

All Participant Call

December 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

New Participants	Ashley Green
Annual Meeting Recap	Dennis Sherba
FDA BEST Initiative	Hussein Ezzeldin, PhD from FDA Francis X. Campion, MD, FACP from MITRE
Hub Updates	Mike Yackanich
TEFCA Update	Jay Johnstone
OPP Updates	Jayme Pina
National Member Match	Mike Yackanich
Marketing Update	Tina Feldmann
Information & Resources	Ashley Green
Q&A	Anyone

New Participants



Congratulations to our newest Participants!



Cozeva was founded to enable payers and providers with the most comprehensive operating system for value-based care.

Cozeva PayerOne Quality named 2025 Best in KLAS for Payer Quality Measurement & Reporting and earned a high performer designation in Risk Adjustment, recognized for Chart Retrieval and Chart Review/Coding Services.

Learn more: [About Cozeva](#)

Committed to Improving Patient Care via Data Exchange

Annual Meeting Recap



2025 Annual Meeting Recap



- eHealth Exchanges Largest Annual Meeting to date
- Gratitude and Transparency
- Data Quality
 - PHI Data Validation
 - USCDI v3
 - FHIR Content Testing
- Public Health
 - ECR via FHIR
 - Immunization Exchange

2025 Annual Meeting Recap



- CMS – Pushing hard on CMS-Aligned network objectives and pledges
 - National Provider Directory
 - CMS serving as Lead for payers
- TEFCA – Change is slower than expected
- Health Care Operations (HCO)
 - Hot topic! Sought after by many payers

Breakout Session: Igniting Interoperability

Real-World FHIR Services and Use Cases

- Overview of eHealth Exchange FHIR services
 - FHIRProxy
 - Da Vinci Clinical Data Exchange (CDex)
 - Task Based Exchange (TBE)
 - SMART on FHIR Proxy
- Related Use Cases
 - FDA BEST Adverse Event Reporting
 - Electronic Prior Authorization
 - Member Match



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

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

Hussein Ezzeldin, PhD, Associate Director for Advanced Technologies, U.S. Food and Drug Administration (FDA),
Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV)

Francis X. Campion, MD, FACP, Clinical Science, Principal, The MITRE Corporation

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eHealth Exchange™

BEST IM Goal

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

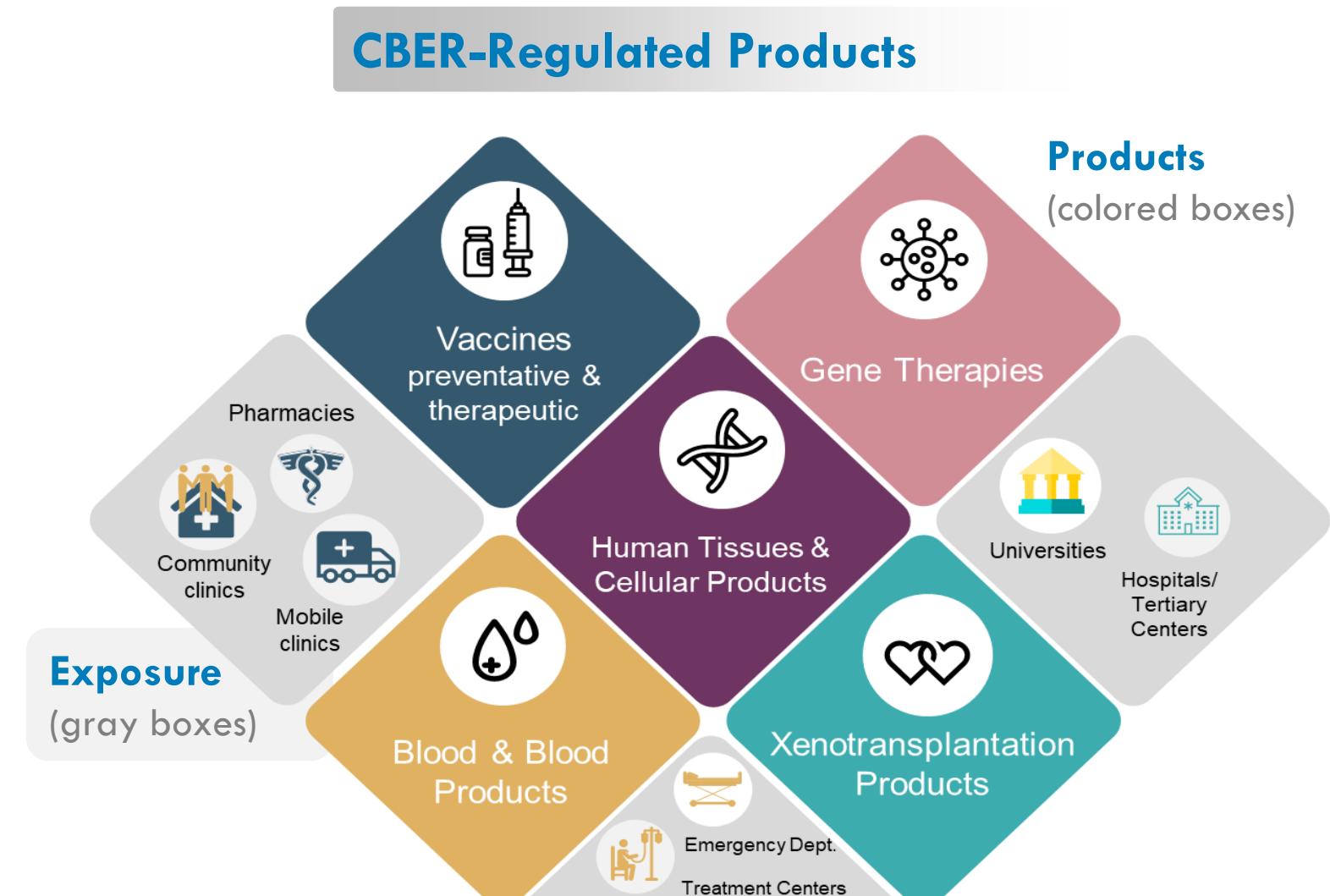


Fig 1: FDA CBER Regulated Products (FDA)



Vaccines and Biologics
Adverse Event Reporting =
Manual Process

The Opportunity

- **Streamline Adverse Event Case Reporting and Reduce Provider Burden**
- **Enable Real-Time Signal Detection and Active Surveillance**
- **Enhance Patient Safety Through Improved Data Quality and Timeliness**
- **Empower Public Health Through Innovation and Collaboration**



BEST IM Program

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

The BEST IM Platform leverages FHIR® standards...

