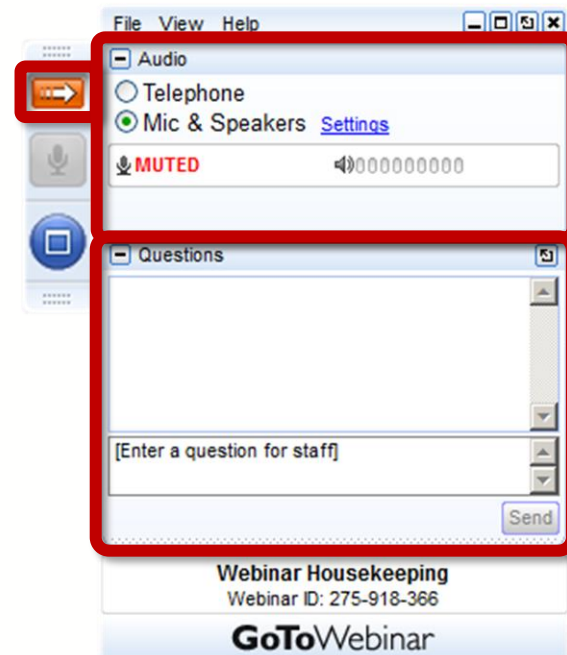


January 20, 2022

# eHealth Exchange<sup>TM</sup>

## 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](mailto:dvandyke@ehealthexchange.org) or 703.864.4062

## Today's Topics

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



# New eHealth Exchange Team Member

eHealth Exchange<sup>TM</sup>

## Introducing Kathryn Bingman

Kathryn Bingman joined the eHealth Exchange in December as the **Vice President of Interoperability Adoption**. She has more than 25 years of experience in healthcare operations and technology and has held leadership positions on the hospital, physician, payer and technology vendor side of the industry, serving as the CIO for both a Hospital and a Health Plan and as a Vice President of a division of Cerner.





# New Participants

eHealth Exchange<sup>TM</sup>

## Congratulations to our newest Participants!

- Food and Drug Administration
- Cambridge Health Alliance
- Boulder Community Health
- VCU Health System Authority
- Montefiore Health System, Inc



Committed to Improving Patient Care via Data Exchange



# *Participation Request*

## FDA Pilot: Adverse Event Exchange via FHIR 2022 Roadmap

eHealth Exchange<sup>TM</sup>

## FDA BEST Initiative Objective

The objective of the Biologics Effectiveness and SafeTy (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 while minimizing the burden on providers through an exchange-based FHIR infrastructure.

## Regulated Products

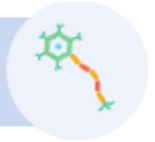
Vaccines (preventative and therapeutic)



Blood (components and derived)



