



# Global Engagement

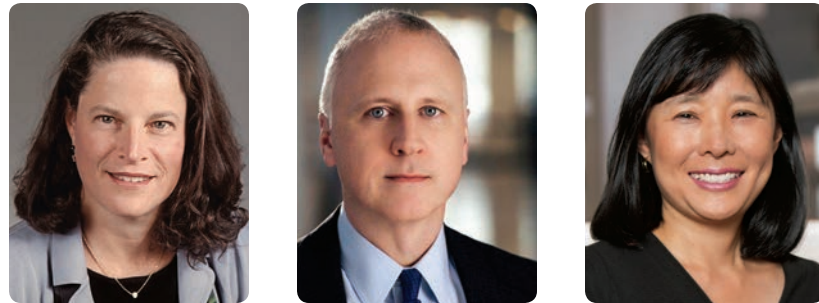


The MRCT Center at Harvard



## OUR MISSION

To improve the design, conduct, and oversight of multi-regional clinical trials, focusing on trials sited in or involving the developing world; to simplify research through the use of best practices; and to foster respect for research participants, efficacy, safety and fairness in transnational, trans-cultural human subject research.



### Dear MRCT Friends,

As we look back on 2014, we are proud of our achievements and very grateful for your ongoing support. It has been a pivotal year for the Multi-Regional Clinical Trials Center at Harvard University (Harvard MRCT) as we have completed several projects, launched new focus areas and expanded our global reach. Our multi-stakeholder collaborative efforts included contributions from over 120 individuals from patients and patient advocate groups to pharmaceutical representatives, from regulatory experts to academic investigators. These individuals have worked tirelessly this year to help us meet our milestones, frame and initiate new projects and ensure target s were met.

In response to the shifting regulatory landscape we launched a new initiative in January on returning aggregate research results to trial participants. We have vigorously advanced this project and developed a robust framework to enable responsible sharing of results to participants. In September, we laid the groundwork for a future project in post-trial responsibilities to participants following study closeout, including access to medicines. As progress and consensus building is often derived from sharing ideas across diverse viewpoints, we were delighted to welcome over 130 registrants to our Post-trial Responsibilities Conference in September to help us understand the issues and move towards potential solutions.

#### 2014 program highlights include:

- Achieving important new milestones in (1) returning aggregate results to study participants and (2) informed consent guidance for data sharing
- Working towards comprehensive India clinical trial regulatory reform
- Launching new projects in causality determination and post-trial access responsibilities

We have continued to grow our global mission of improving the quality of clinical trials through expanded international collaborations including key players in China, India, Korea and Japan.

This progress report provides a glimpse into the progress and milestones achieved by our working groups. Their tenacity and hard work has yielded great returns. As our center evolves, and awareness of our mission grows, so too does the number of opportunities for collaboration and positive impact.

We hope you agree that your resources of time and financial support have been put to good use over the past year and look forward to working with you in 2015. We welcome our partnership with six new sponsors that have joined us this year and our executive and steering committee that continues to support our efforts.

Thanks to you all, we are well positioned to advance our mission in making a difference in the ethical conduct of global clinical trials.

**Barbara Bierer**  
Co-Chair, MRCT

**Mark Barnes**  
Co-Chair, MRCT

**Rebecca Li**  
Executive Director, MRCT

## OUR OBJECTIVES





**Identify Initiatives**

Projects selected for launch will be those with demonstrated:

- Impact
- Significance
- Expertise within our stakeholder base
- Actionable within a defined time line

**Form Working Groups**

Multi-stakeholder teams will be formed through careful selection and include:

- Global diversity
- World class experts
- Enthusiastic leaders
- Deliverables and clear time line

**Pilot Solutions**

Project solutions identified will be:

- Piloted within our sponsor organizations
- Evaluated and results published
- If positive, work towards widespread adoption

**Implement & Adopt**

Project solutions implemented through:

- Training programs conducted by us and through our partner organizations
- Deploying MRCT members and stakeholders to disseminate guidelines and practices
- Working with MRCT partner associations to deploy sustainable training

**Disseminate & Communicate**

The Harvard MRCT team will:

- Identify end users of the project solution
- Deploy the dissemination strategy among our stakeholder base
- Develop a feedback mechanism for providing input into the workproduct for future revisions

**Revise & Improve**

Project deliverables will be:

- Modified with real world experience and feedback
- Updated as global regulations change
- Amended as feedback is provided by users
- Refreshed based on changes in current practices

We have six primary areas of focus this year that address pressing issues in multi-regional clinical trials.

