MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Proceedings
Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard
4th Annual Meeting

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Loeb House at Harvard University • Cambridge, MA

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Executive Summary

The major themes of the MRCT Center 2015 Annual Meeting included Post-trial Responsibilities and Data Transparency.

In 2015, the Post-Trial Responsibilities (PTR) Working Group developed an Ethics Framework with two major deliverables:

- PTR Guidance Document which includes stakeholder roles, bioethics principles, and PTR guidance for continued access to investigational product, related medical care and infrastructure.
- PTR Toolkit which includes conceptual diagrams, scenario tables, points to consider, case studies, and country regulations.

Invited speakers shared their perspectives and areas for revision on the MRCT post-trial ethics framework including:

- Dr. Otmar Kloiber from the World Medical Association addressed in his keynote the evolution of the Declaration of Helsinki on the issue of post-trial access and the current perspective on the topic.
- Dr. Christine Grady from the National Institutes of Health congratulated the team on the ethics framework and suggested strengthening the document through inclusion of a planning section and clarification of key beneficiaries of the document.
- Ms. Elizabeth Frank, patient advocate from the Dana Farber Cancer Institute, stated the guidance document addressed issues that are important for patients and did so in a "participant-centered" manner through respectful terminology.
- Dr. Bernard Lo from the Greenwall Foundation commended the team for their careful conceptualization and reasoning; inclusion of case studies; consideration of context such as disease, country, and lifecycle of the clinical trial; and involvement of multiple stakeholders. He provided comments for consideration on five themes.

A panel discussion with PTR working group participants addressed a number of issues including balancing the extent to which economic factors and the cost burden should weigh on, versus other factors, the determination of post-trial responsibilities; whether the scope of the work should include compensation for injury; and whether post-trial mandates should be expanded beyond that defined in the framework to chronic illnesses.

Second, the Data Sharing and Data Transparency Initiative, which the MRCT Center has launched as a focus area since 2013, was discussed. The current progress focused towards developing a blueprint for a new, not-for-profit entity was presented.

Invited speakers shared their perspectives on the project vision to date:

- Dr. Bernard Lo from the Greenwall Foundation praised the MRCT Center's work and summarized key challenges inherent in the scope including privacy protections, global equity issues and financial sustainability.
- Dr. Frank Rockhold from GlaxoSmithKline spoke about the inherent value of data sharing and the desire to work together with the MRCT Center as a neutral convener to facilitate a cultural shift in this area.
- Dr. Lauren Quattrochi from Sense About Science USA discussed the public misperception of science and the critical gap in understanding and how this affects public policy.
- Dr. Stuart Buck from the Laura and John Arnold Foundation spoke on the Laura and John Arnold Foundation's strong and abiding interest in research integrity (which includes facilitating data transparency). He stressed that until data are combined their usefulness remains limited.

A panel discussion including conference participants focused on how to provide recognition and incentives for the sharing of datasets. In addition, the barriers to data sharing and the motivations for researchers to share their data within a common data platform as a condition for funding were discussed.

Welcome and Introduction

Mark Barnes, J.D., LL.M., and Barbara Bierer, M.D., MRCT Center

MRCT Center Faculty Co-Directors, Mr. Barnes and Dr. Bierer opened the meeting and reviewed the mission of the MRCT center — to engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions. New members of the MRCT Center were introduced including the Laura and John Arnold Foundation (Executive Committee) and Genentech (Steering Committee). A refreshed brand and website was also unveiled.

Keynote Address

Otmar Kloiber, M.D., World Medical Association

Dr. Kloiber, the Secretary General of the World Medical Association (WMA), provided a conceptual backdrop of the WMA's Declaration of Helsinki. This seminal document is one of the ethical underpinnings of the MRCT Center's work on post-trial responsibilities (PTR).

The WMA was founded on September 18, 1947, in Paris, with a current membership of 112 national medical associations globally, representing more than 9 million physicians. One of WMA's historic policies is the Declaration of Helsinki (DOH), initially adopted in 1964 and most recently revised in 2013, which addresses ethical principles for medical research involving human subjects. The DOH aims to protect study participants against dangerous experiments and exploitations through informed consent, ethics committees, and an obligation to make study results public.

The DOH has been revised five times. Many of the revisions were related to use of placebos in research. The 2013 version included higher protection for vulnerable groups, compensation of study participants, more precise and specific requirements for post-study arrangements, and a more systematic approach to the use of placebos, but no inclusion of an explicit "fair benefits" approach.

Post-trial access has proved a controversial issue. A 2004 Note of clarification on the 2000 Edinburgh DOH version states that "post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review." The Declaration of Lisbon on the Rights of the Patient refers to "circumstances where a choice must be made between potential patients for a particular treatment that is in limited supply…. That choice must be based on medical criteria and made without discrimination. [However,] The patient has the right to continuity of health care." According to the 2008 Seoul version of the DOH, "the protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits." And the 2013 Fortaleza version stipulates that each study participant must be adequately informed of post-study provisions, and that in advance of a clinical trial, "provisions for post-trial access for all participants who still need an intervention

identified as beneficial in the trial" should be made by sponsors, researchers and host country governments. This refers to the shared responsibility for post-trial access.

A short discussion revealed that the work of the MRCT Center may lead to new insights for further refinements of the DOH, which continues on as a living document.

Post-Trial Responsibilities

Remit of the Working Group and Overview of PTR Framework

Barbara Bierer, M.D., MRCT Center, and Luann Van Campen, PhD, Eli Lilly and Company

Dr. Bierer and Dr. Van Campen, co-chairs of the MRCT Center Post-Trial Responsibilities (PTR) Working Group, presented an overview of the remit of the Working Group and of the PTR Framework document.

There are multiple directives related to post-trial responsibilities based on ethical principles, but there are no currently available standards with regard to the practical application of those directives. To address this, the MRCT Center held a conference on Post-Trial Responsibilities in September 2014, and launched a 42-member international multi-stakeholder working group in February 2015 to develop a practical and implementable framework for post-trial responsibilities.

The PTR Framework developed by the working group outlines a case-based and principled stakeholder approach to evaluate and guide ethical responsibilities associated with the end of a patient's participation in a clinical trial. (i.e., post-trial responsibilities, or "PTR").

The PTR Working Group also developed consensus definitions on "post-trial responsibilities" and "continued access to an investigational product" and drafted a framework that addresses PTR to research participants and stakeholder responsibilities associated with the benefits of:

- Access to investigational product (primary post-trial benefit)
- Access to associated medical care (collateral post-trial benefit)
- Access to health care infrastructure (collateral post-trial benefit)

The PTR Framework consists of a Guidance Document and Toolkit. The Guidance Document includes stakeholder roles, terminology, bioethics principles related to PTR, stakeholder responsibilities, and PTR guidance in terms of continued access to investigational product and related medical care, and infrastructure. The Toolkit includes conceptual diagrams, scenario tables, points to consider, case studies, and country regulations.