- ...to enable health systems to transfer EHR data via Health Information Exchange (HIE) and Qualified Health Information Network (QHIN) infrastructure
- ...for identifying and reporting Adverse Events such as myocarditis/pericarditis, hypogammaglobulinemia, and anaphylaxis

CBER BEST IM Roadmap



Prototype on Foundational Network

- Built EHR data pipeline
- Developed and validated phenotypes
- Reported on Individual Case Safety Reports (ICSR)

FY19-20

Completed

D.C.
Maryland
Virginia
Florida



Prototype on Exchange Network

- Leveraged pipeline to design a Proof-of-Concept exchange architecture
- Supported with data agreements and standards

FY21

Completed

Operationalized on Foundational Network – piloted scalable phenotypes



Pilot Studies on Exchange Network

- Piloted Adverse Event validation use case on 'First-of-a-kind' networked FHIR (Pull)
- Piloted Adverse Event detected use case with early adopter (Push)

FY22-24

Completed

11 Pilot Participants



Operationalize Exchange Network: Expand Studies

- Mature and expand Adverse Event validation nationally
- Leverage interoperable detection approach

CURRENT EFFORT

FY25+

Ongoing

National Coverage



2025/26 BEST IM Study Topics

1

Myocarditis/Pericarditis (post mRNA vaccine exposure)

**SARS-CoV-2
mRNA vaccines**

Incidence:
Myocarditis/pericarditis occurs in
1-10 cases per 100,000
mRNA-based COVID-19
vaccinated persons.

2

Hypogammaglobulinemia (post administration of CAR T-cell therapy)

**CAR T-cell therapy increasingly
used as a cancer treatment**

Incidence:
Hypogammaglobulinemia is a common
adverse event occurring in 16-60 cases per
100 CAR-T treatments with a range of
severity.

References:

Oster, M. E., et al. (2022). Myocarditis cases reported after mRNA-based COVID-19 vaccination in the US from December 2020 to August 2021. *JAMA*, 327(4), 331–340.

Mevorach, D., et al. (2021). Myocarditis after BNT162b2 mRNA vaccine against COVID-19 in Israel. *New England Journal of Medicine*, 385(23), 2140–2149.

Brudno JN, Maus MV, Hinrichs CS. CAR T Cells and T-Cell Therapies for Cancer: A Translational Science Review. *JAMA*. 2024;332(22):1924–1935.

2025 Study Methodology



FHIR EHR Data + 'Textified' Format

Data sharing via eHealth Exchange (Qualified Health Information Network)



Large Language Model (LLM)-based Pipeline

Identification and adjudication of adverse events (AEs) related to mRNA vaccines



Llama3.3 (LLM)

Use in-house, secure LLMs for Question-answer response using unstructured text documents (e.g., clinical notes) and structured data elements (e.g., ICD-10-CM codes)



Brighton Collaborative AE Definitions

Foundation for myocarditis and pericarditis AE definitions



Three Clinician Adjudicators

Establishment of “gold standard” dataset for validating automated workflows

Study Design

1 Health systems send FHIR identifiers for patients of interest to FDA, e.g., patients who have undergone COVID-19 mRNA vaccination