**1 Clinical Trial Data Sharing and Transparency**

We participated in global conversations regarding clinical trial data sharing. We are now striving towards:

- A framework for best practices for data sharing
- Concise informed consent language to allow for broader data sharing
- Adopting an implementable guidance for how to implement a robust return of study results initiative engaging participants as our partners in research

**2 Data Monitoring Committee (DMC) Training**

We have created a training curriculum for DMCs to increase engagement of experts from emerging countries.

- Promoting training worldwide
- Disseminating best practice guidelines for DMCs
- Creating an educational module for global learning

**3 Ethical Frameworks for Conduct of Clinical Trials**

Representatives from industry, not-for-profits, patients, and academia join to create practical resources for the ethical design and conduct of multi-regional clinical trials. Areas of emphasis include:

- Protocol ethics guidance
- Post trial access responsibilities

**4 Global Regulatory Engagement**

We continue to develop substantive partnerships with leaders in the emerging and developing world. We identify major issues in global clinical trial practice and, in our role as advisors, adopt a country-specific and culturally-relevant approach.

**5 Causality Assessment**

Compensation for injury is predicated on the determination of “relatedness” of the injury or death to participation in the clinical trial. This initiative includes:

- Bringing clarity to the scientific basis for assigning causality
- Preparation of training materials for experts that will be making these determinations

**6 Investigator Competence and Training**

Both the industry’s interest and the public’s interest would be well-served by the development of mechanisms to improve the capacities of investigator teams and sustainable, professionally run research sites. We aim to develop a framework of core competencies for clinical research team members.

## Improving Transparency in Global Clinical Trials through Returning Results to Participants

### WORKING GROUP CO-CHAIRS

Deborah Collyar, *Patient Advocates In Research*  
Laurie Myers, *Merck & Co., Inc.*

### WORKING GROUP MEMBERS

Carmen Aldinger, *Harvard MRCT*  
Salvatore Alesci, *PhRMA*  
Behdash Bahador, *CISCRP*  
Mark Barnes, *Ropes and Gray LLP, Harvard MRCT*  
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David Forster, *WIRB Copernicus Group*  
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Elizabeth Garofalo, *Novartis Pharma AG*  
Pierre Gervais, *QT Research*  
Barbara Godlew, *The FAIRE Company, LLC*  
David Haerry, *European AIDS Treatment Group*  
Laura Hagan, *Merck Serano*  
Zach Hallinan, *CISCRP*  
Sandra Hayes-Licitra, *Johnson & Johnson*  
Cheryl Jernigan, *Susan G. Komen*  
Angelika Joos, *Merck Sharp & Dohme (Europe) Inc.*  
Barbara Kress, *Merck*  
Paulo Lacativa, *CCBR Clinical Research*  
Sarah Larson, *Biogen Idec*  
Yann LeCam, *EURORDIS*  
David Leventhal, *Pfizer*  
Rebecca Li, *Harvard MRCT*  
Craig Lipset, *Pfizer*  
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Alex Nasr, *ABBVIE*  
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Nesri Padayatchi, *University of KwaZulu-Natal*  
Jane Perlmutter, *Gemini Group*  
Mary Ann Plummer, *Johnson & Johnson*  
Sandy Prucka, *Eli Lilly and Co*  
Ben Rotz, *Eli Lilly and Co*  
Beth Roxland, *Johnson & Johnson*  
Rima Rudd, *Harvard School of Public Health*  
Jim Saunders, *New England IRB*  
Jessica Scott, *GlaxoSmithKline*  
Amish Shah, *Harvard Law School*  
Zachary Shapiro, *Harvard MRCT, Harvard Law School*  
Patrick L. Taylor, *Boston Children's Hospital*  
David Walling, *Collaborative Neuroscience Network, Inc.*  
Vanessa Wasman, *WIRB Copernicus Group*  
Sarah White, *Partners HealthCare*  
Marc Wilenzick, *Stonington Heights Advisors*  
Sabune Winkler, *The Harvard Catalyst*  
Elizabeth Witte, *The Harvard Catalyst*



### Returning Results

Returning clinical trial results is an important way for investigators and sponsors to honor the essential contributions and voluntarism of study participants in multi-regional clinical trials, while improving the transparency of those trials.

