

2017 IMPACT REPORT

Harmonizing THE CLINICAL TRIAL ECOSYSTEM



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Dear MRCT Center Friends and Colleagues,

2017 was a year of transitions, opportunities, and accomplishments at the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). As always, we wish to thank you all—our colleagues, sponsors, partners, and friends—for making the year as dynamic and productive as it has been.

The MRCT Center is continuing to promote transparency and responsible sharing of clinical trial research data. Vivli, the data-sharing platform that grew out of the collaborative efforts of MRCT Center stakeholders, was incorporated and awarded non-profit, tax-exempt status this year. Rebecca Li became the Executive Director of Vivli, transitioning to Special Advisor at the MRCT Center. The Vivli platform is a unique partnership with Microsoft and BlueMetal, with its first public preview scheduled for our Annual Meeting. In the meantime, the MRCT Center is developing fit-for-purpose prototype templates that will address governance issues in data sharing. With the European Medicines Agency, we are analyzing the dueling expectations of protecting participant privacy, on the one hand, and anonymizing participant-level data while preserving data quality, on the other.

Our training efforts have grown significantly this year. We hosted the first pilot training on ICH E6(R2), convening regulators and investigators from 14 countries for on-site training at the MRCT Center. We plan to continue to develop our training capacity—providing a home and resource to global regulators and others.

We have made substantial progress on a number of existing projects. The MRCT Center Workgroup on the Return of Individual Results completed its framework guidance and toolkit, which addresses the complexity of sharing

genetic data. With TransCelerate, the MRCT Center submitted a draft guidance to the FDA on the return of plain language summaries to participants. The Post-Trial Responsibilities Workgroup finished both a guidance document and a toolkit.

The MRCT Center has launched several new projects in 2017, two of which are related to the utility and limitations of real world evidence in regulatory decision-making. We are partnering with the Duke-Margolis Center on a project to understand the theoretical framework for real world evidence. In addition to this project, we are collaborating with OptumLabs and others to develop empirical data through retrospective analysis of claims and electronic health data.

On our horizon is a new project to address the lack of diversity in clinical trials—a problem that must be solved, but for which ready answers are currently lacking. This project emanated directly from extensive discussion at the May meeting of the MRCT Center Bioethics Collaborative.

Our work in 2017 illuminates the strength of cooperation, the ability of diverse stakeholders to address complex questions together, and our shared commitment to transforming clinical research.

To our sponsors, we are sincerely grateful for your unwavering support, participation, and engagement. To our collaborators, this work would be impossible without you. To our External Advisory Board, we appreciate your guidance and helpful direction. To our patient advocates and participants, your altruism and humanity sustains us and drives our work. We hope to deserve your confidence as we continue to promote the ethical conduct of clinical trials worldwide.



Barbara Bierer

Barbara Bierer, MD
Faculty Director



Mark Barnes

Mark Barnes, JD, LLM
Faculty Co-Director



R. A. Li

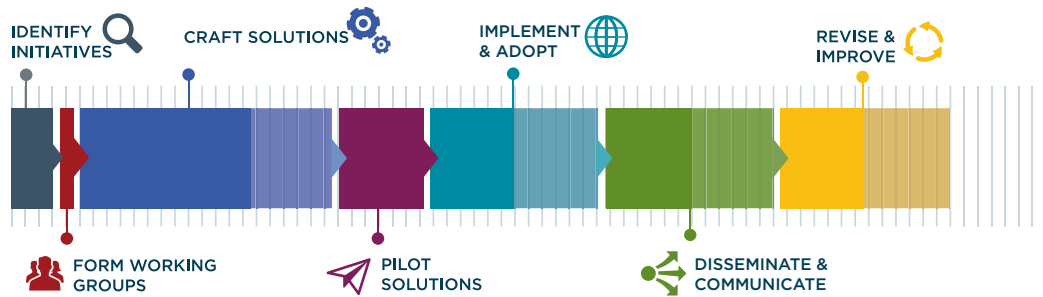
Rebecca Li, PhD
Senior Advisor

OUR VISION

Improve the integrity, safety, and rigor of global clinical trials.

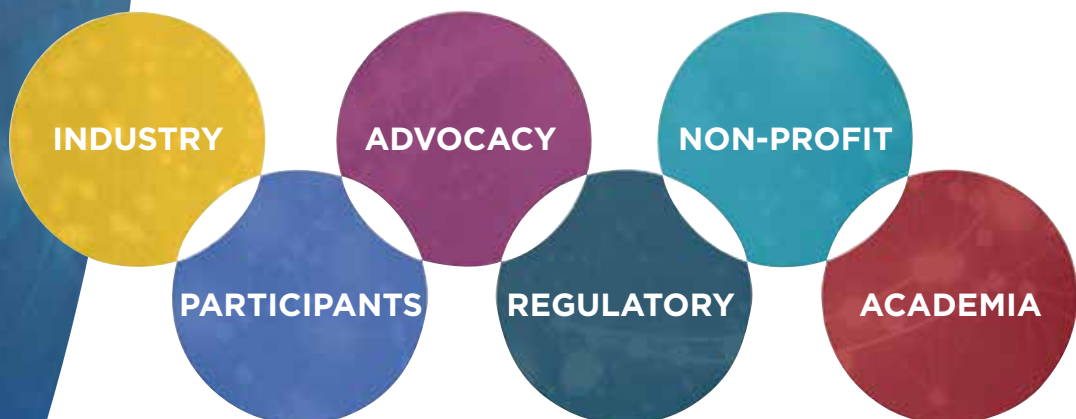
OUR MISSION

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.



