

# BBCIC QUARTERLY

NEWS FROM THE BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM

## LETTER FROM THE PROGRAM DIRECTOR

As we land firmly in the second quarter of 2018, we are off to a very busy year. This has been both a year of changes so far, and one of driving forward on our mission to generate the most robust, unbiased, and cutting-edge data that we can. The world of biologics and biosimilars is constantly changing with new regulatory decisions and marketing decisions and we are uniquely positioned at the forefront with the strength of our multi-stakeholder collaboration.

This year began with a notable change at the helm, as Bernadette Eichelberger, the stalwart visionary behind this tremendous organization entered the next exciting phase of her life: retirement. She had already filled one roll in the name of Charlie Barr, the BBCIC Chief Science Officer, and in January I had the distinct privilege to take over the helm as Program Director. As I said at the 2nd Annual BBCIC Workshop at our office in Alexandria in February, I have had some VERY big shoes to fill. Luckily I have big feet. I am beyond thrilled to be playing an integral roll in this organization and I will do my best to carry on the legacy that Bernadette so aptly began.

We have had many research victories and met some new milestones for the organization. So far we have completed four descriptive analysis research products in insulins, G-CSF, anti-inflammatories, and ESAs. We have also convened four workgroups, with the swithing group just completing their evaluation and compiling their concensus recommendations for how to approach medication switching patterns in observational, claims-based studies. The ICD-9 to ICD-10 mapping group is well underway, as is the NDC/J-Code group tasked with evaluation of coding patterns in claims for biologic and biosimilar products. Finally, the comparative effectiveness research (CER) methods workgroup is scheduled to kick-off in May after some prelimiary literature-review work by our colleagues at Optum.

Later this year, we anticipate convening our first CER research team, which will be a test to the quality of our research capability, the drive of the participants, and the exciting first step to fulfilling the ultimate goal of contributing pivotal research comparing treatment patterns and outcomes of biosimilars and innovator products. Needless to say, this is going to be be a busy and exciting year and I can't wait to keep on going!

Regards,  
Cate Lockhart, MS, PharmD, PhD

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**BBCIC**

**Biologics & Biosimilars**

**Collective Intelligence Consortium**

AMCP BBCIC, LLC

[www.BBCIC.org](http://www.BBCIC.org)

# 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 is in preparation and schedule for Science Committee review in June. An abstract was accepted as symposium at ICPE. Next steps: Descriptive analysis.

### NDC/J-Code

Objective: Investigate the extent to which NDCs are being supplied on physician-office claims. Specifications, protocol, and SOW have been approved by the Science Committee, and data collection is beginning.

### ICD-9 to ICD-10 Mapping

Objective: In preparation for CER projects, all codes are being converted (COMPLEX PROCESS). Code list has been defined and initial mapping has begun.

### 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 kickoff planned for mid-May.

## RESEARCH TEAMS

### INSULINS Descriptive Analysis

Project is complete and the manuscript has been approved by the Science Committee. It will be submitted to the target journal: *Journal of Managed Care & Specialty Pharmacy (JMCP)*. **This is the first full publication from the BBCIC.**

### ANTI-INFLAMMATORY Descriptive Analysis

Project is complete and manuscript is under review by the research team. It is anticipated to undergo review and approval by the Science Committee in June or July and submitted for publication shortly thereafter.

