2022

Annual Meeting

GRAND HYATT WASHINGTON

BEST Exchange Platform

Biologics Effectiveness and Safety (BEST) Initiative

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eHealth Exchange™

Introduction

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
- Xenotransplantation Products

FDA BEST Initiative Objective

The objective of the Biologics Effectiveness and SafeTy (BEST) Initiative is to advance post-authorization biologic-product safety and effectiveness through innovative methods.

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.

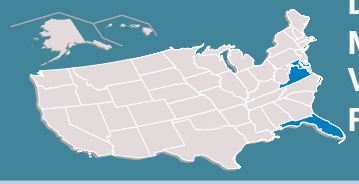
CBER = Center for Biologics Evaluation and Research
FDA = U.S. Food and Drug Administration
OBPV = Office of Biostatistics and Pharmacovigilance

Roadmap: Path to Scalability

FY 19-20

Prototype on Foundational Network

- **E2E** EHR to FDA **Pipeline** built
- **20+ Phenotypes** developed and validated
- **100+ ICSR** cases reported for assessment



D.C.
MD
VA
FL

Prototype on Exchange Network

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

Operationalize BEST Pipeline

- Leverage and **enhance** pipeline
- Pilot **scalable phenotypes** for vaccines outcomes of interest

FY21

FY22

Operationalize BEST Exchange Platform

- Implement **detection** and **validation** Use cases with early adopter participants
- **Mature** and **scale** nationwide

