FDA Exchange Pilot

Production Pilot Adverse Event Case Validation via eHealth Exchange
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
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

- **Delivers FHIR Bundles to FDA BEST Platform**
- **Receives and requests FHIR Bundles from eHx Hub**
- **Receives FDA Requests**
- **Retrieves Patient Data**
- **FHIR Bundles from eHx Members**
- **Presents Cases for Review, ICSRs Developed for Valid Cases**
- **Delivers ICSR to FDA**
- **Vaccine Administered and Recorded in eHealth Exchange Member’s EHR**
- **Potential Adverse Event recorded by eHealth Exchange Member**
- **FDA BEST Platform**
- **BEST Applications**
- **FDA**
- **Receives ICSR**
- **Reviews 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

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**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.
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