This framework was developed by first reviewing case studies and generating a master list of ethical questions surfaced by the cases; secondly, identifying ethical principles relating to PTR and primary stakeholder roles; and thirdly, producing a series of recommendations. PTR was weighted by six inter-related important considerations:

1. Clinical evidence of benefit and no evidence of serious risk for individual participants;
2. Statistical evidence of positive effects and no evidence of serious risk of harm in the study population;
3. Whether imminent risk of death or serious harm if investigational product is discontinued;
4. The investigational product addresses an unmet medical need, in that there are no suitable therapeutic alternatives available to participants;
5. The sponsor is the sole source of the investigational product and there is no alternative access to the product;
6. The provision of the intervention will not adversely affect the viability of the research or the ability to complete the trial(s).

The Framework addresses various scenarios: For access to the investigational product, points to consider include: laws and regulations, benefit and risk, alternative treatments, expected timeline, and the role of the government healthcare system, as well as types of trials and approval status of the investigational product. For access to medical care associated with providing continued access to investigational product, points to consider include: a consideration of components that are necessary to administer the investigational product, local standard of care, ex ante agreements, and whether investigational drugs or devices are approved or rejected by the regulatory authorities. For access to health care infrastructure associated with providing continued access to investigational product, points to consider include: whether investments in local research and healthcare infrastructure are appropriate, removal of equipment or infrastructure improvements at the end of the trial, maintenance of donated infrastructure and equipment, whether research is conducted in a low resource setting, and whether the provision of the investigational product is continued or discontinued. For all three areas--access to the investigational product, access to associated medical care, and access to associated health care infrastructure—the PTR Framework provides guidance as to what the responsibilities are, who is responsible, for how long, and by what mechanism.

Responses from Key Stakeholders

Christine Grady, Ph.D., National Institutes of Health

Dr. Grady congratulated the Working Group on the PTR framework and suggested the following strengths and areas for further clarification.

Strengths:

1. Explicitly expands discussion of PTR beyond access to investigational product.
2. Focuses attention on what is owed to participants in the trial as distinct from other post-trial responsibilities.
3. Explicitly addresses associated medical care in light of continued access.
4. Describes multiple stakeholders and their primary roles, and unambiguously describes their shared responsibilities.

5. Clarifies terminology and existing international guidance.
6. Distinguishes between individual collective benefits and risks and also between primary benefits and collateral benefits.
7. Emphasizes the importance of planning, the context, scope and need for communication and informed consent.
8. Places the roles of the various stakeholders along the spectrum (diagram).
9. Details the sponsor responsibilities, using multiple scenarios such as phases of the trial, approval status, benefit-risk assessment in Section 7. Tables in the Toolkit complement this section by laying it out in tabular form.
10. Not only medicinal products but also medical devices are included, which adds complexity.

Areas for further clarification:

1. Planning: most substantive guidance lacks planning – include a checklist for the planning phases with items to consider and who should be considering these items.
2. Clarification of beneficiaries: To whom are these documents referring? Serious/life-threatening illness are included but also consider including those with chronic diseases. There is no obligation for participants who are screened out.
3. Communication and Informed Consent: Significant number of references to communication; however the actual section termed "Communication" lacks clarity. Both the Investigator and sponsor must consider during planning stage what information must be shared with participants. Participants must be engaged from the beginning and along the way.
4. Economic viability of the research: this is an important yet underdeveloped factor in the framework; currently, there is no guidance of how to weigh this factor in comparison to other considerations.
5. Simplify and summarize: consider inclusion of a guide or diagram for the first-time user to find salient recommendations quickly.

Elizabeth Frank, Dana-Farber Cancer Institute

Ms. Frank provided a patient perspective and highlighted the following strengths and areas for improvement:

Overall the guidance document addressed issues that are important for patients and does so in a "participant-centered" manner through respectful terminology.

Framework

Strengths:

1. Sets expectations for patients early via Informed Consent.
2. Addresses the importance and complexities relating to transferring participants and responsibilities from one entity to another.
3. Shows transparency by communicating intentions to all stakeholders in the process.
4. Acknowledges need for flexibility since benefits of investigational drugs are unknown at start of trial.

Areas for improvement:

1. Address long-term follow-up.
2. Discuss how to handle harm done by the investigational product, during or after the trial.
3. Realize that financial harm can continue after the trial, such as high copayments.
4. Include case examples of how individuals themselves may weigh harms and benefits.

Toolkit

Strengths:

1. Useful examples and participant consequences provided by disease
2. Presentation of dilemmas and points to consider for each case are well conceived

Areas for improvement:

1. Include specific examples and discuss principles of informed consent forms that follow the suggestions of the Guidance: emphasize patient-friendly consent forms and discuss barriers to creation of patient-friendly informed consents.
2. Address responsibilities for long-term follow-up, such as who is responsible for paying for long-term follow-up, how to communicate to participants late-term effects and issues that affect quality of life.
3. Include more guidance on return of results.
4. Add examples of successful patient-assistance programs. Address financial and communication challenges.
5. Expand discussion of benefit and risks for individuals and other stakeholders.

Bernard Lo, M.D., Greenwall Foundation

Dr. Lo summarized commended the PTR team for their careful conceptualization and reasoning; inclusion of case studies; consideration of context such as disease, country, and lifecycle of the clinical trial; and involvement of multiple stakeholders. He provided comments for consideration on five themes:

1. Research institutions as stakeholders: Consider a partnership between academic institutions of the North and South U.S. to implement MRCT recommendations.
2. Community-engaged research:
    a. Include roles for community representatives, such as community advisory boards, in planning and designing of trials, negotiating pre-clinical agreements, and implementing post-trial responsibilities.
    b. Community engagement can add value by raising unrecognized concerns and suggesting ways to increase benefit/risk ratio, such as by representing communities through non-governmental organizations (NGOs), and advocacy groups such as intravenous drug users (IDUs), commercial sex workers, and migrants.
    c. Community engagement can provide justice for communities and not only for individual trial participants, e.g., by considering participants from previous studies and those screened for trials to provide a greater benefit to the population. Consider what is owed to communities that participated in trials and their opportunity costs as well as the benefit provided to communities through collateral or ancillary interventions and investments in infrastructure and social determinants of health.
3. Limits of pre-trial agreements: Do not overemphasize pre-trial agreements since the path to availability of investigational product is not clear at the onset, new sources of funding for intervention may emerge after the pivotal trial results, and bargaining positions are unequal.
4. Benefit to participants in a negative trial: Distinguish random statistical variation and clinically significant benefit. Realize that different individuals will define differently what a clinically significant benefit is, e.g., progress, stabilization, complete remission in refractory cancer, undetectable HIV level. Clarify if lesser levels of benefit call for the same level of responsibility.
5. Compensation for research-related injuries: Distinguish injury directly caused by study intervention from injury caused by the underlying disease or new diseases. Explain what level of care would be given to the injured person.

In sum, Dr. Lo cautioned about taking on too much, but also recommended to add richer clinical details to case studies—starting with a few pragmatic cases--, presenting a branching logic (flow chart) rather than a table, and to become even more inclusive in process.

