

# Biologics Effectiveness and Safety (BEST) Initiative: Pilot Year

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# Outline

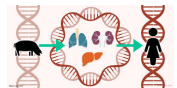
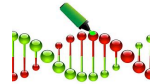
1. What are Biologics?
2. BEST Initiative: a component of the CBER Sentinel Program
  - a. Accomplishments
  - b. Lessons Learned
3. Future Plans

Center for Biologics Evaluation and Research (CBER)

# **WHAT ARE BIOLOGICS?**

# CDER-Regulated Products: Biologics

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





# CBER Active Surveillance Activities

Active surveillance activities with many organizations through contracts and agreements for many years:

- Harvard Pilgrim: Sentinel Program
- HealthCore
- IBM Watson
- Centers for Medicare and Medicaid (CMS)
- Veterans Administration (VA)
- Department of Defense (DoD)
- Indian Health Services (IHS)



# Biologics Active Surveillance Requirements

- Accommodate unique characteristics of biologics
- Expand and scale up surveillance capability and capacity
- Utilize more advanced methodology and technology

**Biologics Effectiveness  
and Safety (BEST)  
Initiative:  
Pilot Program**

- Two 1-year contracts
- Oct. 2017 – Oct. 2018
- IQVIA and OHDSI

# BEST Pilot Objectives

## **CONTRACT 1:** Data, Analytics, Infrastructure for Active Surveillance of Biologics

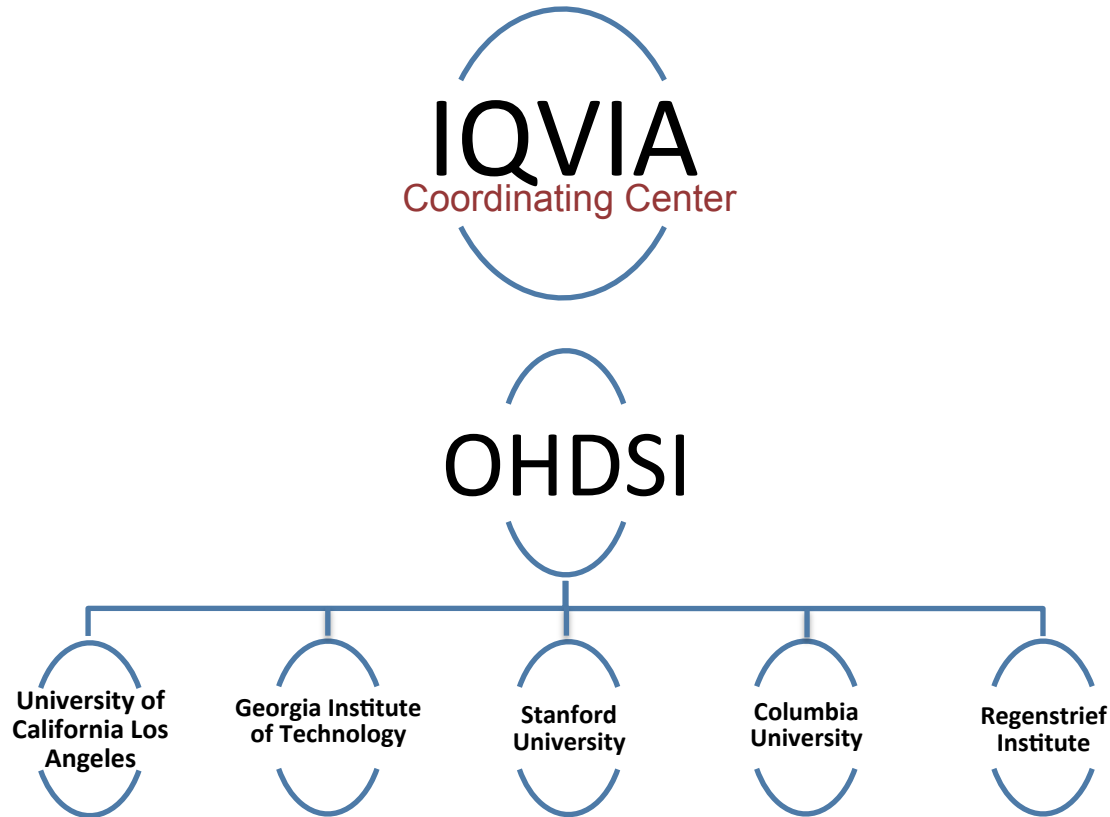
Develop advanced and large-scale surveillance capabilities to meet biologics needs: data sources and analytics

