

BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

LETTER FROM THE EXECUTIVE DIRECTOR

Dear BBCIC Enthusiasts,

Well. This is Weird.

This is certainly not the 2020 any of us had anticipated. I hope each of you, your friends, and your loved ones, are safe and staying healthy. 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 are 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.

And BBCIC work is indeed moving forward: two research projects are making steady progress; the BBCIC Research Framework has been updated based on the vision and input of our participants (see pg. 4); the Communications Committee finalized a new promotional flier, with all of your help, to demonstrate the value of BBCIC Participation to potential participant organizations (see pg. 7); a new Communication Plan is in development to guide our efforts to promote BBCIC research; a task-force is exploring opportunities to update the BBCIC Business Plan to allow for more research under a more diverse scope.

It was disappointing to cancel what would have been the 4th Annual BBCIC Workshop at the AMCP Office in Alexandria, VA. I think you would all agree that the energy, enthusiasm, and ideas that arise any time we all get in a room together is invigorating. We look forward to gathering again as soon as it is safe to do so.

Finally, 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!!!!

A Call for Research Topics is Coming Soon!

Put your thinking caps on and be ready to submit your study ideas

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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: *Journal of the Oncology Practice*

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
- **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

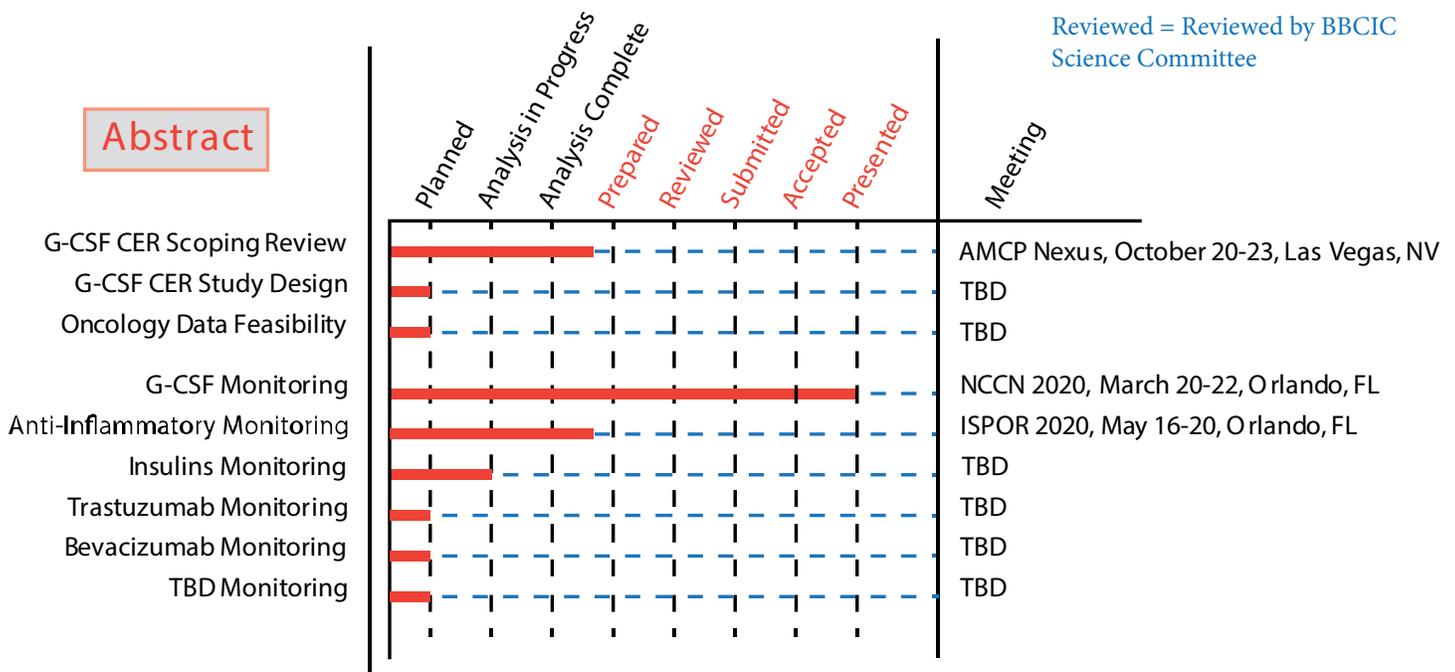
3
Podium

6
Poster

ABSTRACTS IN PREPARATION

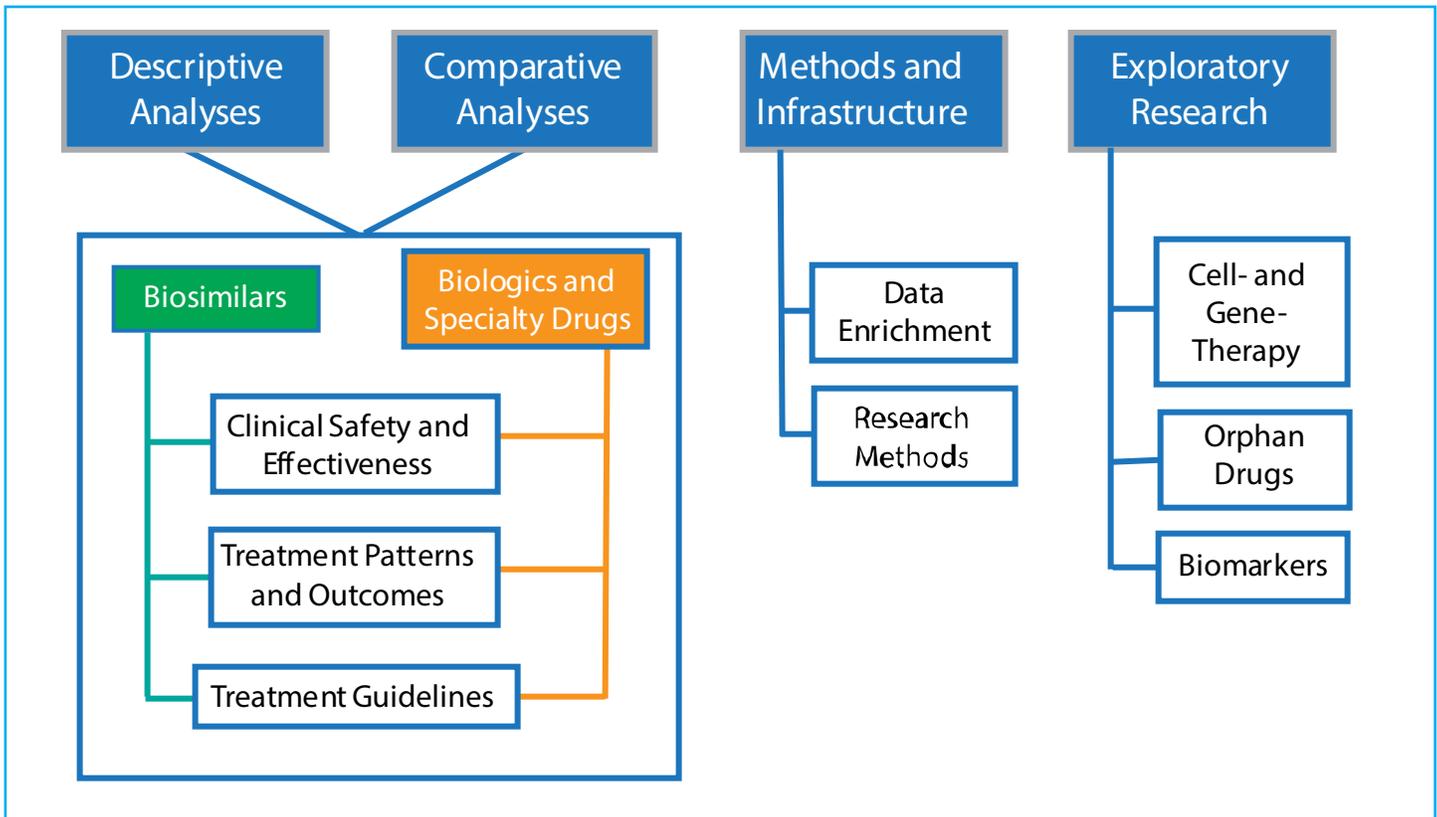
Due to meeting cancellations, we have fewer opportunities than anticipated to present BBCIC research at conferences. Cate was still able to present and moderate a panel at the Festival of Biologics World Biosimilars Congress (March 2-4, San Diego). A poster for the G-CSF monitoring work was accepted at NCCN and was presented electronically. An abstract for poster presentation of the anti-inflammatory monitoring work was accepted at ISPOR, and the abstract will still be published in a Value in Health supplement edition. The ICPE meeting in August was cancelled so we will not have that opportunity to showcase our G-CSF Scoping Review work. We still intend to submit abstracts to AMCP Nexus, as well as meetings coming up in 2021. 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

