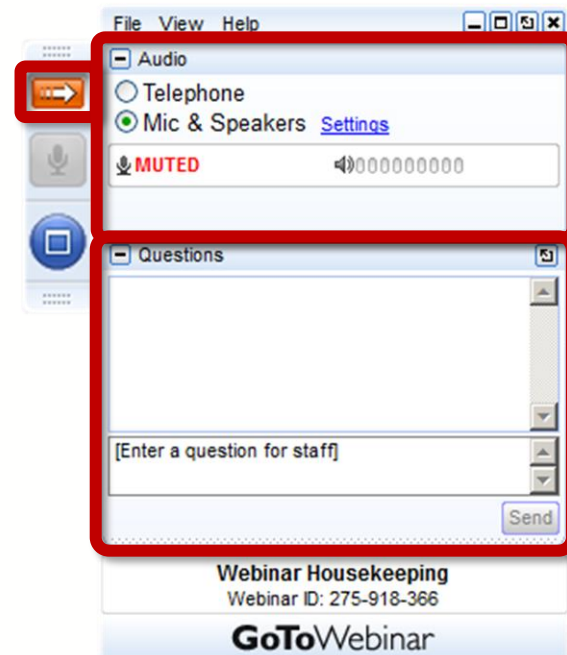


April 21st, 2022

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 Yackanich
4. Content Validation & Testing Innovations	Didi Davis
5. FHIR R4 and Directory Update	Debbie Condrey
6. eCR Update	Jay Johnstone
7. Innovation Grant 2022	Pat Russell
8. New OPP	Pat Russell
9. Contacts	Mark Rogers
10. Q&A	Everyone



New Participants

eHealth ExchangeTM

Congratulations to our newest Participants!

- Tufts Medicine
- Community Health Network
- University of Kansas Hospital Authority



Committed to Improving Patient Care via Data Exchange

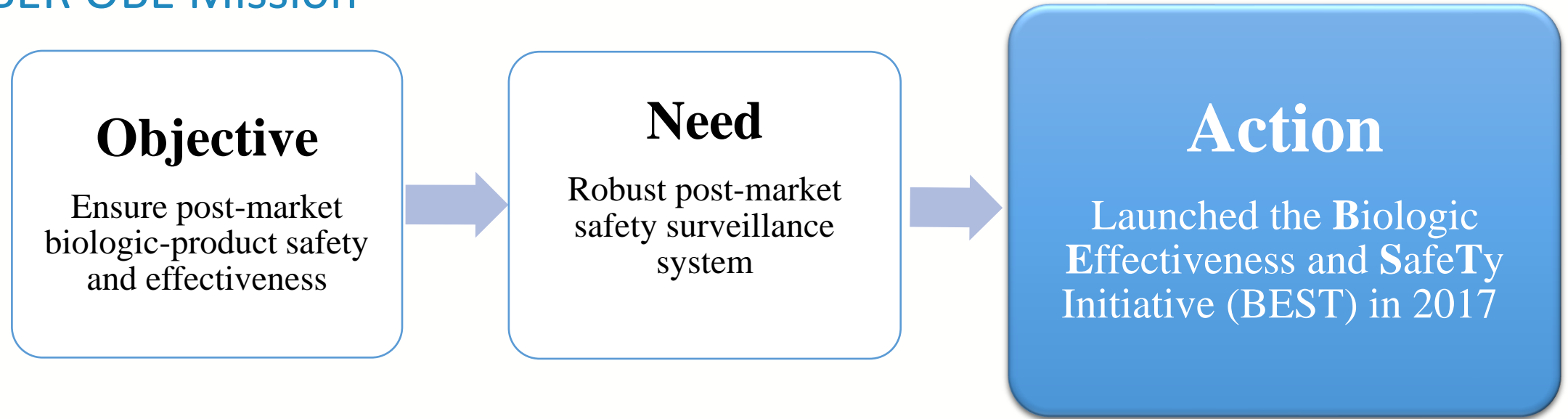


Participation Request

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

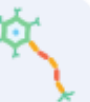
Vaccines (preventative and therapeutic)