Returning results refers to giving clinical trial participants plain language summaries of the trial results, providing information both about the outcome of the study as a whole, and potentially a more detailed description of the individual participant's study arm. While major organizations, including the World Medical Association and the European Medicines Agency, have called for sponsors to institute results return programs, sponsors currently face a number of both logistical and regulatory challenges before instituting a return of results initiative.

With these challenges in mind, Harvard MRCT convened a multi-stakeholder working group, comprised of leaders in academia, industry, patient advocacy and health literacy, to create a guidance document and toolkit that will detail practical solutions.

For additional information on this focus area:  
[mrct.globalhealth.harvard.edu/pages/clinical-trial-data-sharing-and-transparency](http://mrct.globalhealth.harvard.edu/pages/clinical-trial-data-sharing-and-transparency)



Return of Results working group in-person meeting  
September 2014

### MILESTONES

#### JANUARY 2014

#### Harvard MRCT Convenes Multi-Stakeholder Working Group

This multi-stakeholder working group comprised of 53 members from industry, academia, patient advocacy and non-profit centers and addressed comprehensively the challenges related to returning results.

#### SEPTEMBER 2014

#### Harvard MRCT's Working Group Created a Practical Guidance Document and Toolkit for Investigators and Sponsors Wishing to Return Results to Study Participants

This document provides implementable solutions to the problems facing returning results, ranging from answering questions about when to return

results, to providing original templates that can be used to create plain language summaries. This guidance will help to allow an investigator or any sponsor to institute a return of results program.

#### DECEMBER 2014

#### Harvard MRCT Has Engaged with Regulators for Comments and Further Guidance

Sponsors wishing to return results face key questions that are currently unanswered by regulatory authorities. With this in mind, Harvard MRCT has directly engaged regulatory agencies, so that we can develop practical solutions to the questions and challenges facing results returning initiatives.

### A Practical Guide to Data Monitoring Committees

As prior trainees joined DMCs and started to assemble their own teams, we realized the need for a practical document to reinforce the training curriculum. An expert writing team assembled this guide to DMCs that will be released during the Bangkok DMC training in January 2015.

### Data Monitoring Committee Training Objectives

Learning objectives covered during the interactive training include:

- Understand how a DMC functions to oversee trial safety
- Understand how to establish a DMC for a trial
- DMC member roles and responsibilities
- Understand the concepts of monitoring for futility and efficacy
- Learn how multi-regional clinical trials are monitored
- Review in-country regulations for safety monitoring

## Building Data Monitoring Committee Capacity Globally

Harvard MRCT recognizes that the countries in which global trials are conducted are often underrepresented in the Data Monitoring Committees (DMCs) that oversee safety for these trials. The goal of the DMC training initiative is to identify, train and recruit experts from emerging regions who have expertise in medicine or statistics, experience in clinical trials, and who would like to serve on Data Monitoring Committees (DMCs) also termed Data Safety Monitoring Boards (DSMBs).