Otmar Kloiber, M.D., World Medical Association

Dr. Kloiber highlighted the strengths of the PTR framework: It has a high value for those interested in the field of research as the PTR questions have not been addressed sufficiently. In his view, the Framework is directionally correct and closely related to the ethical guidance of the DOH. Dr. Kloiber also provided some questions and challenges:

1. Realize that there is no absolute freedom of experimentation. There is some research that cannot be done.

2. Do not overstress undue inducement by research in the document. Consider how to frame this differently: in resource-poor communities, research is essential to build resilience and capacity.
3. Describe benefits: give this section more attention and to contrast to the different shades of harm.
4. Provide more attention to vulnerable groups, e.g., those who cannot understand the risk-benefits analysis of research.
5. Move tables at the end as they are difficult to comprehend.
6. Consider how to condense the document realizing that in perspective that PTR is just one aspect of a clinical trial.

Panel Discussion

Ricardo Eccard da Silva, Brazilian Health Surveillance Agency (Anvisa); Laurie Letvak, M.D., Novartis, New Jersey; Usharani Pingali, M.D., Nizam's Institute of Medical Sciences, Hyderabad; Wasana Prasitsuebsai, M.D., M.P.H., The HIV Netherlands Australia Thailand Research Collaboration, Bangkok; Daniel Wang, Queen Mary/London School of Economics, London

The panel moderated by the working group co-chairs Barbara Bierer and Luann van Campen addressed the following issues, in response to questions from audience participants:

- Compassionate use - a discussion ensued on the differences between compassionate use and post-trial access or PTR
    - Compassionate use was defined for those who were **not** on a trial as opposed to post-trial responsibilities which is targeted towards those that have participated in a trial.
- Economic factors – the audience discussed the extent to which economic factors and the cost burden should weigh on post-trial responsibilities
    - Respondents from industry did not make distinctions between less expensive or more expensive drugs, but rather in ensuring that there would be no gap in drug availability if patients were benefitting.
    - Each company addressed questions of co-pay differently, some provided the drug free of charge until it became commercially available.
    - Strike balance between flexibility and applicability.
    - Define economic viability of research more clearly.
- Regulations in Brazil – a question was raised on the current applicable laws regarding post-trial access and the effect on sponsors
    - The general rule is that if a patient has a benefit, the sponsor must provide the drug until the patient can access the drug independently.
- Extend PTR to chronic diseases – participants raised whether post-trial responsibilities should be expanded to those patients suffering from chronic diseases

  - Recently a significant number of trials are conducted related to chronic diseases.
  - Many resource-poor countries do not have regulations or guidelines for PTR.
  - Most investigators are uninformed about PTR.
- Compensation for injury – a discussion surrounding whether compensation for injury was within the remit of PTR ensued. It was discussed that this should not be added to the current Framework as this would be beyond the scope of the effort as defined.
  - In India, compensation is mandated to be paid by sponsor for trial-related injury; e.g., if the condition is worse when the drug is stopped than when it started; however, compensation is not mandatory if there are alternative treatments.
- Benefit-risk concept
  - It is not always Yes or No, but a continuum of benefit-risk conceptualization.
  - Consider patients' perspective on what risk they are willing to take.
- Community involvement – this was stressed as an important item to include
  - Involve the community in the planning phase and continued access.
  - This document does not address benefits in the community from which the participants live. This was considered out of scope when framing the work.
- Provision of investigational drug versus comparator – which should be provided in the PTR phase?
  - DOH does not make a differentiation.
  - If the comparator drug is from another company, providing insurance coverage might be one option for continued access.
- Standard of Care should be specified in the documents
  - Explain what standard of care (SOC) are we using: SOC in the community or best SOC in the world?
  - Treatment can be locally available but not accessible to all
- Checklist for IRB – several participants suggested that a tool for IRBs/ECs would be helpful in this area.
  - Share model language for Informed Consent Form (ICF) and Clinical Trial Agreement (CTA)

Data Sharing and Data Transparency

Overview of the Three Workstreams

Rebecca Li, Ph.D., MRCT Center

MRCT Center Executive Director, Dr. Li, presented background on data sharing and an update on current working group progress for the MRCT Center's Data Sharing and Transparency Project.

Clinical trial data sharing is important as it has the potential to accelerate scientific progress and to ultimately improve public health. The current project focuses on the sharing of individual participant-level data with other researchers and the public.

The MRCT Center acts as a neutral convener to create implementable solutions for data sharing among non-profits, industry, patients and patient organizations, academia, government, and professional journals. In February 2013, the MRCT Center launched a working group with 18 stakeholder organizations that convened 4 sub-groups on key issues, and resulted in a May 2013 conference on "Issues and Case Studies in Clinical Trial Data Sharing: Lessons and Solutions." This was followed in March 2015 with a conference on "Promoting Clinical Trial Data Transparency." The MRCT Center working groups developed a common Informed Consent Form and Data Use Agreement, both of which were highlighted in the presentation. Between 2012 and 2015, pharmaceutical, academic, and governmental agencies developed various platforms for clinical trial data sharing; however, these are not interoperable nor are these systems integrated.

The data sharing conference in March 2015 brought together 70 representatives from industry, patient advocate groups, foundations, academia, journals, and others to build consensus on a strategic vision for the future:

1. Expectations and practices of registration and results reporting of all clinical trials would be regularized among industry and academia;
2. Greater access to participant-level clinical trial data could be facilitated;
3. Researchers would be able to access and combine data across various platforms and sponsors, to multiply opportunities for data analysis; and
4. Research participant privacy can be safeguarded

A coordinated, centralized, international, not-for-profit organization would oversee a central user interface with robust search engine functionality. Data requirements would allow for and enable the integration of differing datasets for analysis, and the data platform would accommodate differing expectations and needs.

Presently, the MRCT Center is developing the blueprint for a new, not-for-profit organization whose goal is to create, direct, implement, and oversee a sustainable data-sharing platform in three phases: Strategy (August 2016 – March 2016), Construction (March 2016 – September 2017), and Implementation (September 2017 – Forward). In the Strategy phase, the MRCT Center launched three integrated working groups to develop an organizational blueprint for the suggested not-for-profit entity:

1. MRCT Governance Working Group:
    a. To define purpose, plan, governance and scope of new entity.
    b. The main objectives for this group are to develop a high-level charter, develop principles for organizational leadership, and strategic policy decisions.
    c. The Vision is to maximize the contribution of clinical trial participants to advance science and patient care through the sharing of participant data for further research. The Mission is to develop and maintain an international non-profit entity to promote,

coordinate, and facilitate clinical research data sharing through the creation and implementation of a sustainable global data-sharing platform.

2. Information Technology (IT) Working Group:
    a. To develop global-level IT platform blueprint.
    b. This Workgroup is a collaboration between the MRCT Center and the Institute of Medicine (IOM) and its main objectives are to develop IT infrastructure to enable broad data sharing, and to define scope, utility, and a feature set of the IT platform including data analysis use cases and data submission use cases.
    c. The IT platform will be interoperable, flexible, and accommodating between 3rd Party Hosts, data submitters, and data requesters.
    d. The IT platform infrastructure blueprint will outline the requirements and specifications for a global-level, federated IT platform.
3. Business Model Working Group:
    a. To develop a sustainable business model.
    b. This Workgroup is a collaborative effort between the MRCT Center, the Wellcome Trust, and Deloitte Consulting, with main objectives of producing an environmental scan of current models, developing a sustainable business model for the new entity, and advising on how to develop and capacitate the not-for-profit entity.

