

BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

LETTER FROM THE EXECUTIVE DIRECTOR

HAPPY NEW YEAR!

Actually, it is already February so we are firmly into 2019 at this point, and it has already been a busy one! I can't say I am disappointed to have January behind us as that signifies daylight growing gradually longer and the promise of Spring. This is likely even more profound for those who suffered through the Polar Vortex in January!

At BBCIC we have hit the ground running in the new calendar year, and this is going to be another exciting one. Most notably, we are kicking off our very first Comparative Effectiveness Research (CER) study in G-CSFs! It feels like this has been a long time in coming, but we are more ready than ever to contribute our expertise to the comparative analysis of filgrastim and the available biosimilars. If you are a member of a current BBCIC Participant organization, you are welcome and encouraged to volunteer to serve on this exciting Research Team (contact Cate).

We are also conducting the first phase of what will effectively be our oncology research program. Phase I will be kicked off in the coming month or two, and will include an environmental scan and analysis of available data sources, with recommendations on how best to enrich the existing BBCIC Distributed Research Network to capture outcome variables particular to cancer. This work will position BBCIC to begin conducting product- and disease-specific research in cancer, as more biosimilar products emerge from the pipeline.

Finally, planning has begun for the 3rd BBCIC Annual Meeting to be held on April 2nd, 2019 at the AMCP Office in Alexandria, VA. This is scheduled in conjunction with the FDA Sentinel Annual Public Workshop to be held on April 3rd, 2019. If you are a member of a current BBCIC Participant organization, you are welcome and encouraged to attend. There is always a lot of energy and enthusiasm in the room and it is always great to have a chance to meet face-to-face. **If you have topic ideas for this day-long meeting please send them to Cate.** Hope to see you in April!

Regards,
Cate Lockhart, MS, PharmD, PhD

ATTENTION CURRENT BBCIC PARTICIPANTS!!!!

Please mark your calendars for the BBCIC Annual Meeting at AMCP Headquarters

April 2, 2019 - 9:00am - 5:00pm, Alexandria, VA

If you are able to attend, please RSVP to Cate at clockhart@bbbic.org

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BBCIC

**Biologics & Biosimilars
Collective Intelligence Consortium**

AMCP BBCIC, LLC

www.BBCIC.org

NEW RESEARCH STARTING!

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. Following the patent expiration for filgrastim (Neupogen®, Amgen), several biosimilar agents have been, or are expected to be, approved in the US. Previously, a BBCIC Working Group conducted a descriptive analysis of G-CSFs in the BBCIC's Distributed Research Network (DRN). That analysis was designed to provide information regarding the feasibility of an observational comparative study of G-CSF products in patients at high risk for neutropenia. A manuscript for this work is in development and we anticipate publication by mid-2019.

The BBCIC is announcing a new project to build upon the earlier descriptive analysis and to conduct a formal comparative safety and effectiveness study of the G-CSF originator biologic (filgrastim) versus its biosimilars.

Description of Proposed Work

Phase 1. An environmental scan including a search of the literature and other information sources to further prepare BBCIC in the conduct the comparative study:

- *Exploration and evaluation of potential data sources*
- *Confirmation of outcome measures*
- *Recommendation of appropriate statistical methodologies*

Phase 2. Execution of the research using the BBCIC DRN and any additional data sources identified in Phase 1. This will include the following activities:

- *Research synopsis*
- *Protocol refinement and finalization*
- *Preparation of data specifications*
- *Data collection and analysis*

Final Study Reports will be prepared for both study phases, along with manuscripts intended for publication in a peer-reviewed journal or public dissemination on www.BBCIC.org.

Timeline

The estimated total time for this research is 12 months with work to commence immediately upon Research Team selection and contract execution.

MORE NEW RESEARCH STARTING!

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 products. 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 announcing a new project that will bring together multiple industry sponsors to work collaboratively with the Consortium and its Data and Research Partners to conduct comparative safety and effectiveness studies of oncology products, namely originator biologics versus their biosimilar product(s).

Description of Proposed Work

Phase 1. An environmental scan, including a search of the literature and other information sources, as well as a feasibility assessment of selected data sources identified through the environmental scan will be performed with the overarching goal of preparing BBCIC for the conduct of comparative research for oncology products. This work will include:

- *Environmental scan of potential data sources, including the BBCIC DRN*
- *Identification of outcome measures in general for oncology research*
- *Consideration and recommendation of appropriate statistical methodologies*
- *Feasibility assessment of data sources, including counts of important exposure and outcome variables*