### Increasing the Engagement of Experts

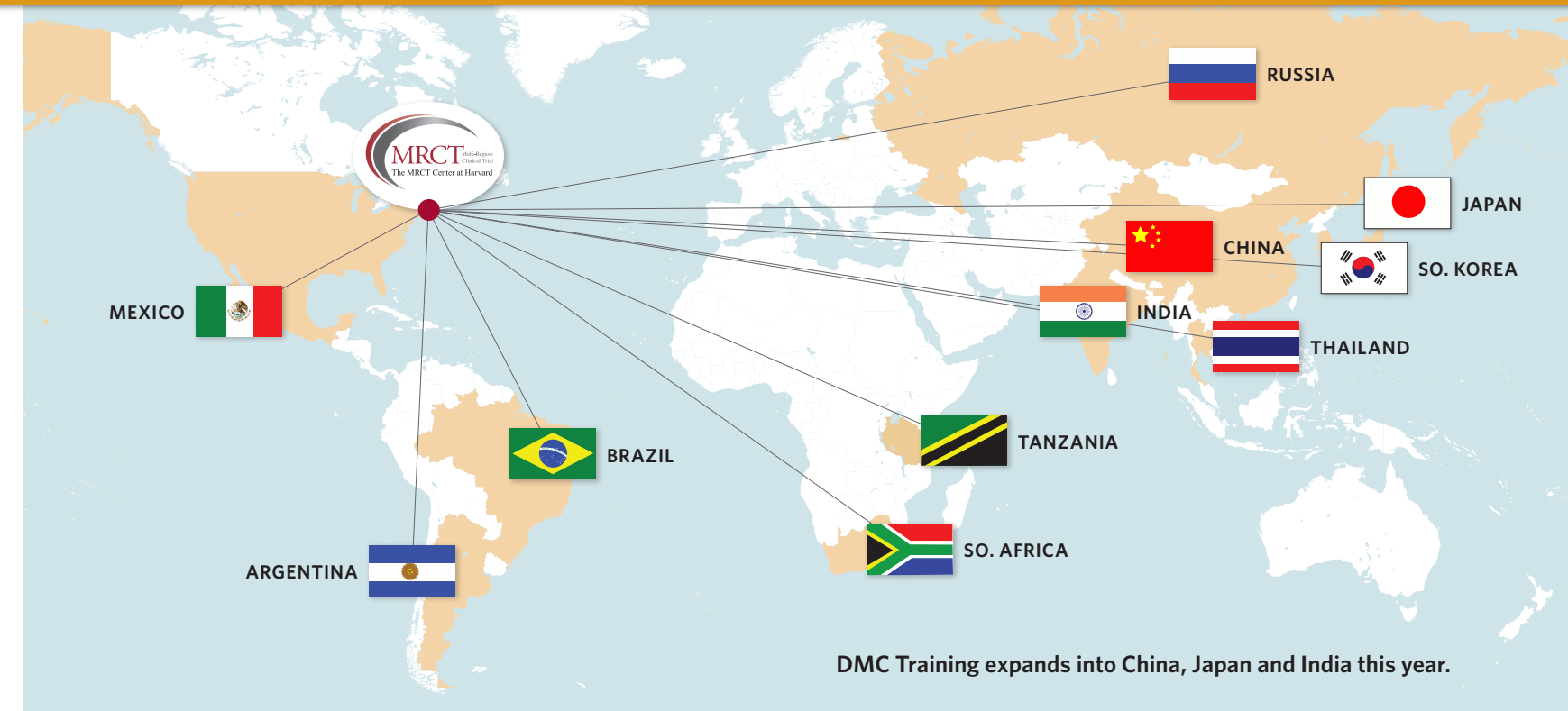
The mission is to increase engagement of experts from emerging world countries on DMCs. Recognizing the need for more engagement, Harvard MRCT created a training program in 2012, the ultimate goal of which was to transform motivated individuals into DMC champions within their home country.

### Focus in Asia

In 2014, our focus has been in Asia with regional trainings held in China, India and Japan and over 120 total participants trained. DMC trainees are drawn from investigators with demonstrated clinical trials experience and prior biostatistics or bioethics training. Additionally, members of industry, clinical research organizations and regulators have been attending trainings to learn more about how DMCs may be implemented in their country.

We thank our fellow presenters and partners in this important endeavor from: Merck, Amgen, Japan Pharmaceutical Manufacturers Association (JPMA), Drug Information Association (DIA) and the Indian Society for Clinical Research (ISCR).

For additional information on this focus area:  
[mrct.globalhealth.harvard.edu/pages/data-and-safety-monitoring](http://mrct.globalhealth.harvard.edu/pages/data-and-safety-monitoring)



### MILESTONES



#### DMC Training in Shanghai, China

Harvard MRCT, Merck, and Amgen partner to bring DMC training to China, hosted by DIA China.



#### DMC Training in Bangalore, India

Harvard MRCT, Amgen and ISCR partner on DMC training in Bangalore in conjunction with the ISCR annual meeting.



#### DMC Training in Tokyo, Japan

Harvard MRCT, Lilly and JPMA collaborate to bring DMC training to Japan.



#### DMC Training in Daegu, South Korea

Harvard MRCT and Daegu Catholic University Medical Center partnered to bring DMC training to South Korea.



## Understanding the Multi-Stakeholder View of Post-Trial Responsibilities

### PHASE 1: Framing the issues

Against the backdrop of the 2013 revision of the Declaration of Helsinki, Harvard MRCT worked towards exploring the expectations behind paragraph 34.

Discussion centered around how various stakeholders viewed post-trial responsibilities.