Blood (components and derived)



Human Tissues and Cellular Products



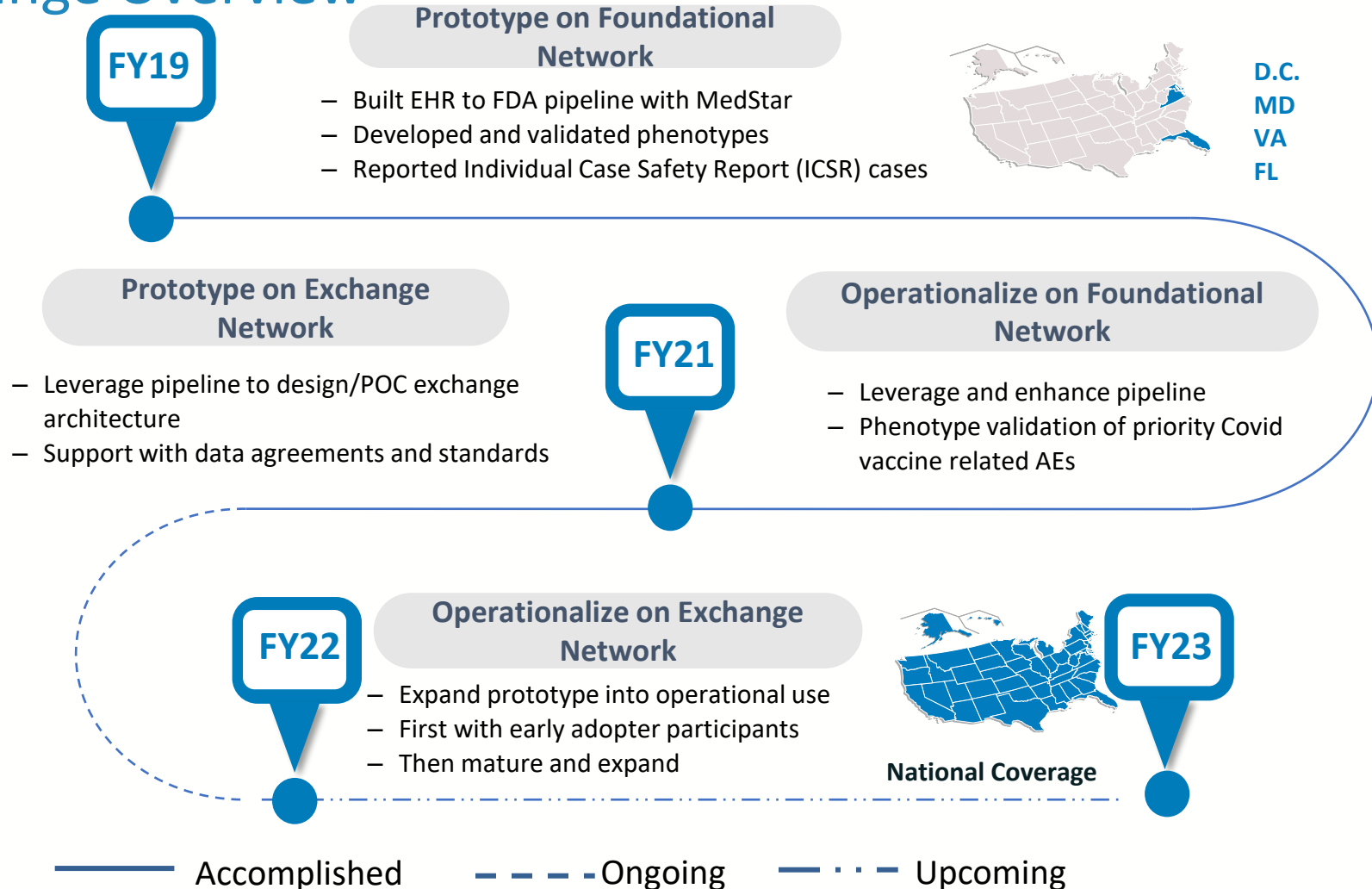
Gene Therapies



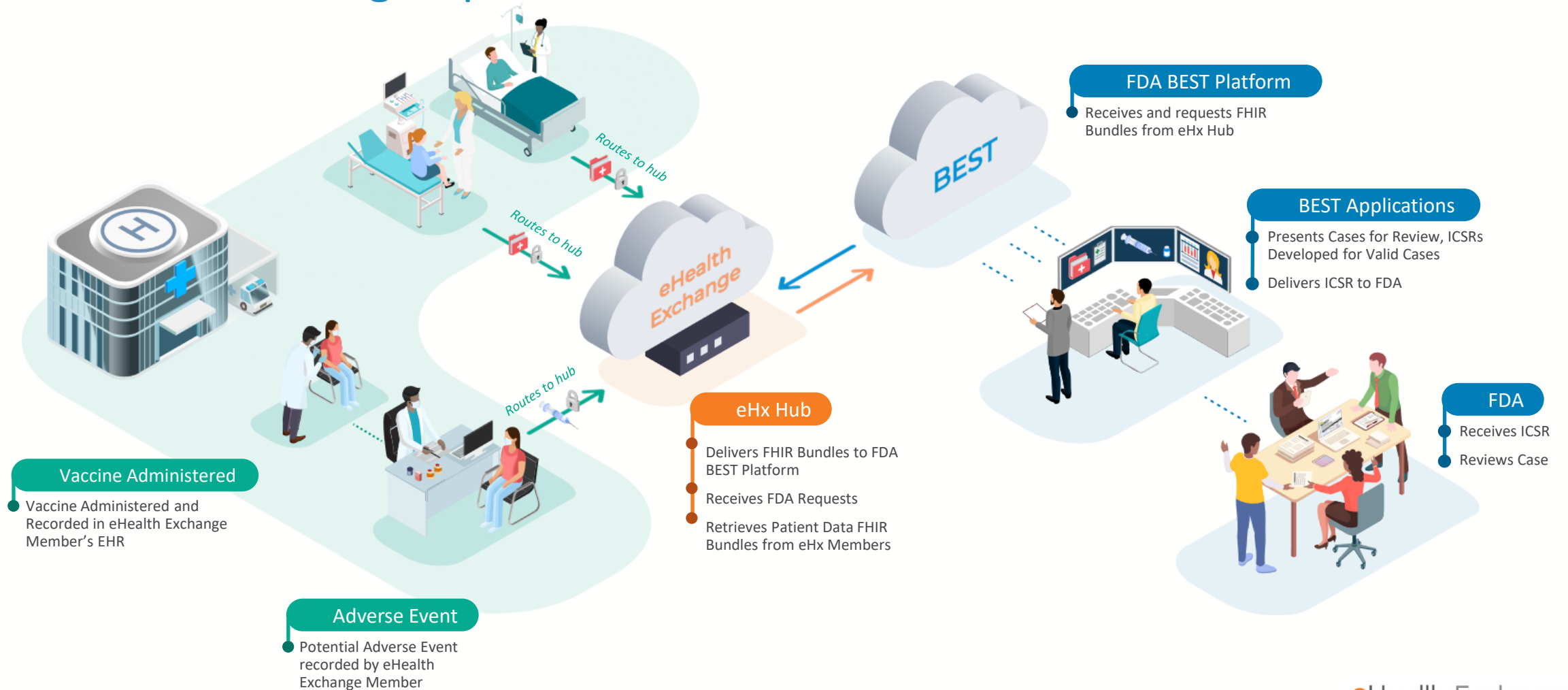
Xenotransplantation Products



FDA Exchange Overview

