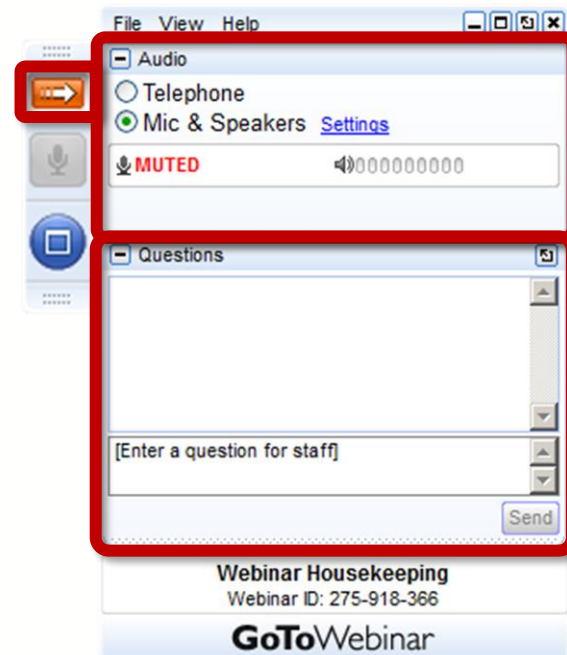June 16th, 2022

eHealth Exchange™

All Participant Call

How Do I Participate?

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

Problems or Questions? Contact Dawn Van Dyke

dvandyke@ehealthexchange.org or 703.864.4062

eHealth Exchange

Today's Topics

1. New Participants	Mark Rogers
2. FDA Pilot	Mike McCune
3. QHIN Updates	Kathryn Bingman
4. eCR Update	Jay Johnstone
5. New Policy (OPP 16)	Pat Russell
6. Coordinating Committee Elections	Pat Russell
7. Contacts	Mark Rogers
8. Q&A	Everyone

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New Participants

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Congratulations to our newest Participants!

- NCH Healthcare System, Inc
- Pluto Health
- Brown & Toland Physicians

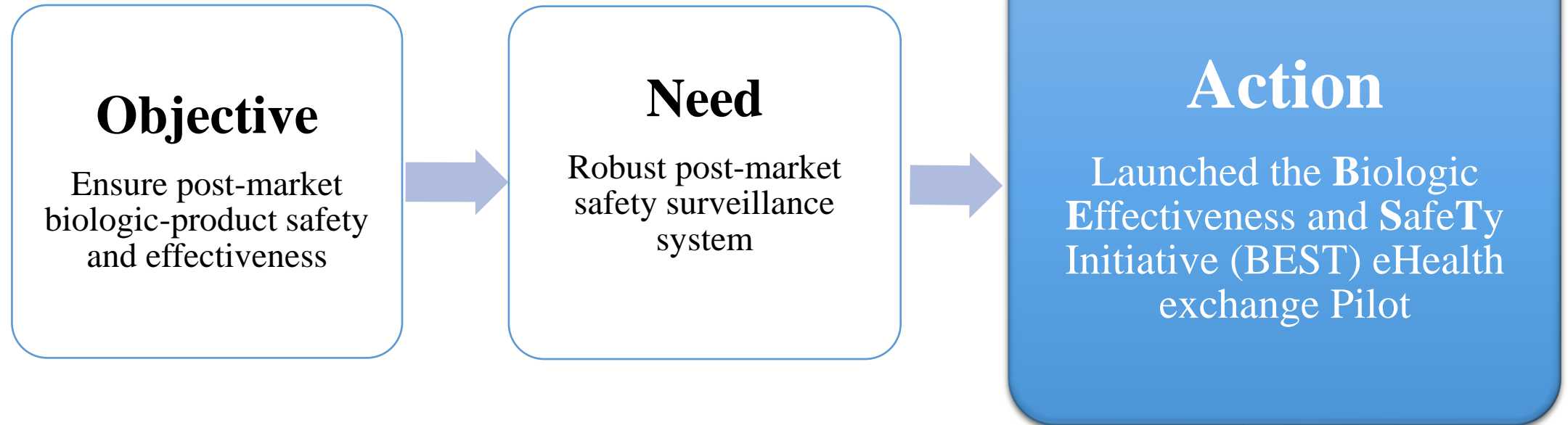Committed to Improving Patient Care via Data Exchange

