

# BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

## LETTER FROM THE EXECUTIVE DIRECTOR

...and just like that, it is May! Is it just me, or do you also feel like January was just yesterday?

True to form, my to-do list has been packed, but we are making great progress! A major in 2019 has been to get publications submitted for all of the great research that we have completed. I am thrilled to announce that the **first official BBCIC research publication has been ACCEPTED!** The exceptional work by the Switching Workgroup, led by Rishi Desai and Joshua Gagne of Brigham & Womens Hospital, will be published in *Pharmacoepidemiology & Drug Safety*! I will send out an announcement as soon as we have a publication date. CONGRATULATIONS! We also have several other manuscripts currently in preparation or review. Please see the Publications Update on pg 5.

BBCIC is also maintaining a steady presence at professional meetings and relevant conferences, with two podium presentations and two posters already presented since January this year. Three poster presentations are coming up at ISPOR (ICD-10 mapping) and ICPE (NDC/J-Code; CER Methods), and the ICD-10 mapping abstract was accepted for podium presentation at ICPE this year! We await decisions on two educational session abstracts submitted for presentation at AMCP Nexus, and have an additional two poster abstracts planned for submission in June.

In April BBCIC hosted the 3rd Annual BBCIC Workshop in Alexandria, VA. I always so look forward to this event when BBCIC Participants come together for a (rare) meeting in-person. We had an interesting program of speakers, and as always when this group gets together, the energy and discussion was truly outstanding! With the success of the BBCIC Live @ Nexus meeting last fall, we are planning another half-day session to be held on October 29 at the beginning of the AMCP Nexus meeting. More details to come, but mark your calendars for another opportunity to meet face-to-face with your BBCIC colleagues!

As always, thank you all for your participation, engagement, and hard work on behalf of BBCIC. You are what makes the important work we do possible! Happy Spring!

Regards,  
Cate Lockhart, MS, PharmD, PhD

### **ATTENTION CURRENT BBCIC PARTICIPANTS!!!!**

**Please work with your colleagues to submit Research Topic Requests by May 31!**

*Please contact Cate at [clockhart@bbcic.org](mailto:clockhart@bbcic.org) for more information*

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**BBCIC**

**Biologics & Biosimilars  
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## NEW RESEARCH UPDATES!

### Comparative Effectiveness Research: G-CSF

#### Background and Rationale

For over two decades, recombinant human granulocyte colony-stimulating factors (G-CSFs) have been used to treat and prevent chemotherapy-induced neutropenia. Currently two biosimilar products to reference filgrastim (filgrastim-sndz, filgrastim-aafi), and two biosimilars to reference pegfilgrastim (pegfilgrastim-jmdb, pegfilgrastim-cbqv) have been approved in the US. Building upon a previous BBCIC descriptive analysis, we are starting our first Comparative Effectiveness Research (CER) project in G-CSFs.

### **The BBCIC is in the final stages of contract negotiation and gearing up to kick-off our first Comparative Effectiveness Research project.**

#### Current Progress

Co-Investigator Selection: We are delighted to have an exceptional team of investigators lead this project

- *Pamala A. Pawloski, PharmD, BCOP, FCCP - Senior Research Investigator, HealthPartners Institute*
- *Cara McDermott, MS, PharmD, PhD - Research Consultant, BBCIC*

Contract execution is in progress and Research Team volunteers from BBCIC have been identified. We anticipate project kick-off in June 2019.

## MEET THE RESEARCH TEAM!

Neil Accortt, PhD - Director, Observational Research, Amgen

Jaclyn Bosco, MPH, PhD - Global Head, Epidemiology & Outcomes Research, IQVIA

Diana Brixner, PhD - Professor and Chair, University of Utah

Terese DeFor - Senior Manager, Research Informatics, HealthPartners

Katie King - Senior Project Coordinator, Harvard Pilgrim Health Care Institute

Annemarie Kline, MS, CHES - Senior Informatics Consultant, Aetna, a CVS Health Company

Brian Lehman, MBA, MHA, RPh - Director, Medical Account Management/Strategic Alliances, Sandoz

Cate Lockhart, PharmD, PhD - Executive Director, BBCIC

Kevin Lu, PhD - Associate Professor, University of South Carolina

Sarah Malek, Project Manager, Harvard Pilgrim Health Care Institute

Jim Marshall - Senior Research Analyst, Harvard Pilgrim Health Care Institute

Aaron Mendelsohn, PhD - Harvard Pilgrim Health Care Institute

Jeremy J. Whalen, PharmD, BCOP - Prime Therapeutics / HOPA

Sophie Zhang, PhD - Senior Researcher, HealthCore

## MORE NEW RESEARCH UPDATES!

### Oncology Feasibility and Data Fitness

#### Background and Rationale

A marked increase in the approval of biosimilar products, particularly in cancer therapy, is anticipated as a result of patent expirations for a number of originator biologics. As such, there is a need to generate robust real-world evidence for biosimilar cancer therapeutics. Given the number of biosimilars in oncology expected to be considered for approval in the near future, BBCIC is establishing the necessary resources to do product- or disease-specific comparative effectiveness research.

