



BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

LETTER FROM THE EXECUTIVE DIRECTOR

Dear BBCIC Enthusiasts,

It is my pleasure to provide you with another fun-filled edition of the BBCIC Quarterly! In keeping with what by now has become the typical BBCIC level of activity, we have accomplished A LOT in the past few months. I hope you are as impressed by our collective progress as I am!

In September we resubmitted a revised grant proposal to PCORI for a second shot at grant funding for our insulins comparative effectiveness study, which includes an exciting patient-engagement element to enrich our data with patient-specific information that is not readily available in the administrative claims of the BBCIC distributed research network (DRN). Revisions were made according to some very constructive feedback from the PCORI reviewers. One of the most notable and influential elements in creating a far better application was inclusion of five diabetes patients, representing three diabetes patient advocacy organizations, who provided enthusiastic support of our study, and gave invaluable input such that we were able to modify the study design to ensure we are answering questions of most relevance to people with diabetes. Funding decisions will be made in February 2020. FINGERS CROSSED!

In October we met for the 2nd annual BBCIC face-to-face meeting held in conjunction with the AMCP Nexus meeting. A total of 20 BBCIC participants, and two guest observers, attended the half-day meeting in National Harbor, MD. As usual when this group comes together, the energy and enthusiasm in the room was palpable and we had some fantastic discussions that will help guide BBCIC further forward. It's such an inspiration to be in a room with so many smart, compassionate, and creative people, and further reinforces the value in coming together twice a year. Stay tuned as we begin planning for the BBCIC Annual Spring Meeting to be held at the AMCP offices in Alexandria, VA!

Happy Holidays!

Regards,
Cate Lockhart, MS, PharmD, PhD

ATTENTION CURRENT BBCIC PARTICIPANTS!!!!

Planning has begun for the 4th Annual BBCIC Meeting at AMCP Headquarters

Date TBD, 2020, Alexandria, VA

Please send your topic ideas to Cate at clockhart@bbcic.org

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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>

ACCEPTED FOR PUBLICATION

ICD-9 to ICD-10 Mapping

Accepted at *Pharmacoepidemiology & Drug Safety*. Citation and link will be available after copy editing.

NDC/J-Code Analysis

Undergoing peer review at *Pharmacoepidemiology & Drug Safety*

IN REVIEW

ANTI-INFLAMMATORY Descriptive Analysis

Undergoing peer review at the *Journal of Managed Care & Specialty Pharmacy*

G-CSF Descriptive Analysis

Undergoing peer review at *Supportive Care in Cancer*

IN PREPARATION

CER METHODS Recommended Best Practices

Not accepted at *Pharmacoepidemiology & Drug Safety*. Revision in preparation for submission to *Drug Safety*

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)

ESA Descriptive Analysis

A white paper is in preparation to post on www.BBCIC.org.

