2020 IMPACT REPORT

MULTI-REGIONAL CLINICAL TRIALS

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

Since mid-March 2020, the MRCT Center team has worked remotely due to the COVID-19 pandemic.

mrctcenter.org

Dear MRCT Center Friends and Colleagues,

The year 2020 has been, is, and will be a memorable year. We hope those of you reading this letter are safe and healthy - and remain so throughout 2021 and the years ahead. We are forever grateful to the first responders and essential workers globally and our colleagues locally who have dedicated themselves to treating those infected and at risk of infection, and to the scientists, trialists, and patients who have advanced the understanding, diagnosis, treatment, and prevention of COVID-19 with breathtaking speed and selfless commitment. The collaboration and humanity of the global community has been inspiring.

The COVID-19 experience has forced all of us to reflect on the importance of our work. In the ecosystem of clinical research, the pandemic has highlighted the criticality of clinical research and, starkly and concurrently, revealed our failure to include and support underserved populations in the research. The MRCT Center's work in Diversity, Inclusion, and Equity in Clinical Research, begun in May 2017 and posted publicly in August of 2020, was timely, called for action, and provided concrete and actionable strategies to make change. The significance of our work in health literacy was reaffirmed as organizations turned to us for tools to develop clear communication to participants, at first for those being invited to consider COVID-19 related studies and later to all potential trial participants and the public.

The COVID-19 pandemic has emphasized how small our world has become and how interconnected we are; it has strengthened our commitment to understand and resolve issues that make cross-border collaboration difficult. One of current efforts in Promoting Global Clinical Research in Children examines the challenges of multinational pediatric research, relying on our global network to help address ethical, regulatory, and practical issues in planning and conducting pediatric research. With a team of collaborators, we are framing a model for cooperative safety surveillance to evaluate whether global collaboration, using different data sources and methodologies, might enhance detection and validation of safety signals earlier or differently. Interrogating observational data is envisioned as a complement to, not a replacement for, current safety surveillance systems. We continue to address challenges in cross-border transfer of research data brought on by differing regulatory regimes, including GDPR.

The mission of MRCT Center remains unchanged – we continue to work with our diverse community of stakeholders to define the emerging issues in global clinical trials and to develop practical approaches to advance the ethics, conduct, and regulatory environment of multisite, multinational clinical trials. This year we celebrate our first decade and look forward with even greater resolve to the future, strengthened by colleagues, friends, and experts, dedicated to improving clinical research and thus health equity for all.

Our work is the result of the collaboration and dedication of an extraordinary and diverse stakeholder group. To our Executive and Steering Committee members, thank you for your continued confidence and commitment to our work. To our External Advisory Board, thank you for guidance and direction. To our Senior Advisors, your experience and knowledge continue to impress us. We are inspired by the skill, experience, and passion of all our collaborators. We are incredibly thankful to the MRCT Center team who has remained focused and ever so productive amidst the challenges of remote work and quarantine while managing new and ongoing initiatives.

To all of our colleagues around the globe, thank you for the efforts you have made in helping the MRCT Center drive change for 10 years. We look forward with renewed spirit and energy to the future together.

Sarah White, MPH
Executive Director

Barbara Bierer, MD
Faculty Director

Mark Barnes, JD, LLM
Faculty Co-Director

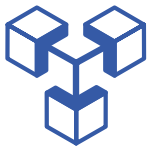
mission

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.

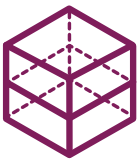
FOCUS AREAS



ETHICS, CONDUCT, AND OVERSIGHT

GLOBAL REGULATORY ENGAGEMENT

CAPACITY BUILDING



TRANSPARENCY

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

IDENTIFY INITIATIVES | IDENTIFY CHALLENGES | CRAFT SOLUTIONS | DISSEMINATE & COMMUNICATE | IMPLEMENT & ADOPT | REVIEW & REFINE

During the COVID-19 pandemic, the MRCT Center's vision to improve the integrity, safety, and rigor of global clinical trials became even more important. The world is primed for making significant change.

What can we do together?

Join us.

Our deepest gratitude to all essential workers for your dedication, courage, and commitment to helping others during the COVID-19 pandemic.

Quality of the Clinical Trial

CLEAR COMMUNICATION

Inclusion

Equity

Capacity Building

Health Literacy

Global Pediatric Research

Return of Results


“Inclusion of all populations is necessary for reasons of justice, health equity, and trust.”
Barbara Bierer, MRCT Center Faculty Director

DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

2020 was a pivotal year for the MRCT Center's Diversity Workgroup.

