

# BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

## LETTER FROM THE PROGRAM DIRECTOR

Since last we met in this newsletter, we have moved through the heart of the summer and now the nostalgia of autumn back-to-school is right around the corner. This past quarter was a busy one, as usual, as we pushed forward on our mission to undertake the most robust, unbiased, and cutting-edge research that we are able to conduct. The world of biologics and biosimilars continues along its variable path with new regulatory and marketing decisions emerging. We at the BBCIC are uniquely positioned at the forefront with the strength of our multi-stakeholder collaboration.

Now over six months into my tenure as Program Director, I have had a learning curve (several curves, some might say) and have come to the second half of 2018 with a clearer vision for BBCIC and a deeper awareness of the day-to-day nuances that make this organization tick. I am working with colleagues on creating more detailed, transparent processes to clearly define expectations for deliverables and the cadence for internal review of our research. We have also convened a Strategic Planning Subcommittee to develop a robust, actionable, visionary plan for the coming years of BBCIC. I am excited about these activities as they signal a tangible growth of the organization as we tackle new aspects of our work through publications and presentations that finalize the first phase of research and start on new projects moving forward.

Speaking of publications and presentations, BBCIC is gearing up to make a splash at the AMCP Nexus meeting, being held October 22-25, 2018 in Orlando, FL. Our research teams are presenting FIVE posters at Nexus, and a proposal I submitted was accepted as an educational session. For more details, please see the News and Events section on pg 4 of this newsletter. The progress and plans for our ongoing and future research activities are also outlined on pg 2-3.

Finally, I look forward to seeing many of you in person at AMCP Nexus. If you would like to set up a specific meeting please don't hesitate to contact me! (My contact information is listed on pg 4)

Regards,  
Cate Lockhart, MS, PharmD, PhD

### **ATTENTION CURRENT BBCIC PARTICIPANTS!!!!**

**Please join us at AMCP Nexus for our first BBCIC Fall Meeting.**

**October 22, 2018 - 8:00am - noon, Orlando, FL**

*If you are able to attend, please RSVP to Cate at [clockhart@bbcic.org](mailto:clockhart@bbcic.org)*

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**BBCIC**

**Biologics & Biosimilars**

**Collective Intelligence Consortium**

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# CURRENT RESEARCH UPDATES

## WORKGROUPS

### Switching

Objective: Treatment of switching/sequencing as a covariate/ confounder in BBCIC CER studies. Literature review and consensus of recommendations is complete. Manuscript submitted for publication in *Pharmacoepidemiology and Drug Safety*.

### NDC/J-Code

Objective: Investigate the extent to which NDCs are being supplied on physician-office claims. Data collection is complete and analysis is underway.

### ICD-9 to ICD-10 Mapping

Objective: In preparation for CER projects, all codes are being converted. Mapping is complete and data verification is underway.

### CER Methods

Objective: Develop best-practices based on current methodology for conducting observational comparative-effectiveness research. Literature review and related report has been completed. Full workgroup has met twice to date.

## RESEARCH TEAMS

### INSULINS Descriptive Analysis

The manuscript is undergoing revisions after peer review comments were received from the *Journal of Managed Care & Specialty Pharmacy (JMCP)*.

### ANTI-INFLAMMATORY Descriptive Analysis

Manuscript is being finalized by the research team and will undergo Science Committee review in September followed by submission to the *Journal of Managed Care & Specialty Pharmacy*.

