

BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

LETTER FROM THE PROGRAM DIRECTOR

....and it is fall....or winter....already....

I am so proud of the BBCIC! Our research truly made a splash at the AMCP Nexus meeting in October in Orlando! We presented FIVE beautiful posters (see photos on pg 4). We presented an educational session that drew approximately 230 attendees, which was remarkable given an overall conference attendance of ~2000 (and a blessing because the room was HUGE so it looked full!). I look forward to the many more conferences in 2019 where BBCIC has the opportunity to further elevate the public face of the amazing and important research we do.

One highlight was the BBCIC Live @ Nexus meeting that we held for a half-day on Monday morning at the beginning of the conference. The impetus for adding a second annual face-to-face meeting for BBCIC participants arose at the BBCIC Annual Meeting in February where multiple attendees found the energy and engagement to be an inspiring way to maintain the momentum of our work. In my opinion it was a wild success and we will be continuing this new "tradition" as a means for connecting on ongoing research, and developing strategies for the years to come. There was very thoughtful discussion around the BBCIC Strategic Plan that was drafted with the help of several stalwart volunteers, and I will share much more as it becomes more refined and reflective of our goals as an organization.

We will of course be holding our Annual Meeting at the AMCP office in Alexandria, VA in the Spring, in conjunction with the Sentinel Annual Public Workshop. (NOTE: The Sentinel meeting has been moved from February to April this year, so please see below to mark your calendar!). Planning will begin for that event in the New Year.

Meanwhile, I had the distinct joy of arriving in Orlando after a super duper fun race at the Head of the Charles Regatta (largest rowing regatta in the world), and looking to round out my year with a week skiing in Sun Valley, Idaho, my home state, with a group of dear friends and family. I am so excited to dive head-first into BBCIC 2019!

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

CURRENT RESEARCH UPDATES

WORKGROUPS

Switching

Objective: Treatment of switching/sequencing as a covariate/confounder in BBCIC CER studies. Manuscript under review at *Pharmacoepidemiology and Drug Safety*.

NDC/J-Code

Objective: Investigate the extent to which NDCs are being supplied on physician-office claims. Data collection and analysis is complete. Abstracts are in preparation for presentation at AMCP Annual Meeting, ISPOR, and ICPE meetings in 2019. A manuscript is also in preparation and expected to be submitted in Q1 2019.

