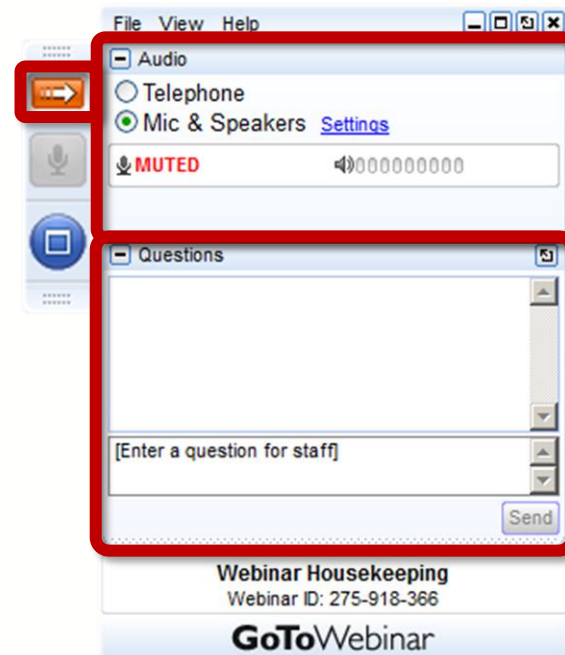


February 17, 2022

eHealth ExchangeTM

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

Today's Topics

| | |
|---|---------------|
| 1. New Participants | Mark Rogers |
| 2. FDA Pilot | Mike McCune |
| 3. FHIR Roadmap Highlights | Mike McCune |
| 4. Content Validation & Testing Innovations | Didi Davis |
| 5. FHIR R4 and Directory Update | Mike McCune |
| 6. eCR Update | Jay Johnstone |
| 7. Changes to Policy | Pat Russell |
| 8. Contacts | Pat Russell |
| 9. Q&A | Everyone |



New Participants

eHealth ExchangeTM

Congratulations to our newest Participants!

- Upstate University Medical Associates at Syracuse, Inc
- Lakeland Regional Health Medical Center



Committed to Improving Patient Care via Data Exchange

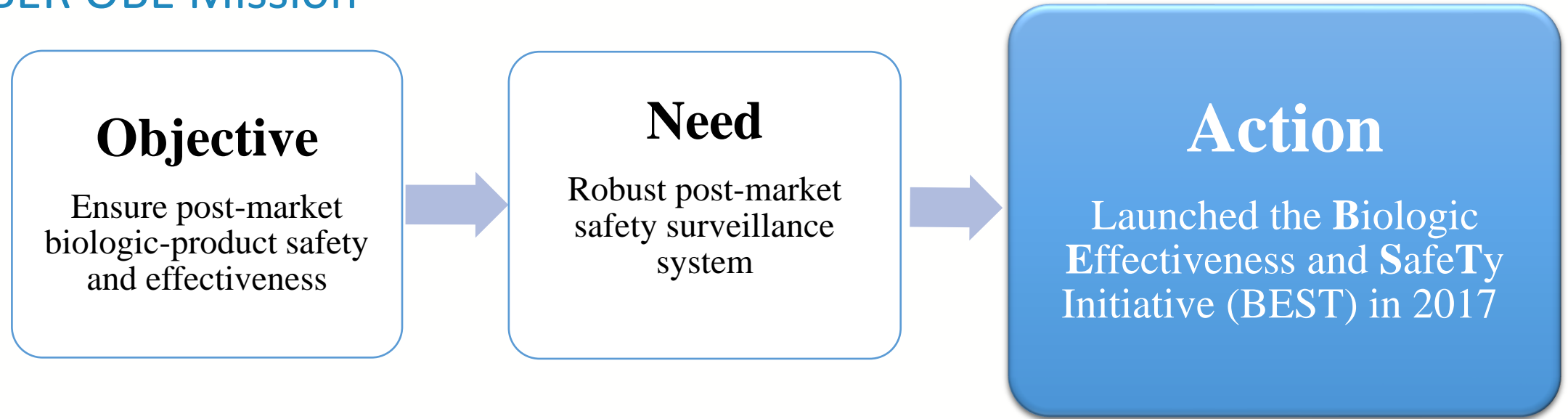


Participation Request

FDA Pilot: Adverse Event Exchange via FHIR 2022 Roadmap

eHealth ExchangeTM

CBER OBE Mission



CBER Regulated Products



Vaccines (preventative and therapeutic)



Blood (components and derived)



Human Tissues and Cellular Products



Gene Therapies



Xenotransplantation Products

FDA BEST Initiative Objective

The objective of the **B**iologicals **E**ffectiveness and **S**afe**Ty** (BEST) Initiative is to ensure post-authorization biologic-product safety and effectiveness through active surveillance

Exchange Pilot Objective

To enable more robust monitoring of post-authorization adverse events (AE) while minimizing the burden on providers through an exchange-based FHIR infrastructure.

