FDA Exchange Pilot

Production Pilot Adverse Event Case Validation via eHealth Exchange

eHealth Exchange™

Image:https://commons.wikimedia.org/w/index.php?curid=525404

Agenda

- Announcement
- What are the FDA objectives?
- What is the primary use case?
- What is the “Ask”?
- What are the expectations?
- FAQ?
- FDA FHIR Acceleration Incentive 2022
- What are the next steps?

Announcing the launch of FDA's BEST* Exchange Pilot

- New Federal agency
  - Welcoming the FDA to the eHealth Exchange!
- New use cases
  - Primary: Validation of an adverse event using FHIR-based clinical data from healthcare providers
  - Secondary: Automated or semi-automated detection of an adverse event using FHIR-based push to the FDA
- Leveraging FHIR R4 and the eHealth Exchange Hub

*BEST – Biologics Effectiveness and SafeTy Initiative

What are the FDA objectives?

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.

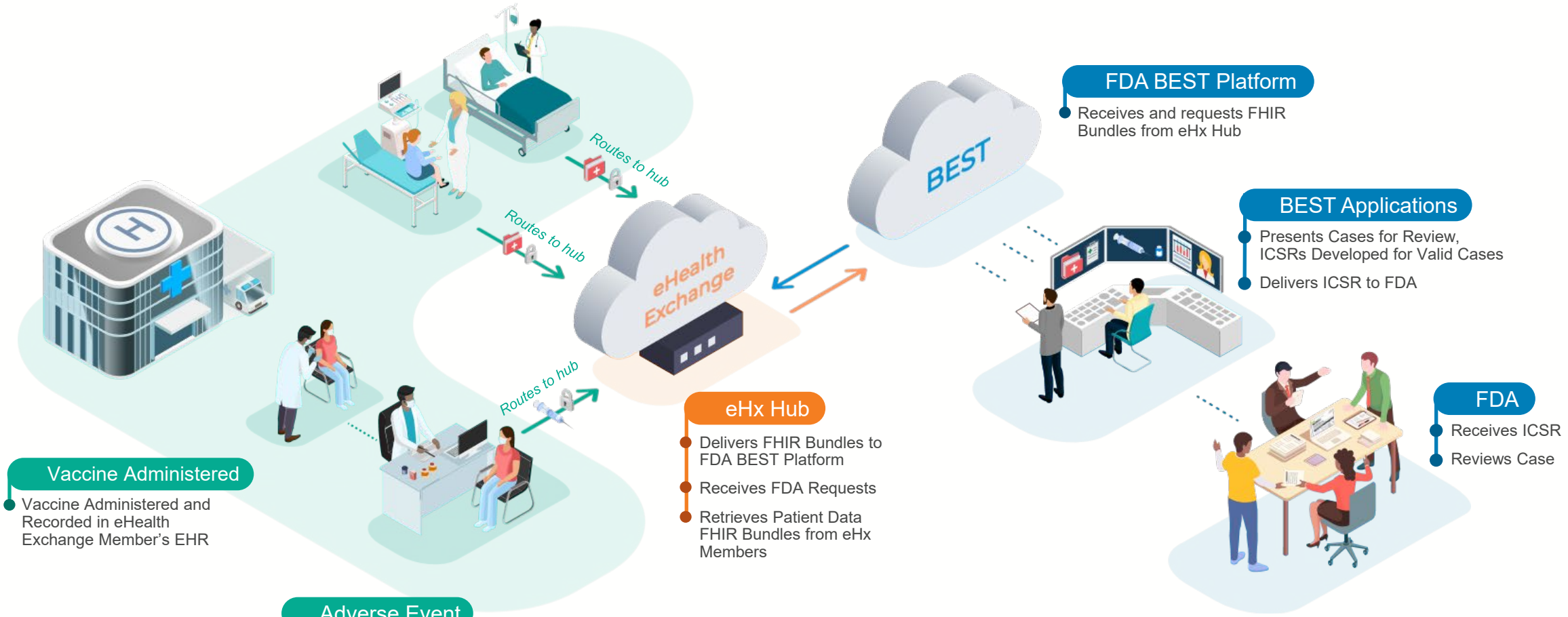
Exchange Pilot Objective

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

Regulated Products

- Vaccines (preventative and therapeutic)
- Blood (components and derived)
- Human Tissues and Cellular Products
- Gene Therapies
- Xenotransplantation Products

FDA BEST operational architecture



What is the primary use case?

