

All Participant Call

June 2025



Housekeeping Items



All lines have been muted to avoid background noise.



Type questions in Q&A section at any time.
We'll open for questions after each agenda topic.



This meeting is being recorded and will be shared via email.

Today's Topics

| | |
|--|---|
| FDA BEST IM*: Accelerating the Automation of Adverse Event Reporting | Hussein Ezzeldin, PhD Francis X. Campion, MD, FACP |
| Public Health Update | Tiffanie Hickman |
| Payer Update | Tiffanie Hickman |
| Use Case Review | Tiffanie Hickman |
| Directory Update | Michael McCune |
| QHIN Update | Michael McCune |
| Coordinating Committee Elections | Jayme Piña |
| Marketing Update | Jayme Piña |
| Information & Resources | Ashley Green |
| Q&A | Anyone |

FDA BEST IM*: Accelerating the Automation of Adverse Event Reporting

Hussein Ezzeldin, PhD

Office of Biostatistics and Pharmacovigilance (OBPV)

Center for Biologics Evaluation and Research (CBER)

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Principal Lead, Digital Health

MITRE

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**Biologics Effectiveness and Safety (BEST) Innovative Methods (IM)*

eHealth Exchange™

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.

2025 Opportunities

BEST IM is now recruiting health systems for two 2025 phenotype validation studies:

1

Myocarditis/Pericarditis post mRNA vaccine exposure

mRNA vaccines include SARS-CoV-2 vaccines and a recently approved RSV vaccine.

Myocarditis/pericarditis occurs in 1-10 per 100,000 vaccinated persons after SARS-CoV-2 vaccine.

2

Hypogammaglobulinemia post administration of CAR-T cell therapy

CAR-T cell therapy increasingly used as a cancer treatment

Hypogammaglobulinemia is a common adverse event (~15-60%) with a range of severity.

- Onboard new health systems -- building on previous BEST IM success with data exchange and grow network of partners for 2026 and beyond.
- Leverage LLMs to enhance information abstraction ability from unstructured data (e.g., clinical notes and radiology reports).
- Create standardized protocols for clinician validation of CQL/LLM detection logic.
- Prepare for expanded library of computable phenotypes.

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: ≤ 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