Regulated Products

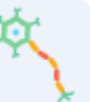
Vaccines (preventative and therapeutic)



Blood (components and derived)



Human Tissues and Cellular Products



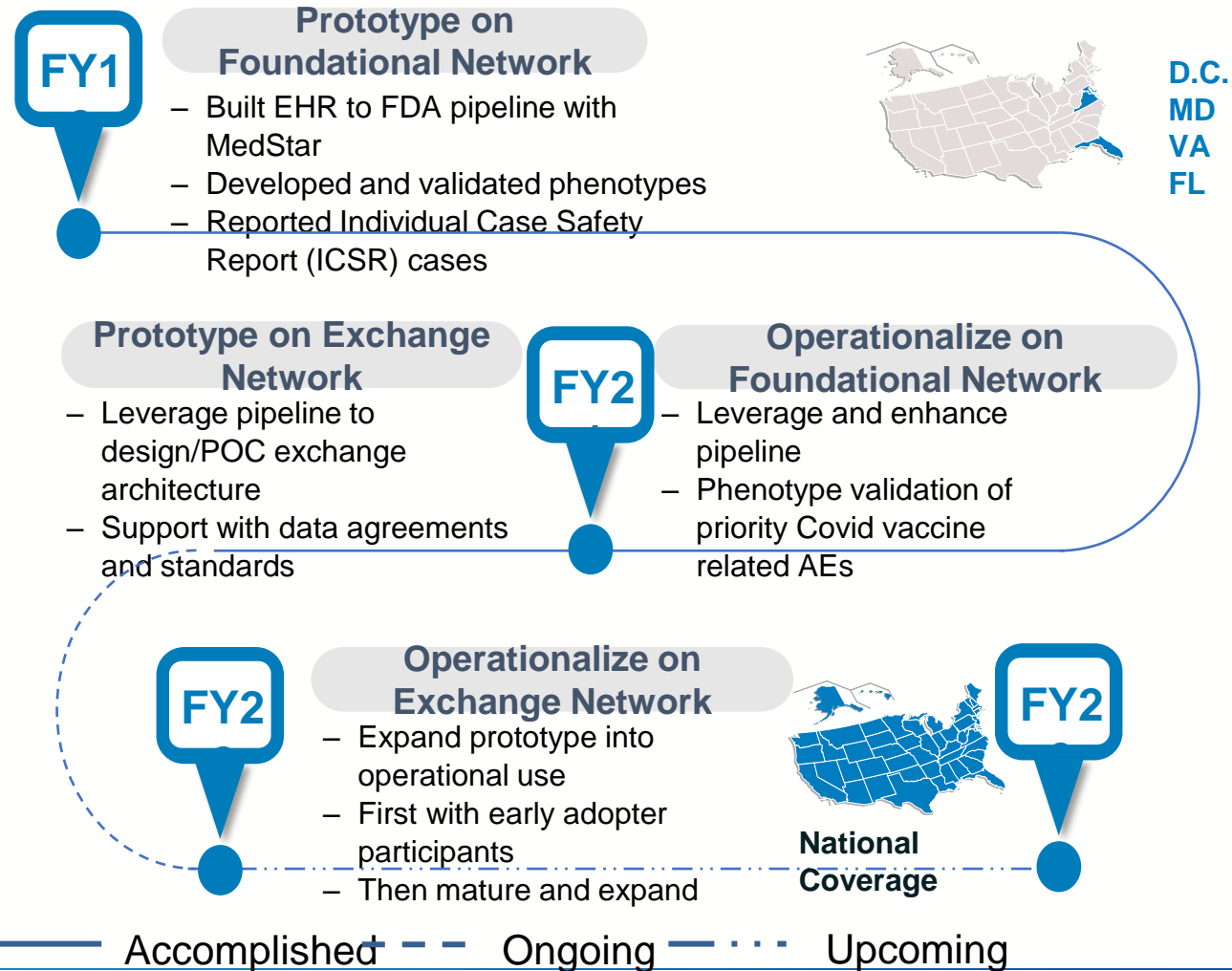
Gene Therapies



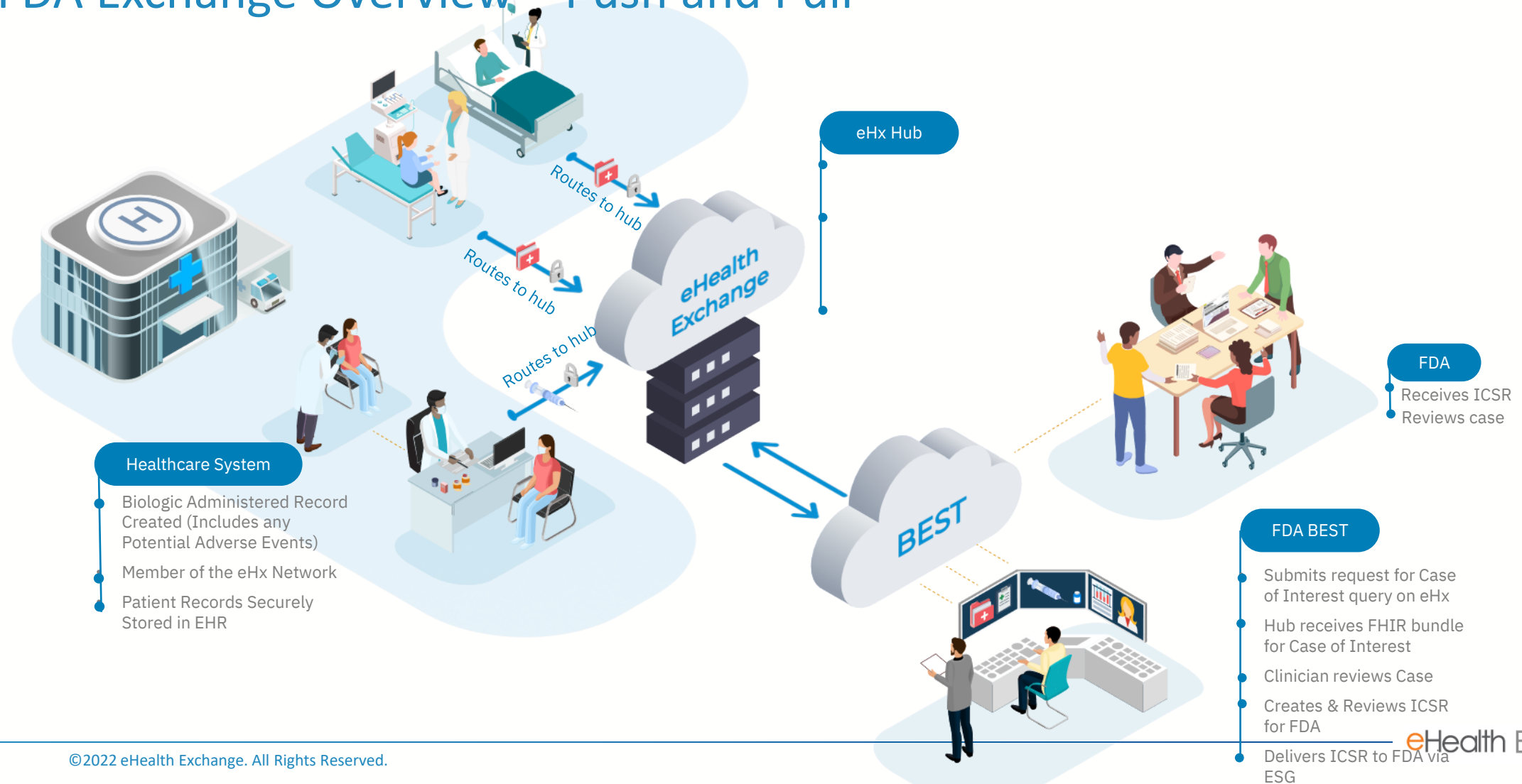
Xenotransplantation Products



FDA Exchange Overview