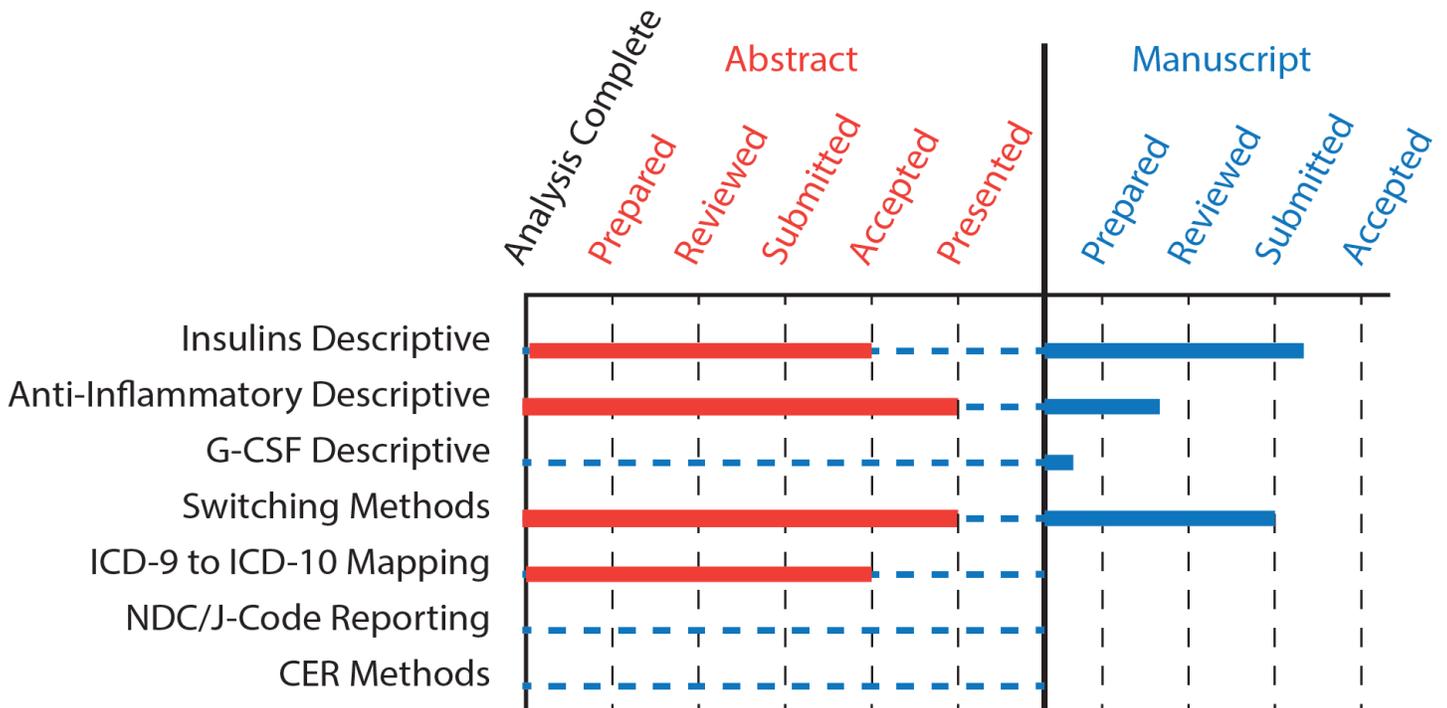
### G-CSF Descriptive Analysis

Manuscript is currently in preparation.