### PHASE 2: Development of a Common Ethical Framework for Post-Trial Responsibilities

The term “post-trial access” is used broadly to connote a wide range of possibilities for providing continued access to study interventions (and potentially other care) once a trial is over, or a subject’s participation has ended.

### DECLARATION OF HELSINKI PARAGRAPH 34

*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.*

Law, policy, and guidance in this area are vague, sometimes conflicting, and generally lacking in concrete solutions for questions regarding post-trial responsibilities. The issues are complex and demand thoughtful discourse to move the clinical trial enterprise towards meaningful solutions.

#### Areas we will address that currently lack clarity include:

- 1 How are recommendations regarding post-trial responsibilities influenced by the trial phase and/or prior experience with the intervention?
- 2 What types of interventions or resources should be included within post-trial responsibilities? Do recommendations include ancillary care, treatment of side effects and adverse events, etc.?
- 3 What is a reasonable duration for post-trial responsibilities to extend?
- 4 What is the mission and purpose of various stakeholders (sponsors, governments, investigators, etc.) in the conduct of clinical research and how do these roles intersect with post-trial access responsibilities?

For additional information on this focus area:  
[mrct.globalhealth.harvard.edu/pages/protocol-ethics-guidance](http://mrct.globalhealth.harvard.edu/pages/protocol-ethics-guidance)



### MILESTONE

SEPTEMBER 2014

#### Conference at Harvard University with the Petrie-Flom Center at Harvard Law School – Post-Trial Responsibilities: Ethics and Implementation

Key stakeholders in the Industry, Government, Academia and Non-profit sectors convened at Harvard to discuss:

- Implications of international guidance on post-trial responsibilities for clinical research sponsors, governments, investigators, and other stakeholders

- Range of perspectives on post-trial responsibilities
- Lessons from successful and unsuccessful attempts to implement post-trial access policies
- Potential scenarios and practical solutions for post-trial responsibilities that may inform policy in this important area moving forward
- Key priorities for a Post-Trial Responsibilities Working Group to be launched by Harvard MRCT



Perry Nisen (GSK) (top left), Richard Moscicki (FDA) (top right), and Hans Eichler (EMA) (bottom) debate the optimal path forward for clinical trial data sharing.

## Engaging Regulators in India, Europe, and the U.S.

There is a spectrum of benefits associated with providing broader access to clinical trial data, ranging from fostered trust and accountability to improved exploration and discovery. At our 2013 Annual Meeting, Harvard MRCT engaged the European Medicines Agency (Hans Eichler, M.D.), U.S. Food and Drug Administration (Richard Moscicki, M.D.) and key industry leaders including Perry Nisen M.D., Ph.D. (GlaxoSmithKline) towards solutions for a balanced approach for data sharing standards and rules of engagement.

## Clinical Trial Regulatory Reform In India

### Crippling Regulations Mean Clinical Trials on Hold

Over the last two years, India has implemented a series of regulations that had a detrimental effect on the Indian clinical research industry. The most damaging provision of the new regulations was the requirement that sponsors provide compensation for any clinical trial participant who is injured or who dies while in a trial, regardless of whether participation in the trial directly caused the injury or death. The provisions also required sponsors to provide compensation for an agent failing to provide its intended therapeutic effect. In response to this increased liability, many global sponsors, such as the National Institutes of Health, placed ongoing clinical trials in India on hold.

### Developing Alternative Reforms

After being apprised of the details of this political and regulatory environment by its contacts within India, Harvard MRCT began working with relevant industry stakeholders and government officials to develop alternative reforms that would not only reinvigorate the industry but also ensure the welfare of trial participants. As part of its engagement, Harvard MRCT convened a two-day roundtable discussion in Delhi between leading academicians, investigators, industry representatives, and government officials. The roundtable culminated with Harvard MRCT meeting privately with the Indian Secretary of Health and Family Welfare to detail consensus opinions reached by the roundtable.

For additional information on this focus area:  
<http://mrct.globalhealth.harvard.edu/pages/global-regulatory-initiative>

## GLOBAL REGULATORY MISSION

### Understand

Understand through discussion with passionate leaders which multi-regional clinical trials issues are most important to our stakeholders.

### Engage

Engage in critical discussions with our global stakeholders to recognize to which regions and issues Harvard MRCT's expertise and skills can add significant value.

### Act

Act to build capacity, offer training and develop policy to enable global change in the conduct of multi-regional clinical trials.