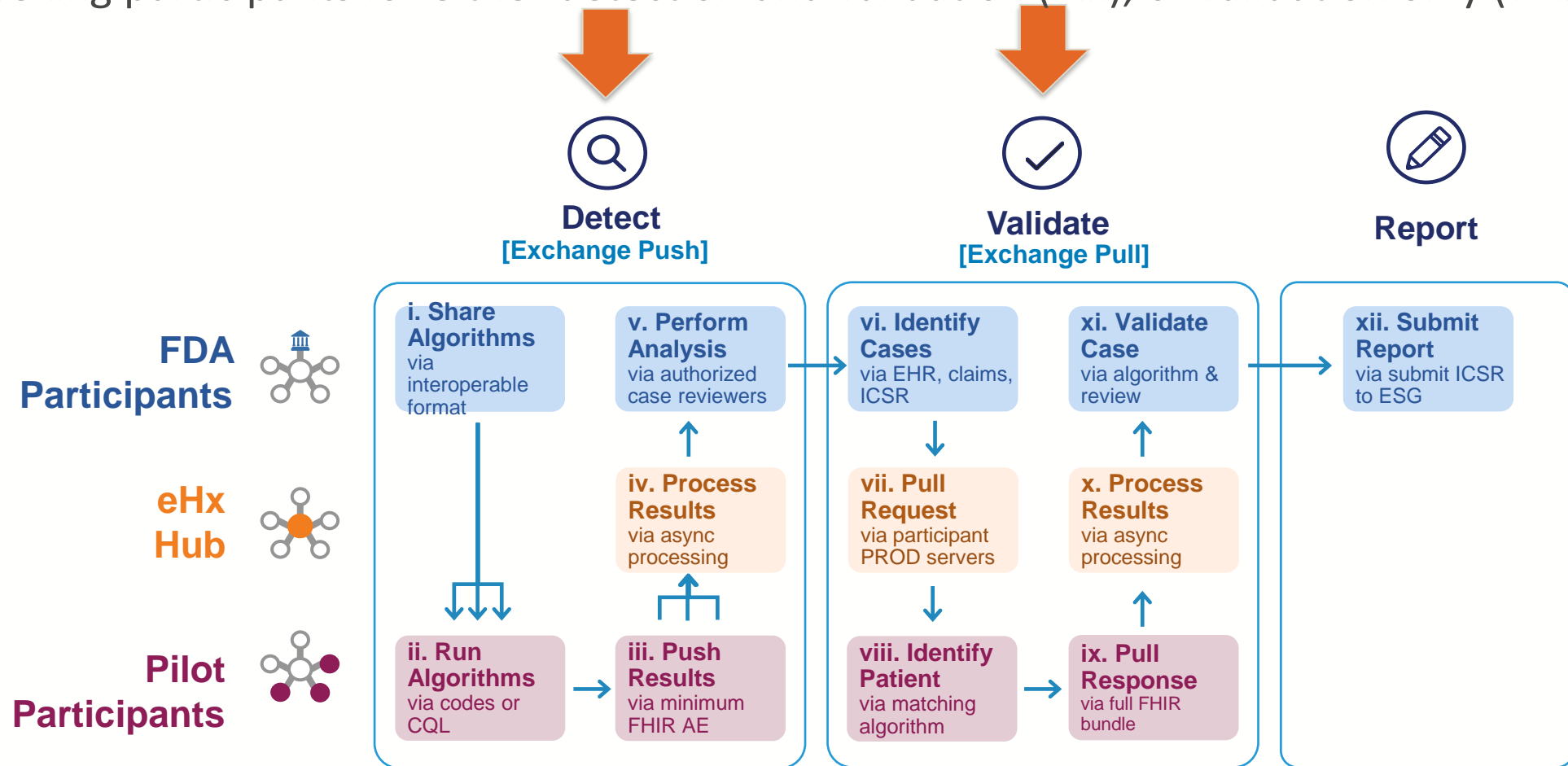


FDA- BEST Exchange Operational Architecture



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)



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*)

Funding: Multiple Potential Sources of Funding are Available

1. eHealth Exchange Innovation Grant
 - The Innovation Grant is available for the FDA pilot project
2. Other sources of funding may also be possible
 - Still being defined-Participation in the reduction fee