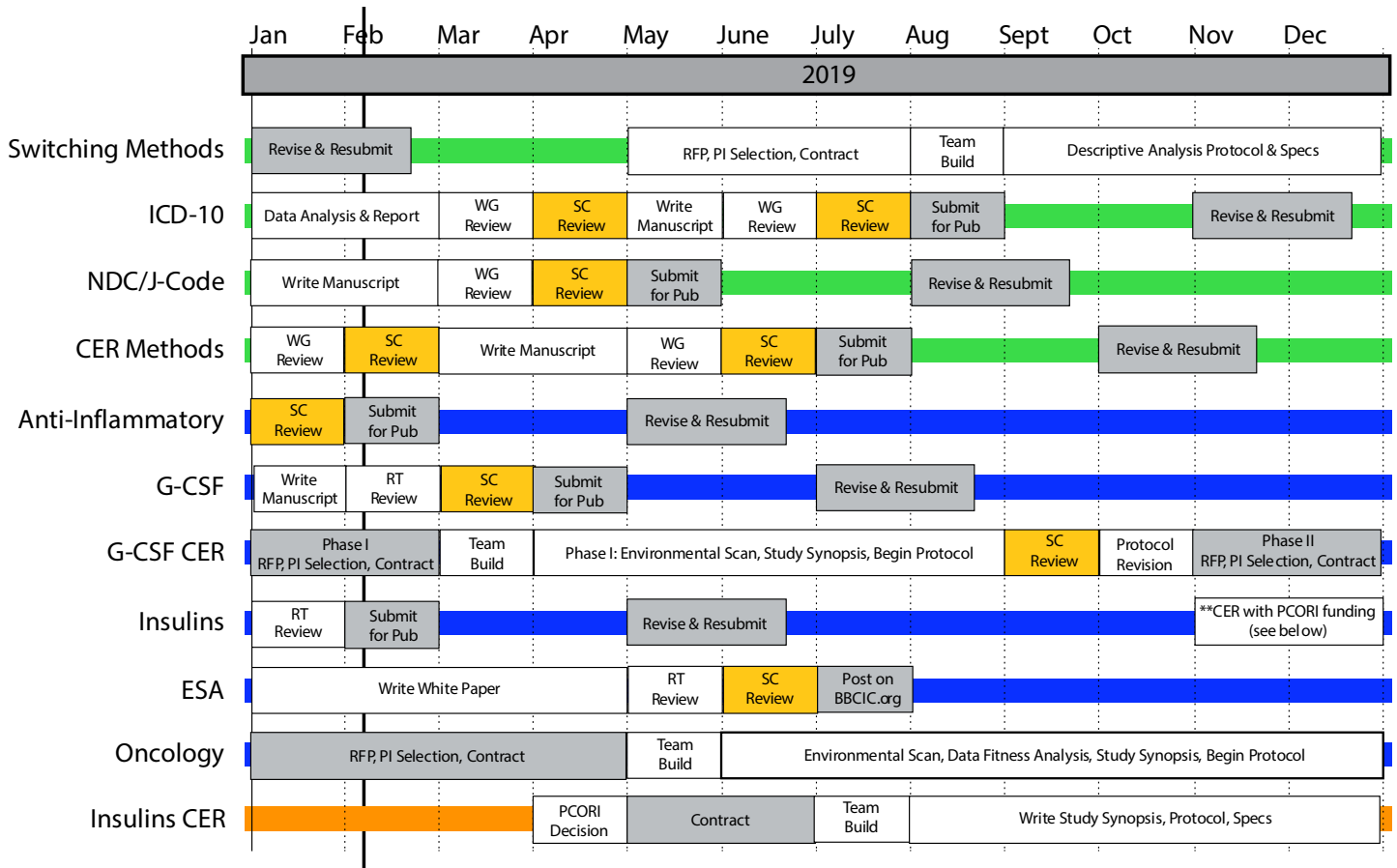
Subsequent phases for this project include protocol development and study execution for a comparative research study(ies). These steps will be informed by the results of this environmental scan and feasibility assessment and will be conducted under separate RFP(s).

A Final Study Report will be prepared addressing the items listed above, along with a manuscript intended for publication in a peer-reviewed journal or public dissemination on www.BBCIC.org.

Timeline

The estimated total time for Phase 1 is approximately 9 months with work to commence immediately upon Research Team selection and contract execution.

PROJECT TIMELINE



2019 ABSTRACTS

Meeting	Meeting Date	Submission Deadline	Topic	Type	Presenting Author	Status
DIA	June 23-27, 2019 San Diego, CA	November	BBCIC	Podium	Cate Lockhart Nancy Lin	Rejected
HCSRN	April 8-10, 2019 Portland, OR	November	BBCIC	Podium	Cate Lockhart Pam Pawloski Jim Marshall	Rejected
			BBCIC	Poster	Sarah Malek	Accepted
AMCP	March 25-28, 2019 San Diego, CA	Dec 17, 2018	NDC	Poster	Sophie Zhang	Accepted
		Oct 15, 2018	BBCIC	Podium	Cate Lockhart Pam Pawloski	Rejected
ISPOR	May 18-22, 2019 New Orleans, LA	Jan 16, 2019	ICD-10	Poster	Seoyoung Kim	Submitted
			ISPOR SIG	Podium	Cate Lockhart	Submitted
ICPE	August 24-28, 2019 Philadelphia, PA	Feb 13, 2019	ICD-10	Poster	Seoyoung Kim	
			CER Methods	Poster	Nancy Lin	
			NDC	Poster	Sophie Zhang	
			BBCIC	Podium	Cate Lockhart BBCIC Workgroups	

2019 PLANNED PUBLICATIONS

INSULINS Descriptive Analysis

Pair of companion articles has been submitted to 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.