**The BBCIC is finalizing contracting to kick-off a project to evaluate and enrich the BBCIC Distributed Research Network specifically for capability in post-marketing observational cancer research.**

#### Current Progress

Principal Investigator Selection. We are delighted to also have an exceptional investigator lead this project

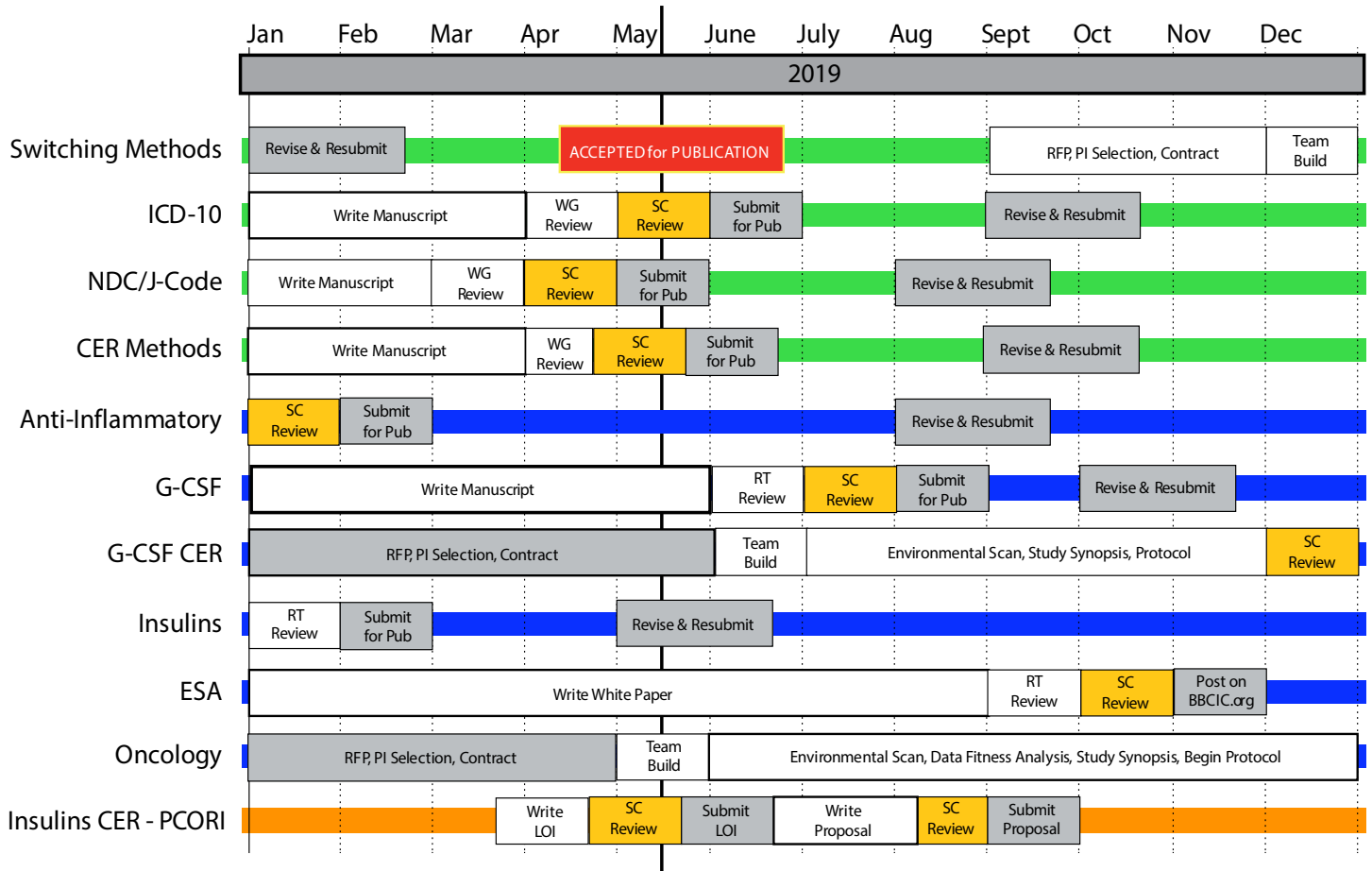
- *Nancy Lin, ScD - Senior Scientist, Optum Epidemiology*

Contracts are being finalized and Research Team volunteers have been identified. We anticipate starting this project in early June 2019.

