# Development and Management of a Distributed Research Network for Evaluating Real-World Outcomes for Originator Biologics and Biosimilars

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BBCIC Biologics & Biosimilars Collective Intelligence Consortium
AMCP BBCIC, LLC

## PROBLEM DESCRIPTION

There exists an important public health need for active and systematic post-marketing evidence generation for biologics, including their corresponding biosimilar products.

## GOAL

To develop an infrastructure to enable active surveillance of the real-world safety and effectiveness of originator biologics and biosimilars.

## OBSERVATIONS

Since its formation, BBCIC has conducted four descriptive studies examining:

- Usage and rates of infections among patients with autoimmune diseases receiving anti-inflammatory biologics
- Treatment patterns and outcomes of adult patients with diabetes who use long-acting or intermediate-acting insulins
- Feasibility of BBCIC data to conduct a comparative study of erythropoietin stimulating agents (ESA) in hemodialysis patients
- Granulocyte-colony stimulating factors (G-CSF) use in breast and lung cancer patient who received chemotherapy with Grade III or IV neutropenic risk.

Each study was led by a team of BBCIC investigators overseen by a multidisciplinary group of stakeholders.

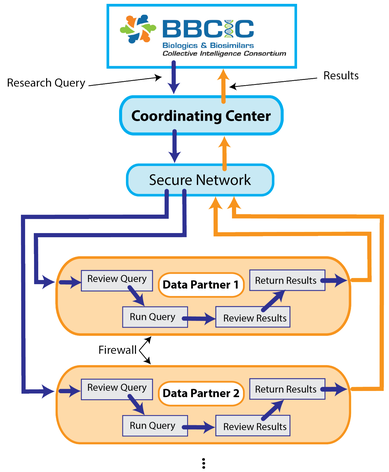
Additional workgroups are focusing on best practices in research design for biologics and biosimilars, including:

- Switching of biologic/biosimilar products in comparative analyses
- Methods for conducting comparative effectiveness research with biologics/biosimilars
- Examination of the use of National Drug Codes (NDCs) for biosimilars for physician-office claims
- Mapping of ICD-9 to ICD-10 codes to enable research involving exposures and outcomes spanning before and after Oct. 2015 (when ICD-10 was launched)

***A forum for collaboration between managed care organizations, integrated delivery networks, PBMs, pharma companies and research institutions***

## PROGRAM DESCRIPTION

The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) is a non-profit initiative created in 2015 under the auspices of the Academy of Managed Care Pharmacy (AMCP). The BBCIC is a participant-supported and funded organization; participants include data partners (in-kind contributions), product manufacturers, managed care organizations, and other non-profit organizations who contribute annual fees. The Consortium uses a distributed research network (DRN) approach that includes medical and pharmacy claims data on more than 100 million patient-lives to perform ongoing analyses of biosimilars and their innovator products.

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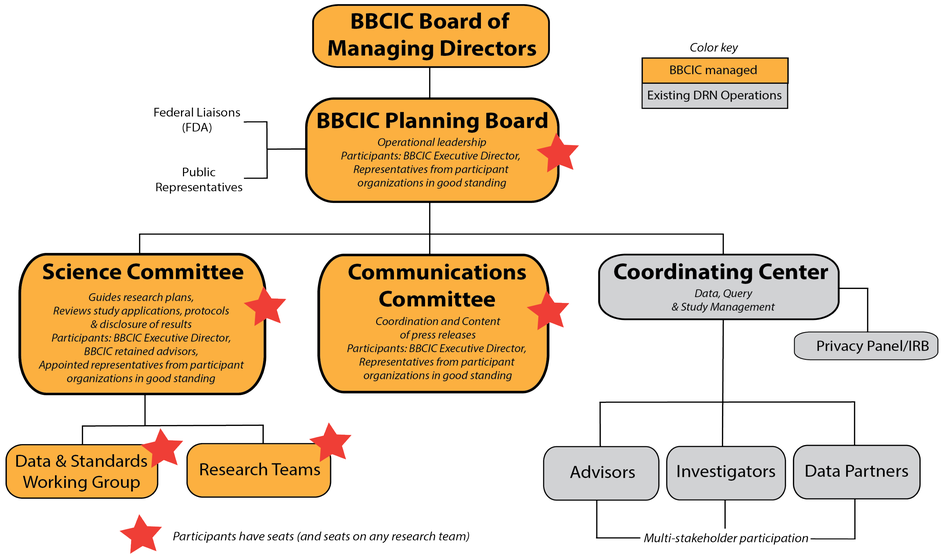
| **BBCIC leverages the Sentinel Initiative** | → | Improves the efficiency and cost-effectiveness of post-marketed observational studies. |
| **BBCIC actively monitors biosimilars and originators** | → | Anonymous data from >100 million patients |
| **BBCIC is a multi-stakeholder collaboration** | → | Diverse expertise allows for a larger voice with more credibility |

**The AMCP BBCIC strategy provides a unique opportunity for Managed Care to support public knowledge of biologic and biosimilar drugs with robust science.**




BBCIC began by creating a transparent governance structure with a Planning Board for operational oversight and a Science Committee to guide research activities. Processes were established for ensuring coordination across key stakeholders including BBCIC leadership, payors (research and data partners), and pharmaceutical sponsors (including sponsors for originator and biosimilar products) who provide financial support for the initiative. A coordinating center manages querying and analytical functions of the Consortium.

BBCIC leverages data and analytic infrastructure of FDA Sentinel System. The Consortium uses the Sentinel Common Data Model for data standardization and Sentinel-based analytic tools for distributed analyses (e.g., characterizing product utilization, defining cohorts of interest) and examining medical product risk and benefit (e.g., frequency of safety and effectiveness outcomes).

BBCIC is focused on transparent, science-focused research. As such, protocols and reports are publicly posted and scientific rigor is maintained by adhering to best practices from regulatory agencies and professional entities and through oversight of the Science Committee.

## FINDINGS/RECOMMENDATIONS

The BBCIC has generated data for each of the four descriptive studies, issuing over 40 queries across the DRN. The established infrastructure and experience from these descriptive analyses position the Consortium well for future analyses to generate real-world evidence for novel biologics and biosimilars.

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