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

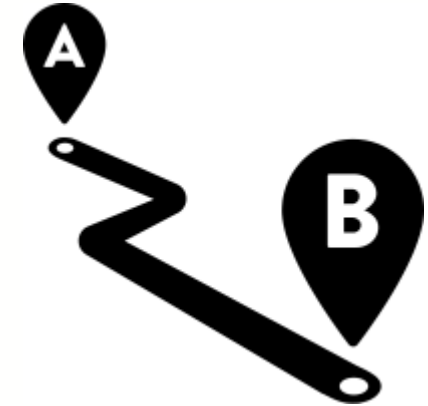
FHIR Proxy Use Case

- Hub as Trusted Third Party/Intermediary
- Hub handles backend authorization (typically OAuth 2.0)
- Requestor only needs one connection to Hub to access many target responder FHIR resource repositories
- Routing is provided as part of request
- Purpose of Use is required to be provided on request
- Optional URL rewriting is available



FHIR Proxy Routing

- URL Path (<Base URL>/<RouteInfo>/...)
 - Chosen by FAST-Exchange (FHIR At Scale Taskforce)
- HTTP Header
 - e.g., X-Destination
- Querystring Parameter
 - Technique currently used for Hub SOAP-based routing
- Embedded within FHIR Payload (POST only)
 - MessageHeader.destination.endpoint (current MedMorph preference)
 - submissionSet.intendedRecipient
- Other Considerations
 - JWT-based (e.g., a routing claim)
 - Hostname-based (e.g., via DNS resolution)



FHIR Proxy Security

- Front-end authorization
 - Two-way/mutual TLS (most likely)
 - Hub as OAuth 2.0 (optional)
 - Active Intermediary
 - Passive Intermediary (token passthru)
 - HL7 UDAP (future)
- Back-end authorization
 - OpenEpic: OAuth 2.0, client credentials grant type, private-key signed JWT to obtain access token
 - CernerConnect: OAuth 2.0, client credentials grant type, with client secret
 - API Key (used in some environments)
 - Token Passthru
- Mediate across different trust domains
 - e.g., eHx to CQ





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 April 7, 2022
 - Content validated logos have been removed from the website for all Participant listings that were previously validated. Only eHealth Exchange Participants with Content NOT Validated will be referenced in the notes section on the 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
- 9 Waivers/Extensions Requested and Approved Remaining with 1 moving to Temporary Suspension
 - Content Not Text



NOTES:

Content Not Validated

Breakdown of Documents Tested by Meaningful Use Version & Standard

- 24,530 Documents Tested as of April 7, 2022
 - 82% Failing
 - 18% Passing
- Breakdown of Documents Tested by Validator Version
 - 56% or 13,832 tested against the Meaningful Use 2015 Edition/HL7 C-CDA R2.1
 - 13% or 3,299 tested against the Meaningful Use 2014 Edition/HL7 C-CDA R1.1
 - 26% or 6,277 tested against the Meaningful Use 2011 Edition/HL7 C-32
 - 5% or 1,054 tested against the CDA R2 validator
 - <1% (.002) or 68 tested against the USCDI V1 validator