## **CONTRACT 2:** Development of New and Innovative Methods for Automated Reporting

Utilize innovative methods such as natural language processing, machine learning, and artificial intelligence to mine unstructured data in EHR data sources to advance surveillance capabilities



# BEST Collaborators: IQVIA and OHDSI



# Data Sources: OMOP CDM

## Claims & Administrative data

~100 million patient records

**Data Sources:**

IQVIA

Regenstrief Institute

## Electronic Health Records

~24 million patient records

**Data Sources:**

Stanford University

Columbia University

Regenstrief Institute

BEST Initiative: Data, Tools and Infrastructure for Surveillance of Biologics (Contract 1)

# ACCOMPLISHMENTS

# Infrastructure

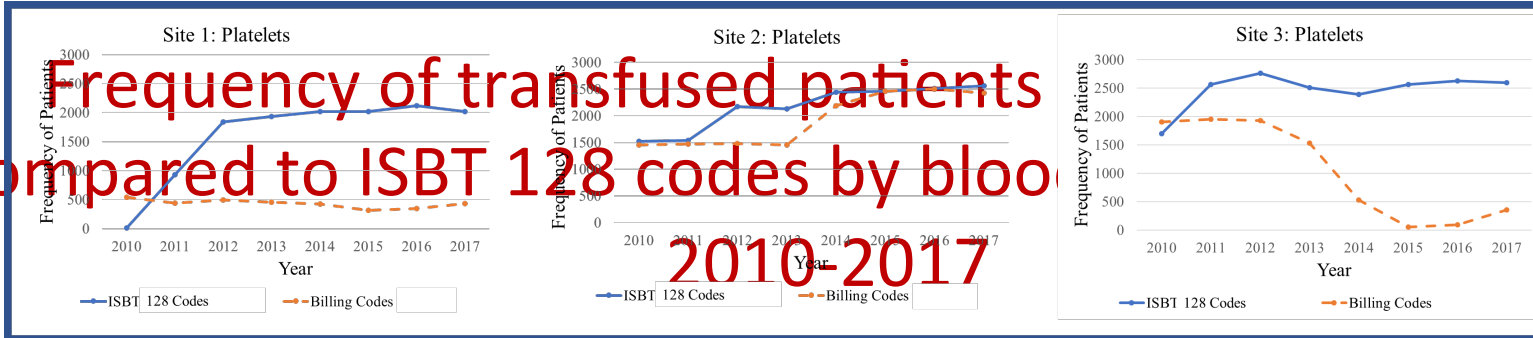
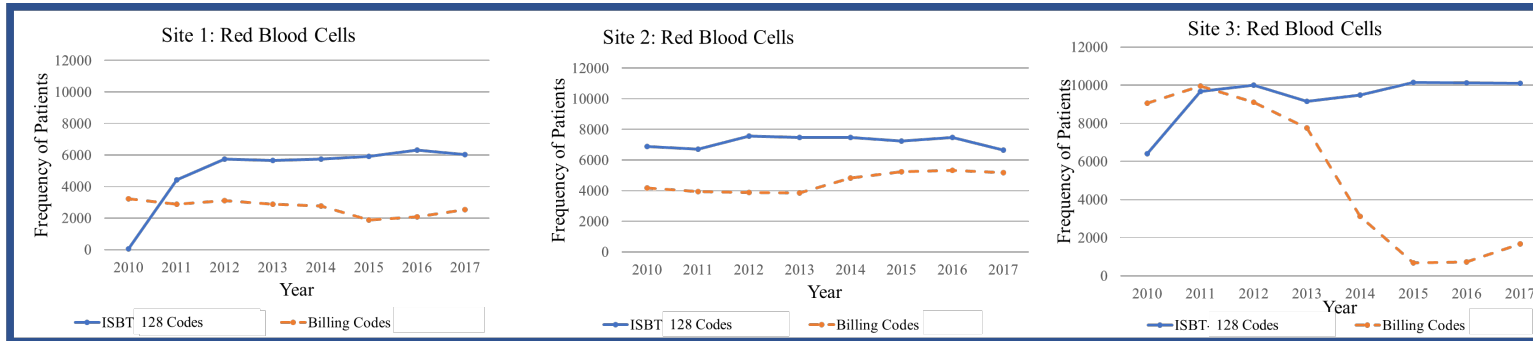
- Considerable infrastructure built- but more to come
- EHR data sources: focus on blood components surveillance
- OMOP CDM: Flexible and expandable
  - Incorporated ISBT 128 coding system