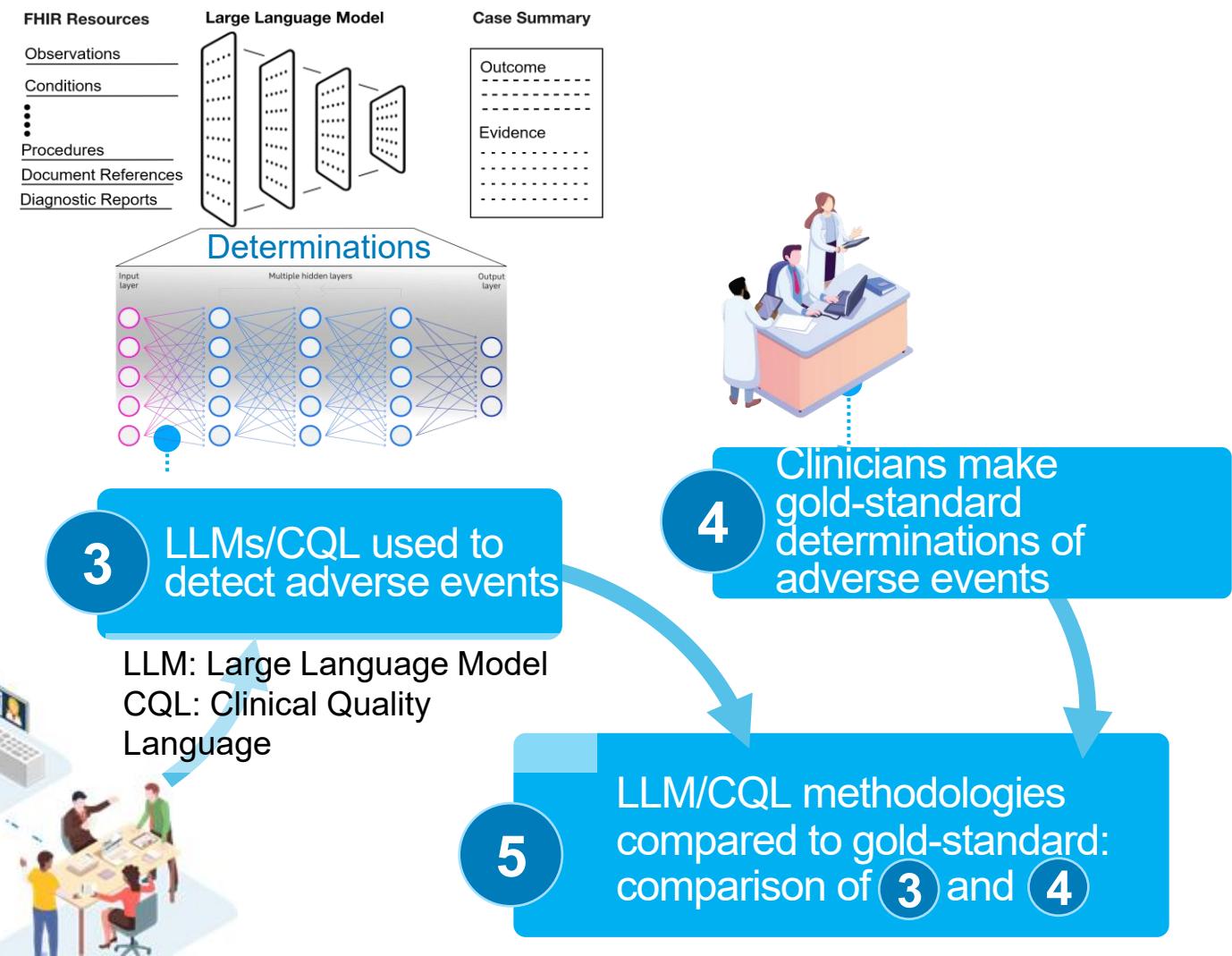
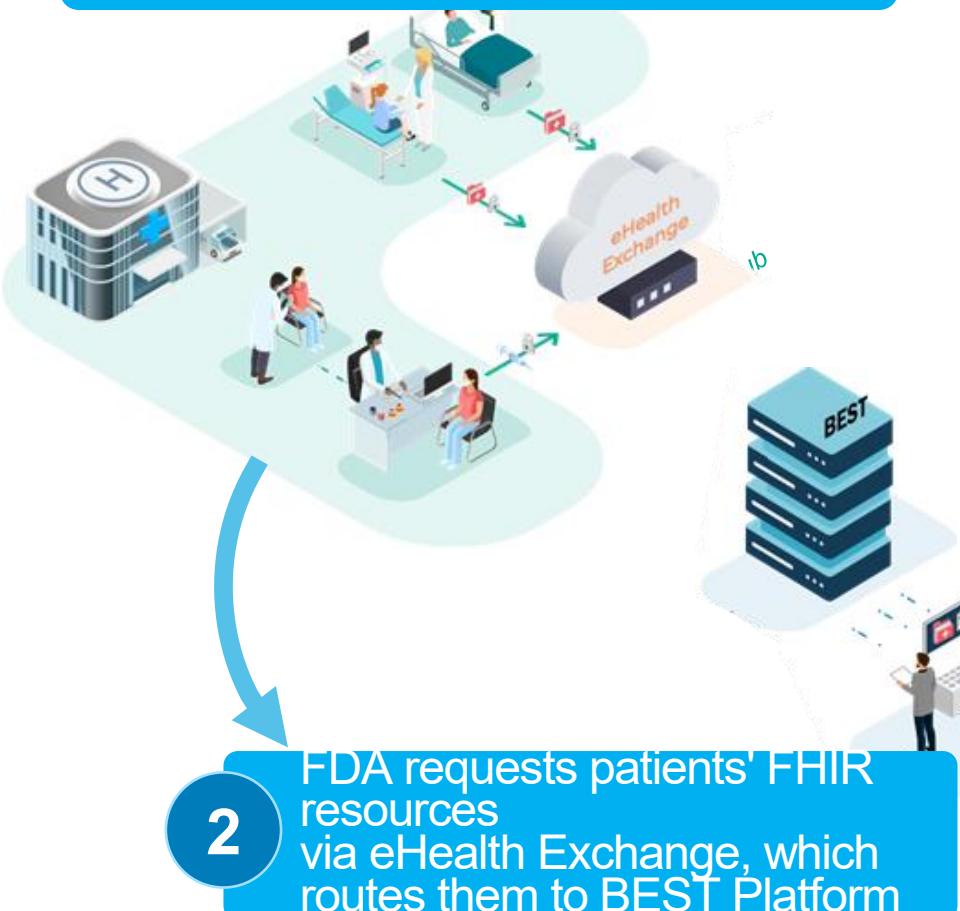


Fig 2: BEST IM Study Design (MITRE)