Participation Request

FDA Pilot: Adverse Event Exchange via FHIR

2022 Roadmap

eHealth Exchange™

CBER OBE Mission

Objective

Ensure post-market biologic-product safety and effectiveness

Need

Robust post-market safety surveillance system

Action

Launched the **B**iologic **E**ffectiveness and **S**afe**T**y Initiative (BEST) eHealth exchange Pilot

CBER Regulated Products

- Vaccines (preventative and therapeutic)
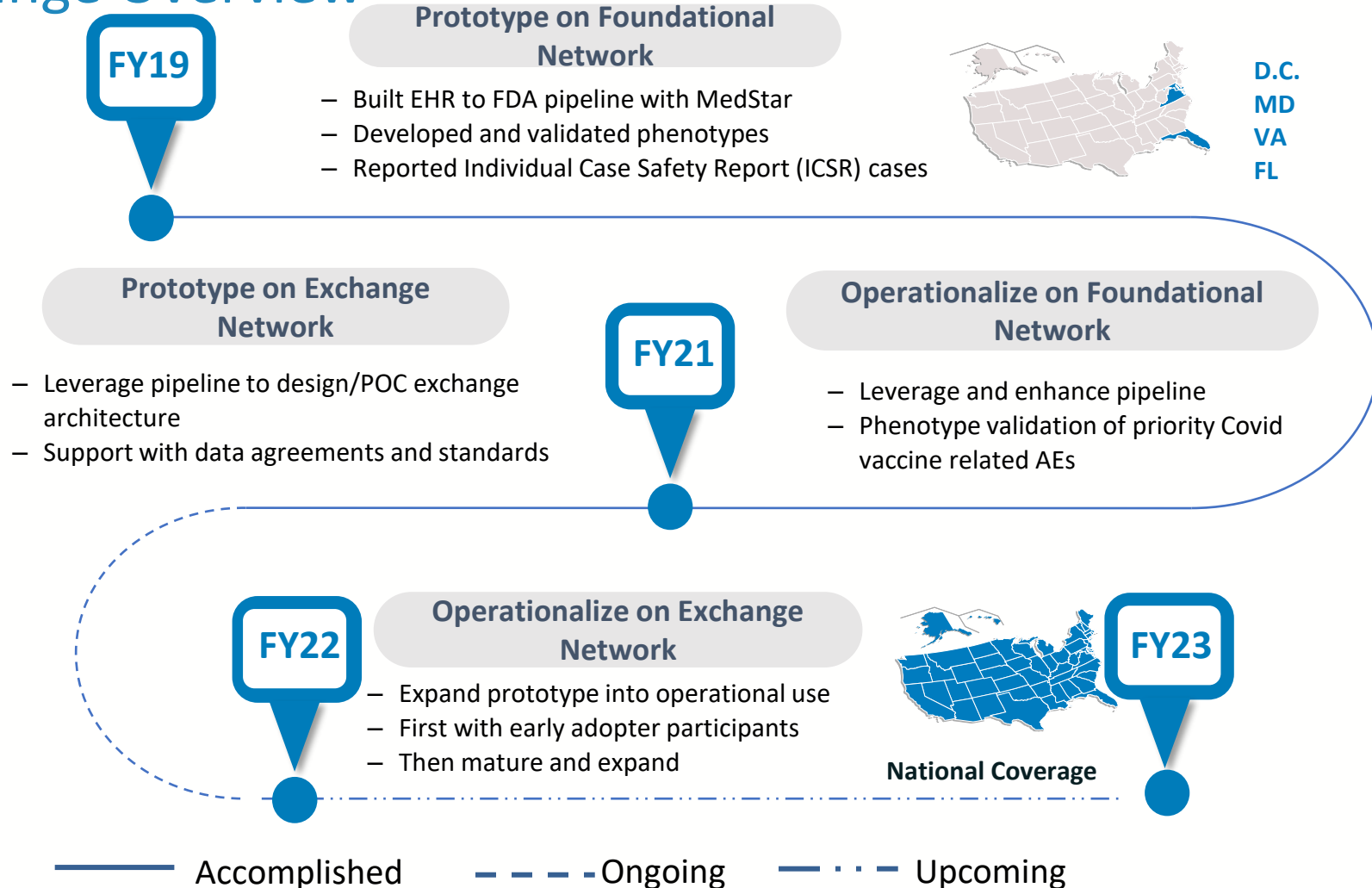- Blood (components and derived)
- Human Tissues and Cellular Products
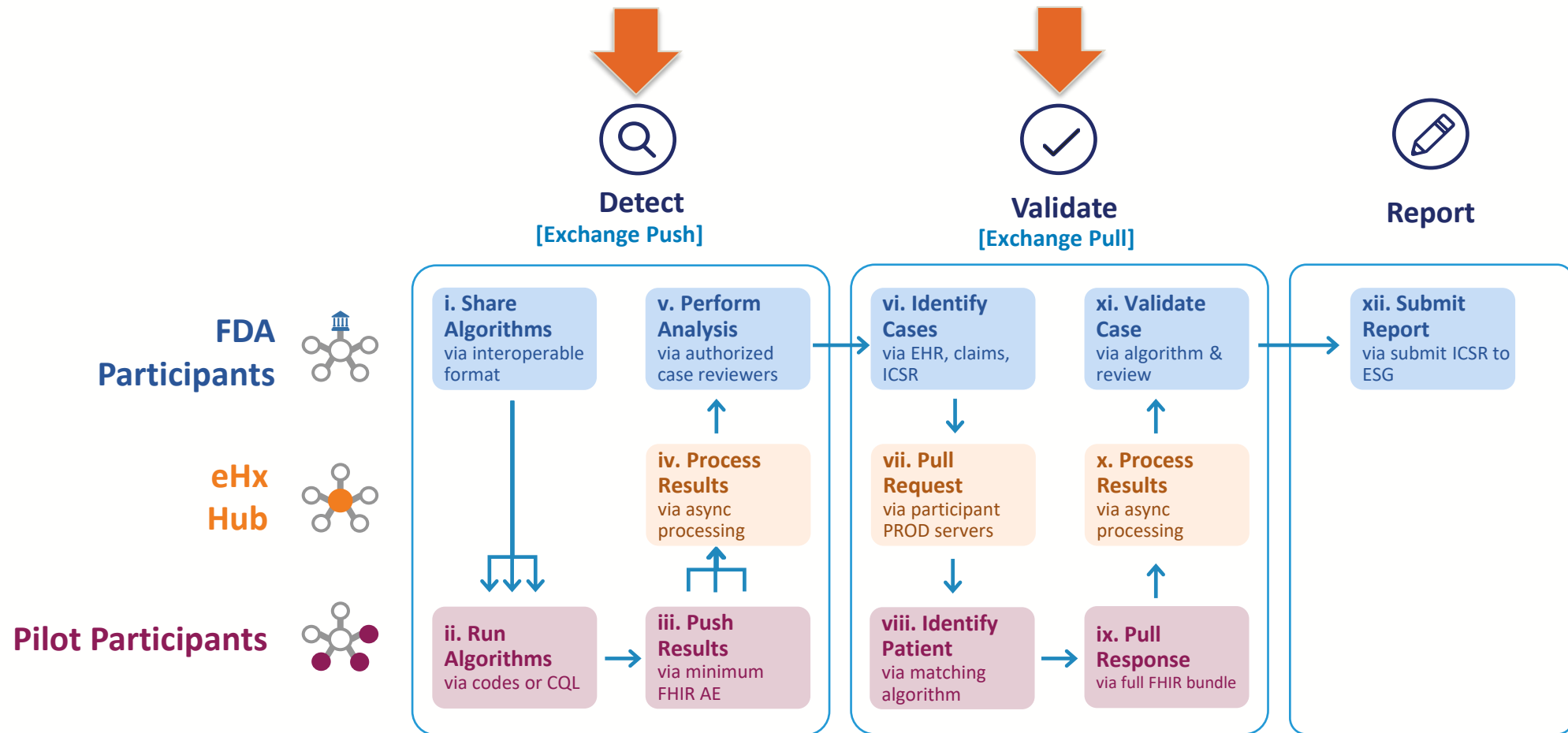- Gene Therapies
- Xenotransplantation Products