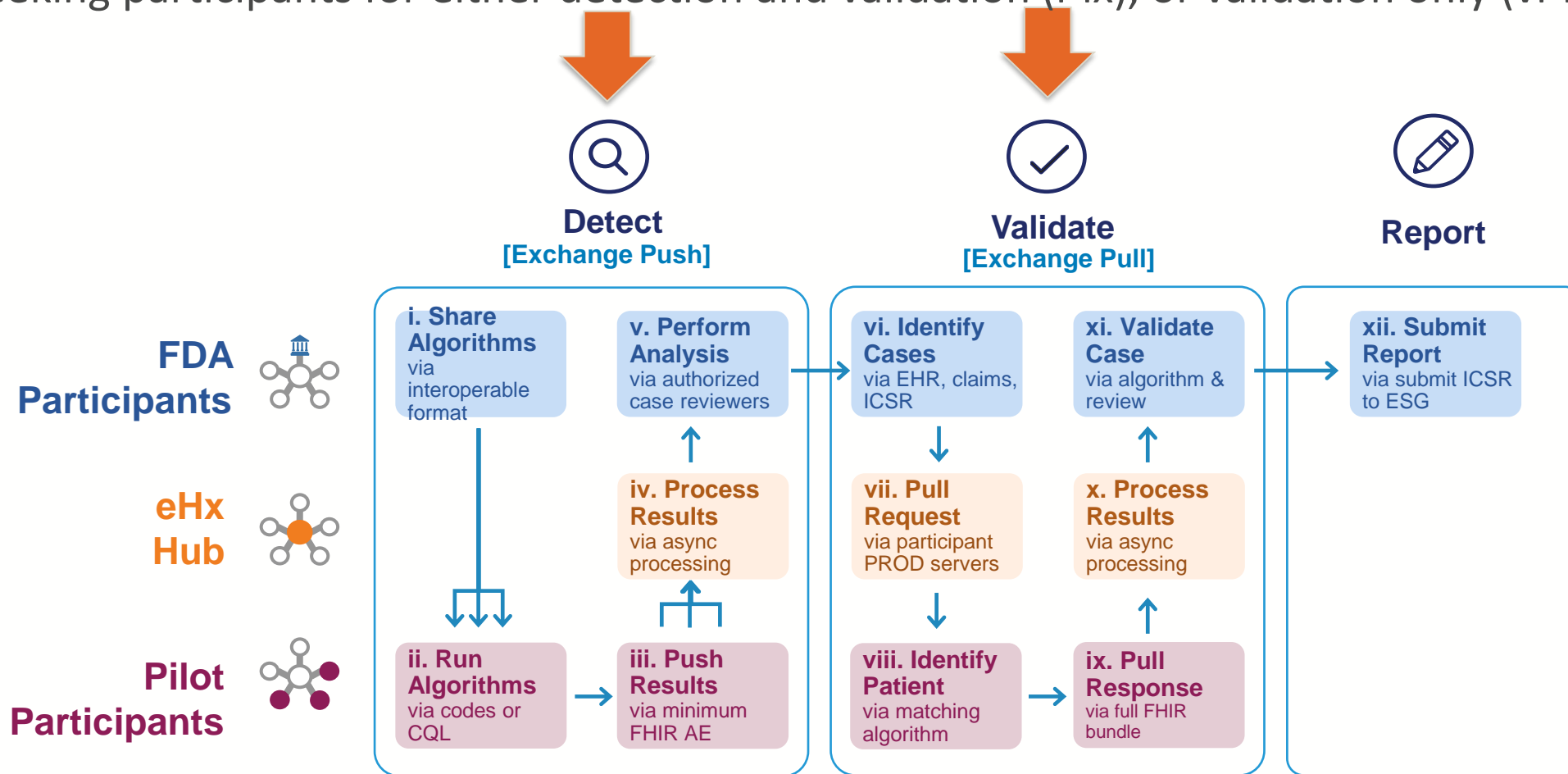


FDA Exchange Overview – Push and Pull

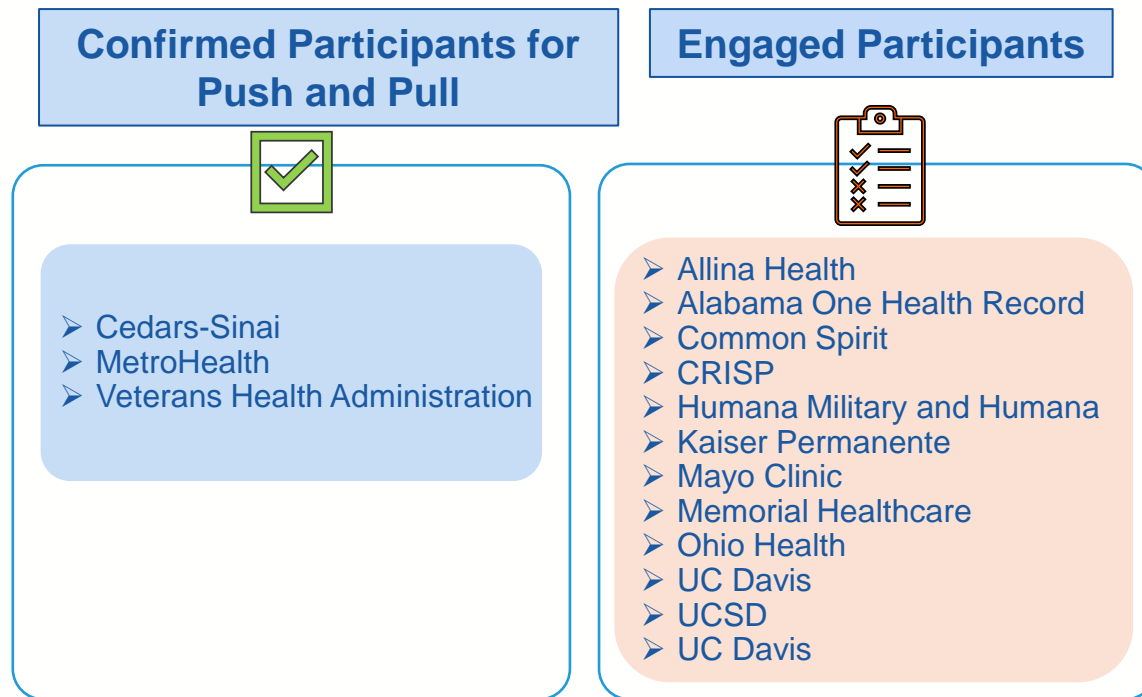


2022 Pilot will focus on both detection (Push) and validation (Pull) use cases

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



Pilot Participation Status-Participants



Participation recruitment is in progress

- Participants are being assessed for the Push or Pull
- In discussion with potential participants for the supports and resources needed for the Pilot participation
- Plan to complete the recruitment for the Pull use case soon
- Please reach out or complete the survey to express interest in the Pilot: [Survey](#)

