eHealth Exchange

All Participant Call

How Do I Participate?



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. Tips & Tricks: Stable vs On-Demand Documents	Mark Rogers
4. eCR Update	Jay Johnstone
5. Coordinating Committee Elections	Pat Russell
6. Contacts	Mark Rogers
7. Q&A	Everyone

New Participants

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eHealth Exchange

Congratulations to our newest Participant!

Deaconess Health System



Committed to Improving Patient Care via Data Exchange



CBER OBE 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 postauthorization 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
OBE = Office of Biostatistics and Epidemiology



FDA Exchange Overview



Prototype on Foundational Network

- Built EHR to FDA pipeline with MedStar
- Developed and validated phenotypes
- Reported Individual Case Safety Report (ICSR) cases



D.C. MD

VA

FL

Prototype on Exchange Network

- Leverage pipeline to design/POC exchange architecture
- Support with data agreements and standards



Operationalize on Foundational Network

- Leverage and enhance pipeline
- Phenotype validation of priority Covid vaccine related AEs

FY22

Operationalize on Exchange Network

- Expand prototype into operational use
- First with early adopter participants
- Then mature and expand



Accomplished

Ongoing



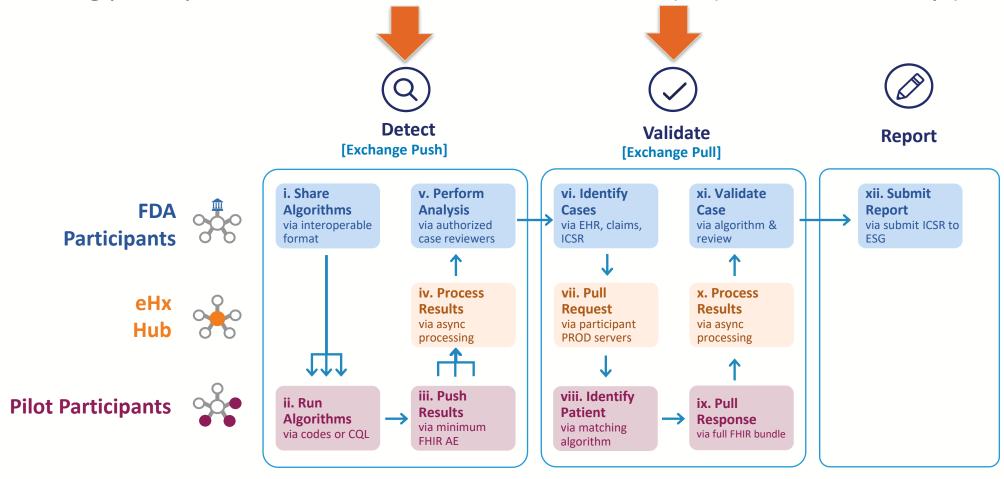


FDA- BEST Exchange Operational Architecture

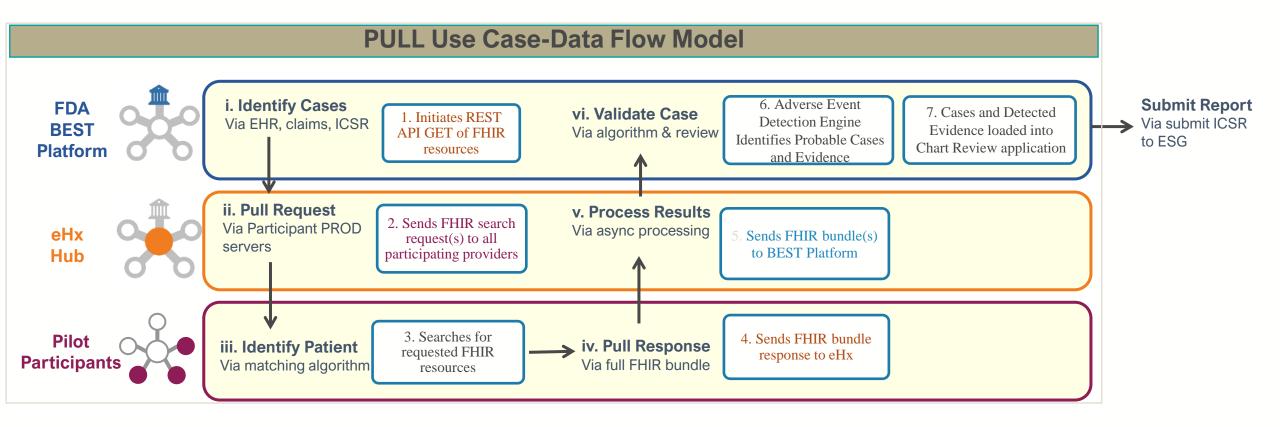


Pilot will focus on detection (Push) and validation (Pull) use cases

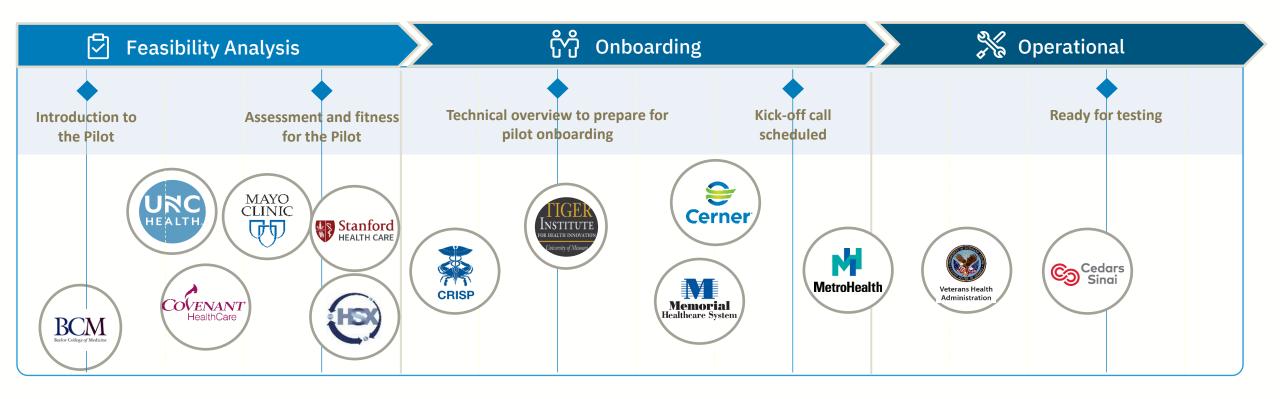
FDA is seeking participants for either detection and validation (i-ix), or validation only (vi-ix)



FDA- BEST Exchange Primary Use Case



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 Kathryn Bingman (<u>kbingman@ehealthexchange.org</u>)

FDA Pilot Questions & Answers

Tips & Tricks

Stable vs On-Demand Documents

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Health Exchange

A Document Entry Type By Any Other Name...

- Documents exchanged via the eHealth Exchange may either be 'Stable' or 'On-Demand'
 - Stable documents do not change after generation. They will not change whether you retrieve it today, next week, or next month.
 - One example might be an Encounter Summary that describes an appendix being removed.