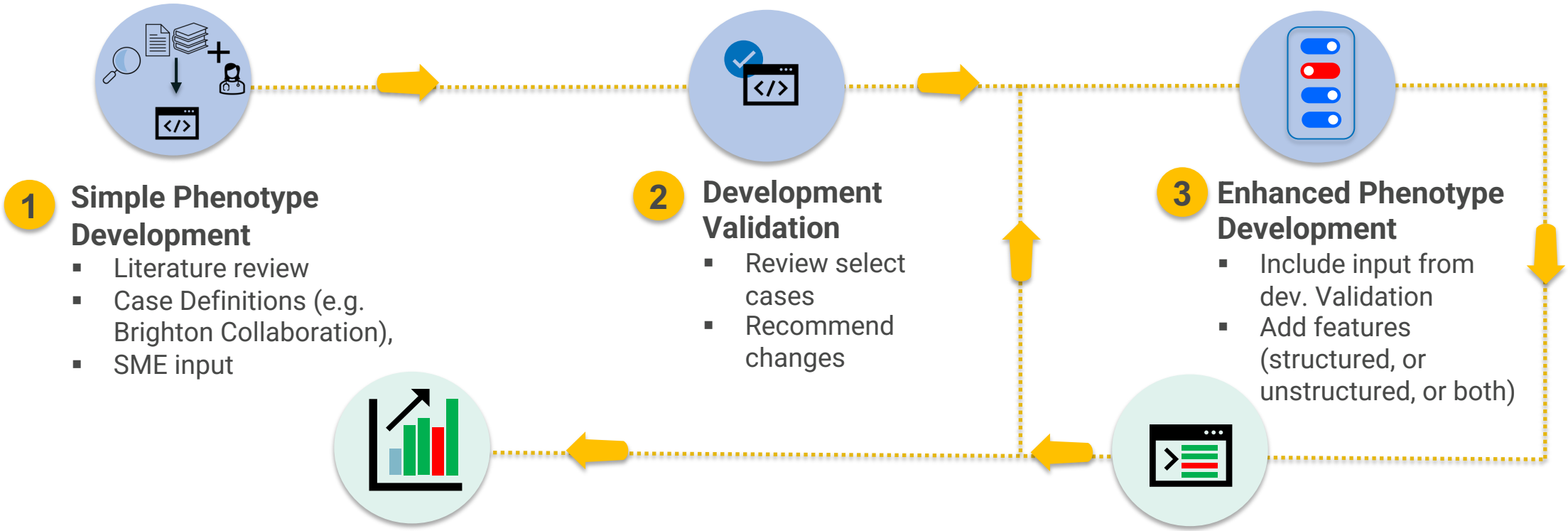
National Coverage

FY23

IBM-2

Accomplished ---- Ongoing

Phenotype Development – Queries/Algorithms Used by BEST



1 Simple Phenotype Development
- Literature review
- Case Definitions (e.g. Brighton Collaboration),
- SME input

2 Development Validation
- Review select cases
- Recommend changes

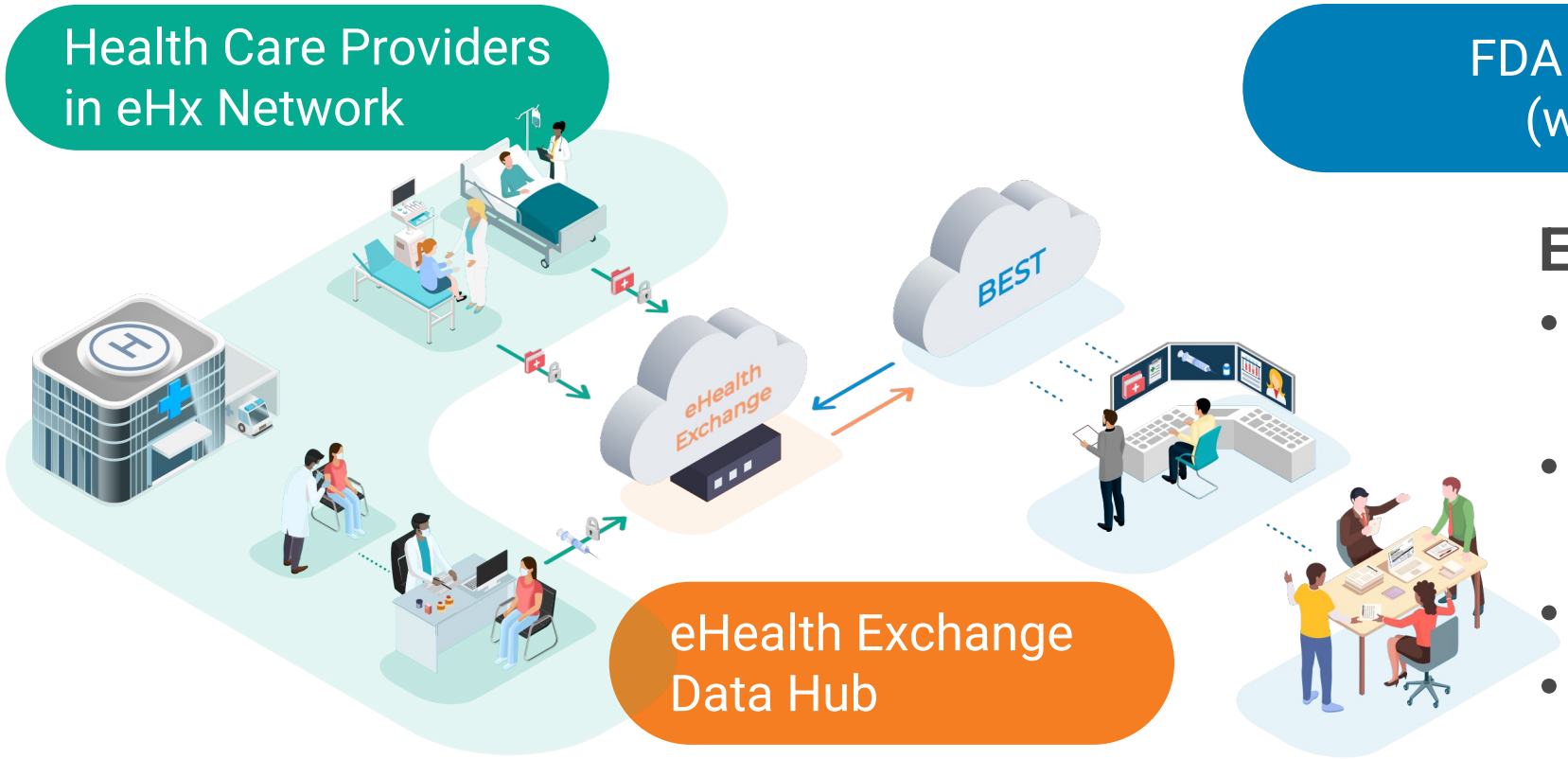
3 Enhanced Phenotype Development
- Include input from dev. Validation
- Add features (structured, or unstructured, or both)