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
- Financial incentive(s)

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*)

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



FHIR Roadmap Highlights

eHealth ExchangeTM

2022 FHIR Roadmap Highlights (Q1-Q2)*



FHIR Directory

Upgrade from Argonaut Project FHIR STU 3 to FHIR R4 so EHRs and HIEs can better import participants' connectivity data



FHIR Proxy

Hub enhancement to support FHIR R4 interactions between Participants



FDA Best Exchange

Adverse Event reporting using FHIR interactions, with custom fan-out using a combination of synchronous and asynchronous interactions.

*Highlights only (not exhaustive list)

*Market disruptions may change these priorities




Content Testing Updates

eHealth ExchangeTM

Participant Status – Content Testing Update

Out of 280 Participants required to pass Content Testing by May 1, 2021:

- **96% or 270** Participants are @ Content Validated Status as of February 3, 2022
 - Increase from 269 in December 2021
- Content validated logos being added in real time to Participant listing on eHealth Exchange website:
 - <https://ehealthexchange.org/participants/> 
- **13** technologies leveraged
 - Audacious Inquiry, Cerner CEP, CONNECT, Diameter Health, Epic, Guardian, Health Catalyst, Intersystems, Lightbeam, Mirth, Nextgen, Orion, SSI, Zen Health
- 10 Waivers/Extensions Requested and Approved Remaining
 - Content Not Text was added to all remaining Participants

NOTES:

Content Not Validated

Breakdown of Documents Tested by Meaningful Use Version & Standard

- 23,226 Documents Tested as of February 3, 2022
 - 82% Failing
 - 18% Passing
- Breakdown of Documents Tested by Validator Version
 - 56% or 13,063 tested against the Meaningful Use 2015 Edition/HL7 C-CDA R2.1
 - 13% or 2,991 tested against the Meaningful Use 2014 Edition/HL7 C-CDA R1.1
 - 26% or 6,057 tested against the Meaningful Use 2011 Edition/HL7 C-32
 - 5% or 1,051 tested against the CDA R2 validator
 - <1% (.002) or 64 tested against the USCDI V1 validator