 - On-Demand documents are generated and regenerated on a consistent basis. The content may change based on when you ask for them.
 - One example might be a Patient Summary, which is continually updated as more allergies/problems/medications are added to their chart.
 - Both Stable and On-Demand documents may be requested during a Document Query using the 'XDSDocumentEntryType' parameter. However, unless you specifically ask for On-Demand, you will only ever get Stable documents.

Why Is This Important?



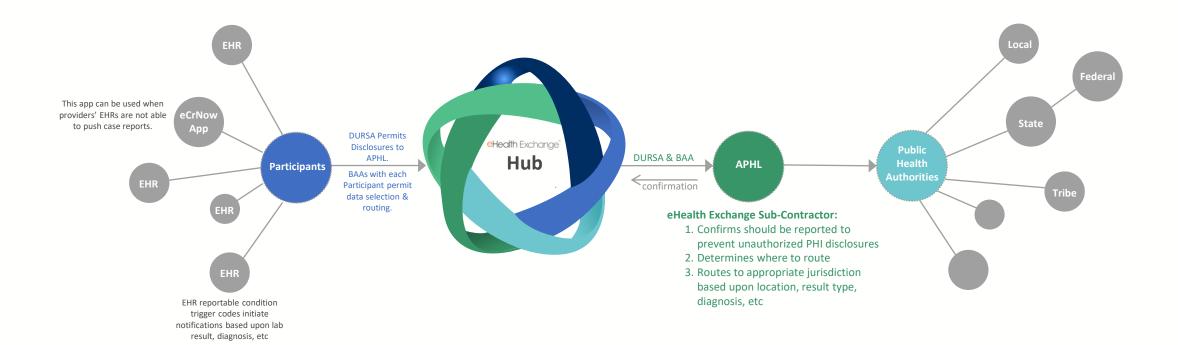
Takeaways

- Some responders may have few or no Stable documents available, just On-Demand.
- Check to see how you are generating your Document Queries!
- More data exchange means more informed patient care, but also data storage needs and so forth.
- Work with your vendor support to evaluate system impact before you start asking for On-Demand documents
 - IHE specification <u>here</u>
 - eHealth Exchange specification <u>here</u>

eCR Update

eHealth Exchange

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 <u>administrator@ehealthexchange.org</u> 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.

Coordinating Committee Elections Health Exchange ©2022 eHealth Exchange. All Rights Reserved.

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	Dede Ainbinder	9/30/2024
	Jarrod Pearson	9/30/2024

2022 Coordinating Committee (CC) Election – Open for Applications!

- 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
- Link to application form: https://www.cognitoforms.com/TheSequoiaProject1/ 2022CoordinatingCommitteeApplication

Contacts **Changing and New Contacts** eHealth Exchange ©2022 eHealth Exchange. All Rights Reserved.

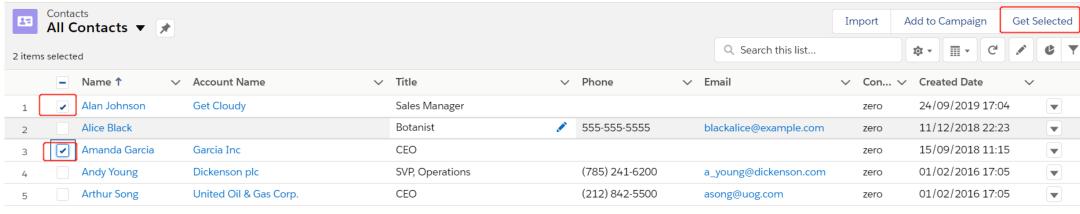
Contacts for Your Organization

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.



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Please Engage! We'd love to hear from you. Health Exchange ©2022 eHealth Exchange. All Rights Reserved.

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20 ANNUAL 22 METING

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 <u>administrator@ehealthexchange.org</u> 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

Questions & Answers

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