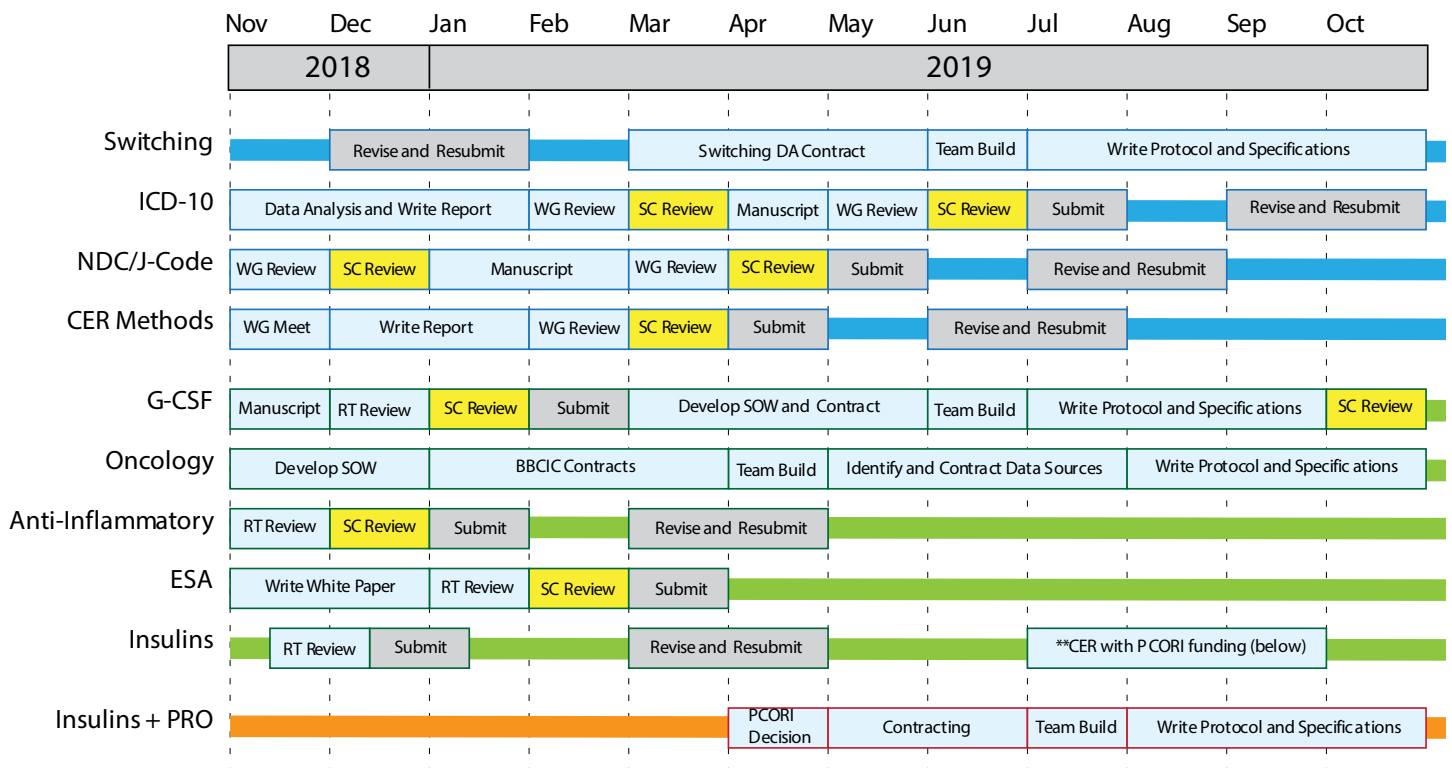
CER Methods

Objective: Develop best-practices based on current methodology for conducting observational comparative-effectiveness research. Full workgroup has met six times and the final report describing the workgroup recommendations is in progress.

ICD-9 to ICD-10 Mapping

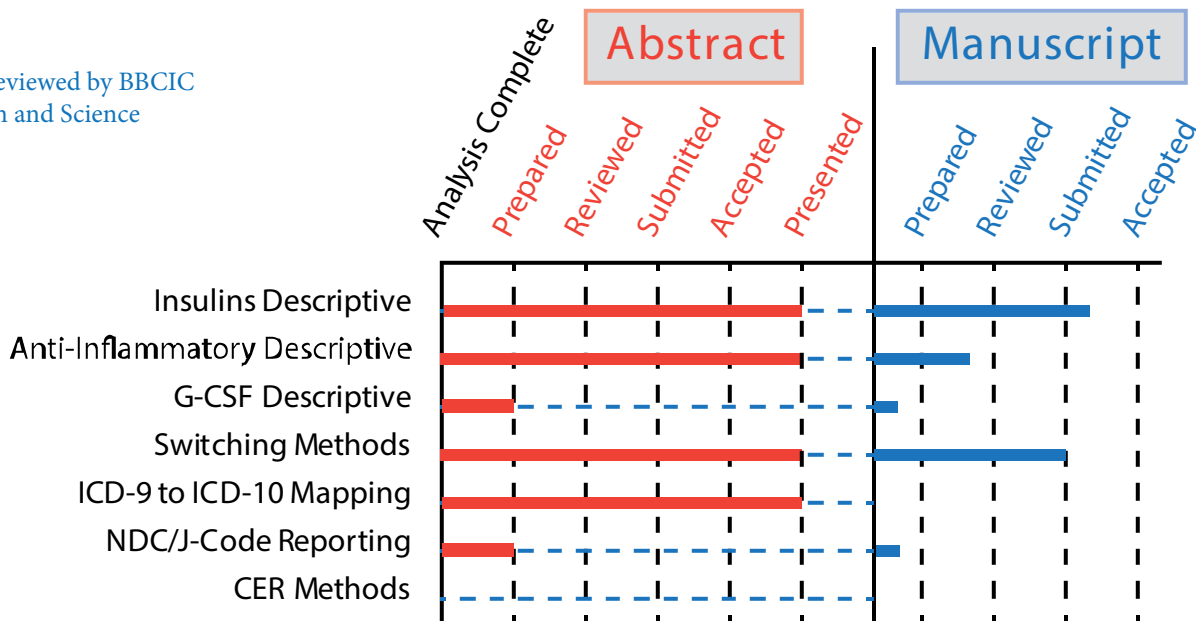
Objective: In preparation for CER projects, all codes for diseases of interest are being converted. Mapping is complete and data verification is underway. We anticipate abstracts will be submitted for presentation at ISPOR and ICPE in 2019. A manuscript will also be prepared.

PROJECT TIMELINE



PUBLICATION TRACKER

Reviewed = Reviewed by BBCIC Research Team and Science Committee



2019 PLANNED PUBLICATIONS

INSULINS Descriptive Analysis

Pair of companion articles will be submitted to the *Journal of Managed Care & Specialty Pharmacy*

ANTI-INFLAMMATORY Descriptive Analysis

Manuscript undergoing Science Committee review 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 will be prepared 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

2019 PLANNED ABSTRACTS

NDC/J-Code Analysis

Target Meetings: AMCP Annual Meeting, ISPOR, ICPE

ICD-10 Mapping

Target Meetings: ISPOR, ICPE, AMCP Nexus

BBCIC General/Biosimilars

Target Meetings: AMCP Annual Meeting, ISPOR, HCSRN, ICPE, Others....

