DIA 2018
GLOBAL ANNUAL MEETING
BOSTON | JUNE 24-28

Thursday, June 28, 2018
Room 204AB

Track 01: Clinical Safety and Pharmacovigilance
Session 404: Payers, Industry and Academia Collaborating on Post-Marketing Surveillance

The BBCIC: Governance and Scientific Operation of a Multi-stakeholder Scientific Research Consortium

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Disclosures

- **Charlie Barr** is a **current employee** of the AMCP BBCIC, LLC
- **Former employee** of Genentech, Roche, Pfizer, Pharmacia and others
- **Financial:** Stock in Roche/Genentech, mutual funds

Agenda 9:00 to 10:15am

- **Charlie Barr**, Chief Science Officer, BBCIC
  - *Governance and Scientific Operation of a Research Consortium (10 min)*
- **Kevin Haynes**, Director of Clinical Epidemiology, HealthCore
  - *Payer contributions to biosimilar safety surveillance (16 min)*
- **Nancy Lin**, Senior Scientist, Optum Epidemiology
  - *Research challenges in biosimilar safety and surveillance (16-18 min)*
- **Hillel Cohen**, Executive Director Scientific Affairs, Sandoz
  - *Pharmaceutical industry experience with biosimilar postmarketing safety (18-20 min)*
- **Discussion and Q&A** (10-15 min)

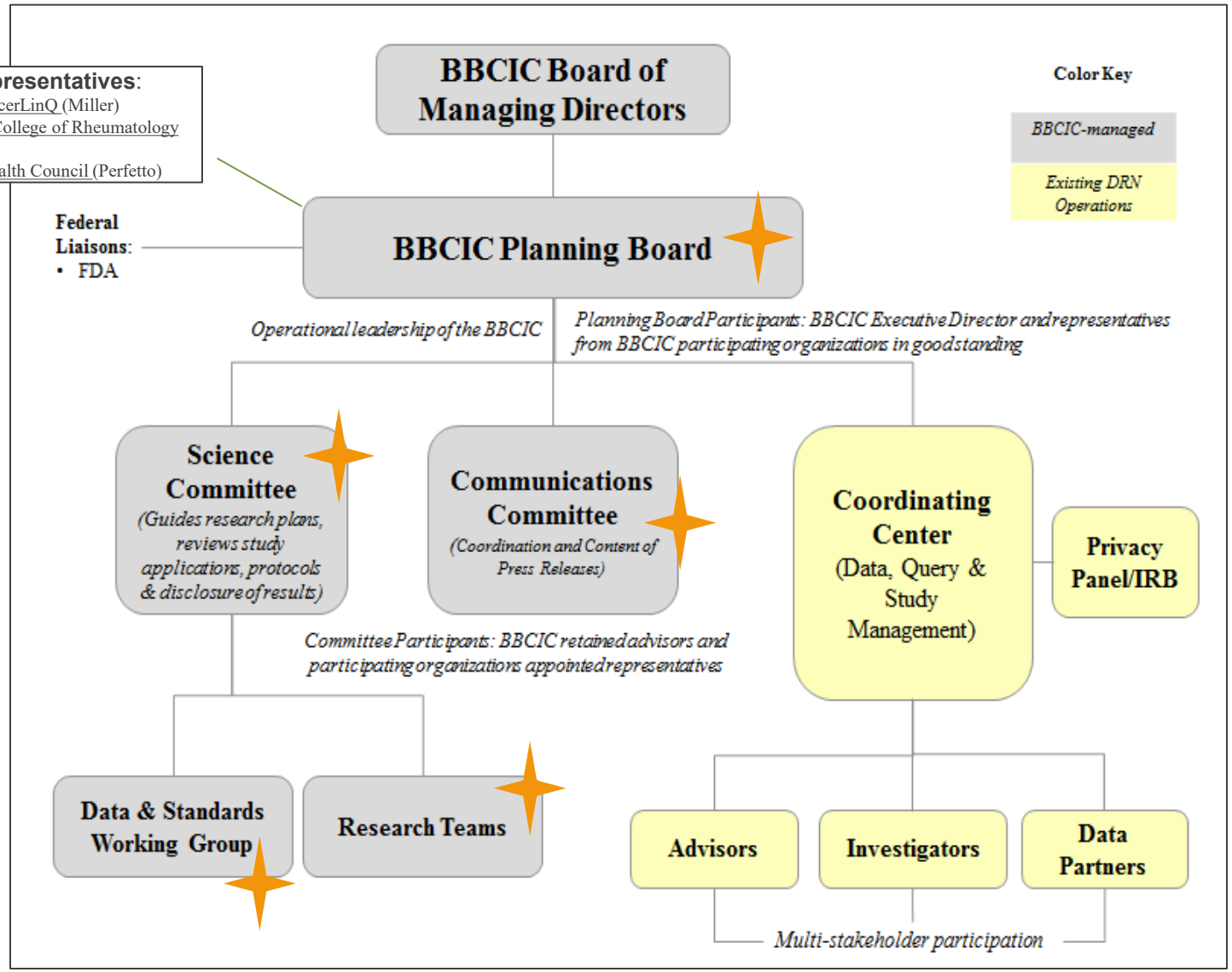
Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)

