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2019 IMPACT REPORT



**MULTI-REGIONAL
CLINICAL TRIALS**

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

Dear MRCT Center Friends and Colleagues,

To fix a problem, you have to understand it, find a workable solution, and then recognize how to implement that solution. And that is what the MRCT Center does in its work — address emerging issues in multi-national clinical trials. The problems have foundations in ethics and law, but they manifest as barriers in the conduct of clinical trials to advance human health. We engage with our multi-stakeholder partners to understand these problems and strive, together, to create practical strategies and tools for our stakeholders to use.

The problems we addressed and the approaches we took this year demonstrate the depth of the work of the MRCT Center. The Research, Development, and Regulatory Roundtable (R3) — developed to focus on the pre-competitive issues in human subjects' research and regulatory oversight — completed its first year of successful and informative meetings. In October, we launched the deliverable for the Health Literacy in Clinical Research project — a website dedicated to clear communications throughout the clinical trial lifecycle. This site hosts resources and tools that sponsors, IRBs, and investigators can use to develop communications for participants in a health literate way. Our Diversity Workgroup has wrestled with the complex issues of diverse representation and inclusion in clinical research — making the scientific and social case for inclusion. Significant effort has focused on offering strategies and solutions to increase inclusion of underrepresented and underserved populations in research. We have recently brought together a diverse stakeholder group to tackle the ethical, legal, and practical barriers in global pediatric research, and we are framing a global approach to proactive safety surveillance.

And more. The pages that follow summarize the projects to which we have committed our efforts. We cannot do justice to any in this short report: we welcome you to contact us if you are interested in learning more and contributing to our mission.

The past 12 months have also been a period of growth for the Center. We welcomed new sponsors to our Executive and Steering Committees; we welcomed new representatives from existing sponsors. The MRCT Center team has doubled in size. And you can now follow our work on Twitter and LinkedIn.

“We are most proud of the way we work — engaging, listening, and learning from our different and diverse stakeholders.”

We are proud of the work we do at the MRCT Center, from the depth of discussion to the tactical use of our tools. But we are most proud of the way we work — engaging, listening, and learning from our different and diverse stakeholders. And none of this work would have been or would be possible without the support of our partners, sponsors, and friends. We continue to be energized by our collaborators, humbled by our patient advocates, and incredibly grateful to our team. To our Executive and Steering Committee members, thank you for your confidence and engagement. To our External Advisory Board, thank you for your thoughtful guidance and direction. To our Senior Advisors, we are grateful for the depth of knowledge you bring to our work. And to all of our colleagues, thank you for the unique perspective each of you bring to help us respond to the everchanging landscape of global clinical trials.



Sarah A White

Sarah White, MPH
Executive Director



Barbara Bierer

Barbara Bierer, MD
Faculty Director



Mark Barnes

Mark Barnes, JD, LLM
Faculty Co-Director

vision

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

mission

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

community

Independent convener for global stakeholders to address critical issues in the ethics, design, conduct, safety, and oversight of international clinical trials. We explore, learn, and engage with dynamic stakeholders to engineer a different approach forward.



The MRCT Center is an academic research and policy center. Our work is grounded in ethics, law, and medicines; our solutions are grounded in practice.

mrctcenter.org

HOW WE WORK

Working with our diverse stakeholder group, we employ a defined and deliberate process to achieve ethical, actionable, and practical solutions. Depending on the initiative, we use one of several approaches to craft solutions.

Workgroup: Large, multi-part issues over an extended period of time

Task Force: Short term for a defined issue

Programmatic Initiative: Regularly-scheduled in-person roundtable focusing on an issue

Global Regulatory Engagement: Consultation by senior team with governments and in-country stakeholders



understand > engage > act

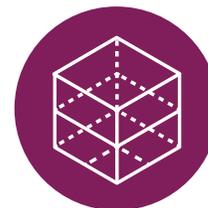
OUR FOCUS AREAS



GLOBAL
REGULATORY
ENGAGEMENT



ETHICS,
CONDUCT, AND
OVERSIGHT



TRANSPARENCY



CAPACITY
BUILDING



The MRCT Center recognizes the need for targeted engagement with global regulators and/or influential thought leaders to create a clinical research ecosystem that is more consistent across countries and regions. To be effective, we engage in trusted partnerships to further a shared mission of improving the ethics, design, conduct, and oversight of multi-regional clinical trials. Since 2013, we have been involved in multiple long-term, in-country engagements. Opportunities to impact the development of clinical trial regulations and infrastructure often arise unpredictably, and we have been responsive to those invitations.

