

BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

LETTER FROM THE EXECUTIVE DIRECTOR

Dear BBCIC Enthusiasts,

I hope you have had a wonderful summer and enjoyed some well-deserved vacation time! I was lucky enough to spend ten days in France in July, including watching the World Cup Final from a pub in Lyon!

Naturally, 2019 has continued to be a busy year, and I am thrilled to announce the publication flood-gates have finally opened! We now officially have FOUR manuscripts that have been published in the *Journal of Managed Care & Specialty Pharmacy*, and *Pharmacoepidemiology & Drug Safety*. Please see pages 3-4 for more details. Congratulations to all for your hard work and dedication in getting these manuscripts out the door!

An exciting development in the world of BBCIC is a NEW WEBSITE! I am currently working with the AMCP Marketing and Communications team, and web developers, to do a much-needed update and face-lift of the website. I hope we will at last have a useful and informative website both for current BBCIC participants, but also others who may be interested in our work. We will send out an announcement when we finally launch!

If you are a currently active BBCIC Participant, expect to see the BBCIC Annual Participant Survey in your inbox soon. This is an important tool for me to make sure BBCIC is meeting your expectations, and that you receive the value you expect from participation. We have questions about how you think things are going, what could be improved, and some topics to help guide our strategic plan. PLEASE PLEASE PLEASE take 10-15 minutes to fill it out!

As always, thank you all for your participation, engagement, and hard work on behalf of BBCIC. You are what makes our important work possible!

Regards,
Cate Lockhart, MS, PharmD, PhD

ATTENTION CURRENT BBCIC PARTICIPANTS!!!!

**Mark your calendar for our Fall Face-to-Face meeting: BBCIC Live@NEXUS!
Tuesday, October 29, 2019 from 8:00am to 12 noon in National Harbor, MD**

More information on page 6. Please RSVP!

Contact Cate at clockhart@bbcic.org for more information

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BBCIC

**Biologics & Biosimilars
Collective Intelligence Consortium**

AMCP BBCIC, LLC

www.BBCIC.org

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 BBCIC is in the finalizing development of the Statement of Work, and contract execution for our first Comparative Effectiveness Research project.

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. Currently two biosimilar products to reference filgrastim (filgrastim-sndz, filgrastim-aafi), and two biosimilars to reference pegfilgrastim (pegfilgrastim-jmdb, pegfilgrastim-cbqv) have been approved in the US. Building upon a previous BBCIC descriptive analysis, we are starting our first Comparative Effectiveness Research (CER) project in G-CSFs.

INFRASTRUCTURE: ONCOLOGY DATA FEASIBILITY

Co-Investigators:

- *Nancy Lin, ScD - Senior Scientist, Optum Epidemiology*

The contract is fully executed and a Kick-Off meeting with the full Workgroup is scheduled for September, 2019. Work has begun, and this project is anticipated to be approximately 10 months in duration.

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 cancer therapeutics. 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.

BBCIC HAS PUBLISHED!!!

Switching Methods

Desai RJ, Kim SC, Curtis JR, Bosco JLF, Eichelberger B, Barr CE, Lockhart CM, Bradbury BD, Clewell J, Cohen HP, Gagne JJ, on behalf of the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) Switching Workgroup. **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>

BBCIC Proof of Concept - Insulins

McMahill-Walraven CN, Kent DJ, Panozzo CA, Pawloski PA, Haynes K, Marshall J, Brown J, Eichelberger B, Lockhart CM. **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>

Insulins Descriptive Analysis

Kent DJ, McMahonill-Walraven CN, Panozzo CA, Pawloski PA, Haynes K, Marshall J, Brown J, Eichelberger B, Lockhart CM. **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>

BBCIC DRN “Gaps” and Potential Solutions

Lockhart CM, McDermott CL, Felix T, Lin ND, Cziraky MJ, Mendelsohn AB, Brown JS. **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>