In August 2020, the MRCT Center released *Achieving Diversity, Inclusion, and Equity in Clinical Research*, a guidance document with accompanying Toolkit. The Guidance Document was crafted over the course of three years and provides a comprehensive overview of the scientific and ethical importance of, and challenges in, diverse inclusion in clinical research. The Guidance Document identifies and analyzes barriers that limit diverse participation, and sets forth resources such as guidance materials, tactical strategies, and tools to make the necessary changes in conceptual, organizational, and operational challenges.

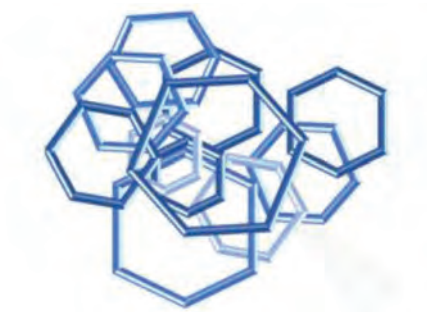
The MRCT Center, supported by the expertise of its workgroup—a diverse set of stakeholders including academic- and industry-based leaders, not-for-profit and institutional representatives, patient advocates and government representatives—is proud of this achievement and grateful grateful for the leadership's role in advising the development of the Guidance Document.

Please visit our Diversity, Inclusion and Equity in Clinical Trials website at mrctcenter.org/diversity-in-clinical-trials/ for more information.

"The opportunity for real success in increasing clinical trial diversity is perhaps greater now than ever given the heightened awareness of healthcare disparities and racial inequities. ***Achieving Diversity, Inclusion and Equity in Clinical Research*** *is a timely, comprehensive document that provides both practical approaches and tools that will help all key stakeholders involved in the research process achieve meaningful participant diversity and inclusion as well as improve patient outcomes, advance health equity, and promote public trust and confidence."*

Luther T. Clark, MD
Deputy Chief Patient Officer/Executive Director, Patient Insights/Diversity Leader, Merck & Co. Inc.

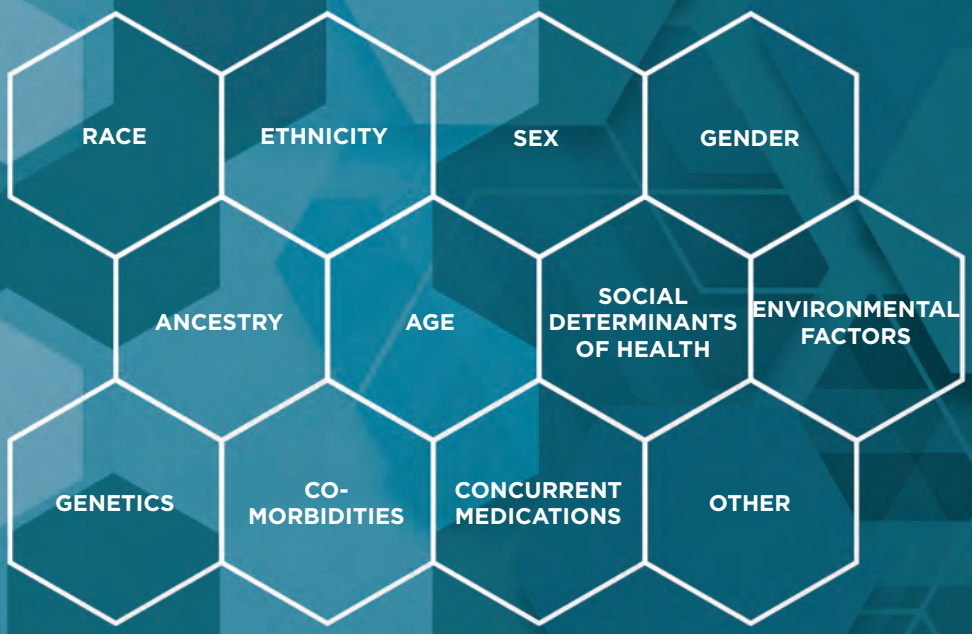
DIVERSITY PROJECT DISSEMINATION



Dimensions of diversity are not independent variables.

- In September of 2020, the FDA Office of Minority Health and Health Equity hosted a webinar to publicly introduce the MRCT Center Guidance Document. Since then, the MRCT Center has prioritized broad dissemination of the Guidance Document's recommendations and practical approaches to shift the paradigm toward inclusion in clinical research.

