Development of a SMART-on-FHIR-enabled Semi-Automated Adverse Event Validation and Reporting Application

Shayan Hobbi, IBM

Agenda

1. Current state of adverse event (AE) reporting
2. Development of a semi-automated solution for adverse event validation and reporting
3. Challenges and Lessons Learned
   - Challenges with Provider-facing SMART connections
   - Data element needs for biologics surveillance and gaps between USCDI Profiles
   - Use of FHIR and USCDI Profiles for Validation and Reporting of Biologics-related Adverse Events
4. Next Steps

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CBER Biologics Effectiveness and SafeTy (BEST) Initiative Mission

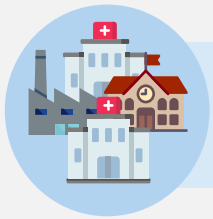
Conduct active surveillance for post-market safety and effectiveness of biologic-products

Current Need

More robust post-market adverse event reporting

CBER Regulated Products

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



Providers & Industry

- Manual **burdensome** process
- **Voluntary** with few incentives

Reporting Systems

- **Lower quality reports** due to integration
- **Under-reporting** due to burden

FDA CBER

- Inadequate data quality and quantity **limit ability to perform active surveillance** of biologic-product risks

Current biologic product AE reporting systems are **manual**, **passive**, and **voluntary**.

As a result, CBER receives **fewer** and **lower quality** reports than needed for its post-market surveillance.

Adverse Event (AE) Validation and Reporting:

Current State

Current

Clinical exposure and outcome

Manual Detection

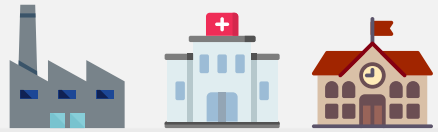
Under-recognition of **Individual flagging** of potential AEs

Manual Validation

Time-intensive to review Potential AEs **not always** **Case definitions** separate

Manual Reporting

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



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Semi-automated AE Validation and Reporting:

Improved Efficiency and Accuracy

Current

Clinical exposure and outcome

Manual Detection

Under-recognition of outcomes

Individual flagging of potential AEs

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

vs.