2019 PLANNED PUBLICATIONS

IN REVIEW

ICD-9 to ICD-10 Mapping

Undergoing peer review at *Pharmacoepidemiology & Drug Safety*

ANTI-INFLAMMATORY Descriptive Analysis

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

NDC/J-Code Analysis

Undergoing peer review at *Pharmacoepidemiology & Drug Safety*

IN PREPARATION

CER METHODS Recommended Best Practices

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

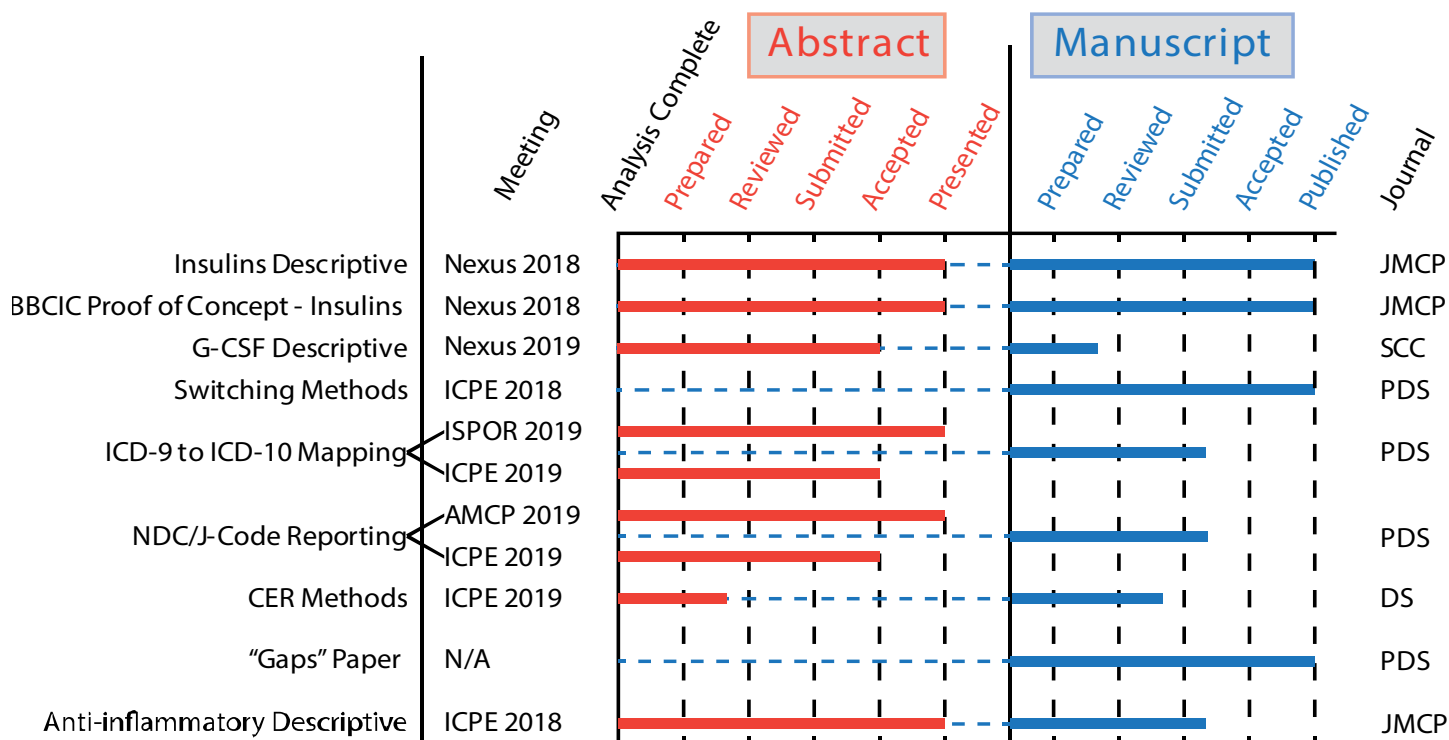
G-CSF Descriptive Analysis

Manuscript is currently in preparation. Target journal *Supportive Care in Cancer*