CBER = Center for Biologics Evaluation and Research / OBE = Office of Biostatistics and Epidemiology

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FDA Exchange Overview

FY19

Prototype on Foundational Network

- Built EHR to FDA pipeline with MedStar
- Developed and validated phenotypes
- Reported Individual Case Safety Report (ICSR) cases

D.C.
MD
VA
FL

Prototype on Exchange Network

- Leverage pipeline to design/POC exchange architecture
- Support with data agreements and standards

FY21

Operationalize on Foundational Network

- Leverage and enhance pipeline
- Phenotype validation of priority Covid vaccine related AEs

FY22

Operationalize on Exchange Network

- Expand prototype into operational use
- First with early adopter participants
- Then mature and expand

FY23

National Coverage

—— Accomplished   - - - -Ongoing   - · - · - Upcoming

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FDA- BEST Exchange Operational Architecture

FDA BEST Platform
Receives and requests FHIR Bundles from eHealth Exchange

BEST Applications
Presents Cases for Review, ICSRs Developed for Valid Cases
Delivers ICSR to FDA

FDA
Receives ICSR
Reviews Case

eHealth Exchange
Delivers FHIR Bundles to FDA BEST Platform
Receives FDA Requests
Retrieves Patient Data FHIR Bundles from eHealth Exchange Members

Vaccine Administered
Vaccine Administered and Recorded in eHealth Exchange Member's EHR

Adverse Event
Potential Adverse Event recorded by eHealth Exchange Member

Routes to eHealth Exchange

2022 Pilot will focus on both detection (Push) and validation (Pull) use cases

FDA is seeking participants for either detection and validation (i-ix), or validation only (vi-ix)

Detect
[Exchange Push]

Validate
[Exchange Pull]

Report

FDA Participants

eHx Hub

Pilot Participants

	Detect [Exchange Push]		Validate [Exchange Pull]		Report
FDA Participants	**i. Share Algorithms** via interoperable format	**v. Perform Analysis** via authorized case reviewers	**vi. Identify Cases** via EHR, claims, ICSR	**xi. Validate Case** via algorithm & review	**xii. Submit Report** via submit ICSR to ESG
eHx Hub		**iv. Process Results** via async processing	**vii. Pull Request** via participant PROD servers	**x. Process Results** via async processing	
Pilot Participants	**ii. Run Algorithms** via codes or CQL	**iii. Push Results** via minimum FHIR AE	**viii. Identify Patient** via matching algorithm	**ix. Pull Response** via full FHIR bundle	

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FDA- BEST Exchange Current and Potential Participants

Feasibility Analysis | **Onboarding** | **Operational**

Introduction to the Pilot

Assessment and fitness for the Pilot

Technical overview to prepare for pilot onboarding

Kick-off call scheduled

Ready for testing

UNC HEALTH

Atrium Health

COVENANT HealthCare

MAYO CLINIC

Stanford HEALTH CARE

HSX

CRISP

Cerner

Memorial Healthcare System

MetroHealth

Veterans Health Administration

Cedars Sinai

eHealth Exchange

Ask: How and why you should participate!

Why participate?

- Support impactful ongoing public health vaccine safety efforts
- Automation of current manual process of reporting
- Authorship on an innovative paper

Interested in being a participant?

