Real-World Research

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Agenda

What is BBCIC?

- Overview
- Participants
- Governance Structure

Current Research

- FDA Grant: 1U01FD007757-01

New Research

- FDA Grant: 1U01FD008041-01

BBCIC
Biologics & Biosimilars
Collective Intelligence Consortium

BBCIC Mission: **To generate reliable real-world evidence that examines the safety and effectiveness of biologics in order to improve public health.**

A non-profit, multi-stakeholder, scientific collaborative – an active and established research function at AMCP.

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BBCIC Overview

Since 2015…

Neutral convener of diverse stakeholders

A think-tank of some of the sharpest minds in **real-world evidence** generation. Every participant has a voice on BBCIC Governance Committees and Research Teams

Paving the way for real-world research

Thinking outside the box. **Advancing the discipline** of real-world evidence, data science, and research methods

Robust and rich data network

Leverages the FDA Sentinel System curated data and analytic toolkit. Research at a unique scale – access to **over 90 million patient lives** in the BBCIC distributed research network

Transparent, Science-Driven Research

Diversity of research topics: Exploring the tough questions with scientific rigor in a collaboration of experts

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BBCIC Participants

AMGEN®

Arthritis Foundation®

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

Boehringer Ingelheim

Elevance Health
carelon℠

CVSHealth
Clinical Trial Services

EXPRESS SCRIPTS®

DEPARTMENT OF POPULATION MEDICINE
HARVARD MEDICAL SCHOOL
Harvard Pilgrim Health Care Institute

HealthPartners® Institute

IQVIA

Optum

PAF Patient Advocate Foundation
Solving Insurance and Healthcare Access Issues | since 1996

PearlDiver™ Healthcare Research

Pfizer

SANDOZ A Novartis Division

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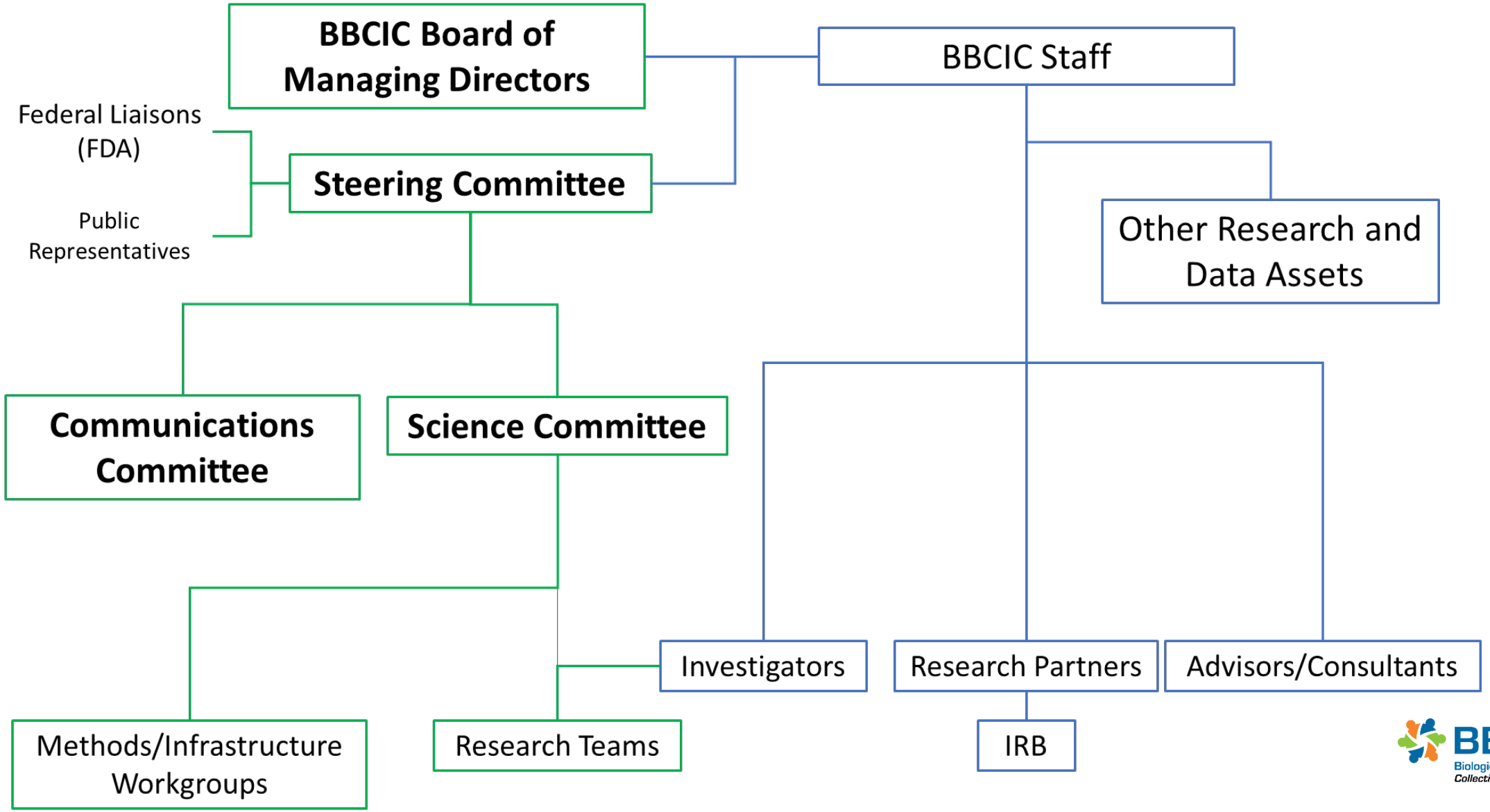
BBCIC Governance



