

BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

LETTER FROM THE EXECUTIVE DIRECTOR

Dear BBCIC Enthusiasts,

Happy New Year! Or at least...Happy First Newsletter of the Year! With the new year, our research teams are continuing their hard work in moving our Oncology Data Feasibility, and G-CSF Comparative Effectiveness projects diligently forward. See page 5 for an update on their progress.

For the fourth consecutive year, we are thrilled to welcome current BBCIC participants to the AMCP Office in Alexandria, VA for our Annual BBCIC Workshop. On March 18th, we will enjoy a rare full day together in what is shaping up to be yet another exciting agenda (see pg 6). This year we are including a “Breakout Workshop” where attendees (both in-person and via teleconference) will have the opportunity to contribute to one of three sessions that will address strategic needs of BBCIC as we continue to transition to the next level of sustainability and success. You will have a choice of defining an updated Mission and Vision statement for BBCIC, helping determine the overall research scope looking to the future, or developing a foundational Communications Strategy and promotional documents to support the publicity and broad dissemination of our important work.

Looking forward: mark your calendar for a BBCIC “Afterglow” party at the AMCP 2020 meeting on April 23, 5:45pm during the Opening Night Reception in the Expo!! BBCIC will have a designated area to showcase our amazing work. I encourage all of you to attend to enjoy some time together. This will also be an opportunity for us to encourage non-participants to join forces with us.

This is so exciting to me: In 2020, the BBCIC officially turns FIVE! We are FIVE YEARS OLD! I’m *so excited* to have a BBCIC Birthday Party at AMCP Nexus in October! There will be cake. I love cake. Especially BBCIC Birthday Cake! Mark your calendar for the bash! (Details to follow when we get closer to the event).

Regards,
Cate Lockhart, MS, PharmD, PhD

ATTENTION CURRENT BBCIC PARTICIPANTS!!!!

**Mark Your Calendars for the 4th Annual BBCIC Meeting at AMCP Headquarters
March 18, 2020, Alexandria, VA**

Please RSVP to Becky Corey at rcorey@bbcic.org if you can attend in person or by teleconference

CONTENTS:

Publication Updates.....	pg 2
2020 Abstracts.....	pg 3
Project Timeline.....	pg 4
Monitoring Queries.....	pg 4
Current Research Updates.....	pg 5
News & Events.....	pg 6



BBCIC

Biologics & Biosimilars

Collective Intelligence Consortium

AMCP BBCIC, LLC

www.BBCIC.org

PUBLICATION UPDATES

PUBLISHED IN 2019

- Desai RJ, et al. **Methodologic considerations for noninterventional studies of switching from reference biologic to biosimilars.** *Pharmacoepidemiol Drug Saf.* 2019;1-13. <https://onlinelibrary.wiley.com/doi/full/10.1002/pds.4809>
- McMahill-Walraven CN, et al. **Harnessing the Biologics and Biosimilars Collective Intelligence Consortium to evaluate patterns of care.** *J Manag Care Spec Pharm.* 2019 Aug. Epub ahead of print. <https://www.jmcp.org/doi/abs/10.18553/jmcp.2019.19041>
- Kent DJ, et al. **Descriptive analysis of long- and intermediate-acting insulin and key safety outcomes in adults with Type 2 diabetes mellitus.** *J Manag Care Spec Pharm.* 2019 Aug. Epub ahead of print. <https://www.jmcp.org/doi/abs/10.18553/jmcp.2019.19042>
- Lockhart CM, et al. **Barriers and facilitators to conduct high-quality, large-scale safety and comparative effectiveness research: The Biologics and Biosimilars Collective Intelligence Consortium experience.** *Pharmacoepidemiol Drug Saf.* 2019;1-3. <https://onlinelibrary.wiley.com/doi/full/10.1002/pds.4885>
- He M, et al. **Mapping from the International Classification of Diseases (ICD) 9th to 10th Revision for Research in Biologics and Biosimilars Using Administrative Healthcare Data.** *Pharmacoepidemiol Drug Saf.* 2019. Epub ahead of print. <https://onlinelibrary.wiley.com/doi/full/10.1002/pds.4933>
- Zhang J, et al. **Capture of Biologic and Biosimilars Dispensings in a Consortium of U.S.-Based Claims Databases: Utilization of National Drug Codes and Healthcare Common Procedure Coding System Modifiers in Medical Claims.** *Pharmacoepidemiol Drug Saf.* 2019. Epub ahead of print. <https://onlinelibrary.wiley.com/doi/full/10.1002/pds.4934>