- Reach out to Mike McCune (mmccune@ehealthexchange.org)
- Complete a brief survey to help determine suitability to meet pilot requirements (such as having a *FHIR R4 endpoint available)*

eHealth Exchange

Glossary of Terms

AE: Adverse event

eHx: eHealth Exchange

CBER: Center for Biologics Evaluation and Research

ESG: Electronic Submission Gateway

EHR: Electronic health record

FDA: U.S. Food and Drug Administration

FHIR: Fast Healthcare Interoperability Resources

ICSR: Individual Case Safety Report

OBE: Office of Biostatistics and Epidemiology

FDA Pilot Questions & Answers

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QHIN Updates

What Is the ONC TEFCA?
The [Trusted Exchange Framework and Common Agreement](#) outlines a common set of principles, terms, and conditions to support the development of a **Common Agreement** that would help enable nationwide exchange of electronic health information (EHI) across disparate [health information networks](#) (HINs).

What Is a QHIN?
A QHIN (Qualified Health Information Network) is a Health Information Network that has been determined by the RCE (Recognized Coordinating Entity) to be qualified.

What Is the QTF?
The QTF (QHIN Technical Framework) supports the core QHIN-to-QHIN exchange by specifying the functional and technical requirements that each QHIN must fulfill under the Common Agreement and to meet the requirements of the Standard Operating Procedures (SOPs)

Permitted Exchange Purposes

- Treatment
- Payment
- Health Care Operations
- Public Health
- Government Benefits Determination
- Individual Access Services

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TEFCA Goals, Benefits & Timeline

GOAL 1
Establish a universal policy and technical floor for nationwide interoperability

GOAL 2
Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value

GOAL 3
Enable individuals to gather their health care information

Individuals
Use an app to access their own records from TEFCA-connected sources located across the nation.

Providers and Health Systems
Improve care, coordination and population health by obtaining a more informed picture of care across settings through fewer connection points.

Public Health
Improve quality, reduce costs, and expand public health interoperability.

Payers
Get and share data needed for care management, value-based care, payer-to-payer exchange, etc.

Health Information Networks
Enhance the value of network participation and lower the cost of connecting with other networks.

Technology Developers
Provide a scalable policy and technical ecosystem for innovation.

Researchers (Future)
Improve quality, reduce costs, and expand participation in clinical research.

For more detail on the benefits of TEFCA for stakeholders, see factsheets at: https://rce.sequoiaproject.org/tefca-and-rce-resources/

2021
- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Q2 of 2022
- QHINs begin signing Common Agreement and applying for designation

2023
- Establish Governing Council
- Follow change management process to iterate Common Agreement, SOPs, and QTF, including to support FHIR-based exchange

| 2021 | 2022 – Q1 | Q2 | Q3 | Q4 | 2023 |

Q1 of 2022
- Publish Common Agreement Version 1
- Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap
- Initiate work to enable FHIR-based exchange
- Public education and engagement
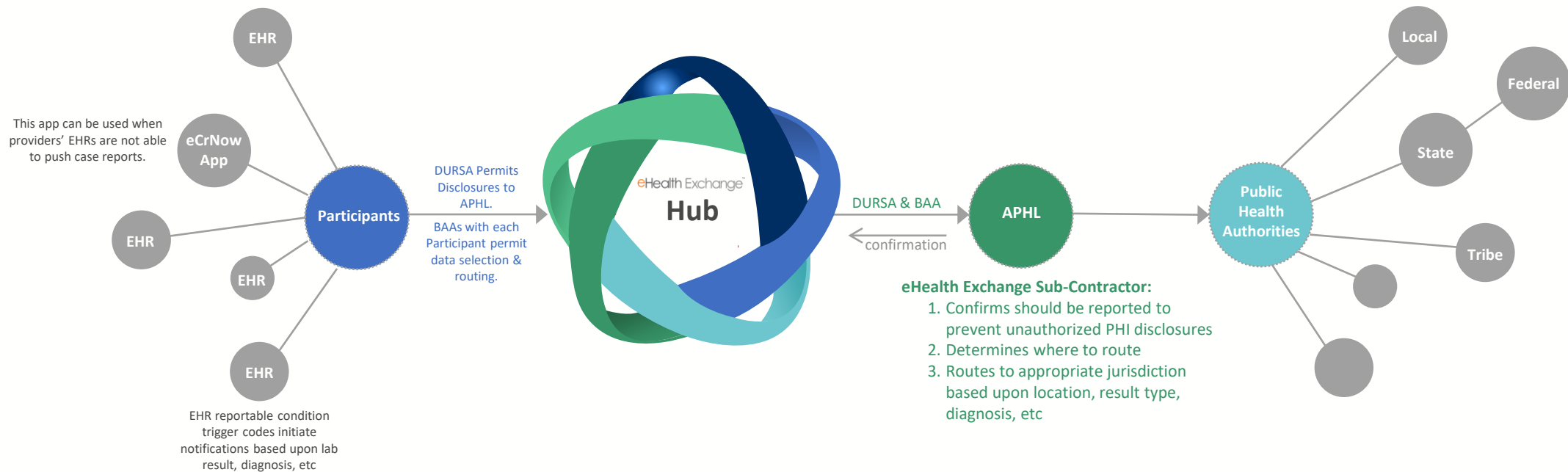
Q3 and Q4 of 2022
- Onboarding of initial QHINs
- Additional QHIN applications processed
- RCE establishes Transitional Council
- RCE begins designating QHINs to share data
- Prepare for TEFCA FHIR exchange pilots