## MILESTONES



### JANUARY 2014

#### Harvard MRCT Convenes Roundtable Discussion Between Indian Government and Industry

Issues discussed included trial injury compensation, the benefits and risks of requiring audiovisual recording of informed consent, the utility of data from foreign clinical trials for India regulatory approvals, the required accreditation of ethics committees, investigators, and clinical trial sites. Consensus recommendations were presented to the Indian Secretary of Health and Family Welfare. The recommendations are also available on Harvard MRCT's website.

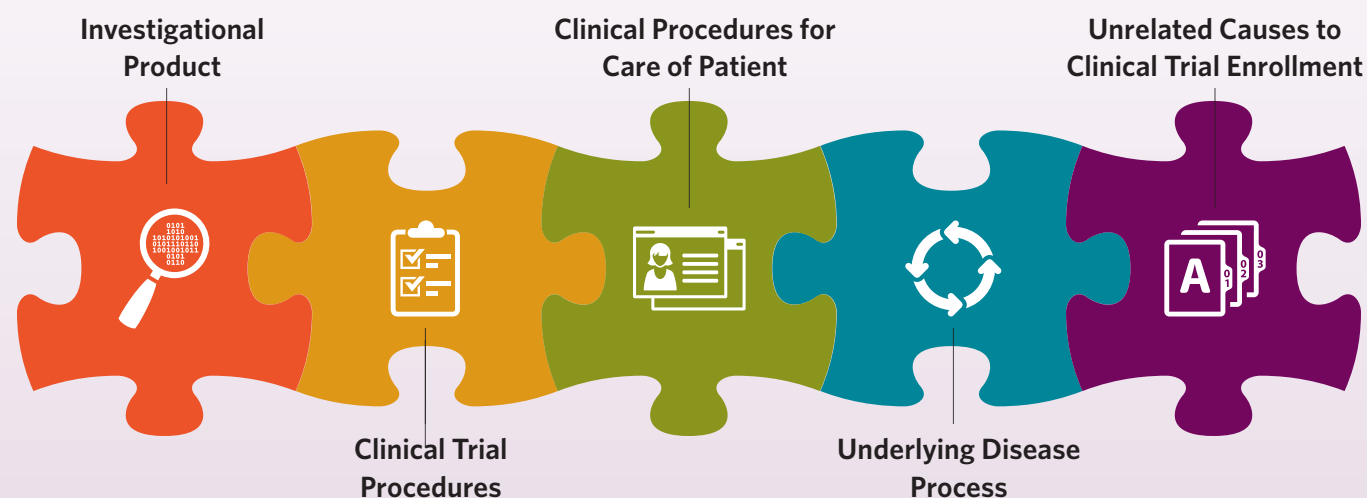
### JUNE 2014

#### Harvard MRCT Submits Comments to Ministry of Health and Family Welfare Regarding Draft Rules to Amend the Indian Drugs and Cosmetics Rules

In April 2014, the Indian Government proposed amendments to scale back many of the regulations it imposed in 2013. Harvard MRCT provided detailed commentary on the proposed amendments in an effort to ensure that the amendments would adequately address the deficiencies of the 2013 regulations.

## PROPOSED FRAMEWORK

Factors To Consider In Determining Causality of Adverse Event



## MILESTONES

APRIL 2014

**Causality Workgroup Launched in Delhi, India**

Harvard MRCT traveled to Delhi to launch the group in conjunction with the Indian Society for Clinical Research and Indian Council for Medical Research. The group's deliverables and plan for implementation were outlined.

DECEMBER 2014

**Causality Training Module and Materials are Drafted for Harvard MRCT Executive Committee Review**

This module will be piloted in India November 2014 by Harvard MRCT.

## A Scientific Approach to Causality Assessment in Clinical Trials

In April 2014, Harvard MRCT partnered with the Indian Society for Clinical Research to establish a Causality Workgroup. The co-chairs of the workgroup are Usharani Pingali of the Nizam's Institute of Medical Sciences and Shoibal Mukherjee of Quintiles. Other integral members of the workgroup include Anirban Roy Chowdhury of Merck, Ritika Bajaj of Biogen Idec, and Veena Jaguste of Amgen. The goal of the workgroup is to create guidance documents and training materials to enable clinicians and ethics committee members to determine causality for participant injuries, illnesses or death occurring in the course of a clinical trial.

As countries such as India begin incorporating causality analysis into their injury compensation mandate, the modules created by the workgroup will assist ethics committees and investigators in making causality determinations.

For additional information on this focus area:  
[mrct.globalhealth.harvard.edu/pages/causality-assessment](http://mrct.globalhealth.harvard.edu/pages/causality-assessment)

## Improve Compliance through Competency

A universally applicable, globally relevant framework that identifies relevant competency domains and associated skills necessary to conduct clinical trials has been developed in collaboration with a number of institutions including ACRP, DIA, MAGI, Transclerate and others. A competency-based approach has been embraced by several institutions and training organizations to standardize training requirements and define performance evaluations.

Possible uses of and outcomes that can result from the adoption and use of the Core Competency Framework:



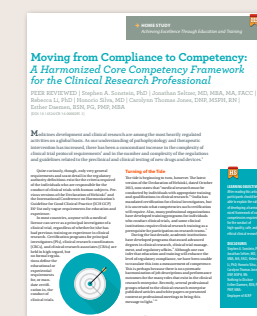
For additional information on this focus area:  
[mrct.globalhealth.harvard.edu/pages/investigator-competence](http://mrct.globalhealth.harvard.edu/pages/investigator-competence)

## 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

## MILESTONE



SUMMER 2014

**Simultaneous publication of the framework in *Clinical Researcher, Journal of Clinical Research Best Practices and Applied Clinical Trials***

The core competency framework attempts to bridge the gap between "what to do" and "how to do it." The framework identifies competency domains and associated cognitive skills required to conduct a quality and ethical clinical trial.

[www.coapcr.org/wp-content/uploads/2014/10/Clinical-Research-Competencies.pdf](http://www.coapcr.org/wp-content/uploads/2014/10/Clinical-Research-Competencies.pdf)

## CLINICAL TRIAL DATA SHARING & RETURN OF RESULTS

### RETURN OF RESULTS



#### Return of Results Summary Guidance

A practical guidance document for all sponsors (industry, non-profit, academic) that addresses key challenges in returning results and potential solutions.

[mrct.globalhealth.harvard.edu/harvard-mrct-return-results-guidance-2014](http://mrct.globalhealth.harvard.edu/harvard-mrct-return-results-guidance-2014)



#### Health Research Authority Draft Document "Guidance on Participant Information at the End of a Study (Active)" Comments

Harvard MRCT commented on a number of important areas in this document that would benefit from further consideration and/or clarification.

[mrct.globalhealth.harvard.edu/harvard-mrct-comments-uk-hra](http://mrct.globalhealth.harvard.edu/harvard-mrct-comments-uk-hra)

### INFORMED CONSENT AND DATA SHARING



#### FDA Document 2014-16492, Draft Informed Consent Information Sheet and FDA-2013-N-0271: Availability of Masked and De-identified Non-Summary Safety and Efficacy Data Comments

Harvard MRCT commented on this new proposed guidance including considerations for inclusion of individuals of low literacy and numeracy, non-English speakers, and vulnerable populations.

[mrct.globalhealth.harvard.edu/files/mrct/files/harvard\\_mrct\\_fda\\_ic\\_final\\_comments\\_9\\_12\\_14.pdf](http://mrct.globalhealth.harvard.edu/files/mrct/files/harvard_mrct_fda_ic_final_comments_9_12_14.pdf)



#### Harvard MRCT Provides Informed Consent Template Language to Enable Data Sharing

Harvard MRCT's Data Sharing Implementation workgroup has drafted language that may be used in consent forms to enable confidential data sharing.

[mrct.globalhealth.harvard.edu/pages/clinical-trial-data-sharing-and-transparency](http://mrct.globalhealth.harvard.edu/pages/clinical-trial-data-sharing-and-transparency)

## PROTOCOL ETHICS



#### Post Trial Access Responsibilities

Proceedings from September 18th conference highlighting the range of perspectives on this issue.

[mrct.globalhealth.harvard.edu/mrct-post-trial-responsibilities-conference-proceedings-september-18-2014](http://mrct.globalhealth.harvard.edu/mrct-post-trial-responsibilities-conference-proceedings-september-18-2014)



#### Ethics Training Module Launched with Partner Global Health Training Centre

An e-learning resource was created by the University of Oxford's Global Health Network adapted from the Harvard MRCT Ethics Tool kit to promote clear documentation of ethical issues in the design of studies.