The next major milestone will be a conference March 21-22, 2016 at the Wellcome Trust at which the MRCT Center and collaborators will present, review, and seek endorsement of, and feedback on, plans to date. Following this conference, the MRCT Center and partners will move forward to establish and empower the new entity. In the Implementation phase, the new not-for-profit entity will commence operation of directing, implementing and overseeing a broad data-sharing platform.

Responses from Key Stakeholders

Bernard Lo, M.D., Greenwall Foundation

Dr. Lo spoke about the IOM's report on clinical trial data sharing, "Sharing clinical trial data: maximizing benefit, minimizing risk," concluding that a number of key questions remain after the issuance of the report, such as: What data will be shared? With whom? When in the life cycle of the clinical trial should data be shared? Under what conditions? He praised the MRCT Center's Data Sharing and Transparency Project for regularizing expectations and practices, adopting a common platform and data specification portal, and striving to share participant-level data. Importantly, in his talk, Dr. Lo summarized these future challenges inherent to the MRCT initiative:

1. Governance
    a. Governance should be adaptive to respond to innovations in clinical trials, such as comparative effectiveness trials without individual consent, and changes in laws and regulations
    d. Work towards converging criteria for access

e. Clarify the role of participants, disease advocacy groups, communities in governance

2. Current privacy protections
   a. Privacy policies vary among countries
   b. The effectiveness of data use agreements that prohibit attempts to re-identify is unclear
   c. New privacy threats
      i. Large breaches (state-sponsored attacks; malware)
      ii. Increased variety and types of data (genomic sequencing; mHealth: lifestyle, location, social interactions)
      iii. Re-identification is increasingly possible using additional data sets and big data analytics
      iv. Best practices for privacy and security need to evolve (assess vulnerability to attacks by adversaries; new collaborations, *e.g.*, big data companies)
3. Develop a data-driven learning system for clinical trial data sharing- collect outcomes data, e.g., requests, access, denials, reason for denial; adverse events; publications, advances in knowledge; unanticipated adverse consequences
4. Understanding data sets - importance of sharing metadata including full protocol, SAP, code; a dataset without context/guidance has significantly lower value
5. Global equity issues - *i.e.*, will system be affordable to clinical trials and investigators in developing countries?
6. Global IP challenges - may competitors register identical drugs in countries with weak regulatory data protection?
7. Financial sustainability: Who is going to pay for clinical trial data sharing in the long run? For example, attract new Internet philanthropists; recruit them and engage with them intellectually
8. Issues managing dual focus: *i.e.*, balancing short-term needs with long-term vision

Despite these challenges, which the MRCT Center is aware of and is addressing head-on together with key stakeholders, Dr. Lo's concluding message of encouragement and excitement rang clearly: "Carry on, full steam ahead!"

Frank Rockhold, Ph.D., GlaxoSmithKline

Dr. Rockhold spoke about the value of data sharing, specifically about GSK's desire to work with MRCT as a neutral convener to facilitate a cultural shift in this area. As a community, industry, academia, and other stakeholders strive to share clinical trial data because it is how to best honor the human participants who put themselves at risk in research trials. The benefit(s) of sharing clinical trial data with researchers has not been fully exploited. Creating and governing a generalized data sharing entity is outside of the vision and mission of GSK, which is why it is essential to partner with the MRCT Center and others. He outlined the following positive points and then commented on important challenges:

Positives:

1. Encourages the MRCT Center, Wellcome Trust, and others to continue to drive discussions as neutral parties
2. The current initiative provides a space for stakeholders and existing initiatives to engage together
3. Helps to continue to promote a cultural shift towards transparency and greater sharing of data

Challenges:

1. Where are the data to be housed? Significant resources are needed to house the data in a secure environment - who pays/maintains it?
2. How do you weigh the needs/wishes of the data generators alongside data requesters/users?
3. Data privacy - within a central system, network is required to guarantee that data privacy is upheld
4. Consider carefully how software is provided. If users are to obtain value out of the data, who provides analytic tools? Do we provide R/SAS? How is licensing negotiated?
5. What if data cannot be downloaded given data privacy issues? If it is required that data be downloadable, it may limit who donates their data
6. Data standards are very important: if you want to combine multiple trials, compatibility is a requirement

In summary, Dr. Lo concluded the Data Sharing Workgroup is on the right track given the difficult challenges ahead.

Lauren Quattrochi, Ph.D., Sense about Science USA

Dr. Quattrochi discussed the rampant public (mis)perception of science and how it often leads to a critical gap in understanding and mistrust of science. This gap in turn may affect personal decision-making and public policy. The mission of the organization, *Sense About Science USA*, therefore, is "to create and curate a national conversation surrounding the value of scientific progress and the importance of evidence and transparency." As a recent example, she cited data from the Pew Research Center on the discrepancies that often exist between the lay public *vs*. scientific leaders on a number of key issues: *e.g*., vaccination of children, safety of genetically modified foods and climate change.

Moreover, in addition to *Sense About Science*, she is also Director of *AllTrials*, a patient-driven movement that desires for all clinical trials (past, present, and future) to be registered, thereby facilitating public sharing of their methods and summary results. Dr. Quattrochi believes that, with respect to the MRCT Center's vision, *AllTrials* could serve as an important partner to ensure that patients and other community stakeholders (researchers, clinicians, *etc.*) are engaged in clinical trial transparency efforts globally and locally.

Lastly, Dr. Quattrochi commented on newer strategies in data-sharing platforms that could enable patients in any clinical trial to provide their data on their terms, which represent important innovations in health-related data access and data sharing. She believes that such tools will be incredibly important for empowering patients and informing growth within the area of data science and data transparency.

Stuart Buck, J.D., Ph.D., Laura and John Arnold Foundation

The Laura and John Arnold Foundation (LJAF) has a strong interest in research integrity including engaging with organizations who facilitate data transparency. As Vice-President of research integrity, Dr. Buck spoke about his own experiences in research integrity, striving to reproduce key findings within the psychology research field. Dr. Buck's publication was one of the first systematic attempts to assess reproducibility in the scientific literature. At present, there are many data-sharing initiatives attempted globally; yet many are isolated efforts. The problem remains that until these data are combined, their usefulness and value remains limited. To this end, the LJAF has awarded the MRCT Center a grant to convene stakeholders representative of all data users and generators to empower a new entity and build a global data sharing infrastructure with buy-in from stakeholders. Mr. Buck concluded that it is important to attract data users/generators from across the clinical trials community to foster shared responsibility, joint ownership in the sharing of data, as well as discovery and transparency.

Panel Discussion

The initial discussion focused on providing recognition and incentives for the publication/sharing of datasets. There is often a considerable amount of work needed to prepare data into a format that is suitable and useful for sharing (person-hours, financial burden etc.), which provides new challenges. As discussed, a key issue is not merely uploading the data into the system; it is starting a data system to prove a data-sharing concept.

Moreover, there are specific barriers that need to be addressed, e.g., issues relating to the ownership of data that may conflict with motivations for sharing. Yet, an incentive to keep in mind is that sharing information is a better way to design research and help patients. Academicians will benefit from data sharing as well. Meta-analyses will likely occur within academic communities, so the need to share data is vital to these efforts. To this end, a possible strategy to ensure sharing is to withhold a portion of funding until data have been published—some journals are already doing this to advance data sharing. The data must be supplied and posted as important steps of the publication process.