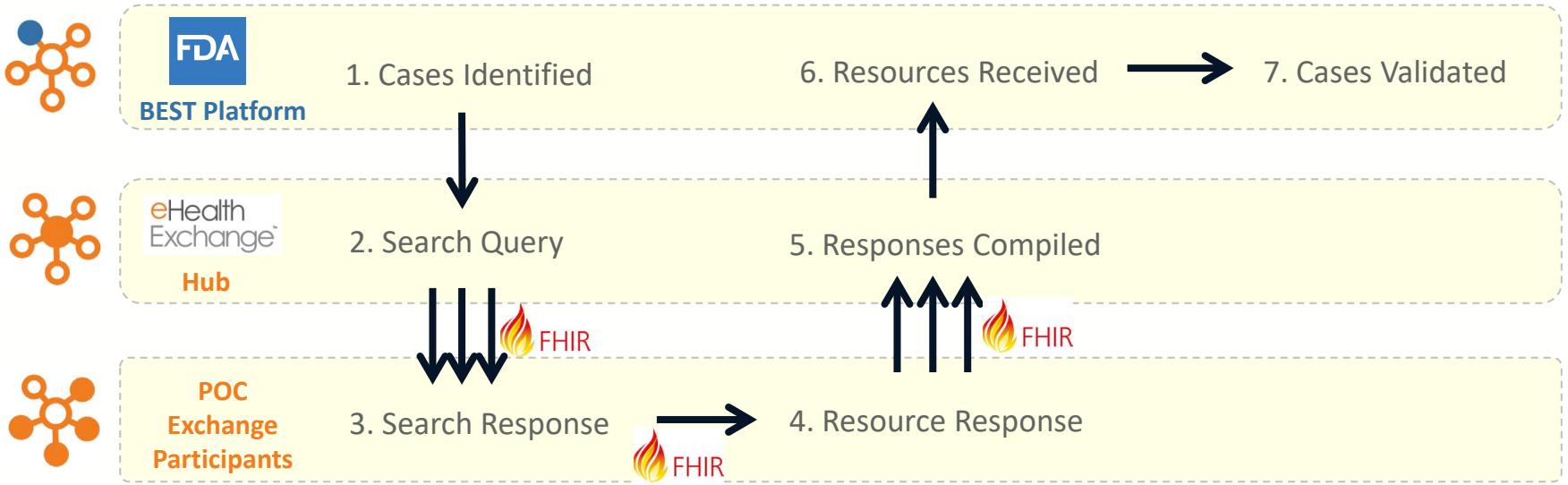
FDA BEST: Exchange Production Pilot

Objective

To retrieve sample EHR data through the eHx Hub to demonstrate the feasibility of a scaled infrastructure for clinical validation of previously identified AE cases

Details

Query eHx Participants for production data using FHIR r4



Note: Detailed data flow is in the appendix-BEST Exchange Pull Use Case

FDA BEST Production Pilot: The “Ask”

- **Status**: We have successfully completed a Proof of Concept in 2021 and are now completing an eHx VAL and PROD roll-out in 2022.
- **Ask**: Consider participating in the Production Pilot by acting as a responding gateway to inbound FHIR resource queries/retrieval.
- **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.

What are the FDA BEST Production Pilot expectations?

Connectivity with Epic is simple and proven

1. **Provide**: You provide your connection information
2. **Authorize**: You authorize the eHealth Exchange / FDA FHIR client to connect to your Epic site
3. **Populate**: You populate a few test patients
4. **Test**: FDA tests with synthetic patients and then live patients
5. **Pilot Go Live**: The expectation is that the Pilot will ultimately become a production exchange system

Frequently Asked Questions

- **Q:** What's the expected time commitment?
  - **A:** Less than 4 hours
- **Q:** What versions of Epic are supported?
  - **A:** Oct 2021 or later
- **Q:** Is the ability to respond to FDA queries required?
  - **A:** Yes, in FHIR r4 format
- **Q:** Is the ability to push notifications to the FDA required?
  - **A:** No. This is optional. FHIR r4 format preferred, but other formats can be considered.
- **Q:** Can we have a quick call to explore more before we commit?
  - **A:** Yes! We'd welcome a chance to informally explore this with you. Please contact KBbingman@ehealthexchange.org to set up a discussion.
- **Q:** Is there a development environment we can start testing with immediately?
  - **A:** Yes. Please contact us to get the access information and/or to set up some testing sessions.
- **Q:** What security models are supported?
  - **A:** Supports existing Epic security for a backend FHIR application

Frequently Asked Questions (Contd.)

- **Q:** What are the legal requirements?
  - **A:** No new legal requirements have been identified. Please confirm appropriately.
- **Q:** What is the Purpose of Use?
  - **A:** Public Health
- **Q:** Has this use case been tested with other Epic sites?
  - **A:** Yes, three Epic sites have successfully tested non-PHI exchanges.
- **Q:** Are there any new eHx fees?
  - **A:** NO! In fact, there MAY be a limited financial incentive. TBD.
- **Q:** What is the Minimal Data Set?
  - **A:** For query: Patient and at least one of Condition, Encounter, Immunization. Other resources are optional. We can share a data specification. See this appendix.
- **Q:** What is the timeframe?
  - **A:** For developmental testing: we can test immediately. For the Production Pilot: starting in April 2022
- **Q:** Will PHI be exchanged?
  - **A:** Yes. Both synthetic and live patient data is in scope.

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!

What are the next steps?

- Please contact eHealth Exchange to explore FDA connectivity further at:

  administrator@ehealthexchange.org