OUR COMMUNITY

The MRCT Center functions as a neutral convener for stakeholders from industry, academia, participant and patient advocacy groups, non-profit organizations, and regulatory agencies to take on critical issues in the conduct and oversight of international clinical trials. Working in the pre-competitive space, our multidisciplinary teams foster respect for clinical trial participants by working to improve the ethics, safety, and transparency of clinical trials.

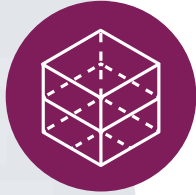




PROMOTING Harmonization

We believe in the extraordinary potential of clinical trials to transform scientific knowledge and public health. By working with diverse stakeholders to develop principles, training efforts, technical and practical guidelines, toolkits, and resources for the design and conduct of international clinical trials, we aim to protect the rights and welfare of clinical trial participants and to ensure the scientific validity of resulting studies.

FOCUS AREAS



DATA TRANSPARENCY: We reduce barriers to clinical trial data sharing and develop practical, actionable solutions, including platform technologies (e.g., Vivli) and models for appropriate governance. We honor clinical trial participants by developing guidance for safeguarding participant privacy, return of aggregate and individual results, and plain language communication.



ETHICAL FRAMEWORKS: We develop guidance, resources, and tools that promote safe and ethical clinical trials.



GLOBAL REGULATORY: We engage global regulatory leaders to promote convergence between country-specific regulations and internationally accepted guidance. Our approach involves working with local partners to develop country-specific and culturally-relevant solutions to emerging issues in international clinical trials. We are helping to develop an approach to, and an understanding of, the utility and limitations of real world evidence to support global regulatory decision-making.



TRAINING: We build capacity by training regulatory authorities and clinical trial professionals with a particular focus in low- and middle-income countries.



GLOBAL REGULATORY

REAL WORLD EVIDENCE

The regulatory framework by which real world evidence (RWE) is used to support regulatory decision-making is currently being defined in an international context. The MRCT Center is involved in multiple projects to help define data sources, study design, statistical approaches, and policies to support the application of RWE in drug development.

FOCUS ON REGULATORS

The MRCT Center strives to engage regulators and influential thought leaders around the world to develop authentic partnerships with those who seek to improve the ethics and design of multi-regional clinical trials. As advisors and trainers, we provide both international perspectives on country-specific issues, and recommendations to regulators and clinical researchers.

Over the last four years, the MRCT Center has worked closely with India's health and policy leaders to determine tractable solutions to regulatory reform issues. In 2017, the MRCT Center submitted substantive comments to the Indian authorities related to provisions on post-trial access, compensation and medical management, ancillary care, ethics committees, and informed consent.

GLOBAL REGULATORY CAPACITY-BUILDING

We engage stakeholders in assessing the changing clinical trial regulatory environment, in understanding and improving clinical trial regulations, and in promoting science and public health. As an Asian Pacific Economic Corporation (APEC) Pilot Center of Excellence, we have focused our training on global regulators — advancing good clinical practice (GCP) and ICH guidelines in clinical trial design and conduct.

UNDERSTAND

ENGAGE

ACT

Milestones

MAY 2017: Submitted comments to India on draft new rules for drugs and clinical trials.

JULY 2017: Launched RWE projects in collaboration with (1) Duke-Margolis Center and (2) OptumLabs.

OCTOBER 2017: Conducted ICH E6 (R2) training of regulators and others.

PLANNED

WINTER/SPRING 2018: MRCT Center and Indian Council of Medical Research Joint Conference.

APRIL 2018: APEC pilot Center of Excellence training on MRCTs and newly developed ICH-E17 guidelines.

TRAINING

TRAINING FOR GLOBAL REGULATORS

The skills and experience of regulators, investigators and study staff, research ethics boards, coordinators, and data monitoring committees vary widely around the world. In 2017, the MRCT Center has focused on inviting international regulators and key clinical research leaders to onsite training at Harvard.



Participants of October 2017 ICH GCP pilot training event for global clinical regulators.

ICH GCP TRAINING

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) endorsed a training effort to ensure proficiency and understanding of ICH guidelines by regulators and industry. The MRCT Center was selected to conduct the first training in 2017. A multi-stakeholder program committee planned and, in October 2017, conducted the Good Clinical Practice (GCP) pilot training for regulators from emerging economies, which focused on ICH E6(R2).