## MEET THE RESEARCH TEAM!

Sanjeev Balu, PhD - Head, HEOR/RWE, US Biosimilars, Sandoz  
Maria Bottorff, PharmD, BCOP - Clinical Oncology Pharmacist, Loyola University / HOPA  
Jaclyn Bosco, MPH, PhD - Global Head, Epidemiology & Outcomes Research, IQVIA  
Terese DeFor - Senior Manager, Research Informatics, HealthPartners  
Prasad Gawade, PhD - Observational Research Senior Manager, Amgen  
Cynthia Holmes, PharmD, MS - Director, Healthcare solutions, Abbvie  
Katie King - Senior Project Coordinator, Harvard Pilgrim Health Care Institute  
Sam Li, PhD - Assistant Professor, University of Tennessee  
Cate Lockhart, PharmD, PhD - Executive Director, BBCIC  
Sarah Malek - Project Manager, Harvard Pilgrim Research Institute  
Jim Marshall - Senior Research Analyst, Harvard Pilgrim Health Care Institute  
Ali McBride, PharmD, MS, BCOP, FAzPA, FASHP, Clinical Coordinator Hem/Onc, Univ. of Arizona  
Cara McDermott, PharmD, PhD - Research Consultant, BBCIC  
Cheryl McMahill-Walraven, MSW, PhD - Director, Informatics, Aetna, a CVS Healthcare Company  
Aaron Mendelsohn, PhD - Harvard Pilgrim Health Care Institute  
Pamala A. Pawloski, PharmD, BCOP, FCCP - Research Investigator, HealthPartners  
Gary Yee, PharmD - Professor and Associate Dean, University of Nebraska

# PROJECT TIMELINE



# 2019 ABSTRACTS

| Meeting       | Meeting Date                              | Submission Deadline | Topic       | Type   | Presenting Author   | Status            |
|---------------|---|---------------------|-------------|--------|---|-------------------|
| ISPOR         | May 18-22, 2019<br>New Orleans, LA        | Jan 16, 2019        | ICD-10      | Poster | Seoyoung Kim  | Accepted          |
|               |   |                     | ISPOR SIG   | Podium | Cate Lockhart   | Accepted          |
| ICPE          | August 24-28, 2019<br>Philadelphia, PA    | Feb 13, 2019        | ICD-10      | Podium | Mengdong He   | Accepted          |
|               |   |                     | CER Methods | Poster | Nancy Lin   | Accepted          |
|               |   |                     | NDC         | Poster | Sophie Zhang  | Accepted          |
|               |   |                     | BBCIC       | Podium | Cate Lockhart<br>BBCIC Workgroups                               | Rejected          |
| AMCP<br>Nexus | Oct 29-Nov 1, 2019<br>National Harbor, MD | April 14, 2019      | G-CSF       | Podium | Cate Lockhart<br>Cara McDermott<br>Pam Pawloski                 | Submitted         |
|               |   |                     | EU/US Data  | Podium | Cate Lockhart<br>Hillel Cohen<br>Jaclyn Bosco<br>Julie Marechal | Submitted         |
|               |   | June 12, 2019       | BBCIC       | Poster | Aaron Mendelsohn  | Not Yet Submitted |
|               |   |                     | G-CSF       | Poster | Cate Lockhart   | Not Yet Submitted |

# 2019 PLANNED PUBLICATIONS

## SWITCHING Methods Best Practices

ACCEPTED FOR PUBLICATION by *Pharmacoepidemiology & Drug Safety*

## INSULINS Descriptive Analysis

Pair of companion articles are in revision after peer-review by the *Journal of Managed Care & Specialty Pharmacy*

## ANTI-INFLAMMATORY Descriptive Analysis

Undergoing final revisions followed by submission to the *Journal of Managed Care & Specialty Pharmacy*

## G-CSF Descriptive Analysis

Manuscript is currently in preparation. Target journal TBD

## ESA Descriptive Analysis

A white paper is in preparation to post on [www.BBCIC.org](http://www.BBCIC.org).

