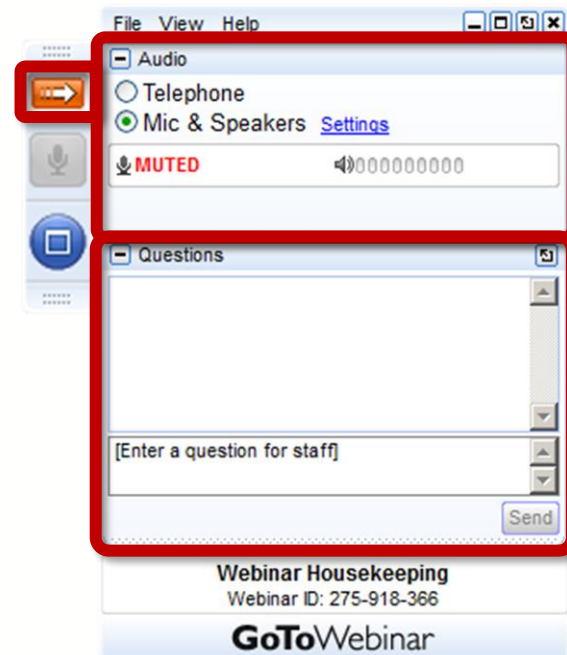


October 20th, 2022

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	Abhi Pandey
3. FHIR R4 Directory	Mike Yackanich
4. Contacts	Mark Rogers
5. Q&A	Everyone



New Participants

eHealth ExchangeTM

Congratulations to our newest Participant!

- McLeod Health
- Total Community Options, dba InnovAge



Committed to Improving Patient Care via Data Exchange



Participation Request

FDA Pilot: Adverse Event Exchange via FHIR 2022 Roadmap

eHealth ExchangeTM

CBER OBPV Mission

Ensure post-market biologic-product safety and effectiveness

Regulated Products

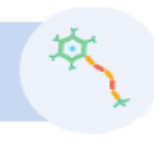
Vaccines (preventative and therapeutic)



Blood (components and derived)



Human Tissues and Cellular Products



Gene Therapies



Xenotransplantation Products



FDA BEST Initiative Objective

The objective of the Biologics Effectiveness and SafeTy (BEST) Initiative is to ensure post-authorization biologic-product **safety and effectiveness** through leveraging eHealth Exchange national connectivity.

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.