2019 ABSTRACTS

PRESENTED SO FAR IN 2019

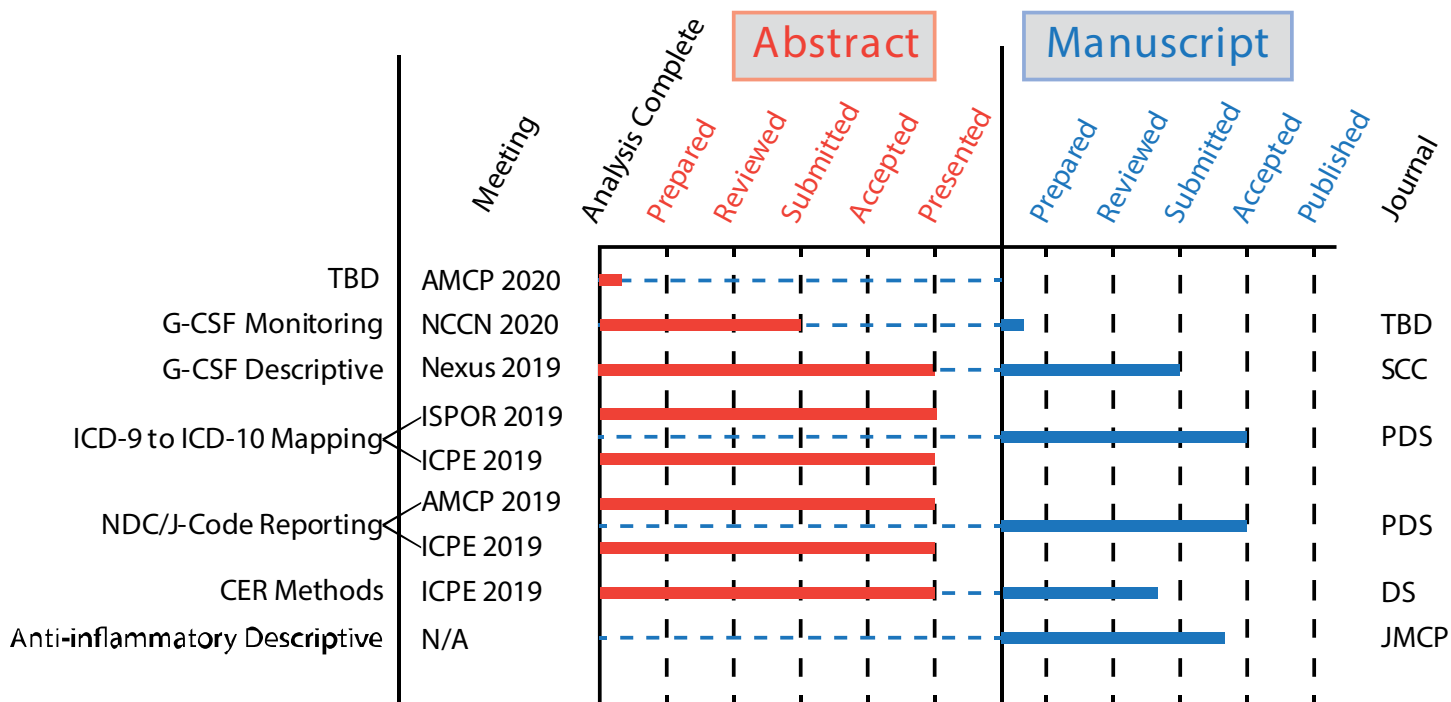
6
Podium

6
Poster

ABSTRACTS IN PREPARATION

Meeting	Submission Deadline	Topic	Type	Presenting Author
AMCP 2020	December 12, 2019	Insulins Monitoring	Poster	TBD
		Anti-Inflammatory Monitoring	Poster	TBD
ISPOR 2020	January 15, 2020	G-CSF Systematic Review	Poster	Cara McDermott