Promotional flyer for ICH GCP Training. The October ICH training engaged 25 participants from 14 countries. We appreciate the dedication and commitment of 6 experienced trainers.

Milestones

FEBRUARY 2017: MRCT Center endorsed as Pilot Center of Excellence for Multi-Regional Clinical Trials (MRCTs) and Good Clinical Practice (GCP).

MARCH 2017: MRCT Center selected to conduct pilot training on ICH guidelines.

MAY 2017: First planning committee meeting for ICH E6(R2) pilot training.

JUNE 2017: First planning committee meeting for APEC CoE pilot training.

OCTOBER 2017: 3-day pilot training at Harvard on ICH E6(R2) GCP.

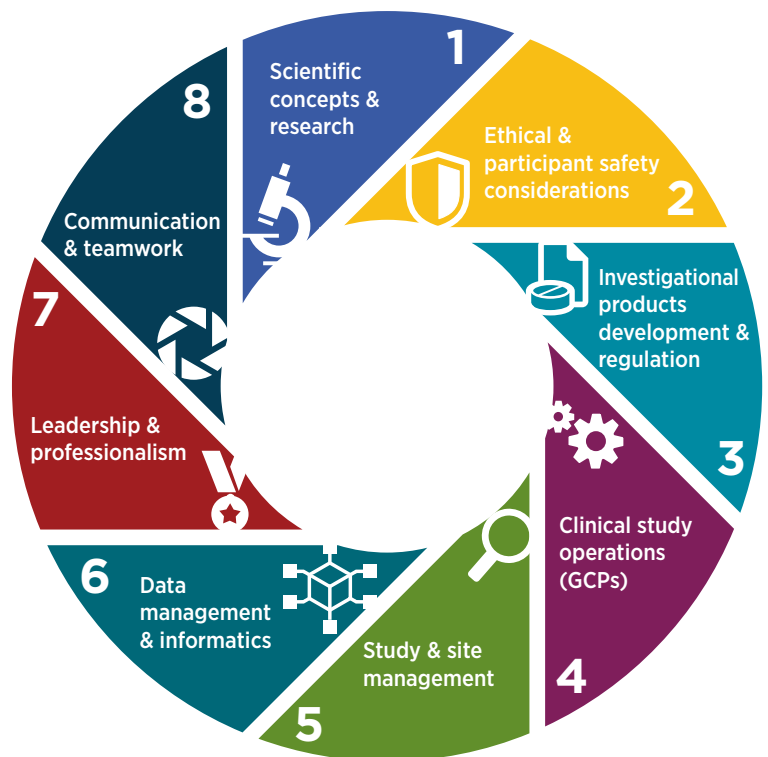
CORE COMPETENCIES OF CLINICAL RESEARCH PROFESSIONALS

The MRCT Center anchors the Joint Task Force for Clinical Trial Competency (JTF), which has developed a Harmonized Core Competency Framework to align clinical investigators and study staff worldwide around a comprehensive set of competencies for the profession.

In 2017, the JTF released the Core Competency Framework Version 2.0, integrating suggested changes from those who have utilized the framework over the last three years. In addition, the JTF created a website (<https://www.clinicaltrialcompetency.org>) to make resources and educational materials widely available.

“For the first time, a universally applicable, globally relevant framework exists that identifies the competency domains and the associated cognitive skills necessary to conduct a high-quality, ethical, and safe clinical trial.”

— Member of the Joint Task Force for Clinical Trial Competency



Harmonized Core Competency Framework, updated based on user feedback
See <http://www.clinicaltrialcompetency.org/framework-1/>

Milestones

MAY 2017: Joint Task Force for Clinical Trial Competency launched website at ClinicalTrialCompetency.org.

SEPTEMBER 2017: Joint Task Force for Clinical Trial Competency launched Version 2.0 of Core Competency Framework.

DECEMBER 2017: Joint Task Force introduced escalating competencies to enable professional development from the fundamental level to more advanced levels.



ETHICAL FRAMEWORKS

BIOETHICS COLLABORATIVE

As an innovative and neutral forum, the MRCT Center Bioethics Collaborative convenes diverse stakeholders to discuss emerging issues related to the ethical conduct of global clinical research. Several meetings have taken place:

- **Expanded access to investigational products.** From this, we developed a Toolkit and *Points to Consider on Expanded Access to Investigational Products* for Investigators, Sponsors, and IRBs, released in late 2017.
- **Early termination of clinical trials for operational, institutional, or commercial reasons.** Premature termination generally results in abrogation of generalizable knowledge—to the detriment of clinical trial participants who have accepted risk without the possibility of benefit.
- **Representation of race, ethnicity, gender, and sex in clinical trials.** On the basis of this discussion, the MRCT Center launched a new project on Diversity in Global Clinical Trials.
- **Recruitment of and fair payment to international research participants.** Currently, there is a lack of comprehensive, operational frameworks to guide investigators in designing, and IRBs in evaluating, recruitment methodologies and payment proposals for international research participants.