# Infrastructure

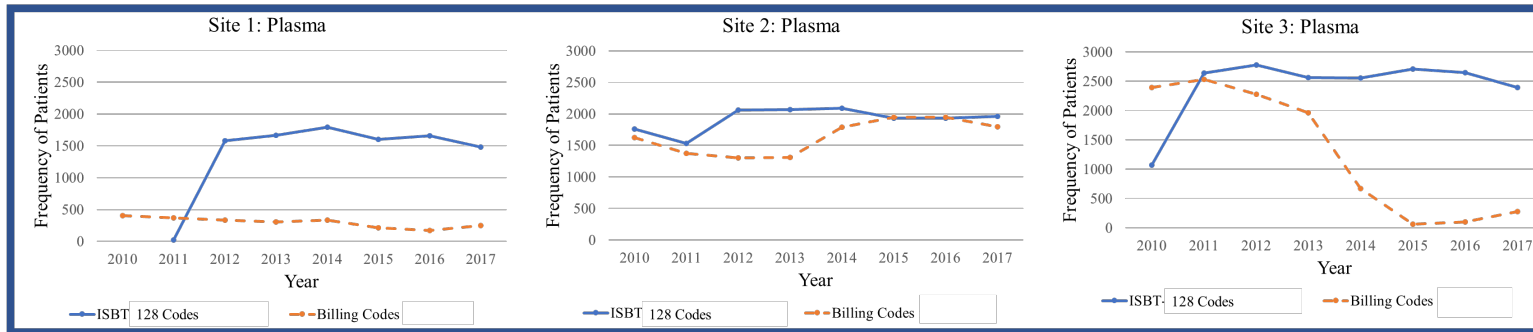
- Reduced data lag from 9-12 months to 3-4 months
- Analytics applicable to diverse and large-scale data sources to scale up capacity

# Blood Transfusion

- Assessed utilization of blood components
  - Red blood cells (RBC), platelets, plasma
- Using ISBT 128 and billing coding systems



Frequency of transfused patients compared to ISBT 128 codes by blood product sites, 2010-2017