- Multi-stakeholder, non-profit, scientific public service initiative that will monitor biosimilars and corresponding novel biologics for effectiveness and safety

- **Mission**: To provide a range of research services that support the following value propositions
  - Address important questions about the use, impact, safety, and clinical effectiveness of biologics and biosimilars on human health.
  - Increase the rigor and credibility of real world evidence
  - Provide access to a large population for epidemiologic studies and health services research
  - Improve the efficiency and cost-effectiveness of post-marketed observational studies
  - Develop standard approaches to common data needs and address gaps in tools and methods

www.bbcic.org

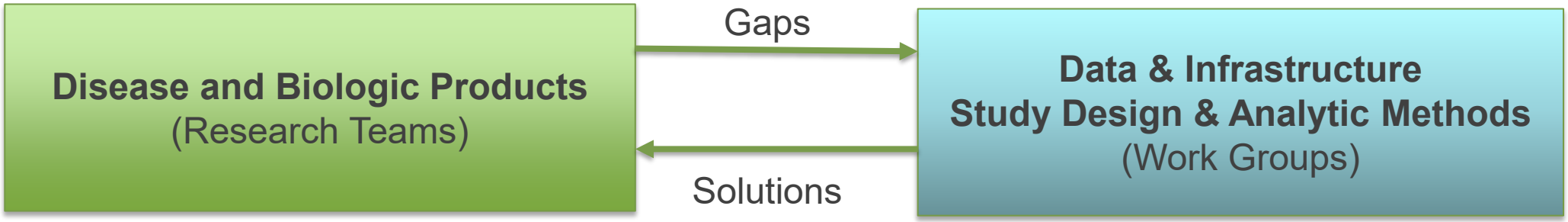
BBCIC Governance



Strengths of BBCIC

- **Stakeholders** play an active and extensive role
- **Focus** on biologic class and diseases for new biosimilars
- **Descriptive analysis**
  - To understand patients, disease, treatments, outcomes
  - To understand data, methods, gaps, possible solutions
- **Comparative analysis**
  - Both safety and effectiveness
  - All biosimilars for originator biologic
- **Active surveillance**
- **Leverage Sentinel**

BBCIC Scientific Operations



Part 1. Descriptive Studies
- ESAs
- GCSF
- Insulins
- Anti-Inflammatory agents

Part 2. Hypothesis-driven Comparative Safety and Effectiveness Studies

<u>Data Availability & Characterization</u>
- Capture of NDC on medical claims
- Impact of ICD-9 to ICD-10 transition and algorithms for mapping

<u>Study Design & Methods</u>
- Switching study design & analytic approaches (anti-inflammatories)
- Comparative safety & effectiveness study design & analytic approaches (insulins)

Joint ISPOR/ISPE Task Force and Summit on RWE in Health Care Decision Making Oct. 20, 2017

Three articles published jointly in 2017:

- *Pharmacoepidemiology and Drug Safety*
- *Value in Health*

- Berger ML, Sox H, Willke RL, et al. **Good practices** for RWD studies of treatment and/or comparative effectiveness.
- Wang S, Schneeweiss S, Berger ML, et al. **Reporting** to improve **reproducibility** and facilitate **validity assessment** for healthcare database studies v1.0.
- Greenfield S. Making RWE more useful for **decision making**.

ISPOR: International Society of Pharmacoeconomics and Outcomes Research
ISPE: International Society of Pharmacoepidemiology

Good Practices for RWE Studies of Treatment Effectiveness and Comparative Effectiveness

7 Recommendations of Joint ISPOR/ISPE Task Force:

- **Define study** (questions and purpose)
  - *Exploratory*
  - *Hypothesis evaluating treatment effectiveness* (HETE)
- **Public posting** of **study protocol** and **analysis plan**
- **Publish study results** (or post on website)
- **Enable replication** (same data and analyses)
- **Confirm important findings** (2nd data source & population)
- **Publicly address methodologic criticism** after publication
- **Include key stakeholders** in design, conduct & dissemination