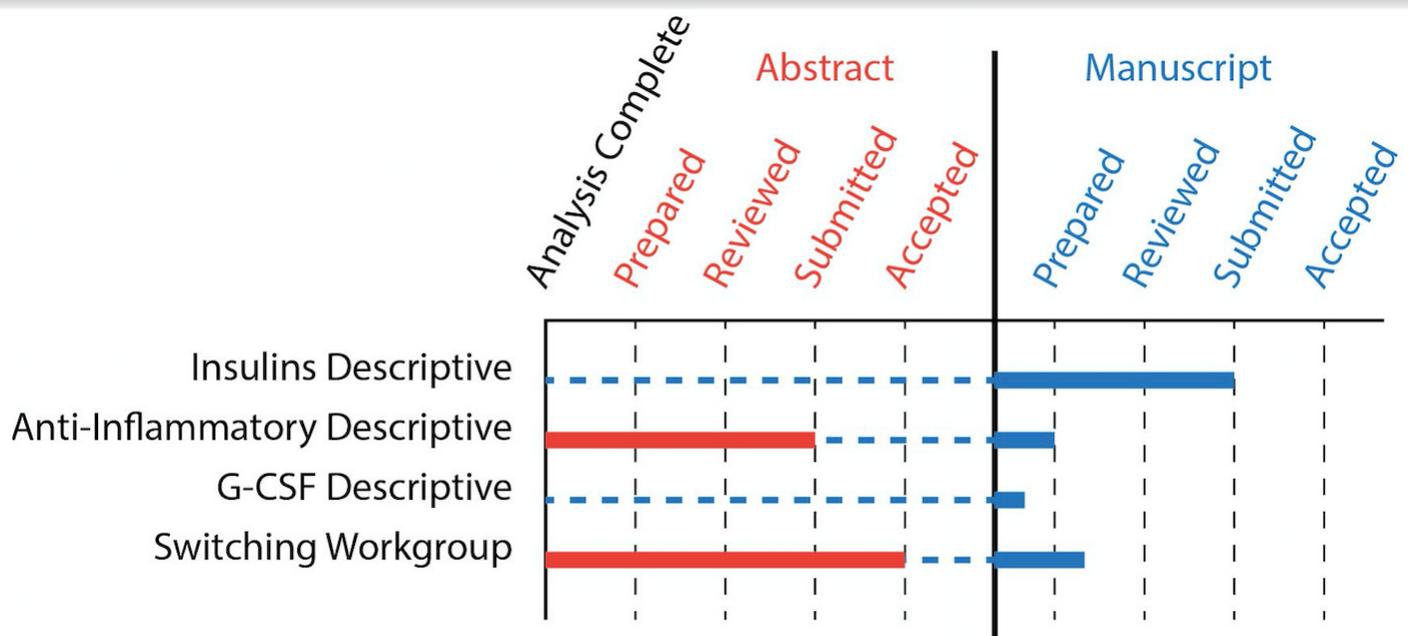
### G-CSF Descriptive Analysis

Project is complete and manuscript is currently in preparation. It is anticipated to undergo review and approval by the Science Committee in July and submitted for publication shortly thereafter.

### ESA Descriptive Analysis

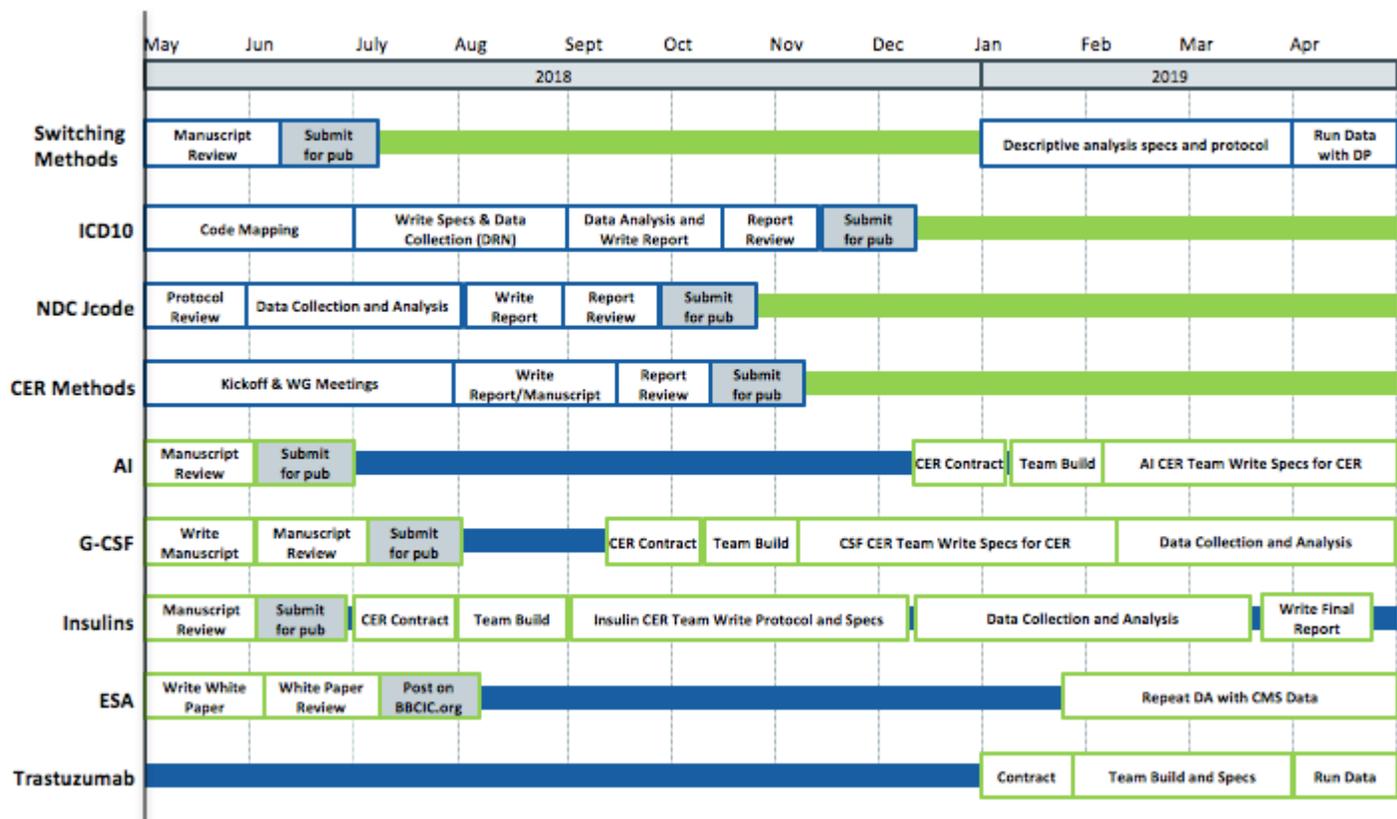
Project is complete and the results, unsurprisingly, showed the data in the BBCIC DRN is not as rich as other sources such as USRDA in capturing patients on hemodialysis. A white paper is in preparation to post on [www.BBCIC.org](http://www.BBCIC.org). Additional data sources including the CMS full data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