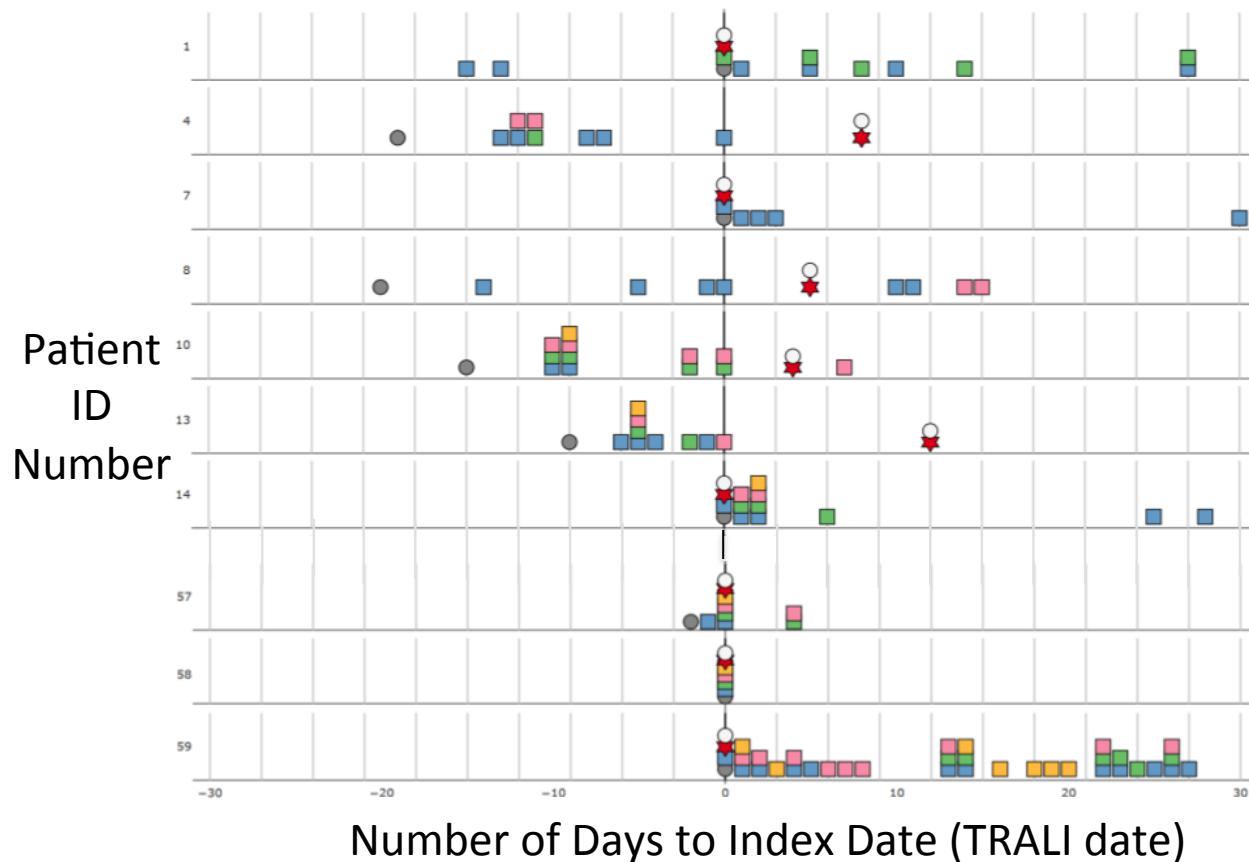


# Transfusion-Related Adverse Events

- Transfusion-Related Acute Lung Injury (TRALI):  
test case
- Explored temporality between transfusion and TRALI
  - Difficult to establish



# Temporality between blood transfusion & TRALI diagnosis



- Admission Date
- Red Blood Cell
- Platelets
- Plasma
- Cryoprecipitate
- ★ TRALI
- Discharge Date

# Lessons Learned

- Fair amount of infrastructure to be built
- Data quality control and assurance
  - Diverse data sources provide diverse data quality
  - Standardize and harmonize different data sources
  - Different data sources consistently mapped to CDM
  - Quality checking of data beyond simple counts and logic check necessary
  - Stability, consistency, and completeness essential
- Research vs. regulatory requirements and needs



BEST Initiative: Data, Tools and Infrastructure for Surveillance of Biologics (Contract 1)

## **FUTURE PLANS**

# BEST Initiative continues...

Two new 5-year contracts awarded Sept. 2018

**CONTRACT 1: Surveillance Infrastructure**

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**CONTRACT 2: Innovative Methods**

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- IQVIA and OHDSI
- Acumen
- IBM
- Dovel Technologies

# Challenges

1. Develop standard data quality control processes and set up a threshold for acceptable data quality
2. Standard data curation methods
3. Establish temporality between events
4. Linkage of claims and EHR data sources to enrich data

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Thank You