BBCIC
Biologics & Biosimilars
Collective Intelligence Consortium
AMCP BBCIC, LLC

FDA U.S. FOOD & DRUG ADMINISTRATION

Biosimilars, Utilization, and Post-Marketing Surveillance in the United States

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ISPOR Meeting, Baltimore, MD
Monday, May 21
3:45 PM – 4:45 PM

Overview

- FDA's Approach to Post-marketing Surveillance and Studies of Biosimilars
  - Background on biosimilars and safety surveillance
  - Post-marketing studies conducted by FDA
  - Challenges with observational research

- A Multi-Stakeholder Approach to Post-Marketing Surveillance and Studies of Biosimilars
  - First Wave of Approved Biosimilars
  - BBCIC: Addressing Challenges and Opportunities
  - BBCIC: Progress to Date

FDA's Approach to Postmarketing Surveillance and Studies of Biosimilars

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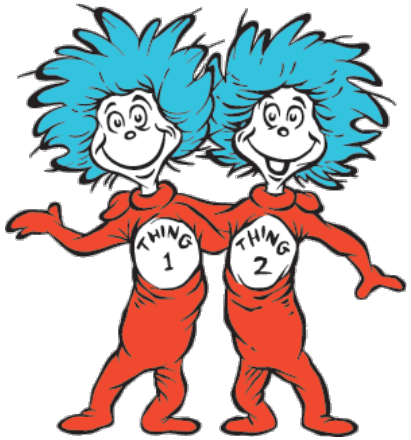


Disclaimer and Disclosure

- The views expressed in this presentation are those of the presenter and should not be construed as FDA's views or policies
- No conflicts of interest to disclose

Biosimilar Terms and Definitions

- *Biosimilar* or *Biosimilarity* – "the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product" [PHS Act Section 351(i)(2)]
- *Reference Product* – "the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)" [PHS Act Section 351(i)(4)]
- *Interchangeable* or *Interchangeability* – "the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product" [PHS Act Section 351(i)]
- *Switching Study* or *Studies* – "a clinical study or studies used to determine the impact of alternating or switching between the proposed interchangeable product and the reference product" [FDA Draft Interchangeability Guidance, January 2017)

Basic Principles of Safety Surveillance

- Multidisciplinary, lifecycle approach
  - Management of postmarketing safety begins early in the product's lifecycle (pre-FDA approval)
- Use all available data sources
  - FDA Adverse Event Reporting System (FAERS), medical literature, Periodic Safety Reports, clinical studies, preclinical studies
- Risk-based approach
  - As with all new drug products, FDA conducts robust safety surveillance for newly approved biosimilars, with focus for all new biologics and biosimilars on
    - Immunogenicity
    - Medication errors

Safety Issue: Immunogenicity

- The propensity of a therapeutic protein product to generate immune responses to itself and to related proteins or to induce immunologically related adverse clinical events*
- Anti-drug antibody (ADA)
  - *No effect* ADA
  - *Pharmacokinetic-altering* ADA
  - *Neutralizing* ADA (inhibit functional activity of the biological product)
    - *Cross-reactive neutralizing* ADA
  - *Hypersensitivity* ADA
- Product-related factors
- Patient-related factors

**Guidance for Industry: Immunogenicity Assessment for Therapeutic Protein Products is available at https://www.fda.gov/downloads/drugs/guidances/ucm338856.pdf*

What We Look for in Immunogenicity Reports to FAERS

- ADA-related terms (e.g., *Drug specific antibody present*, *Neutralising antibodies positive*, *Non-neutralising antibodies positive)*
- Reduced efficacy or change in pharmacokinetics
- Hypersensitivity events
  - Early (e.g., anaphylactic reactions)
  - Delayed (e.g., serum sickness, immune complex disease)
- Description of a product quality issue
- Reports for specific patient population

Safety Issue: Medication Errors

- FAERS reports describing medication errors associated with
  - Product names
  - Labels and labeling
  - Packaging
  - Product design
- Includes:
  - Inadvertent product substitution
  - Name confusion
  - Use errors related to the delivery device and container closure systems
  - Unintended duplicate therapy

Nonproprietary Naming of Biological Products

Final Guidance issued January 2017

1. Nonproprietary names (i.e. proper names) for biological products should include **a core name attached by a hyphen to an FDA-designated suffix that is devoid of meaning.**
   - For example, for hypothetical products sharing the fictitious core name *replicamab*, the proper names would include a unique suffix:
     - Originator biological product : *replicamab-cznm*
     - Related biological product: *replicamab-rzbh*
     - Biosimilar product: *replicamab-hixf*

2. A unique suffix should be **designated for each originator biological product, related biological product and biosimilar product**.
   - FDA is continuing to consider the format of the suffix for interchangeable biological products.

Naming Convention: Objectives

Transparency:

- Allows identification of products for safe use and pharmacovigilance
- Facilitates prescribing and dispensing of the intended product
- Patients and providers want to know what the patient received

Trust:

- Practitioners and patients want FDA and others to have the tools available to perform product-specific pharmacovigilance in all settings of care

Uptake:

- Enhanced prescriber and public confidence facilitates market uptake

Safety Surveillance Challenges

- FAERS Reports
  - Product attribution
    - Distinguishing suffix may be omitted in the report
    - Manufacturers submit reports under their application number
      - Include reports in which the suspect product could not be confirmed
  - Identification of immunogenicity events
    - ADA testing rarely reported
    - Signs and symptoms of delayed hypersensitivity/immune-complex disease difficult to recognize
  - Methods to compare the safety profile of the biosimilar to that of the reference product in FAERS

Biosimilar Use for Surveillance Purposes

- Periodic Drug Use Data on all new biosimilars and their reference drugs
  - Helps put a potential safety signal in FAERS into context
  - Captures trends in prescribing, but not granular enough to explain those trends
    - Cannot differentiate between initiation and switching
    - Does not capture reasons for switch (e.g., cost, formulary)

Postmarketing Studies Conducted by FDA

- Biosimilar Use Studies
  - Appropriate capture of exposure will be useful for future studies in that population-based data source
- Switching Methods Studies
  - To inform the design of future studies in that population-based data source
- Safety or effectiveness studies in population-based data sources if a signal warrants further investigation

Data to Support Interchangeability

"…our current thinking is that postmarketing data collected from products first licensed and marketed as a biosimilar, without corresponding data derived from an appropriately designed, prospective, controlled switching study or studies, generally would not be sufficient to support a demonstration of interchangeability."

FDA Draft Guidance on Considerations in Demonstrating Interchangeability With a Reference Product, January 2017

Systematic Literature Review of Switching Studies (Cohen et al., Drugs 2018;78(4):463-478) – approx. 1/3 published studies reviewed were observational studies

Challenges in Conducting Observational Studies of Biosimilars

- Data Sources
- Exposure
- Outcomes
- Study Design

Challenges – Data Sources

- Biosimilar approval and uptake vary in different countries
  - Implications for study size, different patient population
- Approved indications for a biosimilar differ by country
  - Different risk profile populations, limits generalizability to US target populations
- Reimbursement and formularies affect who gets drugs
  - May impact internal validity of study (selection bias)

Challenges – Exposure

- Impact of US naming convention on exposure ascertainment in population-based data sources remains unknown
  - J codes vs. NDCs – need to understand which is more frequently used for each specific biosimilar
    - Self-administered biologics might get NDCs
  - Need to study utilization of J codes (e.g., temporary, new biosimilar-specific, codes with modifiers for older biosimilars)
    - Potential misclassification of new users
  - How might traceability affect internal validity of population sources?
  - Indication specific dosing and starter-doses need to be considered

Challenges – Outcomes

- What are the clinical events most likely to occur based on differences in immunogenicity, and how well are they captured in the data sources?
  - All Biologics (Hypersensitivity events; diminished efficacy)
  - Product Specific (e.g., Epoetin-Induced PRCA)
- Need for validation analyses for safety outcomes
- Effectiveness measures are not typically collected in claims data

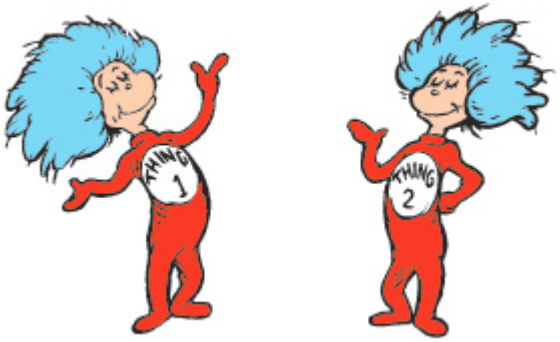
Challenges – Design Considerations

- Sample size considerations (e.g., new user design)
- Careful consideration in defining episodes of use and minimum at risk period
- Patients who switch to a biosimilar may differ in important ways from patients who initiate a biosimilar without prior reference product use
  - Careful consideration and assessment of these potential differences should be explored to inform the decision of which patients to include in a study cohort
- Substantial confounding may be present given frequent co-morbidities in population receiving biologics

Comparative Observational Studies

- New User Comparison
  - Restricted study population, particularly if only newly diagnosed patients are studied
  - Does not study outcomes that might be related to switching
- Switch from reference product to biosimilar vs. remain on reference product
  - Can match on length of prior reference product use, but restricts study population
  - Other than formulary restrictions, reasons for switch unlikely to be captured (confounding)
- Complex Study Designs (including multiple switches)

Time to Switch Speakers!



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- C. Lockhart is an employee of the BBCIC
- M. Cziraky is an employee of HealthCore and participates in the BBCIC as Chair of the Planning Board

Outline

- First Wave of Approved Biosimilars
- BBCIC: Addressing Challenges and Opportunities
- BBCIC: Progress to Date

FIRST WAVE OF BIOSIMILARS

Biosimilars approved in US (as of May 20, 2018)

Date of FDA Approval		Biosimilar Product	Reference Medicine	Manufacturer
1	March 6, 2015	Zarxio® (filgrastim-sndz)	Neupogen®	Sandoz
2	April 5, 2016	Inflectra® (infliximab-dyyb)	Remicade®	Celltrion/Pfizer
3	August 30, 2016	Erelzi® (etanercept-szzs)	Enbrel®	Sandoz
4	September 23, 2016	Amjevita® (adalimumab-atto)	Humira®	Amgen
5	April 21, 2017	Renflexis® (infliximab-abda)	Remicade®	Samsung Bioepis/Merck
6	July 20, 2017	Lusduna™ (insulin glargine)*	Lantus®	Merck/Samsung Bioepis
7	August 25, 2017	Cyltezo™ (adalimumab-abdm)	Humira®	Boehringer-Ingelheim
8	September 14, 2017	Mvasi™ (bevacizumab-awwb)	Avastin®	Amgen/Allergan
9	December 1, 2017	Ogivri™ (trastuzumab-dkst)	Herceptin®	Mylan/Biocon
10	December 13, 2017	Ixifi™ (infliximab-qbtx)	Remicade®	Pfizer
11	May 15, 2018	Retacrit™ (epoetin alfa-epbx)	Epogen®/Procrit®	Hospira

*Lusduna™ (insulin-glargine) was approved as a follow-on biologic on Aug 5, 2015 – referencing Lantus®

Biosimilars Review & Report. https://biosimilarsrr.com/us-biosimilar-filings/ (accessed March 13, 2018)
US Food and Drug Administration CDER List of Licensed Biological Products http://www.fda.gov (accessed March 13, 2018)

Biosimilars Anticipated in US (as of May 15, 2018)

Filing Date		Expected Date of FDA Decision	Biosimilar Product	Reference Product	Manufacturer
1	June 30, 2017	April 5, 2018 FDA CRL; manufacturing plant issues	Truxima™ (rituximab)	Rituxan®	Celltrion/Teva
2	July 31, 2017	April 5, 2018 FDA CRL; manufacturing plant issues	Herzuma™ (trastuzumab)	Herceptin®	Celltrion/Teva
3	July 31, 2017	Q2 2018	TBD™ (trastuzumab)	Herceptin®	Amgen/Allergan
4	Sept 12, 2017	Q3 2018	TBD™ (filgrastim)	Neupogen®	Adello
5	Sept 12, 2017	May 2, 2018 FDA CRL	TBD™ (rituximab)	Rituxan®	Sandoz
6	December 20, 2017	Q4 2018	TBD™ (trastuzumab)	Herceptin®	Samsung Bioepis
7	Jan 15, 2018	Q4 2018	TBD™ (adalimumab)	Humira®	Sandoz
8	Aug 9, 2016/ May 3, 2018	TBD	TBD™ (pegfilgrastim)	Neulasta®	Coherus Biosciences
9	Feb 16, 2017	June 2018	TBD™ (pegfilgrastim)	Neulasta®	Mylan/Biocon
10	Q3 2017	April 23, 2018 FDA CRL; nonclinical issues	TBD™ (trastuzumab)	Herceptin®	Pfizer

CRL = complete response letter

Biosimilars Review & Report. https://biosimilarsrr.com/us-biosimilar-filings/ (accessed May 15, 2018)

Biosimilars Approved by EMA (through January 2018)

Year of EMA Approval	Biosimilar Product	Reference Product	Number of Products
2006	Somatropin	Norditropin®	1
2007	Epoetin alfa	Epogen®	3
2007	Epoetin zeta	Retacrit®	2
2008/2009/2010/2013/2014	Filgrastim	Neupogen®	7
2013/2014	Follitropin alfa	Gonal-f®	2
2013/2016	Infliximab	Remidade®	3
2014/2017	Insulin glargine	Lantus®	3
2016	Enoxaparin sodium	Lovenox®	2
2016/2017	Etanercept	Enbrel®	2
2017	Adalimumab	Humira®	4
2017	Insulin lispro	Humalog®	1
2017	Rituximab	Rituxan®	6
2017	Teriparatide	Forteo®	2
2017	Trastuzumab	Herceptin®	2
2018	Bevacizumab	Avastin®	1

TOTAL APPROVALS = 41

An additional 16 biosimilars are under review by EMA in 2018

European Medicines Agency. www.ema.europa.eu (accessed May 8, 2018)
Generics and Biosimilars Initiative. http://www.gabionline.net/Biosimilars/General/Biosimilars-applications-under-review-by-EMA-January-2018 (accessed May 8, 2018)

BBCIC:
ADDRESSING CHALLENGES AND OPPORTUNITIES

BBCIC - Background

A non-profit, multi-stakeholder, scientific public service initiative conducting rigorous post-marketing observational research to monitor biosimilar products and novel biologics for effectiveness and safety

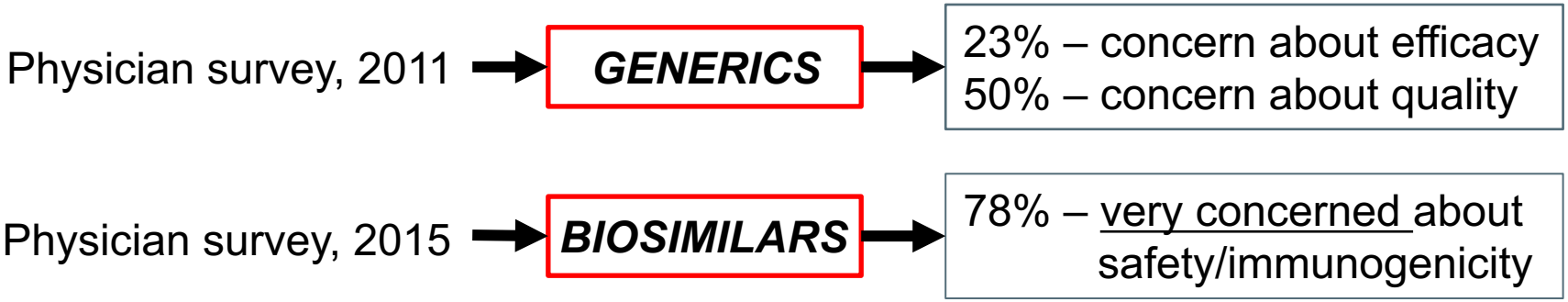
BBCIC Purpose: Why the BBCIC Is Needed

Generics saved the US $1 trillion in past decade *but it took 20 years.*

–Generics are safe and effective, resulting in increased patient access to critical medications.

–Slow generic uptake influenced by anecdotal reports that got wide press coverage.

–Lingering uncertainty among physicians and patients about safety and comparability.



- Shrank et al. Ann Pharmacotherapy, 2011;45(1):31-8.
- http://www.gastro.org/press_releases/2015/7/29/national-survey-reveals-gastroenterologists-views-on-biosimilar-drugs

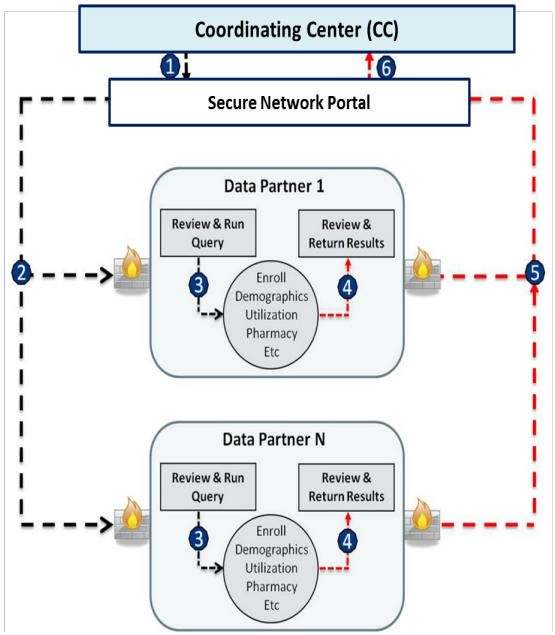
BBCIC Surveillance –Leveraging Sentinel Capabilities

The AMCP BBCIC strategy provides a unique opportunity for Managed Care to support public knowledge of biologic and biosimilar drugs with robust science.

BBCIC leverages the Sentinel Initiative → Improves the efficiency and cost-effectiveness of post-marketed observational studies.

BBCIC actively monitors biosimilars and innovators → Anonymous data from ~150 million patients

BBCIC is a multi-stakeholder collaboration → Diverse expertise allows for a larger voice with more credibility



1- CC submits query on behalf of work group (a computer program)

2- Data Partners retrieve query

3- Data Partners review and run query against their local data

4- Data Partners review results

5- Data Partners return results to CC via secure network

6- Results aggregated by CC and sent to work group

A forum for collaboration between managed care organizations, integrated delivery networks, PBMs, pharma companies and research institutions

BBCIC Spearheading Change: RWD, RWE & CURES

RWE and Regulatory Use— 21st Century Cures requires FDA to establish a program to evaluate potential use of RWE for approval of new indications or to satisfy post-approval study requirements, label expansion or revision, and benefit/risk profiles

RWE & Biosimilar Interchangeability, Switching Studies

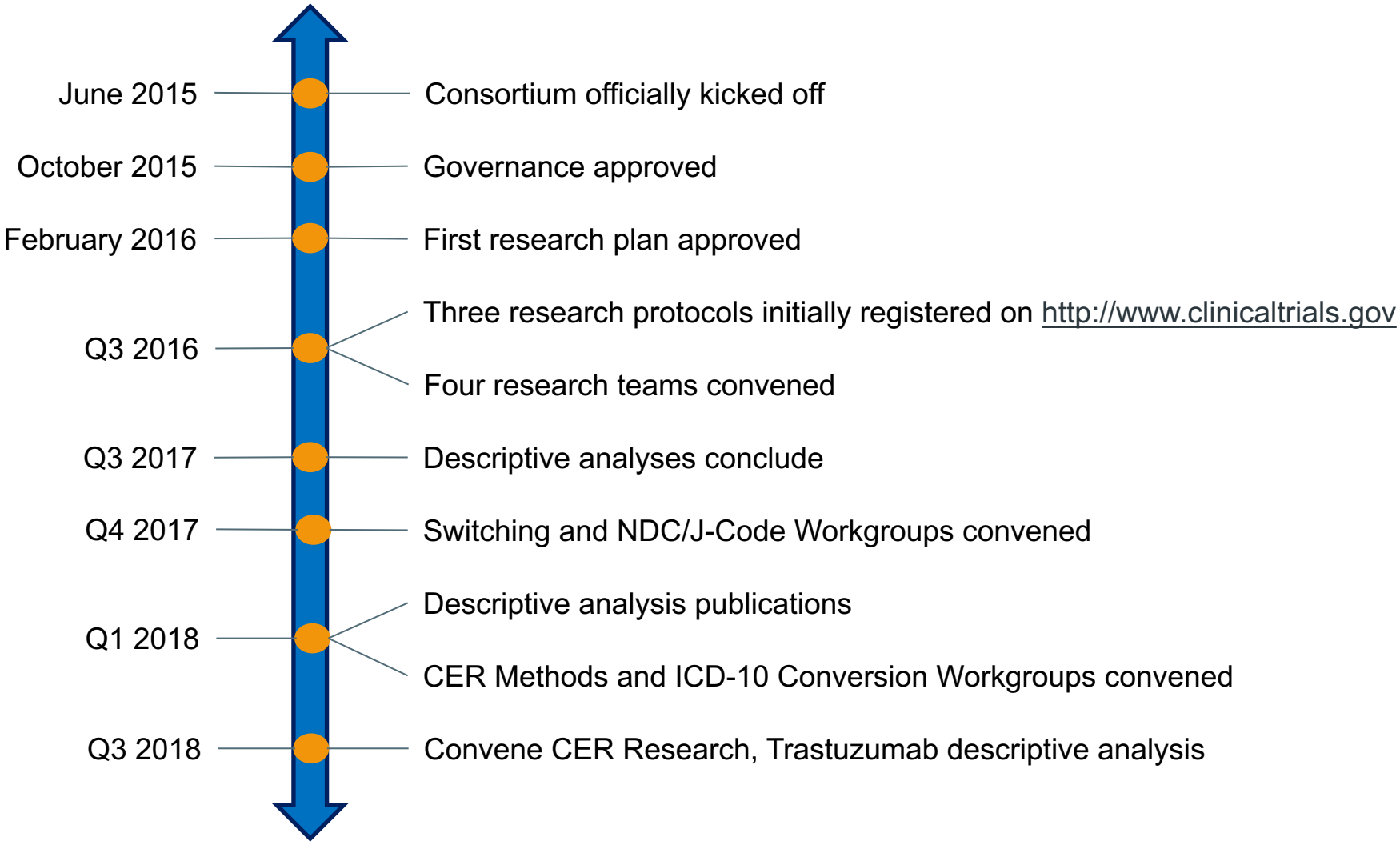
- FDA current position: RWE can help address residual uncertainties and determine additional data needs, but is not a basis for securing an interchangeability designation absent a clinical, multi-switching study, draft guidance states
- BBCIC has convened a workgroup to define best practices for characterizing switching patterns and for applying these patterns as covariates/confounders in comparative studies.
- BBCIC goal is to design and run switching studies with sufficient reproducibility across RWE sources to allow FDA to reconsider its position.

https://healthpolicy.duke.edu/sites/default/files/atoms/files/rwe_white_paper_2017.09.06.pdf

BBCIC Governance Overview

- The BBCIC Charter outlines transparent organized process for conducting research. There are no surprises.
- CER protocols, designed by KOLs and following ISPOR-ISPE guidelines, must explicitly pre-specify the epidemiologic, statistical and clinical thresholds required to identify a safety-related finding.
- 18 founding participants including Managed Care Organizations, Integrated Delivery Networks, PBMs & Harvard-Pilgrim Health Care Institute
- Public representatives on Planning Board: ASCO, American College of Rheumatology, National Health Council

BBCIC Progress to Date



BBCIC:
PROGRESS TO DATE

Descriptive Analysis Research Teams

In 2016, the BBCIC Science Committee convened 4 research teams to conduct descriptive analyses using the BBCIC DRN

Project	Disease Indications	Drugs
Insulins	• Diabetes	Insulin
Colony Stimulating Factors (G-CSF)	• Febrile Neutropenia risk reduction in non-myeloid malignancies treated with myelosuppressive anti-cancer drugs associated with a febrile neutropenia	Filgrastim (Neupogen), PEG-filgrastim (Neulasta), TBO-filgrastim, filgrastim-sndz (Zarxio)
Anti-Inflammatories	• Rheumatoid Arthritis • Psoriasis • Psoriatic Arthritis • Ankylosing Spondylosis • Ulcerative Colitis • Crohn's Disease	Adalimumab (Humira), infliximab (Remicade),infliximab-dyyb (Inflectra), infliximab-abda (Renflexis), rituximab (Rituxan), tocilizumab (Actemra), abatacept (Orencia), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), ustekinumab (Stelara), secukinumab (Cosentyx), natalizumab (Tysabri), golimumab (Simponi)
Erythropoeitin-Stimulating Agents (ESA)	• Anemia (CKD, Hemodialysis)	Epoetin alfa (Epogen, Procrit) darbepoetin alfa (Aranesp), methoxy polyethylene glycol-epoetin beta (Mircera)

Insulins Descriptive Analysis

Challenges – Design Considerations

Insulins

- **Objective**: To describe treatment patterns and outcomes of adult patients with diabetes who use long-acting (LAI) or intermediate-acting (NPH) insulin in a large distributed research network.
- **Outcomes**: (1) major cardiac events, combined; severe hypoglycemic events; (2) A1C baseline and follow-up

Results

	N	MACE, events/10,000 yr-at-risk	Severe Hypoglycemia, events/10,000 yr-at-risk
T1DM	4,591	40.2	34.9
T2DM	103,951	676.9	96.9

Conclusions

- Outcome rates were consistent with other clinical and observational studies.
- Significant diabetic diagnosis inconsistency, variation in days supply and use of rapid acting insulin and sulfonylurea adherence requires additional methods development.
- Careful study design, attention to length of episode gaps and use of algorithms to accurately identify patients with Type 1 and Type 2 diabetes, is essential.
- With the BBCIC DRN we are able to reliably identify and characterize exposures, outcomes, and potential confounders for a large population of people with diabetes.

G-CSF Descriptive Analysis

Challenges – Outcomes

G-CSF

- **Objective**: To provide a descriptive analysis of granulocyte colony-stimulating factor (G-CSF) use in patients diagnosed with breast or lung cancer and who received chemotherapy with Grade III or IV neutropenic-risk (NRGIII-IV) defined by National Comprehensive Cancer Network (NCCN) clinical guidelines, and to inform development of an observational comparative safety and effectiveness study of G-CSF biosimilars and innovators.
- **Outcomes**: (1) rate of hospitalizations for febrile neutropenia in G-CSFs users; (2) severe neutropenia; anaphylaxis; combined measure of bone pain, glomerulonephritis, capillary leak syndrome, hyperleukocytosis and splenic rupture.

Results

- Having only 3 (breast) and 1 (lung) high neutropenic risk regimens limited exposure
- Hospitalization for neutropenia occurred in 3% of episodes, similar to previous studies.
- ANC results were not reliably captured, as expected (often not in claims collected in a hospital outpatient or integrated delivery network setting)

Conclusions

- This large scale descriptive analysis provides initial evidence that the BBCIC DRN can produce incidence and event rates similar to those produced by both randomized clinical trials and observational studies, and that the important covariates and confounders are able to be measured.
- Including a broader population of breast and lung cancer patients, and adding data sources such as Medicare will increase the number of exposures and thus sample size for future CER studies.

Research Update – 2018 Summary

Challenges – Outcomes

Anti-Inflammatory

- **Objective**: To describe patients with autoimmune diseases receiving biologics, and recommend approaches for future comparative safety and effectiveness studies.
- **Outcomes**: Serious infections, defined as infections that required hospitalization.

Results

- When stratified by treatment, infection rates were lowest for patients initiating TNF agents for both RA and psoriasis, psoriatic arthritis, ankylosing spondylitis and non-biologic agents for IBD.

	N (% female)	Anti-TNF biologic use	Serious Infection, incidence/100 person yr (95% CI)
RA	111,611 (75%)	79%	9.8 (9.5-1.0)
Ps, PsA, AS	61,959 (52%)	89%	7.1 (6.8-7.5)
IBD	30,628 (51%)	98%	14.2 (13.6-14.8)

Conclusions

- This large descriptive analysis provides initial evidence that the BBCIC DRN can produce event rates similar to those from earlier pivotal studies.
- There is a challenge in identifying effectiveness measures beyond surrogates such as dosage or therapy change. We are pursuing a study to link PRO and clinical measures to administrative claims.

Manuscript in Preparation

Research Update – 2018 Summary

Challenges – Data Sources

ESA	• **Objective**: To conduct a feasibility analysis to assess the ability to use the currently available BBCIC data to conduct an observational comparative safety and/or effectiveness study of ESA biosimilars and innovators in hemodialysis (HD) patients. • **Outcomes**: chronicity of HD among patients identified among selected BBCIC data partners; sufficiently similar population of HD patients as described by the USRDS
Results	• The BBCIC HD population is sufficiently similar to the USRDS population for both age and sex distributions • The BBCIC HD population is **not** sufficiently similar to the USRDS population for duration of dialysis (only 0.5% of patients have >365 days). • Data Granularity of the BBCIC Common Data Model is not as strong as Medicare full data set for ESRD (e.g., lab results and ESA dosing)
Conclusions	• This work highlights the importance of identifying the correct data sources. • A Comparative Effectiveness Study is being designed to include the Medicare full data set to capture the more granular data elements and longitudinal exposures of patients undergoing HD.

Workgroups

In 2017, the BBCIC Science Committee convened 4 workgroups to develop best practices in research methodology and a platform for future studies

Project	Challenges Addressed	Study Goal
Switching	• Design Considerations	Treatment of switching/sequencing as a covariate/confounder in BBCIC CER studies
CER Methods	• Design Considerations	Develop best-practices based on current methodology for conducting observational comparative-effectiveness research
NDC / J-Code	• Exposures • Outcomes	Investigate the extent to which NDCs are being supplied on physician-office claims
ICD-10 Mapping	• Exposures • Outcomes	In preparation for future descriptive and CER projects, ICD-9 codes are being mapped to ICD-10 codes to allow utilization of data both before and after October 2015.

Lessons Learned - Infrastructure Improvements

Data Improvements

- Address multiple gaps identified in descriptive analyses
- Pilots with Patient Reported Outcomes from MTM or Specialty Pharmacy providers
- Pilots with mobile health patient reported outcomes tied longitudinally to the Common Data Model

Add Data Partners

- Cancer Research Network
- Medicare ESRD Full data set
- Anthem HealthCore Integrated Research Environment (HIRE)
- ASCO CancerLinQ

Expand Common Data Model

- Outcomes measures

BBCIC Future Directions

Expanded Research Scope

- Beginning COMPARATIVE EFFECTIVENESS RESEARCH in 2018!
  - Insulins
  - Anti-Inflammatory
  - G-CSF
- We are the BIOLOGICS and Biosimilars Collective Intelligence Consortium
- Opportunities for drug class or disease level research

Expanded Partnerships

- Pursuing partnerships to leverage resources for specific projects
- Seeking new participating members (manufacturers, managed care, PBMs, research organizations, data partners)

Expanded Communications Plan

- PUBLICATIONS!!
- Increased public exposure to research programs and results

For more information on BBCIC

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Summary (1)

- FDA conducts rigorous safety surveillance for immunogenicity and medication errors beginning early in the product lifestyle.
- FDA conducts post-marketing studies on:
  - Biosimilar Use
  - Switching Methods
  - Safety or effectiveness if a signal warrants further investigation
- Challenges in conducting observational research on biosimilars:
  - Data Sources
  - Exposure
  - Outcomes
  - Study Design

Summary (2)

- BBCIC is a non-profit, multi-stakeholder, research consortium addressing a need for robust evidence surrounding biologic and biosimilar products
- Leverages the Sentinel infrastructure
- Access to data from over 150 million patients in the US
  - Exploring additional data sources to address needs
- Successfully completed four descriptive analyses
- Pursuing post-marketing comparative effectiveness studies as well as defining best-practices in methodology

Questions?