[globalhealthtrainingcentre.tghn.org/essential-elements-ethics/](http://globalhealthtrainingcentre.tghn.org/essential-elements-ethics/)

## GLOBAL REGULATORY ENGAGEMENT



#### Executive Summary of AIIMS/Harvard MRCT/AHERF Roundtable

Summary of recommendations embodying the consensus of various stakeholders including leading academics, industry and government officials who attended the invitation-only meeting on regulatory reform in India.

[mrct.globalhealth.harvard.edu/executive-summary-aiimsharvard-mrctaherf-roundtable](http://mrct.globalhealth.harvard.edu/executive-summary-aiimsharvard-mrctaherf-roundtable)

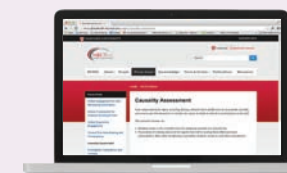


#### Financial Express "Clinical Trials, a Lost Opportunity for India"

An Op-Ed discussing the current state of affairs for Indian clinical trials, published November 3, 2014.

[mrct.globalhealth.harvard.edu/india-clinical-trials-op-ed-financial-express](http://mrct.globalhealth.harvard.edu/india-clinical-trials-op-ed-financial-express)

## CAUSALITY ASSESSMENT



#### Training Module for Causality Assessment Released

A best practice primer for determination of causality of an adverse event and likelihood it is caused by the investigational product. This guidance can be used to deliver training in various international settings.

[mrct.globalhealth.harvard.edu/pages/causality-assessment](http://mrct.globalhealth.harvard.edu/pages/causality-assessment)



## Thank you Harvard MRCT friends for making 2014 a year of tremendous progress.

We are so grateful for all of you that have been on this journey with us towards a better world for clinical trials. Your work as co-chairs, workgroup members, reviewers and ambassadors for Harvard MRCT is greatly appreciated.

### Moving Forward into 2015

We will not falter from our mission to impact pressing issues in multi-regional clinical trials and we will continue to build our work globally.

We look to 2015 to be one in which we continue at an invigorating pace, forge new partnerships and make even greater strides. We will delve deeper into areas such as offering guidance in regulatory harmonization in the area of returning results to study participants and the provision of access to medicines to participants after a trial has ended. We also hope that we might engage those of you that have not yet actively participated to bring new perspectives and solutions to the challenges you face in your own work.

This year we have expanded our stakeholders to include more patient advocates and investigators in our work—those at the front lines of clinical research and those most directly impacted by our projects. We look to include patients, patient advocates and investigators in all aspects of our work in 2015.

We also hope to expand our sponsor base of support and collaborators to ensure our objectives and projects can expand to meet the needs of the global clinical trials community.

Thank you,  
The Harvard MRCT Team

**THANK YOU FOR CONTRIBUTING YOUR EXPERTISE** to improve the quality standards for global clinical trials and for engaging with other like-minded organizations and stakeholders to address the common challenges associated with globalization of clinical research. Your commitment ensures that your institution continues to be a leader to the ethical conduct of clinical trials and benefits from best practice discussions and Harvard MRCT projects.

### EXECUTIVE COMMITTEE

Amgen, Inc.  
Bill & Melinda Gates Foundation  
Brigham and Women's Hospital  
Deloitte Consulting  
GlaxoSmithKline  
Johnson and Johnson  
Kowa Research Institute  
Merck

MRCT Center at Harvard  
Novartis  
Pfizer  
PhRMA  
Ropes and Gray LLP  
Sanofi  
Takeda Pharmaceuticals International, Inc.

### STEERING COMMITTEE

ACI Clinical  
AAHRPP  
Association of Clinical Research Professionals  
Biogen Idec  
CDISC  
Chesapeake IRB  
CMed  
Comprehensive and Integrative  
Medicine Institute  
DIA  
Eli Lilly and Co.  
FHI 360  
Harvard Clinical Research Institute  
ICON

Indian Society of Clinical Research  
IndiPharm  
Norwich Clinical  
Ohio State University  
PRIM&R  
Quintiles  
School of Medicine, Catholic University of Daegu  
Society for Clinical Research Sites  
SynRG Research Group  
Target Health Inc.  
Veristat  
VIS Research Institute  
Western Institutional Review Board  
Copernicus Group



**The MRCT Center at Harvard**



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