CBER-BESTIM@fda.hhs.gov

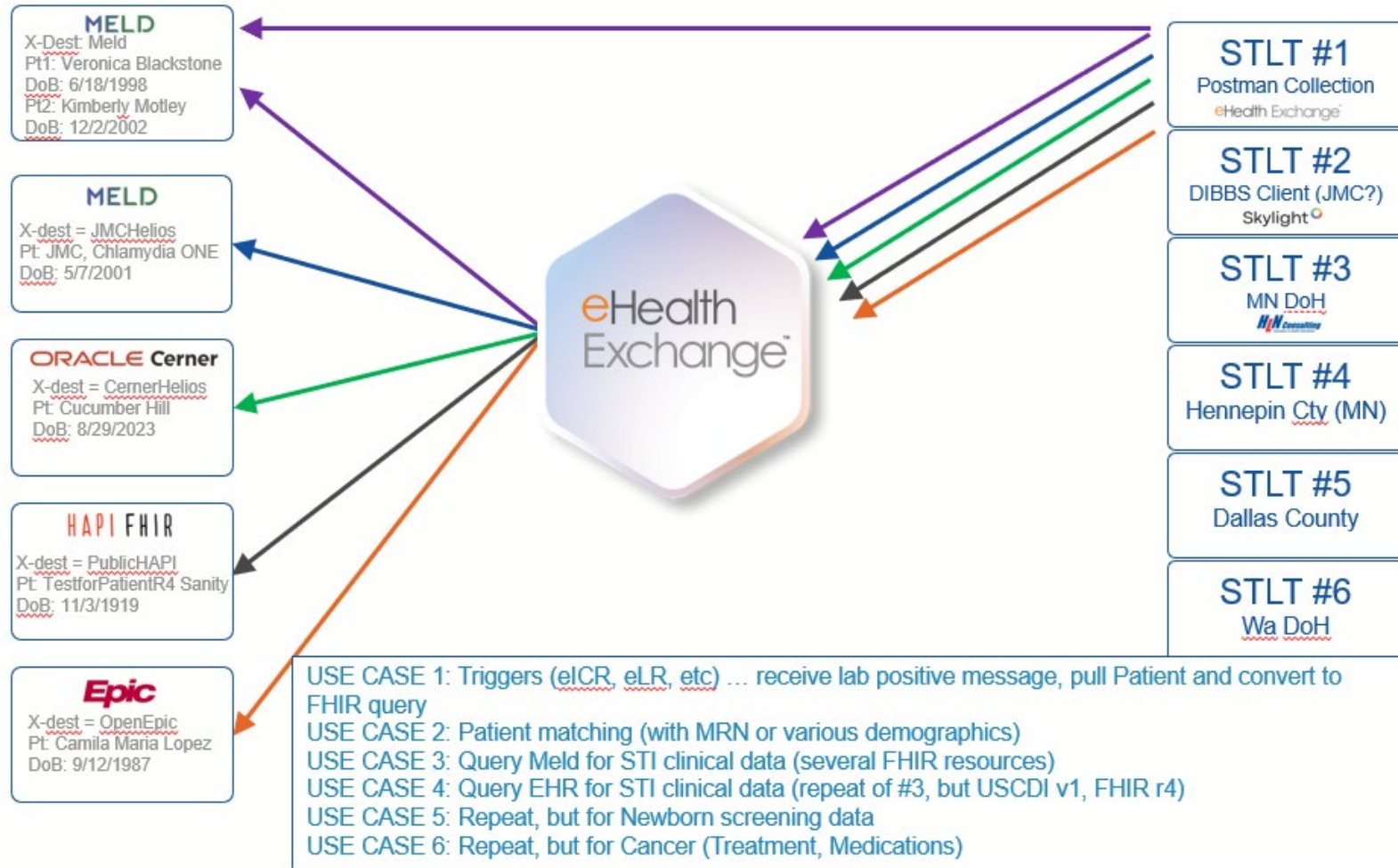


<https://bestinitiative.org/>

Public Health Update



Public Health Update



- eHealth Exchange participated in the Helios virtual FHIR Connectathon on June 3rd and 4th primarily in the Query and response track.
- eHealth Exchange provided details on the Task Based Exchange workflows specifically the Fan-Out that was presented the first time last year..

Public Health Cont.

- To see slide materials and information on the Connectathon [Helios Virtual FHIR Connectathon June 2025 - Helios – Confluence](#)
- Call to Action: To participate in a public health pilot, please reach out to eHealth Exchange Admin administrator@ehealthexchange.org for more information or questions.

Payer Update



Payer Update

- eHealth Exchange will be participating in the CMS Connectathon with DaVinci Trebuchet and other payer use cases on July 15-17th. The Connectathon is virtual and free to register.
- eHealth Exchange is starting a pilot in August with Blue Cross and Blue Shield Association with Payer-to-Payer use case including Bulk FHIR.
- Our SoF Proxy application has been tested with both Epic and Oracle.
- Don't forget about the CMS-0057 final Rule regarding ePA and CDex. Impacted payers are required to implement certain provisions by January 1, 2026 and have until primarily January 1, 2027, to meet the application programming interface (API) requirements in this final rule.
 - eHealth Exchange is looking for providers to expand the pilots with our payer participants.

Use Case Review

Use Cases

- eHealth Exchange is working to expand the content on our website for use cases
- 2025 goal: individual use case webpages
- Allows for filtering by target audience

<https://ehealthexchange.org/use-cases/>

There are many benefits of eHealth Exchange participation! - [Learn More](#)

eHealth Exchange


What We Do ▾ Our Network ▾ Who We Are ▾ Resources ▾ Events ▾

Q Contact Us Join Our Network 16

Use Cases

Our use cases expand with community interest and leverage cutting-edge technology to serve the public good, enhance your workflows, and minimize effort.


Filter by type: All Providers Payers Public Health Federal Agencies Individuals



Treatment/Care Coordination

Enables access to critical information to support improved care coordination for patients by their providers during transitions of care


Providers Federal Agency



Encounter Alerts

Enables event notification of clinical encounters (with robust clinical details) to state & regional HIEs to populate longitudinal patient records


Providers Payers



Task Based Exchange

Enables clinical data exchange that focuses on how to get data out of EHRs and into the hands of other people who need it – like patients, providers and public health.