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

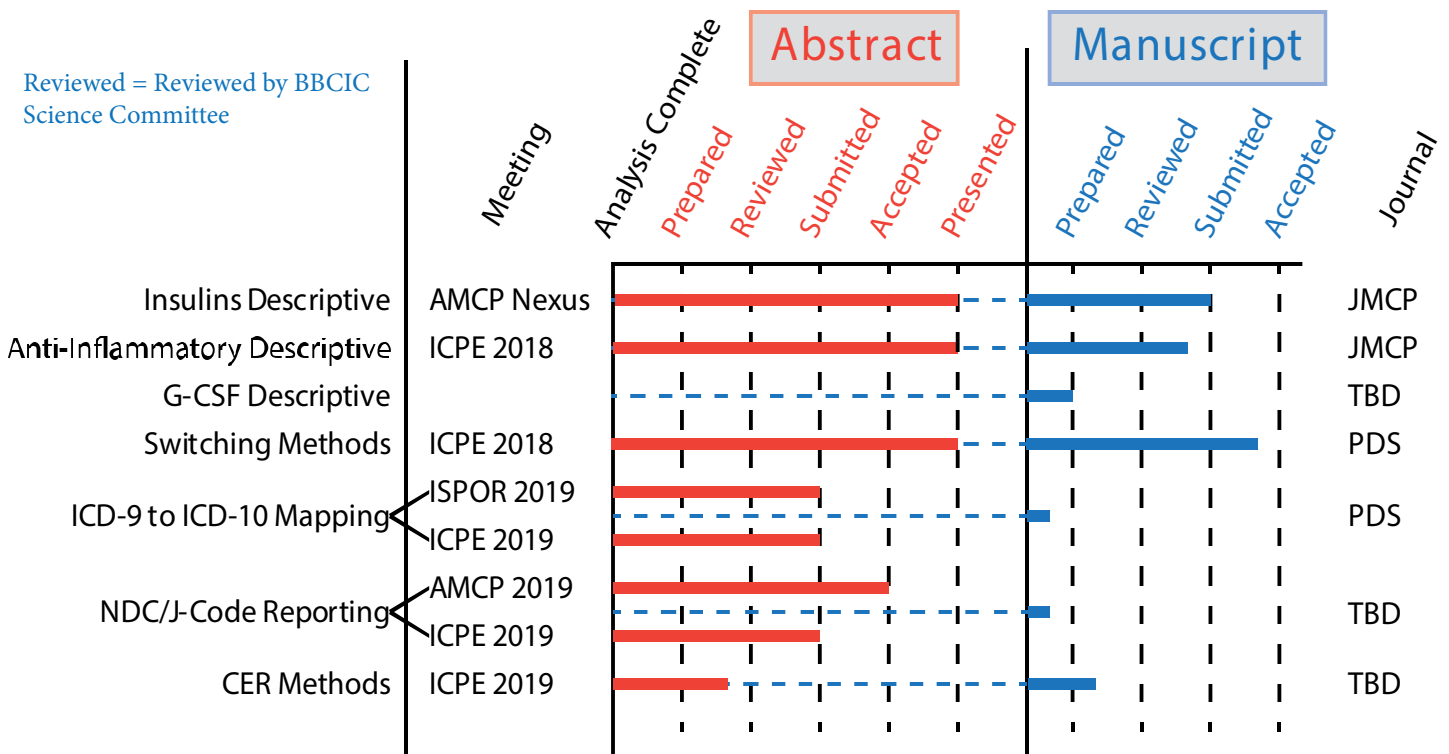
CER METHODS Recommended Best Practices

A manuscript is in preparation 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

PUBLICATION TRACKER



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

NEWS AND EVENTS

Other Invited Podium Presentations:

Cate Lockhart of BBCIC was the Chair and a presenter at the CBI 14th Annual Biosimilars Summit in **Alexandria, VA, January 23-24, 2019**; Cate Lockhart was also invited to speak at the 3rd Annual Biosimilars & Biologics BioTech Pharma Summit in **Porto, Portugal, March 21-22, 2019**.

UPCOMING RESEARCH

WORKGROUPS

Switching Methods Descriptive Analysis

After completing an in-depth evaluation and recommendations for best practices for handling switching in observational research, we are preparing for the next phase of the Switching Methods Workgroup, planned to convene in 2019. The details and specific research goals of this study are being formulated, but will undoubtedly include a descriptive analysis of switching patterns in the BBCIC Distributed Research Network.

COMPLETELY UNRELATED TO RESEARCH....



Head of the Charles Regatta. Boston 2018

BBCIC CONTACT INFORMATION

Cate Lockhart, PharmD, PhD

Executive Director

Email: clockhart@bbcic.org

Phone: (703) 684-2646

OR VISIT US AT: WWW.BBCIC.ORG