Our work in **India**

Over the course of 6 years, the MRCT Center's steadfast commitment helped to ensure a positive outcome that culminated in the finalization of India's **New Drugs and Clinical Trial Rules, 2019**, in March. Considered a trusted partner, the Drugs Controller General of India (DCGI) asked the MRCT Center to host a special presentation and discussion for a multi-stakeholder group with the DCGI.

Changes in New Drugs and Clinical Trials Rules, 2019, include:

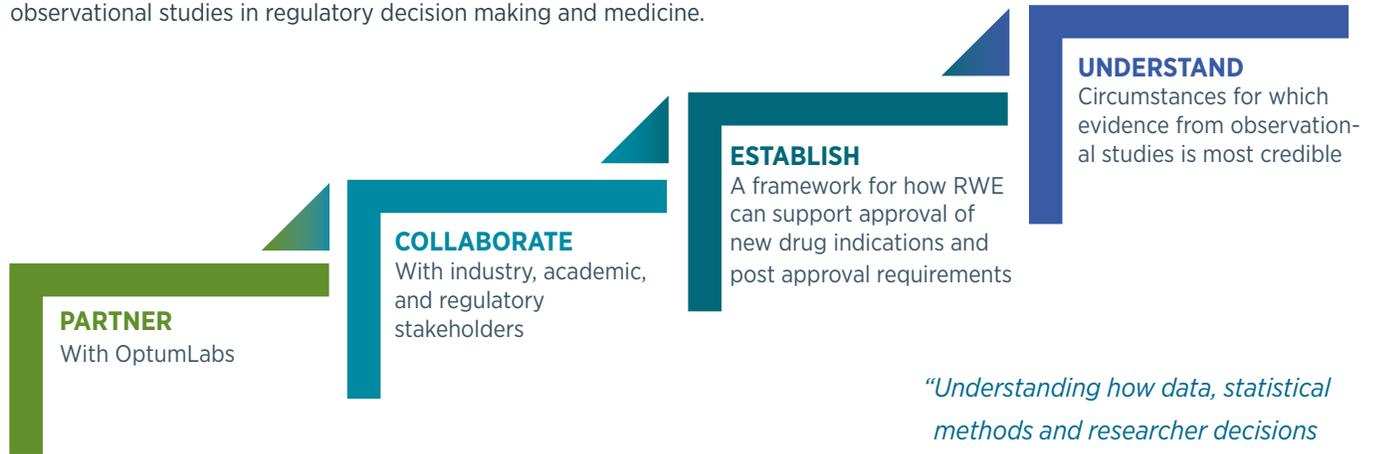
- Compensation reform
- Relatedness/Causality determination
- Medical management only as long as the injury is related to the trial
- Post-Trial Access to new drugs or INDs
- Audio-Visual Recording of informed consent for vulnerable participants
- "Academic Trial" defined and clarified
- Many additional provisions



OPERAND

Observational Patient Evidence for Regulatory Approval and Understanding Disease

The MRCT Center, in partnership with OptumLabs, designed the OPERAND project to better inform the use of Real-World Evidence (RWE) from retrospective observational studies in regulatory decision making and medicine.



This project will replicate clinical trials using retrospective de-identified electronic health records (EHR) and administrative claims data from the OptumLabs Data Warehouse. In 2019, research collaborators from Brown University and Harvard Pilgrim Health Care Institute were selected and began the process of independently replicating two clinical trials — ROCKET for atrial fibrillation and LEAD-2 diabetes control. The results of the first phase of replication were discussed at the Duke Margolis Center for Health Policy on October 3, 2019.

“Understanding how data, statistical methods and researcher decisions influence observational study results is key to enabling innovation in the use of real-world evidence for regulatory decision making.”