LLM-Enabled Methods

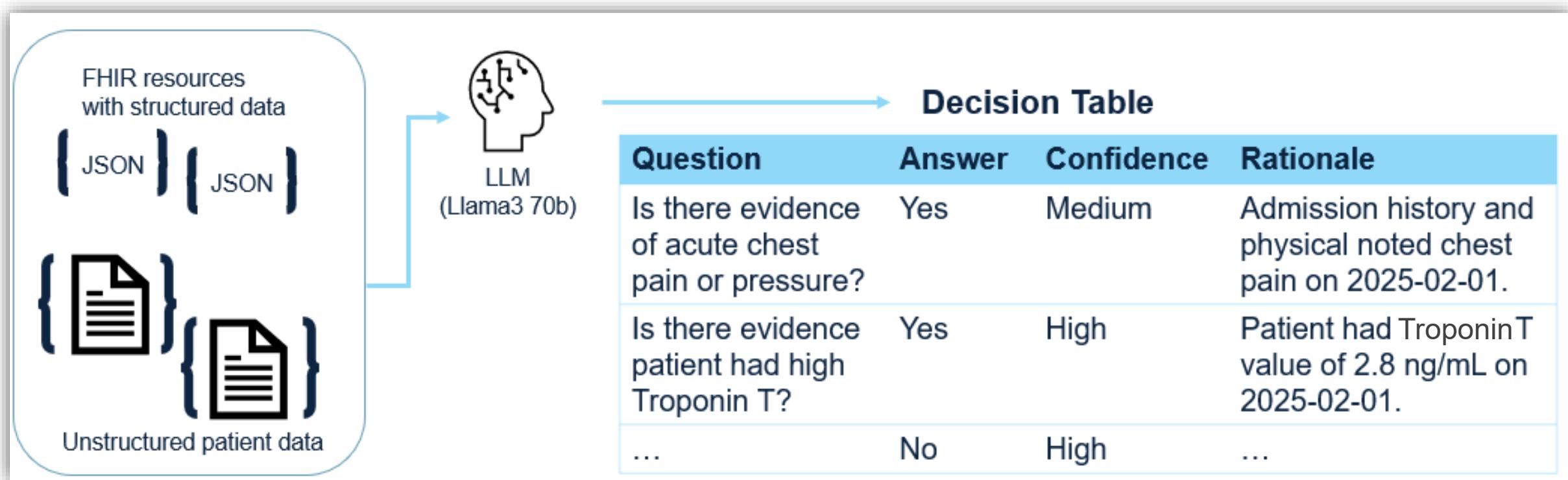


Fig 3: BEST IM LLM Advanced Methods (MITRE)

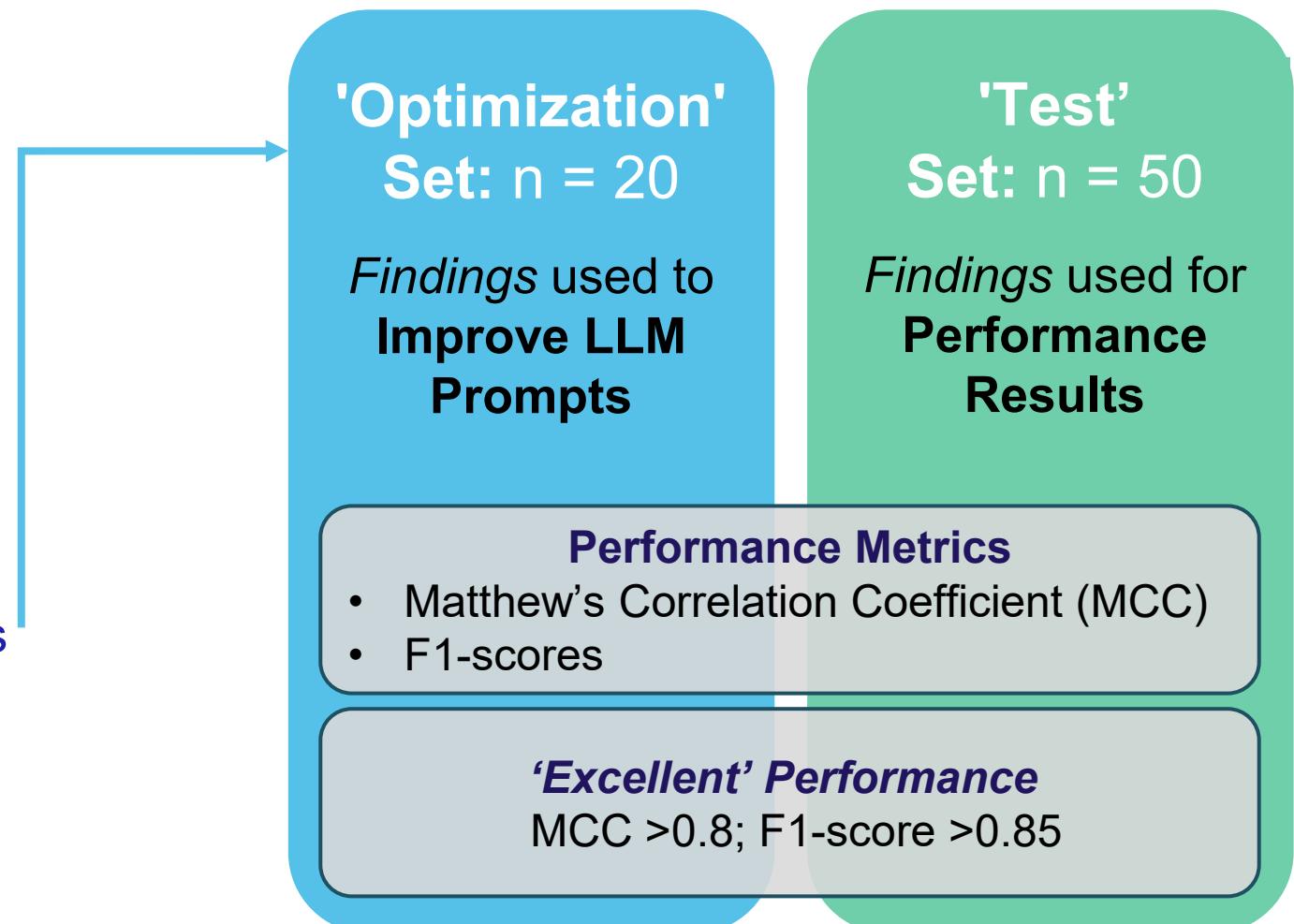
2025 Study Overview

Participants:

- Cedars-Sinai Medical Center
(Los Angeles, CA)
- Johns Hopkins Health System
(Baltimore, MD)

Total Cases:

- 70 cases of myocarditis / pericarditis



“Test” Set Results: LLM Assessment Summary

How well did the LLM do compared to humans?	
	Performance on phenotype components <ul style="list-style-type: none">“Excellent” in determining presence of symptoms and echocardiogram abnormalities“Lower” performance in determining if specific cardiac biomarkers were above thresholds
	Outcome Determination <ul style="list-style-type: none">Excellent performance when used with CDS* enginesModerate Performance for zero-shot outcome determinationOngoing optimization aims to improve the LLM performance
	Causality Determination <ul style="list-style-type: none">Causality was not addressed in this study
	Future Studies <ul style="list-style-type: none">Making “causality” and “severity” determinations will require further optimization of logic and LLM prompts

* CDS - Clinical Decision Support

Next Steps

- **Study Scalability:** Participant network expansion
- **Human-Machine Teaming:** User interface and information abstraction enhancements
- **Protocol Standardization:** Computable AE Phenotypes, LLM detection logic, clinician validation
- **Validation Expansion:** New phenotypes tested and validated
- **Publication of Findings:** Results sharing

Participation Benefits



Innovate to Improve Patient Safety

Demonstrate public health leadership and community benefit.