Human Tissues and Cellular Products



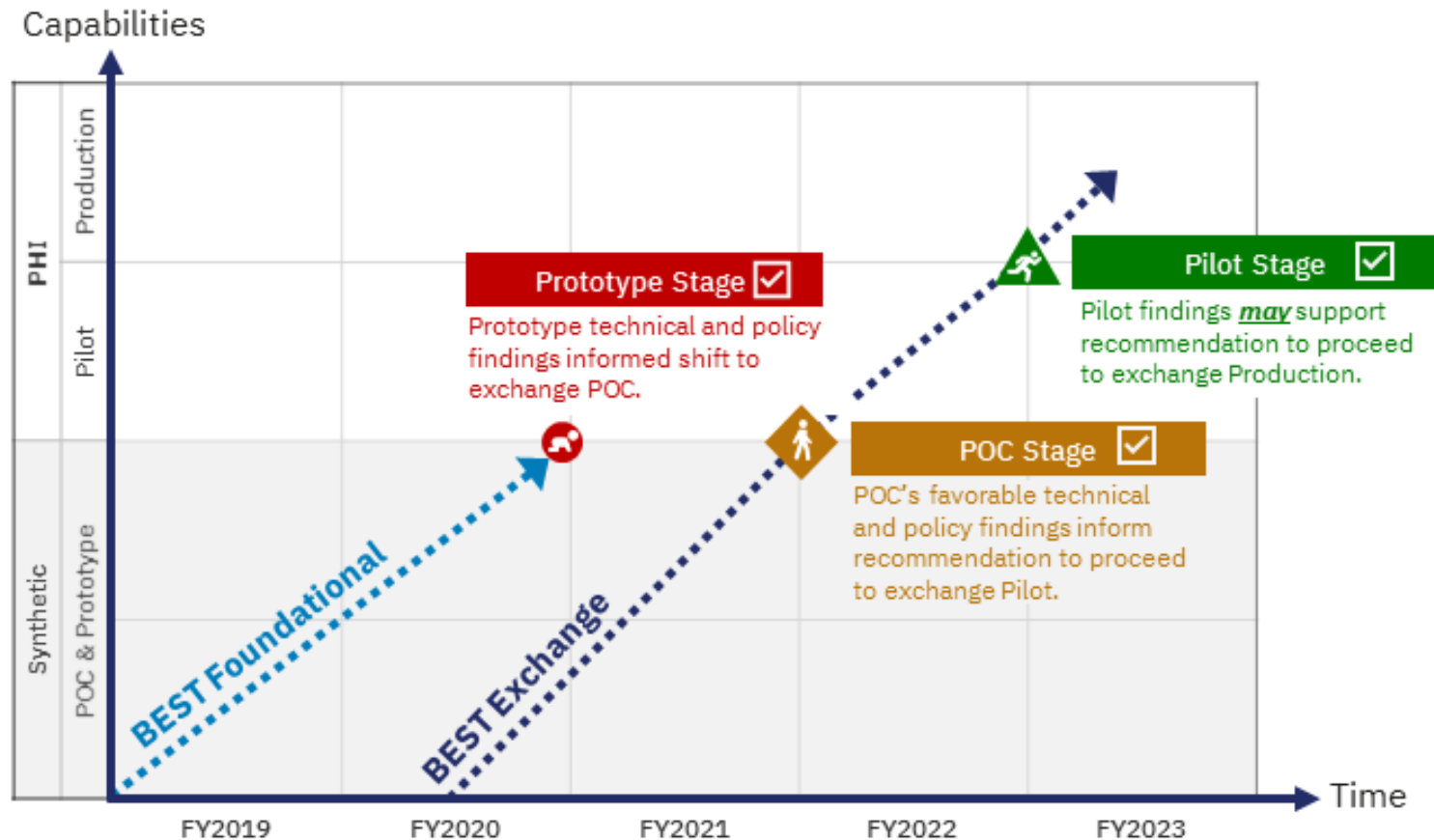
Gene Therapies



Xenotransplantation Products



# FDA Exchange Overview



## FDA Exchange Overview (Cont.)

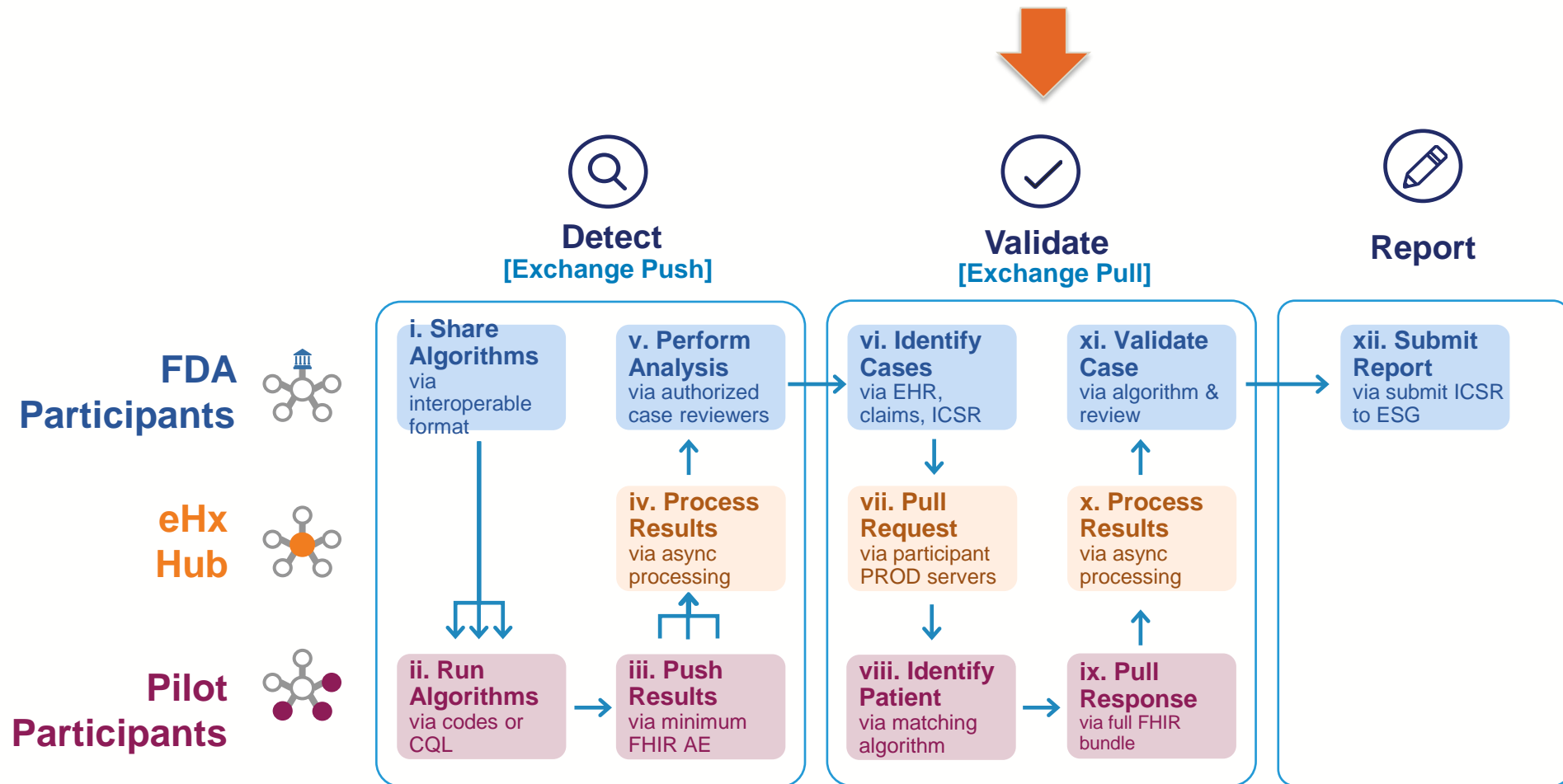
**2021 – Proof of Concept (Completed):** FDA joined eHx and built a Proof of Concept using synthetic data to connect to 5 participants' FHIR endpoints to create an efficient decision support environment