MULTI-REGIONAL CLINICAL TRIALS
BIOETHICS
COLLABORATIVE

SPONSORS

- Genentech, Inc.
- Johnson & Johnson
- Merck & Co., Inc.
- Pfizer, Inc.
- Sanofi
- Takeda Pharmaceuticals U.S.A., Inc.

PLANNING COMMITTEE MEMBERS

- Christine Grady
Department of Bioethics, National Institutes of Health
- Nina Hill
Pfizer, Inc.
- Ariella Kelman
Genentech, Inc.
- Craig Lipset
Pfizer, Inc.
- Sandra Morris
Johnson & Johnson
- Jessica Scott
GlaxoSmithKline
- Jina Shah
Genentech, Inc.
- Lana Skirboll
Sanofi
- Kathleen Stern
Takeda Pharmaceuticals U.S.A., Inc.
- Walter Straus
Merck & Co., Inc.
- Robert Truog
Center for Bioethics, Harvard Medical School



DATA TRANSPARENCY

The MRCT Center supports the sharing of research results from clinical trials with study participants, including summary results in plain language and individual study results (e.g., results of and assignment to study arm, incidental findings, and clinical and research results).



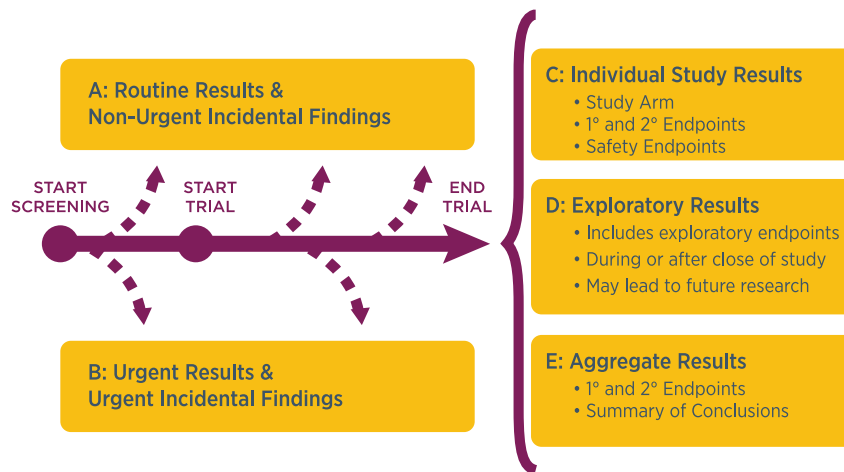
RETURN OF AGGREGATE RESULTS

The Aggregate Results Guidance Document and Toolkit were updated to correspond with the newly released European Commission’s guidance. In collaboration with TransCelerate Biopharma, and with the support of > 30 signatories, we submitted a Draft FDA Guidance on Provision of Plain Language Summaries (<https://www.regulations.gov/docket?D=FDA-2017-D-5478>).



RETURN OF INDIVIDUAL RESULTS

We finalized the Recommendations Document and Toolkit on sharing individual results, which address genetic and genomic data. We conducted an international survey to learn more about communication between sponsors, principal investigators, and study participants. Survey results reveal strategies for improving and refining the transmission of information.



Milestones

MARCH 2017: Released Version 3.0 of MRCT Return of Aggregate Results Guidance document and Version 3.0 of MRCT Return of Aggregate Results Toolkit.

JUNE & SEPT 2017: Submitted Draft Guidance on Provision of Plain Language Summaries to FDA (<https://www.regulations.gov/docket?D=FDA-2017-D-5478>).

JULY 2017: Presented results of a survey about participant preferences for sharing research results, in collaboration with MGH Benson-Henry Institute, CIMI, and DCUMC.

OCTOBER 2017: Submitted Recommendations Document for Return of Individual Results to National Academy of Science, Engineering and Medicine Consensus Study.

DECEMBER 2017: Released Return of Individual Results Recommendations Document and Toolkit for Return of Individual Results to Participants.