— William Crown, OptumLabs

In 2020, OPERAND will build on the previous work to understand how the drugs of the replicated clinical trials will perform with a more expansive population. We hope that the work of OPERAND will ultimately have direct applicability to decisions of payers and the clinical decision-making of physicians.



OPTUM Labs®





Impact of **GDPR** on clinical research

The European Union's General Data Protection Regulation (GDPR), which focuses on the processing of personal data of individuals located in any member state of the European Economic Area (EEA), took effect on May 25, 2018. The law had an immediate impact on clinical research generally and multi-regional clinical trials specifically.

The MRCT Center has led an effort in 2018 and 2019 to understand the key issues and implications of the GDPR on multi-regional clinical trials, clinical research, and public health. The effort includes a broad multi-national and multi-stakeholder group including government, industry, and academia. The effort aims to devise common solutions to the issues facing the global research community under the GDPR while simultaneously allowing primary and secondary research to be conducted in a manner that is consistent with relevant ethical and legal requirements.



Promoting global clinical research in **children**

Critical to the health of a population is the development and administration of safe and effective therapeutic products for children. Although some countries have well-established regulatory frameworks for research involving pediatric populations, many countries do not. As a consequence, pivotal pediatric trials fail to complete and children are prescribed therapeutic products for which information regarding safety or efficacy is inadequate.

In 2019, the MRCT Center initiated a workgroup to explore the ethical, legal, and pragmatic barriers of pediatric trials.

Our work in 2020 will seek to develop guidance for model and existing pediatric regulations and provide the research community with the tools to facilitate multi-national pediatric drug development.



Health literacy in clinical research

One out of every three people has difficulty understanding and using the health information they receive. Not only does this affect access to health care and treatment — it impacts clinical research. The MRCT Center believes that all clinical research communications for participants should be clear and understandable. In October of 2019, the MRCT Center launched its Health Literacy in Clinical Research website. The website is the culmination of incredible efforts by the MRCT Center’s Health Literacy in Clinical Research workgroup that sought to develop resources that help communicators present health literate information at all points of the participant’s clinical trial journey.

The MRCT Center’s approach to this initiative has included:



WORKGROUP

Establish a dynamic workgroup of diverse stakeholders.



WEBSITE

Designing a website that provides a user-friendly, usability-tested interface.



IDENTIFY CHALLENGES

Identifying the health literacy challenges and resulting opportunities.



DISSEMINATE

Disseminating the resources widely.



SOLUTIONS

Constructing systems-based solutions so that all clinical research stakeholders can integrate health literacy at all points of the clinical trial life cycle.



FEEDBACK

An openness to ongoing contributions and continual improvement.



BEST PRACTICES

Developing clinical research focused content via the literature on health literacy, best practices, expert input and consultation, and workgroup consensus.

2020 Future Directions:

- Continuing work to advance clear communications in research
- Global health literacy resources
- Continuing dissemination
- Website enhancements
- User experience evaluations



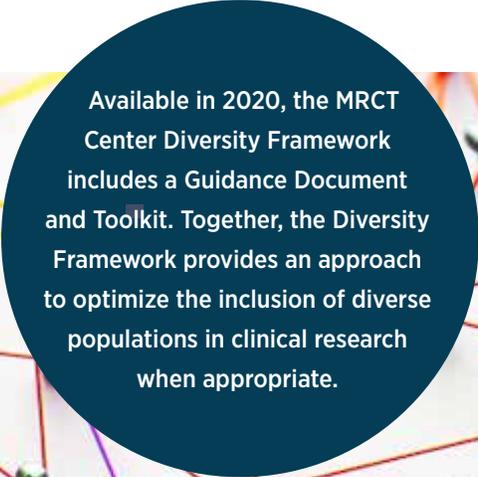
mrccenter.org/health-literacy



Diverse representation and inclusion in clinical research

In the US and abroad, randomized clinical trials continue to fail to enroll participant populations that reflect the composition of the general population or the population most affected by the disease. The MRCT Center continues our work to understand and balance the scientific and ethical challenges to diverse representation and inclusion in clinical trials.