A broad definition of diversity



mrctcenter.org/diversity-in-clinical-trials/

- The MRCT Center hosted the 'Leaning In: A Webinar Series' that provided in-depth discussion into the Guidance Document topics. Each webinar also included guest speakers and stakeholders involved in creating the change through lived and learned experience.
- In December 2020, the MRCT Center also hosted a virtual meeting in collaboration with the FDA on 'Heterogeneity of Treatment Effects in Clinical Trials: Methods and Innovations.'

Each stakeholder has individual and cooperative roles and responsibilities in promoting diversity in clinical research.

In 2021, the MRCT Center will continue this important work through several channels:

- The MRCT Center will focus on hard-to-reach underserved groups, communities, and subpopulations who may require additional considerations for inclusion in clinical research.
- With involvement from our diverse and multi-stakeholder community, the MRCT Center will host a series of **roundtable discussions** with the goal of establishing actionable best practices, necessary collaborative activities, and metrics that would benefit us all in order to actualize the change required. The MRCT Center will lead a task force on the roles and responsibilities of research ethics committees in achieving appropriate representation in clinical research.
- The MRCT Center believes a **clinical research workforce** should be diverse and trained in the skills necessary to support, understand and communicate with a culturally diverse participant population. In 2021, we will explore workforce development in clinical research.