Providers Individuals Federal Agency Public Health




Clinical Data Exchange (CDex)

Enables clinical data exchange between providers and payers for: attachments for claims, prior authorization, documentation, quality programs and risk adjustment

LEARN MORE →


Providers Payers



Prior Authorization

Streamlines and automates prior authorization decisions and provides real-time determinations

Providers Payers




Payer Data Exchange (PDex)

Enable Payer-to-Payer and Payer-to-Provider exchange for claims and encounter data


LEARN MORE →

Providers Payers




Public Health Reporting

Enables providers to push discrete notifications (not full case reports) to



Electronic Case Reporting (eCR)

Enables providers' EHRs to automatically




Electronic Case Investigations

Provides the ability to query and retrieve additional information in response to a

Use Cases

- The first three pages are live now: CDex, PDex and eCR




Clinical Data Exchange (CDex)

Enables clinical data exchange between providers and payers for: attachments for claims, prior authorization, documentation, quality programs and risk adjustment

[LEARN MORE →](#)


[Providers](#) [Payers](#)



Prior Authorization

Streamlines and automates prior authorization decisions and provides real-time determinations

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Payer Data Exchange (PDex)

Enable Payer-to-Payer and Payer-to-Provider exchange for claims and encounter data

[LEARN MORE →](#)

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There are many benefits of eHealth Exchange participation! - [Learn More](#)

eHealth Exchange

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USE CASE

Clinical Data Exchange (CDex)

Enables clinical data exchange between providers and payers for claim attachments, prior authorization, additional documentation to support medical necessity, quality programs and risk adjustment

[View Demo](#)



You are already doing this today, why not make it easier?

Providers have been responding to payer requests for additional clinical information for decades, but without using national standards backed by a multi-party trust agreement.

The hard way

Providers succumb to each payer's preferred method to submit the required information, creating a multitude of manual back-and-forth information requests via:

- Web portals
- Fax
- Phone calls
- Snail mail

Creating inefficient processes that create strain on administrative staff

The new way

Implementation of HL7® Da Vinci CDex automates clinical data exchange between payers and providers using FHIR® standards.

eHealth Exchange further simplifies the process by allowing payers to connect with multiple providers and providers to connect with multiple payers using our single trust agreement, like our DURGA.



Exchange with confidence

HL7® Da Vinci technical specifications have been designed by providers and payers to establish a provider-payer clinical exchange.

- Providers can only retrieve data for attributed members when they share full demographics.
- Providers consent to exchange when they are satisfied HIPAA Minimum Necessary has been addressed. This is often solved by payers retrieving data only for each data-based encounter.

Let us show you how it works



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Use Case Webpage Breakdown

- Short description
- Video demonstration
- Challenge/Solution
- Benefits
- Workflow diagram
- Technical Specifications

Technical Specifications

| | |
|--|---|
| Da Vinci Clinical Data Exchange (CDex) | HL7.FHIR.US.DAVINCI-CDEX\Home – FHIR v4.0.1 |
| CDex Task Data Request Profile | CDex Task Data Request Profile – Da Vinci Clinical Data Exchange (CDex) v2.1.0 (fhir.org) |
| CDex Purpose of Use Value Set | CDex Purpose of Use Value Set – Da Vinci Clinical Data Exchange (CDex) v2.1.0 (fhir.org) |
| SMART App Launch | http://hl7.org/fhir/smart-app-launch |
| US Core Implementation Guide | http://hl7.org/fhir/us/core |
| Da Vinci Health Record Exchange (HReX) | Home – Da Vinci Health Record Exchange (HReX) v1.1.0 |

Directory Update

Directory Sub-participants – what are they?

- Sub-participants are a relatively new type of directory entry. Sub-participants typically represent one of two things:
 - Logical entities that serve to group provider locations. For example, a hospital system or a state or region that is serviced by an HIE. The service delivery role location type is “administrative”.
 - Physical provider locations. For example: a hospital, a clinic, a doctor’s office.

Sub-participants with Endpoints

- The directory now allows sub-participants that are published with endpoints. There can be a hierarchy of endpoints. Here are some scenarios for endpoint publication:
 1. Publish endpoints for the participant but not for any of the sub-participants. This would imply that you can query the participant, and the participant will fan-out the request to all the sub-participants. Since there are no endpoints for sub-participants, the sub-participants cannot be targeted individually. This is the “traditional approach”.
 2. Publish endpoints for all the sub-participants directly below a participant but not for the participant. This indicates you must target the sub-participants directly.
 3. Combine #1 and #2: Publish endpoints for all the sub-participants directly below a participant and for the participant. The endpoints for the participant imply that you can query the participant and the participant will fan-out the request to all the sub-participants. If you don't have this fan-out capability, then this approach should not be used. You can also send requests directly to a sub-participant if you don't want data from all sub-participant members.