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eCR Update

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Pushing Electronic Case Reports (eCR) is **Live**!

This app can be used when providers' EHRs are not able to push case reports.

EHR

eCrNow App

EHR

EHR

EHR

Participants

EHR reportable condition trigger codes initiate notifications based upon lab result, diagnosis, etc

DURSA Permits Disclosures to APHL.

BAAs with each Participant permit data selection & routing.

Hub
eHealth Exchange

DURSA & BAA

confirmation

APHL

eHealth Exchange Sub-Contractor:
1. Confirms should be reported to prevent unauthorized PHI disclosures
2. Determines where to route
3. Routes to appropriate jurisdiction based upon location, result type, diagnosis, etc

Public Health Authorities

Local

Federal

State

Tribe

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eCR is LIVE!

eCR is live at no additional cost to your organization. To onboard, follow these steps:

1. Confirm your gateway supports ITI-41 & ITI-80.

2. Confirm you have completed Hub Initiator Testing.

3. Notify administrator@ehealthexchange.org your organization wants to push electronic case reports to APHL (Association of Public Health Laboratories).

4. eHealth Exchange will provide an introduction to the AIMS team, as well as an onboarding checklist of about 7 questions.

5. The checklist will ask for your Push Notification Endpoints (aka RR endpoints) for both Val and PRD, as well as your IP addresses for both VAL and PRD.

6. eCR testing is required to be conducted in a VAL environment, so we will need to confirm that your validation certificate is installed and not expired.

7. APHL/AIMS will also provide some needed documentation on their side. Your organization will be asked to join a pre-scheduled cohort call to discuss progress, troubleshooting, and timelines.

8. Once testing is complete in VAL, the functionality will be activated in PRD on a scheduled "go-live" date.

New OPP

Addition of OPP#16 – Participants Must Use Hub for All Transactions

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New OPP#16 - Participants Must Use Hub for All Transactions

- Went into effect May 1, 2022 after the 30-day objection period
- Requires Participants to use the Hub for all Transactions with other eHealth Exchange Participants for initiating and responding to queries and to discontinue the use of point-point connections with other Participants is 12/31/2022.
- Benefits:
  - ✓ Reduction of Participants' cost and effort associated with creating and maintaining point-to-point connections.
  - ✓ Provides Participants with additional capabilities in the Hub such as fan-out requests, operation monitoring, and message transformations.
- Exceptions can be submitted for Coordinating Committee approval
  - To request the exception form, contact Pat Russell by email at prussell@ehealthexchange.org
  - Requests are reviewed and approved on the monthly Coordinating Committee call

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Coordinating Committee Elections