IBM BEST Pipeline

Clinical exposure and outcome

Automated Detection

AI algorithm scores potential cases

Batch detection, more focus on patient care

Semi-Automated Validation

Evidence integration reduces burden

Flagged and prioritized cases sent for review

Case definition integrated

Semi-Automated Reporting

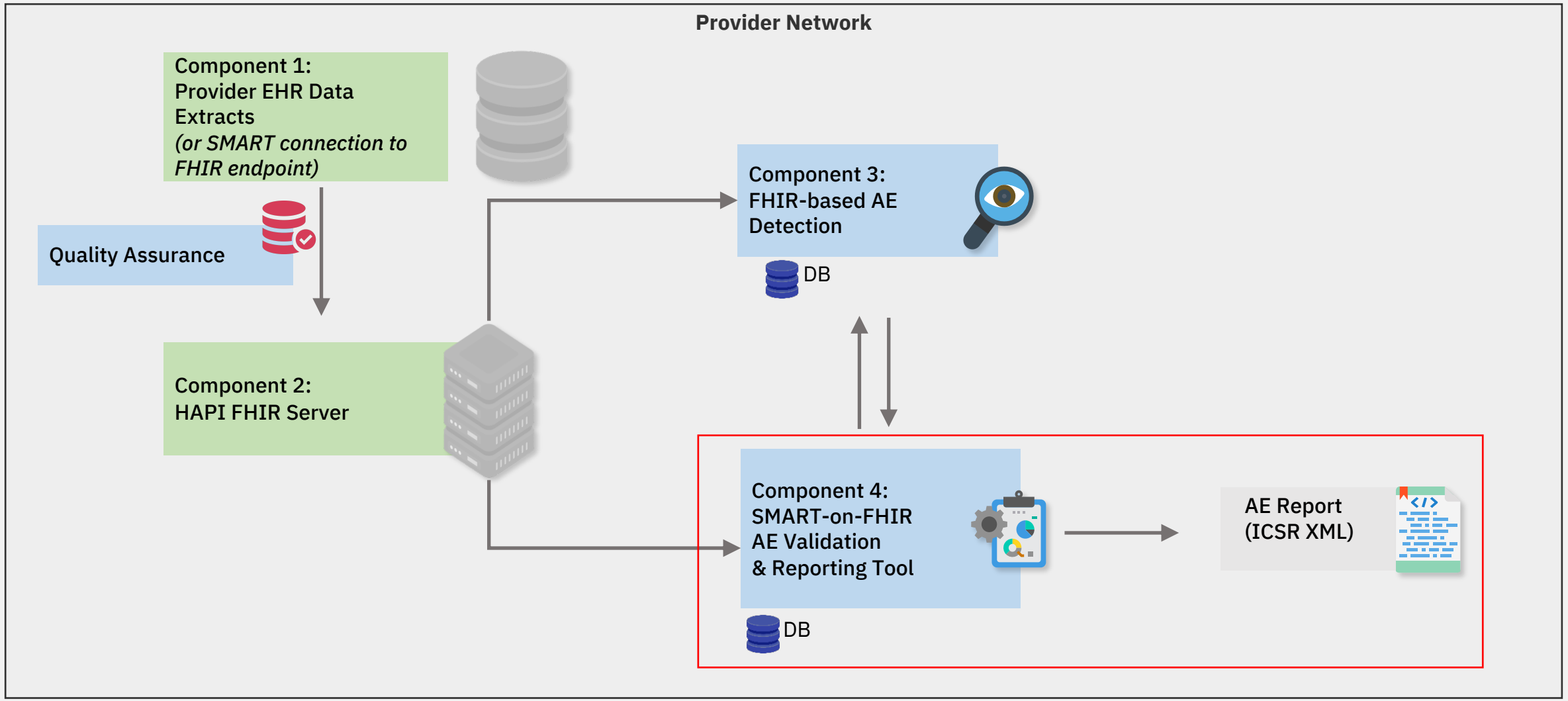
Auto-population of granular ICSR evidence

Generation of evidence-based ICSR narrative

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

Current BEST Infrastructure:

Semi-automated AE Validation and Reporting

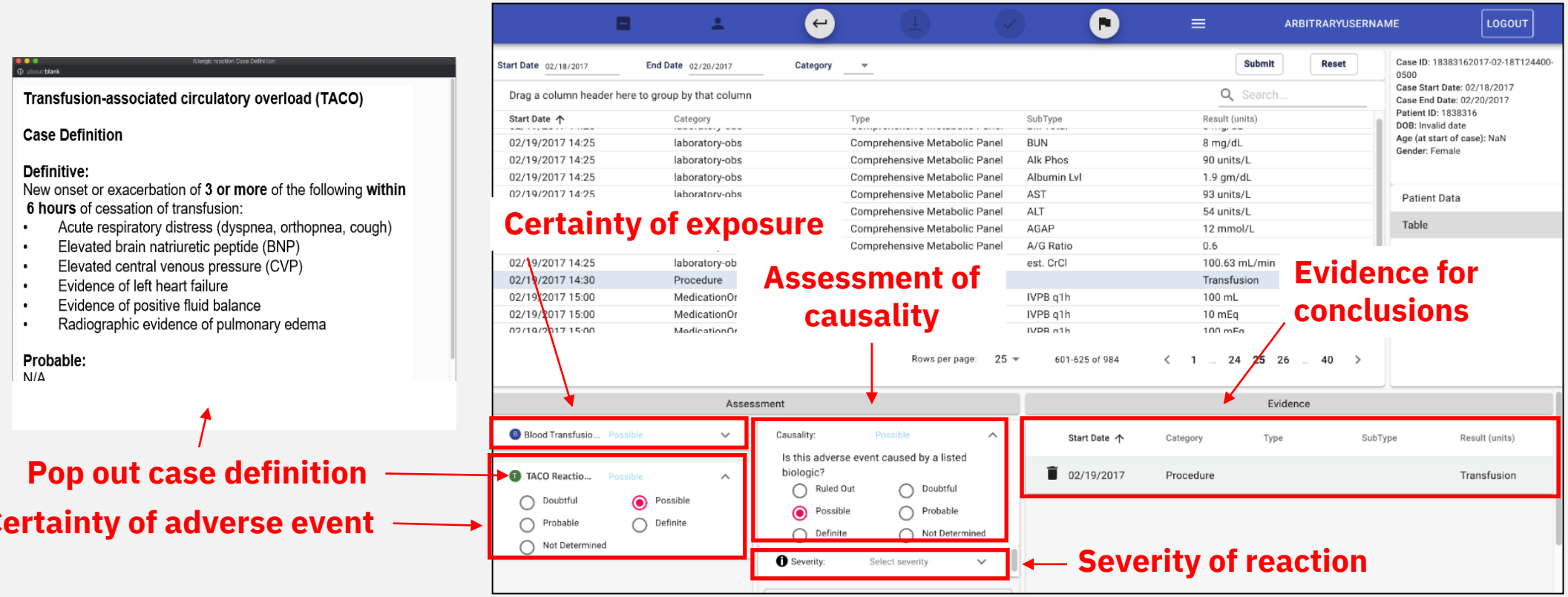


Semi-Automated Outcome Validation

SMART-on-FHIR Chart Review Tool: Enables semi-automated clinical assessment with an intuitive UI, that can plug into SMART-on-FHIR enabled EHR endpoints

Abstraction: Allows for simplified visualization of patient EHR information

Classification: Reviewers efficiently document information related to classification, including:



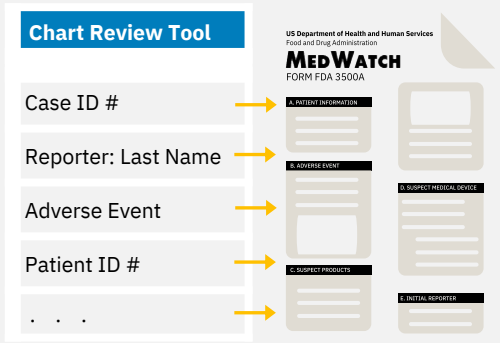
*Simulated data

Reporting: ICSR Auto-population

Step 1

Reviewer confirms evidence and other information prior to submission

Step 2



Reviewer clicks to auto populate ICSR report

Step 3

Reviewer completes final check and then submits

Features: Auto-population and generation of ICSR from FHIR to XML format *(with functionality for final review and editing)*
Impact: Increased efficiency through auto-population of ICSR

**Simulated data*

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Challenges with Provider Facing SMART-on-FHIR Connections

1. **Often documentation for EHR-hosted SMART sandboxes was far more complex for provider-facing connections, compared to the patient-facing scope.**
   1. This was relatively minor, and was resolved by contacting teams hosting SMART sandboxes

2. **Time for providers to review and approve SMART app connection to production FHIR endpoint**
   1. This is a significant investment and can take up to 7-9 months, depending on the provider.
   2. Often, test data in the test environments are not reflective of production data (especially for transfusion patients)

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EHR Data Elements of Interest for Biologics AE Reporting

EHR Data Elements of Interest *(Vaccine AE Example)*		Detection Features
Exposure	• 2017-02-17 11:20 – (NDC: 70461-019-03, Brand: Fluad, Lot number: XR20192913)	• Flu_Vaccine_Administered= True
Labs	• Hemoglobin – 7.2 grams/L • Hematocrit – 25% • WBC count – 7,200/mcL • Viral Panel Test - Negative	• Viral_rule-out = True
Diagnoses	• Guillain-Barre Syndrome, Other neurological symptoms	• Relevant_Diagnosis = True
Notes	Physician Progress Note: 6-weeks following influenza vaccination, patient exhibited symptoms for Guillain-Barre Syndrome. Other viral tests rule-out other viral causes of GBS Vital Signs: • Blood pressure increase – 111/72 to 123/95 mmHg • HR increase from 92 to 119 bpm • Viral Serology Test– Negative	• GBS_Diagbosis = True • Post_exposure_diagnosis= True