## BBCIC DRN Data Gaps and Potential Solutions

A manuscript is in preparation to describe the BBCIC experience in identifying, addressing, and exploring solutions to data gaps

## CER METHODS Recommended Best Practices

A manuscript is in internal BBCIC review to describe the findings and recommendations of the BBCIC CER Methods Workgroup

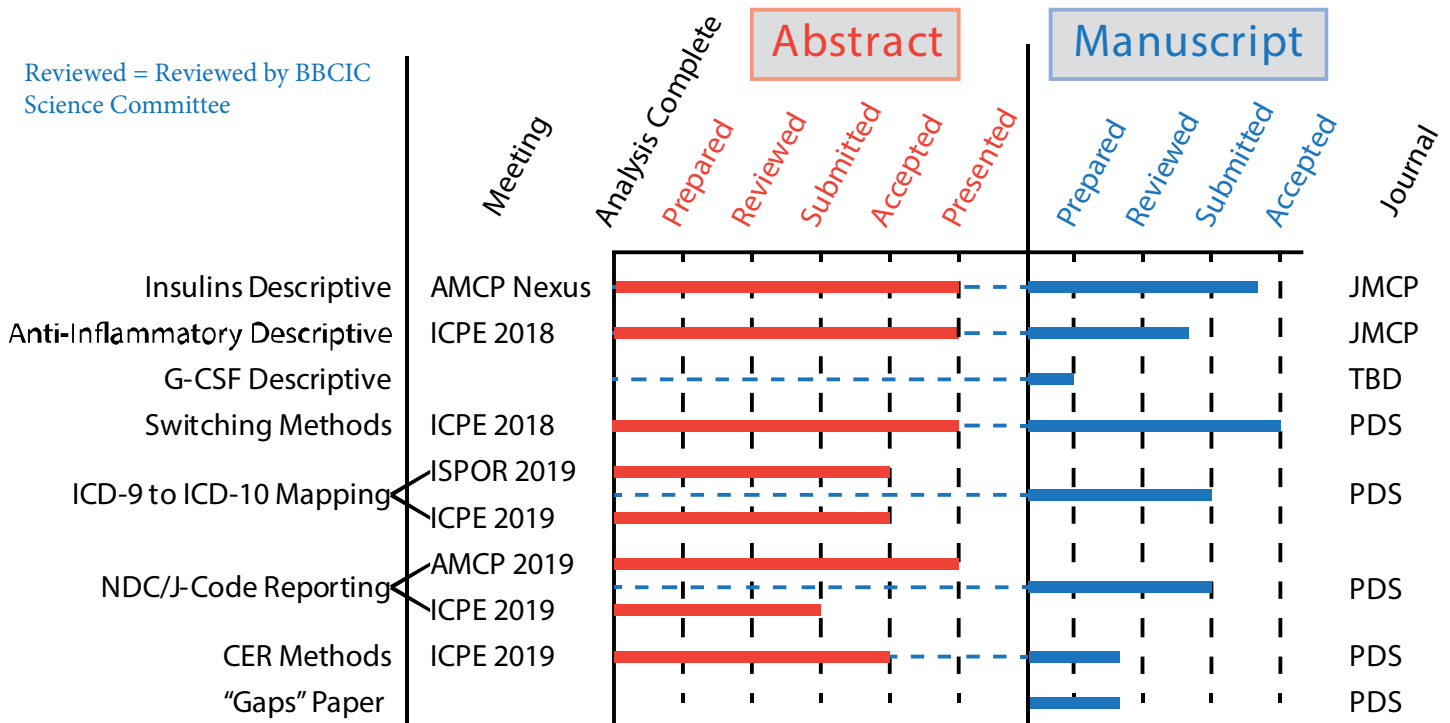
## G-CSF Comparative Effectiveness Research

A manuscript is anticipated to describe BBCIC approach to designing a large-scale, multi-source observational CER study

## ICD-9 to ICD-10 Mapping

Undergoing final BBCIC review followed by submission to *Pharmacoepidemiology & Drug Safety*

# PUBLICATION TRACKER



JMCP = Journal of Managed Care & Specialty Pharmacy  
PDS = Pharmacoepidemiology & Drug Safety  
TBD = To Be Determined

On **April 2, 2019**, BBCIC Participants met at the AMCP Offices in Alexandria, Virginia for the 3rd Annual BBICC Workshop, one of two opportunities in the year for meeting in person.