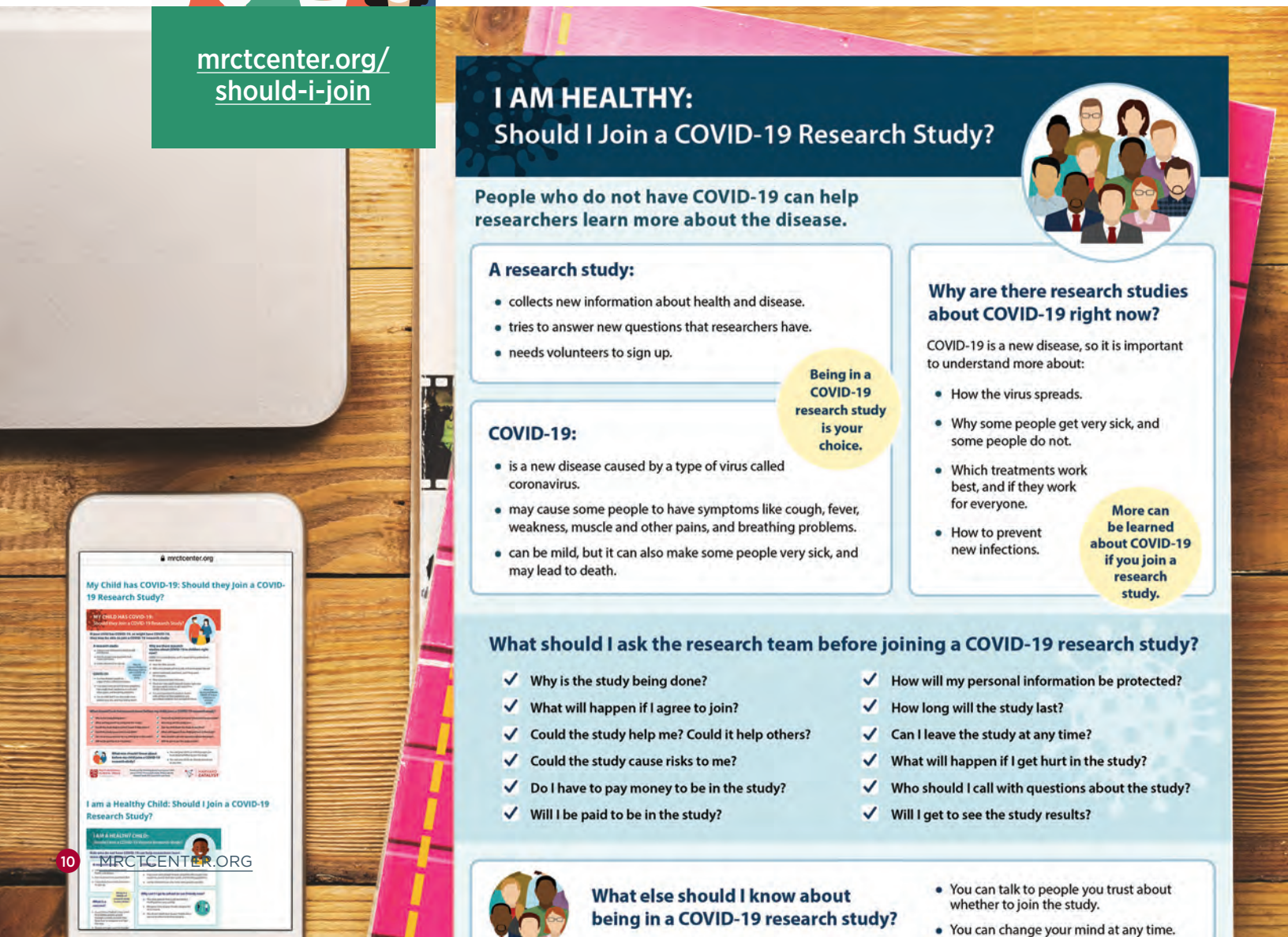
"SHOULD I JOIN" CLINICAL RESEARCH FLYERS

The MRCT Center developed resources to improve the way stakeholders recruit, consent, and conduct studies, with the aim of benefiting potential, enrolled, and past study participants.

Relying upon our health literacy experience, the coronavirus pandemic presented the opportunity for us to focus more deliberately on direct-to-consumer materials that support participant autonomy and informed decision making about whether to join COVID-19 research studies. The resulting portfolio of introductory COVID-19 research flyers lays the foundation to increased understanding about research and what information should be provided when considering research participation. Further, recognizing the unfortunate lack of diversity in enrollment to COVID-19 trials to date, this suite of flyers was translated into Spanish to provide an additional resource to support representative and inclusive research.

The MRCT Center remains devoted to supporting ongoing efforts to reach communities who are underserved and under-represented in research.

mrctcenter.org/should-i-join



HEALTH LITERACY GLOSSARY

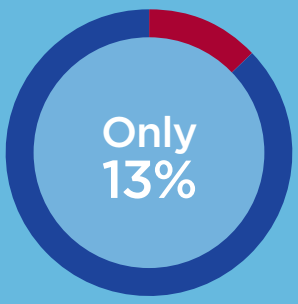
Representativeness and inclusivity in research is predicated on having a common language from which to garner understanding of critical and complex research concepts.

Too often, terms and definitions are too technical and not used consistently by stakeholders across the clinical research industry. This means that patients, participants, and their caregivers are left having to interpret multiple different meanings in order to try to make sense of what they are being asked to participate in.

While a variety of health-related glossaries do already exist, there is to date no dedicated **clinical research** glossary that has been collaboratively developed by consensus with a broad group of stakeholders, including patients and advocates, to arrive at participant-friendly definitions. To that end, in 2020 the MRCT Center renewed its commitment to promoting health literacy in clinical research by piloting the development of a plain language clinical research glossary. Focusing on a subset of research terms and available in 2021, the pilot results will be comprised of a description of activities undertaken, including the steps to develop definitions and build consensus, the process to manage and maintain the glossary-generation activities, and recommendations for potential expansion to a full-scale initiative.

"The plain language clinical research glossary will help support patient/participant/caregiver understanding of research terminology and help clinical research stakeholders who are tasked with creating research materials."

MRCT Center Glossary Pilot Team Charter



of Americans have a proficient level of health literacy.

About nine out of ten people need extra help understanding the health information they receive.

mrctcenter.org/health-literacy

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.

The MRCT Center Bioethics Collaborative traditionally meets three to four times per year, and meetings were transitioned to a virtual format in response to the pandemic. In June 2020 an additional meeting was added to specifically address issues related to COVID-19.

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

Genentech, Inc.

Eli Lilly & Co.

Johnson & Johnson

Merck & Co., Inc.

Pfizer Inc.

Sanofi

Takeda Pharmaceuticals International, Inc.

2020 Meetings

MULTI-REGIONAL CLINICAL TRIALS
BIOETHICS COLLABORATIVE

FEBRUARY 11, 2020

Pragmatic Clinical Trials and Real-World Evidence

JUNE 1, 2020

COVID-19 and Ethical Challenges for Clinical Research

OCTOBER 1, 2020

Patient Advocacy and Engagement in Clinical Research

NOVEMBER 16, 2020

Artificial Intelligence in Clinical Research

Research, Development, and Regulatory Roundtable

JULY 7, 2020

Foreign Influence in Clinical Research

Impact of Fraud and Abuse Laws on Clinical Research

Legal and Regulatory Issues Related to COVID-19 in Human Subjects Research

NOVEMBER 5, 2020

Legal Perspectives on Scientific Misconduct in Academia and Industry

RESEARCH, DEVELOPMENT, AND REGULATORY ROUNDTABLE (R3)

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.

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

Advarra

Boehringer Ingelheim

Dana-Farber Cancer Institute

Genentech, Inc.

International Society for Biological and Environmental Repositories

Johnson & Johnson

Merck & Co., Inc.

Pfizer, Inc.

Sanofi

Takeda Pharmaceuticals International, Inc.