Identifying Directory Entries with a Unique ID (OID)

- OID assignment
 - An OID is a unique ID which is typically obtained from a registration authority such as HL7 to provide some level of global uniqueness. At a minimum, the ID will be unique per registration authority. Here's an example of an OID that represents a participant:
 - 2.16.840.1.113883.3.346
 - An OID must be unique per directory, but there is an exception: We cannot publish an entry in the eHealth Exchange directory with the same OID used in the Carequality directory, if the Carequality directory entry provides endpoints. The Hub only stores one set of endpoints per OID, and we cannot convert a Carequality connection to an eHealth Exchange connection.

OID Collision – an OID cannot be used twice in the directory

Question: If my organization is a HIE and I supply a connection to another participant already listed in the directory, how should that be done?

Answer: To publish a participant already listed in the directory under your HIE, you will need to supply a different OID than what is already used for that participant.

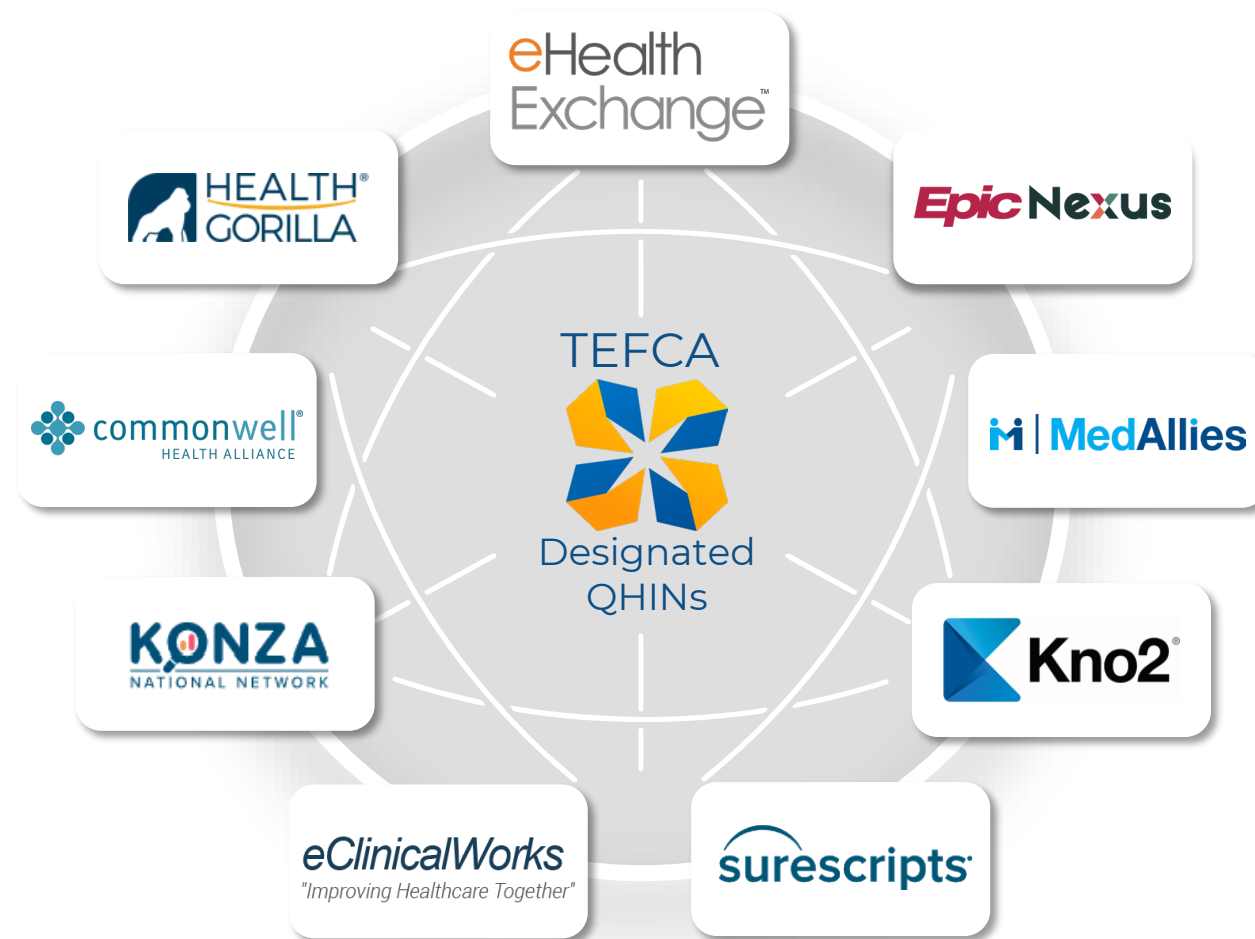
We need to understand the nature of the participant connection being published under your HIE.