### ESA Descriptive Analysis

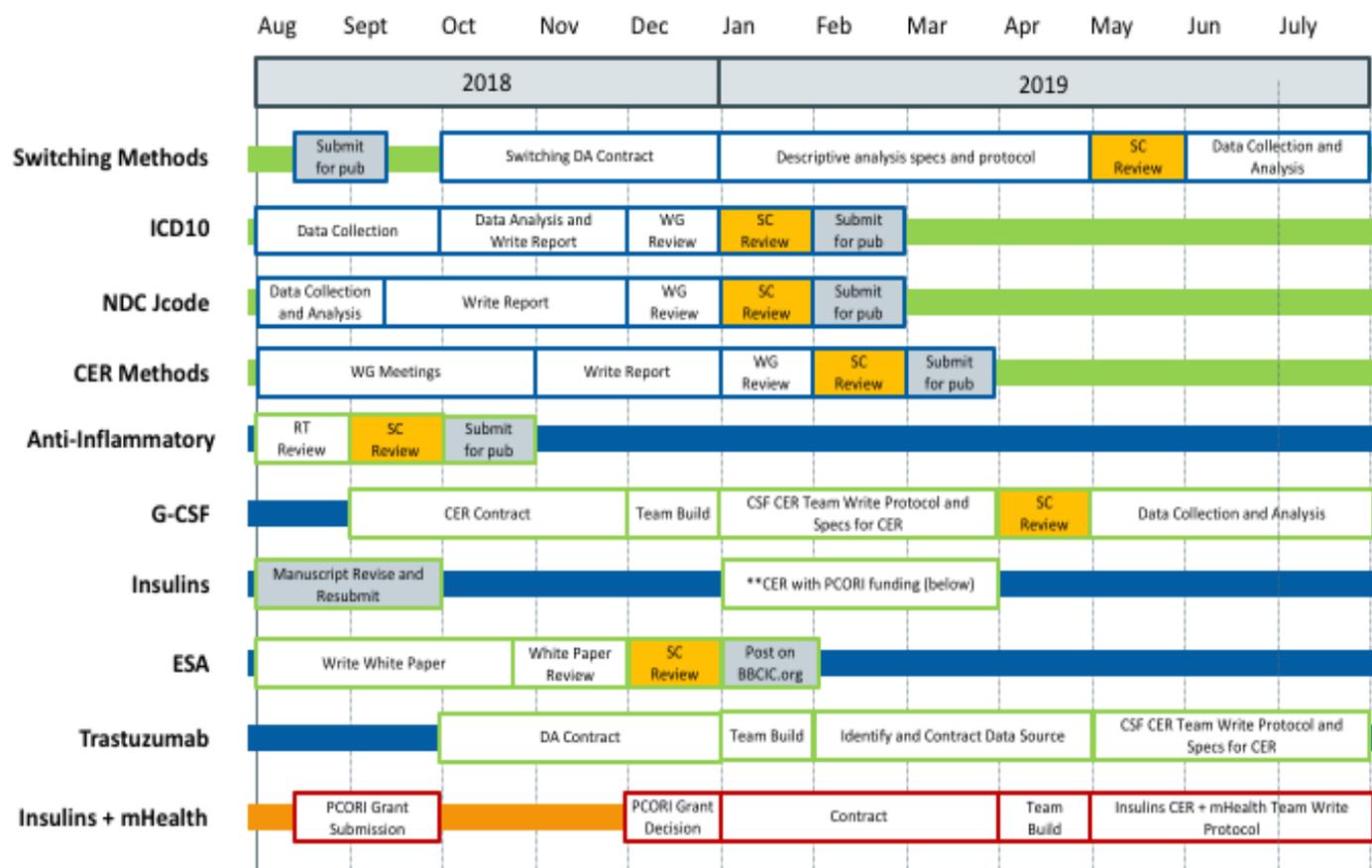
Project is complete and the results, unsurprisingly, showed the data in the BBCIC DRN is not as rich as other sources such as USRDA in capturing patients on hemodialysis. A white paper is in preparation to post on [www.BBCIC.org](http://www.BBCIC.org). Additional data sources including the CMS full data set are being explored to fill the gap.

# PUBLICATION TRACKER



Reviewed = Reviewed by BBCIC Research Team and Science Committee

# PROJECT TIMELINE



## 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 end of the year. A call for volunteers to participate on the Research Team will be forthcoming in September.

### DESCRIPTIVE ANALYSES

#### Trastuzumab 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 in October as we begin planning for this project.

### WORKGROUPS

#### Switching Methods Descriptive Analysis

The next phase of the Switching Methods Workgroup is planned to convene in Q4 2018. This study will include an in-depth discussion of best practices for study design, and a descriptive analysis to test study designs in the BBCIC DRN.

## NEWS AND EVENTS

BBCIC Principal Investigator Rishi Desai from Brigham and Women's Hospital, and co-authors from the Switching Workgroup team presented a symposium entitled "Methodologic Considerations for Non-Interventional Studies Evaluating Outcomes of Originator-To-Biosimilar Switching" at the International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) meeting held **August 22-26 in Prague, Czech Republic**.

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BBCIC Principal Investigator Jie "Sophie" Zhang, PhD, from HealthCore, presented a poster on behalf of the Anti-Inflammatory Descriptive Analysis Research Team entitled "Incidence Rate of Serious Infections in Patients Receiving Biologic Anti-Inflammatory Agents for Treatment of Rheumatologic, Dermatologic, and Gastrointestinal Conditions" at the International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) meeting held **August 22-26 in Prague, Czech Republic**.

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BBCIC has a total of FIVE abstracts that were accepted for poster presentation at **AMCP Nexus, October 22-25, 2018, Orlando, FL**:

**Development and management of a distributed research network for evaluating real-world outcomes for biologics and their 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 biologics and biosimilars.** Presenting Author: Mengdong He (Brigham & Women's Hospital)

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**AMCP Nexus:** A proposal by Cate Lockhart of BBCIC entitled "The State of U.S. Biosimilar Utilization and Post-Marketing Surveillance Initiatives to Support Treatment and Coverage Decisions" was accepted for presentation as an Educational Session, which will be on **Wednesday, October 24, 3:00pm - 4:30pm, Orlando, FL**

## BBCIC CONTACT INFORMATION

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