HARMONIZED GOVERNANCE TOOLS

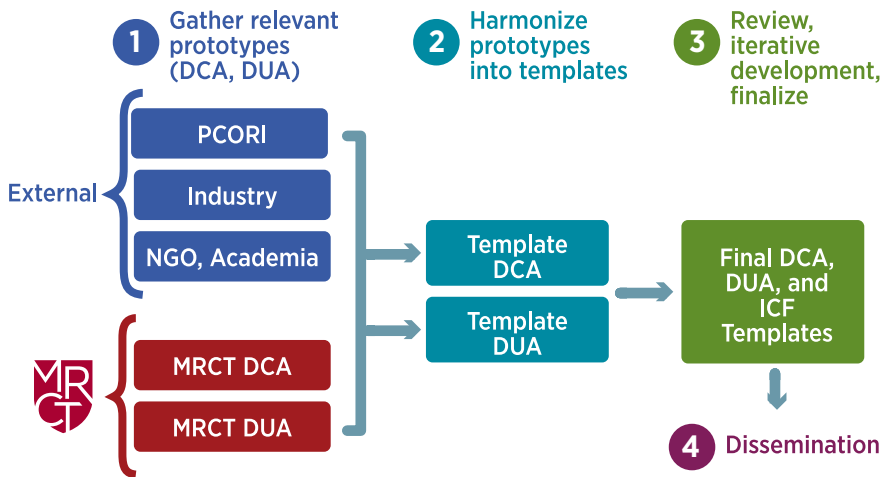
Data sharing allows sponsors and investigators to honor the essential contributions and volunteerism of clinical trial participants, to ensure reproducibility, and to enable the maximal use of data by the research community. Despite a willingness to share data, however, contractual agreements for data can pose barriers, thereby delaying and limiting the potential for data sharing.

The MRCT Center has initiated efforts to harmonize data sharing governance processes, including data use agreements (DUAs), data contributor agreements (DCAs), and participant informed consent language (ICF Templates). We are partnering in these efforts with the Patient-Centered Outcomes Research Institute (PCORI), the Vivli Center for Global Clinical Trial Research Data, and others.

Milestones

JUNE 2017: MRCT Center and PCORI Kickoff Meeting.

SEPTEMBER 2017: First PCORI Open Science Pilot Project Meeting.



Development plan for harmonized governance tools



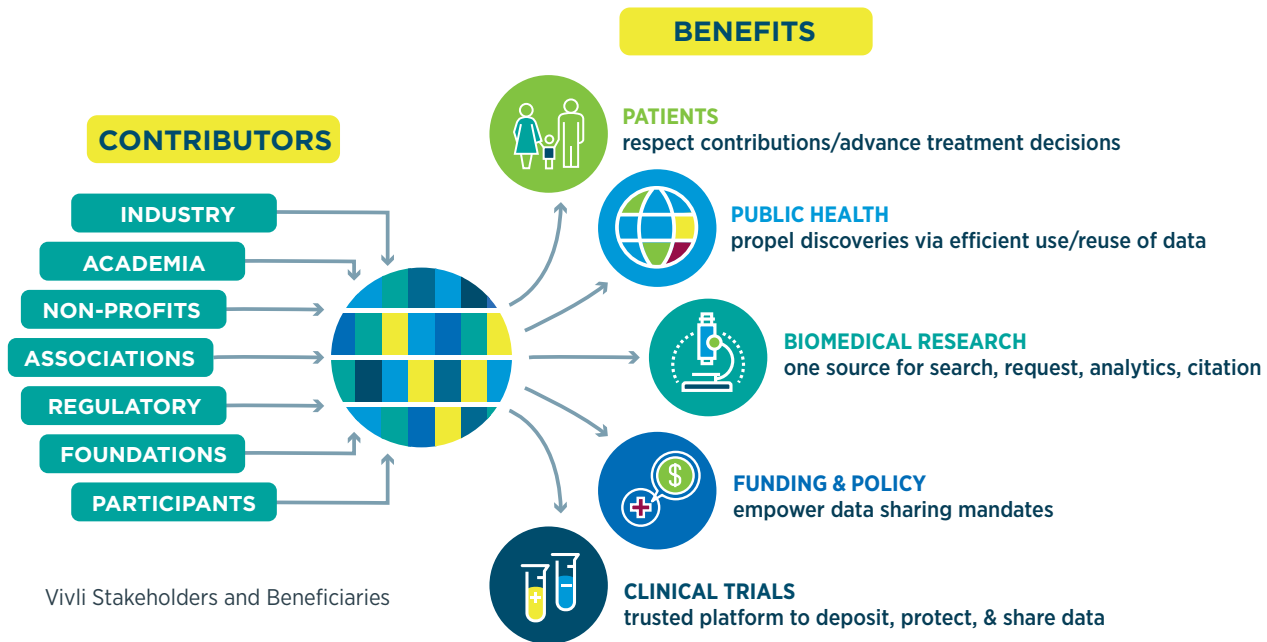
DATA TRANSPARENCY

VIVLI CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Since 2015, when we received the initial grant from the Laura and John Arnold Foundation to initiate the work towards launching Vivli as an independent entity, we have taken major steps forward in designing and realizing the vision of building a universal platform for clinical research data.



A not-for-profit 501(c)(3) entity, Vivli was launched this year as a permanent vehicle for the development, management, and governance of a global clinical research data-sharing platform.



Milestones

MARCH 2017: Vivli attains 501(c)3 non-profit status and launches as an independent entity.

APRIL-AUG 2017: Vivli convenes the Board of Directors and secures initial funding.