**2022 – Pilot (Planned):** FDA is proceeding with a Pilot that will deploy the BEST exchange platform in a secure cloud environment to connect to participants' EHR data

**Ask to Participants:** FDA is currently seeking participants for the Pilot to:

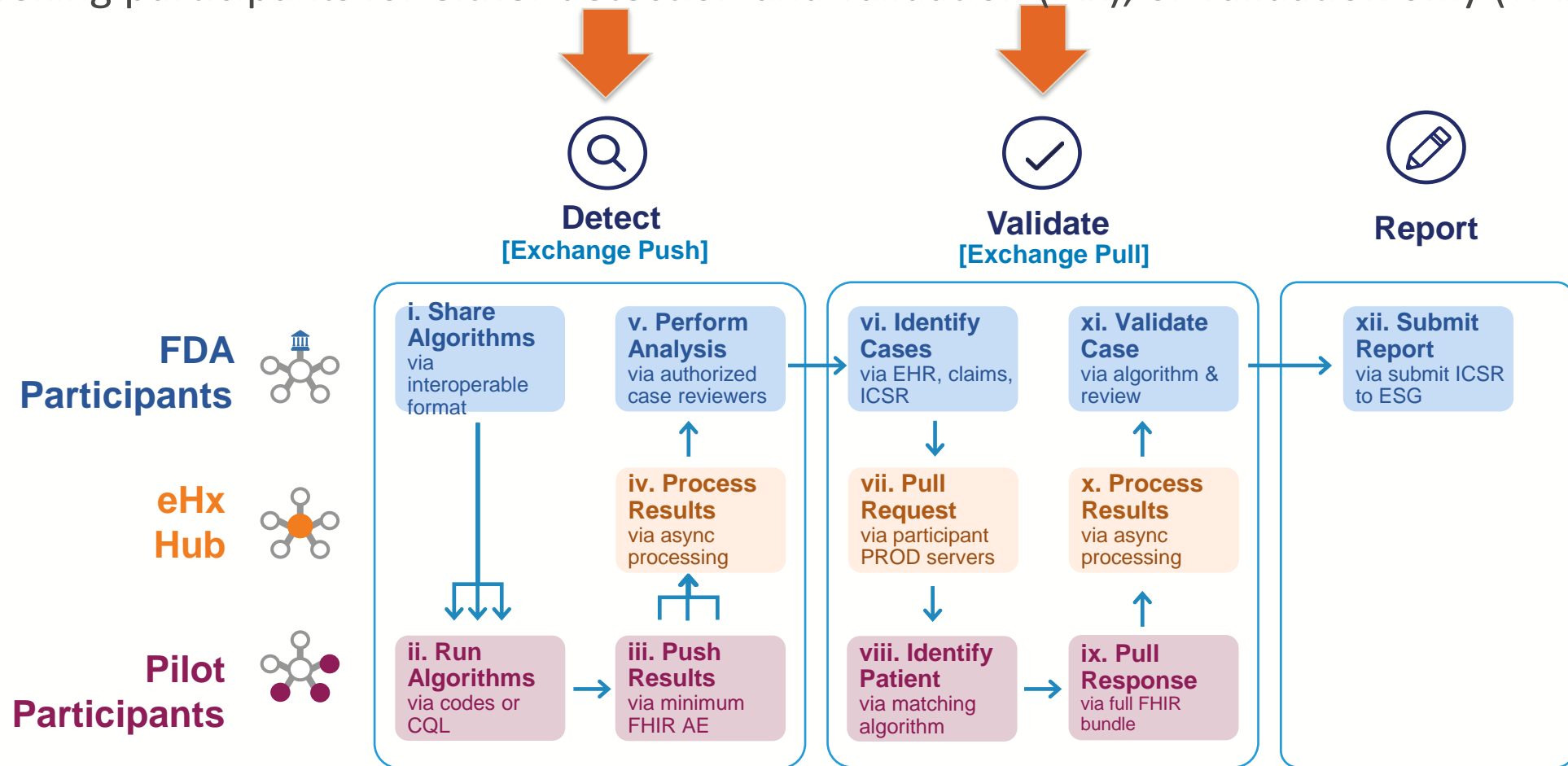
- Detection (Push): Receive algorithms to detect potential adverse events (AEs) from the platform, run the algorithms on EHR data, and push the results to the eHx Hub  
*and/or*
- Validation (Pull): Identify patients with detected potential AEs via pull request from the eHx Hub, pull responses, and send to the eHx Hub

