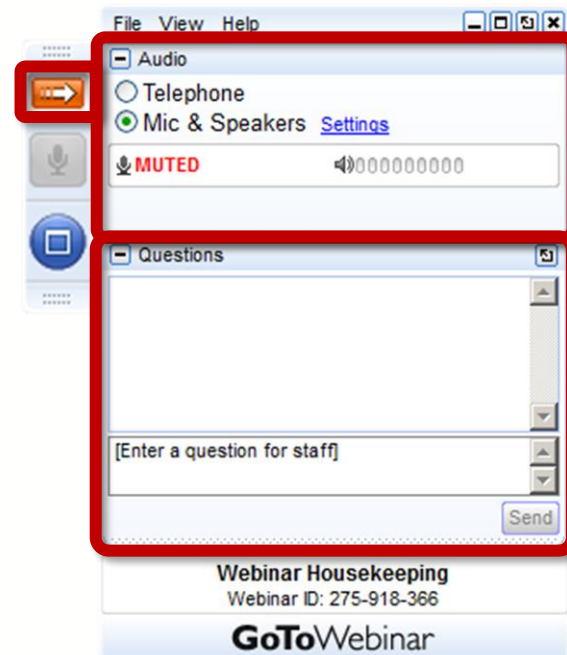


May 19th, 2022

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. 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



New Participants

eHealth ExchangeTM

Congratulations to our newest Participants!

- TidalHealth
- Baptist Health System, Inc
- Piedmont Healthcare



Committed to Improving Patient Care via Data Exchange



Participation Request

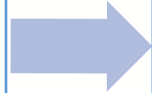
FDA Pilot: Adverse Event Exchange via FHIR 2022 Roadmap

eHealth ExchangeTM

CBER OBE Mission

Objective

Ensure post-market
biologic-product safety
and effectiveness



Need

Robust post-market
safety surveillance
system



Action

Launched the **Biologic
Effectiveness and SafeTy**
Initiative (BEST) eHealth
exchange Pilot

CBER Regulated Products



Vaccines (preventative and therapeutic)



Blood (components and derived)