Washington University in St. Louis

Due to the onset of the COVID-19 pandemic, the R3 was transitioned to a virtual format. The R3 has evolved to optimize the virtual meeting experience. Beginning with the November 2020 meeting, R3 virtual meetings were shortened in length, focused on a single topic, and reconfigured to increase discussion between attendees. Further, the number of R3 meetings in the upcoming year will increase from three to six.

PROMOTING GLOBAL CLINICAL RESEARCH IN CHILDREN

Global clinical research in children is a particularly acute challenge as most pediatric biomedical conditions are sufficiently rare that they require multisite and often international collaboration. That collaboration itself is challenged by different regulations—or none at all—and differing interpretations of ethical principles for research. As such, the MRCT Center is focused on generating and advancing a comprehensive series of tools to promote the harmonization of global pediatric research.

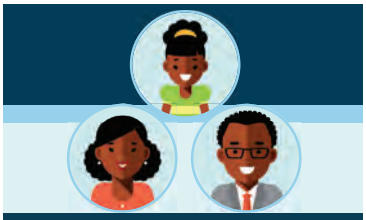
Meeting regularly since October of 2019, this project focuses on the ethics and international regulations of pediatric clinical trials The main workgroup, comprised of ~75 diverse stakeholders, represents a range of perspectives from academia, industry, regulatory agencies, not-for-profit organizations, trial networks, patients and patient advocacy organizations, and existing pediatric research initiatives.

The group is focused on the following cross-cutting thematic issues:

- **Decision making for children's participation in biomedical research.**
- **Risk/benefit considerations for pediatric research.**
- **Challenges in implementation of global pediatric clinical trials, including those encountered and remedied during the COVID-19 pandemic.**

"It is one thing to refer to a body of abstract knowledge and another to have meaningful conversation, in real time, about nuance and practical logistics when implementing ethical research practices. The MRCT Center pediatric project is an incredible opportunity for international experts to discuss important topics and challenge each other to define consistent and actionable ethical parameters that remain relevant across cultural and ethnic traditions. The attention paid to the parent/guardian voice and non-adult research subject is particularly valuable."

