealth Exchange will slowly roll out the My Portal Directory to all participants over the rest of 2025.

# Marketing Update

# Designated Qualified Health Information Networks



**Candidate QHINs**

Netsmart  
surescripts

**Intent to Apply**

ORACLE  
Health

# HIMSS25 Video Resources



## **TEFCA Public Health Reporting: A Breast Cancer Story and Demo**

Video: <https://youtu.be/dqcU5T6qQ4M>

## **Networked FHIR: Scalable Exchange Between Payers, Providers and Public Health**

Video: <https://youtu.be/ljEDfRj32XA>

Slides: [Networked FHIR Presentation](#)

## Use Case Video Resources

**Task Based Exchange Overview and Demo:** <https://youtu.be/NjXs2tNRQgU>

**Clinical Document Exchange (CDex) Overview & Demo:** <https://youtu.be/cbycmE-qhuU>

**Bulk FHIR Overview for HEDIS Reporting:** [https://youtu.be/\\_Sd-6FvJTHc](https://youtu.be/_Sd-6FvJTHc)

**SMART on FHIR Proxy Demo for Prior Authorization:** <https://youtu.be/vqeUJRqyfZI>

Subscribe to our YouTube Channel: [eHealth Exchange - YouTube](#)

# Upcoming Webinars

## eHealth Exchange Technical Workgroup

- **April 3 | 4-5:00 PM**

## eHealth Exchange All Participant Call

- **April 17 | 1-2PM ET**

## eHealth Exchange TEFCA Updates Webinar

- **May 13 | 3:30-4:30 PM ET**



# Upcoming Conferences

## April

None at this time.

## May

[APHL Annual Conference](#)

May 5-8 | Oregon

[KLAS K2 Collaborative  
Payer/Provider Summit](#)

May 20-22 | Salt Lake City | UT

## June

[CSTE 2025 \(Council for the State &  
Territorial Epidemiologist\)](#)

June 8-12 | Grand Rapids, MI

[AHIP 2025 \(America's Health  
Insurance Plan\)](#)

June 17-19 | Las Vegas, NV

[InterSystems Ready Global Summit](#)

June 22-25 | Orlando, FL

## Save the Date – 2025 Annual Meeting

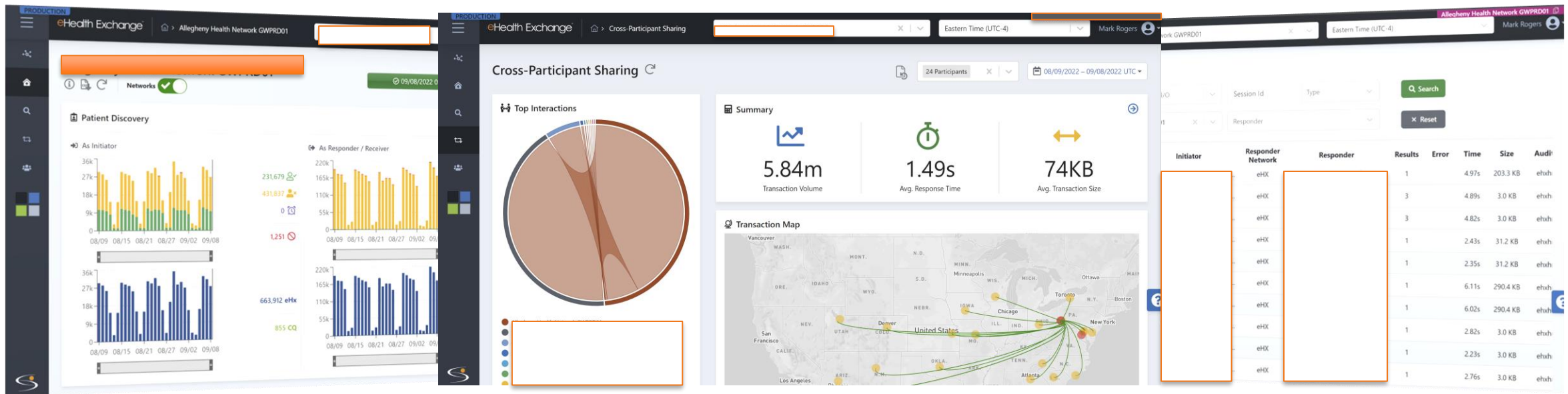


- Back to Nashville, TN
- November 18, 2025
- Co-located again with The Sequoia Project and Carequality following November 19-20, 2025
- Embassy Suites by Hilton Downtown Nashville

# Information & Resources



# Your Hub Dashboard – Your web portal providing interoperability insights.



- Identify transaction volume, response times, drill-down, & download.
- Who is querying your organization?
- Where are your clinicians searching?
- How much care occurs outside your organization?

Access Hub Dashboard: <https://insightsprod.ehealthexchange.org/#/hub>

# Monthly Technical Work Group

**Every 1<sup>st</sup> Thursday 4-5pm Eastern:**

**Typical Topics:**

1. Technical Specifications
2. Testing
3. Hub Updates
4. Capacity planning [Final Thursday each month]

Request an invite: <https://ehealthexchange.org/technical-workgroup-form/>

# Contacts for Your Organization

We want to ensure that we are reaching the right people at your organization with our communications.

- If you have had recent or past changes and are unsure if we have an updated list: email [administrator@ehealthexchange.org](mailto:administrator@ehealthexchange.org) requesting the Contact List Template to complete and return.
- The template asks name, title, phone number, email address, and what type of emails the resource should receive.
- This will assist eHealth Exchange and each Participant in knowing that the communication we send is received appropriately.

# How might I obtain assistance?

What	Who	How
Certificates	DirectTrust Support	<a href="mailto:support@directtrust.zohodesk.com">support@directtrust.zohodesk.com</a>
Technical Support	Technical Support	<a href="mailto:servicedesk@hub.ehealthexchange.org">servicedesk@hub.ehealthexchange.org</a>
Testing Questions	Testing Team	<a href="mailto:testing@ehealthexchange.org">testing@ehealthexchange.org</a>
Questions about the DURSA, policy, or anything else!	Administrator	<a href="mailto:administrator@ehealthexchange.org">administrator@ehealthexchange.org</a>

Visit: <https://ehealthexchange.org/contact-us/>

The logo for eHealth Exchange, featuring the word "eHealth Exchange" in a white sans-serif font. The letter "e" is orange, and a small trademark symbol (TM) is located at the end of the word. The logo is centered over a background of a hexagonal grid with orange and blue dots and lines.

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[BeMyQHIN.com](http://BeMyQHIN.com)