# PUBLICATION TRACKER

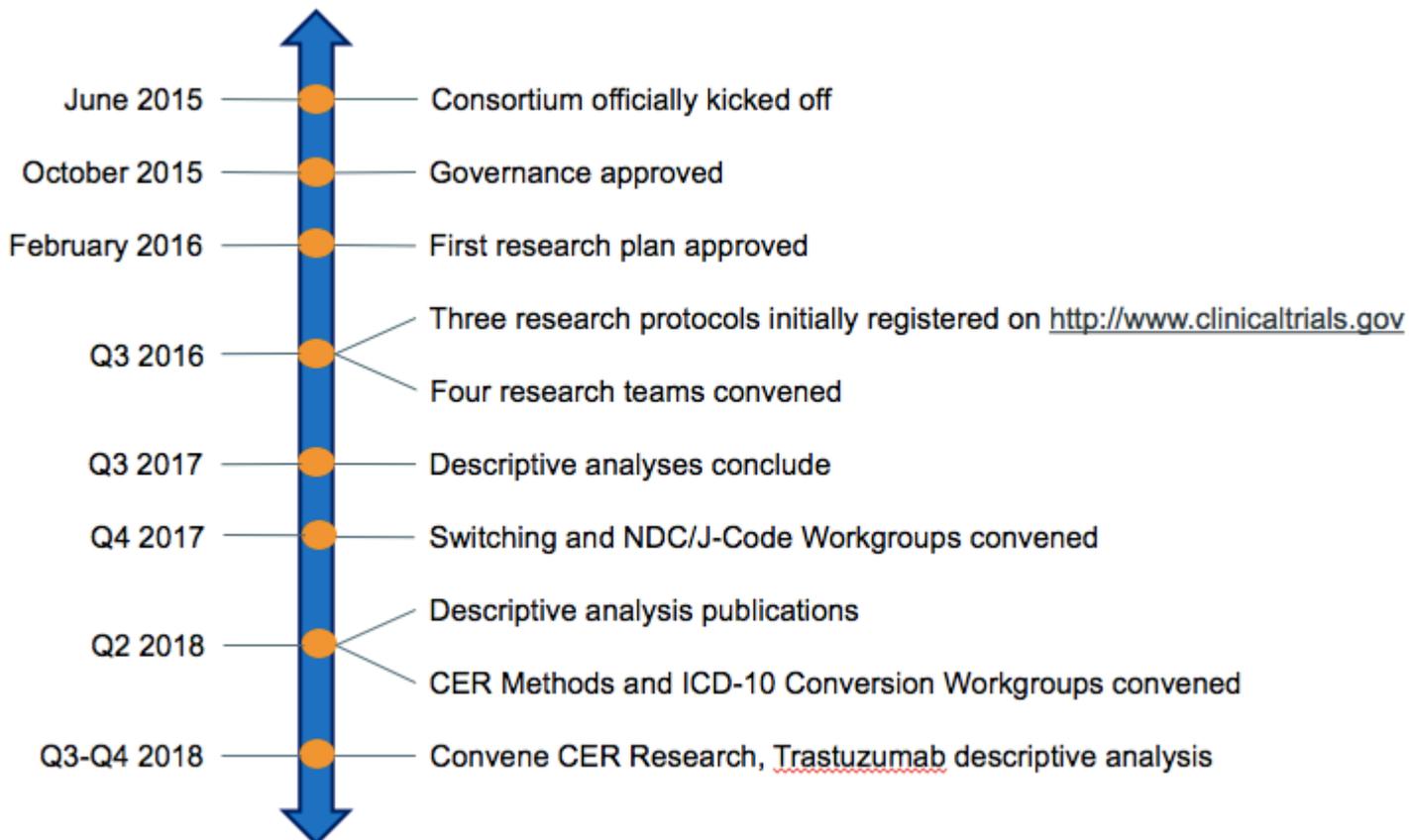


Reviewed = Reviewed by BBCIC Research Team and Science Committee

# PROJECT TIMELINE



# NOTABLE MILESTONES



## NEWS AND EVENTS

Pam Pawloski of HealthPartners presented a poster on the work of the BBCIC at the Health Care Systems Research Network (HCSRN) Conference held in Minneapolis on April 11-13, 2018. HCSRN is an organization with a goal, in part, to encourage and facilitate collaboration on research that improves health and healthcare for individuals and populations. Pam noted there was "...a lot of interest in our poster and the work we're doing."



Congratulations to BBCIC Principal Investigators Rishi Desai, PhD, and Joshua Gagne, PharmD, ScD, from Brigham and Women's Hospital, and the rest of the Switching Workgroup team for acceptance of their abstract entitled "Methodologic Considerations for Non-Interventional Studies Evaluating Outcomes of Originator-To-Biosimilar Switching." They will be presenting a symposium at the International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) meeting held **August 22-26 in Prague, Czech Republic**. Other presenters are Seoyoung Kim, also of Brigham and Women's Hospital, Jeffrey Curtis of the University of Alabama at Birmingham, Jaclyn Bosco of IQVIA, and Brian Bradbury of Amgen.

Congratulations also to BBCIC Principal Investigators Jie "Sophie" Zhang, PhD, and Kevin Haynes, PharmD, PhD, from HealthCore, and the rest of the Anti-Inflammatory Descriptive Analysis Research Team for acceptance of their abstract entitled "Incidence Rate of Serious Infections in Patients Receiving Biologic Anti-Inflammatory Agents for Treatment of Rheumatologic, Dermatologic, and Gastrointestinal Conditions." They will be presenting a poster at the International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) meeting held **August 22-26 in Prague, Czech Republic**. Other authors are Gayathri Sridhar of HealthCore, Charles Barr and Bernadette Eichelberger of BBCIC, and Kevin Haynes of HealthCore.

**ISPOR:** Cate Lockhart of BBCIC, Mark Cziraky of HealthCore, and Mike Blum of FDA will be presenting a workshop entitled "Biosimilars, Utilization, and Post-Marketing Surveillance in the United States." **Monday, May 21, 3:45pm - 4:45pm, Baltimore, MD**

**DIA:** Charlie Barr of BBCIC, Kevin Haynes of HealthCore, Nancy Lin of Optum, and Hillel Cohen of Sandoz will be presenting a session entitled "Payers, industry, and Academia Collaborating on Post-Marketing Surveillance." **Thursday, June 28, 9:00am - 10:15am, Boston, MA**

## BBCIC CONTACT INFORMATION

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