

Biologics & Biosimilars Collective Intelligence Consortium Awarded \$1.4 Million Grant From the FDA

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ALEXANDRIA, Va.--(BUSINESS WIRE)-- TheBiologics & Biosimilars Collective Intelligence Consortium (BBCIC) today announced that it has been awarded a \$1.4 million grant from the Food & Drug Administration (FDA) to enable biosimilar research. The grant will support a new BBCIC study focused on identifying opportunities and challenges in using foreign real-world data (RWD) to accelerate the biosimilars approval process.

The study, "Bridging the Gap: Using Foreign Real-World Data to Inform Interchangeable Biosimilar Approvals," will leverage RWD from the United States, Italy, and Denmark to develop recommendations to the FDA on how to address the challenges of using foreign RWD in its regulatory decision-making process for biosimilars. Co-investigators on this study include Dr. Gianluca Trifirò, Professor of Pharmacology at the University of Verona, and Dr. Jesper Hallas, Professor of Clinical Pharmacology at the University of Southern Denmark.

"The current approval process for biosimilar products is complex, delaying patients' access to cost-effective therapies," said Cate Lockhart, Executive Director of the BBCIC. "Using real-world data from foreign countries could help improve the FDA's work and ultimately help patients receive access to approved therapies in a timelier manner. We're proud that the FDA has awarded BBCIC this grant to fund our study, which aligns with the FDA's mission to make safe and effective drugs available to patients nationwide."

The Academy of Managed Care Pharmacy (AMCP) established the BBCIC in 2015 to address anticipated needs for evidence generation for novel biologics, their corresponding biosimilars, and other related products. AMCP remains committed to supporting BBCIC's mission of generating reliable real-world evidence that examines the safety and effectiveness of biologics in order to improve public health and provide high-quality and cost-effective medications

to millions of patients across the United States.

About BBCIC

The BBCIC is a collaboration of managed care organizations, integrated delivery systems, pharmacy benefit management firms, research institutions, and pharmaceutical companies. The BBCIC is the only research network dedicated to post-marketing assessment of biosimilars. To date, the following organizations have made financial and in-kind commitments: AbbVie, Aetna/CVS Health, Amgen, Anthem/Carelon, Apobiologix, Arthritis Foundation, Boehringer Ingelheim Pharmaceuticals, Inc, Express Scripts, Inc., Group Health Cooperative/Kaiser Permanente of Washington Research Institute, Harvard Pilgrim Health Care Institute, HealthPartners Institute, Henry Ford Health System, Hematology Oncology Pharmacy Association, IQVIA, Momenta Pharmaceuticals, Inc., Merck, Optum, Patient Advocate Foundation, Pfizer, and Sandoz.

For more information, visit www.BBCIC.org.

About AMCP

AMCP is the professional association leading the way to help patients get the medications they need at a cost they can afford. AMCP's diverse membership of pharmacists, physicians, nurses, biopharmaceutical professionals, and other stakeholders leverage their specialized expertise in clinical evidence and economics to optimize medication benefit design and population health management and help patients access cost-effective and safe medications and other drug therapies. AMCP members improve the lives of nearly 300 million Americans served by private and public health plans, pharmacy benefit management firms, and emerging care models.

For more information, visit www.amcp.org.

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