4 Development Validation
- Review select cases
- Examine/omit/Add features (usually unstructured)

5 Formal Validation
- Apply phenotype to validation set
- Estimate final performance metrics

FDA BEST Exchange Platform Overview

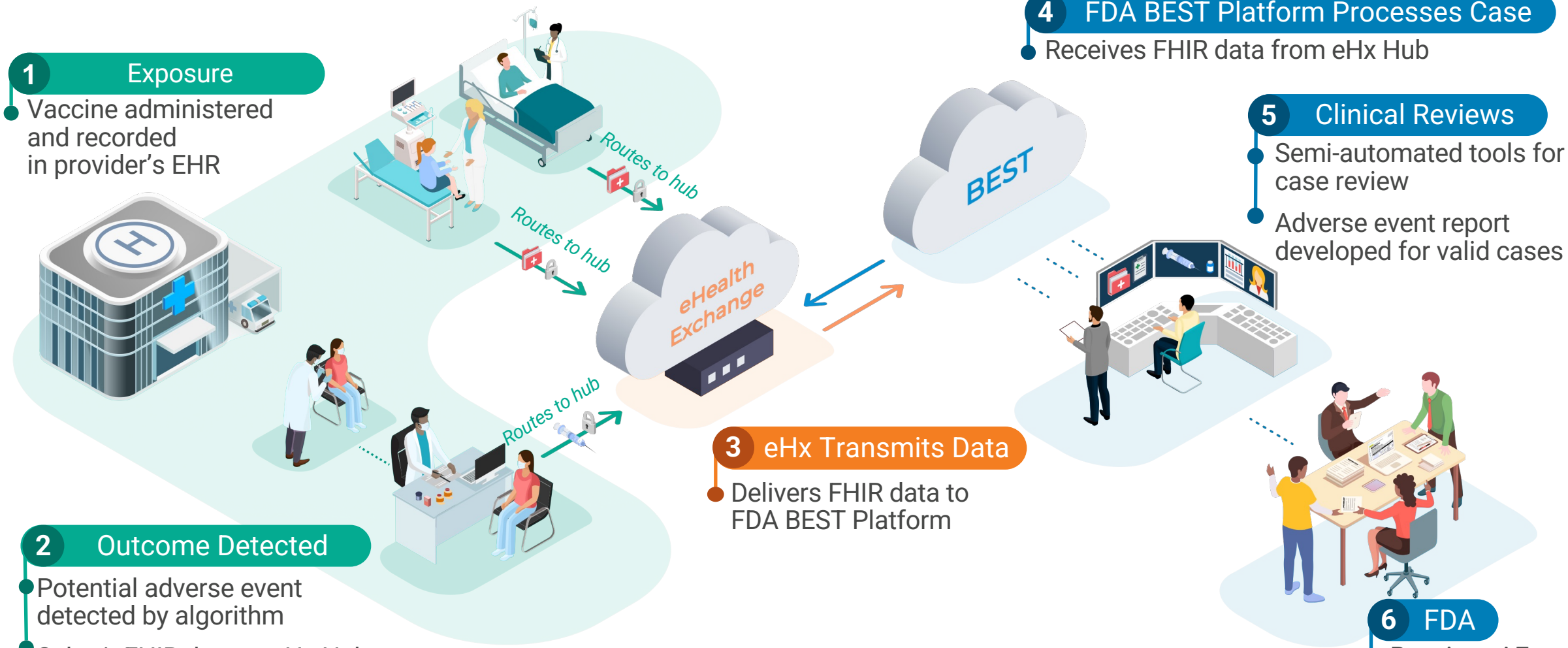
Among the First Public Health HL7® FHIR® National-scale System



Expected Benefits:

- Uses existing FHIR R4 endpoints
- Reduced burden for responders
- Reduced latency
- Efficiencies in EHR data requests

Use Case: Detect, Validate, and Report Adverse Event Cases



1 Exposure

- Vaccine administered and recorded in provider's EHR

2 Outcome Detected

- Potential adverse event detected by algorithm
- Submit FHIR data to eHx Hub for FDA BEST delivery

3 eHx Transmits Data

- Delivers FHIR data to FDA BEST Platform

4 FDA BEST Platform Processes Case

- Receives FHIR data from eHx Hub

5 Clinical Reviews

- Semi-automated tools for case review
- Adverse event report developed for valid cases