Berger ML, Sox H, Willke RJ et al. *Value in Health* 2017;20:1001-8

Seeking gold standard evidence

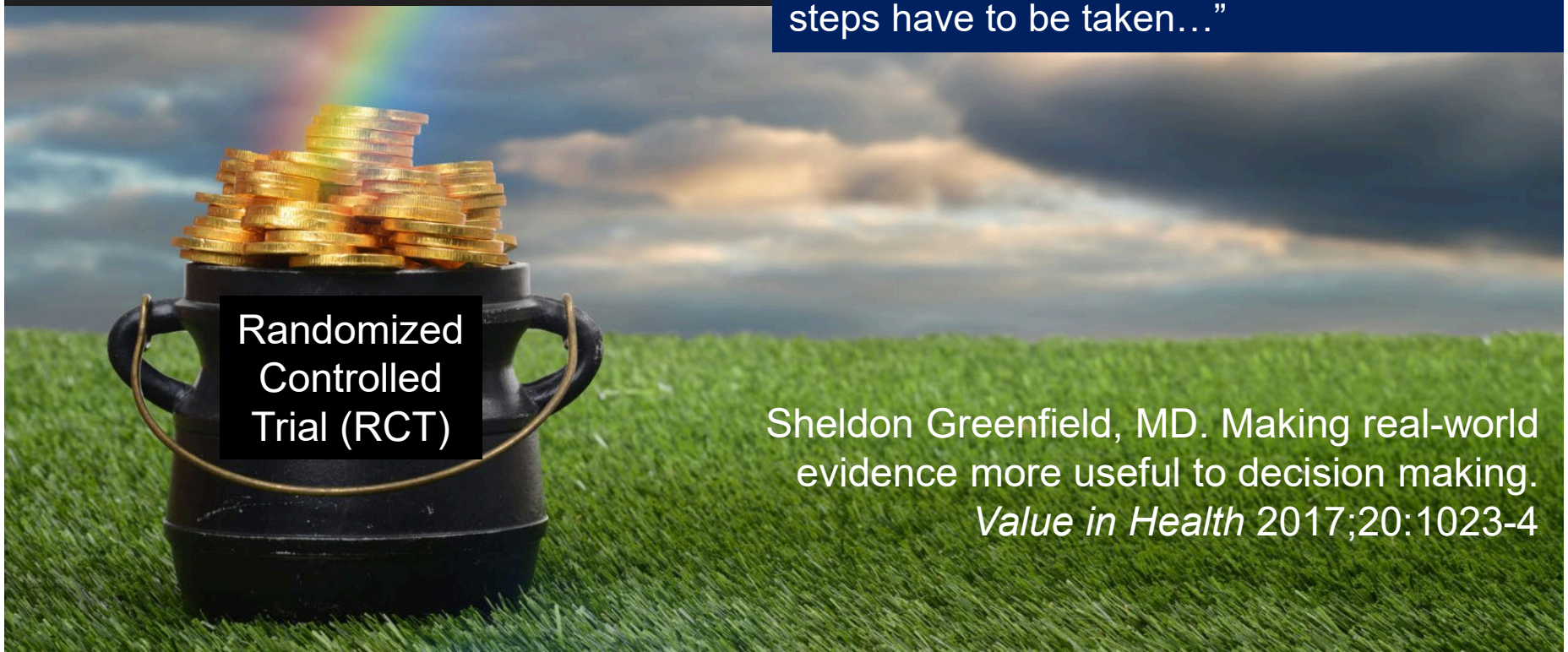
"…RCT* data are also increasingly being seen as problematic not only because of

- the [high] costs,
- the [short] length of the studies, and
- the exclusion of major segments of the population

but also because of the controversies surrounding RCT interpretation."

"Real-world evidence (RWE) holds enormous promise, with some of that promise beginning to be realized in the evaluation of harms.

However, in order to accomplish major strides in harms assessment, and ultimately in the evaluation of effectiveness, many steps have to be taken…"



Sheldon Greenfield, MD. Making real-world evidence more useful to decision making. *Value in Health* 2017;20:1023-4

Advancing the science of real-world evidence

"The ISPOR paper lays out the potentially solvable barriers in its general recommendations. The recommendations are parsimonious and refer to the companion paper by developed by ISPE…on the transparency needed for reproducibility."

"The goal is praiseworthy because of the aspiration to be able to draw 'causal conclusions' in combination with experimental studies [RCTs]…"

"Multiple converging sub-studies from the same populations, or independent studies combining multiple data sources, could bring real-world data closer to 'causality' and could be perceived as acceptable alternatives to randomized trials."

Sheldon Greenfield, MD. Making real-world evidence more useful to decision making. *Value in Health* 2017;20:1023-4

Using the best available evidence

- "Many questions about a drug remain unanswered at the time of approval"
- "It is not feasible to answer all of these questions with traditional RCTs."
- "The FDA uses RWE for regulatory decisions, albeit primarily related to safety. Nevertheless, for some drugs, the demonstration of efficacy has been based on RWE from case series or registries."

Jonathan P. Jarow, Lisa LaVange, Janet Woodcock.
Multidimensional Evidence Generation and FDA Regulatory Decision Making Defining and Using "Real-World" Data.
Journal of the American Medical Association (JAMA) 2017;318(8):703.

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Thank You

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