

BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

LETTER FROM THE EXECUTIVE DIRECTOR

Dear BBCIC Enthusiasts,

I hope each of you, your friends, and your loved ones, are safe and staying healthy. As Fall fast approaches and we feel refreshed from vacation (or not) and kids get back to school (or not), we are looking forward to September and beyond to feel like the Groundhog Day most of 2020 has been.

At BBCIC we are extremely fortunate to continue our work from home, but we recognize that many across the country and around the world are not so lucky. We remain committed to continued good stewardship of our resources, and sensitivity to the shifting priorities of many participants who find themselves stretched for time with unexpected responsibilities that could only arise from a pandemic. We are truly grateful for your continued support and engagement as important BBCIC work moves forward.

Our two primary research projects continue making steady progress (see pg. 5), and we continue to submit manuscripts (see pg. 2) and abstracts to present in the virtual environment (see pg. 3). We recently issued a call for Research Topic Requests to current BBCIC Participants - an opportunity for all individuals and organizations to propose research study ideas for BBCIC projects. The BBCIC Science Committee is reviewing five new proposals and will be recommending the 2021 Research Agenda to the BBCIC Planning Board and Board of Managing Directors for approval in coming months. Once finalized, the 2021 Agenda will be published at www.bbcic.org.

In spite of AMCP Nexus going virtual, BBCIC is planning to host our annual half-day workshop for Current Participants in October via videoconference (see pg. 6). Even though we are unable to meet in person yet, I am excited for the energy, enthusiasm, and ideas that arise any time we all get together. We look forward to gathering again as soon as it is safe to do so. Finally, stay tuned for information to celebrate BBCIC's 5th Birthday! Cake is encouraged.

Stay safe and sane(ish)!

Regards,

Cate Lockhart, MS, PharmD, PhD

ATTENTION CURRENT BBCIC PARTICIPANTS!!!!

Mark your Calendar to attend our annual BBCIC Live! (Virtually) BBCIC Participant meeting on October 15, 2020 1:00 - 4:00pm (Eastern) via videoconference (see pg. 6)

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BBCIC

Biologics & Biosimilars

Collective Intelligence Consortium

AMCP BBCIC, LLC

www.BBCIC.org

PUBLICATION UPDATES

PUBLISHED

- 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>
- McMahon-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>
- Zhang J, et al. **Incidence of Serious Infections and Design of Utilization and Safety Studies for Biologic and Biosimilar Surveillance.** *J Manag Care Spec Pharm.* 2020. Apr;20(4):417-490. <https://doi.org/10.18553/jmcp.2020.26.4.417>

IN REVIEW

- **G-CSF Descriptive Analysis** Undergoing peer review: *Journal of the National Comprehensive Cancer Network*
- **G-CSF Monitoring Query Report** Undergoing peer review: *Drugs - Real World Outcomes*
- **Anti-Inflammatory Monitoring Query Report** Submitted: *Pharmacoepidemiology & Drug Safety*

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
- **Insulins Monitoring Query Report**
Research Briefs in preparation for each Monitoring Query for submission (Journals TBD)