Human Tissues and Cellular Products

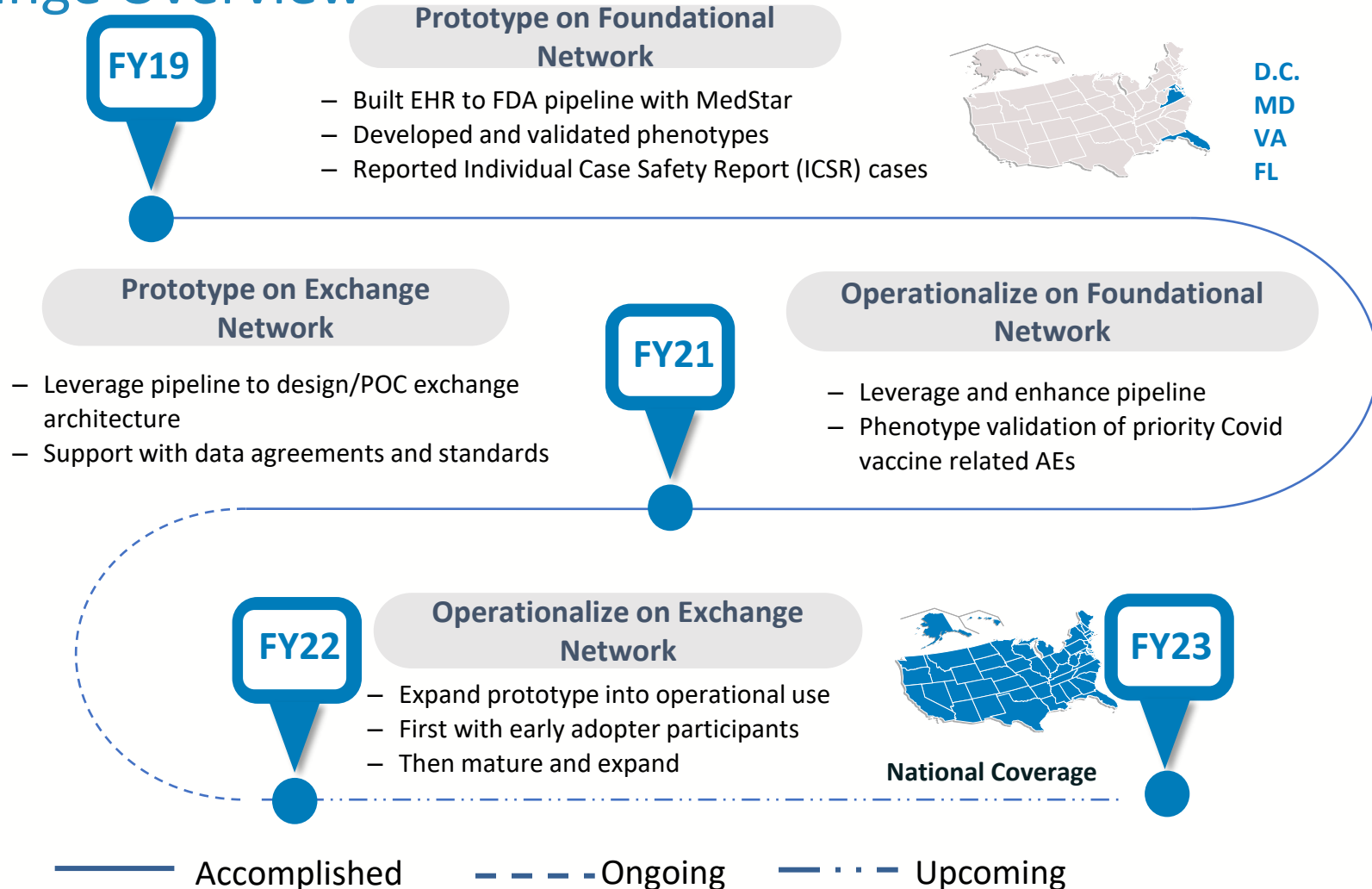


Gene Therapies

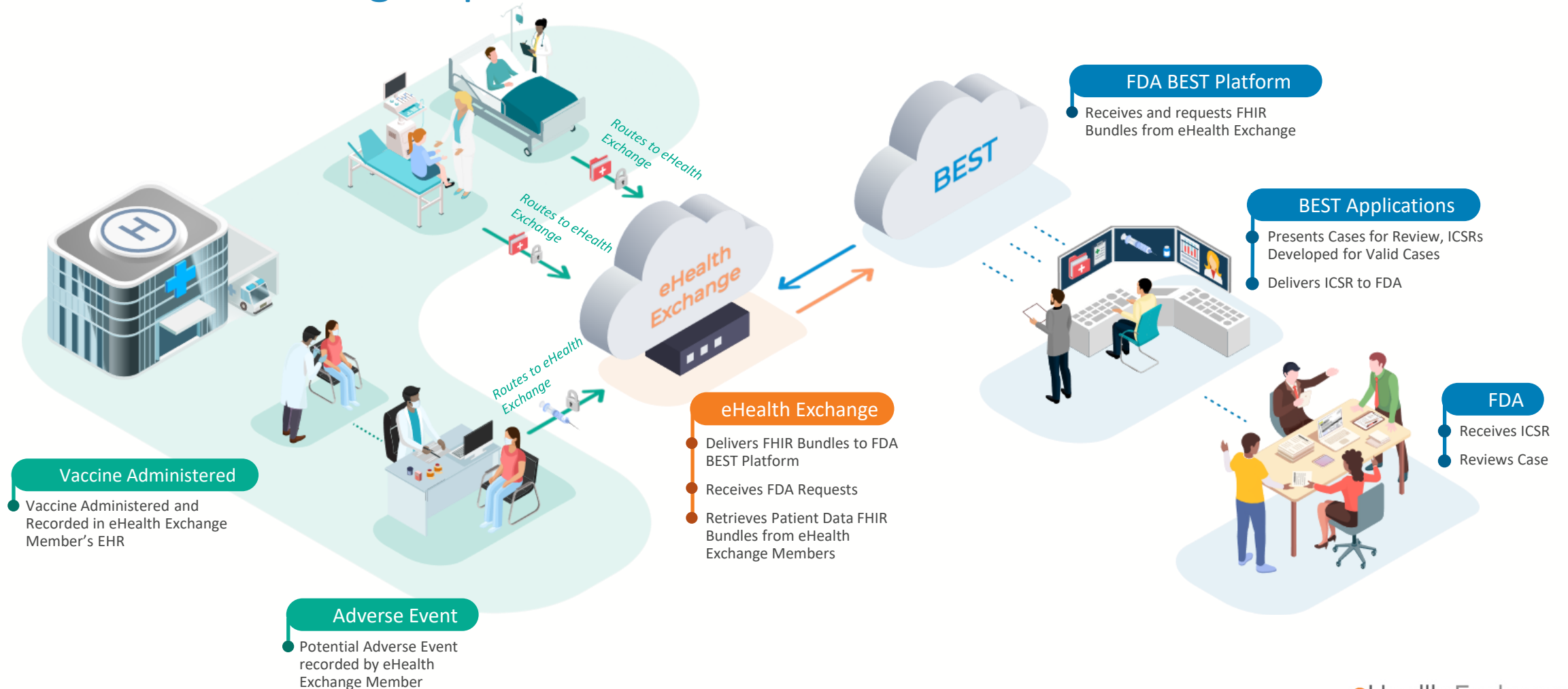


Xenotransplantation Products

FDA Exchange Overview

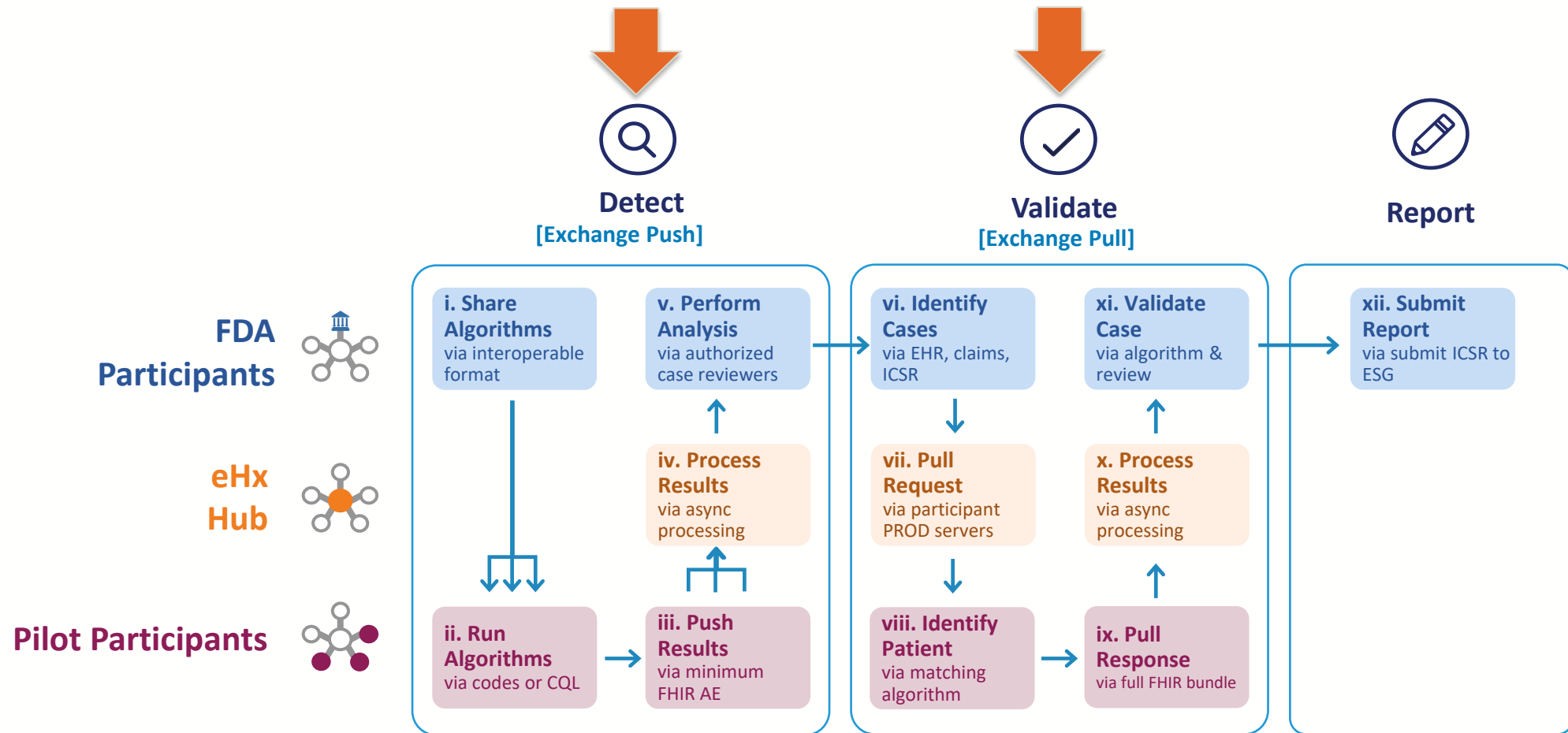


FDA- BEST Exchange Operational Architecture



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*)

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 (Q2-Q3)*

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.