Testing Innovations

eHealth ExchangeTM

Testing Innovations Planned for 2022

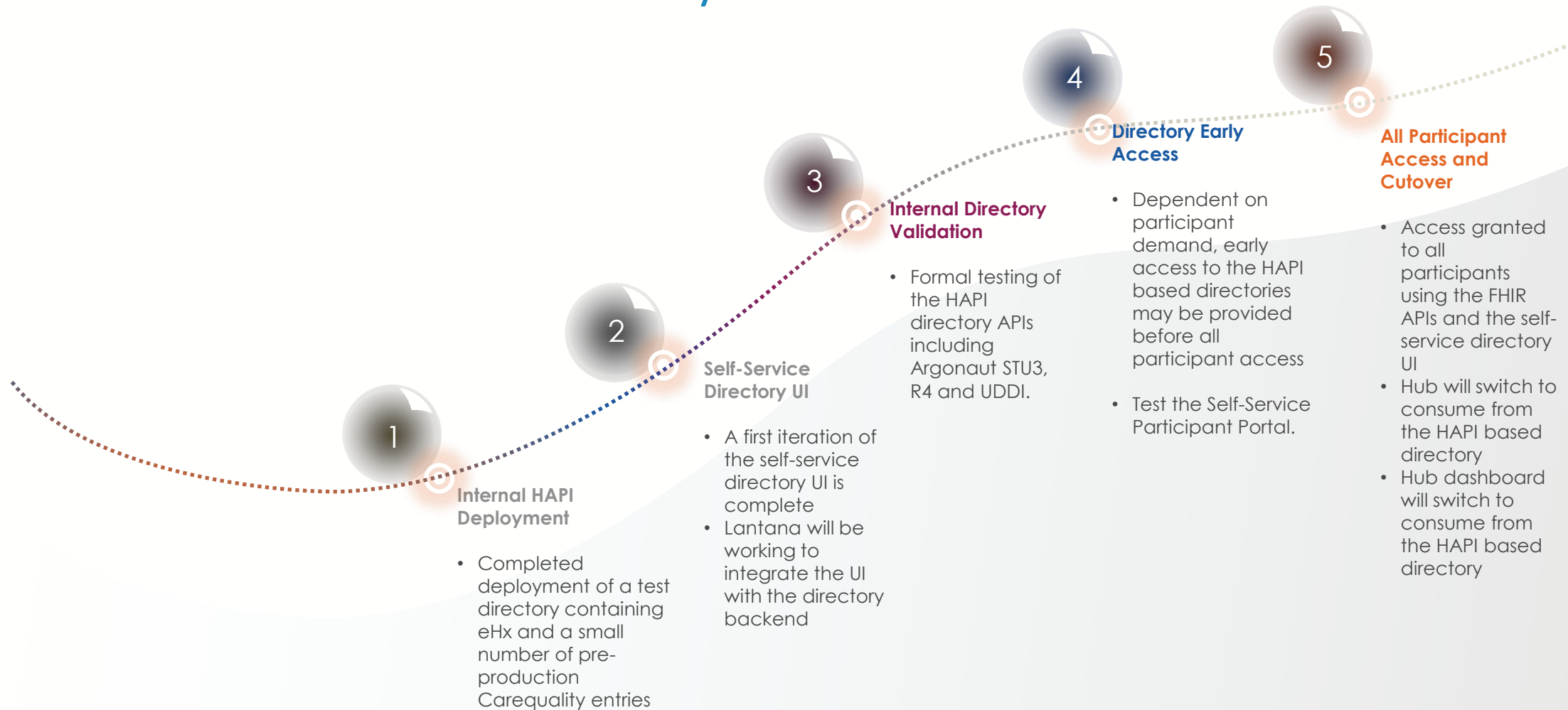
- Production PHI Content Testing Proof of Concept for VA/DoD Partner's Data Quality
 - **Similar** to the existing Content Testing Program in that it examines the exchanged data content for conformance
 - With a few **key differences**:
 - PHI-enabled in secure HIPAA Hosted environment
 - Active with live exchange randomly sampled from Hub transactions
 - Tooling expected to be available Summer 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 Fall 2022



FHIR R4 and Directory Update

eHealth ExchangeTM

Transition to FHIR R4 Directory – Milestones



Transition to FHIR R4 & Directory Update

- Lantana, our Directory partner, has delivered the full functionality for the new R4 Directory as well as the Self-Service Participant Module
- The latest iteration of the FHIR R4 IGs will be available soon for review on the eHealth Exchange website. An updated version was received on Wednesday, April 13th. This will be loaded to:
<https://ehealthexchange.org>, navigate to Resources >> Technical Specifications
- 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>