2022 Coordinating Committee (CC) Seats

	Representative	Term Date
HIO	Mike Dittemore, RN	9/30/2022
	John Kansky	9/30/2023
	Pam Matthews	9/30/2024
IDN	Patti Cuartas, PA	9/30/2023
	Matt Eisenberg, MD	9/30/2022
	Ryan Stewart	9/30/2023
Other	Paul Matthews	9/30/2022
	Open	9/30/2024
	Jarrod Pearson	9/30/2024

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2022 Coordinating Committee (CC) Election Timeline

- Nominating Committee – Ryan Stewart, Dignity Health; John Kansky, IHIE; Pam Matthews, eTHIN; Hussein Ezzeldin, FDA
- Announce elections during monthly All Participant
- July 15 - Email Participant notice for elections
- July 18 – August 5 - Open for applications
- August 8 - 12 - Nominating Committee Review Applications
- August 12 - Nominating Committee finalizes slate of nominees
- August 16 - Coordinating Committee approves slate of nominees
- August 22-26 - Participants Vote
- August 29 - Sept 2 - Time for a runoff if needed
- Sept 15 - Notice to Participants on monthly All Participant Call
- Sept 12 – October 1, Orientation
- Sept 20 - New Coordinating Committee Members shadow CC Call
- October 18- First New CC Member meeting

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Contacts

Changing and New Contacts

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Contacts for Your Organization

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

In January we started a process to reach out yearly to request confirmation of the contacts we have listed and any updates. Some of you may have received a request.

Thank you for returning your updated contact list to us! It is appreciated.

- 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.

Contacts
All Contacts ▾

Import | Add to Campaign | Get Selected

2 items selected

Search this list...

		Name ↑	Account Name	Title	Phone	Email	Con...	Created Date	
1	✓	Alan Johnson	Get Cloudy	Sales Manager			zero	24/09/2019 17:04	▾
2		Alice Black		Botanist	555-555-5555	blackalice@example.com	zero	11/12/2018 22:23	▾
3	✓	Amanda Garcia	Garcia Inc	CEO			zero	15/09/2018 11:15	▾
4		Andy Young	Dickenson plc	SVP, Operations	(785) 241-6200	a_young@dickenson.com	zero	01/02/2016 17:05	▾
5		Arthur Song	United Oil & Gas Corp.	CEO	(212) 842-5500	asong@uog.com	zero	01/02/2016 17:05	▾

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Please Engage!

We'd love to hear from you.

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2022 ANNUAL MEETING

SAVE THE DATE

THURSDAY
DECEMBER 15TH

See https://ehealthexchange.org/event/2022-annual-meeting
for more information

Technical Work Group

Thursdays 4-5pm Eastern: email administrator@ehealthexchange.org for an invite

Typical Topics:

1. Technical Specification Creation
   a) Push notifications
   b) Populating directory with hospital locations
   c) Broadcast query
   d) FHIR Directory
   e) Consumer access
   f) Carequality harmonization
   g) Controlled Unclassified Information (CUI) Marking
2. Testing
3. Hub Updates
4. Capacity planning [Final Thursday each month]

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How might I obtain additional information?

How	When	Where
Visit eHealth Exchange Website	Any time	https://ehealthexchange.org
Monthly Participant Web Meetings	3rd Thursday of Each Month at 1 pm ET	https://ehealthexchange.org/events
Weekly Technical Workgroup	Thursdays 4-5 ET	https://ehealthexchange.org/events
Email	Any time if you have a specific question	administrator@ehealthexchange.org
Annual Meeting	December 15, 2022	On Site Washington, D.C.

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How might I obtain assistance?

How	Who	Where
Certificates	Direct Trust Support	support@directtrust.zohodesk.com
Hub and Hub Dashboard Assistance	Hub Service Desk	servicedesk@hub.ehealthexchange.org
Directory Assistance, setup, changes	Tech Support	techsupport@ehealthexchange.org
Testing Questions	Testing Team	testing@ehealthexchange.org
Questions about DURSA/OPP's	Administrator	administrator@ehealthexchange.org

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Questions & Answers

Please e-mail questions or concerns to administrator@ehealthexchange.org

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