In 2019, with our workgroup of diverse stakeholders, including academic- and industry-based leaders, not-for-profit institutional representatives, patient advocates and government representatives, we drafted the first version of the Diversity Framework Guidance Document which aims to substantiate and qualify the value of diversity to the science of biological variability, treatment discovery, health care, and justice. The Guidance Document identifies and analyzes barriers that limit diverse participation, and sets forth resources such as guidance materials, tactical strategies, and tools to advance required changes to conceptual, organizational, and operational challenges.



Available in 2020, the MRCT Center Diversity Framework includes a Guidance Document and Toolkit. Together, the Diversity Framework provides an approach to optimize the inclusion of diverse populations in clinical research when appropriate.



MULTI-REGIONAL CLINICAL TRIALS
**BIOETHICS
COLLABORATIVE**

The MRCT Center Bioethics Collaborative convenes diverse stakeholders to define and study emerging ethical issues in global clinical research. Meetings bring together individuals from academia, industry, patient advocacy groups, ethics committees, and government to share, define, study, and propose solutions in the context of the design, conduct, and oversight of multi-national clinical trials.



JANUARY 2019:
**Impact of Social Media on Clinical
Trial Integrity**

Social media use in clinical research carries potential risks, including the possibility that trial participants become unblinded or act on inappropriate information propagated by other participants. Attendees delineated risks and discussed risk-minimization strategies that still permit participants to garner the social support benefits of online interaction.



MARCH 2019:
**Secondary Uses of Health Care
Data for Clinical Trial Recruitment:
Legal and Regulatory Ambiguities**

Attendees turned to Office of Clinical Research (OCR) and Health Insurance Portability and Accountability Act (HIPAA) guidance to determine if previously collected healthcare data could be reused for clinical trial recruitment. A researcher may conduct recruitment in this manner but cannot sell protected health information (PHI) or use it for marketing. If recruitment is framed as a 'health care operation,' then a third-party vendor may also recruit using repurposed healthcare data.



MAY 2019:
**Impact of Mobile Devices and
Wearable Technologies on the
Design and Conduct of Clinical
Research**

Mobile technology use in clinical research raises privacy concerns. Clinical trial stakeholders should be cognizant of third-party data usage, the amount of data privacy information that should be disclosed in the informed consent process, and how much risk technologies and their inherent data vulnerabilities pose to participants.

**The MRCT Center is grateful
to the following sponsors
of the MRCT Center Bioethics
Collaborative:**

- Genentech, Inc.
- Johnson & Johnson, Inc.
- Merck & Co.
- Pfizer, Inc.
- Sanofi
- Takeda Pharmaceuticals
International, Inc.

Join us: MRCT@bwh.harvard.edu



The Research, Development, and Regulatory Roundtable (R3) is a neutral forum wherein policymakers, legal counsel, academicians, industry representatives, and global regulators present, discuss, and deliberate pre-competitive issues in drug and device development, regulatory oversight of clinical trials, and human subjects research. The R3 is a cooperative endeavor coordinated by the MRCT Center and Ropes & Gray LLP.

Research,
Development,
and
Regulatory
Roundtable



**AUGUST 2019 (PART 1):
Exporting from China for Research:
Biospecimens, DNA and Data**

Attendees learned how to navigate China's new regulations governing the collection, use, and exportation of biospecimens with the purpose of treating biospecimens as a component of national security.

**(PART 2):
Legal and Ethical Issues in the
Enrollment of a Company or Institu-
tion's Own Employees and Students
in Research Studies**

Employees and students could be considered vulnerable populations in their own institution's research, but attendees learned that research may proceed with special consideration towards preventing coercion, research bias, and privacy violations.

**OCTOBER 2019:
Ethical Challenges in Adaptive
and Platform Trials**

Adaptive and platform trials raise ethical concerns related to the informed consent process, the maintenance of clinical equipoise, and the principle of justice. Attendees addressed these concerns and suggested navigating them is more straightforward when the trial design is tailored to the scientific question.

