Biologics Effectiveness and Safety (BEST) Initiative: First Year

Dr. Azadeh Shoaibi PHD, MHS

October 12, 2018
Expansion of CBER Sentinel Program

INTRODUCTION
CBER Sentinel Vision is...

...to create and utilize an effective national post-market surveillance system for CBER-regulated products to provide data for evidence-based regulatory decisions to ensure the safe and effective use of biologic products.
CBER Regulated Products Biologics

• Vaccines (preventative and therapeutic)
• Blood (components and derived)
• Human Tissues and Cellular Products
• Gene Therapies
• Allergenics
• Xenotransplantation Products
• Devices Related to Biologics
Uniqueness of Biologics

Safety Surveillance
- Newly approved products needing near-real time electronic health information
- Continuous and active surveillance during pandemics and epidemic emergence

Health Information
- Significantly different billing, coding, and reimbursement practices from drugs
- Need data from multiple sources: blood and tissue banks, registries, pharmacies, various point of care in different care settings

Population Characteristics
- Large sized data representing: healthy population and high risk populations like pregnant women, elderly, children, immunocompromised
- Long- follow up period
Priorities and Objectives in 2017

• To increase capacity to conduct more simple and complex queries
• To decrease the overall cost of running multiple studies
• To reduce the data lag giving us access to current data
• To access Electronic Health Record (EHR) data source which have clinical rich and granular data
Access diverse sources of electronic health care data

Expand network of multidisciplinary collaborators

Implement advanced and efficient scientific methodology for regulatory purposes

Construct a cost-effective and sustainable post-market surveillance program
BEST Collaborators

- IQVIA*
  Coordinating Center

- OHDSI
  Observational Health Data Sciences and Informatics

- University of California, LA

- Georgia Institute of Technology

- Stanford University

- Columbia University

- Regenstrief Institute

Methods Development

Data Collaborators

*Also provides claims and hospital billing data
# Objectives for Pilot Program

<table>
<thead>
<tr>
<th>CONTRACT 1: Data, Tools and Infrastructure for Surveillance of Biologics</th>
</tr>
</thead>
<tbody>
<tr>
<td>To develop additional surveillance capabilities specifically required for biologics:</td>
</tr>
<tr>
<td>• Access to EHR data sources</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTRACT 2: Development of New and Innovative Methods for Automated Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>To utilize innovative methods such as natural language processing, machine learning, and artificial intelligence to mine unstructured data in EHR data sources</td>
</tr>
</tbody>
</table>
BEST Initiative: Data, Tools and Infrastructure for Surveillance of Biologics

ACCOMPLISHMENTS: FIRST YEAR
Enhanced Infrastructure

Major expansion and enhancement of biologics surveillance system

– Addition of EHR data sources
– Shorter data lag: data refreshed at least quarterly
  • Less than 4 months
Data Sources

Claims/Administration Billing Data
- ~100 million Patients
- Data Sources:
  - IQVIA LRxDx
  - IQVIA Hospital Billing

Electronic Health Records Data
- ~20 million Patients
- Data Sources:
  - Stanford University
  - Columbia University
  - Regenstrief Institute
Enhanced Infrastructure

Major expansion and enhancement of biologics surveillance system

– Addition of EHR data sources
– Shorter data lag: data refreshed quarterly
– Flexible and expandable common data model (CDM)
Enhanced Infrastructure

Major expansion and enhancement of biologics surveillance system

– Addition of EHR data sources
– Shorter data lag: data refreshed quarterly
– Flexible and expandable common data model (CDM)
– Access to flexible analytic capabilities
Flexibility with *ad hoc* Programming

- Programming for any questions of interest
- Iterations of programs after assessing feasibility
BEST Initiative: Data, Tools and Infrastructure for Surveillance of Biologics

CHALLENGES
**Strengths**
- Access to EHR
- Flexible CDM
- Direct communication with data partners

**Weaknesses**
- Data Quality
- Lack of Personnel
- Timeliness
- Quality of Deliverables

**Opportunities**
- Expanding infrastructure needed for surveillance of biologics

**Threats**
- Unstable infrastructure
- Lose scientific and regulatory credibility
BEST Initiative: Data, Tools and Infrastructure for Surveillance of Biologics

FUTURE PLANS
New Contract

Contracts awarded....further expansion to included multiple contracts...additional data bases...
Summary

• Addition of EHR data sources
• Access to data 1 – 4 months old
• Use of a flexible and expandable CDM
• Access to flexible analytic capabilities
• Use of innovative methods to identify and report blood transfusion-related adverse events
• Significant cost reduction
Acknowledgements

- CBER Sentinel Central Team
  - Kinnera Chada, PhD
  - Joyce Obidi, PhD
  - Kristin Sepulveda
- Office of Biostatistics and Epidemiology Staff
- Members of CBER product offices

- IQVIA
- OHDSI
- BEST Data Collaborators
  - Columbia University
  - Indiana University/Regenstrief Institute
  - Stanford University
- BEST Partners
  - Georgia Tech
  - UCLA