JULY 2017: Vivli selects Microsoft as its strategic IT partner in developing the Vivli platform.

DECEMBER 2017: First public preview of Vivli platform.

DATA AUTHORS AND CREDIT FOR DATA SHARING

Increasingly, biomedical sciences are a data-driven endeavor. When publications rely on data that have been previously generated and shared, the contributions of the original data generators are not recognized in a systematic and standardized way. The MRCT Center, in collaboration with the Association of American Medical Colleges and the New England Journal of Medicine, is developing the criteria and system for recognition of generators of data in a way that is meaningful, standardized, and accepted by researchers, academic institutions, journals, and funders.

Milestones

MAY 2017: Kick-off teleconference.

JULY 2017: In-person planning meeting at the *New England Journal of Medicine*.

SEPTEMBER 2017: Technical and Integration Meeting.

PLANNED

EARLY 2018: Conference on Credit for Data Sharing.



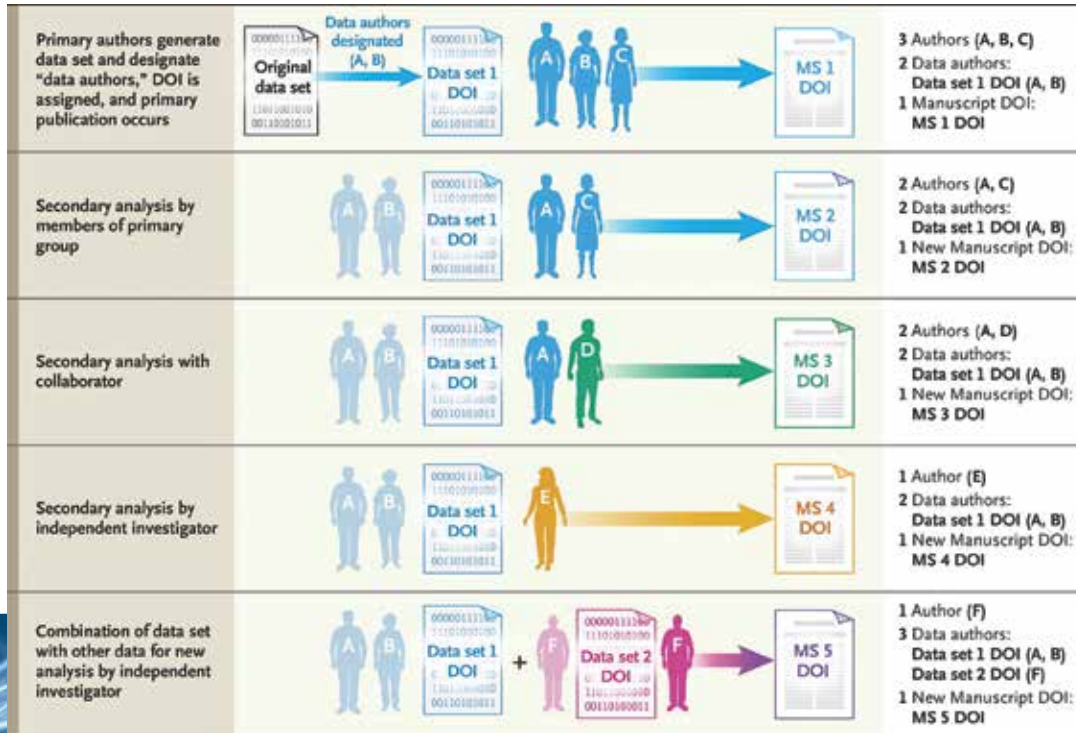
The NEW ENGLAND JOURNAL of MEDICINE



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

By developing a systematized, consistent, and universal method for giving credit to researchers who generate, manage, and/or share data, we seek to create legitimate and lasting incentives for data sharing.



Tracing a Data Set to Provide Credit for Data Sharing

From *New England Journal of Medicine*, Bierer BE, Crosas M, Pierce HH, Data Authorship as an Incentive to Data Sharing, 376(17): 1684-1687. Copyright (c) 2017 Massachusetts Medical Society. Reprinted with permission.

PROJECTS INITIATED IN 2017



REPRESENTATION OF DIVERSE POPULATIONS IN CLINICAL TRIALS

In order to produce generalizable knowledge, studies should ideally enroll participants that are representative of the general population or the disease distribution. Nevertheless, in many clinical trials, sex/gender and ethnic diversity is lacking. This presents a problem, since intrinsic and extrinsic factors may affect the safety and efficacy of medicines for certain subgroups. Consequently, the MRCT Center aims to bring together a work group of diverse stakeholders, including academic- and industry-based leaders, not-for-profit and institutional representatives, regulators, and patients/patient advocates to develop a framework and guidance document. This workgroup will highlight the inclusion of diverse populations — with a special focus on sex/gender and ethnic subgroups — in the design, recruitment, methodology, and analysis of multi-regional clinical trials.