Gianna McMillan, DBe, Program Administrator, LMU Bioethics Institute

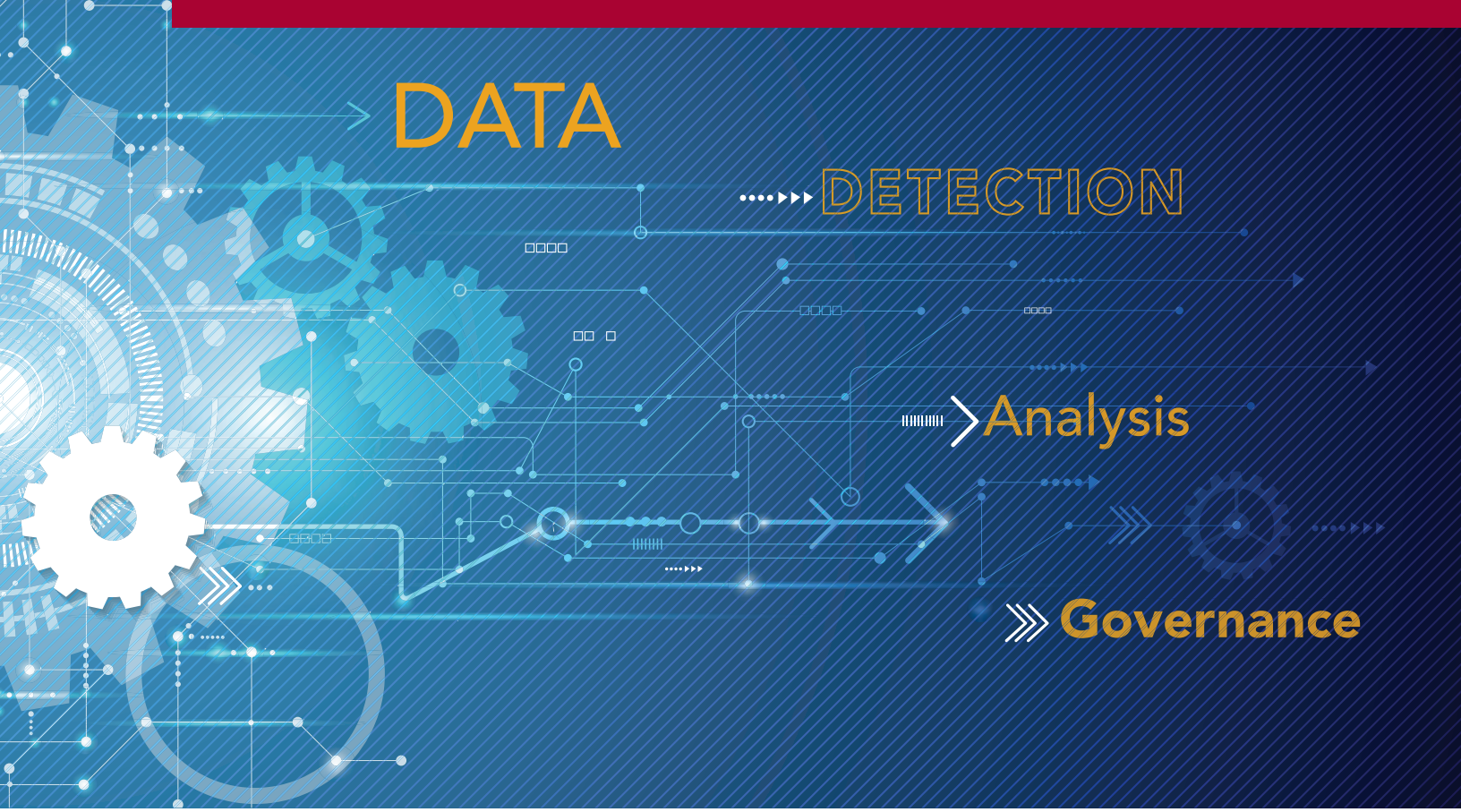


mrctcenter.org/
assent-to-consent

Addressing a gap in education

A suite of educational materials is being developed for youth (age 12-17 and ultimately younger children as well) to address a gap in existing information. The suite of brochures is intended to provide youth a foundation for conversations with researchers and staff, their doctors, family members, and others. The materials emphasize the voluntary nature of research and also describe the constraints of the research process. These brochures, drafted by student interns and reviewed by existing youth advisory networks, address a range of issues such as: explaining clinical research; privacy issues; what happens to one's collected data; and explaining assent.

"Assent to consent," the first in the series, provides information to youth enrolled in a clinical trial by a parent/guardian who are turning the legal age for consent; this brochure has received the iCAN (International Children's Advisory Network) "Seal of Approval."



PROACTIVE SAFETY SURVEILLANCE

Ensuring the safety of biological products, drugs, and devices in healthcare remains the shared responsibility of regulatory, academic, and industry-related-stakeholders. Yet current safety surveillance systems rely mostly upon analysis of spontaneous and voluntary reports, administrative claims, electronic medical records, and some post-marketing pharmacovigilance studies. As a result, some adverse events are not identified until after market approval and wider dissemination to patients.

The MRCT Center's Proactive Safety Surveillance Initiative aims to advance safety surveillance systems through collaboration, transparency, and innovation. In 2020, the multidisciplinary core team drafted the conceptual framework, intended to complement current surveillance methods, for what the future of drug safety could look like. The vision involves the use of an array of novel signal detection methods, observational data sources and real-world data (RWD) to interrogate the performance of different analytical methods on different RWD sources (e.g., electronic health records, claims, etc.). Our work will continue in 2021. While ambitious, the core team is convening an international consortium to advance and improve the validity and timeliness of safety signals for the benefit of the global community and public health.

Aligning Aggregate Safety Reporting

In the post-market setting, every country has some schedule of formal post-market reporting of drug safety events, reports that are separate from signal identification. This periodic reporting is critically important for review of drug safety, surveillance systems, and pharmacovigilance activities by both the regulatory authorities and the manufacturer. Over the last year, the MRCT Center held conversations with various global pharmaceutical companies to better appreciate the need for and demands of continuing analysis and reporting of safety, efficacy, and effectiveness data of marketed products (e.g., Periodic Safety Update Reports and Periodic Benefit-Risk Evaluation Reports). While there was universal agreement on the need for continued systematic analysis of marketed products, the preparation of the reports appeared onerous, nuanced, and varied across regulatory authorities. We are currently exploring potential solutions to simplify, align, and harmonize reporting while enhancing its utility.

Aligning Aggregate Safety Reporting aims to align and harmonized post-market regulatory reporting requirements to enhance utility while minimizing administrative burden.

EUROPEAN UNION GENERAL DATA PROTECTION REGULATION (GDPR)

The European Union's General Data Protection Regulation (GDPR), which focuses on the processing of personal data that occurs in any member state of the European Economic Area (EEA) or that concerns individuals located in any member state of the 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 first addressed issues related to the effect of GDPR on multi-regional clinical trials in 2013 and has continued its work since.

Since the effective date of the GDPR, the MRCT Center has organized meetings and public presentations with key stakeholders to understand the issues and implications of the GDPR on multi-regional clinical trials, clinical research, and public health.

2020 MRCT Center and Ropes & Gray efforts

November 2019: Co-sponsored a meeting with Intelligence in Science (ISC), the National Institutes of Health, and others in Brussels, Belgium, that brought together GDPR stakeholders and members of the European Commission to discuss key challenges of GDPR for research.

March 2020: Publication in Nature Publishing's *European Journal of Human Genetics* on the challenges of GDPR to secondary research.

April 2020: Input paper in response to the European Commission's call for feedback on the GDPR as part of the Commission's preparation of a report on GDPR.

October 2020: Publication in *Science* entitled "How to fix the GDPR's frustration of global biomedical research: Sharing of data for research beyond the EU must improve."

The effort includes a broad multi-national and multi-stakeholder group including government, industry, and academia. In July 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-U.S. Privacy Shield, one of the mechanisms available for the transfer of personal data from the EEA to the United States. In its written opinion, the CJEU also questioned the validity of transfers of personal data from the EU to the U.S. given concerns about U.S. national security laws. In the fall of 2020, the MRCT Center conducted an in-depth review of the effect of the CJEU's decision on EU-U.S. transfers of personal data for research purposes.

INTERPRETATION AND APPLICATION OF ICH E6 (R2) ONLINE TRAINING

The overall goal of this training is to provide an overview on how to apply the ICH E6(R2) Good Clinical Practice Guideline.

cpd.partners.org/mrct

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 February 2020, the MRCT Center launched a free, self-paced, introductory 10-module online course, "Interpretation and Application of ICH E6(R2)," that reflects the ICH Guideline for GCP. Completing this certificate course fulfills the requirements of the U.S. National Institutes of Health (NIH) and of TransCelerate Biopharma Inc. for GCP training. This online course has been particularly valuable during the ongoing pandemic to enable participants around the world to complete GCP training. As of November 9, 2020, more than 1,160 individuals from over 70 countries have engaged in this training and more than 540 participants have completed all ten modules.

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY (JTF)

The JTF Framework defines the knowledge, skills and attitudes necessary for conducting safe, ethical and high-quality clinical research.

mrctcenter.org/clinical-trial-competency/

In February 2020, the Joint Task Force for Clinical Trial Competency (JTF), hosted by the MRCT Center, released Version 3.1 of the JTF Framework which includes competencies that relate to clinical project management and technology-based enhancements to the clinical research enterprise.

In March 2020, the Japanese translation of the JTF Framework was added to the JTF website, in collaboration with Japan's National Cancer Center Hospital and Osaka University. Translations of the JTF Framework into French, Portuguese and Italian are being reviewed and harmonized and are slated to be available in 2021.

In June 2020, the MRCT Center launched an online survey that asked individuals who function in all aspects of the clinical research enterprise to self-assess their competency level for each of the eight domains of the JTF Core Competency Framework. As of November 11, 2020, more than 660 individuals have completed the survey. We plan to compare the results to a similar survey we conducted in 2015.

RETURN OF INDIVIDUAL RESULTS REVISION

Returning individual results honors the essential contributions and voluntarism of study participants in clinical trials, while improving the transparency of those trials. In 2017, the MRCT Center released the *Return of Individual Results* to Participants Recommendations Document and Toolkit.

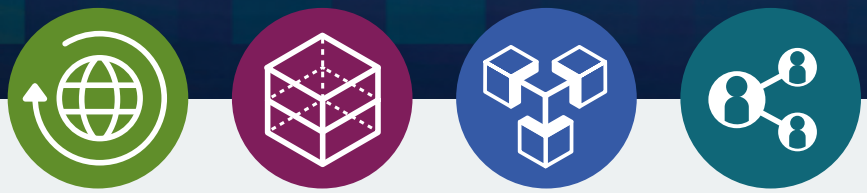
In 2021, the MRCT Center plans to revisit and update our work based on stakeholder feedback, user experience, and patient/participant views. Improving our resources for the research community acknowledges the progress that has been made and underscores that the process and understanding of returning information to participants is evolving.

RADx-UP INITIATIVE

The MRCT Center is participating in the RADx-Underserved Populations (RADx-UP) project. The RADx-UP is a follow on project to NIH's ongoing Rapid Acceleration of Diagnostics (RADx) project that seeks to identify candidates for point-of-care COVID-19 testing, acceleration, scale-up, and validation of technologies, and development of approaches to testing itself.