### **31 Participants: 24 in person, 7 via teleconference**

### **18 Organizations Represented:**

Aetna, AMCP, AMCP Foundation, American Society of Clinical Oncology (ASCO), Amgen, Arthritis Foundation, BBCIC, Boehringer-Ingelheim, Brigham & Womens Hospital, US Food and Drug Administration (FDA), HealthCore, HealthPartners, Hematology/Oncology Pharmacy Association (HOPA), IQVIA, Medicines for Europe, Optum, Sandoz, University of Utah

#### **SUMMARY**

##### **International Perspective - European Landscape**

We started the morning exploring the biosimilar experience in Europe, with perspectives from Medicines for Europe providing their view on successes and continued opportunities. While there is more experience with biosimilars overall in Europe, utilization varies between and within countries. There may be interest BBCIC research, and opportunities to build relationships with our fellow research and data organizations in Europe.

##### **International Perspective - Data Capabilities**

Next we took a deeper dive into the data sources that are currently being used for observational research in Europe, with the goal of sparking ideas for how (and if) BBCIC may leverage the European experience or identifying potential collaboration opportunities.

##### **U.S. Perspective**

Returning to the US, we got an update on the current biosimilar landscape and an overview of some FDA guidances and draft guidances that may be relevant to biosimilars. The morning sessions reinforced the important work BBCIC is doing in contributing to the scientific describing biosimilars and novel biologics

##### **BBCIC Coordinating Center - Sentinel Update**

The BBCIC Coordinating Center provided an update on the FDA Sentinel Initiative and how it may impact the capabilities of BBCIC research using the Common Data Model. There are opportunities for the work of FDA to inform some projects that BBCIC may have interest in pursuing.

##### **Patient Perspective**

We were thrilled to have the Arthritis Foundation provide a patient perspective for one group affected by availability of biosimilars. For patients, cost is a major barrier for treatment access, and there is a need for education to increase awareness of biosimilars. Patients get much of their information from their doctors, and want some control in their treatment choices. The Arthritis Foundation is working with patients and provider groups to support their educational needs.

## SUMMARY CONTINUED

**BBCIC 2019 Research Updates** - See pg 2-3 above for an update on current research

### **BBCIC 2018 Recap**

There is still interest in developing a more robust communication plan for dissemination of BBCIC research, including maintaining a presence at relevant professional/society meetings. Monitoring queries are underway, and we are seeking input on the report format. We are considering a suggestion to expand the product list for monitoring queries and decrease the frequency of queries if that will generate more broadly useful information.

### **Strategic Plan**

A subcommittee met last fall to brainstorm a Strategic Plan to push BBCIC forward from a start-up to grown-up organization. With input from BBCIC participants, we developed a cohesive plan, around four primary efforts: Technical Excellence, Operational Excellence, Thought Leadership, and Financial Stability and Growth. Over 30 action items were identified to start us on the path toward an even stronger BBCIC.

### **Open Discussion**

We closed the day with an open discussion and opportunity to revisit topics from the day, and share ideas that may not have been discussed. All of this great discussion is being considered and relevant ideas are being transformed into action items to further bolster BBCIC efforts. It takes a village to grow a consortium!

## NEWS AND EVENTS

### **BBCIC out in the Wild:**

Cate Lockhart (BBCIC) gave a presentation entitled “*The State of US Biosimilar Utilization and Post-Marketing Surveillance Initiatives to Support Treatment and Coverage Decisions*” as an invited speaker at the **3rd Annual Biosimilars & Biologics BioTech Pharma Summit in Porto, Portugal, March 21-22, 2019.**

Sarah Malek (Harvard Pilgrim Health Care Institute - BBCIC Coordinating Center) presented a poster entitled “*Perspectives from a Coordinating Center: Lessons Learned from the Biologics and Biosimilars Collective Intelligence Consortium*” at the **Health Care Systems Research Network (HCSRN) Annual Meeting in Portland, OR, April 8-10, 2019.**

John Barron (HealthCore) presented a poster on behalf of the BBCIC NDC/J-Code Workgroup entitled “*Capture of Biologic and Biosimilar Dispensings in a Consortium of U.S.-Based Claims Databases - Utilization of National Drug Codes and HCPCS Modifiers in Medical Claims*” at the **AMCP Annual Meeting in San Diego, CA on March 25-28, 2019.**

## BBCIC CONTACT INFORMATION

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