REAL WORLD EVIDENCE

Derived from data sources such as electronic health records, claims data, registries, and mobile devices, real world evidence (RWE) has the potential to bring innovative products to patients more quickly. Unlike randomized controlled trials (RCTs), which may not be representative of a general population due to strict inclusion and exclusion criteria, RWE may more closely identify how an investigational product will perform in a general population. To address the absence of widely accepted best practices for utilizing RWE, the MRCT Center embarked on a two-part project to develop and test a framework for using RWE in label expansion of an approved drug.

The two parts of this project are as follows:

- Define a framework to establish best practices for utilizing RWE to pursue label expansion of an approved drug, in collaboration with Duke-Margolis Center.
- OPERAND: An empirical project to understand the utility and limitations of observational data, in collaboration with OptumLabs.

Milestones

MARCH 2017: Started collaborating with Duke-Margolis Center for Health Policy to develop a framework for real world evidence for regulatory decision-making.

SEPTEMBER 2017: Launched Project OPERAND (Observational Patient Evidence for Regulatory Approval and uNderstanding Disease) in partnership with OptumLabs. Convened key stakeholders from industry, academia, and regulatory agencies to discuss appropriate utilization of observational data in comparative effective research and regulatory review/approvals.



SELECTED PUBLICATIONS & ACCOMPLISHMENTS

SELECTED PUBLICATIONS (PLEASE SEE INSET FOR COMPLETE LIST)

HHS Finalizes Comprehensive Revisions to the Common Rule.

Barth A, Peloquin D, **Bierer BE, Barnes M.**

Bloomberg BNA Life Sciences Law & Industry Report 11 LSLR 03. Jan 2017.

Data Authorship as an Incentive to Data Sharing.

Bierer BE, Crosas M, Pierce HH.

New England Journal of Medicine 376(17):1684-1687. Mar 2017.

Reconciling Personal Data Consent Practices in Clinical Trials with the EU General Data Protection Regulation.

Barnes M, Massey R, Peloquin D, Wallace N.

Bloomberg BNA Medical Research Law & Policy Report 16 MRLR 18. Sept 2017.

MRCT CENTER-DEVELOPED RESOURCES

Return of Aggregate Results Guidance Document (Version 3.0)- March 2017

Return of Aggregate Results Toolkit (Version 3.0) - March 2017

Principles of Post-Trial Responsibilities (Version 1.1) - June 2017

Return of Individual Results to Participants: Principles (Version 2.1) - June 2017

Post-Trial Responsibilities Framework: Continued Access to Investigational Medicines Guidance Document (Version 1.1) - June 2017

Post-Trial Responsibilities Framework: Continued Access to Investigational Medicines Toolkit (Version 1.0) - June 2017

Joint Task Force for Clinical Trial Competency (JTF) Harmonized Core Competency Framework (Version 2.0) - September 2017

MRCT Center Expanded Access to Investigational Products Points to Consider for Sponsors, Investigators, and IRBs on Expanded Access to Investigational Products (Version 1.0)- November 2017

Return of Individual Results to Participants Recommendations Document (Version 1.2)- December 2017

Return of Individual Results to Participants Toolkit (Version 1.1)- December 2017

RECOGNITION AND AWARDS

February 2017: MRCT Center endorsed as a Pilot Center of Excellence (CoE) for Multi-Regional Clinical Trials (MRCTs) and Good Clinical Practice (GCP) by the Asia-Pacific Economic Corporation (APEC)

May 2017: MRCT Center selected to conduct first pilot training on Good Clinical Practice (GCP) based upon scientific and regulatory principles outlined in ICH E6(R2) Guidelines by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)



MRCT

MRCT COMMITTEES

Thank you to our sponsors for contributing both expertise and support towards improving the quality standards of clinical trials. Your contributions ensure that we, collectively and collaboratively, commit to the ethical conduct of clinical trials across the globe.

EXTERNAL ADVISORY BOARD (EAB)

Launched in 2016, the EAB reviews and advises the MRCT Center's vision, projects, and long-term strategy. The EAB provides a critical outside perspective on our work. We wish to express our sincerest gratitude to the members of the EAB for their time, expertise, and guidance.

Dr. Bernard Lo (Chair)
Greenwall Foundation

Dr. Joshua Boger
Vertex Founder and former CEO

Dr. Cristina Csimma
*Biopharmaceutical Board Director
and Independent Consultant*

Dr. Jeffrey Drazen
New England Journal of Medicine

Dr. Atul Gawande
Ariadne Labs

Dr. Margaret Hamburg
*Global Advisory Council,
Harvard University*

Dr. Michael Rosenblatt
Flagship Ventures

Dr. Ara Tahmassian
Harvard University

EXECUTIVE COMMITTEE

Amgen, Inc.
Bill & Melinda Gates Foundation
Brigham and Women's Hospital
Eli Lilly and Co.
GlaxoSmithKline
Harvard University
Johnson & Johnson
Kowa Co., Ltd.
Laura and John Arnold Foundation
Merck & Co., Inc.
Pfizer, Inc.
PhRMA
Ropes & Gray LLP
Takeda Pharmaceuticals U.S.A., Inc.