CBER = Center for Biologics Evaluation and Research

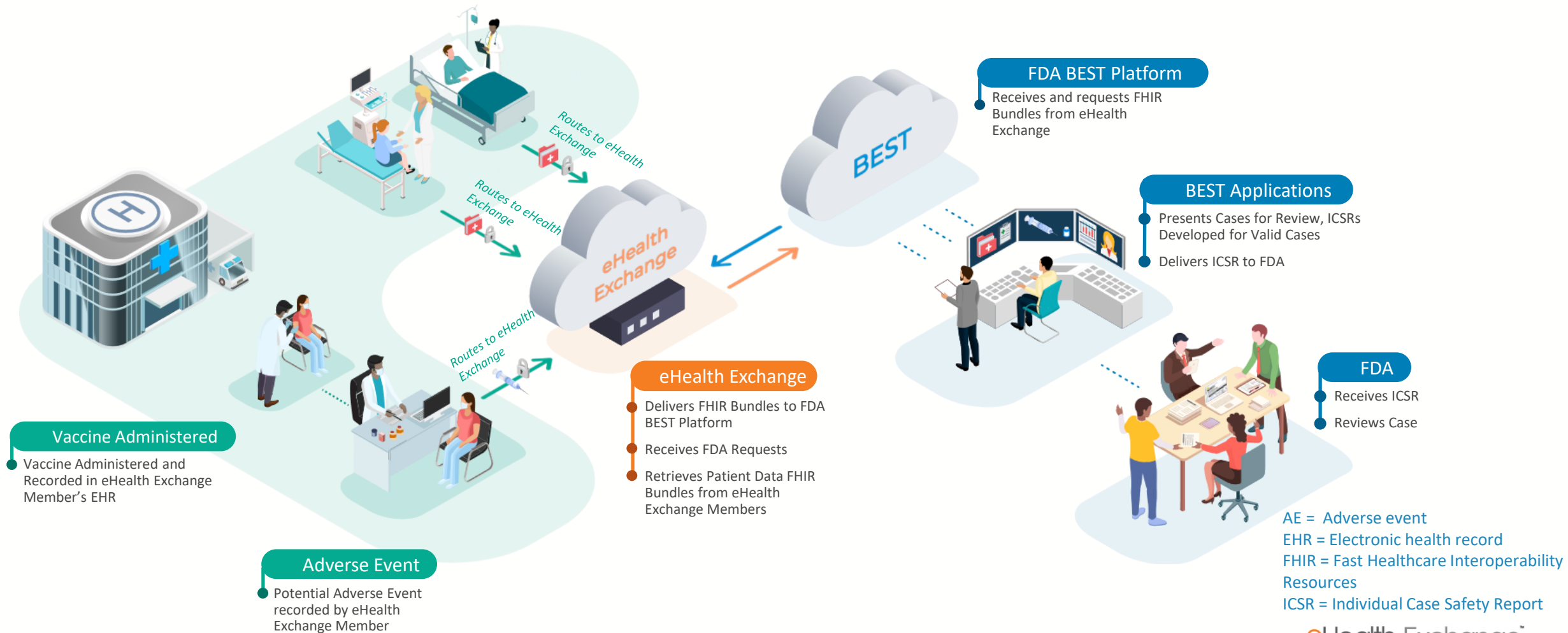
FDA = U.S. Food and Drug Administration

OBPV = Office of Biostatistics and

Pharmacovigilance