# 2021 – POC focused on validation of synthetic cases via 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)



# Ask: How and why you should participate!

## Why participate?

- Support impactful ongoing public health vaccine safety efforts
- Authorship on an innovative paper
- Financial incentive(s)

## Interested in being a participant?

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

# FDA Pilot Questions & Answers



# FHIR Roadmap Highlights

eHealth Exchange<sup>TM</sup>

## 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 Exchange<sup>TM</sup>

## 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 January 6, 2022
  - Increase from 266 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

- 22,852 Documents Tested as of January 6, 2022
  - 82% Failing
  - 18% Passing
- Breakdown of Documents Tested by Validator Version
  - 56% or 12,886 tested against the Meaningful Use 2015 Edition/HL7 C-CDA R2.1
  - 13% or 2,868 tested against the Meaningful Use 2014 Edition/HL7 C-CDA R1.1
  - 26% or 5,995 tested against the Meaningful Use 2011 Edition/HL7 C-32
  - 5% or 1,047 tested against the CDA R2 validator
  - <1% (.002) or 56 tested against the USCDI V1 validator



# Testing Innovations

eHealth Exchange<sup>TM</sup>

## 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
- 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](#)



# FHIR R4 and Directory Update

eHealth Exchange<sup>TM</sup>

## Transition to FHIR R4 and Directory Update

- The latest iteration of the FHIR R4 IGs is complete based on changes made in the past 2 months.
- Updates to transforms to convert data from existing directories into FHIR R4 are complete.
- The HAPI FHIR R4 server environment has been updated to accommodate backwards compatible endpoints for those not ready to implement R4. As part of this, Lantana has reverse engineered the transforms noted above to accommodate bi-directional conversion of data from the existing directory format to FHIR R4.
- Validation of data against the FHIR R4 IGs is complete.
- HAPI development work by Lantana is complete.
- We continue to work with the UI/UX vendor and Lantana on the eHX Participant Self-Service Portal (GUI).