6 FDA

- Receives AE report
- Reviews case

Use Case: Requesting Clinical Charts for Validation of Reported Cases

1 FDA

Identify AE case of interest that requires additional data

2 BEST Applications

Use provided patient demographics to prepare additional data request

3 FDA BEST Platform

Requests and receives FHIR data from eHx Hub

4 eHealth Exchange

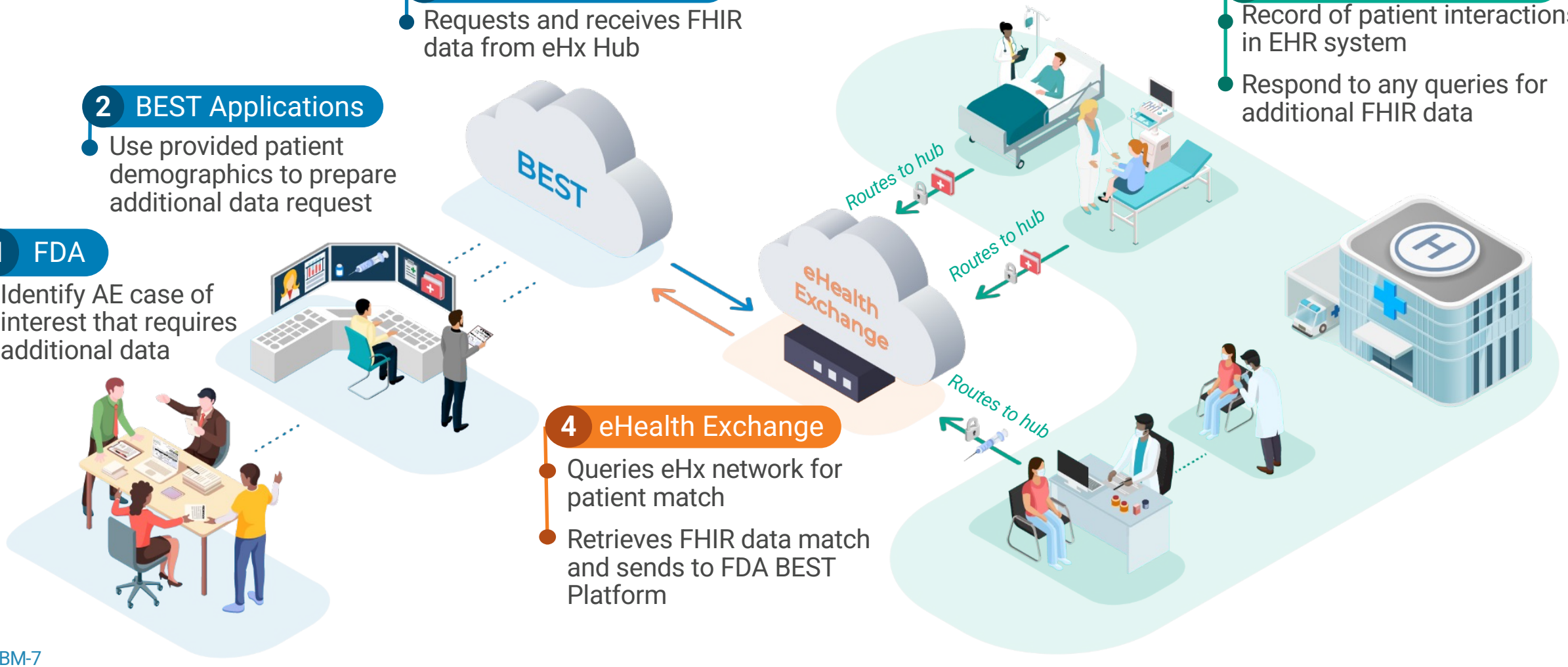
Queries eHx network for patient match

Retrieves FHIR data match and sends to FDA BEST Platform

5 Provider EHR System

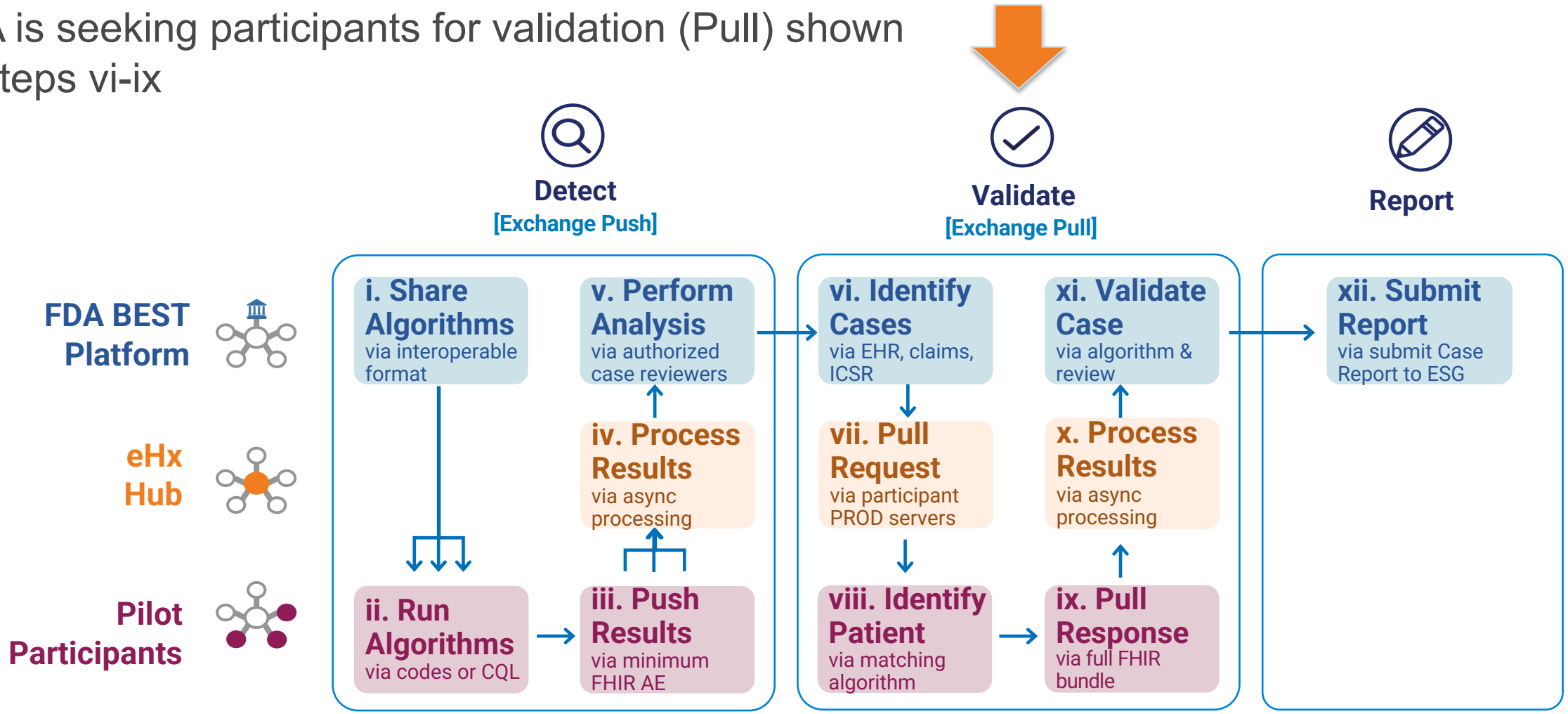
Record of patient interactions in EHR system