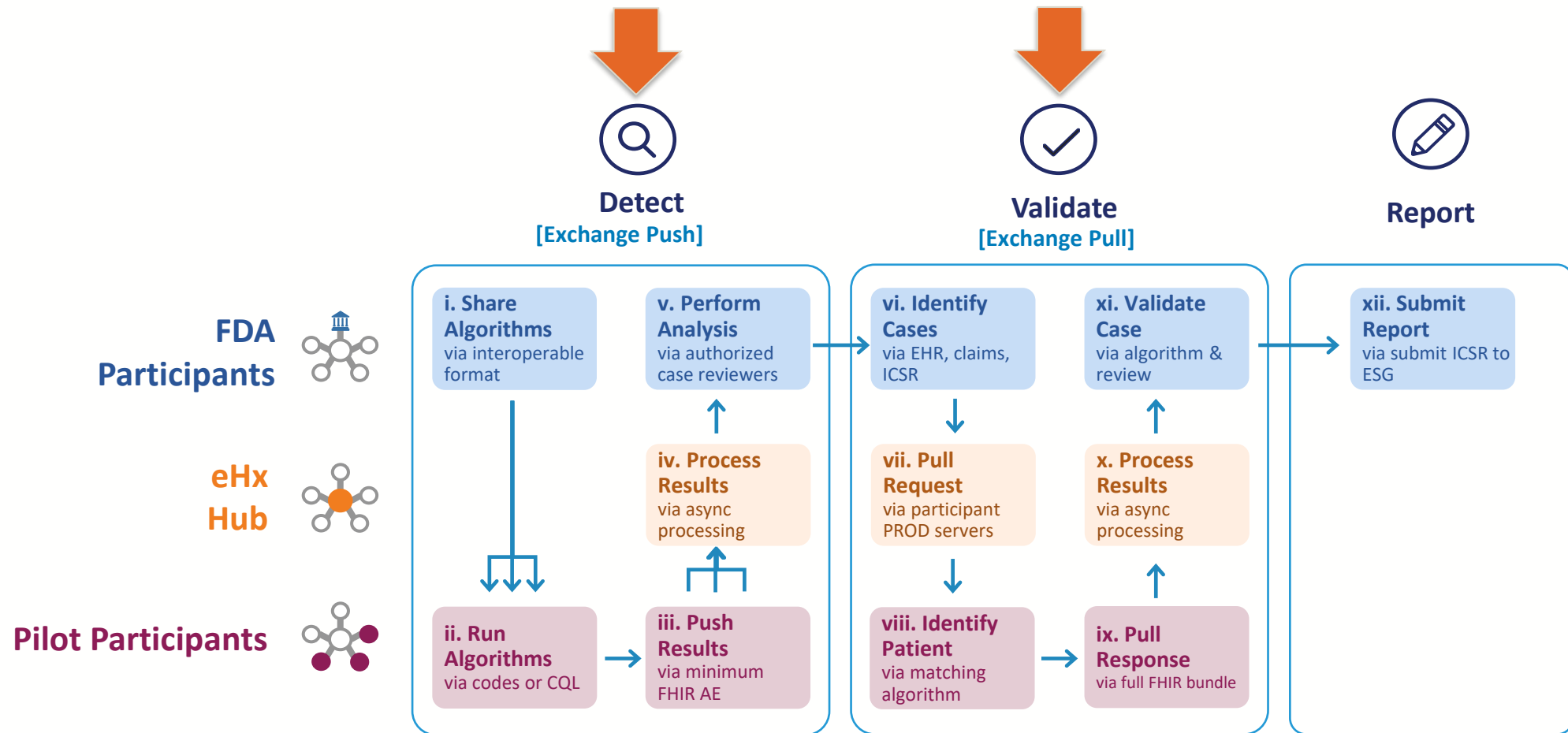
eHealth Exchange

FDA- BEST Exchange Operational Architecture



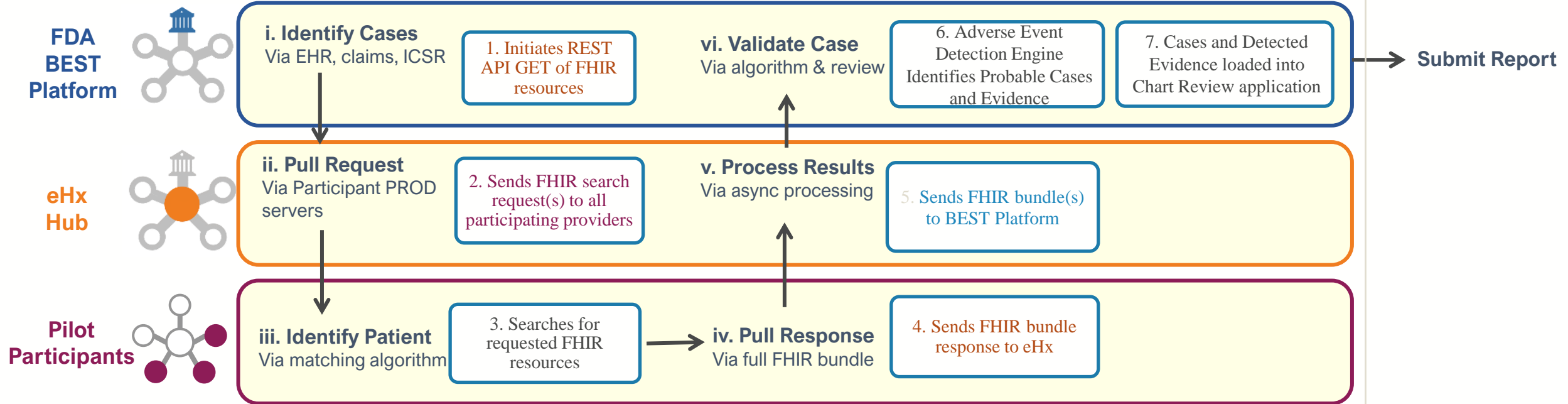
Pilot will focus on detection (Push) and validation (Pull) use cases