# Directory Introduction

## Directory Purpose

- The eHealth Exchange directory conveys each participant's web service endpoints for exchanging patient clinical data. This is traditionally done with the transactions of patient discovery, query for documents and retrieve documents.
- In the future, FHIR endpoints may be published in the directory to exchange patient clinical data via FHIR.
- In addition to web service endpoints, organizational address and organizational contacts are listed along with data elements such as:
  - Hub service subscriptions
  - Administrative status
  - Hub routing status (Hub responder, Hub initiator, Hub responder and initiator, testing)
  - State(s) of operation
  - Use cases

# Directory Usage

## Suggested Directory Usage

- To be effective, the directory must have the latest information so participants can connect to your organization.
- The web service endpoints must be correct for your organization or the Hub will not be able to connect to your responding gateway.
- Please retire and inactivate legacy gateway entries to avoid confusion – email [techsupport@sequoiaproject.org](mailto:techsupport@sequoiaproject.org)
- Please keep your organization's directory entry name up to date using a publicly consumable “doing business as” name. Coming up in 2022, participants will use a web-based search portal to find participant provider locations on a U.S. map. The “doing business as” name will come from the directory and may be associated to each provider location.
- Your organization must authorize a response for clinical data requests to every participant listed in the eHealth Exchange directory. \* If your organization limits authorization by the home community ID (HCID) of the requester, then the directory provides a list of each participant's HCID.
- In addition, if you are exchanging with Carequality, you must authorize a response to all entries in the Carequality directory. A new HubAware Carequality directory (with a list of both eHealth Exchange and Carequality entries) is now available under FHIR STU3 only and will be available using FHIR R4 in the future.

# Directory Additions and Modifications

## New or Modified Directory Elements - Highlights

- State(s) of Operation – a list of state(s) where your organization does business. For example, the state(s) where your organization has provider or payer locations.
  - To be used with the group query feature in the future.
  - Note: This used to be called “U.S. state of HIE”
- Per organization:
  - National Provider Identifier (NPI)
  - Clinical Laboratory Improvement Amendments (CLIA) Number for laboratories
  - CMS Certification Number (CCN)
- Defined under each Organization address location:
  - Role: provider, agency, research, payer, diagnostics, supplier, HIE/HIO, member
  - Service delivery role type: Hospital, gastroenterology lab, ER, inpatient laboratory, etc.
    - **Note: This will be critical for the CY 2022 release of the web-based search portal**
- Defined per Endpoint:
  - Downtime (scheduled downtime)

# Directory Additions – population of sub-participant entries

## New Directory Capability

- With the R4 HAPI based directory release, your organization can add a sub-participant directory entry that defines a provider or payer which is accessible under your participant gateway.
- A typical sub-participant directory entry could define a hospital, clinic or doctor's office that has contributed patient information accessible under your participant gateway.
- The eHealth Exchange has curated hospital sub-participant information for many of our participants and plans to populate accumulated hospital provider information in the directory during CY 2022.

# Directory Consumption

## **FHIR Client API**

- Access the directory with a FHIR client using a FHIR API key provided by Sequoia technical support – email [techsupport@sequoiaproject.org](mailto:techsupport@sequoiaproject.org) for a FHIR API key
  - Provides access to both FHIR STU3 and FHIR R4 APIs
  - Provides read-only access – no update or create operations

## **Web-based Directory Portal**

- Coming in FY 2022 at about the same time as the FHIR R4 release - details to be communicated as delivery nears
- Role based access for updates to existing directory entries and creation of new directory entries
- Drop-down selections for entries where possible
- Download the entire directory for offline review

## **UDDI (SOAP API) API continued support**

- The new FHIR HAPI based directory will support a traditional UDDI/SOAP interface
- Newer data elements introduced with STU3/R4 will not be available under the UDDI/SOAP interface
- Access will utilize SSL/TLS certificate-based security, as in the past – directory clients may optionally verify the UDDI server certificate

# Background - Reason for Directory Changes

## Current state

- Current directories are based on an unofficial release of FHIR prior to STU3
- Previous implementation guide (IG) is just a PDF. No formal definitions (in the form of FHIR conformance resource) for profiles, extensions, value sets, and code systems
- Unable to use off the shelf FHIR tooling without modification
- Unable to transfer content to other FHIR servers without modification

## Future state

- Directories based on the official release of FHIR R4
- IGs created using FHIR resources such as StructureDefinition, ValueSet, etc. and run through the FHIR IG publisher
- Compliant content will work with FHIR reference implementations, the FHIR validator, FHIR servers, etc. out of the box

# Change Highlights

## The changes fall into 3 key categories

- Basic structural repairs
- STU3 IG updates (not in production)
- R4 IG updates

## Implementation Guide Snapshot

### Chapter 1: Introduction

#### 1.1. Introduction

The Sequoia Project® Healthcare Directory is designed to accommodate the needs of Sequoia Project initiatives.

The primary use case for the directory is the acquisition of organization-level information, including electronic end points. The Sequoia Project is a heavily engaged member of the three main organizations creating the technical standards used by the directory, including the Argonaut Project, HL7, and IHE International. Many of the characteristics of the current FHIR Provider Directory Standard for Trial Use v3 reflect Sequoia Project contributions to, and requirements of, the standard.