Testing Innovations

eHealth ExchangeTM

Testing Innovations Planned for 2022

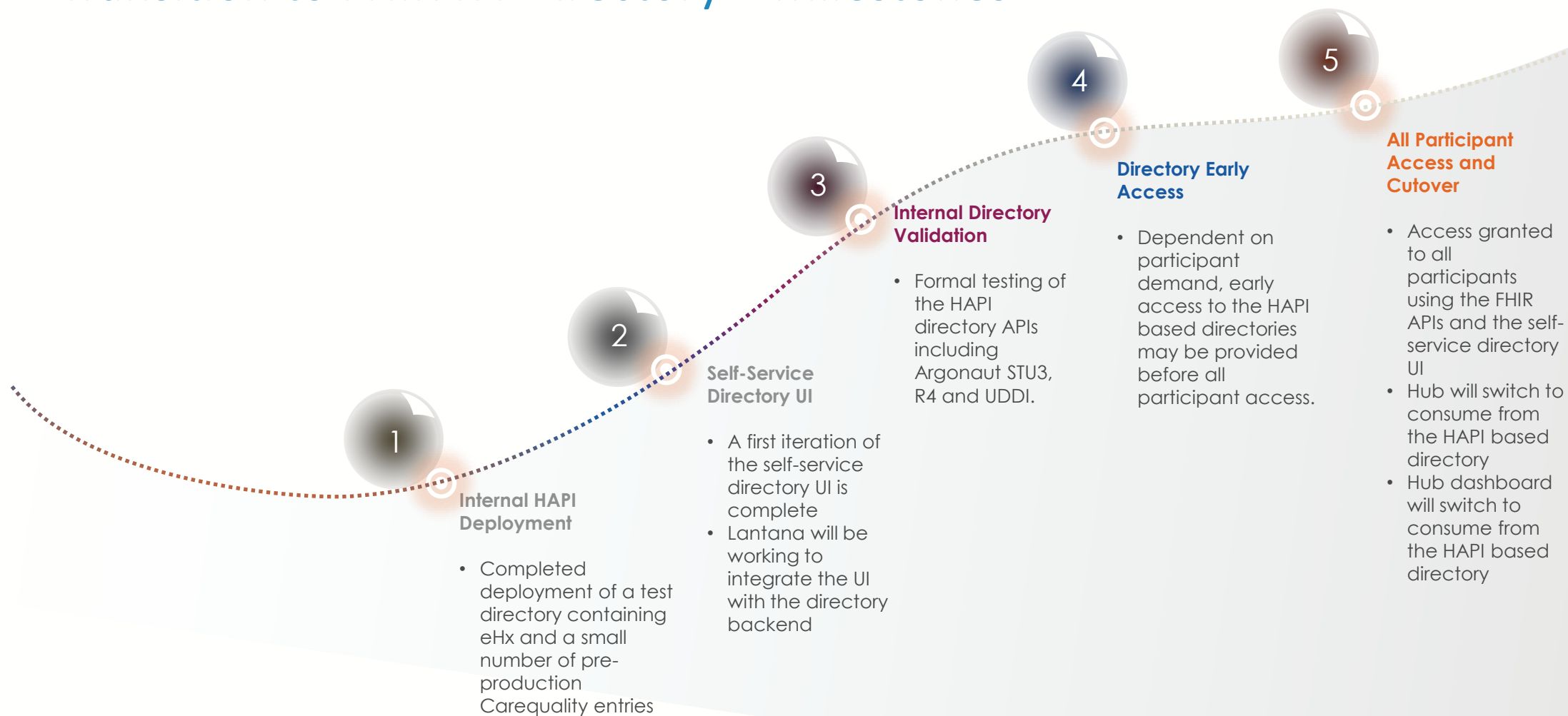
- Production PHI Content Testing Proof of Concept for VA/DoD Partner's Data Quality
 - **Similar** to the existing Content Testing Program in that it examines the exchanged data content for conformance
 - With a few **key differences**:
 - PHI-enabled in secure HIPAA Hosted environment
 - Active with live exchange randomly sampled from Hub transactions
 - Tooling expected to be available Spring 2022
- FHIR Query Initiator and Responder Transport Testing Capabilities
 - New Vendors onboarding wish to begin leveraging FHIR transports for onboarding to the eHealth Exchange
 - Testing conformance for the [Carequality FHIR-Based Exchange Implementation Guide](#)
 - Tooling expected to be available Summer 2022



FHIR R4 and Directory Update

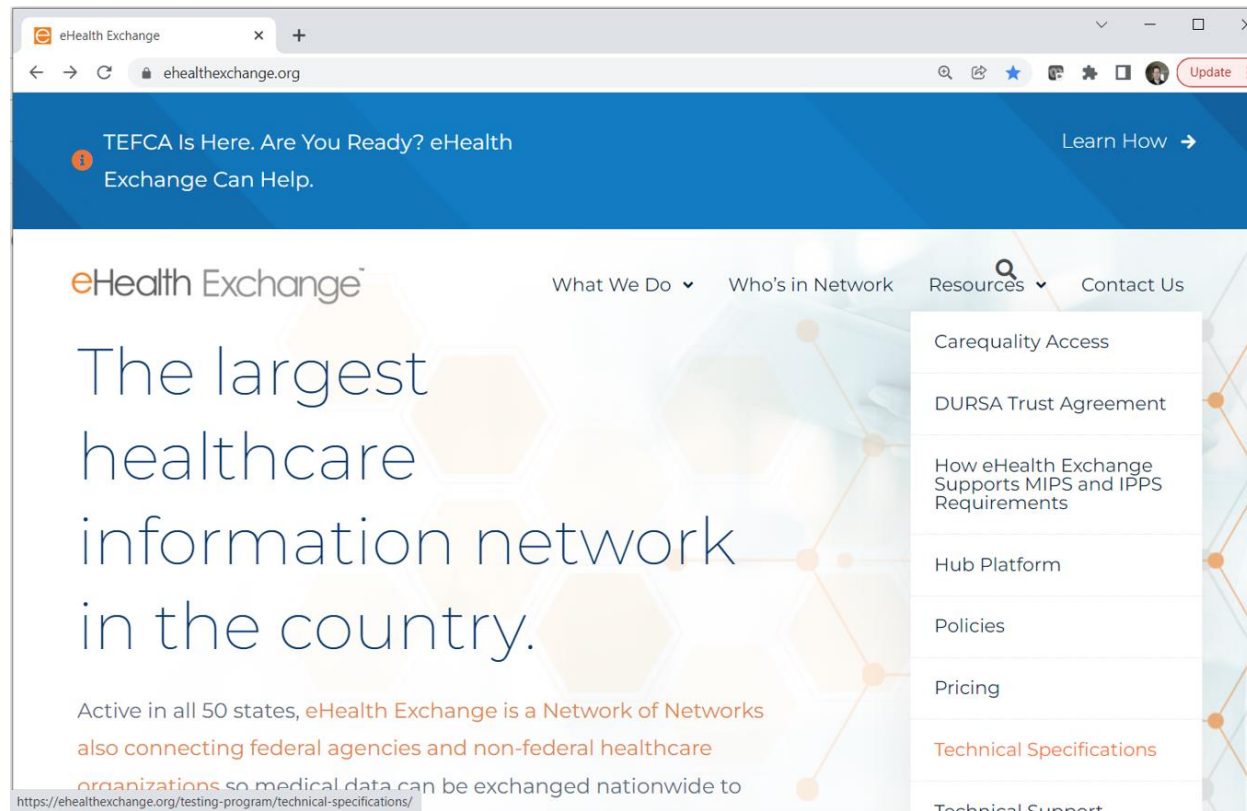
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Transition to FHIR R4 Directory – Milestones



