Perspectives from a Coordinating Center: Lessons learned from the Biologics and Biosimilars Collective Intelligence Consortium

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BBCIC Biologics & Biosimilars Collective Intelligence Consortium
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BACKGROUND

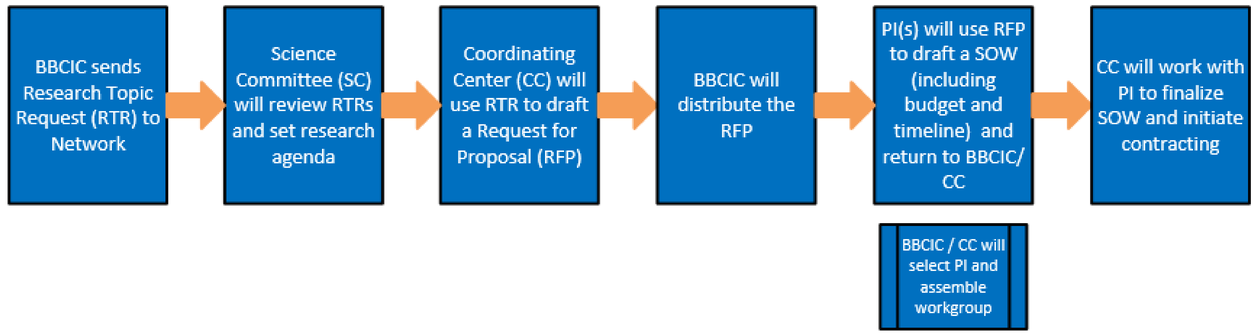
The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) was established in 2015 to generate real-world evidence on the safety and effectiveness of novel biologics and biosimilars. Harvard Pilgrim Health Care Institute (HPHCI), a Health Care Systems Research Network (HCSRN) member serves as the BBCIC Coordinating Center (CC). Aetna, Harvard Pilgrim Health Care, HealthCore, HealthPartners, Kaiser Permanente Washington Health Research Institute, and Optum are participating research partners.

METHODS

BBCIC is structured as a multi-use, multi-site Distributed Research Network (DRN). It is a non-profit subsidiary of the Academy of Managed Care Pharmacy, overseen by a Board of Managing Directors. BBCIC is funded by pharmaceutical manufacturer contributions and in-kind health plan contributions. The Annual Research Plan is developed by a Science Committee and approved by a Planning Board with representation from all stakeholders. The Science Committee and Planning Board are composed of representatives from participating organizations. BBCIC activities are contracted independently with HPHCI serving as the Prime site; to date, eight workgroups have been formed and two workgroups are in development. All stakeholders can propose Research Topic Requests (RTRs) for consideration and participate in funded research workgroups. BBCIC leverages infrastructure from the FDA Sentinel Initiative, specifically data formatted in the Sentinel Common Data Model (SCDM) and publicly available analytic tools. Partners retain physical control of their data and only de-identified summary level information is shared with the CC. Each participating organization has obtained separate non-human subjects Institutional Review Board (IRB) determination.

RESULTS

Administrative
Establishing the Consortium and individual workgroups required development of Statements of Work (SOWs), budgets, execution of contracts, and IRB submissions for the six participating research partners and additional investigators. Sufficient time must be allocated for these project start-up activities to ensure clarity and avoid later delays; expectations regarding time needed for project initiation should be clearly communicated. SOW terminology should be consistent, and deliverables clearly defined. Expectations for dissemination, including authorship, should be included, and a dissemination process should be established and enforced.



Infrastructure
The infrastructure and capabilities of the FDA Sentinel Initiative was leveraged by the BBCIC, allowing research to be initiated quickly because it eliminated the need to develop new SAS code "analytic tools" or curate a new data source. However, the need to train stakeholders in the capabilities of the tools and data slowed decision making as many stakeholders were unfamiliar with the existing Sentinel resources or the benefits and limitations of the DRN operating model. Training sessions and education materials were needed to address knowledge gaps. Training sessions should be offered annually to capture recurring updates made to the analytic tools and data and as an opportunity to train new BBCIC members.

Workgroups
Operating multiple concurrent work groups required significant coordination and prioritization, especially for workgroups that queried data and competed for analyst resources. Large workgroups faced challenges making timely decisions and progress on research design; detailed workflows to define process and responsibilities helped mitigate these issues. Smaller workgroups or forming a subset "core team" can mitigate delays. A central repository to share documentation and facilitate communication is crucial. Dedicated project management support is imperative to ensure timelines and deliverables are met and to keep the project within scope.

Year 1 Workgroups (Descriptive Analyses):

- Insulins (Aetna)
- Granulocyte-colony stimulating factors (HealthPartners)
- Anti-Inflammatories (HealthCore)
- Erythropoiesis-stimulating agents (HPHCI)

Year 2 Workgroups:

- Comparative Effectiveness Research (CER) Methods (Optum)
- ICD-10 Mapping (Brigham and Women's Hospital)
- NDC/Jcodes (HealthCore)
- Switching (Brigham and Women's Hospital)

Year 3 Workgroups:

- Oncology (Optum)
- GCSF CER (HealthPartners)

CONCLUSION

Managing a multi-use, multi-site DRN is complex. The complexity is heightened with an intricate governance structure that includes multiple stakeholder groups. Constant assessment, responsiveness to a fluid environment, effective communication and clear expectations are essential to success.

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