**Simulated data*

EHR Data Elements of Interest for Biologics AE Reporting

EHR Data Elements of Interest

(Transfusion AE Example)

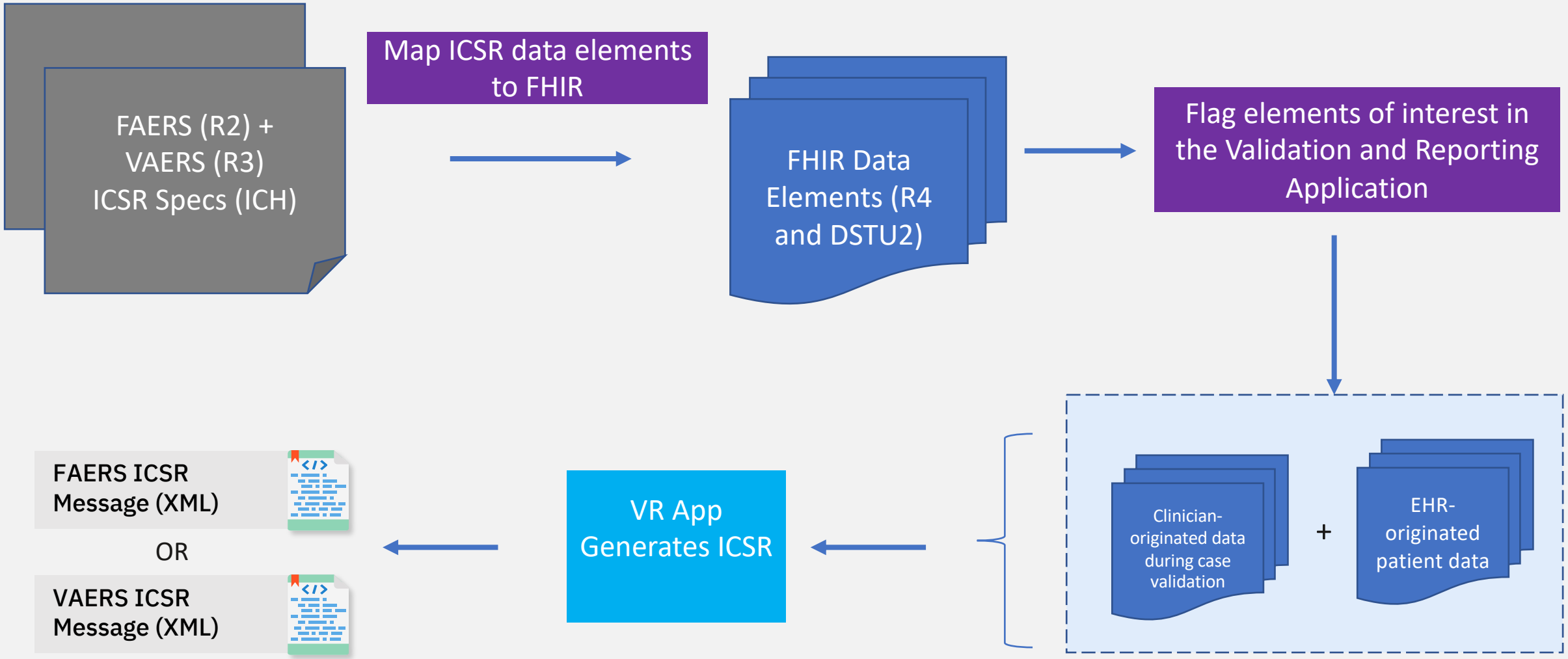
	EHR Data Elements of Interest	Detection Features
Exposure	• 2017-02-17 11:20 – Packed RBC transfused (ISBT Product: E4306) • 2017-02-19 14:30 – Packed RBC transfused (ISBT-128: W23456789012121)	• Transfusion_Administered = True
Labs	• Hemoglobin – 7.2 grams/L • Hematocrit – 25% • WBC count – 7,200/mcL • Brain natriuretic peptide - 110 pg/mL • AST – 150 IU/L, ALT – 71 IU/L	• BNP>100 = True
Diagnoses	• Anemia, Abnormal liver function tests, Dysmenorrhea	• Relevant_Diagnosis = True
Notes	Physician Progress Note: 3 hours following the second transfusion, developed dyspnea, drop in SPO2, mild edema, increase in blood pressure and tachycardia. CXR showed bilateral pulmonary edema. Patient was then treated with Lasix and O2 and vital signs returned to baseline within two hours. Vital Signs: • Blood pressure increase – 111/72 to 123/95 mmHg • HR increase from 92 to 119 bpm • SpO2 decrease – 97% to 88%	• Dyspnea = True • Pulmonary_Edema = True • New_Diuretic = True • Sp02<90 = True