2020 ABSTRACTS

PRESENTED OR
ANTICIPATED IN 2020

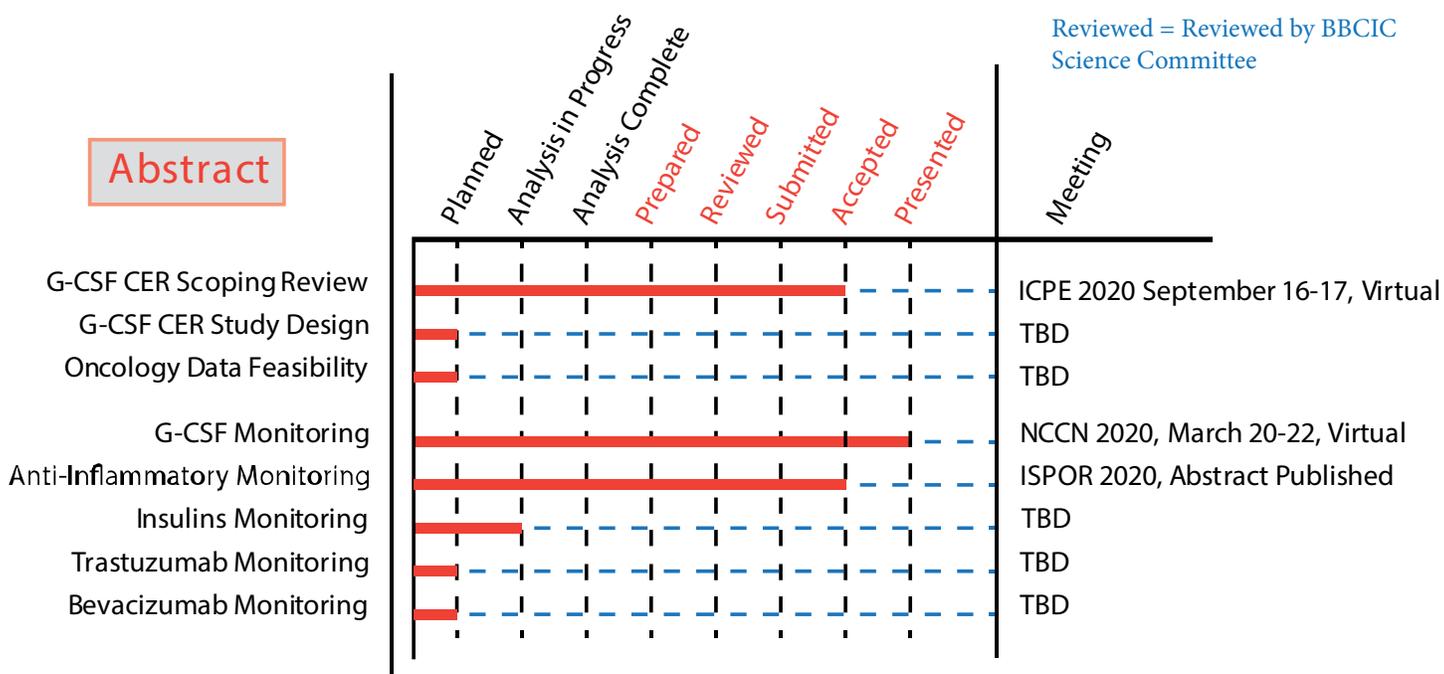
3
Podium

3
Poster

ABSTRACTS IN PREPARATION

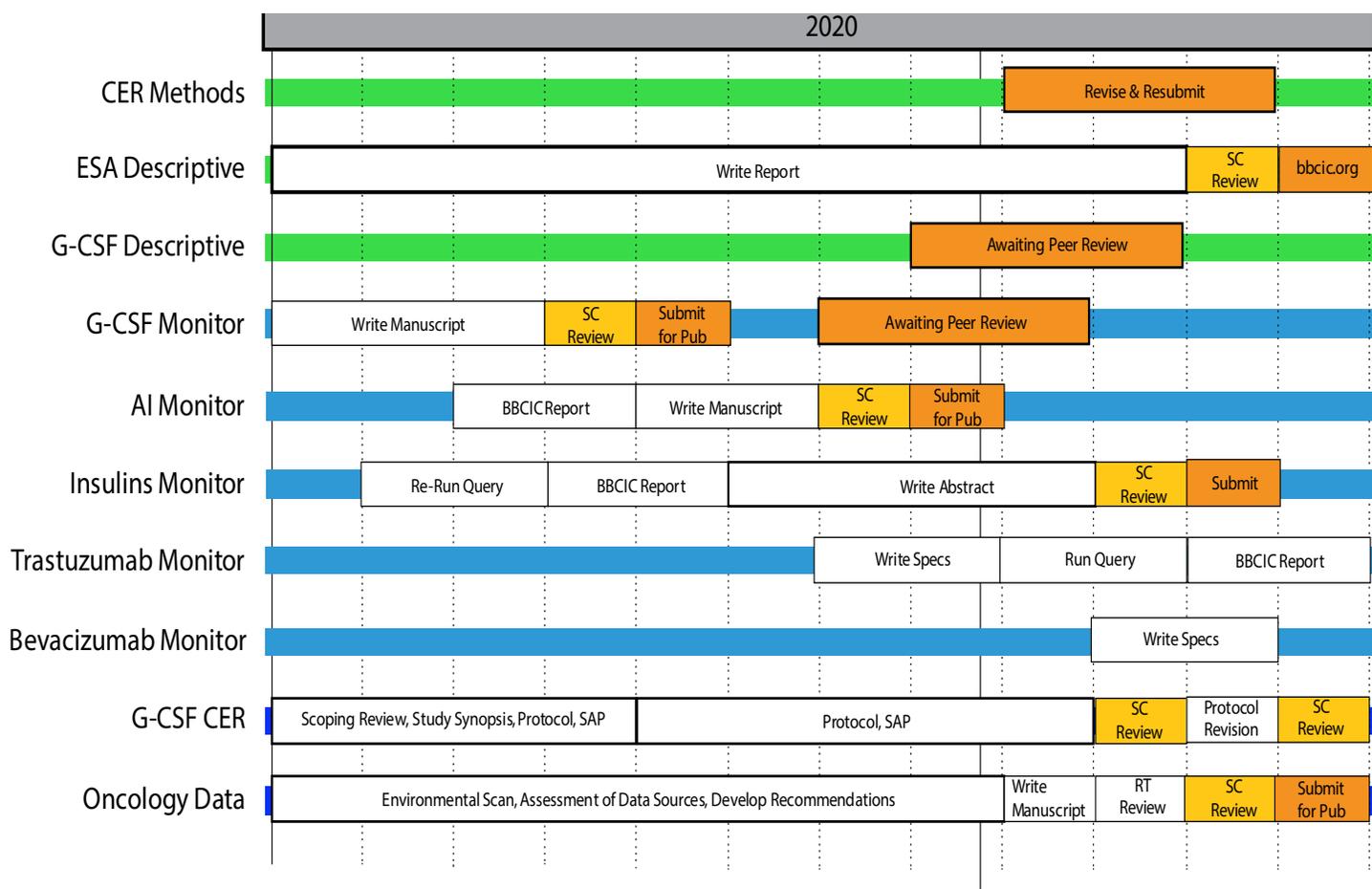
Due to meeting cancellations, we have fewer opportunities than anticipated to present BBCIC research at conferences. The ICPE meeting in August was cancelled and converted to virtual format, to be held on September 16-17, 2020, where we will showcase a poster of our G-CSF Scoping Review work. An abstract for an education session, and one for a poster describing the final results of the G-CSF Scoping Review were both rejected by AMCP Nexus. We still intend to submit abstracts to meetings coming up in 2021, including the results of the trastuzumab monitoring query that will be submitted for presentation at the NCCN Annual Meeting. Additional planned abstracts are shown below. 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



CER = Comparative effectiveness research
 G-CSF = granulocyte colony stimulating factor
 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. The Science Committee is in the process of identifying the priority products or drug classes to include in the series in 2021.

2020 MONITORING PLAN

- **Insulins** Re-run of specifications designed in 2019 - analysis underway
- **Trastuzumab** New specifications in development - planned in late Q3 of 2020
- **Bevacizumab** New specifications in development - planned in Q4 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, pegfilgrastim) and related biosimilars