**NOVEMBER 2019 (PART 1):
Regulatory Challenges for
Decentralized Clinical Trials:**

Attendees discussed regulatory and operational challenges to implementing decentralized clinical trials, including navigating health profession licensures across borders and ensuring safety and privacy during home visits by research team members.

**(PART 2):
Revised Common Rule and
sIRB Ambiguities**

Attendees considered regulatory ambiguities regarding transitioning studies to the Revised Common Rule and single IRB requirements. The Revised Common Rule's objective to relieve regulatory burden was maintained throughout the discussion.

The MRCT Center is grateful to the following sponsors of the R3:

Advarra

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Clinical Research

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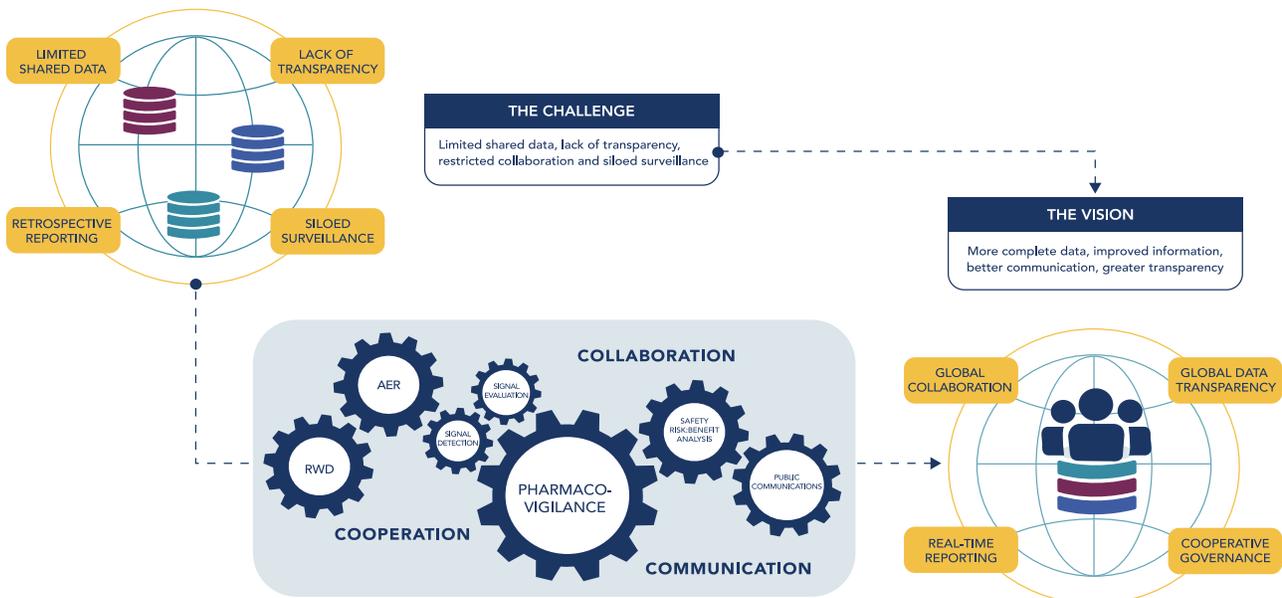
Proactive **safety** surveillance: a global approach

Ensuring the safety of biological products, drugs, and devices in healthcare is the shared responsibility of regulatory, academic, and industry-related stakeholders. Safety data are collected and analyzed throughout clinical trials and product development, as well as post market approval through spontaneous adverse event reporting and analysis of observational data. Some adverse events, however, only surface after regulatory approval and adoption as a consequence of wider dissemination to patients, indicating the use of administrative claims, electronic medical records and analysis of spontaneous or voluntary post-market adverse event reports more closely represents the product in the real-world setting.