STEERING COMMITTEE

Association for the Accreditation
of Human Research Protection Programs,
Inc. (AAHRPP)
Association of Clinical Research
Professionals (ACRP)
Baim Institute for Clinical Research
Biogen Idec
Clinical Data Interchange Standards
Consortium, Inc. (CDISC)
Chesapeake IRB
Comprehensive and Integrative Medicine
Institute (CIMI)
Critical Path Institute
Daegu Catholic University Medical Center
(DCUMC)
Deloitte Consulting
Duke Clinical Research Institute (DCRI)
European Clinical Research Infrastructure
Network (ECRIN)
Genentech, Inc.
Indian Society for Clinical Research
Novartis
PRAXIS Australia
PRIM&R
QuintilesIMS
Quorum Review IRB
Sanofi
Target Health, Inc.
UCB
Veristat, LLC
Western Institutional Review Board
Copernicus Group



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

14 Story Street, 4th Floor, Cambridge, MA 02138, USA

mrctcenter.org



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

2017 PUBLICATIONS

ARTICLES

HHS Finalizes Comprehensive Revisions to the Common Rule.

Barth A, Peloquin D, **Bierer BE, Barnes M.**

Bloomberg BNA Life Sciences Law & Industry Report 11 LSLR 03. Jan 2017.

Public Engagement, Notice-and-Comment Rulemaking, and the Common Rule.

Lynch HF, Cohen IG, **Bierer BE.** *IRB: Ethics & Human Research* 39(1). May 2017.

http://www.thehastingscenter.org/irb_article/public-engagement-notice-comment-rulemaking-common-rule/

Data Authorship as an Incentive to Data Sharing.

Bierer BE, Crosas M, Pierce HH.

New England Journal of Medicine 376(17):1684-1687. Mar 2017.

Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations.

Gelinas L, Pierce R, Winkler S, Cohen IF, Lynch HR, **Bierer BE**

American Journal of Bioethics 17(3): 3-14. Mar 2017.

Institutions as an Ethical Locus of Research Prioritisation.

Gelinas L, Lynch HF, **Bierer BE,** Cohen IG. *Journal of Medical Ethics.* Apr 2017.

<http://jme.bmj.com/content/early/2017/04/06/medethics-2017-104165.long>

Building workforce capacity abroad while strengthening global health programs at home: participation of seven Harvard-affiliated institutions in a Health Professional Training Initiative in Rwanda.

Cancedda C, Riviello R, Wilson K, **Bierer BE,** et al. *Academic Medicine* 92(5): 649-58. May 2017.

What do Revised US Rules Mean for Human Research?

Nichols L, Brako L, Rivera SM, Tahmassian A, Jones MF, Pierce HH, **Bierer BE.**

Science 357(6352): 650-651. Aug 2017.

SACHP Releases Guidance on Broad Consent Under Revised Common Rule.

Caron M, Flaherty J, Barth A, **Barnes M.**

Bloomberg BNA Life Sciences Law & Industry Report 11 LSLR 18. Sept 2017.

Reconciling Personal Data Consent Practices in Clinical Trials with the EU General Data Protection Regulation.

Barnes M, Massey R, Peloquin D, Wallace N.

Bloomberg BNA Medical Research Law & Policy Report 16 MRLR 18. Sept 2017.

Extraterritorial Effect of the GDPR and Implications for U.S. Academic Medical Centers Treating EU Patients

McCrystal T, Massey R, Peloquin D, Wallace N, **Barnes M.**

Bloomberg BNA Medical Research Law & Policy Report 16 MRLR 21. Nov 2017.

FDA Eases Administrative Burdens on Expanded Access Use.

Barth A, Levine G, Thornton L, **Barnes M.**

Bloomberg BNA Medical Research Law & Policy Report 16 MRLR. Nov 2017.

BOOK CHAPTERS

Legal and Regulatory Issues in Biospecimen Research: National and International Perspectives.

Peloquin D, **Barnes M, Bierer BE.**

In *Specimen Science: Ethics and Policy Implications*. Cambridge, MA: The MIT Press; 2017.

ESSAYS & BLOGS

Common Rule Revisions: Impact of Public Comment, and What's Next?

Lynch HF, Cohen IG, **Bierer BE** *Hastings Bioethics Forum: Clinical Trials and Human Subjects Research.*

Feb 2017 <http://www.thehastingscenter.org/common-rule-revisions-impact-public-comment-whats-next/>

Revised Common Rule Shapes Protections for Research Participants: Implications for Institutions, Investigators, and Participants.

Bierer BE, Barnes M, Lynch HF.

Health Affairs. May 2017. <http://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0307>

For more information, visit www.mrctcenter.org/resources