Respond to any queries for additional FHIR data

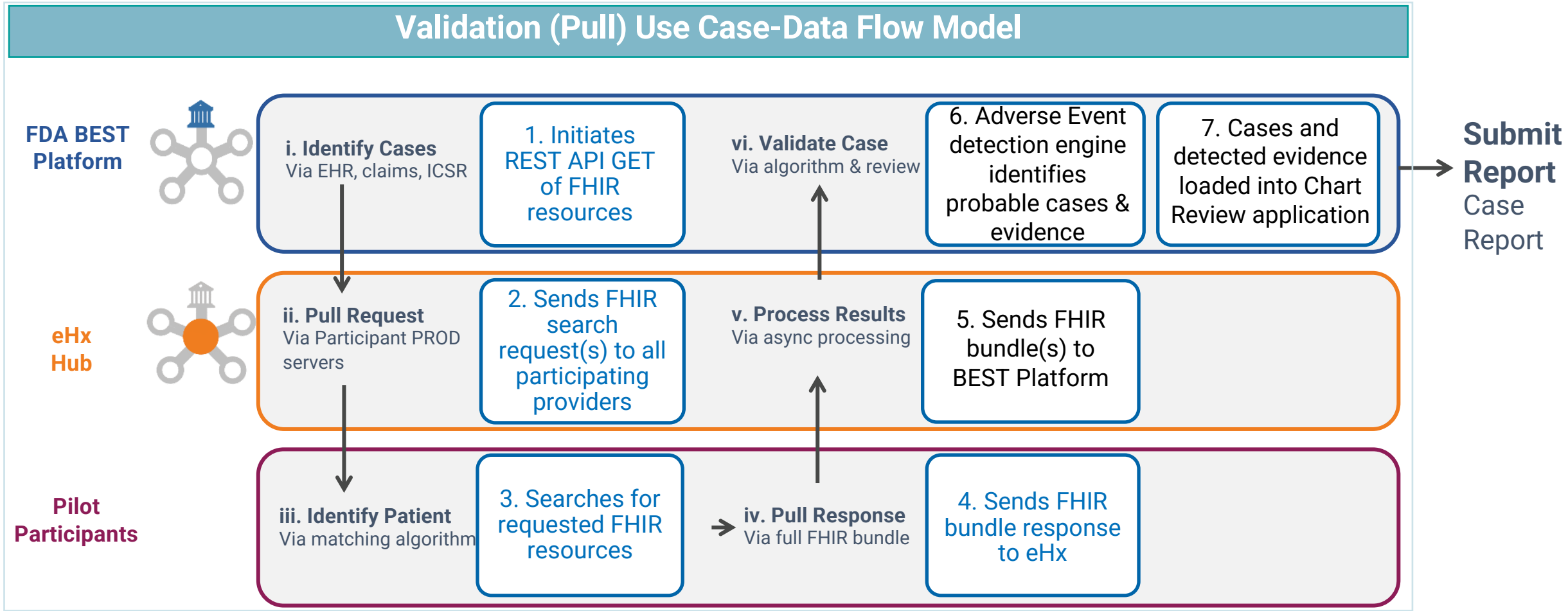


Pilot Focus on Detection (Push) and Validation (Pull) Use Cases

FDA is seeking participants for validation (Pull) shown as steps vi-ix



Participant Steps in Validation Pilot Use Case



Requested FHIR Resources for BEST Exchange Pull Use Case

Resource name	Is this resource one of the core FDA desired resources?	Is this resource considered part of the minimal data set?
AllergyIntolerance	Yes	Yes
Binary	Yes	Yes
CarePlan	Yes	
Condition	Yes	Yes
Device		
DeviceRequest		
DiagnosticReport	Yes	Yes
DocumentReference	Yes	Yes
Encounter	Yes	Yes
EpisodeOfCare		
Goal		
Immunization	Yes	Yes
ImmunizationRecommendation		
Location		Yes
Medication	Yes	Yes
MedicationDispense		
MedicationRequest		Yes
NutritionOrder		
Observation	Yes	Yes
Patient	Yes	Yes
Practitioner	Yes	
PractitionerRole	Yes	
Procedure	Yes	Yes
ValueSet	Yes	

Why and How to Participate?

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
- **Interested in being a participant?**
  - Reach out to Michael McCune (mmccune@ehealthexchange.org)
  - Schedule an Introductory Call
- **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.

Current Participants and Acknowledgements

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.

Recruitment Status

31 Participants interested:
- 13 Engaged participants for the feasibility analysis
- 11 Participants in the feasibility analysis
- 7 Participants Connected with Platform

BEST-Exchange Participants

- Baylor College of Medicine
- Cedars-Sinai Health System
- Covenant HealthCare
- Memorial HealthCare System (FL)
- UNC Healthcare System
- WellSpan Health
- Veterans Health Administration

References

- Standards
  - BEST FHIR IG
  - BEST FHIR on ISA
  - Biologically Derived Products on USCDI
- Conferences
  - FHIR Dev Days 2020, Development of a SMART-on-FHIR enabled Semi-Automated Adverse Event Validation & Reporting Application / Presentation Recording
  - HL7 Connectathon 2021, BEST FHIR Implementation Guide
  - AABB 2021, Development of an Application that Semi-Automates Clinician Verification and Reporting of Transfusion Allergic Reaction Cases
- Publications
  - The Food and Drug Administration Biologics Effectiveness and Safety Initiative Facilitates Detection of Vaccine Administrations from Unstructured Data in Medical Records through Natural Language Processing
  - Detection of Allergic Transfusion-Related Adverse Events from the Electronic Medical Record
- GitHub Repos
  - Rapid Term Set Generator