MULTI-REGIONAL CLINICAL TRIALS

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

Executive Committee Meeting

June 22, 2023
Hybrid meeting

Today's Agenda

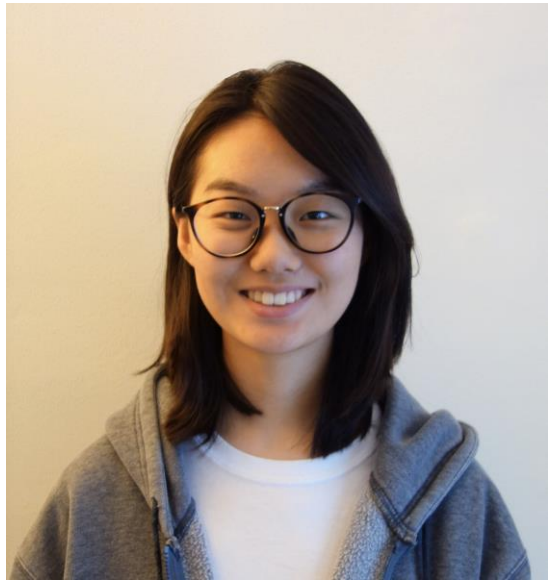
Time	Topics
9:00-9:15 AM EDT	Welcome
9:15-10:45 AM EDT	Horizon Scanning & Emerging Issues

10:45-12:30 PM EDT	Discussion of Ongoing Work
	• International Framework for Specimen Sharing – the Seattle Principles
	• Convergence Diversity Project
	• Diversity, Inclusion, and Equity in Clinical Research
	  ○ Diversity Action Plan (DAP)
	  ○ Global DEI

12:30-1:45 PM EDT	Working Lunch
1:45-2:00 PM EDT	Discussion of Ongoing Work, cont. • International Capacity for Regulatory and Ethics Committee Review • Distinguishing the EC from the SC • Additional Discussion, Questions, & Thoughts
1:45-2:00 PM EDT	Wrap up and Closing • June and Fall Virtual Events

Something fun to start with….

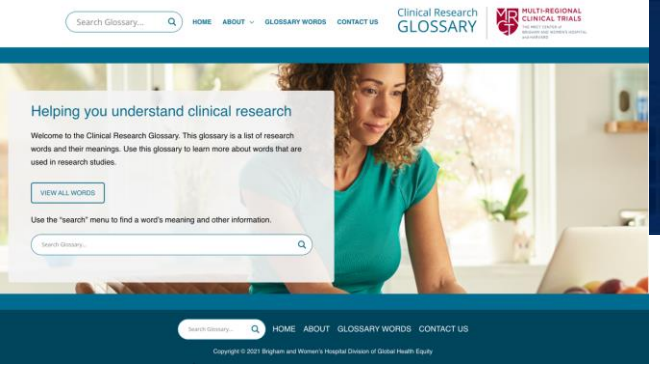
Introducing our new MRCT Center Student Researchers, Creative Design!



Yimeng (Anna) