DEAR MRCT CENTER FRIENDS,

With the ongoing support of our sponsors and friends, 2015 was an extraordinary year for the Multi-Regional Clinical Trials (MRCT) Center. We transitioned to a new home in the Division of Global Health Equity at Brigham and Women’s Hospital, which has enabled us to expand and enhance our role in global regulatory engagement, training, and policy development aimed at improving the implementation of clinical trials around the world. Fueled by the tireless efforts of more than 120 volunteer members who participate in our initiatives, we have made significant strides in current projects and have launched a number of exciting new initiatives.

In February, we launched a new program on Post-Trial Responsibilities that emanated from last year’s Post-Trial Responsibilities Conference. More than 50 of you participated in the PTR Working Group, evaluating case studies and other sources to produce a Principled Framework that addresses the complex bioethical issues during the period between the completion of a clinical trial and product launch. In 2015 we also launched the China Clinical Regulatory Program – an effort with global impact and a focus on the regulatory science of multi-regional clinical trials.

OTHER 2015 PROGRAM HIGHLIGHTS INCLUDE:

• Convening a 2 day conference of thought leaders in clinical data transparency to propel the vision of a new platform to enhance interoperability and cooperation
• Launching Governance, IT and Business Models work streams to carry forward the goal of establishing a global platform for clinical trial data transparency with capacity for real world data
• In collaboration with TransCelerate, disseminating and updating the Return of Results Guidance Document and Toolkit that was instrumental in drafting the Health Research Authority (HRA) and European Union (EU) guidance
• Continuing India regulatory engagement through editorials, recommendations, and communication with key stakeholders
• Using China as a model, we are developing a novel framework, harmonized to ICH guidance, regarding how countries can consider the importance of ethnic factors, trend consistency and the definition of region in the evaluation on drug efficacy and safety for the design of MRCTs. This work will be broadly applicable
• Continuing our successful in-person training efforts in Bangkok, Cape Town and Johannesburg to build capacity in regions where the need is greatest

We celebrate our fifth anniversary by launching a redesigned and refreshed look and brand to define our mission more crisply.

This report sets forth the MRCT Center’s progress in achieving our goals and advancing our mission in 2015. Building on the foundations of last year’s milestones, we have deepened and diversified our portfolio through the contributions of members from academia, industry, government, regulators, not-for-profit organizations, NGO’s, foundations, patients and patient advocates.

Sponsors both new and ongoing have been a boundless source of support and a driving force behind the Center.

We look forward to working with you in 2016. Thank you for helping us to advance our mission to improve global clinical trials by developing standards, establishing best practices, identifying opportunities for improvement, and working to improve the integrity, safety, and rigor of such trials.

Barbara Bierer, MD
Faculty Co-Director

Mark Barnes, JD, LLM
Faculty Co-Director

Rebecca Li, PhD
Executive Director
**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.

The MRCT Center develops guidance, training resources and tools that promote safe and ethical clinical trials. We perform our work through convening of representatives from industry, not-for-profit organizations, patients and patient advocacy groups, and academia to create practical resources for the ethical design and conduct of multi-regional clinical trials.
HOW WE WORK

IMPLEMENTATION STRATEGY

IDENTIFY INITIATIVES

PROJECTS SELECTED WILL BE THOSE WITH DEMONSTRATED:
• Global impact
• Significance
• Expertise within our stakeholder base
• Actionable within a defined timeline

FORM WORKING GROUPS

MULTI-STAKEHOLDER TEAMS WILL BE FORMED THROUGH CAREFUL SELECTION AND INCLUDE:
• Global diversity
• World class experts
• Enthusiastic leaders

CRAFT SOLUTIONS

PROJECT SOLUTIONS WILL BE DEVELOPED BY WORKING GROUPS ACCORDING TO:
• Accepted ethical standards
• Real world practicality
• Actionability
• Long term sustainability
• Deliverables and a clear timeline

PILOT SOLUTIONS

PROJECT SOLUTIONS IDENTIFIED WILL BE:
• Piloted within our sponsor organizations
• Evaluated and results published
• If positive, work toward widespread adoption

IMPLEMENT & ADOPT

PROJECT SOLUTIONS WILL BE IMPLEMENTED THROUGH:
• Training programs conducted by us, our stakeholder organizations, and collaborators
• Disseminating guidelines and practices
• Working with MRCT Center collaborators to deploy sustainable training

DISSEMINATE & COMMUNICATE

THE MRCT CENTER TEAM WILL:
• Identify end users of the project solution
• Deploy the dissemination strategy
• Develop a feedback mechanism for providing input into the work product for future revisions

REVISE & IMPROVE

PROJECT DELIVERABLES WILL BE:
• Modified with real world experience and feedback
• Updated as global regulations change
• Refreshed based on changes in current practices

To See Our Resources Please go to mrctcenter.org/resources and View by Project
FOCUS AREAS

TRANSPARENCY – The MRCT Center examines barriers to transparency, including clinical trial data sharing, and develops practical, actionable solutions driven through multi-stakeholder participation. Our current projects include returning results to study participants as well as development of a global infrastructure for sharing of participant-level clinical trial data.

ETHICAL FRAMEWORKS – The MRCT Center develops guidance, resources and tools that promote safe and ethical clinical trials. We perform our work through the convening of representatives from industry, not-for-profit organizations, patients, patient advocacy groups, and academia to create practical resources for the ethical design and conduct of multi-regional clinical trials.

GLOBAL REGULATORY ENGAGEMENT – The MRCT Center engages global regulatory leaders to promote convergence between local regulations and internationally accepted best practices. Our approach involves working with our stakeholders to identify emerging issues in global clinical trial practice. In our role as advisors, we help to develop country-specific and culturally-relevant solutions and to work with local partners to strive towards regulatory harmonization.

TRAINING – The MRCT Center offers training courses, in conjunction with a local partner, to principal investigators, ethics committee members, regulators and other clinical trial staff to build capacity with a focus on sites and personnel in emerging economies. It is critical that trials are conducted ethically and overseen by experienced and competent professionals and at well-qualified sites that have the necessary resources and appropriate human research protections.

INTEGRITY AND SAFETY – The MRCT Center builds capacity of data monitoring committees and others to promote effective safety and efficacy monitoring and to ensure the integrity of clinical trials. We develop resources and conduct trainings in areas such as pharmacovigilence and causality determination for those who conduct multi-regional clinical trials.
TRANSPARENCY

CLINICAL TRIAL DATA SHARING AND TRANSPARENCY EFFORTS

In March of 2015, the MRCT Center, along with the Wellcome Trust and Laura and John Arnold Foundation, hosted a conference on Data Sharing, which assembled international stakeholders from industry, academia, patient advocates, and non-profit and government organizations. From this conference emerged a consensus on a future strategic vision for global clinical trial data sharing where expectations and practices of registration and results reporting of all clinical trials would be regularized, greater access to participant-level data could be facilitated, data sets could be interoperable and analyzed across data generators and existing platforms, and research participant privacy would be effectively safeguarded.

The MRCT Center, the Laura and John Arnold Foundation, Wellcome Trust, the Institute of Medicine and Deloitte Consulting have partnered to create a blueprint by 2016 for a new, not-for-profit organization whose goal is to create, direct, implement and oversee a new, sustainable data-sharing platform consistent with the shared vision from the 2015 MRCT Center data sharing conference. To establish the framework for the new not-for-profit organization, the MRCT Center and collaborators launched three parallel workgroups to provide domain-specific expertise: (1) governance, (2) information technology (IT), and (3) business models, to ensure sustainability.

The governance workgroup was tasked with defining the purpose, plan and scope of the new entity, establishing the new steering committee remit and specifications, and developing high-level governing principles. To date the governance workgroup has developed the new entity vision, mission, and charter and has established high-level governing principles that will guide the organization and the construction of a flexible and dynamic IT platform. The IT workgroup was tasked with developing use cases, determining required IT specifications for the new platform and developing an IT blueprint for the future. The business models workgroup was asked to develop (a) sustainable business model(s) that will supply seed funding for the start-up of the new entity as well as a plan for longitudinal support.
MARCH 30-31, 2015:
MRCT CENTER CLINICAL TRIAL DATA TRANSPARENCY CONFERENCE
Key stakeholders in the industry, government, academia and non-profit sectors, and patient advocate representatives, convened at Harvard to discuss a future vision for global clinical trial data sharing.

SPRING 2015:
LAUNCH OF THE MRCT/WELLCOME TRUST DATA SHARING GOVERNANCE WORKGROUP
This multi-stakeholder workgroup, comprised of members from industry, academia and non-profit sectors is comprehensively addressing the remit and vision of the new data sharing entity and governing principles that will guide its inception.

SUMMER 2015:
LAUNCH OF THE MRCT/IOM DATA SHARING IT WORKGROUP
This workgroup is a partnership between the MRCT Center and the Institute of Medicine, comprised of members from industry and academia with focused IT expertise to develop key specifications for a new data-sharing platform.

FALL 2015:
LAUNCH OF MRCT/WELLCOME TRUST DATA SHARING BUSINESS MODELS WORKGROUP
As a collaborative effort of the MRCT Center and Wellcome Trust and with support from Deloitte Consulting, this workgroup is developing a business model to ensure the work of the data-sharing project is sustainable and viable long into the future.

WINTER 2015
COMPLETION OF USE CASES FOR THE DATA SHARING PLATFORM
The IT workgroup completed use case documents that will inform the required specifications for the data platform and highlight associated policy issues.

WORKING GROUP MEMBERS

George Alter,
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Barbara Bierer,
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RETURN OF RESULTS

Returning results refers to providing clinical trial participants with plain language summaries of the outcomes of the trial in which they participated.

DISSEMINATION OF RETURN OF RESULTS GUIDANCE DOCUMENT AND TOOLKIT

The MRCT Return of Results Working Group has created two companion documents currently in use by a number of stakeholder groups:

- MRCT Return of Results Guidance Document Version 2.0 - The Guidance Document includes organizational processes and logistics for returning aggregate results to participants as well as guidance on the content of result summaries and health literacy.
- MRCT Return of Results Toolkit Version 2.0 - The Toolkit comprises sample templates for communicating study results, an endpoint table with simple language, neutral language guidance, a checklist for research result summaries reviewers, and samples from external sources.

After presentations in a variety of national and international conferences, the Return of Results Working Group integrated feedback, both written and oral, from a variety of stakeholders. We are currently working with collaborators including industry partners, TransCelerate Biopharma and the Health Research Authority (HRA) United Kingdom to facilitate standardization and implementation.

DEVELOPMENT OF RETURN OF AGGREGATE RESULTS MATERIALS FOR NON-WESTERN, NON-TRADITIONAL MEDICINE

Working with the Daegu Catholic University Medical Center/Comprehensive and Integrative Medicine Institute and CISCRP, the MRCT Center launched a new project to adapt a US- and Western medicine-centric guidance to enable returning results to participants in South Korea, as a model for returning results in non-Western cultures and for integrative medicine trials. Further, we plan to develop tools to understand participant preferences and comprehension that can be utilized not only in South Korea but more generally.

LAUNCHING A WORKING GROUP TO ADDRESS THE RETURN OF INDIVIDUAL RESULTS

This multi-stakeholder group will be launched on 16 December 2015 and augments and complements return of aggregate results to participants. This work group will: (1) determine what types of individual research results and incidental findings should be offered to participants, (2) define methods to facilitate disclosure of incidental findings and study-arm information to individuals, (3) define ethical and practical dimensions relating to the disclosure of individual genomic results, and (4) create best practices to manage disclosure and follow-up of individuals.
MILESTONES

MARCH 2015:
• Released MRCT Return of Results Guidance Document and Toolkit Version 1.0

AUGUST 2015:
• Launched new project to return results in non-Western culture

OCTOBER 2015:
• Released MRCT Return of Results Toolkit Version 2.0

NOVEMBER 2015:
• Released MRCT Return of Results Guidance Document Version 2.0

DECEMBER 2015:
• Launch of new working group on return of individual results to study participants

RETURN OF INDIVIDUAL RESEARCH RESULTS AND INCIDENTAL FINDINGS TO PARTICIPANTS

BACKGROUND: The MRCT Center previously developed guidelines for the return of aggregate results to research study participants; this project will focus on returning individual results to study participants.

PROBLEM STATEMENT: Patients desire to receive both individual and aggregate research data from clinical studies in which they participated. For return of individual results (genomic data, incidental findings and study arm information) standard guidelines and criteria to facilitate this process are lacking.

APPROACH: Launch diverse workgroup comprised of multi-stakeholders (including academic- and industry-based leaders, not-for-profit institutional representatives, and patients/patient advocates) that will provide guidance on return of individual results to study participants.

QUESTIONS TO BE ADDRESSED:
• Which individual results should be offered?
• There is a continuum of elective provision of results versus the obligation to provide information relevant to an individual’s health status and future decision-making. Where should this line be drawn?
• How should the results be offered (processes)?
• What should be the timing for providing individual results?

Individual-level results may include pharmacogenomic/genomic results, incidental findings (IFs), clinical laboratory results, and results of the study arm.
ETHICAL FRAMEWORKS

DEVELOPMENT OF A COMMON ETHICAL FRAMEWORK FOR POST-TRIAL RESPONSIBILITIES

Ethical responsibilities that follow the completion of a clinical trial have become a topic of increasing concern in the medical community, particularly acute in trials conducted in developing countries. Paragraph 34 of the Declaration of Helsinki (DOH) was intended to provide guidance on the matter, and stated:

“In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process” — DOH 2013 Paragraph 34

Ambiguities remain including precisely what responsibilities are owed, when and to whom, and how these responsibilities should be shared among stakeholders. Considerations such as the balance of safety and efficacy, the needs assessment of the person and disease, and the timing of these post-trial responsibilities are not clear. These ambiguities left sponsors, government regulators, and other stakeholders uncertain as to how to ensure that their ethical responsibilities to trial participants were fulfilled.

Following the MRCT Center’s 2014 conference, “Post-Trial Responsibilities: Ethics and Implementation,” the Center gathered more than 40 stakeholders from 8 countries to form a working group to examine post-trial responsibilities. The Post-Trial Responsibilities (PTR) working group is comprised of academics, practitioners, industry representatives, government representatives, and patient advocates. Meeting biweekly, the group engaged in a thorough process of 1) Defining relevant terms and outlining the scope of the project; 2) Evaluating relevant case studies involving PTR in developing countries; 3) Generating ethical principles based on case study evaluations; 4) Producing a ‘Principled Framework’ comprised of a Guidance Document and Toolkit that will provide guidance on PTR issues to regulators, institutional review boards (IRBs), academics, industry, trade organizations, non-profit organizations, governments, and patient groups.

STEP 1 – DEFINITIONS AND PROJECT SCOPE
The group generated definitions of key terms related to the project, such as post-trial responsibilities and post-trial access to an investigational drug. After some deliberation, the group decided to concentrate the scope of the Framework on responsibilities to participants in clinical trials.

STEP 2 – CASE STUDIES
The group discussed 9 case studies, concerning interventions in countries around the world, which gave rise to challenging bioethical questions related to PTR. Based on these case studies, the group generated a list of questions that captured the key issues faced by sponsors, investigators, regulators, and others wrestling with post-trial responsibilities.

STEP 3 – ETHICAL PRINCIPLES OF PTR
The group identified and elucidated ethical principles that are implicated in the determination of post-trial responsibilities, including nonmaleficence, beneficence, distributive justice, justice as reciprocity, and autonomy.

STEP 4 – PRINCIPLED FRAMEWORK
Writing collaboratively, the PTR working group produced a draft of the Principled Framework, comprised of a Guidance Document and Toolkit, which incorporates both principles and practical concerns in providing guidance on the determination and allocation of post-trial responsibilities. Almost all group members contributed to writing, editing, and reviewing the draft.
PRINCIPLED FRAMEWORK FOR POST-TRIAL RESPONSIBILITIES — PTR Working group members completed the first draft of the Principled Framework on PTR, which includes:

- A Guidance Document with:
  - Introduction to the initiative and the issues at hand
  - Relevant definitions generated by the group and other institutions
  - Ethical principles implicated in considerations of PTR
  - Overall considerations for PTR such as delineating the scope of “benefit,” pre-trial planning, informed consent, and the study setting
  - Considerations for access to the investigational drug, medical care, and infrastructure, including what the responsibilities are, who is responsible, for how long, and how will specific conditions be addressed
  - Special considerations for unique situations

- A Toolkit with:
  - Scenario Tables
  - Points to consider
  - Case studies
  - Overview of country regulations regarding PTR
  - Conceptual diagrams for the spectrum of PTR

WORKING GROUP MEMBERS

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CHINA REGULATORY PROJECT

A multi-regional clinical trial (MRCT) is a clinical trial simultaneously conducted in multiple regions or countries. Almost all registration trials conducted for purposes of drug approval are MRCTs, however China has rarely participated in global MRCTs despite its vast population and importance. Recent regulatory reforms by the China FDA (CFDA) have outlined the requirements for MRCT participation in the country, but challenges remain. While the new IMCT (international multi-regional clinical trial, as MRCT is termed in China) regulatory guidance provides procedural requirements on the design and implementation of an MRCT, it does not address important statistical and scientific issues in protocol design and data analysis. If the current regulations do not resolve these technical and scientific issues, essential new drugs and therapies that would be most efficiently tested through the MRCT paradigm of drug development will be hindered and the people of China will not have access to necessary treatments. Our work to date has direct impact on how to conduct benefit/risk assessment for new drugs and on drug development in China and rest of world.

In March 1, 2015 the CFDA issued a final “Guidance for International Multicenter Clinical Trials (IMCT) Trial Implementation”. The MRCT Center has worked to deliberate potential scientific interpretations to these guidelines in areas of ambiguity. Specifically the project proposes to:

1. Define how countries may consider the role and importance of ethnic factors in the design and conduct of multi-regional clinical trials
2. Understand the background and rationale of ICH E5, ICH E17 as it pertains to the Chinese IMCT guidance and how the guidance may be interpreted in light of the current and planned ICH guidance
3. Propose a new vision for the traditional definition of region — not defined by geographic boundaries — that instead focuses on the concept of sub-population, informed by known and presumptive intrinsic (e.g. genetic, drug metabolic pathways) and extrinsic (e.g. diet, concurrent drug administration, local medical practice) factors
4. Develop methods for analyzing the consistency of subpopulations and the overall study data (trend analysis) for key safety and efficacy outcomes, including frequentist and Bayesian approaches
5. Develop a method of quantifying the risk/benefit ratio for consistency for clinical trials data

MILESTONES

JUNE 2015
• Launch of the China Consistency Working Group.

JULY 2015
• Launch of the Key Internal / External Factors Effect on Efficacy and Safety Working Group

AUGUST 2015
• Launch of the Defining Region Working Group

OCTOBER 26, 2015
• Multi-regional Clinical Trials – Scientific and Regulatory Workshop Forum

The MRCT Center and Peking University collaborated to develop a framework, harmonized to ICH guidance, regarding how countries can consider the importance of ethnic factors, trend consistency and the definition of region in the evaluation on drug efficacy and safety for the design of MRCTs. The workshop convened regulators and academic and industry leaders to discuss the scientific principles underlying global regulatory decision-making for MRCTs.

CHINA PROGRAM STEERING COMMITTEE MEMBERSHIP

The steering committee includes more than 30 diverse members representing industry, government, and academia, located in China and the U.S.
In 2013 India implemented a series of regulations with a crippling effect on its clinical research industry. On July 31, 2015, India issued an amendment to balance the most problematic provisions of the earlier regulations, including:

- Finalization of the compensation formulas for death and injury
- Narrowing the requirements for audio-visual recording from all informed consents to only those of vulnerable subjects
- Clarification that free medical management is to be provided until causality of adverse events has been established

This amendment has served to mitigate the negative effects of the 2013 regulation. The MRCT Center has made additional recommendations regarding compensation requirements; conduct of clinical trials, including the number of clinical trials an investigator can undertake and the capabilities of sites for clinical trials; considerations of standard of care; clarification of definitions (e.g. "vulnerable subjects," "ancillary care," "medical management"); training and accreditation of ethics committees, principal investigators, and sites; and communication among others.

**MILESTONES:**

- BNA article published 2015 – India’s Proposed Amendments to the Drug and Cosmetics Act: Compensation for Injuries to Clinical Trial Participants and the Criminalization of Clinical Research
- October 2015 Meeting with Key stakeholders
- Our work in India continues with key stakeholders in India in recognition of the unique complexities in the Indian clinical trial regulatory framework. In addition, India is a leader in promoting mandatory compensation for death and injury and mandatory universal accreditation of sites, investigators, and ethics committees.
- The MRCT Center together with our collaborators in India will continue to strive for clarity and definition where necessary and provide and encourage training and education of sponsors, investigators, and sites
TRAINING

Industry sponsors, regulators, human research participants, and the public require assurance that clinical trials are conducted ethically by experienced and competent professionals and at well-qualified sites that have the necessary resources to ensure human research protection. We have developed a series of in-depth clinical research training modules to enable capacity building in the emerging world. This supports the mission of our center by furthering the support of clinical research by freely sharing knowledge expertise and tools developed at the center.

OUR TRAINING COURSES ARE:
- Offered in-person in Cambridge, MA or in-country
- Tailored to local regulatory requirements
- To date, registration free for attendees
- Hosted by a local partner
- Training materials made available to allow local experts to sustain in-country programs and refresher courses
- Case-based to ensure interaction consistent with adult pedagogy
- Continually updated and refreshed based on participant feedback

MRCT CENTER IN PERSON TRAINING SESSIONS
Our training model includes the identification of an in-country local partner to work with us to identify the appropriate audience, and to qualify and choose investigators, local industry, regulators and ethics committee participants.

TRAINING DOMAINS and CORE COMPETENCIES

1. Scientific Concepts and Research Design
2. Ethical Considerations, Patient Care and Safety
3. Medicines Development and Regulation
4. Clinical Trials Operations (Good Clinical Practice)
5. Study and Site Management
6. Data Management and Informatics
7. Leadership and Professionalism
8. Communication and Teamwork
INTEGRITY AND SAFETY

The MRCT Center’s focus on integrity and safety in clinical trials has centered on three primary areas – data monitoring committees, causality assessment, and pharmacovigilence.

DATA MONITORING COMMITTEE TRAINING

The MRCT Center’s Data Monitoring Committees (DMC) initiative aims at identifying, training and recruiting experts who have expertise in medicine, ethics or statistics and experience in clinical trials, with a particular focus on those individuals from emerging countries. To balance the representation on DMCs, also termed Data Safety Monitoring Boards (DSMBs), the MRCT Center provides comprehensive DMC training to selected individuals who are willing to serve.

In 2015, the MRCT Center conducted DMC capacity building trainings in Thailand and in South Africa.

The training in Thailand, conducted in conjunction with the HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT), focused on regulatory issues pertaining to DMCs in Thailand; understanding how trials can be monitored by DMCs and the responsibilities of DMC members. The 62 participants included representatives from Cambodia, India, Indonesia, Japan, Malaysia, Myanmar, Pakistan, Philippines, Singapore and Thailand and included investigators and biostatisticians from academia, government and local clinical research organizations.

The training in South Africa, conducted in collaboration with the Global Health Network and the University of the Witwatersrand, focused on the roles and responsibilities of DMC members; the DMC charter; communication between DMC and other parties; monitoring for safety, efficacy and futility; important causality definitions and distinction between cause and correlation; and safety reporting procedures. The 70 participants included clinical trial investigators and statisticians.

MILESTONES

JANUARY 2015:
Training in Bangkok, Thailand

NOVEMBER 2015:
Training in Johannesburg and in Cape Town, South Africa
MRCT COMMITTEES

Thank you to our sponsors for contributing your expertise and resources towards improving the quality standards clinical trials. Your contributions ensure that your institution continues to be a leader in its commitment to the ethical conduct of clinical trials and benefits from best practice discussions and MRCT projects.

EXECUTIVE COMMITTEE

- Amgen, Inc.
- Bill & Melinda Gates Foundation
- Brigham and Women's Hospital
- GlaxoSmithKline
- Johnson and Johnson
- Kowa Pharmaceuticals
- Laura and John Arnold Foundation
- Merck
- Pfizer
- PhRMA
- Ropes and Gray LLP
- Takeda Pharmaceuticals

STEERING COMMITTEE

- The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
- ACI Clinical
- Association of Clinical Research Professionals (ACRP)
- Biogen Idec
- Catholic University of Daegu, South Korea
- Clinical Data Interchange Standards Consortium, Inc. (CDISC)
- Chesapeake IRB
- Comprehensive and Integrative Medicine Institute (CIMI)
- Critical Path Institute
- Deloitte Consulting
- Drug Information Association (DIA)
- Eli Lilly and Co.
- Genentech
- Harvard Clinical Research Institute (HCRI)
- Indian Society of Clinical Research
- Norwich Clinical
- Novartis
- PRIM&R
- Quintiles
- Quorum Review IRB
- Sanofi
- Target Health Inc.
- Veristat
- Western Institutional Review Board Copernicus Group