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.



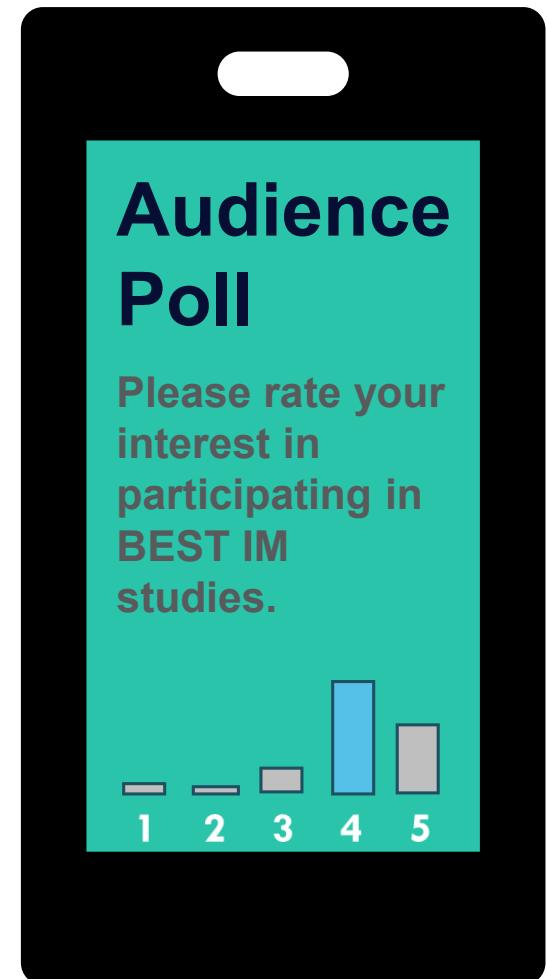
Publish Findings

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



2026 BEST IM Studies

- **Who:** eHealth Exchange participating members
 - Opt into any, or all, of the studies.
- **What:** EHR data for the evaluation of biologics-related adverse events.
- **How:** Utilize existing connectivity established through the eHealth Exchange.
 - Use existing Public Health exchange purpose allowed under the eHealth Exchange DURSA. Participants do NOT need additional data use agreements.
 - Studies are conducted as public health surveillance and are not human subjects research; local IRB consultation may still be required per institutional policy.



Financial incentives will be available to a limited number of participants for the CY2026 studies

Thank you!



CBER-BESTIM@fda.hhs.gov

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Hub Maintenance Event

Change Reminder



Hub Maintenance Events – Summary

EFFECTIVE JANUARY 5th 2026



Every 2nd & 4th Wednesday
10:00 AM ET



Every 1st & 3rd Wednesday
10:00 AM ET



Every Thursday
10:00 AM ET



Every Thursday
5:00 PM ET

FHIR Hub Environment Upgrade

Status Update



What is the “FHIR Hub” ?

The FHIR Hub is the eHealth Exchange environment that supports FHIR-based interactions. This is separate from the Hub environment that is used for SOAP-based IHE exchange.

The following services have been available and are actively in use:

FHIRProxy

Foundational service that provides connectivity to participants who are engaged in FHIR exchange on the eHealth Exchange network.

Task Based Exchange

Layered service that leverages FHIRProxy to support an asynchronous FHIR workflow modelled after the HL7 Da Vinci Project CDEx Task-based Approach specification.

SMART on FHIR Proxy

Intermediary service that leverages the SMART on FHIR standard to facilitate a many-to-many connectivity model between Provider and Payer organizations. This service also leverages the FHIRProxy service for secure connectivity to FHIR servers.

FHIR Hub Upgrade

What?

A version upgrade of the technology platform to the latest version of InterSystems IRIS for Health.

Why?

New features, performance and stability improvements, and preparation for new use cases and workflows.

When?

The upgrade process began on 12/2 and will continue through 12/3. Testing and validation will be completed on 12/4.

Upgrade was completed on 12/3

There was no service interruption

Services remain up and available. No new customizations will be developed or deployed.

Impacts?

Services remain up and available.

A code freeze will be in place until ~mid-September. During this time no new customizations will be developed nor deployed.

Configuration updates can be performed, as needed.

TEFCA Update

QTF v2.1 and GBD SOP



QHIN™ Technical Framework Version 2.1

RCE Developed Resources

Download online resources exclusive to the RCE and TEFCA below



Technical Requirements

- [!\[\]\(d49f07473e21d70ef9ade82c6eff4bc9_img.jpg\) QHIN Technical Framework \(QTF\) Version 2.1](#)
- [!\[\]\(953709a7564354e79c8677a878aa20b0_img.jpg\) Technical Trust Requirements](#)
- [!\[\]\(887c095daed5549396c9ef0c31e8f647_img.jpg\) Delegation of Authority SOP](#)
- [!\[\]\(98908bfb5bc8db4e4c86f5bfc45db907_img.jpg\) Facilitated FHIR Implementation SOP](#)
- [!\[\]\(0ba3b7d8e9329aac62a31b8061cc7eda_img.jpg\) RCE Directory Service Requirements Policy SOP](#)
- [!\[\]\(c5de30c45f6ea5497c6648986e515d88_img.jpg\) RCE Directory Service Implementation Guide 1.8.1](#)
- [!\[\]\(b68c3ad84dabec5b68e78dbc56faba65_img.jpg\) QHIN Cybersecurity Certification](#)

QHIN Technical Framework (QTF)