ESA Descriptive Analysis

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

PUBLICATION TRACKER



DS = Drug Safety

JMCP = Journal of Managed Care & Specialty Pharmacy

PDS = Pharmacoepidemiology & Drug Safety

SCC = Supportive Care in Cancer

Reviewed = Reviewed by BBCIC Science Committee

2019 ABSTRACTS

PRESENTED SO FAR IN 2019

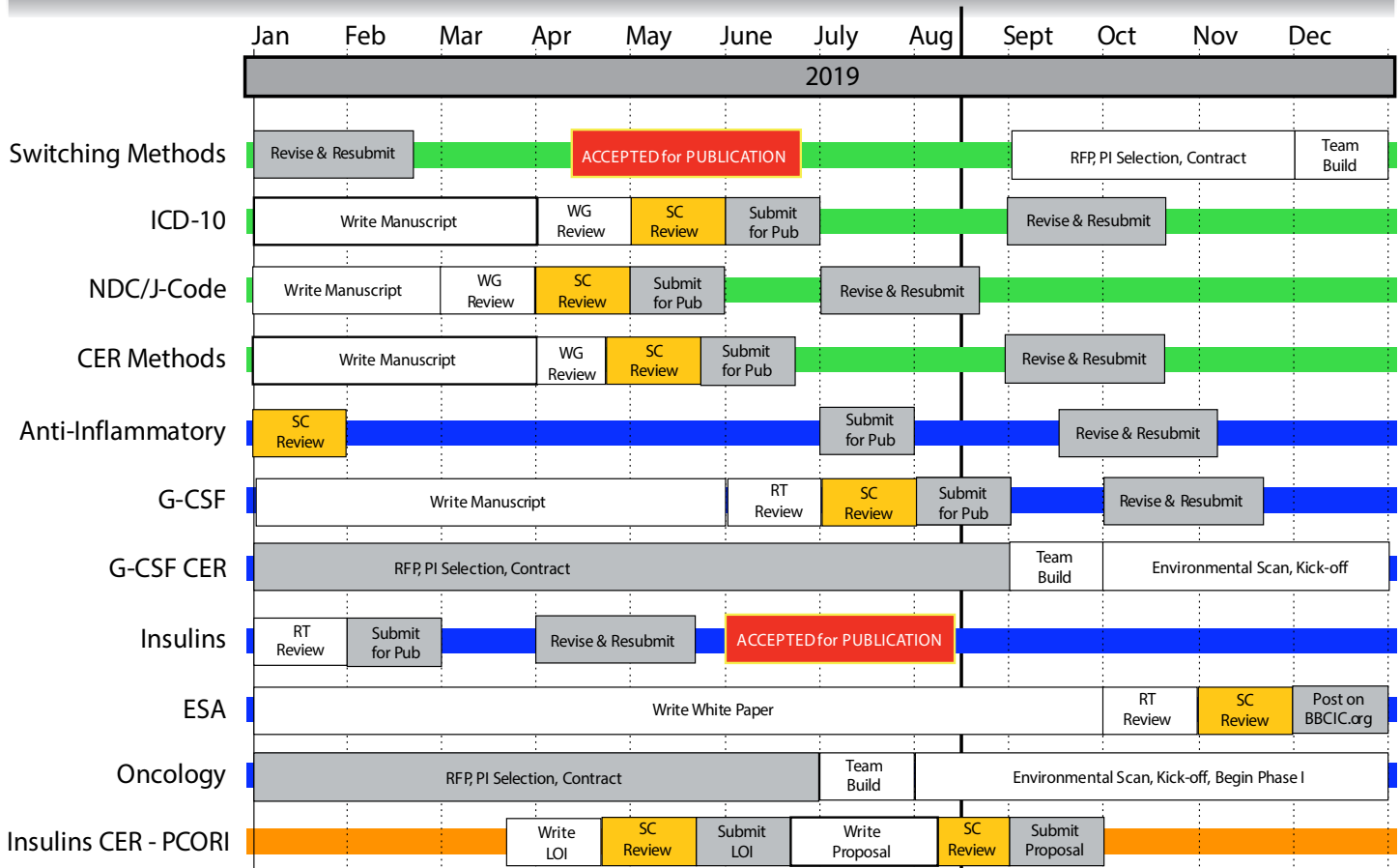
3
Podium

3
Poster

UPCOMING

Meeting	Meeting Date	Topic	Type	Presenting Author	Status
ICPE	August 24-28, 2019 Philadelphia, PA	ICD-10	Podium	Mengdong He	Accepted
		CER Methods	Poster	Nancy Lin	Accepted
		NDC	Poster	Kevin Haynes	Accepted
AMCP Nexus	Oct 29-Nov 1, 2019 National Harbor, MD	G-CSF	Poster	Cate Lockhart	Accepted
		Biosimilars	Podium	Cate Lockhart Gillian Woolett Molly Leber	Accepted

PROJECT TIMELINE



Mark Your Calendar!!

For the second year, BBCIC will be holding a Live@NEXUS meeting! This is an opportunity for all active BBCIC participants to meet Face-to-Face. Here are the basic details:

What:	BBCIC Live@NEXUS
When:	Tuesday, October 29, 2019 8:00am to 12-noon
Where:	National Harbor, MD Room TBD
Of Note:	We will have coffee, continental breakfast, and snacks available

Tentive Topics Include:

- * Update on current research projects
- * Strategic Planning
- * Patient and Payer perspectives on biosimilars - remind us WHY we are doing this important work!

PLEASE **RSVP** if you plan to attend (email Cate at clockhart@bbcic.org)

NEW for 2019: BBCIC NEXUS RECEPTION!!!! (come party with the nerds!)

All current BBCIC participants will be invited, as well as some key stakeholders from outside organizations. This is an opportunity for us to socialize with one another, but also to brag about the amazing work of BBCIC to our colleagues who are not current participants (but SHOULD BE!). Tentative date/time is **Tuesday, October 29, 2019 at 5:00pm - 7:00pm** (Room TBD).

Invitations will be forthcoming, but if you already know you can attend please **RSVP** at clockhart@bbcic.org.

Also, if you have **any colleagues from other not-currently-BBCIC-participant organizations who you think would benefit and be interested** in the work we do, please send those names and email addresses (and title, company if possible) to Cate by September 30, 2019. I will invite them to join us at the reception.

BBCIC CONTACT INFORMATION

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OR VISIT US AT: WWW.BBCIC.ORG