To further incentivize data-sharing practices among academicians, the panel proposed having NIH and/or the Gates Foundation to adopt and use a common data platform as a condition for funding, thereby ensuring that individuals comply. The panel discussed how the health data science community must set a low threshold for getting research data into a platform and to educate stakeholders so that they can learn how to best use and manage datasets.

Broadly, then, the challenge is to make new sharable data that is interactive with existing datasets. The panelists concluded that much of what the Data Sharing IT Workgroup will need to do is set new standards in this area with respect to data mapping and data merging.

Closing Remarks

Barbara Bierer, MD, and Mark Barnes, JD, LLM, MRCT Center

In their closing remarks, the leaders of the MRCT Center thanked all of the speakers for their insightful comments and service on their respective panels and workgroups. The MRCT Center has received and will continue to receive important feedback from stakeholders and community members to help focus its work and mission. They remarked that this is only possible with continued commitment, energy, and effort, which are incredibly appreciated. Underpinning all of the MRCT Center's work is a mutual drive to conduct ethical clinical trials worldwide, in a way that beneficial to everyone. They thanked all participants, sponsors, and encouraged attendance at the 2016 conference.

Appendix 1: Meeting Participants

Last Name:	First Name:	Company:	Job Title:	Affiliation:
Aldinger	Carmen	MRCT Center	Program Manager	Staff
Alesci	Salvatore	Takeda Pharmaceuticals	Head Global Science & Biomedical Policy	Sponsor
Allen	Mary Ellen	Genentech, Inc.	Assistant General Counsel, Specialist	Sponsor
Barnes	Mark	MRCT Center / Ropes & Gray	Faculty Co-Director / Partner	Speaker / Faculty
Bierer	Barbara	MRCT Center	Faculty Co-Director	Speaker / Faculty
Birkett	Audrey	CISCRP	Project Manager	
Buck	Stuart	Laura and John Arnold Foundation	VP of Research Integrity	Sponsor
Carbone	Kathy	Biogen	Director of Quality Operations Capabilities	Sponsor
Carmona	Juan	Harvard Medical School & MRCT Center	Biomedical Scientist and Student	Staff

Childers	Karla	Johnson & Johnson	Senior Director, Strategic Projects	Sponsor
Claiborne	Anne	Institute of Medicine	Senior Program Officer	
Clemens	Jennifer	CISCRP	Project Manager	
Cohen	Theodora	HCRI	Executive Director, Biostatistics and ARO Services	Sponsor
Coleman	Linda	Quorum Review IRB	Director of Regulatory Affairs & General Counsel	Sponsor
Coulbourne	Kelly	AstraZeneca	Clinical Trial Transparency Information Manager	
Dainesi	Sonia	UCB Brazil	Medical Director	
Dolz	Felipe	Sanofi	VP, Global Regulatory Policy and Intelligence	Sponsor
Drazen	Jeffrey	New England Journal of Medicine	Editor-in-Chief	
Dull	Peter	Bill & Melinda Gates Foundation	Integrated Clinical Vaccine Development	Sponsor
Feige	Michelle	AAHRPP	Executive Vice President	Sponsor
Frank	Liz	Dana Farber/Harvard Cancer Center	Patient Advocate	Speaker
Garabedian	Geoff	Quintiles Advisory Services	SVP and Managing Director	Sponsor
Goldsmith	Jennifer	Brigham and Women's Hospital	Brigham and Women's Hospital	DGHE
Grady	Christine	National Institutes of Health	Chief, Department of Bioethics	
Hallinan	Zachary	CISCRP	Director, Patient Communication and Engagement	
Hill	Nina	Pfizer, Inc.	Vice President, Science Policy & Advocacy	Sponsor
Houde	Jaime	EMD Serono	Manager of Clinical Trial Transparency	
Hurley	Elisa	PRIM&R	Executive Director	Sponsor
Jeong	Jaehong	DCUMC / CIMI	Medical Doctor / GUMC Visiting Scientist	Sponsor
Kelman	Ariella	Genentech, Inc.	Senior Group Medical Director	Sponsor
Kloiber	Otmar	World Medical Association	Secretary General	Speaker

Kress	Barbara	Merck & Co., Inc	Department Head, Trial Disclosure	Sponsor
Letvak	Laurie	Novartis	VP & Head, Clinical Development Policy	Sponsor
Levin	Jason	MadPow		
Li	Rebecca	MRCT Center	Executive Director	Staff
Lo	Bernard	Greenwall Foundation	President	
Marino	Heather	MRCT Center	Program Manager	Staff
Mastroleo	Ignacio	Program of Bioethics, FLACSO Argentina	Researcher	
McNair	Lindsay	WIRB-Copernicus Group	Chief Medical Officer	Sponsor
Mitchel	Jules	Target Health Inc.	President	Sponsor
Morris	Sandra	Johnson & Johnson	VP Strategy Realization	Sponsor
Neville	Jon	Critical Path Institute	Assistant Director, Data Standards Architecture	Sponsor
Okada	Ellie	Boston Cancer Policy Institute	Senior Fellow, President	
Otte	Adrian	Amgen	VP Global Development Operations	Sponsor
Perlmutter	Jane	Gemini Group	Founder and President	
Pingali	Usharani	Nizam's Institute of Medical Sciences	Professor (Addl) and Head	
Prasitsuebsai	Wasana	HIV-NAT, the Thai Red Cross AIDS Research Centre	Pediatrician and research physician	
Prucka	Sandra	Eli Lilly and Company	Consultant Scientist	Speaker / Sponsor
Pulford	David	GlaxoSmithKline	Senior Scientific Investigator	Sponsor
Quattrochi	Lauren	Sense About Science	Director of AllTrials Campaign, USA	Speaker
Rockhold	Frank	GlaxoSmithKline	Senior Vice President, GCSP	Speaker/Sponsor
Rosenfeld	Stephen	Quorum Review IRB	Executive IRB Chair	Sponsor
Rossi	Juliana	Eli Lilly (Brazil)	Clinical Operations Manager	Sponsor
Russell	Donald	Eli Lilly and Company	Senior Director, Global Clinical Operations	Sponsor

Scott	Jessica	GlaxoSmithKline	Director, Medical Advocacy & Policy	Sponsor
Shin	Im Hee	DCUMC / CIMI	Professor / Harvard MRCT Fellow	Sponsor
Silva	Ricardo	Brazilian Health Surveillance Agency - Anvisa	Specialist in Health Surveillance	
Silver	Lori	Partners In Health	General Counsel	
Sleeper	Lynn	Boston Children's Hospital/Harvard Medical School	Scientific Dir, Cardiol Clin Research/Assoc Prof.	
Sloan	Victor	UCB Biosciences	VP, Development Strategy Lead	
Taber	Magdalena	Consultant	Independent Consultant	
Teden	Patricia	Teden Consulting LLC	Consultant	
Turik	Michael	Eli Lilly and Company	Sr Director Clin Pharm; Chair Bioethics Cmte	Sponsor
Ulrich	Jocelyn	PhRMA	Senior Director	Sponsor
Van Campen	Luann	Eli Lilly and Company	Sr Advisor and Head of Bioethics	Speaker / Sponsor
Wang	Daniel	Queen Mary, University of London	Lecturer	
Wendell	Jeff			
Wright	David	Kowa Research Institute, Inc.	Senior Director, Regulatory Affairs	Sponsor
Zhou	Yijie	ABBVIE	Associate Director, Statistics	
Zhou	Yun-Ping	Merck & Co., Inc	Global Director, Sci & Med and Patient Perspective	Sponsor