Transition to FHIR R4 Directory – Next Steps

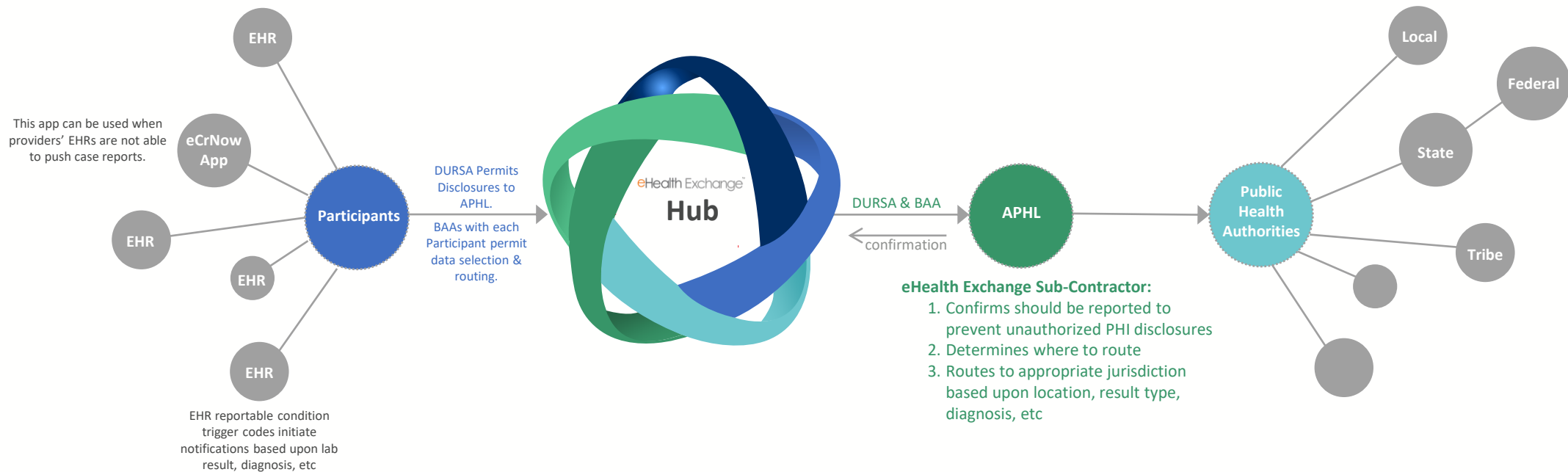
- We would like to have your feedback
 - Pilot testing: You may test directory consumption before you switch from using the current STU3 based directories to the new FHIR HAPI directories; see the endpoint options below.
- Directory endpoints options will be made available with the new FHIR HAPI directories:
 - 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
- An internal implementation team has been assembled and a date will be selected soon for transition to the new FHIR R4 Directory structure. More information to come soon
- Send feedback/questions to techsupport@ehealthexchange.org or admin@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.



Innovation Grant 2022

eHealth ExchangeTM

Innovation Grant 2022

- **Goals:**
 - **Provide more value** to existing participants, to attract new participants, and to provide compelling communication opportunities
 - **Accelerate interoperability** across the network.
 - **Increase centralized data exchange** through the eHealth Exchange Hub.
- **Eligibility:**
 - Open to eHealth Exchange Participants and any eHealth Exchange eligible applicants
 - Grant applicants must meet the eligibility criteria outlined in OPP#1. Grant applicants that are not Participants must submit an application to join eHealth Exchange with their grant Intention to Respond. eHealth Exchange staff must have validated participation eligibility before the applicant's grant proposal can be evaluated.

Award Highlights



Up to three (3) awards will be made in the form of a milestone driven grant for year 1



Up to \$100,000 per awardee plus year 1 eHealth Exchange Participation fees will be credited



Annual eHealth Exchange Participant fees will be waived in year 2 as long as the awardee is in full production by end of year 1



eHealth Exchange reserves the right to:

- * Not make any grant awards if the applications submitted are not acceptable.
- * Actual grant award amounts are determined by eHealth Exchange and are based on the proposed projects and their complexity.
- * The number of awards could change based on the availability of funds.