Please see the [change logs](#) in this documentation for information about changes to this document, and to the software and operations described by this document.

#### 1.2. Conventions Used

XML examples in this documentation use the following formatting convention:

```
<partOf>
  <!--Home Community ID of parent org, if any-->
  <identifier>
    <use value="official"/>
    <type value="HCID"/>
    <system value="http://www.hl7.org/oid"/>
    <value value="1.1.1.1"/>
  </identifier>
</partOf>
```

Text to be entered at a terminal uses the following formatting convention:

```
curl -X GET "https://server.com/abc"
```

# Structural Repairs

## Goal

- Core FHIR STU3 compatibility for resource instances
- Minimum necessary to allow directory content to be processed using FHIR STU3 libraries and stored on complaint STU3 FHIR servers

## Key Changes

- Fixed elements that were out of order
- Corrected misspelled element names
- Changed non-FHIR elements to extensions
- Added missing required elements where possible (system for known codes, etc.)

## Implementation

- Fixes were implemented using transforms on the Organization, Endpoint, and Location resources
- A reverse (unfix) transform was also created for backwards compatibility



*It's like retrofitting an iconic bridge to bring it up to building code.*

# STU3 IG Updates

## Purpose

- Express the old PDF IG content using FHIR conformance resources and FHIR tooling

## Details

- Created StructureDefinition, ValueSet, and CodeSystem resources for all computable content
- Converted PDF prose documentation to markdown and XHTML for inclusion in the IG
- Extracted FHIR examples from the PDF and converted to FHIR XML Resources that validate against the computable IG content

Content

Detailed Definitions

Mappings

XML

JSON

SD.1 StructureDefinition-SequoiaOrganization

SD.1.1 Formal Views of Profile Content [↗](#)

Description of Profiles, Differentials, and Snapshots.

The official URL for this profile is: <https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/SequoiaOrganization>

Published on Sat Apr 04 05:05:16 EDT 2020 as a active by .

This profile builds on [US Core Organization Profile](#)

Text Summary

Differential Table

Snapshot Table

XML Template

JSON Template

All

Name	Flags	Card.	Type	Description & Constraints
Organization		0..*	US Core Organization Profile	US Core Organization Profile
Domains	S	0..*	Coding	Domains URL: <a href="https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/Domains">https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/Domains</a> Binding: Domains (required)
HubServiceSubscriptions	S	0..*	Coding	HubServiceSubscription URL: <a href="https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/HubServiceSubscriptions">https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/HubServiceSubscriptions</a> Binding: Hub Service Subscriptions (required)
AdministrativeStatus	S	0..1	Coding	Extension URL: <a href="https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/AdministrativeStatus">https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/AdministrativeStatus</a> Binding: Administrative Status (required)
HubRoutingStatus	S	0..1	Coding	Extension URL: <a href="https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/HubRoutingStatus">https://sequoiaproject.org/fhir/sphd-stu3/StructureDefinition/HubRoutingStatus</a> Binding: Hub Routing Status (required)
Identifier	S	1..*	Identifier	Identifies this organization across multiple systems
active	S	1..1	boolean	Whether the organization's record is still in active use
type	S	1..*	CodeableConcept	Kind of organization Binding: OrganizationType (required)