**Simulated data*

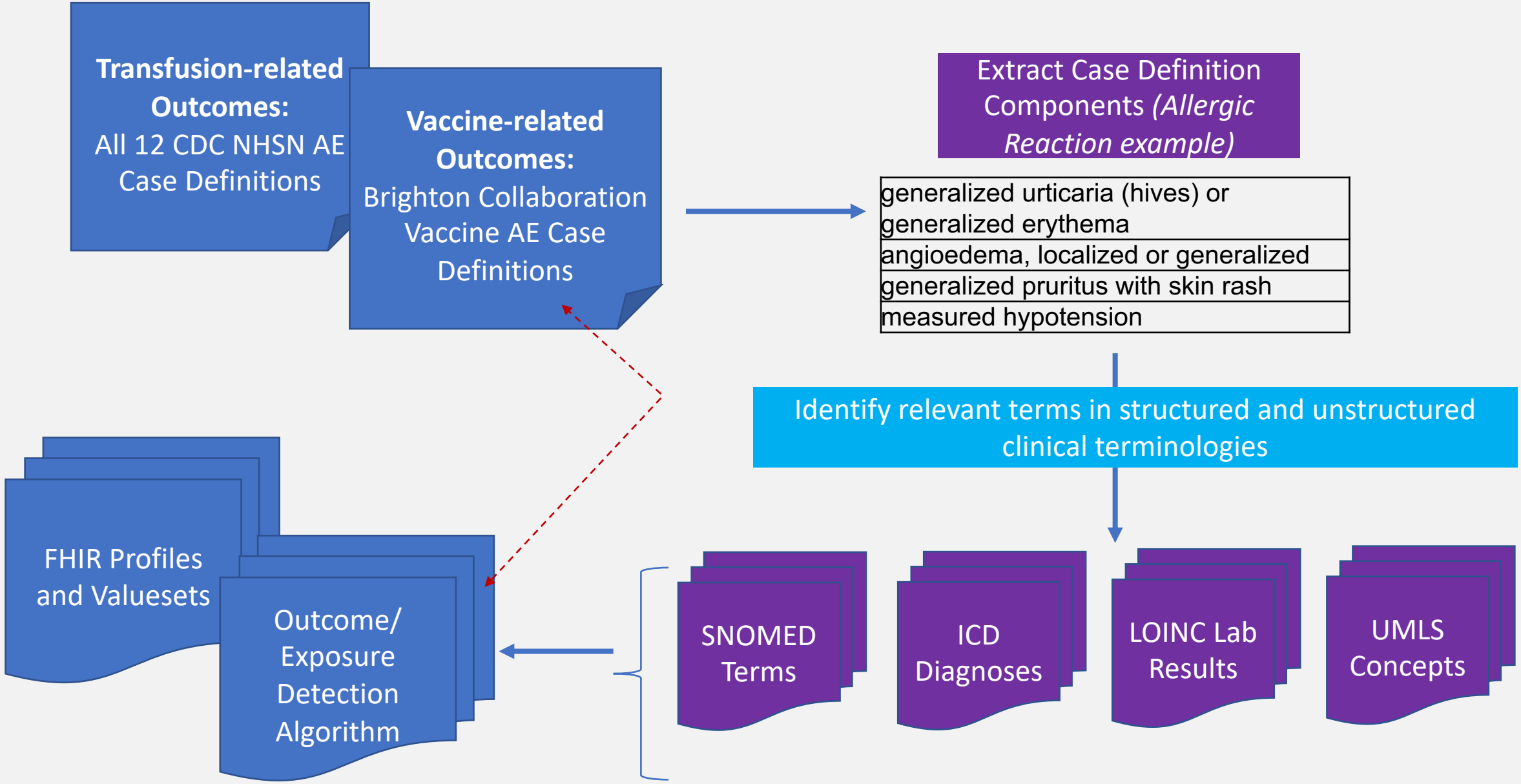
EHR Data Elements of Interest for Biologics AE Reporting