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

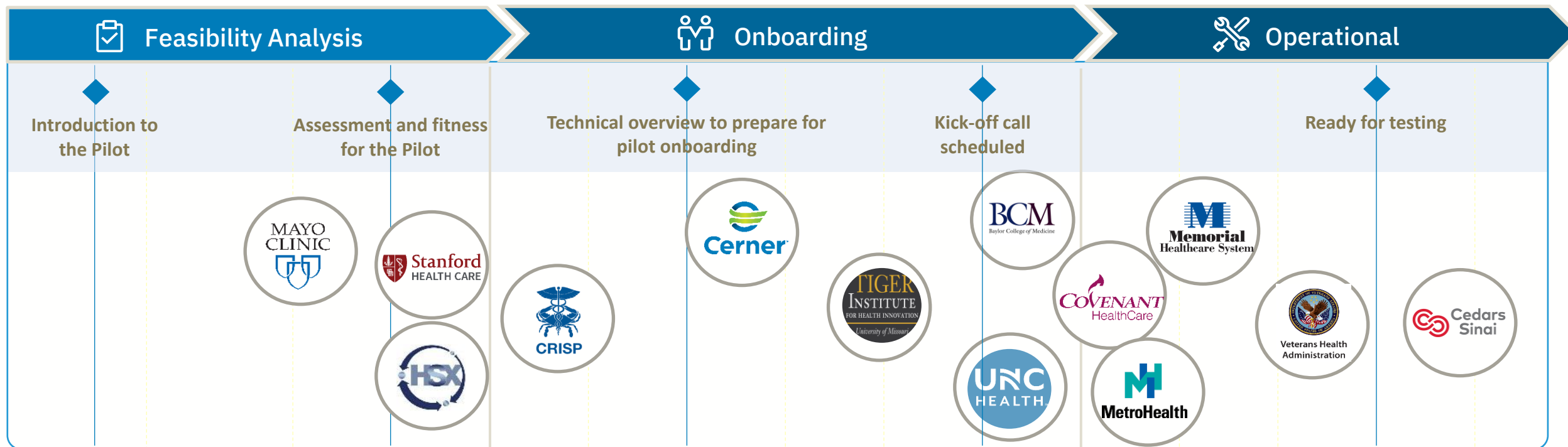


FDA- BEST Exchange Primary Use Case

PULL Use Case-Data Flow Model



FDA- BEST Exchange Current and Potential Participants



FDA Best Production Pilot: The “Ask”

- **Ask:** Consider participating in the Production Pilot by acting as a responding gateway to inbound FHIR resource queries/retrieval.
- **Why participate?**
 - Support impactful ongoing public health vaccine safety efforts
 - Automation of current manual process of reporting
 - Authorship on an innovative paper
- **Level of Effort:** <4 hours. eHx will provide set up guidance.
- **Stretch Goal:** For Participants to send a FHIR message to the FDA, via the eHx Hub, notifying the FDA of potential adverse reaction events.
- **Interested in being a participant?**
 - Reach out to Michael McCune (mmccune@ehealthexchange.org)



FDA FHIR Acceleration Incentive 2022



eHealth Exchange plans to waive up to fifteen (15) non-federal Participants' annual participation fee for one year if they successfully respond to FDA's Production FHIR R4 APIs in accordance with FDA BEST exchange requirements by 3-31-2023.



Only the first 15 to successfully go-live by this date will have fees waived at their annual renewal after they've been live for at least six months.

Goals

1. **Reduce clinician burden!**
2. **Improve public health!**
 - Increase pandemic response
 - Improve vaccine safety
3. **Accelerate FHIR adoption!**

Respond to FDA's requests for vaccine adverse event data using FHIR!