- Describes the functional and technical requirements that a Health Information Network (HIN) must fulfill to serve as a QHIN™ under TEFCA™
- Specifies the technical underpinnings for TEFCA Exchange, QHIN technical capabilities and services, and certain other responsibilities, some of which extend to Participants and Subparticipants
- Focuses on technical and functional requirements for three information exchange modalities for QHINs:
 - QHIN Query
 - QHIN Message Delivery
 - Facilitated FHIR

QTF Version History



QTF 2.1 Updates

- Effective Date - TBA
- Renumbering of Requirement IDs
 - V2.0 used sequential numbering (QTF-001 > QTF-133)
 - V2.1 uses section-based numbering:
 - Connectivity: QTF-101 – QTF-102
 - Certificate Policy: QTF-201 – QTF-202
 - Secure Channel: QTF-301 – QTF-304

QTF 2.1 Updates

- [QTF-811] As of **January 1st, 2027**, all information sent MUST conform to **USCDI V3.1** data classes, data elements, and vocabulary requirements.
 - V2.0 required conformance to USCDI v3.0 by January 1st, 2026
- [QTF-1204] A QHIN MUST update the RCE Directory Service with any new Participant and Subparticipant Initiating Nodes at least **two business days** prior to the Participant and Subparticipant commencing production activities.
 - V2.0 required 48 hours prior to prod activities

QTF 2.1 Updates

- [QTF-710] Initiating QHINs **MAY** direct a Query to a specific Responding Node in the XCPD [ITI55] Request by including the Responding Node's HomeCommunityId in the **receiver/device/asAgent/representedOrganization/id/@root** attribute
- [QTF-711] If the **receiver/device/asAgent/representedOrganization/id/@root** attribute is populated with the HomeCommunityId of a Responding Node, the Responding QHIN **MUST** respond with information from the Responding Node corresponding to that HomeCommunityId.

QTF 2.1 Updates

- [QTF-1513 – QTF-1519] (I)ACP Handling
 - New OIDS for consent document format
 - Required document-resource-id name syntax:
<DocumentEntry><><Repository><><HCID>
 - Responding Node SHOULD attempt to retrieve (I)ACP document via Document Query/Retrieve Workflow. If not retrieved, appropriate error MUST be returned

OID	Representation
urn:oid:2.16.840.1.113883.3.7204.1.1.1.2.1	(I)ACP Document contains access consent and is in scanned PDF format of a signed document
urn:oid:2.16.840.1.113883.3.7204.1.1.1.2.2	(I)ACP Document contains access consent and is in XACML format
urn:oid:2.16.840.1.113883.3.7204.1.1.1.2.3	(I)ACP Document contains access consent and is in HL7 FHIR® Consent Resource format
urn:oid:2.16.840.1.113883.3.7204.1.1.1.2.4	(I)ACP Document contains access consent and is in Kantara Consent Receipt format

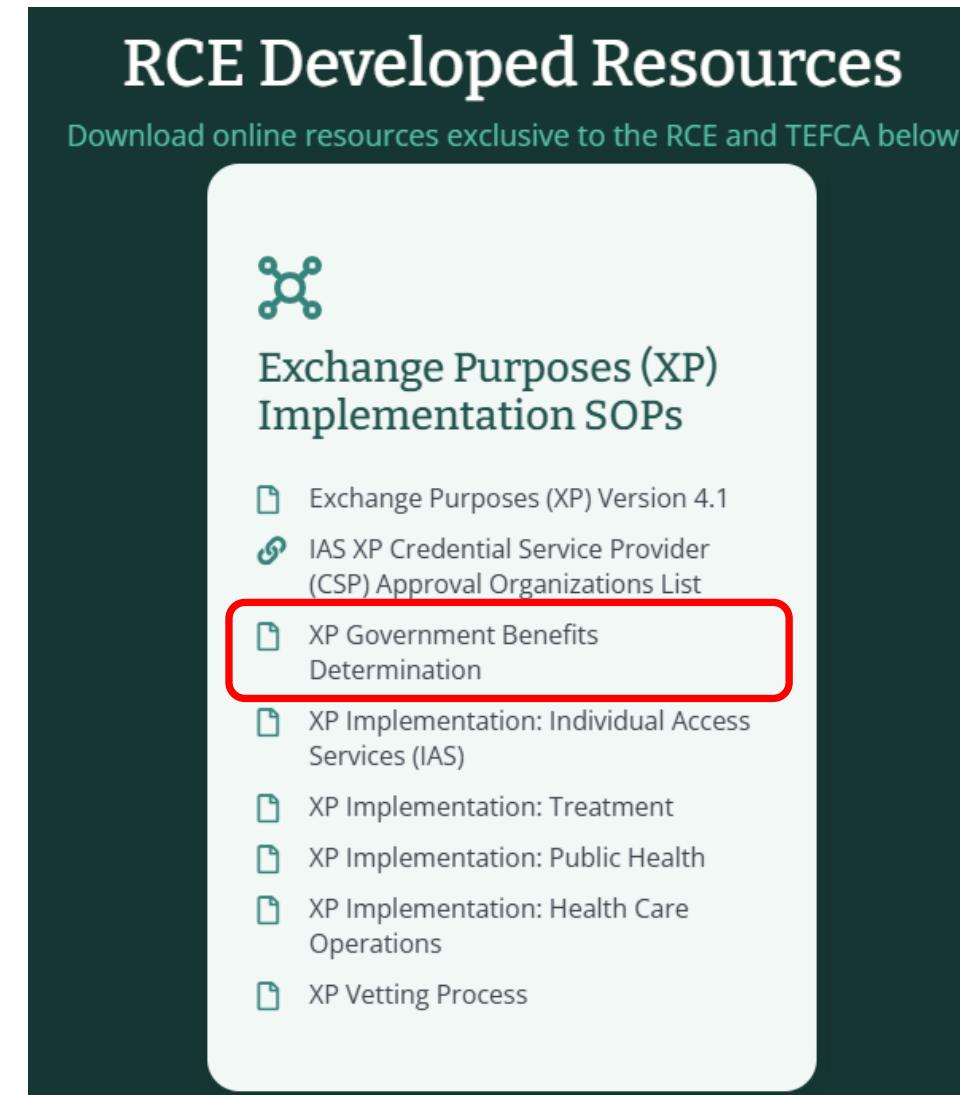
QTF 2.1 Updates

- [QTF-1301 – QTF-1303] Auditing
 - New auditing requirements for QHINs
 - QHINs must be able to export audit logs in a readable, schema-defined format that can be mapped to ATNA
 - Auditing requirements further specified by IHE transactions and relevant SOPs
- [QTF-1801] Performance Measures
 - Initiated transactions reported by Purpose of Use