Data Element	Direct EHR Extract	HL7 CDA	FHIR R4 (USCDI)
Unstructured Data	Available in native format	Available in XML Format	Linked via DocumentReference Resource
Refresh	Live, but queries return static extracts.		**Live, but queries return static extracts. Subscription/push model is live.**
Vaccine Exposures	Identified by RxNORM, CPT, HCPCS and NDCs.		**Identified with CVX. NDCs not included.**
	Lot number and manufacturer available if recorded with administration		
Blood Component Exposure	ISBT-128 + HCPCS/CPTs available if recorded.		**ISBT-128 codes and other transfusion elements NOT included**
Outcome Diagnoses	Diagnoses and Problems recorded with sufficient granularity		
Other fields needed for ICSR Reports	Generally available		**Minor additions needed for patient and organization resource**

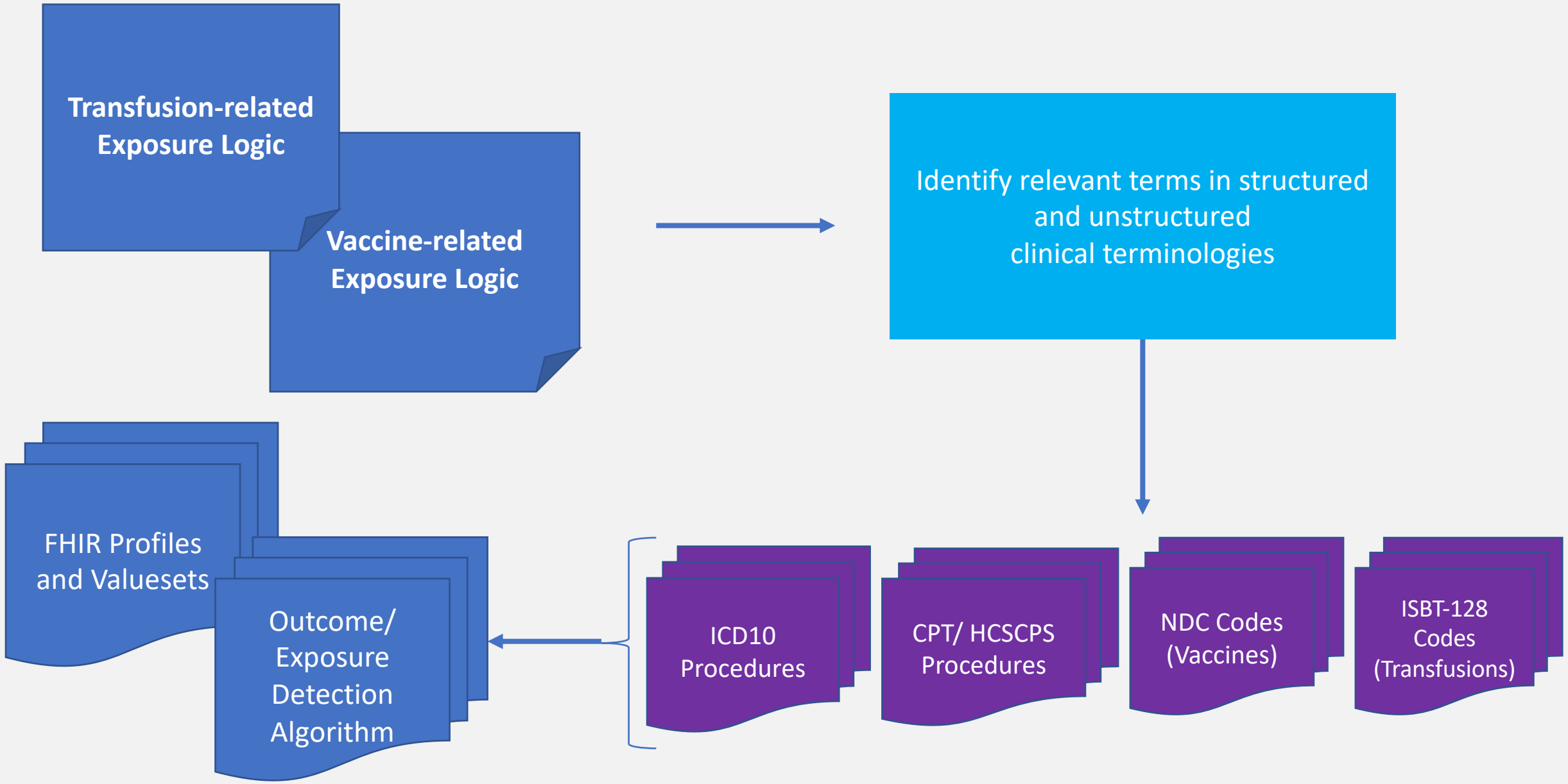
ICSR Generation Overview



Identify Data Elements Needed for Outcomes Detection



Identify Data Elements Needed for Exposure Detection



Compile Data Needs into Implementation Guide

Transfusion-related Exposures

Vaccine-related Exposures

Transfusion-related Outcomes: All 12 CDC NHSN AE Case Definition Components

Vaccine-related Outcomes: Select Brighton Collaboration Vaccine AE Case Definition Components

FAERS (R2 + *FAERS Blood DTD*) ICSR Specs (ICH)

VAERS (R3) ICSR Specs (ICH)

Outcomes/Exposure Detection and Validation

ICSR AE Reporting

FHIR Data Elements and Valuesets

FHIR Profiles and Implementation Guide

Note: Any images, videos, or other representations of an individual's health record shown on slides is synthetic and does not contain actual patient data.

FHIR Profiles included in BEST Implementation Guide

1. **Patient, Practitioner, Organization, Observation, Procedure, Condition, Immunization**
2. **New Resources for USCDI: MedicationAdministration, AdverseEvent, BiologicallyDerivedProduct**

3. **Main data element gaps between current surveillance needs and USCDI:**
   - **MustSupport: ISBT-128 codes** for blood and tissues
     - Added BiologicallyDerivedProduct to capture transfusion exposure details, and link to Procedure resource
   - **MustSupport: NDC codes** for Vaccines and other blood products, allergenics, and advanced therapies to sufficiently identify granular details for products
   - **Other fields needed for ICSR reporting**
     - Added AdverseEvent resource so EHRs can store AE reports directly in EHR