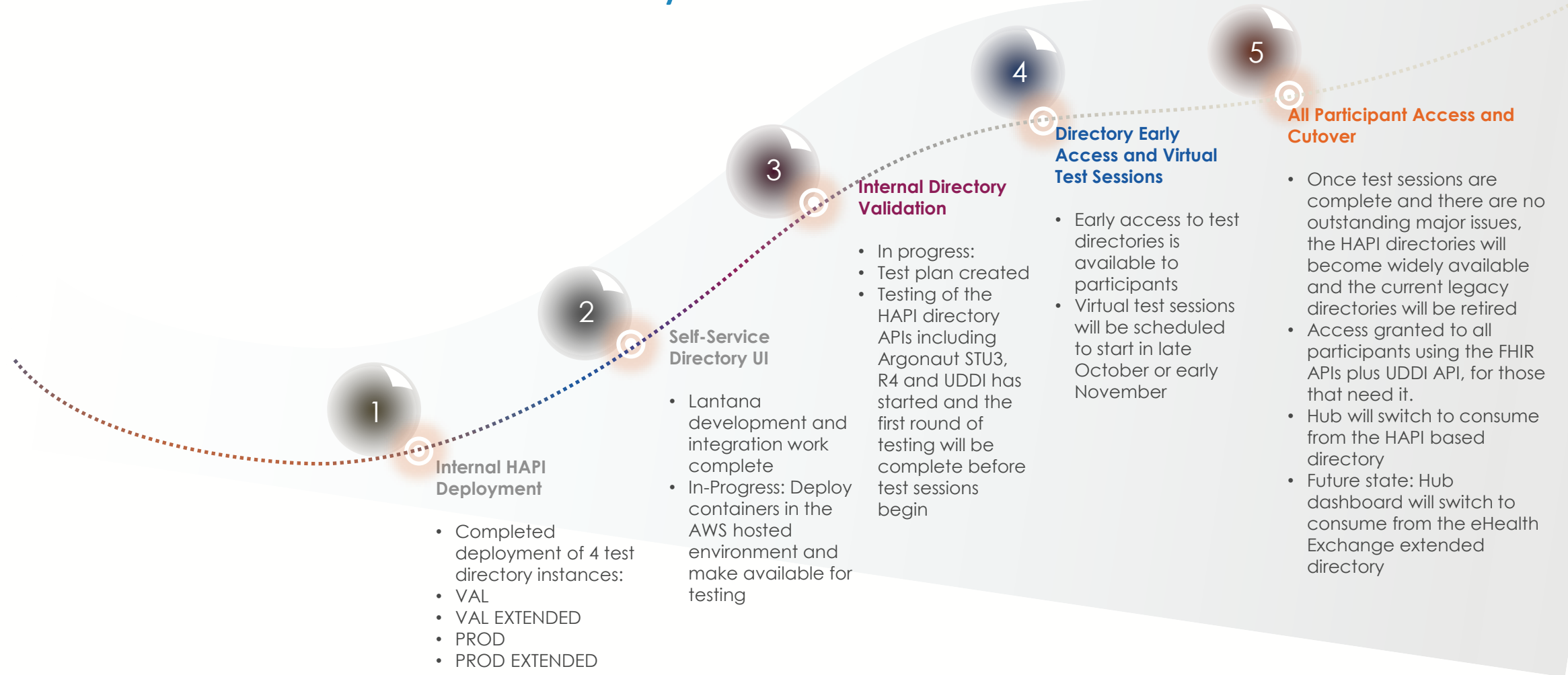
FDA Pilot Questions & Answers



FHIR R4 Directory Test Sessions and Directory Rollout Plans

eHealth ExchangeTM

Transition to FHIR R4 Directory – Milestones



New HAPI Directory APIs – 3 API Choices

FHIR Client API

- Access the directory with a FHIR client using a FHIR API key provided by Sequoia technical support – email techsupport@ehealthexchange.org for a FHIR API key
 - Provides access to both **Argonaut STU3 FHIR** (same as the current directory offering) and **FHIR R4** APIs
 - Typically provides read-only access – no update or create operations

UDDI API (SOAP 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
- **No access** to sub-participant entries
- Access will require SSL/TLS certificate-based security only, as in the past

New HAPI Directories and Hub endpoints

FHIR Client API and Hub endpoints

- Unlike the current directories, using the FHIR APIs, there are no longer separate directories for direct endpoints and Hub endpoints.
- To obtain Hub endpoints using the FHIR APIs, use the FHIR operation \$hub-aware. For example:
 - For all FHIR R4 entries with Hub endpoints:
[https://directory.prd.ehealthexchange.org/fhir/Organization/\\$hub-aware](https://directory.prd.ehealthexchange.org/fhir/Organization/$hub-aware)
 - For a single FHIR R4 entry with Hub endpoints:
[https://directory.prd.ehealthexchange.org/fhir/Organization/2.16.840.1.113883/\\$hub-aware](https://directory.prd.ehealthexchange.org/fhir/Organization/2.16.840.1.113883/$hub-aware)