FHIR Directory

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

*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 with target (typically OAuth 2.0)
- Requestor only needs one connection to Hub to access many target responder FHIR resource repositories
- Routing MUST be provided on request
- Purpose of Use MUST be provided on request
- Initial support includes FHIR search and read only
- Optional URL rewriting is available

FHIR Proxy Actor Requirements

Initiator

1. Public ip address(es) must be added to FHIR Proxy inbound allow-list
2. Establish mTLS connection (v1.2+) to FHIR Proxy (using eHx certificate)
3. Include target for routing within the request* (X-DESTINATION HTTP Header)
4. Include Purpose of Use within the request (X-POU HTTP Header)

<https://terminology.hl7.org/3.1.0/ValueSet-v3-PurposeOfUse.html>

*List of FHIR targets will be provided once you are engaged for testing

Target

1. Public ip address must be added to the FHIR Proxy outbound allow-list
 2. FHIR Proxy configured for target's security model (e.g. OAuth 2.0 API Key, others)
 3. Target deploys and authorizes eHealth Exchange FHIR application (e.g. OpenEpic backend application)*
 4. Allow mTLS connection (v1.2+) from FHIR Proxy (using eHx certificate)
 5. Purpose of Use will be included in request
- * eHealth Exchange can provide detailed procedures for Epic-based targets.



<https://fhir001val.ehealthexchange.org/ehx/1.0/r4/fhirproxy>

SAMPLE REQUEST

Retrieve Capability Statement from Target FHIR Resource Repository

cURL Example

```
curl --location --request GET  
'https://fhir001val.ehealthexchange.org/ehx/1.0/r4/fhirproxy/metadata' \  
--header 'Accept: application/json, application/*+json, */*' \  
--header 'X-Request-Id: 9d485a66-1ced-4f52-96cf-c66694efa467' \  
--header 'Content-Type: application/fhir+json; charset=UTF-8' \  
--header 'X-DESTINATION: 1.1.2.2.3 ' \  
--header 'X-POU: TREAT '
```

SAMPLE REQUEST

Patient Search Request to Target FHIR Resource Repository

cURL Example

```
curl --location --request GET 'https://fhir001val.ehealthexchange.org/ehx/1.0/r4/fhirproxy/Patient?  
address=3268%20West%20Johnson%20St.&address-city=Garland&address-postalcode=75043  
&address-state=TX&family=Lopez&given=Camila&birthdate=1987-09-12' \  
--header 'Accept: application/json, application/*+json, */*' \  
--header 'X-Request-Id: 2c485a66-1ced-4f52-96cf-c66694efa955' \  
--header 'Content-Type: application/fhir+json; charset=UTF-8' \  
--header 'X-DESTINATION: 1.1.2.2.3' \  
--header 'X-POU: TREAT'
```

FHIR Proxy – Quick Start Guide

FHIR Proxy BaseURL
<https://fhir001val.ehealthexchange.org/ehx/1.0/r4/fhirproxy>

Initiator Checklist

1. Email techsupport@ehealthexchange.org to notify of interest in engaging for FHIR Proxy testing in the role of a FHIR initiator
 - a) if possible, include public ip address(es) from which your FHIR requests will originate
 - b) eHx will then
 - i. contact you and provide list of existing eHx Participant HCIDs who have engaged with us as a target FHIR responder
 - ii. add your public ip addresses to the FHIR Proxy inbound allow list (if provided)
2. Prepare your FHIR client to initiate requests as follows:
 - a) send to the FHIR Proxy BaseURL
 - b) include your eHx client certificate to establish mutual TLS connection to the FHIR Proxy
 - c) set X-DESTINATION HTTP Header value to the HCID of one of the current FHIR responders
 - d) set X-POU HTTP Header value to a valid purpose of use (<https://terminology.hl7.org/3.1.0/ValueSet-v3-PurposeOfUse.html>)