ACCEPTED FOR PUBLICATION

Zhang J, et al. **Anti-inflammatory descriptive TITLE.** *J Manag Care Spec Pharm.* In press.

IN REVIEW

G-CSF Descriptive Analysis Undergoing peer review at *Supportive Care in Cancer*

IN PREPARATION

- **CER METHODS Recommended Best Practices** Revision in preparation for submission to *Drug Safety*
- **ESA Descriptive Analysis** A white paper is in preparation to post on www.BBCIC.org.
- **G-CSF CER Scoping Review** Review and analysis are underway, with submission anticipated by mid-2020
- **G-CSF Monitoring Query Report**
- **Anti-Inflammatory Monitoring Query Report**
- **Insulins Monitoring Query Report**
Research Briefs in preparation for each Monitoring Query for submission at a clinical journals (TBD)

2020 ABSTRACTS

PRESENTED OR
ANTICIPATED IN 2020

4
Podium

6
Poster

ABSTRACTS IN PREPARATION

There are as many as TEN abstracts planned (or submitted) so far for presentation in 2020 or early 2021. For the second consecutive year, Cate served as a Co-Chair and session moderator at the Specialty Therapies and Biosimilars Conference, hosted by CBI/Informa, which was a great opportunity to promote the important work of BBCIC. She is preparing for podium presentations at the Festival of Biologics World Biosimilars Congress (March 2-4, San Diego), as well as the upcoming ISPOR and ICPE meetings. The Abstract Tracker below lists additional abstracts that are currently planned. Note that many of them do not have specific target meetings identified and we will be seeking input and suggestions for appropriate audiences.

ABSTRACT TRACKER

Abstract	Reviewed = Reviewed by BBCIC Science Committee							Meeting
	Planned	Analysis in Progress	Analysis Complete	Prepared	Reviewed	Submitted	Accepted	
G-CSF CER Scoping Review - Initial	█							ICPE 2020, Aug 26-30, Berlin, Germany
G-CSF CER Scoping Review - Final	█							TBD
G-CSF CER Study Design	█							TBD
Oncology Data Feasibility	█							TBD
G-CSF Monitoring	█							NCCN 2020, March 20-22, Orlando, FL
Anti-Inflammatory Monitoring	█							ISPOR 2020, May 16-20, Orlando, FL
Insulins Monitoring	█							TBD
Trastuzumab Monitoring	█							TBD
TBD Monitoring	█							TBD
TBD Monitoring	█							TBD