The RADx-Underserved Populations (RADx-UP) project is focused on implementation strategies specifically to enhance testing of COVID-19 in underserved, underrepresented, and/or vulnerable populations. The Harvard T.H. Chan School of Public Health and Harvard Catalyst are the recipients of a RADx-UP grant and invited the MRCT Center to lead the Human Participant Research Unit and to help create a community-based Ethics and Equity Board. The Ethics and Equity Board will monitor and advise on testing, implementation, and mitigation strategies to limit community transmission, while balancing the preservation of access to health care and other necessary resources for participants, their families and communities.

Current and Past Projects



Overview of 10 years of 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 Individual Results (project revision)**
- Return of Aggregate Results
- Tools for Data Sharing
- Vivli: Global Clinical Trial Data Sharing Platform

Bolded projects are currently active projects.

Ethics, Conduct and Oversight

- **Advancing the Clinical Trial Enterprise**
- Health Literacy in Clinical Research
  - **Collaborative Cross-Industry Glossary for Clinical Research**
- **Diversity, Inclusion and Equity in Clinical Trials**
- **Proactive Safety Surveillance: A Global Approach**
- Post-Trial Responsibilities
- Protocol Ethics E-Learning
- **The MRCT Center Bioethics Collaborative**
- **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)**

DISSEMINATION AND COMMUNICATION: SELECTED 2020 PUBLICATIONS AND PRESENTATIONS

For selected MRCT Center 2020 publications and presentations, please visit MRCTcenter.org/mrct-center-2020-dissemination

Committing to the Inclusion of Diverse Populations in Clinical Research
Ahmed HR, Strauss DH, Bierer BE. *Therapeutic Innovation & Regulatory Science*, January 2020. DOI 10.1007/s43441-019-00020-6

Issues in the registration of database studies
Zarin DA, Crown WH, **Bierer BE.** *Journal of Clinical Epidemiology* 121: 29-21, February 2020. DOI: 10.1016/j.jclinepi.2020.01.007

Economic vulnerability and payment for research participation
Gelinas L, White SA, Bierer BE. *Clinical Trials.* February 2020. DOI: 10.1177/1740774520905596

Primed to comply: Individual participant data sharing statements on ClinicalTrials.gov
Statham E, White SA, Sonwane B, Bierer BE. *PLOS ONE*, February 2020. DOI: 10.1371/journal.pone.0226143

Disruptive and avoidable: GDPR challenges to secondary research uses of data
Peloquin D, DiMaio M, Bierer BE, Barnes M. *European Journal of Human Genetics*. March 2020. DOI:10.1038/s41431-020-0596-x

Time for NIH to lead on data sharing
Sim I, Stebbins M, **Bierer B,** Butte AJ, Drazen J, Dzau V, Hernandez AF, Krumholz HM, Lo B, Munos B, Peraksis E, Rockhold F, Ross JS, Terry SF, Yamanoto KR, **Zarin DA, Li R.** *Science 367 (6484)*, 1308-1309, 20 March 2020. DOI: 10.1126/science.aba4456

Diagnostic testing for COVID-19: Considering false positive and false negative results
Zarin DA, Lau J. April 2020. https://mrctcenter.org/wp-content/uploads/2020/04/zarin-lau-interpreting-dx-tests-for-COVID.pdf

From Genetics to Genomics: Facing the Liability Implications in Clinical Care
Marchant G, **Barnes M**, Evans JP, LeRoy B, Wolf SM. *Journal of Law, Medicine & Ethics* 48: 11-43. Spring 2020. DOI: 10.1177/1073110520916994

Aggregating data from COVID-19 trials
Ogburn EL, **Bierer BE**, Brookmeyer R, Choirat C, Dean NE, Gruttola VD, Ellenberg SS, Halloran ME, Hanley DF, Lee JK, Wang R, Scharfstein DO. *Science 368(6496)*, 12 June 2020. DOI: 10.1126/science.abc8993

Health Literacy in Clinical Research: Practice and Impact - Proceedings of a Workshop
Wojtowicz A, French MG (Rapporteurs); Assaf AR, **Bierer BE**, Davis TC, McCormack L, Myers L, O'Leary C, Nassi PJP, Spears P, Wilkins CH (Planning Committee) Citro C, **Baedorf Kassis S** (Reviewers). *National Academies Press,* Washington, DC. http://nap.edu/25616

Challenges of "Return to Work" in an Ongoing Pandemic
Barnes M, Sax PE. *NEJM*, June 2020. DOI: 10.1056/NEJMsr2019953

Rethinking ethical oversight in the era of the learning health system
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