Q4 2023

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BBCIC Biologics & Biosimilars Collective Intelligence Consortium QUARTERLY

A Note from the Executive Director

As we close out yet another year-in-the-life as a consortium, the EIGHTH year-in-the-life in fact, I always enjoy reflecting on all we have accomplished in the past 12 months. While we are in the middle of it, it is hard to see the forest for the trees, but when we look back at the year it always amazes me how much we are able to accomplish! Check out a few highlights in my most recent letter.

Read the Full Letter

In the News

Now Available! Biosimilar Care: An Interactive Web App for Providers

Gain essential information on the expanding landscape of biosimilars by accessing the BioSim.Care app. Brought to you by AMCP Foundation and the Biosimilars Council, you can expect to find useful resources for engaging patients during the switch to a biosimilar and understanding managed care requirements to ensure that your patients have appropriate and prompt access to necessary care. Explore the BioSim.Care app today.

Read More

BBCIC FDA Grant Update

We have been making great progress on our first FDA grant, which was awarded in September of last year! The study titled, “Improving the Efficiency of Regulatory Decisions for Biosimilars and Interchangeable Biosimilars by Leveraging Real-World Data to Produce Real-World Evidence” assesses the use of real-world data to support regulatory requirements for interchangeable biosimilars.

Since the beginning of this project, our focus has been on Aim 1 activities, including a comprehensive literature review and detailed regulatory assessment to identify where RWD/RWE has been or could be used in a regulatory submission for biosimilarity or interchangeability. We presented a poster at ISPOR Europe 2023 on our findings from the literature review.

We convened an expert panel in July and a second discussion in September to identify not only where RWD/RWE could be used for biosimilar development but also how it could be applied to meet detailed regulatory requirements. we will prepare a detailed report including recommendations and strategies for incorporating RWD/RWE in biosimilar and interchangeable biologic development from a regulatory perspective in the United States.

For the next steps, the BBCIC Research Team has begun planning the clinical study emulation from the test case scan that identified existing studies that have been used or are in progress to assess interchangeability for regulatory evaluation. Our two research partners in the BBCIC network are one large national insurer and one regional integrated delivery network. A protocol will detail our RWD study design according to the test case and following best practices for target trial emulation.

View the Annual Report

New Publications

We had a great year of having three manuscripts published! The three manuscripts can be viewed at:

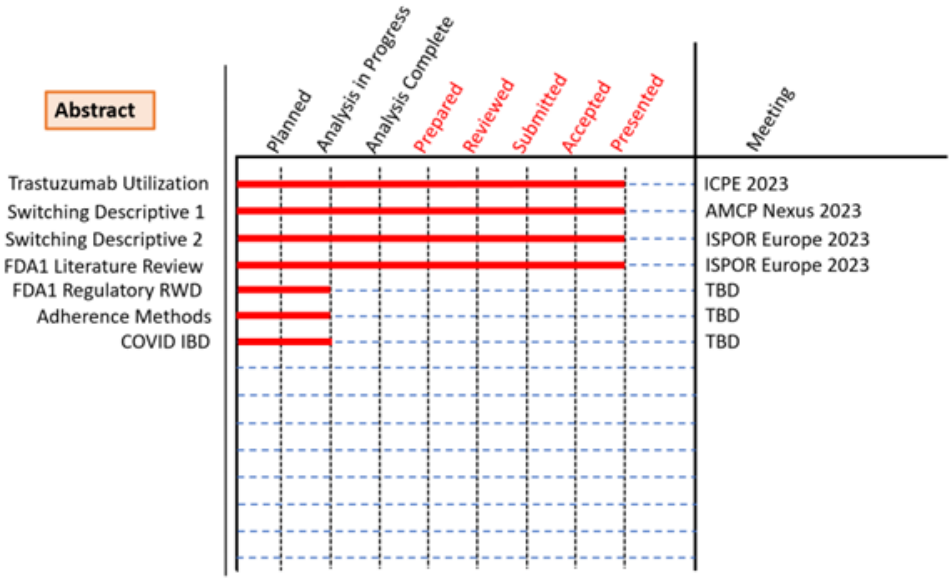
- Identification of cancer chemotherapy regimens and patient cohorts in administrative claims: challenges, opportunities, and a proposed algorithm
- Utilization, User Characteristics, and Adverse Outcomes of Insulin Glargine Originators and Follow-on Drug in Patients with Diabetes in the US
- Real-world switching and discontinuation outcomes of infliximab biosimilars in patients with rheumatoid arthritis: a scoping review

Current Research

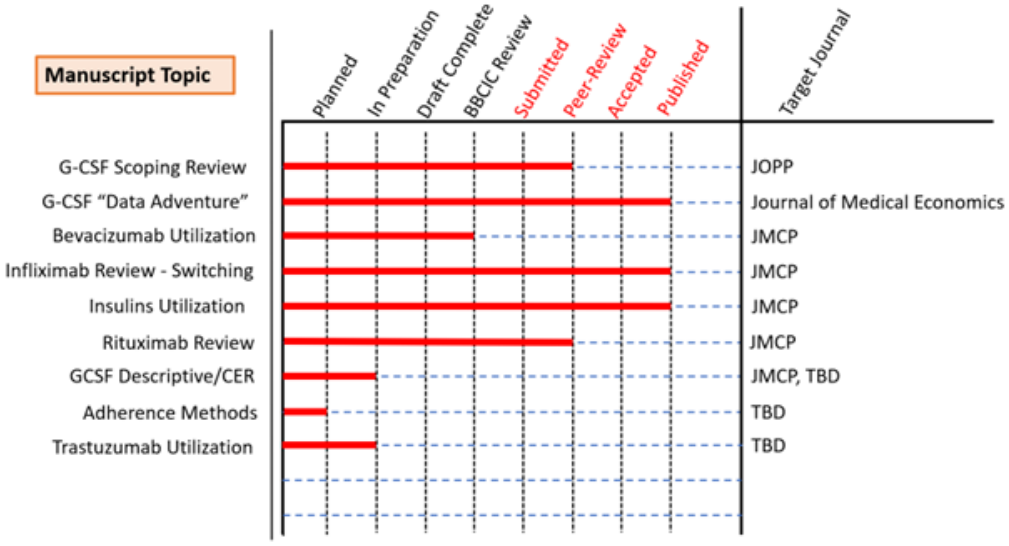
Please visit us online for descriptions and status of our current and upcoming research!

See Current Research

Abstract Tracker



Manuscript Tracker



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