- A comprehensive Scoping Review of the literature is being finalized 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
- A poster describing the findings of the Scoping Review will be presented at the ICPE Annual Meeting, which is now being held virtually on September 16-17, 2020.
- 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 partners 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
- Request for Information: A feasibility and capabilities survey was submitted to 18 candidate data sources to evaluate:
 - Interest and willingness of the candidate data source/partner to collaborate with BBCIC
 - Feasibility (and research capability if relevant) of conducting BBCIC research
 - 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
- To date, 6 responses have been received, and at least 1 more expected
- The trastuzumab monitoring query will be run and analyzed in the next month

BBCIC LIVE! (VIRTUALLY)

As we were unable to hold our annual Spring Face-to-Face meeting this year, and the AMCP Nexus meeting is being held virtually, we are planning a virtual half-day meeting in October.

Mark Your Calendar!

Thursday, October 15, 2020 1:00pm - 4:00pm ET

We will meet via videoconference, details are forthcoming.

Tentative Agenda:

- * **Guest Speakers - TBD**
- * **Strategic Plan - 2021 Update**
- * **Business Model Expansion - Update**

Please send any other discussion topics to Cate at clockhart@bbcic.org

BBCIC BIRTHDAY PARTY!



BBCIC is FIVE years old!!!

Please stay tuned for information about a celebration!

BBCIC CONTACT INFORMATION

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