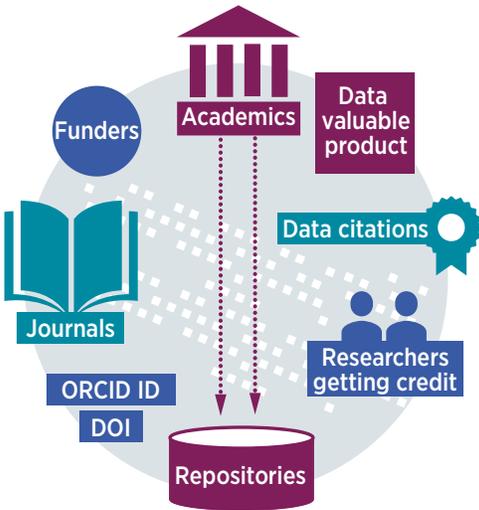
Convened by the MRCT Center in collaboration with others, the Proactive Safety Surveillance Initiative aims to improve upon the current safety surveillance systems by developing a framework to guide regulatory, academic and industry-related stakeholders in best practices for post-market surveillance and information dissemination. A partnership of stakeholders with different perspectives and approaches will enable the evaluation and adaptation of new technologies, methodologies, and insights to better support the determination of the medical significance and validity of safety signals for the global community. While inevitably challenging, we believe exploration of such a system holds the promise of increasing the timely detection, validation, and communication of important safety information.

“Combining real world safety data from non-traditional sources such as electronic health records and insurance claims with traditional sources of safety data has the potential to inform medical practice more quickly than current systems permit. Through MRCT Center’s leadership, I am confident that the collaboration among many will result in an enhanced, proactive global model for safety surveillance which will ultimately improve safety for patients everywhere.”

— Joanne Waldstreicher, MD
Chief Medical Officer
Johnson & Johnson



Credit for data sharing



Biomedical sciences are a data-driven endeavor, but individuals who share data are rarely recognized for data preparation and curation nor for making data available to others for secondary analysis.

The MRCT Center, in partnership with the Association of American Medical Colleges (AAMC) and the New England Journal of Medicine (NEJM), has advocated for a system that tracks the origin and uses of datasets over time so that data generators may receive appropriate recognition for their contributions to scientific knowledge.

This dataset-centric system of recognition allows for the linking of research funding sources, data generators, researchers, institutions, repositories, data sharing platforms, and publications or other scholarly products via the use of Persistent Identifiers (PIDs).

Advancing

the clinical trial enterprise

Clinical trials are a critical component of the medical evidence base. Evidence that substantial numbers of trials do not contribute meaningful information to the evidence base raises both ethical and scientific concerns. Participants assume the risks and burdens of a study, while mistakenly believing that they are contributing to medical progress. At the same time, these non-informative trials divert participants, researchers, and other resources from more valuable trials, potentially making it more difficult to reach enrollment targets.

This program focuses on efforts to increase the impact of clinical trials by ensuring that each new trial that is initiated addresses an important question, is designed appropriately, and is conducted and reported in accordance with scientific standards.

APPROACH

We will conduct a suite of activities aimed at addressing three problems affecting trials conducted at US academic medical centers:

1. trials that are unlikely to advance science or answer clinical questions
2. inadequate reporting of trials
3. poor scientific oversight of trial conceptualization, design and conduct



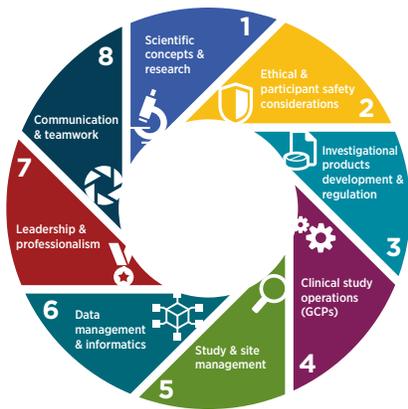
Successful GCP and MRCT training in **Canada**

The MRCT Center is an Asia-Pacific Economic Cooperation (APEC) Training Center of Excellence (CoE) in the area of Multi-Regional Clinical Trials (MRCT) and Good Clinical Practice (GCP) Inspection and a Training Partner of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

In that capacity, the MRCT Center, in collaboration with Health Canada, conducted a 3-day training workshop in Ottawa, Canada, in February 2019. Seventy professionals from Canada participated in an in-depth and interactive training. Senior staff from Health Canada, Danish Medicines Agency, U.S. Food and Drug Administration (FDA), industry, and MRCT Center facilitated the interactive sessions.