UDDI API (SOAP API) and Hub endpoints

- The base URI remains the same for direct and Hub endpoints but the path changes. For example:
 - Direct endpoints with the UDDI API:
 - <https://directory.prd.ehealthexchange.org/uddi>
 - Hub endpoints with the UDDI API:
 - <https://directory.prd.ehealthexchange.org/uddi-hubaware>

Virtual Test Sessions for New HAPI Directories

Virtual test sessions will be available to all participants:

- Multiple virtual test sessions for the HAPI test directories will be scheduled late October and early November
- Prior to each virtual test session, the test directories will be refreshed with the latest data from the legacy directories.
- Please join the virtual test sessions:
 - If you need technical assistance
 - If you would like to debug a directory issue
 - If you have questions that are best handled interactively.
- HAPI test directories will generally be available outside of virtual test sessions, unless participants are notified otherwise.

Virtual test sessions will continue based on participant demand

- We will work to prioritize and resolve participant reported issues between test sessions

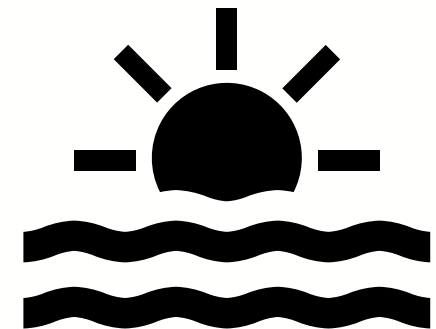
Rollout of New HAPI Directories and Retirement of Legacy Directories

Rollout of the new HAPI directories to all participants:

- The new HAPI directories will become widely available for consumption once all major directory issues have been resolved, including participant reported issues and issues discovered by the eHealth Exchange testing team.
- **Goal:** Rollout the HAPI directories for general availability by late November 2022 or December 2022

Legacy directory retirement

- The legacy directories will be retired and will no longer be accessible once the HAPI directories become generally available to all participants.
- Once the retirement occurs, the eHealth Exchange will attempt to forward requests for the legacy directories to the new HAPI directories. This is currently under investigation and may not be feasible due to the complexity of the forwarding configuration.



FHIR R4 Directory Questions & Answers



Contacts

Changing and New Contacts

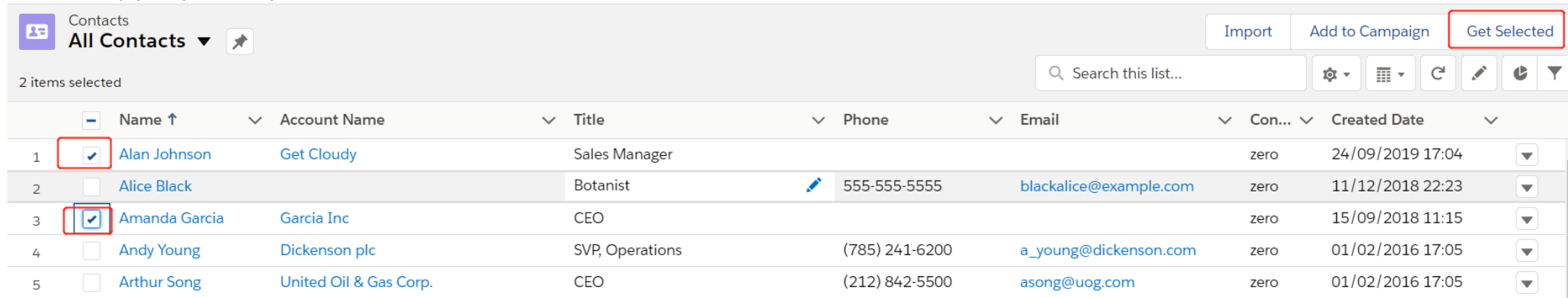
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Contacts for Your Organization

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									Import	Add to Campaign	Get Selected
All Contacts ▼											
2 items selected									Search this list...		
	<input type="checkbox"/>	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

eHealth ExchangeTM
intends to apply to be a QHIN.



Visit www.bemyqhin.org to learn more.

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 15, 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

eHealth ExchangeTM
intends to apply to be a QHIN.



Visit www.bemyqhin.org to learn more.

Questions & Answers

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