September 15th, 2022

# eHealth Exchange

## 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

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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. Coordinating Committee Elections	Pat Russell
4. Contacts	Mark Rogers
5. Q&A	Everyone

## **New Participants**

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## Congratulations to our newest Participant!

- Bozeman Health
- Santa Clara Valley Medical Center Hospitals and Clinics
- Emory Healthcare
- Phelps Health
- San Francisco Department of Health
- St Jude Children's Research Hospital



#### Committed to Improving Patient Care via Data Exchange

## Participation Request

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

## eHealth Exchange

## **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

7





#### Xenotransplantation Products

## **FDA BEST Initiative Objective**

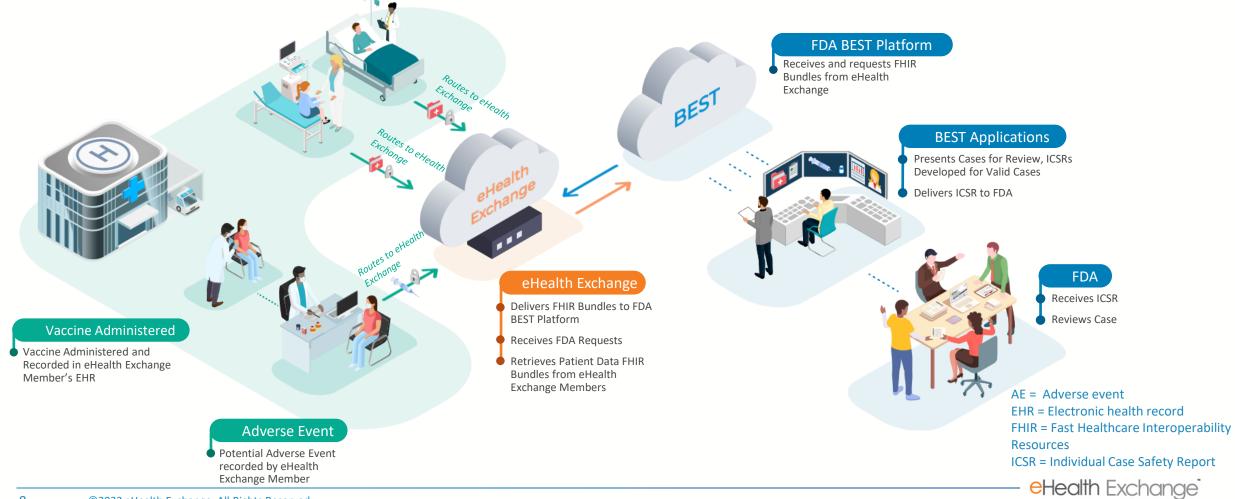
The objective of the Biologics Effectiveness and SafeTy (BEST) Initiative is to ensure postauthorization biologic-product safety and effectiveness through leveraging eHealth Exchange national connectivity.

## **Exchange Pilot Objective**

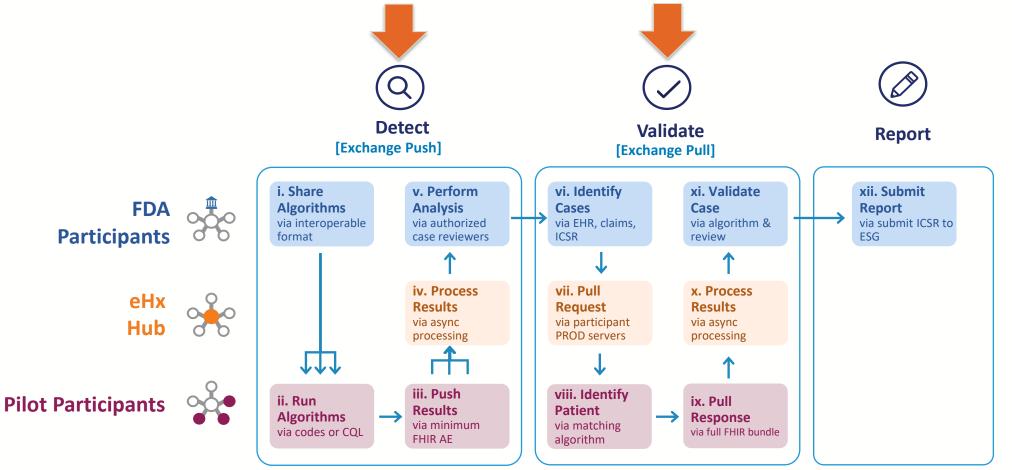
To enable more robust monitoring of postauthorization adverse events while minimizing the burden on providers through an exchange-based FHIR infrastructure.

> CBER = Center for Biologics Evaluation and Research FDA = U.S. Food and Drug Administration OBPV = Office of Biostatistics and Pharmacovigilance CHeolth Exchange