# FHIR R4 Implementation Guides (IGs)

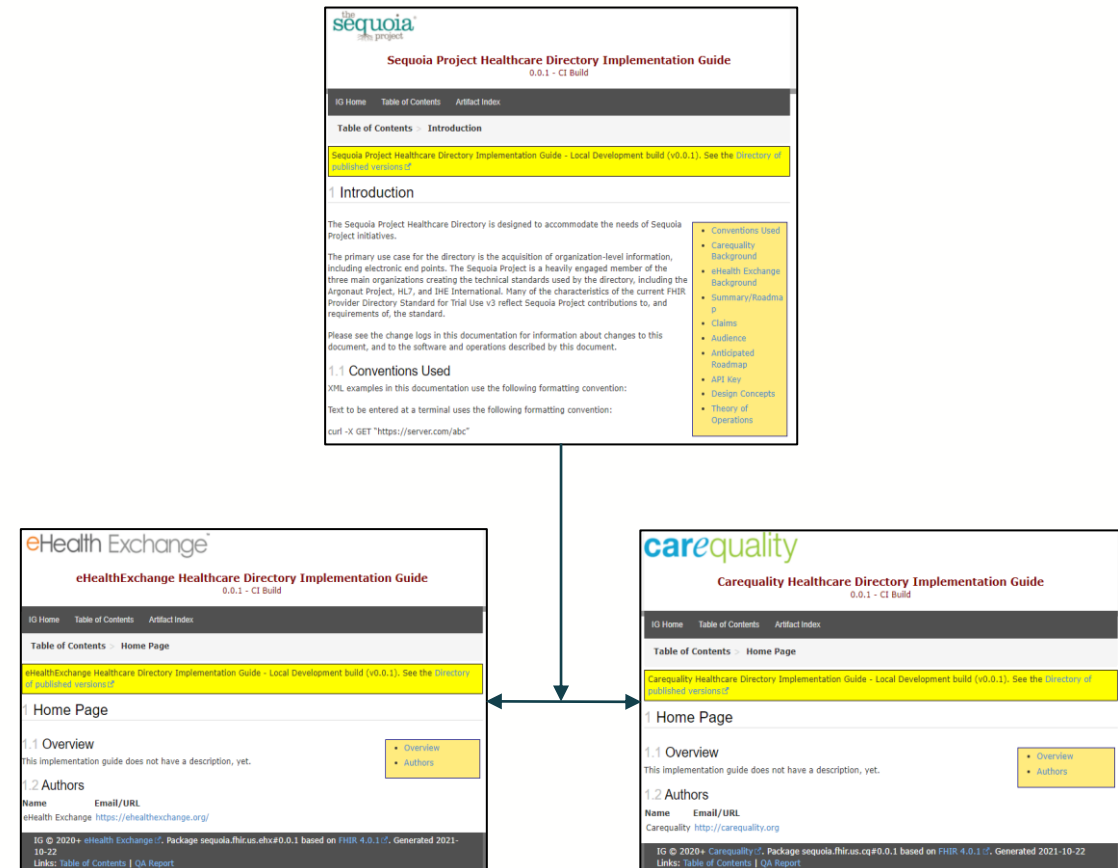
## Purpose

- Port the FHIR STU3 IG to R4
- Separate eHealth Exchange and Carequality requirements

## Details

- Resulted in 3 IGs:
- Sequoia base IG for common requirements
- eHealth Exchange and Carequality IGs for their specific requirements (dependency on the Sequoia IG)
- Upgraded all profiles and extensions for FHIR R4
- Profiles inherit from US Core (FHIR R4 version) where available
- Changed names, URLs, etc. to conform with FHIR publishing best practices
- Added custom branding to all IGs
- Created R4 transforms for converting legacy content and validated the result against the IGs.

