CBER BEST IM Exchange Pilot
Biologics Effectiveness and Safety Innovative Methods

Hussein Ezzeldin, PhD
Analytics and Real-World Evidence Branch (ARWEB)
Division of Analytics and Benefit-Risk Assessment (DABRA)
Office of Biostatistics and Pharmacovigilance (OBPV)
Center for Biologics Evaluation and Research (CBER)
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Outline

• Background
• Exchange Pilot
• Results
• Conclusion and Summary
Background: CBER Portfolio

CBER-Regulated Products

- Vaccines preventative & therapeutic
- Gene Therapies
- Human Tissues & Cellular Products
- Blood & Blood Products
- Xenotransplantation Products

Exposure

- Pharmacies
- Community clinics
- Mobile clinics
- Universities
- Hospitals/Tertiary Centers
- Emergency Dept. Treatment Centers
# Background: Challenges

## Clinical exposure and potential outcome

### Current

**Manual Detection**
- **Individual flagging** of potential AEs
- **Under-recognition** of outcomes

**Manual Validation**
- **Time-intensive** to review dispersed data
- Potential AEs **not always communicated**
- **Case definitions** separate

**Manual Reporting**
- **Data re-entry** to report externally
- **Lack of granularity** in report evidence

### Future

**Automated Detection**
- **Batch detection**, more focus on patient care
- **AI algorithm** scores potential cases

**Semi-Automated Validation**
- **Evidence integration** reduces burden
- **Flagged and prioritized** cases sent for review
- **Case definition** integrated

**Semi-Automated Reporting**
- **Auto-population** of granular ICSR evidence
- **Generation** of evidence-based ICSR narrative

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**BEST Platform** demonstrates use of innovative methods to **reduce burden**, while increasing **quantity** and **quality** of AE reports

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ICSR, individual case safety report
BEST* Innovative Methods (IM) Initiative developed a Pilot Platform to address current challenges through AI and automation.
Validation (Pull) Use Case

1. FDA
   Identify case of interest that requires additional data

2. BEST Applications
   Use provided patient demographics to prepare additional data request

3. BEST FHIR Exchange Platform
   Requests and receives FHIR data from eHx Hub

4. eHealth Exchange
   Queries eHx network for patient match
   Retrieves FHIR data match and sends to Health Data Exchange Platform

5. Provider EHR System
   Record of patient interactions in EHR system
   Respond to any queries for additional FHIR data

eHx, eHealth Exchange
Detection (Push) Use Case

1. Exposure
   - Vaccine administered and recorded in provider's EHR

2. Outcome Detected
   - Potential adverse event detected by algorithm
   - Submit FHIR data to eX Hub for delivery to Health Data Exchange Platform

3. eX Transmits Data
   - Delivers FHIR data to Health Data Exchange Platform

4. BEST FHIR Exchange Platform
   Processes Case
   - Receives FHIR data from eX Hub

5. BEST Application
   Clinical Reviews
   - Semi-automated tools for case review
   - Adverse event report developed for valid cases

6. FDA
   - Receives AE report
   - Reviews case

eX, eHealth Exchange
Pilot Participants

https://ehealthexchange.org/participants/?participant_type=fda-pilot
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Pilot Results

- **271** post-vaccination AE were queried
- Across **11** different health provider data partners (Epic EHRs)

* Patients EHRs
Conclusion and Summary

- For CBER’s use case, **the overall data quality meets general requirements**, as partner’s EHR HL7® FHIR® APIs are showing high adherence to USCDI data set
  - **Variability** - even with same EHR vendor - in security authorization settings, required trial and error with individual partners
    - The team worked with EHR vendors to create a new policy that standardizes this process across partners to reduce the connection set-up time
- Important gaps include, **lack of inclusion in USCDI data set**, and **varying levels of completeness** across partners
- The BEST team continues to enhance the Platform infrastructure to enhance CBER’s passive and active post-market surveillance capabilities:
  - improve our querying capabilities
  - efficiently federate AE detection logic
  - conduct evaluation and validation studies
Acknowledgement

**FDA CBER**  
Barbee Whitaker, Artur Belov, Jane Mutanga, Brian Hively, Richard Forshee, Steven Anderson

**IBM**  
Lance Jones, Matthew Deady, Brian Goodman, Haley Huang, Deepa Youssef, Kathryn Matto

**eHx**  
Jay Nakashima, Eric Heflin, Mike Y and Mike M

**Pilot Participant**
- CEDARS-SINAI HEALTH SYSTEM (early adopters)
- VETERANS HEALTH ADMINISTRATION (VHA) (early adopters)
- WELLSPAN HEALTH
- UNC HEALTH CARE SYSTEM
- SOUTH BROWARD HOSPITAL DISTRICT DBA MEMORIAL HEALTHCARE SYSTEM
- STANFORD HEALTH CARE
- THE METROHEALTH SYSTEM
- ALTRU HEALTH SYSTEM
- BAYLOR COLLEGE OF MEDICINE
- COVENANT MEDICAL CENTER
- GREENWOOD COUNTY HOSPITAL BOARD DBA SELF REGIONAL HEALTHCARE
- LEGACY HEALTH SYSTEM
References

- Vaccine Administrations From Unstructured Data in Medical Records Through Natural Language Processing
- Detection of allergic transfusion-related adverse events from electronic medical records
- FDA 2021 Science Forum: CBER BEST: Leveraging AI to Build an Automated Adverse Event Reporting System
- AI article about BEST C2 in FDA 2021 Science Forum July 2021
- Balloted BEST FHIR IG
- BEST FHIR IG on Interoperability Standards Advisory (ISA)
- BEST HL7 Case Study