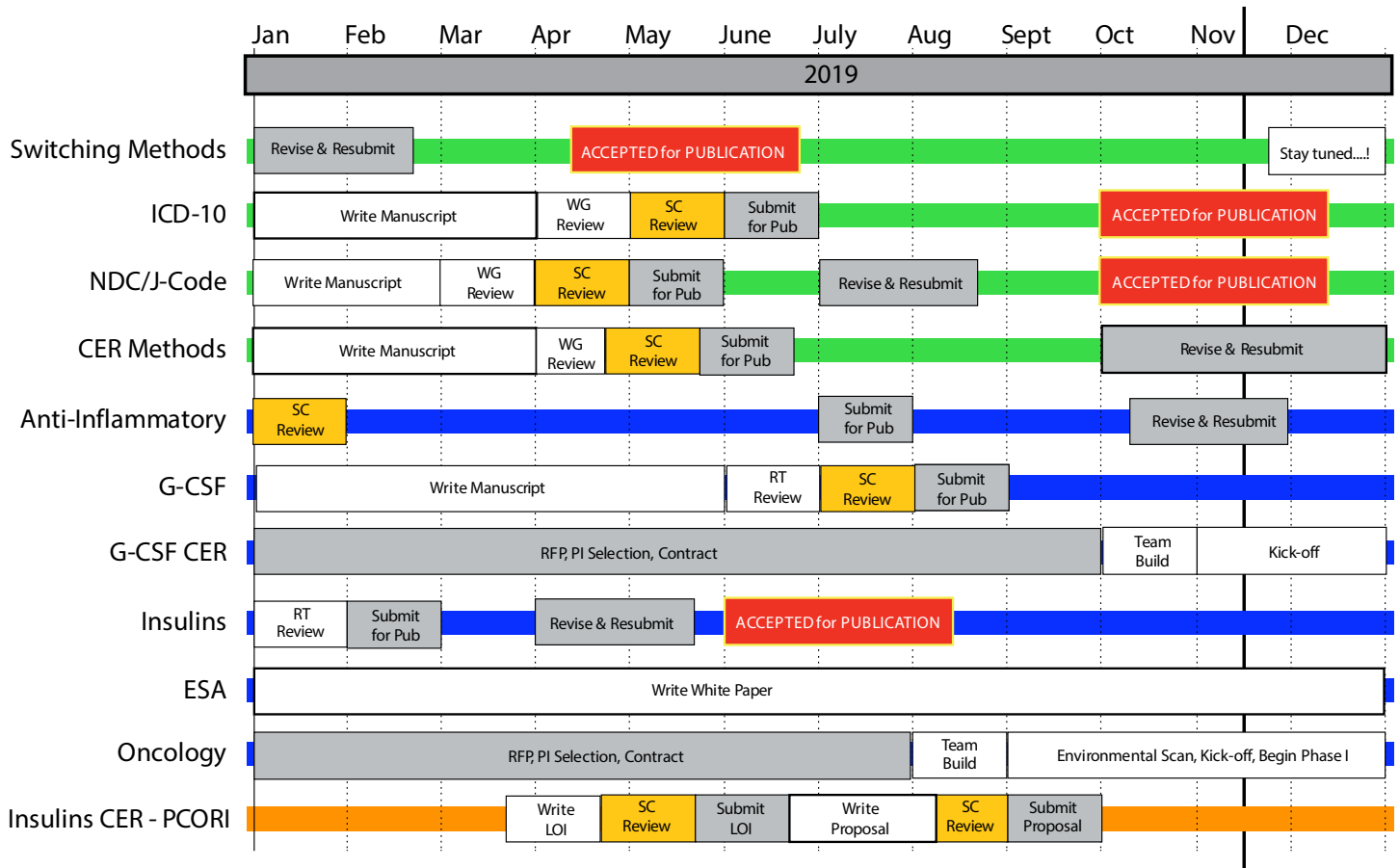
PUBLICATION TRACKER



DS = Drug Safety
 JMCP = Journal of Managed Care & Specialty Pharmacy
 PDS = Pharmacoepidemiology & Drug Safety
 TBD = To Be Determined
 SCC = Supportive Care in Cancer

Reviewed = Reviewed by BBCIC Science Committee

PROJECT TIMELINE



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

The G-CSF CER Research Team held their kick-off meeting in November, 2019. Work is underway.

INFRASTRUCTURE: ONCOLOGY DATA FEASIBILITY

Co-Investigators:

- Nancy Lin, ScD - Senior Scientist, Optum Epidemiology

The Oncology Data Workgroup held their kick-off meeting in September, 2019. Work is underway.

Brief Recap of the BBCIC Live@NEXUS Meeting

22 current BBCIC participants and guests met on October 29, 2019, in National Harbor, MD, for the 2nd Annual Face-to-Face workshop held in conjunction with the AMCP Nexus meeting.

Here is a brief summary of the discussion for each agenda topic:

Agenda Item 1: Switching - Phase 2 Study (presenter/facilitator Aaron Mendelsohn, HPHCI)

Discussion centered on study design and methods considerations for building on the foundation work by the BBCIC Switching Methods Workgroup to take the study into the BBCIC DRN using rheumatoid arthritis (RA) as a test case. It was noted that the Veterans Administration (VA) has data on biosimilar switching, and VA data might be a source worth exploring for future BBCIC research. After some debate around the benefits and concerns of including different disease states, it was recommended that this initial study focus on RA. It may be worth coordinating with health plan partners to identify formulary changes that dictate product switching, although that admittedly may require the comparison group to be before/after treatment switching, which may not be ideal, but still could be informative.

Agenda Item 2: Perspectives - A Payer Approach to Biosimilars (Christina Barrington, Priority Health)

Priority Health added the infliximab biosimilar product Inflectra and Renflexis as preferred agents to the formulary. Patients over age 18 were switched. The health plan worked closely with manufacturers to ensure the switch was not a financial hardship for patients. Priority Health has a risk sharing model, so oncologists have started reaching out about use of biosimilars. Over 50% of the Medicare population, and 98% of the commercial/Medicaid population switched, and resulted in a 20% savings in the first year.

Agenda Item 3: Results of the 2019 Annual BBCIC Participant Survey (Cate Lockhart, BBCIC)

This summer, a survey was circulated to all BBCIC participants to get a pulse on how we are doing, what is going well, and what opportunities there are for improvement. THANK YOU to all who responded, it truly guides us toward improving BBCIC and your experience as an essential part of the organization. Here are some highlights:

Eighteen members responded to the survey:

Research Partner - 39%; Non-profit – 17%; Manufacturer – 17%, Academic – 11%; Other – 17%

Social Media

* 67% of respondents use some type of social media daily

* When asked what platforms BBCIC should use, LinkedIn (87%) and Twitter (56%) were most popular

Satisfaction with BBCIC Participation

* All respondents indicated they were Satisfied (61%) or Very Satisfied (39%) with participation in BBCIC

* 39% of respondents indicated they were More Satisfied this year compared to last year

* 61% of respondents indicated they were Equally Satisfied this year compared to last year