Exchange Purpose: Government Benefits Determination SOP

RCE Developed Resources

Download online resources exclusive to the RCE and TEFCA below



-  Exchange Purposes (XP) Implementation SOPs
 -  Exchange Purposes (XP) Version 4.1
 -  IAS XP Credential Service Provider (CSP) Approval Organizations List
 -  **XP Government Benefits Determination**
 -  XP Implementation: Individual Access Services (IAS)
 -  XP Implementation: Treatment
 -  XP Implementation: Public Health
 -  XP Implementation: Health Care Operations
 -  XP Vetting Process

Government Benefits Determination

- New Purpose of Use codes!!
 - T-GOVDTRM
 - Government Benefits Determination
 - T-GOVDTRM-SSD
 - SSA Only
 - T-GOVDTRM-ACP
 - (I)ACP Retrieval

T-GOVDTRM

- Used by all non-SSA entities for determination of government benefits, as permitted by Applicable Law
- Responding Nodes **SHOULD** Respond to Queries for T-GOVDTRM in accordance with Framework Agreements and Applicable Law
- Supported Transactions:
 - QHIN Message Delivery
 - QHIN Query
 - FHIR Push
 - FHIR Query
 - FHIR Response

T-GOVDTRM-SSD

- Used by the SSA and its delegates for data collection to support Social Security Disability Insurance and Supplemental Security Income determinations
- SSA MUST coordinate with Responding Nodes prior to sending queries in order to determine readiness. Responding Node MUST respond after pre-coordination
- SSA MUST use the new direct query patient discovery flow
 - QTF Patient Discovery Alternate Flow 1 [QTF V2.1 p 11]
- SSA MUST assert an (I)ACP
 - QTF Patient Discovery Alternate Flow 2 [QTF V2.1 p 12]
- Supported Transactions:
 - QHIN Query

T-GOVDTRM-ACP

- Responding Node **MUST** retrieve and store (I)ACP
 - QTF Patient Discovery Alternate Flow 2 [QTF V2.1 p 12]
- Supported Transactions:
 - QHIN Query

Resources

- RCE Developed Resources
 - <https://rce.sequoiaproject.org/tefca-and-rce-resources/>
- QTF Version 2.1
 - <https://rce.sequoiaproject.org/wp-content/uploads/2025/12/QTF-2.1-Draft-12.04.25-clean1.pdf>
- XP Government Benefits Determination SOP
 - <https://rce.sequoiaproject.org/wp-content/uploads/2025/12/Government-Benefits-Determination-XP-SOP-v1.0.pdf>
- Social Security Administration Electronic Health Document IG for a Health Participant, Version 5.0
 - https://github.com/SSAgov/HealthIT/blob/master/SSA_Electronic_Health_Document_Implementation_Guide.pdf

OPP Updates



Purpose of Use Code – “NOTIFICATION”

- The CC approved a Use Case for “Encounter Alerts (Notification)” in 2016 that would allow HIEs to share ADTs under the HL7 v2 specification
- Manifest MedEx and CRISP have been working with eHealth Exchange to implement this Use Case, and the question arose of how to handle the PoU string.
- The technical specification does not establish or require a particular PoU value for this Use Case
- eHealth Exchange will not be receiving ADT notifications directly from providers and will not be impacting ADT revenue HIEs collect.

Rationale for New PoU Code

- ADTs are shared in support of a variety of Permitted Purposes, and there is currently no standard Purpose of Use code that appropriately captures this, nor is leaving this value blank a workable/scalable solution.
- In surveying how this has been implemented in California and New York, we found that CA uses a non-standard PoU, and NY imposes strict limitations on participation in its alerting use case that are not consistent with the eHealth Exchange Use Case.

OPP#18 - Health Notifications Purpose of Use

- Approved
 - The new OPP is intended to supplement the HL7 v2 standards currently referenced in the Use Case Performance & Service Specifications
 - Notice was sent via email to Participants providing a 30-day objection period
 - OPP#18 will be published to the eHealth Exchange website



OPP #17 - Sub-Participant Identification to Support Transparency & Trust



Requirement #1: Specifying the Originating Entity in Each Request for Data

- Identify the participant ultimately responsible for requesting data using the SAML **organization-Id** attribute.

Requirement #2: Populating the eHealth Exchange Directory with Sub-Participants

- Populate the directory with sub-participants to the extent practical to reflect a participant's constituency that requests data. (identify entities that contribute to patient data)

***If your organization is not able to meet these requirements or will not be able to upgrade to the Epic Feb 25 release (or later) and complete the necessary build steps by the end of this calendar year, you must request an extension to OPP#17 with a plan to come into compliance by December 15, 2025.**