Appendix 2: Meeting Agenda

Monday, 14 December 2015 **Conference Dinner** **Rialto Restaurant, The Charles Hotel** **1 Bennett Street, Cambridge, MA**	
6:00 – 8:30	Dinner for Executive and Steering Committee, Conference Speakers, Post-Trial Responsibilities Working Group Members

Tuesday, 15 December 2015 **MRCT Center Annual Meeting** **Loeb House, 17 Quincy Street, Cambridge, MA**		**Facilitator/Speaker**
7:30 – 8:00	Breakfast, Registration	
8:00 – 8:15	Welcome & Introductions	Barbara Bierer Mark Barnes
8:15 – 8:45	Keynote Address by Otmar Kloiber	Otmar Kloiber
8:45 – 9:15 9:15 – 10:00	**Post-Trial Responsibilities** • Remit of the Working Group • Overview of PTR Framework Responses from key stakeholders: • Christine Grady (National Institutes of Health) • Elizabeth Frank (Dana-Farber Cancer Institute) • Bernard Lo (Greenwall Foundation) • Otmar Kloiber (World Medical Association)	Barbara Bierer Luann Van Campen
10:00 – 10:45	PTR Working Group members commentary: • Ricardo Eccard da Silva (Anvisa, Brazil) • Laurie Letvak (Novartis, New Jersey, U.S.) • Usharani Pingali (Nizam's Institute of Medical Sciences, Hyderabad, India)	Barbara Bierer Luann Van Campen

	• Wasana Prasitsuebsai (The HIV Netherlands Australia Thailand Research Collaboration, Bangkok, Thailand) • Daniel Wang (Queen Mary / London School of Economics, London, U.K.) Group Discussion – Q&A	
10:45 - 11:00	Break	
11:00 – 11:30	**Data Sharing and Data Transparency** Overview of the three work streams: • Governance Work Stream • Business Models Work Stream • Information Technology Work Stream	Rebecca Li
11:30 – 12:00	Responses from key stakeholders: • Bernard Lo (Greenwall Foundation) • Frank Rockhold (GSK) • Lauren Quattrochi (Sense about Science USA) • Stuart Buck (Laura and John Arnold Foundation)	Mark Barnes
12:00 – 12:30	Group Discussion – Q&A	Mark Barnes
12:30 – 12:45	Closing Remarks	Barbara Bierer Mark Barnes
12:45 – 1:00	Lunch Members of Executive and Steering Committee and participants from sponsor companies obtain lunch	

Appendix 3: Speaker Biographies

Mark Barnes, J.D., LL.M, is the faculty co-chair of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard and practices law as a partner at Ropes & Gray LLP, where he represents academic institutions and industry in matters related to research with humans and animals, clinical trials, research grants and contracts, and research fraud.

Mark's law practice and his teaching at Yale focus on health care law and finance, human and animal research, stem cell and genetic research, research grants and contracts, research misconduct, and international research.

Mark formerly served at Harvard as the Senior Associate Provost and University Senior Research Officer and started and directed Harvard's HIV/AIDS treatment programs in Nigeria, Tanzania and Botswana. He serves on the Ethics Working Group of the NIH's HIV Prevention Trials Network (HPTN) and is the ethics advisor to HPTN Trial 071 in South Africa and Zambia. Mark has held senior appointed positions in the New York City and State departments of health.

Barbara E. Bierer, M.D., is the faculty co-chair of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), a Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston and a hematologist/oncologist. She is the Director of the Regulatory Foundations, Ethics and the Law Program of the Harvard clinical and translational sciences center. Previously she served as senior vice president, research at the Brigham and Women's Hospital for 11 years, and was the institutional official for human subjects and animal research, for biosafety and for research integrity. She initiated the Brigham Research Institute and the Innovation Hub (iHub), a focus for entrepreneurship and innovation. In addition, she was the Founding Director of the Center for Faculty Development and Diversity at the BWH.

In addition to her academic responsibilities, she serves on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R), dedicated to promoting the ethical conduct of biomedical and behavioral research; Management Sciences for Health (MSH), an international organization working in partnership globally to strengthen health care, local capability, and access; and the Edward P Evans Foundation, a foundation supporting biomedical research. Previously she has served as the chair of the Board of Directors of the Association for Accreditation of Human Research Protection Programs (AAHRPP) and as chair of the Secretary's Advisory Committee on Human Research Protections, HHS. She has authored or co-authored over 180 publications and is on the editorial boards of a number of journals including *Current Protocols of Immunology.*

Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.

Stuart Buck, J.D., PhD., leads the Laura and John Arnold Foundation's Research Integrity initiative, which seeks to improve the quality and reliability of scientific research in fields ranging from economics to cancer cell biology. In addition, he helps ensure that research supported by LJAF is as rigorous as possible, and that the Foundation's major investments are themselves evaluated by independent experts.

Stuart is an attorney and research expert with a background in education policy. He has written and co-written numerous scholarly articles that have appeared in journals such as the *Harvard Law Review*, *Education Economics*, *Education Next*, *Phi Delta Kappan*, and *Review of Public Personnel Administration*. Stuart has testified before the U.S. Commission on Civil Rights, and has been a panelist at major academic conferences, including the Association for Education Finance and Policy, the Association for Public Policy Analysis and Management, and the Harvard Program on Education Policy and Governance. He is the author of a Yale University Press book on education in the African-American community, *Acting White.*

Stuart holds a Ph.D. in education policy from the University of Arkansas, where he studied econometrics, statistics, and program evaluation; a J.D. with honors from Harvard Law School, where he was an editor of the *Harvard Law Review*; and bachelor's and master's degrees in music performance from the University of Georgia.

Ricardo Eccard da Silva, has worked at the Brazilian Health Surveillance Agency (Anvisa) since 2005 evaluating drug related clinical trial projects. He is responsible for inspecting various clinical sites in Brazil and also attending inspections conducted by the FDA (US Food and Drug Administration) in Brazilian clinical sites. Riccardo is also a qualified inspector by World Health Organization in Indonesia.

Ricardo graduated in *Biomedical Science in 2004 in Brazil and* Masters in Health Science at the University of Brasília, Brazil in 2014. Currently, Ricardo is a Doctoral Student in the Health Science program at the University of Brasília. He has developed a doctoral project on mapping of clinical trials in Brazil, Denmark, The Netherlands, Israel, Finland, Estonia, Ukraine, Malaysia, Egypt, South Korea, Japan, Russia, India, China, South Africa, Peru, Mexico, Chile, Colombia, Argentina, Turkey, Singapore and Thailand.