## IG Inheritance Model

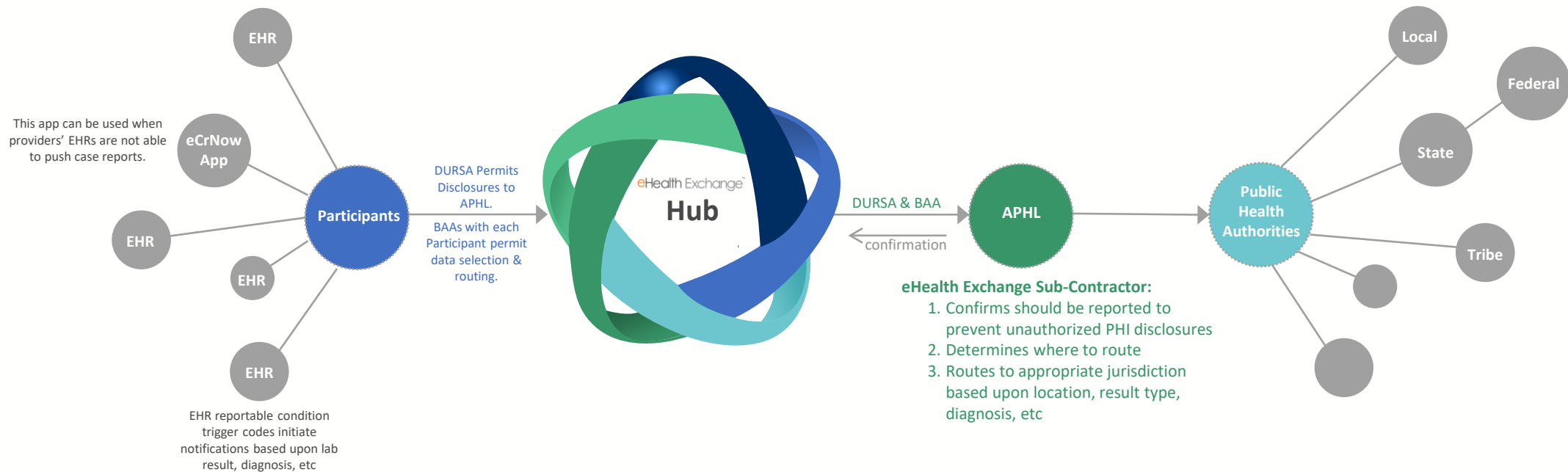




# eCR Update

eHealth Exchange<sup>TM</sup>

# 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](mailto: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.



# Contacts

Changing and New Contacts

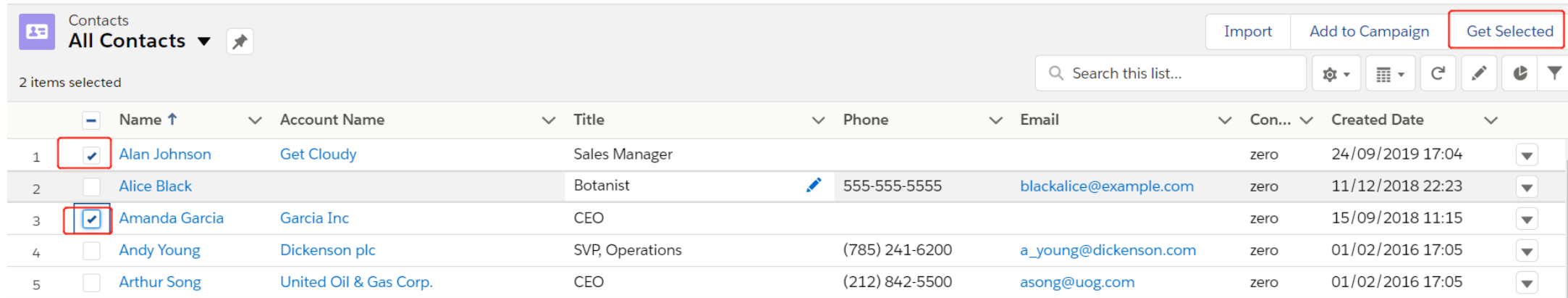
eHealth Exchange<sup>TM</sup>

# Contacts for Your Organization

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

We find out that resources are no longer working in the organization and we send a contact list template to someone in the organization to get an updated contact list.

- If you have had recent or past changes and are unsure if we have an updated list: email [administrator@ehealthexchange.org](mailto: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.



The screenshot shows a web interface for managing contacts. At the top, there's a header with 'Contacts' and 'All Contacts' with a dropdown arrow. To the right are buttons for 'Import', 'Add to Campaign', and 'Get Selected' (highlighted with a red box). Below the header, it says '2 items selected'. A search bar with the placeholder 'Search this list...' is present. The main area is a table with columns: Name, Account Name, Title, Phone, Email, Con..., and Created Date. The first two rows are highlighted in grey, and the first and third rows have their selection checkboxes checked and highlighted with red boxes.

	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	<a href="mailto:blackalice@example.com">blackalice@example.com</a>	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 href="mailto:a_young@dickenson.com">a_young@dickenson.com</a>	zero	01/02/2016 17:05
5	<input type="checkbox"/> Arthur Song	United Oil & Gas Corp.	CEO	(212) 842-5500	<a href="mailto:asong@uog.com">asong@uog.com</a>	zero	01/02/2016 17:05

[This Photo](#) by Unknown Author is licensed under [CC BY-SA](#)



# Please Engage!

We'd love to hear from you.

eHealth Exchange<sup>TM</sup>

# 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	<a href="https://ehealthexchange.org">https://ehealthexchange.org</a>
Monthly Participant Web Meetings	3rd Thursday of Each Month at 1 pm ET	<a href="https://ehealthexchange.org/events">https://ehealthexchange.org/events</a>
Weekly Technical Workgroup	Thursdays 4-5 ET	<a href="https://ehealthexchange.org/events">https://ehealthexchange.org/events</a>
Email	Any time if you have a specific question	<a href="mailto:administrator@ehealthexchange.org">administrator@ehealthexchange.org</a>
Annual Meeting	December 2022	On Site Washington, D.C.

## How might I obtain assistance?

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

# Questions & Answers

Please e-mail questions or concerns to  
[administrator@ehealthexchange.org](mailto:administrator@ehealthexchange.org)