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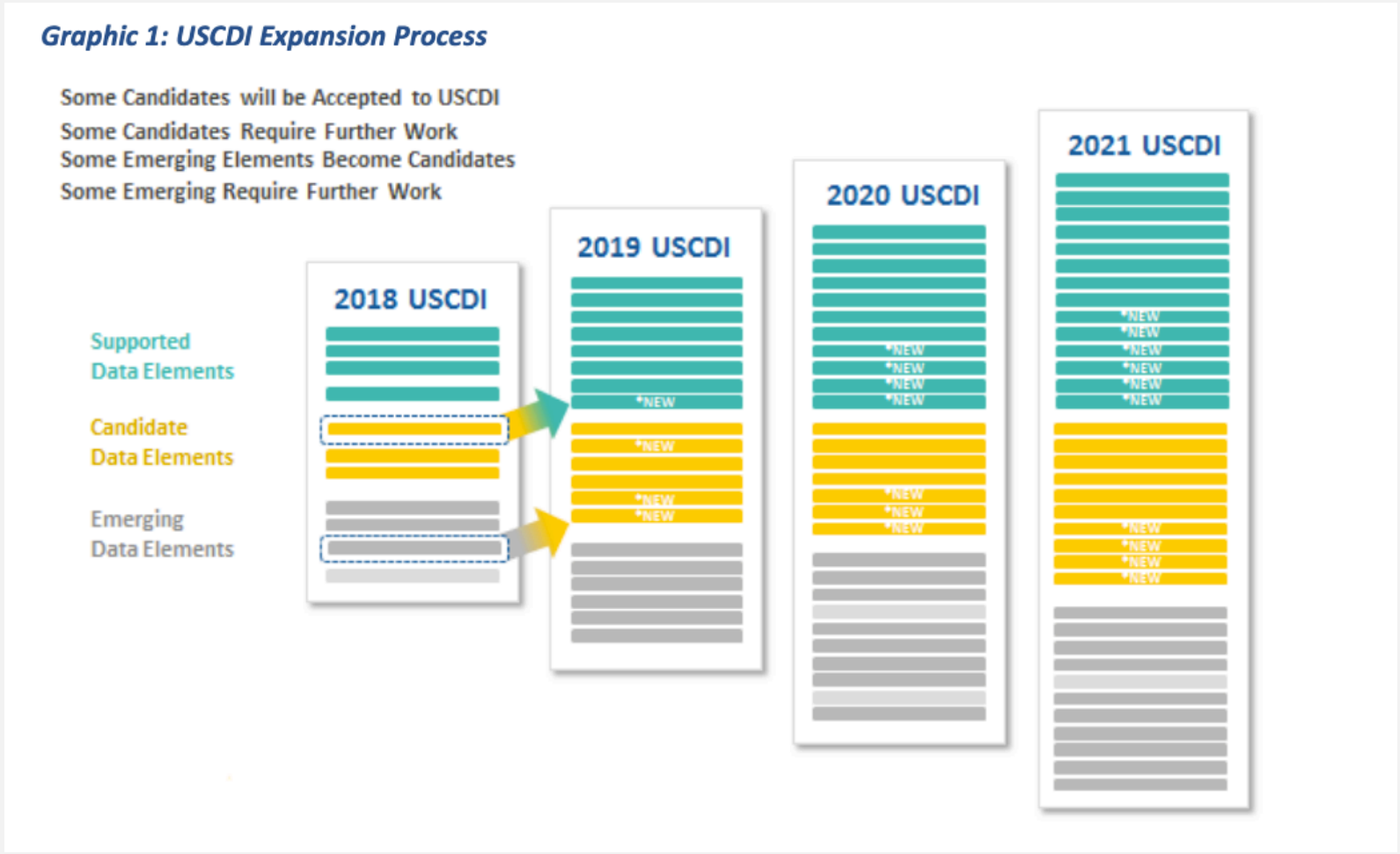
Next Steps: Implementing the Implementation Guide!



Source: https://www.healthit.gov/sites/default/files/draft-uscdi.pdf

US Core FHIR Implementation Guides: https://www.hl7.org/fhir/us/core/

- Goal is to add in data elements to future versions of the USCDI for safety and effectiveness surveillance of biologic products, in addition to coordination of care for patients.
- FDA CBER and IBM have created a FHIR Implementation Guide for capturing the data elements needed for biologics surveillance (including ISBT codes for blood, and NDC codes for Vaccines)
- IG to be circulated in appropriate HL7 workgroup(s) for review

Questions?

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