FHIR Proxy – *Quick Start Guide*

Target Checklist

1. Email techsupport@ehealthexchange.org to notify of interest in engaging for FHIR Proxy testing in the role of a FHIR target
 - a) if possible, include public ip address(es) of your FHIR Server(s)
 - b) eHx will then
 - i. add your public ip addresses to the FHIR Proxy outbound allow list (if provided)
 - ii. contact you to review the implementer-specific onboarding process and eHx FHIR application deployment steps
2. Deploy the eHealth Exchange backend FHIR application
 1. eHx can provide detailed procedures for Epic-based targets. Others are TBD
 2. After deployment, eHx will proceed with required security model configuration within the FHIR Proxy that is needed to connect to the target Oauth Server and FHIR Resource Repository

NOW AVAILABLE !!!
(in Hub Validation Environment)

FHIR Proxy – *Engage With Us!*

techsupport@ehealthexchange.org

Or

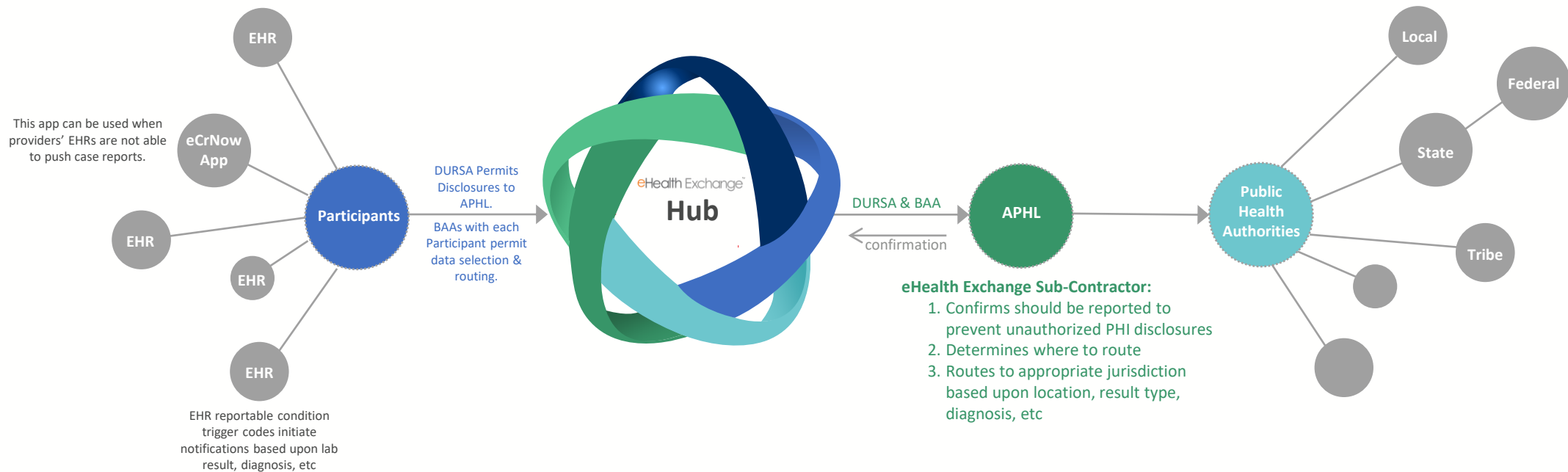
administrator@ehealthexchange.org



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.



New OPP

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

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



Coordinating Committee Elections

eHealth ExchangeTM

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
	Paul Matthews	9/30/2022
Other	Open	9/30/2024
	Jarrold Pearson	9/30/2024

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**



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></div> Account Name	<div><div></div></div> Title	<div><div></div></div> Phone	<div><div></div></div> Email	<div><div></div></div> Con...	<div><div></div></div> Created Date	<div><div></div></div>
1	<div><div><div></div></div> Alan Johnson</div>	Get Cloudy	Sales Manager			zero	24/09/2019 17:04	<div><div></div></div>
2	<div><div><div></div></div> Alice Black</div>		Botanist	<div><div></div>555-555-5555</div>	blackalice@example.com	zero	11/12/2018 22:23	<div><div></div></div>
3	<div><div><div></div></div> Amanda Garcia</div>	Garcia Inc	CEO			zero	15/09/2018 11:15	<div><div></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></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></div></div>

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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 Exchange™

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