#### **FDA- BEST Exchange Operational Architecture**

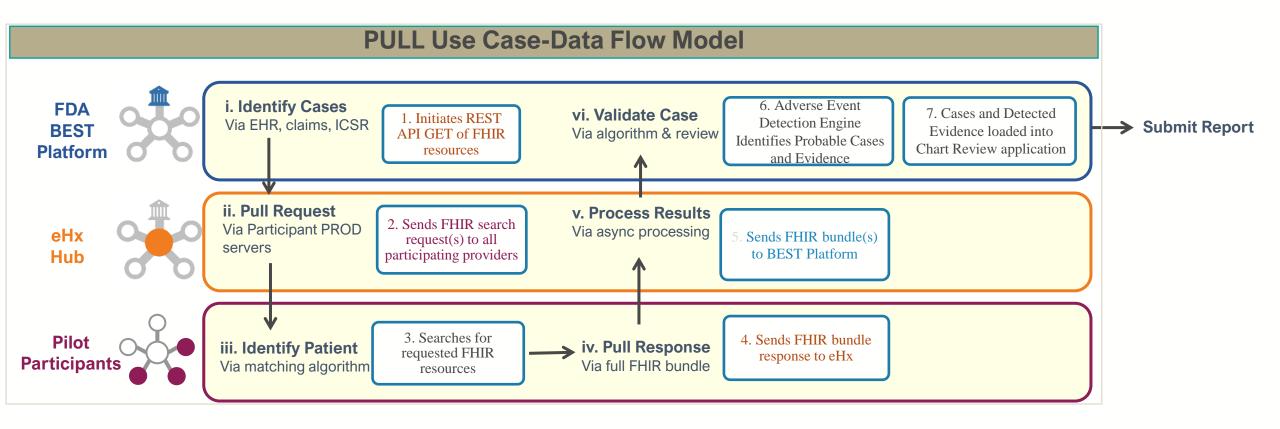


## **Pilot will focus on detection (Push) and validation (Pull) use cases** FDA is seeking participants for either detection and validation (i-ix), or validation only (vi-ix)



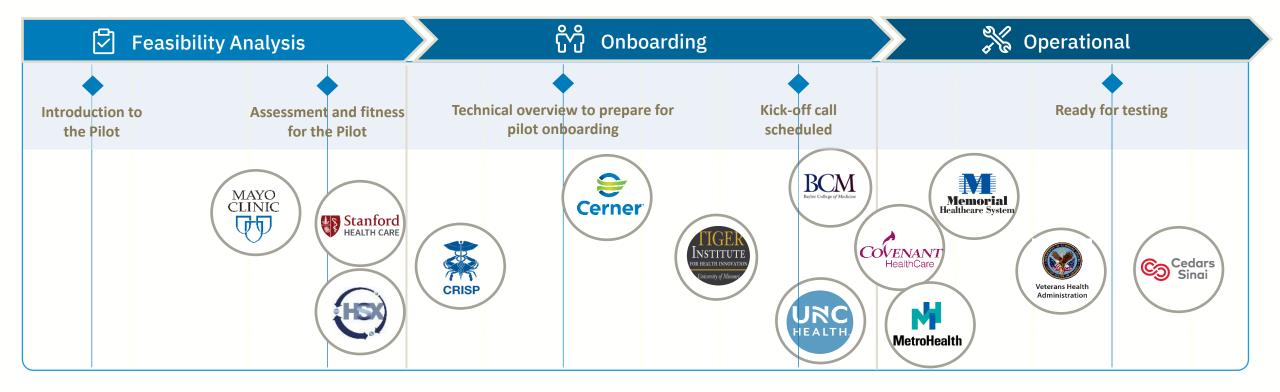
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## **FDA- BEST Exchange Primary Use Case**



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## **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.

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- Interested in being a participant?
  - Reach out to Kathryn Bingman (kbingman@ehealthexchange.org)

## FDA Pilot Questions & Answers



## **Coordinating Committee Elections**

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## 2022 Coordinating Committee (CC) Election Timeline

#### **Nomination Applications:**

• August 5 – Applications Closed

#### Nominating Committee Submits Nominations:

• August 16

#### Voting:

• August 22-26, Participants Vote (1 vote per Participant organization)

#### Term Begins:

• October 18- First New CC Member meeting

#### **2022** Coordinating Committee Ballot:

- Health Information Organizations (HIE, HIN)(1 seat)
  - ✓ Jaime Bland (CyncHealth)
  - ✓ Jason Buckner (Manifest Medex)
- Other (Vendors, Service Providers, Ambulatory Groups, Payers, Dialysis orgs, etc.) (3 seats)
  - ✓ Paul Matthews (OCHIN)
  - Eric Liederman, MD (Kaiser)(employed by health plan and ambulatory groups)

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- ✓ Lindsey Elkind (DaVita)
- ✓ Zach Finn (Centralis Health)
- ✓ Derek Plansky (Health Gorilla)
- Health Systems (1 seat)
  - ✓ Matt Eisenberg, MD (Stanford)

## 2022 Coordinating Committee (CC)

	Representative	Term Date					
	Jaime Bland	9/30/2025					
HIO	John Kansky	9/30/2023					
	Pam Matthews	9/30/2024					
	Patti Cuartas, PA	9/30/2023					
Health Systems	Matt Eisenberg, MD	9/30/2025					
	Ryan Stewart	9/30/2023					
	Paul Matthews	9/30/2025					
Other	Eric Liederman	9/30/2024					
	Derek Plansky	9/30/2024					

## Contacts

**Changing and New Contacts** 

## eHealth Exchange

### **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

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 This will assist eHealth Exchange and each Participant in knowing that the communication we send is received appropriately.

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item	s select									Q Search this list			¢.	•	C		¢
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1		Alan Johnson		Get Cloudy		Sales Manager					Z	ero	24/09	9/2019	17:04		
2		Alice Black				Botanist		555-555-5555		blackalice@example.com	Z	ero	11/12	2/2018	22:23		
3		Amanda Garcia		Garcia Inc		CEO					Z	ero	15/09	9/2018	11:15		
4		Andy Young		Dickenson plc		SVP, Operations		(785) 241-6200		a_young@dickenson.com	Z	ero	01/02	2/2016	17:05		
5		Arthur Song		United Oil & Gas Corp.		CEO		(212) 842-5500		asong@uog.com	Z	ero	01/02	2/2016	17:05		

## Please Engage!

We'd love to hear from you.

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# 20 ANNUAL 22 MEETING

# THURSDAY DECEMBER 15TH

See <u>https://ehealthexchange.org/event/2022-annual-meeting</u> 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	<pre>support@directtrust.zohodesk.com</pre>
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