Topics of interest include clinical trials, global public health, technological innovation, public health system in poor and emerging countries, bioethics, regulatory issues, neuroscience and psychopharmacology.

Ricardo is also a member of International Conference Harmonization – ICH Multi-Regional Clinical Trials E17 group.

Elizabeth Frank -- Liz Frank's experience as a patient and research advocate stems from her personal experience as an 11 year breast cancer survivor, her experience working with local and national advocacy organizations, as well as her prior work experience. Liz' primary work venue is at the Dana Farber Cancer Institute, where she serves as Lead Advocate for the Dana Farber/Harvard Cancer Center (DF/HCC) Breast Cancer Advocates, a group of well-informed breast cancer advocates whose focus is on working with researchers engaged in translating the findings of the lab to clinically useful treatments for patients.

Bringing a patient perspective to clinical trial design has also been a focus, through her work at the Dana Farber/Harvard Cancer Center, The DF/HCC Breast SPORE, The Translational Breast Cancer Research Consortium, and The NCI Breast Cancer Steering Committee. Through these organizations, Liz is also involved in several projects related to biospecimen banking, and the ways that we approach patients in the consenting process for clinical trials. The types of communication and information patients need, and the manner in which they are provided information are of great interest to Liz, both during the cancer treatment process and after.

Christine Grady, Ph.D, is a nurse-bioethicist who currently serves as the Chief of the Department of Bioethics at the National Institutes of Health Clinical Center and as a Commissioner on the President's Commission for the Study of Bioethical Issues. Her research contributions are both conceptual and empirical and are primarily in the ethics of clinical research, including informed consent, vulnerability, study design, recruitment, and international research ethics, as well as ethical issues faced by nurses and other health care providers.

Dr. Grady has authored more than 100 papers in the biomedical and bioethics literature and authored or edited several books, including *The Oxford Textbook of Clinical Research Ethics*. Her work is known internationally, she has lectured widely on ethical issues in clinical research and clinical care, HIV disease, and nursing. She is an elected fellow of the American Academy of Nursing and of the Hastings Center, and a senior research fellow at the Kennedy Institute of Ethics. She holds a B.S. in nursing and biology from Georgetown University, a M.S.N. in community health nursing from Boston College, and a Ph.D. in philosophy from Georgetown University.

Otmar Kloiber, M.D. -- After studying medicine at the University of Cologne, Otmar Kloiber joined the Department of Biochemistry at the University of Minnesota, Duluth in 1985. He returned as a research fellow to the Max-Planck-Institute for Neurological Research in Cologne in 1986 where he previously prepared his doctoral thesis.

In 1991, he joined the German Medical Association where he was in charge of the International Department including its work on European Union Issues as well as the support for doctors associations, orders and chambers in the then new democracies of central and east Europe. He participated in the creation of medical and health insurance laws as well as rules for professional conduct.

Among other functions, he served as member of the German Parliament study commission "Law and ethics of Modern Medicine" in its 14 electoral term 2001 and 2002. He provided expertise to the Economic and Social Committee of the European Union in the design of their Public Health Program and contributed to the policy work of the World Medical Association in its Medical Ethics and Socio-Medical Affairs committee. Dr. Kloiber finally left the German Medial Association as its Deputy Secretary General.

Since 2005, he has served as Secretary General of the World Medical Association (WMA), which is the global organization of currently 106 national medical associations. He is interested in the development of deontology under the influence of health system organization and its relation to the provision of medical care. In the cooperation with and work for the World Medical Association, he has participated in the development of major health policies and guidelines for more than 20 years. Dr. Kloiber has been awarded an honorary doctorate by the University Victor Babesis, Timisoara, Romania and he is fellow at the at the Center for Global Health and Medical Diplomacy, University of North Florida where he also has been Clinical Professor in health administration from 2009 to 2013.

Laurie Letvak, M.D., is Vice President and Head of Clinical Development Policy at Novartis, a position she has held since June 2014.

Laurie has been with Novartis for over 20 years in a variety of positions. She played a key role in the development of Glivec® since joining the International Project Team in 2001, responsible for Global Medical Affairs. From 2008-2012, she was the Global Program Head for Glivec and Tasigna®. In this role, she was responsible for leading the global development efforts for both drugs, including registration programs for new indications.

Laurie assumed the position of Global Development Head for the Critical Care Franchise in 2012. In that role, she was responsible for the strategic development and execution of plans for the evolving portfolio, which focused on specialty cardiovascular (with emphasis on heart failure) and metabolic products, particularly for lipids and atherosclerosis.

Laurie received her undergraduate and medical degrees from Cornell University. She did her internal medicine training at Boston University and her Hematology-Oncology fellowship at New York University Medical Center and worked for Lederle Laboratories with experience in Medical Development and Business Development prior to joining Novartis in 1994.

Rebecca Li, Ph.D., has over 17 years of experience spanning the entire drug development process with experience in Biotech, Pharma and CRO environments. Dr. Li currently serves as the Executive Director of the Multi-regional Clinical Trial Center at Brigham and Women's Hospital and Harvard. The Center was chartered to improve the design, conduct and oversight of multi-regional clinical trials in the developing world and simplifying research through best practices. She was also a Fellow in the Division of Medical Ethics at Harvard Medical School. Prior to joining Harvard, Dr. Li served as the VP of Clinical Research at the New England Research Institutes for 6 years. She also was employed at Wyeth Research as the Associate Director in Translational Clinical Research. She earned her PhD in Chemical and Biomolecular Engineering from Johns Hopkins University.

Bernard Lo, M.D., is President of the Greenwall Foundation, whose mission is supporting bioethics research and young researchers in bioethics. He is Professor Emeritus of Medicine and Director Emeritus of the Program in Medical Ethics at the University of California San Francisco (UCSF). A member of the Institute of Medicine (IOM), Dr. Lo served on the IOM Council and chaired the Board on Health Sciences Policy. He chaired IOM committees that made recommendations on conflicts of interest in medicine and on responsible sharing of clinical trial data. He served on the IOM committee, *Dying in America*.

Dr. Lo serves on the Board of Directors of Association for the Accreditation of Human Research Protection Programs (AAHRPP) and on the Medical Advisory Panel of Blue Cross/Blue Shield. Formerly he was a member of the National Bioethics Advisory Commission, the NIH Recombinant DNA Advisory Committee, and Ethics Subcommittee of the Centers for Disease Control and Prevention.

Dr. Lo and his colleagues have published around 200 peer-reviewed articles on ethical issues concerning decision-making near the end-of-life, oversight of research, the doctor-patient relationship, and conflicts of interest. He is the author of Resolving Ethical Dilemmas: A Guide for Clinicians (5th ed., 2013) and of Ethical Issues in Clinical Research (2010). He continues to care for a panel of primary care internal medicine patients at UCSF.

Usharani Pingali, M.D., currently works as Professor and Head of the Clinical Pharmacology and Therapeutics department at Nizam's Institute of Medical Hyderabad. Dr. Pingali has more than 20 years of experience in clinical research. Some of her work experience includes, Phase I to IV clinical trials (conducted 8 Phase I clinical trials and more than 50 Phase III –IV clinical trials including Multinational Global trials) in Type 2 Diabetes mellitus, Dyslipidemia, Hypertension, Osteoarthritis, and Bronchial asthma; auditing of clinical research projects; scientific evaluation of herbal drugs using modern research methodologies; evaluating endothelial dysfunction and studying effect of pharmacological interventions and herbal formulations on its reversal; Pharmacovigilance and Drug safety; teaching and training of PhD and DM students in Clinical Research and GCP; developing Non-Invasive pharmacodynamic methods for evaluation of drugs; and organizing workshops on clinical pharmacodynamics and pharmacokinetics.