JTF Joint Task Force for Clinical Trial Competency



The MRCT Center hosts the Joint Task Force (JTF) for Clinical Trial Competency, a multi-stakeholder team dedicated to identifying and disseminating a framework with the skills necessary to be a clinical trial professional. The framework has been adopted by entities in various countries around the world including Australia, Brazil, Mexico, South Africa and the United Kingdom. In 2019, the MRCT Center co-led a workgroup that developed modifications to the Core Competency Framework to add project management-specific competencies.

mrtcenr.org/clinical-trial-competency/

GLOBAL IMPACT

In 2019, the MRCT Center added a Spanish translation of the Core Competency Framework to the project specific website and is pursuing translations into additional languages including French, Japanese, and Portuguese.



“The Mexican Association of Professionals Specialized on Clinical Research (APEIC), has adopted the JTF Competency Framework since its first launching. ... We certainly think that whoever is involved in clinical trials should know, understand, and adopt the JTF Competency Framework, and that this will contribute to our general goal as Clinical Research Professionals.”

— Jose Luis Viramontes, MD
President APEIC



Online training



Interpretation and application of ICH E6 (R2)

Comprehensive online training of the fundamental concepts of Good Clinical Practice are critical for clinical research stakeholders. The MRCT Center collaborated with a task force of sponsors and partners to create an interactive online course on the application of the revised Guideline for Good Clinical Practice E6(R2) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use (ICH). The course is freely accessible for regulators, sponsors, IRBs, and clinical site use.

cpd.partners.org/mrct

Visit the MRCT Center website to learn more about all the MRCT Center projects:



Global Regulatory Engagement

- Country regulatory engagements in China and India
- Impact of GDPR on Clinical Research
- OPERAND Project for Real World Evidence
- Promoting Global Clinical Research in Children



Transparency

- Balancing Data Anonymization with Data Utility
- Credit for Data Sharing
- Return of Aggregate Results
- Return of Individual Results
- Tools for Data Sharing
- Vivli: Global Clinical Trial Data Sharing Platform



Ethics, Conduct and Oversight

- Advancing the Clinical Trial Enterprise
- Diverse Representation and Inclusion in Clinical Research
- Health Literacy in Clinical Research
- The MRCT Center Bioethics Collaborative
- Post-Trial Responsibilities
- Proactive Safety Surveillance: A Global Approach
- Protocol Ethics E-Learning
- The Research, Development, and Regulatory Roundtable (R3)



Capacity Building

- Causality Training
- Data Monitoring Committee Training
- Good Clinical Practice (GCP) and Multi-Regional Clinical Trial (MRCT) Training (in-person and online)
- Joint Task Force for Clinical Trial Competency (JTF)

mrctcenter.org

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

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SELECTED 2019 PUBLICATIONS

Universal Funder Responsibilities That Advance Social Value

Bierer BE, Strauss DH, White SA, Zarin DA

American Journal of Bioethics, 18(11), Nov 2018; DOI: 10.1080/15265161.2018.1523498

Guidance Regarding Interaction Between GDPR and EU Clinical Trials Regulation Leaves Several Questions Unanswered

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Journal of Clinical and Translational Science. 2(6): 356-363, May 2019, DOI: 10.1017/cts.2018.340

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Annals of Internal Medicine, 7 May 2019; DOI: 10.7326/M19-0440

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Contemporary Clinical Trials, 84. July 2019. DOI: 10.1016/j.cct.2019.105812

Harms from Uninformed Clinical Trials

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JAMA, July 25; DOI: 10.1001/jama.2019.9892

The Culture of Trial Results Reporting at Academic Medical Centers

Zarin D.

JAMA Intern Med, October 2019, DOI: 10.1001/jamainternmed.2019.4200

Quality Assurance and Quality Improvement Handbook for Human Research

Howes LM, **White SA**, **Bierer BE**

Johns Hopkins University Press, November 2019

10-Year Update on Study Results Submitted to ClinicalTrials.gov

Zarin D, Fain KM, Dobbins HD, Tse T, Williams RJ

NEJM 381:1966-1974, November 2019; DOI: 10.1056/NEJMSr1907644



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