- For example, do you provide all the data available from the participant just the same as if you made a direct connection to the participant or is it a subset of data or a specific use case?
- **Note: We may need directory enhancements to describe this type of scenario.**

QHIN Update



Designated Qualified Health Information Networks



**Candidate
QHINs**

 **Netsmart**

Oracle Health Information Network
logo to be provided when available



eHealth Exchange QHIN Participant Stages

Live



**1 Federal Agency,
2 HIEs, and
Nationwide Public Health**

Testing



4 HIEs

Intent to Participate



8 HIEs

Alabama One Health Record (ALOHR) Update



**ALOHR began initiating query-based exchange on
Tuesday, April 8th**

Alabama One is eHealth Exchange's first organization to begin *querying* the TEFCA network for Treatment purposes

They have over 10 SubParticipants querying the TEFCA network,
with more to follow in the coming weeks

Coordinating Committee Elections

Background

The Coordinating Committee manages the Network, not to be confused with the eHealth Exchange Board that manages the Company running the network. The Coordinating Committee is granted formal authority under the DURSA to oversee and facilitate continued development, implementation, and operation of the eHealth Exchange Network. The Coordinating Committee does have 3 members on the Board at the same time.

The DURSA and Operating Policy and Procedure #2: Coordinating Committee General Operating Procedures, establish the composition of the Coordinating Committee and provide additional background information. [Please click here to view a copy of OPP #2.](#)

Expectations of Coordinating Committee Members

The primary purpose of the Coordinating Committee is to govern the eHealth Exchange and provide strategic direction to assure continued growth and innovation. Key responsibilities include:

- Administration and maintenance of the DURSA, which serves as the legal and policy framework for the network and eHealth Exchange Operating Policies and Procedures (OPPs), including outage notices, breach notification, dispute resolution, issue resolution, and change management
- Implementation and support of the onboarding and participant / product testing process
- Assessment of ongoing performance of the eHealth Exchange implementation components (e.g. implementation specifications, test cases, test data sets, testing tools, legal framework, governance processes, network grievance process, service registry, digital certificates) and evaluating the need and readiness for other components, as needed
- Development of connectivity strategies and evaluation of new use cases to increase connectivity and transaction volumes for eHealth Exchange Participants
- Fulfilling all other responsibilities delegated by the Participants to the Coordinating Committee

Experience and Skills

Because the focus of the Coordinating Committee is to set the strategic direction for the network, the ideal candidate should meet the following criteria:

- Full Time Employee or Independent Contractor of the Non-Federal or Federal Participant
- Should be a senior-level executive within the organization
- A minimum of 10 years' experience in the HIE / HIT industry or similar industries
- Extensive knowledge of the HIE / HIT industry, including HIE governance and implementation
- Knowledge of HIE / HIT policy along with operational knowledge of how HIE works
- Insights into the HIE / HIT market dynamics, and the role that a successful public-private collaborative can play in advancing implementation of HIE, etc.
- Experience serving on other corporate board or governing bodies
- Ability to participate in a minimum of 80% of the CC calls (1 per month), special e-mail votes, and ad hoc calls as necessary, and reviewing materials. (Time commitment is approximately 4 hours a month)
- Willingness to serve a 3 year term

2025 Coordinating Committee Seats

| Representative | Term Date |
|-------------------------------|-----------|
| Dan Paoletti | 9/30/2026 |
| John Kansky | 9/30/2026 |
| Pam Matthews | 9/30/2027 |
| Patti Cuartas | 9/30/2026 |
| Matt Eisenberg | 9/30/2025 |
| Paul Matthews | 9/30/2025 |
| Arun Gopalan | 9/30/2026 |
| Open (formerly Sheryl Turney) | 9/30/2027 |
| Julie Riddler | 9/30/2027 |