National Member Match

Use Case

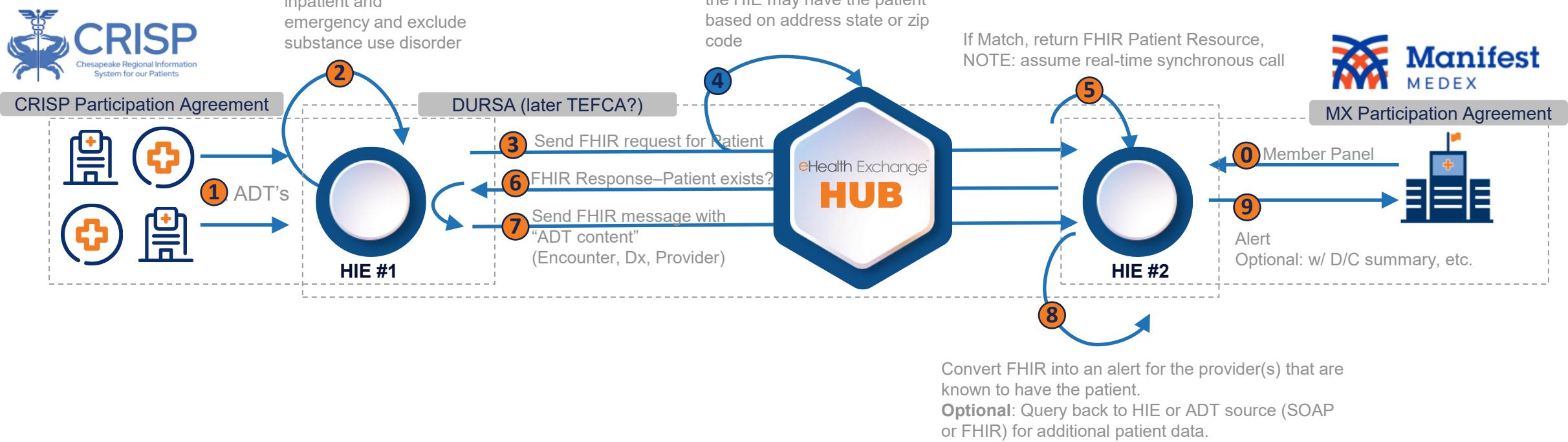
Update – now live in production!



National Member Matching Service

Use Case

As a Payer (or a Provider with value-based care contracts), I want to be triggered about all member encounters (from anywhere in the U.S.), to then obtain episodic clinical data to update priorities for care management teams, update gaps-in-care, and update risk stratification.



Marketing Update



Annual Meeting Content Coming Soon!

Whether you joined us in Nashville or followed along from afar, we're excited to share all

2025 Annual Meeting content will be made available to the public:

- full session recordings
- downloadable presentations
- photo gallery capturing the day

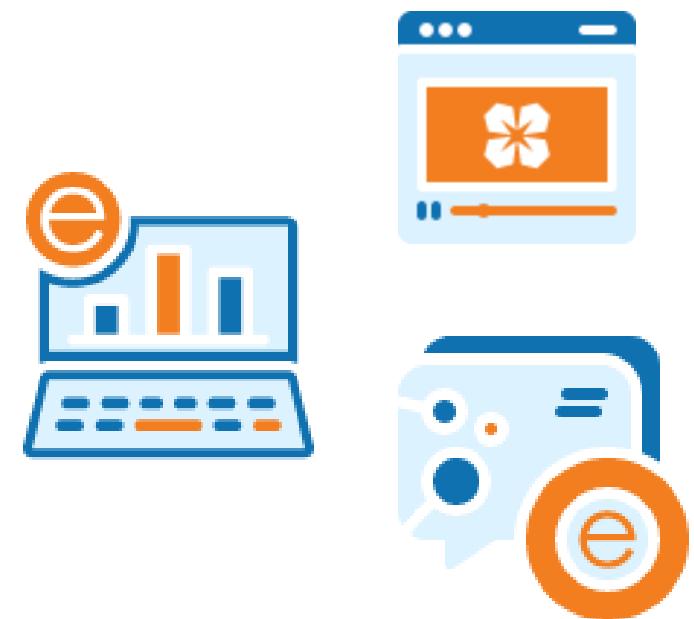
Thank you again for being part of this year's event. We hope these materials continue to spark ideas, conversations, and progress long after Nashville.



2026 Events and Webinars

We are working to finalize the webinar and event schedule for 2026.

You will be preregistered for the All Participant call and an email will be sent announcing the schedule.





eHealth Exchange

ANNUAL MEETING

LOST PINES RESORT & SPA

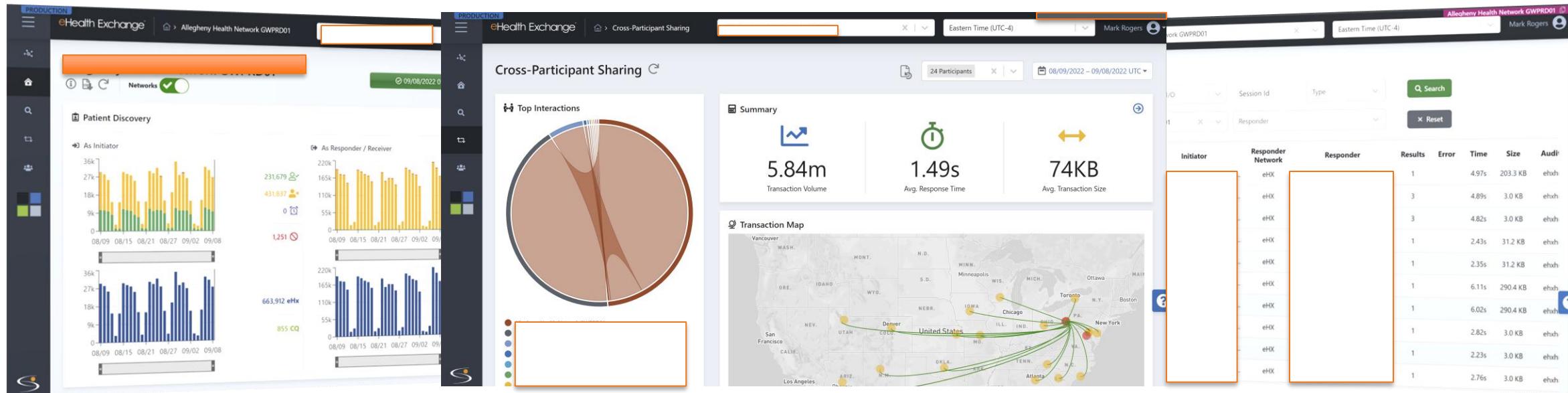
Save the Date!

October 27, 2026

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/>



ehealthexchange.org