G-CSF Descriptive Analysis

Target Meetings: TBD

CER Methods

Target Meetings: ISPOR, ICPE, AMCP Nexus

NEWS AND EVENTS

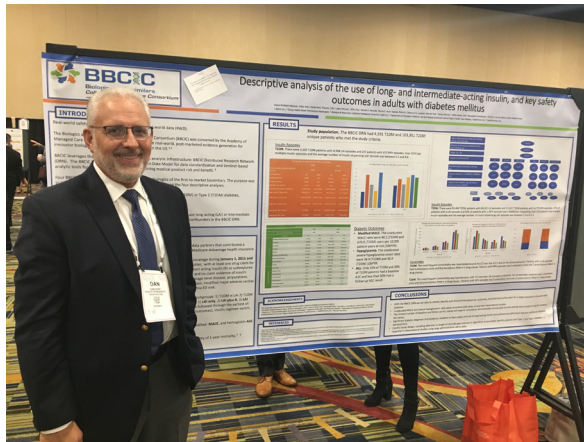
BBCIC presented FIVE posters at AMCP Nexus, October 22-25, 2018, Orlando, FL



Development and Management of a Distributed Research Network for Evaluating Real-World Outcomes for Originator Biologics and Biosimilars. (GOLD RIBBON WINNER!). Presenting Author: Aaron Mendelsohn (Harvard Pilgrim Healthcare Institute)



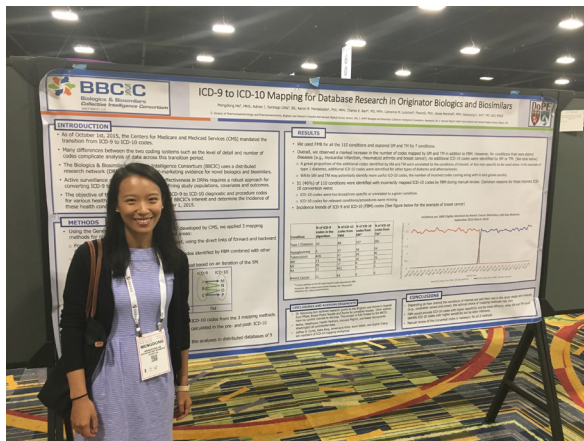
Evaluating Biologics and their Biosimilars using a Distributed Research Network to Demonstrate Real-World Outcomes. Presenting Author: Pamala A. Pawloski (HealthPartners)



Descriptive Analysis of the use of Long- and Intermediate-Acting Insulin, and Key Safety Outcomes in Adults with Diabetes Mellitus. Presenting Author: Daniel J. Kent (Kaiser Permanente of Washington Research Institute)



Differentiation of Adults with Type 1 versus Type 2 Diabetes in Administrative Claims Analysis: Experience from the Biologics and Biosimilars Collective Intelligence Consortium. Presenting Author: Cheryl N. McMahon-Walraven (Aetna)



ICD-9 to ICD-10 Mapping for Database Research in Originator Biologics and Biosimilars. Presenting Author: Mengdong He (Brigham & Women's Hospital)

**POSTERS AVAILABLE AT
WWW.BBCIC.ORG**

NEWS AND EVENTS

AMCP NW Affiliate: Cate Lockhart of BBCIC was invited to present at the recent meeting on **November 7, 2018 in Seattle, WA**. Her presentation was entitled “Biosimilars in the U.S.: Landscape, Utilization, and Post-Marketing Surveillance to Support Treatment and Coverage Decisions.”

Other Invited Podium Presentations:

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

UPCOMING RESEARCH

COMPARATIVE EFFECTIVENESS

G-CSF Comparative Effectiveness Analysis

We are in the contracting and team-building phase of our first comparative effectiveness study to compare the G-CSF originator biologic (filgrastim) to available biosimilars in the US (filgrastim-sndz). The Research Team is expected to kickoff in Q4 of 2018 and research will commence in earnest by the beginning of the year. A call for volunteers to participate on the Research Team will be forthcoming.

DESCRIPTIVE ANALYSES

Oncology Data Feasibility and Descriptive Analysis

We anticipate beginning the contracting and team-building process by the end of 2018 to commence research in Q1 2019. A call for volunteers to participate on the Research Team will be forthcoming as we begin planning for this project.

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.

BBCIC CONTACT INFORMATION

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