2025 Coordinating Committee Election Timeline

July

August

September/October



1. Announce during All Participant Call – May, June, July
2. September 2-8: Time for a runoff if needed

Marketing Update

Upcoming Webinars and Conferences

June

CSTE 2025

June 8-12 | Grand Rapids, MI

All Participant Call

June 12 | Virtual

AHIP 2025 (America's Health Insurance Plan)

June 17-19 | Las Vegas, NV

InterSystems Ready Global Summit

June 22-25 | Orlando, FL

July

Technical Workgroup

July 10 | 4-5PM ET

All Participant Call

July 17 | Virtual

August

Technical Workgroup

August 7 | Virtual

MESC 2025

August 11 | Milwaukee, WI

TEFCA Updates Webinar

August 12 | 3:30-4:30PM ET

All Participant Call

August 21 | Virtual

BCBS eSolutions Xchange

August 24-27 | Kansas City, MO

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

Hotel Booking is officially open!
[2025 Annual Meeting - eHealth Exchange](#)

COMING SOON: Registration and Call for Abstracts

eHealth Exchange Monthly Newsletter

- eHealth Edition was launched January 2025
- Distributed monthly, the last week of the month
- Automatically gets sent to primary, project and operations contacts for our participants
- Available to all others by subscribing from our [News & Insights webpage](#)

[Subscribe to Newsletter](#)

eHealth Edition

MONTHLY NEWSLETTER

MAY 2025

NEWS

eHealth Exchange Honored with KLAS Points of Light Award for Advancing Automated Prior Authorization via Networked FHIR Service



eHealth Exchange once again has been recognized by KLAS Research with a prestigious Points of Light Award for its groundbreaking work in health data interoperability. The recognition stems from a collaborative case study titled "Automating Prior Authorization via a Networked FHIR Service," which showcases a scalable solution to one of healthcare's most burdensome administrative processes.

[Read Press Release](#)

2025 ANNUAL MEETING

Hotel Block Open

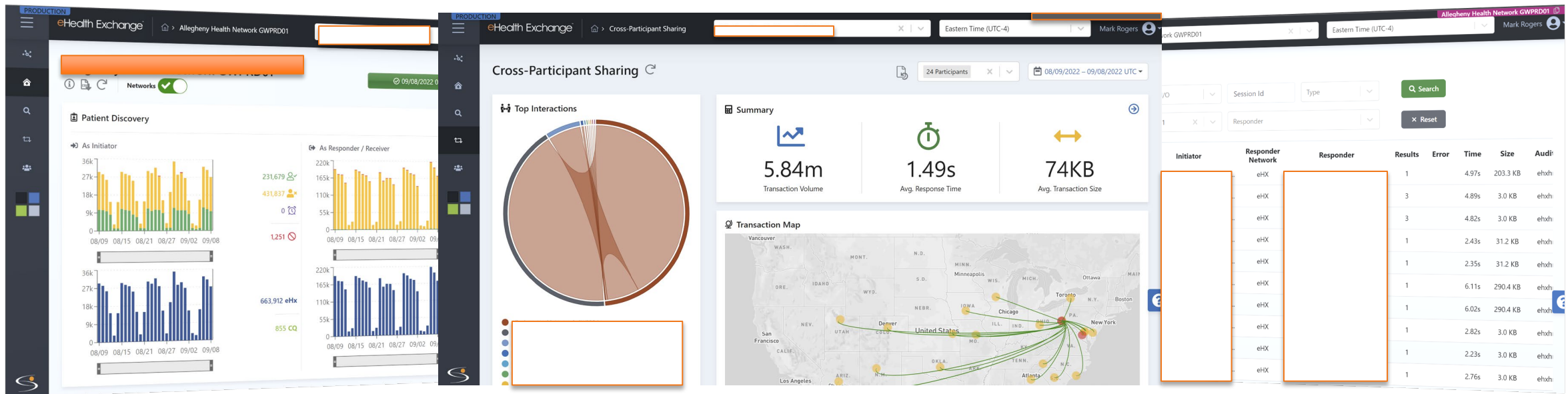
We will be back in Tennessee at the Embassy Suites by Hilton Downtown Nashville for the eHealth Exchange Annual Meeting November 18, 2025.



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 1st 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 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 | support@directtrust.zohodesk.com |
| Technical Support | Technical Support | servicedesk@hub.ehealthexchange.org |
| Testing Questions | Testing Team | testing@ehealthexchange.org |
| Questions about the DURSA, policy, or anything else! | Administrator | administrator@ehealthexchange.org |

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



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