Key Dates

Activity	Due Date
Grant Instructions and Guidance Released	3/21/2022
"Intent to Reply" Due and Closing Date for Questions	4/29/2022
Responses to Questions	5/6/2022
Proposals Due	7/1/2022
Awardees Notified	8/2/2022
Awardee Agreement Discussions Begin	8/6/2022
Awardee Agreement Executed	8/30/2022
Grant Start Date – Year 1	1/1/2023
First Phase of Grant – Year 1 (Funding Milestone 1 of 4)	5/30/2023
Standards and Technology Development Completed	
Second Phase of Grant – Year 1 (Funding Milestone 2 of 4)	08/30/2023
Hub Testing Completed	
Third Phase of Grant – Year 1 (Funding Milestone 3 of 4)	11/30/2023
Partner Testing Completed	
Fourth Phase of Grant – Year 1 (Funding Milestone 4 of 4)	12/31/2023
Implementation Guide/Production	



New OPP

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

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

- Approved on March 15, 2022 by the Coordinating Committee
- Participant Objection Period- March 31- April 29, 2022
 - If fewer than 1/3 of eHealth Exchange Participants object, the changes will go into effect 5/1/2022
 - Affects 29 Participants
- 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.
 - ✓ Provides the Coordinating Committee the ability to monitor all network traffic volume, response times, downtime, and exchange patterns.
- Policy Includes:
 - ✓ The requirements
 - ✓ The process to request an exception
 - ✓ The timeframe to discontinue the use of point-to-point connections with other eHealth Exchange Participants (12/31/2022)



Contacts

Changing and New Contacts

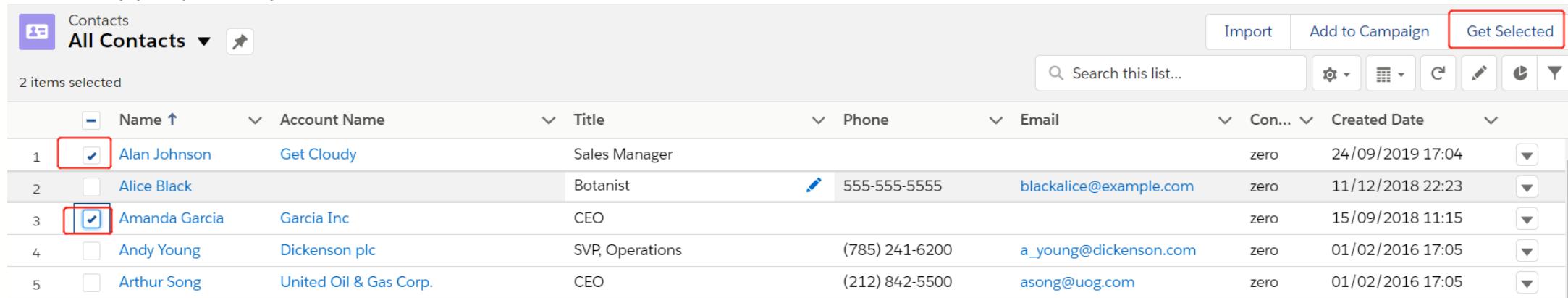
eHealth ExchangeTM

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									
2 items selected									
Search this list...									
	Name ↑	Account Name	Title	Phone	Email	Con...	Created Date		
1	<input checked="" type="checkbox"/> Alan Johnson	Get Cloudy	Sales Manager			zero	24/09/2019 17:04		
2	<input type="checkbox"/> Alice Black		Botanist	555-555-5555	blackalice@example.com	zero	11/12/2018 22:23		
3	<input checked="" type="checkbox"/> Amanda Garcia	Garcia Inc	CEO			zero	15/09/2018 11:15		
4	<input type="checkbox"/> Andy Young	Dickenson plc	SVP, Operations	(785) 241-6200	a_young@dickenson.com	zero	01/02/2016 17:05		
5	<input type="checkbox"/> 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.

eHealth ExchangeTM

The logo for eHealth Exchange, featuring the word "eHealth" in orange and "Exchange" in white, with a small trademark symbol (TM) to the upper right of "Exchange".

eHealth ExchangeTM

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]

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