BBCIC RESEARCH FRAMEWORK - UPDATED



BBCIC research priorities fall into four primary categories as illustrated above. Research projects may utilize the BBCIC Distributed Research Network (DRN), where we have access to ~95 million patient lives in administrative claims, but we also consider projects that drive BBCIC DRN data capabilities and expand our existing resources. Here we provide more detail describing projects that may fall within each category.

Studies should be focused on biologic drugs, including, but not limited to, biosimilars or reference biologics for which a biosimilar is available or anticipated.

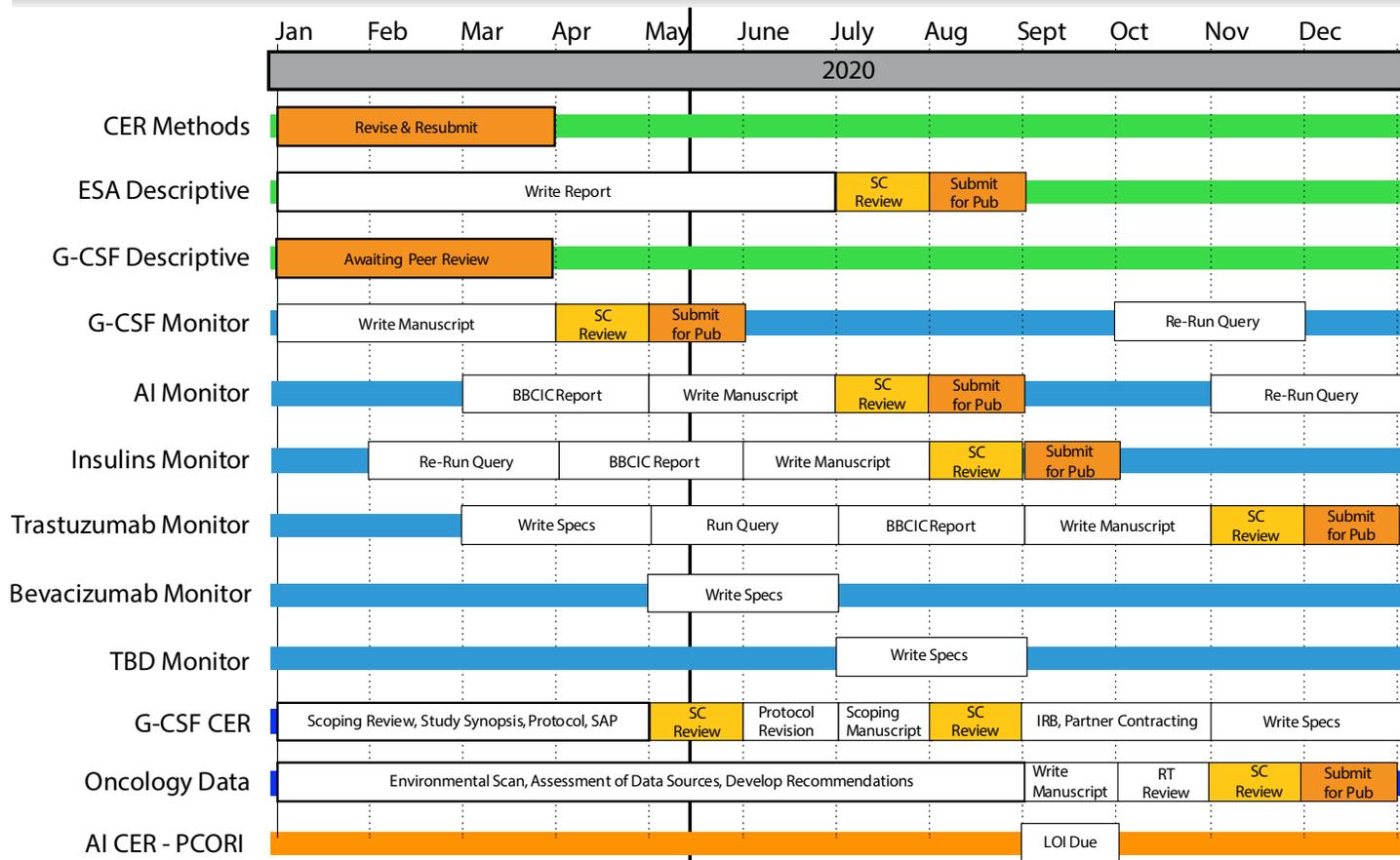
Descriptive and Comparative studies should fall into one of three further subcategories:

- Clinical Safety and/or Effectiveness
- Treatment Patterns and Outcomes (e.g., assessing care pathways)
- Treatment Guidelines (e.g., comparing outcomes among patients treated according to established guidelines vs those not treated according to guidelines, evaluating outcomes where there are multiple acceptable choices, etc.)

Priority Drug/Disease Areas (in no particular order)

- **Oncology** (non-pediatric) – particularly in cases where there are multiple products or treatment regimens available
- **Inflammatory Conditions** (e.g., rheumatology, gastroenterology, dermatology)
- **Insulins**
- Others may also be reviewed based on market demand or FDA approvals

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
- **Bevacizumab** 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, 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
- An abstract describing the initial findings of the Scoping Review was submitted for presentation at the ICPE Annual Meeting, August 26-30, 2020, Berlin, Germany; however, that meeting was cancelled
- 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
 - 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
- The workgroup is developing specifications for the trastuzumab monitoring query to use as a test case.

NEW! BBCIC PROMOTIONAL FLIER

We are thrilled to have a new flier to showcase the value of BBCIC participation! Please contact Cate if you would like a PDF copy to share the word about the amazing work of BBCIC with your network!



What's your toughest question about Biologics, including Biosimilars?

The **Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)** is the only research consortium dedicated to addressing important questions about the real-world use, safety, clinical effectiveness, and impact of biologics, including biosimilars, on human health.

BBCIC is a non-profit, multi-stakeholder, scientific collaborative dedicated to real-world evaluation of biologics, including biosimilars.

BBCIC provides **scientific evidence** to inform treatment and coverage decisions.

BBCIC is a **recognized authority** and **thought leader** on biologics, including biosimilars.

In just **the last 2 years**, BBCIC has:

- A proven research record with 7+ peer reviewed manuscripts from 8+ completed research projects, as well as multiple ongoing research projects
- Delivered 15+ Presentations and invited Keynotes at major national and international Scientific Conferences

Join BBCIC and collaborate with experts from over 15 organizations representing:

- Academic Experts
- Health Plans and PBMs
- Healthcare Practitioners
- Non-Profit Organizations
- Patient Organizations
- Pharmaceutical Manufacturers
- Public Representatives

Join us today! Visit www.bbcic.org or contact Cate Lockhart, PharmD, PhD at clockhart@bbcic.org

BBCIC is an initiative of
 AMCP



Robust and rich data network

Leverages the FDA Sentinel System curated data and analytic toolkit. Research at a unique scale – access to **over 90 million patient lives** in the BBCIC distributed research network



Neutral convener of diverse stakeholders

A think-tank of some of the sharpest minds in **real-world evidence** generation. Every participant has a voice on BBCIC Governance Committees and Research Teams



Paving the way for real-world research

Thinking outside the box. **Advancing the discipline** of real-world evidence, data science, and research methods



Transparent, Science-Driven Research

Diversity of research topics: Exploring the tough questions with scientific rigor in a collaboration of experts



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