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Grant ID: 1U01FD007757-01

Project Title: Improving the Efficiency of Regulatory Decisions for Biosimilars and Interchangeable Biosimilars by Leveraging Real-World Data to Produce Real-World Evidence

September 2022 – August 2024

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Context and Definitions

Real-World Data (RWD)	Patient DATA collected from a variety of sources	• Electronic health records (EHR) • Insurance claims • Registries • Patient-generated
Real-World Evidence (RWE)	Clinical EVIDENCE derived from analysis of RWD	• Randomized trials • Pragmatic trials • Observational studies

Why? → 21st Century Cures Act (2016)

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https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

Project Overview

- Objective: To assess the potential of real-world data (RWD) and real-world evidence (RWE) to streamline the pre-market regulatory approval process of biosimilars and interchangeable biologics

Specific Aim 1	• Determine the quality of RWD and the relevance of RWE for regulatory decision-making
Specific Aim 2	• Use RWD/RWE to emulate an FDA evaluation of interchangeability of a biosimilar drug

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Project Overview

Specific Aim 1

- Determine the quality of RWD and the relevance of RWE for regulatory decision-making

Task 1a: Literature Review

Search strategy: (real world OR real-world OR real-world data OR real-world evidence) AND (regulatory OR FDA OR Food and Drug Administration OR EMA OR European Medicines Association)

11,050 References Identified
7,307 Unique References

Task 1b: Regulatory Assessment

18+ products approved with RWD

Task 2: Expert Panel

Task 3: Quality of RWD

Task 4: Relevance of RWE

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Project Overview

Specific Aim 2

- Use RWD/RWE to emulate an FDA evaluation of interchangeability of a biosimilar drug

Task 1: Test Case Selection

Task 2: Target Trial Emulation

- Target trial emulation criteria:
  1. Eligibility criteria
  2. Treatment strategies being compared
  3. Assignment procedures
  4. Follow-up period
  5. Outcomes of interest
  6. Causal contrast(s) of interest
  7. Analysis plan

Task 3: Analysis Across Data Sources

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Grant ID: 1U01FD008041-01

Project Title: Bridging the Gap: Using Foreign Real-World Data to Inform Interchangeable Biosimilar Approvals

September 2023 – August 2025

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Project Overview

- Objective: To assess the quality, completeness, relevance, and fitness for use of non-US data for US FDA regulatory decisions.

Specific Aim 1	• Evaluate the feasibility and validity of a biosimilar interchangeability (e.g., switching) study using real-world data from the United States and sources from outside the United States
Specific Aim 2	• Develop recommendations for the FDA on how to address the challenges of using real-world data from outside the United States in its regulatory decision-making processes

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Summary

- Two proposals awarded to BBCIC
- Advancing the use of RWD
- Supporting regulatory efficiency

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Thank You!!!

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