Transition to FHIR R4 & Directory Update – Implementation Guide review

- The latest iteration of the FHIR R4 IGs are available for review on the eHealth Exchange website.
 - From <https://ehealthexchange.org>, navigate to Resources >> Technical Specifications:



Transition to FHIR R4 and Directory Update – Review IGs

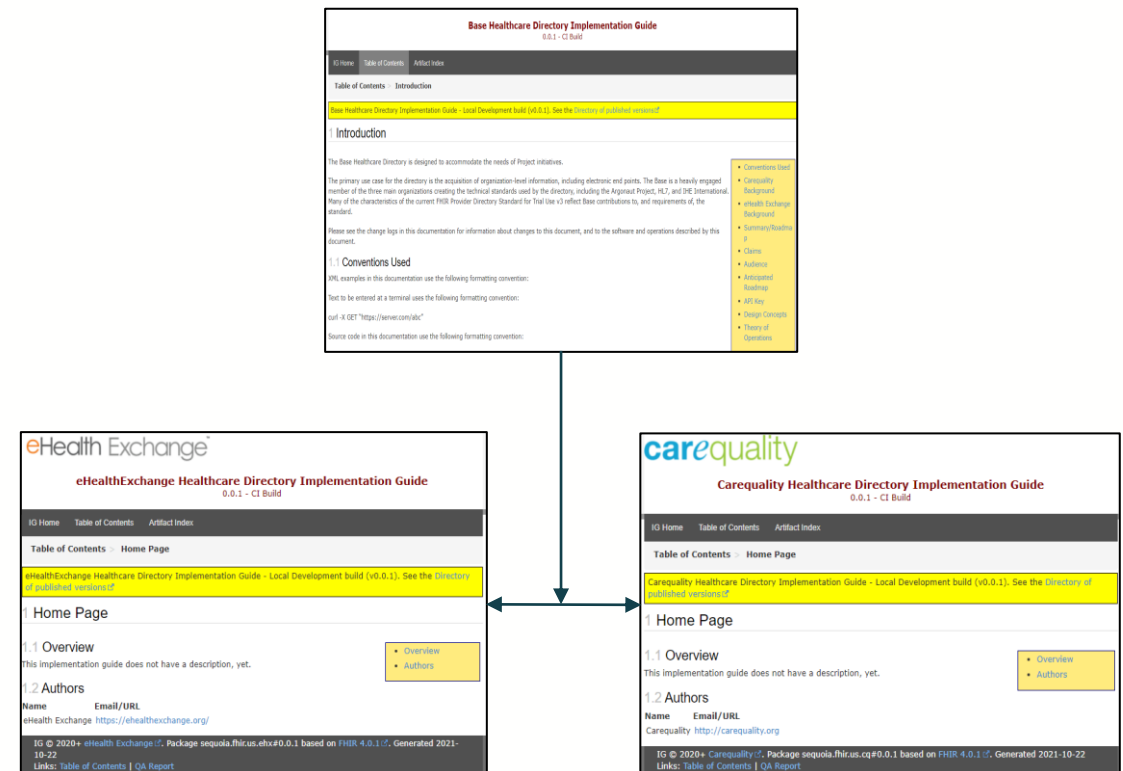
- The Base FHIR R4 IG and eHealth Exchange FHIR R4 IG are at the bottom of the technical specifications page under the Directory Implementation Guides section
- Direct link: <https://ehealthexchange.org/testing-program/technical-specifications>

FHIR R4 Implementation Guide (IG) Hierarchy

Details

- There are a total of 3 IGs:
- Base IG for common requirements
- eHealth Exchange and Carequality IGs for their specific requirements (dependency on the Base IG)
- Profiles inherit from US Core (FHIR R4 version) where available

IG Inheritance Model



FHIR R4 IGs – Provide feedback

How do I provide feedback on the FHIR R4 implementation guides?