CER = Comparative effectiveness research

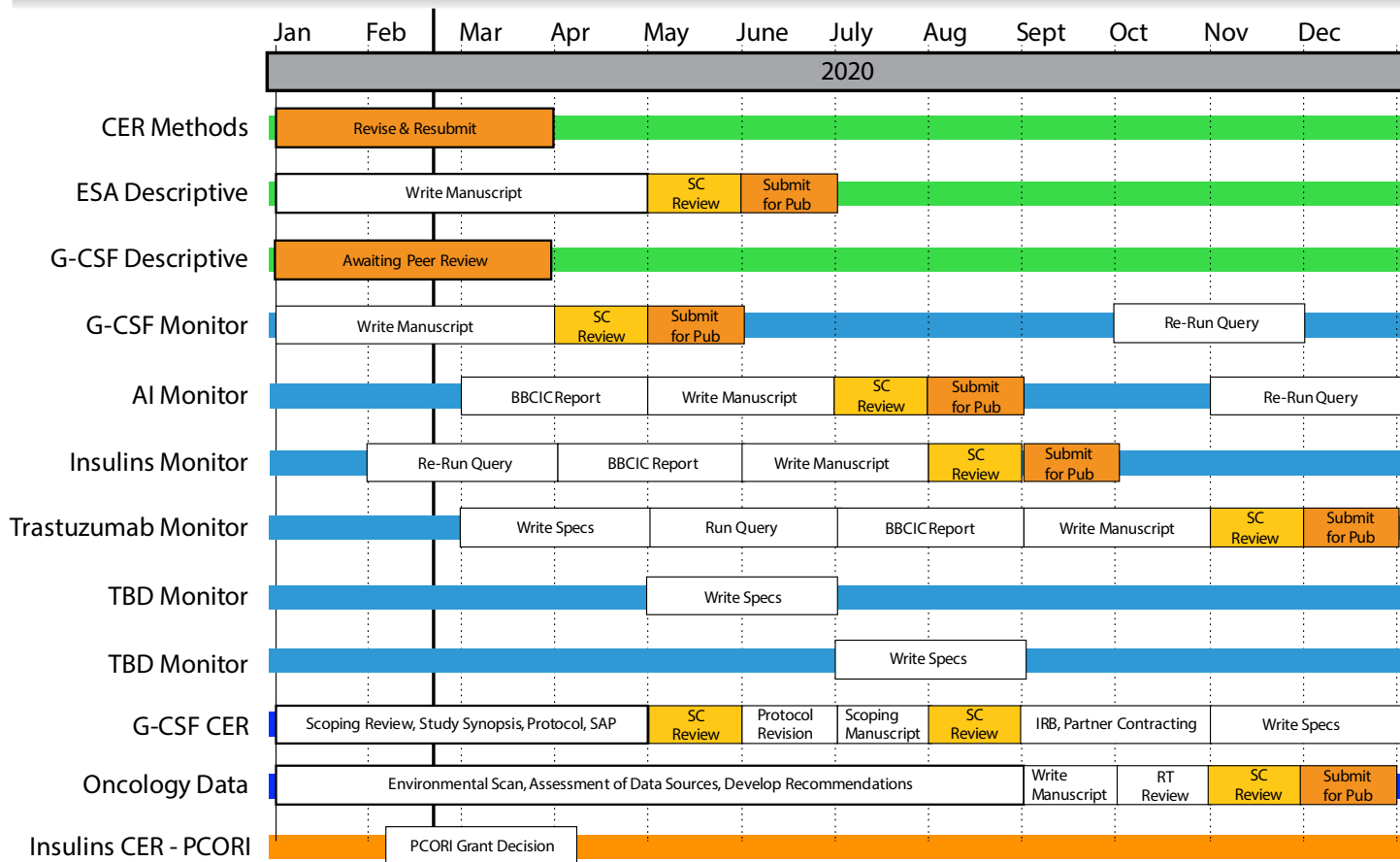
G-CSF = granulocyte colony stimulating factor

ICPE = International Conference on Pharmacoepidemiology and Therapeutic Risk Management

NCCN = National Comprehensive Cancer Network

TBD = to be determined

PROJECT TIMELINE



MONITORING QUERIES

BBCIC is utilizing our Distributed Research Network to regularly monitor utilization of biologic products, including biosimilars. This monitoring includes basic demographic and clinical information describing the cohorts of patients who are treated with the products of interest according to the BBCIC Science Committee. There are two listed as TBD, and the Science Committee will identify the priority products or drug classes to complete the series in 2020.