Open Responses

- * Respondents felt BBCIC was doing a good job this year in getting manuscripts published, and that we are making good progress; however, some still feel the pace is slow
- * BBCIC is gaining traction
- * There is still interest in increasing the visibility of BBCIC and showcasing our important work
- * One suggestion was to continue with momentum-based activities. BBCIC is very credible, but still evolving, and the more work completed increases the credibility
- * Overall, BBCIC leadership and our governance is very strong
- * There is interest in expanding our oncology focus, and there are opportunities to showcase our strengths and capabilities in diseases treated with biologics, even if biosimilars are not imminently available
- * We should strive for a future when our research can be used to inform treatment and coverage decisions

Agenda Item 4: Strategic Plan (Aaron Mendelson, HPHCI; Nancy Lin, Optum; Mark Cziraky (HealthCore)

Where are we now? Update on 2019 work (Aaron Mendelsohn)

In the fall of 2018, BBCIC prepared a Strategic Plan to help guide our growth and transition from “start-up” to “grown-up” as an organization. Many of the items in the Plan were focused on building the BBCIC infrastructure, including development of processes and procedures to improve efficiency and provide transparent expectations for participants, and update of the BBCIC website. Work continues, and we will be revisiting the Strategic Plan to identify areas where updated goals are needed, and to establish a more robust longer-term plan with concrete actions to achieve our goals.

Research Topic Brainstorm (Nancy Lin)

Nancy facilitated this open discussion to begin considering a broader research agenda, including identification of specific lines of inquiry of interest to include, but not limited to, biosimilar research. Through the lively discussion, several ideas resonated with the group:

- Treatment guidelines (e.g., compare outcomes of patients treated or not treated according to guidelines to provide an evidence base around improving patient care)
- Infrastructure (e.g., are there certain questions we can answer or that we can't answer in claims data but we may want to add for future projects?)
- REMS (e.g., what is the impact on patient outcomes due to these risk mitigating efforts?)
- Orphan Drugs (e.g., most are biologics, how can we add to the evidence?)
- CAR T and gene therapy (e.g., identify standards and provide coding – there is a gap in the understanding of the value and it is important to build the framework now)
- Biobetters (e.g., what is the impact, next-generation of reference, impact for biosimilars?)

BBCIC Processes and Procedures (Mark Cziraky)

What processes and procedures should BBCIC develop to make our research and the overall organization function more efficiently? Suggestions included the following, but we continue to pursue opportunities for generating new documentation to improve the efficiency and transparency of BBCIC research

- Communication plan around projects and manuscript publications
- Foster faster input and throughput procedure for ideas
- Develop template to engage with pharma companies to increase participation.

NEWS AND EVENTS

Welcome Becky Corey!

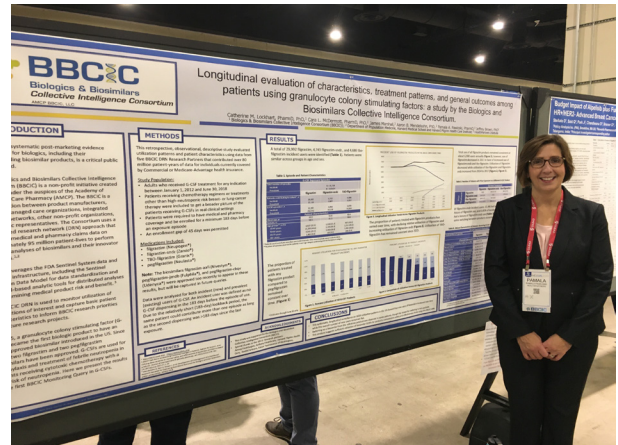
I am thrilled to introduce you to our newest (first!?) BBCIC Staff member! Those of you who were able to attend our face-to-face meeting on October 29th had the opportunity to meet her -- on her THIRD DAY of employment with us -- and I'm sure you could already see her enthusiasm, professionalism, and general good fit for our organization. Becky joins us after over 16 years working for our friends at ISPOR, where she had a major hand in facilitating the growth we have all witnessed in that organization. She joins BBCIC as the Manager of Projects and Operations, and is already proving to be an invaluable asset in starting to better develop our infrastructure. Becky will be involved in contracting, will help us develop the processes and procedures we need to function at our best, will help develop and facilitate a communication plan to include a social media presence, and has already started to keep some of us on task with her project management skills. You will all have a chance to interact with Becky as she settles more and more into her new role. Please join me in welcoming her to our family! Becky can be reached at rcorey@bbcic.org or 703-684-2625.



BBCIC PARTICIPANTS IN ACTION AT AMCP NEXUS!



Jeremy Whalen, who represents HOPA in BBCIC, presenting in his Halloween mask (since the posters were presented on October 31)



Pam Pawloski presents a poster of our Monitoring Query work, on behalf of the BBCIC and the G-CSF research team.

BBCIC CONTACT INFORMATION

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