- For any suggested IG changes or concerns that could lead to a change, send an email to techsupport@ehealthexchange.org which will open a case.
- For questions or requests for clarification, please send an email to mmccune@ehealthexchange.org.
 - Note: You may optionally use techsupport@ehealthexchange.org if you would like formal tracking with an eHealth Exchange case but please copy mmccune@ehealthexchange.org.

Transition to FHIR R4 Directory – Early Access program?

Request for your feedback:

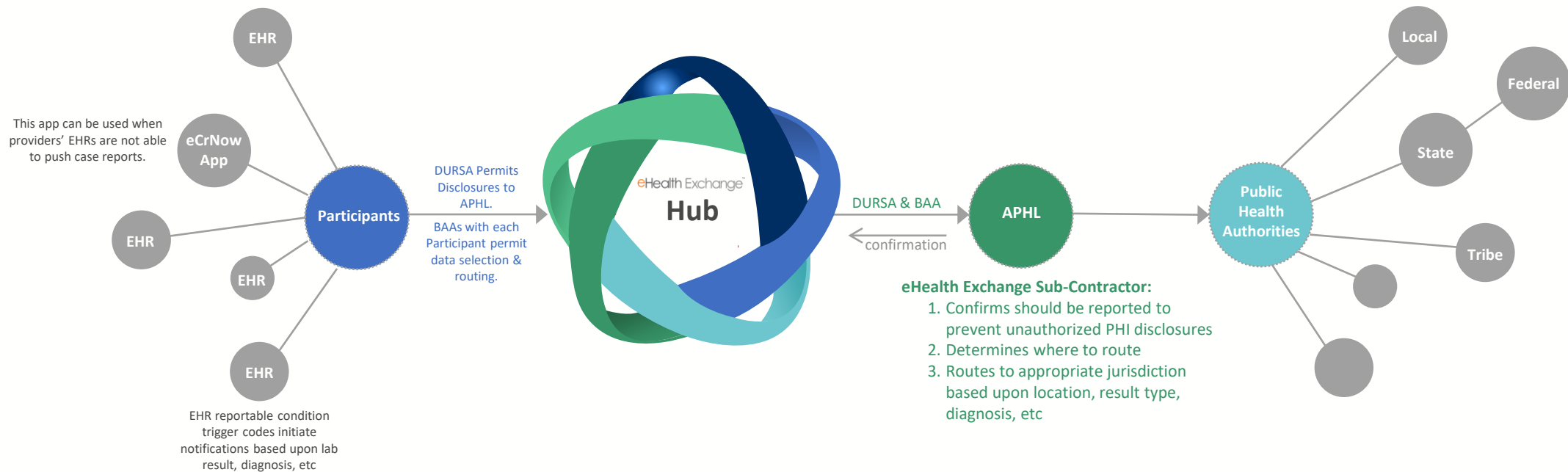
- Does your organization desire “early access” to the new FHIR HAPI directories before it is made generally available to all participants?
 - Do you desire access with a FHIR API client for technical “power users”?
 - Do you desire access using the self-service directory UI currently under development?
 - Do you desire access using both of the approaches mentioned above?
 - **Consideration:** You may test directory consumption before you switch from using the current STU3 based directories to the new FHIR HAPI directories; see the endpoint options below.
- Several directory endpoints will be made available with the new FHIR HAPI directories:
 - Argonaut STU3 endpoint which replicates the STU3 API available with the current eHx directories
 - UDDI (SOAP API) endpoint which replicates the API available with the current eHx directories
 - FHIR R4 API endpoint (“net new” to participants)
- Send feedback to mmccune@ehealthexchange.org



eCR Update

eHealth ExchangeTM

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



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.



Changes to Policy

Revision to OPP#2 –General Operating Procedure

eHealth ExchangeTM

Revisions to OPP#2 – General Operating Procedure

Background:

- ONC has had an ex officio seat on the Coordinating Committee (CC) that they have not appointed a representative for several years
- When asked about appointing a resource, they continue to decline, as recent as January 2022, to have a resource appointed on the CC

OPP#2 Revision Summary:

- Removes references for ONC Representative in Section III.A.3, Section III.B.6, and Section III.C.3
- CC approved removal of the sections listed on February 15, 2022.

Next Steps

- An email will be sent on February 28 notifying the Participants of the 30-day objection period (March 1-30)
- Per the DURSA if fewer than 1/3 of the Participants object, the updated OPP will be in effect March 31, 2022



Contacts

Changing and New Contacts

eHealth ExchangeTM

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...

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

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Please Engage!

We'd love to hear from you.

eHealth ExchangeTM

Technical Work Group

Thursdays 4-5 ET.

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]

Please Attend:

- <https://zoom.us/j/5128970748>
- Meeting ID: 512 897 0748
- One tap mobile: +16699006833,,5128970748#

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 13, 2022 | On Site Washington, D.C. |

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 |

Questions & Answers

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