Dr. Pingali has also received a number of scientific awards for her work including the LK Oration in 2012, the UK Seth Gold medal for best research paper in clinical pharmacology, the PP Suryakumari Medal for best research publication in diabetes, Ford Foundation Travel Fellowship, and the Ati Vishisht Chikitsa Gold Medal from Association of College of Chest Physicians, New Delhi. She is also a member of National and International Societies, the National Regulatory Committees and a member of editorial board of various National and International Journals. She has published about 90 research articles in National and International Journals and contributed to 36 chapters to various research books. In 2011, she co-Edited a text book in clinical research entitled, "A Practical Guide to Human Research and Clinical Trials".

Wasana Prasitsuebsai, M.D., M.P.H., completed her pediatric residency training at the Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand and completed her Masters of Public Health at the University of New South Wales in Sydney. Dr. Prasitsuebsai has worked as a research physician in HIV and infectious diseases since 2005. She is currently a pediatrician and research physician at the HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT), The Thai Red Cross AIDS Research Center. She participated in over 50 clinical trials as a principal investigator, project leader or co-investigator. These include studies that are part of the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Group, the South East Asia Infectious Disease Clinical Research Network (SEAICRN), the Therapeutics Research, Education, and AIDS Training in Asia (TREAT Asia) and HIV-NAT. She is currently a principal investigator for an NIH (R01) study in Asia. Her expertise ranges from pharmacokinetics, HIV co-infection, complications, IND and strategic studies in children and adolescents. Aside from research, she also provides HIV training to other professional healthcare workers in the Asian region and organizes social events to raise fund for HIV-infected children in Thailand.

Lauren Quattrochi, Ph.D., M.A., M.A., is a neuroscientist who guides the campaign for AllTrials USA at Sense About Science, a non-profit focused on equipping the public with tools and knowhow to navigate evidence-based research. She specializes in educating the public on breakthrough science, correcting popularized pseudoscience and bringing about awareness on clinical trial transparency in the USA. She earned her doctorate from Brown University in Molecular Pharmacology and Physiology, where she discovered a novel third subtype of photoreceptor. Throughout her career, she has had a passion for science communication, teaching and outreach. In parallel to her research at Brown University, she founded and leads a group for graduate women in science and engineering (GWiSE) to create network opportunities for a community for women striving in the sciences. Dr. Quattrochi has also designed and implemented diverse science courses that have been internationally recognized and awarded. She has organized science communication conferences from inception to implementation and been trained in administrative leadership through the Executive Scholars Program. Before her doctorate, she earned her first Master's in 2009 from Brown University while working full-time at Pfizer Inc in pre-clinical drug discovery, excelling in areas of drug metabolism, in-silico pharmacokinetic modeling and excipient formulations. Before working at Pfizer, she performed research along the US Coast guard in oil spill culprit identification using portable Raman Spectroscopy.

Frank Rockhold, M.D., is Head of Global Clinical safety and Pharmacovigiliance at GlaxoSmithKlin. While he is primarily known for his expertise in biostatistics and clinical trial design, for the past ten years Frank has also been a leader within GSK and in the scientific community as a whole in promoting data disclosure and transparency in clinical research. He has served for 9 years on the board of directors of CDISC (the non-profit Clinical Data Interchange Standards Consortium) and is past president of the SCT. He has over 150 publications and presentations in major scientific journals across a wide variety of topics and has held adjunct faculty appointments at five universities, including his current post as Affiliate Professor of Biostatistics and Virginia Commonwealth University Medical Center. Frank is a former President of the Society for Clinical Trials and a Fellow of both of the Society the American Statistical Association. He is also an inaugural member of the PCORI Clinical Trials Advisory Panel.

Luann E. Van Campen, Ph.D., M.A., is Senior Advisor and Head of the Lilly Bioethics Program at Eli Lilly and Company. Since 2008, she has been the Company's bioethics technical expert and has developed and led the Company's innovative bioethics initiatives. She serves as the executive secretary of the Lilly Bioethics Advisory Committee (BEAC). Dr. Van Campen also serves on several academic and professional ethics working groups. Prior to this role, Dr. Van Campen was a Scientific Communications Consultant and was responsible for developing policies, procedures, processes, and tools for global scientific publishing across the lifecycle of compound development. She also coordinated scientific communications for two Lilly Neuroscience drugs. Dr. Van Campen's Lilly contributions have been recognized with several awards including, the Lilly Research Laboratories President's Award, the Six Sigma Black Belt Team Excellence Award, two Quality Advocate Awards, and "They're Making a Difference" Recognition.

Before joining Lilly in 2000, Dr. Van Campen worked in the fields of hearing science and clinical audiology for 13 years. She completed her clinical fellowship with Vanderbilt University Medical School and the Bill Wilkerson Center (Nashville, TN), and then served on the faculty of the University of Oklahoma Health Sciences Center (Oklahoma City, OK) in the Otorhinolaryngology department. During her faculty tenure, she was the lead investigator for a multi-site, longitudinal study examining the auditory and vestibular sequelae following the Oklahoma City Bombing and served on a national Blast Injuries Studies Steering Committee. Subsequent to this, she was a visiting scientist with the Centers for Disease Control and Prevention's (CDC), National Institute for Occupational Safety and Health (NIOSH) (Cincinnati, OH). Dr. Van Campen has co-authored a variety of scientific articles and presentations. Her specialties include evoked potentials, auditory and vestibular diagnostics, blast trauma, noise exposure, mood disorders, scientific publishing, and bioethics.

Dr. Van Campen earned a BS in Speech Pathology and Audiology from Miami University (Oxford, OH), a MS in Audiology with a minor in Psychology from Purdue University (West Lafayette, IN), a PhD in Hearing Science with a minor in Neuroscience from Vanderbilt University (Nashville, TN), and a MA in Bioethics from Trinity International University (Deerfield, IL).

Daniel Wei L. Wang, Ph.D, MSc., is a Lecturer in Health and Human Rights at Queen Mary, University of London. Before joining the School of Law at Queen Mary, he was a LSE Post-doctoral Fellow (2012-2013) and taught at the University of Sao Paulo and at the Brazilian National School of Public Administration. Daniel's work appeared in some of the most important journals in the areas of health, law and human rights, such as the *Journal of Law Medicine & Ethics*, *Health Economics Policy and Law, The Human Rights Law Review* and *The Modern Law Review.* The Ministry of Health and the Ministry of Social Development in Brazil bestowed on Daniel the prize for the best article on the right to social assistance in 2014. Daniel holds a Bachelor in Law, a Bachelor in Social Sciences and a Master in Law from the University of Sao Paulo, Brazil. He also holds a Master in Philosophy and Public Policies and a Law PhD from the London School of Economics and Political Science (LSE).