2020 MONITORING PLAN

- **Insulins** Re-run of specifications designed in 2019 - planned in Q1 of 2020
- **Trastuzumab** New specifications in development - planned in late Q1-early Q2 of 2020
- **TBD Product/Class** To be determined by the BBCIC Science Committee - planned in Q2 of 2020
- **TBD Product/Class** To be determined by the BBCIC Science Committee - planned in Q3 of 2020
- **G-CSF** Re-run of specifications designed in 2019 - planned in late Q3 - early Q4 of 2020
- **Anti-Inflammatories** Re-run of specifications designed in 2019 - planned in Q4 of 2020

COMPARATIVE EFFECTIVENESS: G-CSF

Co-Investigators:

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

Evaluating the comparative safety and effectiveness of G-CSF originator biologics (filgrastim) and related biosimilars

- The Statement of Work and project management plan have been finalized
- A comprehensive Scoping Review of the literature is underway to describe the current landscape of observational research in G-CSFs, to evaluate outcomes and methods use in other studies, and identify opportunities to address limitations in the existing body of literature
- An abstract describing the initial findings of the Scoping Review has been submitted for presentation at the ICPE Annual Meeting, August 26-30, 2020, Berlin, Germany
- The study design and protocol are drafted and undergoing rigorous review by the Research Team and will be reviewed in detail by the Science committee
- The Statistical Analysis Plan will be drafted upon finalization of the study protocol.

INFRASTRUCTURE: ONCOLOGY DATA FEASIBILITY

Principal-Investigator:

- Nancy Lin, ScD - Senior Scientist, Optum Epidemiology

Feasibility assessment of available oncology data sources to enrich existing BBCIC capabilities in conducting research in oncology

- A convenience literature search was completed to provide an initial horizon scan to identify data sources and/or collaboration partner that could address BBCIC needs in enriching our current data capabilities to evaluate clinical and effectiveness outcomes in cancer care
- The team has identified a list of candidate data sources and data vendors that capture additional important clinical granularity
- A feasibility and capabilities survey is under development for the team to begin reaching out to the identified data sources that will evaluate:
 - Interest and willingness of the candidate data source/partner to collaborate with BBCIC
 - Feasibility (and research capability if relevant) of conducting BBCIC research, including richness of the data to answer research questions of interest to BBCIC
 - Capabilities in conducting research under the BBCIC framework
 - Whether and how the BBCIC framework may need to change to accommodate the oncology research that we intend to pursue

NEWS AND EVENTS

PLEASE JOIN US! The 4th Annual BBCIC Workshop is fast approaching

**Please RSVP to Becky (rcorey@bbcic.org)
if you can attend in person or via teleconference**

4TH ANNUAL BBCIC WORKSHOP AGENDA

Where: AMCP Headquarters - Alexandria, VA

When: March 18, 2020; 9:00am - 5:00pm

TIME	TOPIC	SPEAKER
9:00 - 9:30am	Breakfast, Welcome and Introductions	Susan Cantrell, Nancy Lin, Mark Cziraky, Cate Lockhart
9:30 - 10:00am	Framework to Evaluate Real-World Endpoints	Jeff Allen, Friends of Cancer Research
10:00 - 10:45am	Oncology Data Feasibility Workgroup	Nancy Lin
10:45 - 11:00am	BREAK	
11:00 - 11:15am	G-CSF Scoping Review	Cara McDermott
11:15 - 12:00pm	G-CSF CER Protocol	Pam Pawloski
12:00pm	Working Lunch	
12:15 - 12:45pm	FDA Sentinel Update	Bob Ball, FDA
12:45 - 1:00pm	BREAK	
1:00 - 2:30pm	Breakout Workshop Sessions <ul style="list-style-type: none">• Mission and Vision Statements• Research Plan• Communications Plan	All
2:30 - 2:45pm	BREAK	
2:45 - 3:15pm	Breakout Report - Mission and Vision	Delegate from workshop
3:15 - 3:45pm	Breakout Report - Research	Delegate from workshop
3:45 - 4:15pm	Breakout Report - Communications	Delegate from workshop
4:15pm	Wine and Cheese Reception	

BBCIC CONTACT INFORMATION

Cate Lockhart, PharmD, PhD
Executive Director
Email: clockhart@bbcic.org
Phone: (703) 684-2646

OR VISIT US AT: WWW.BBCIC.ORG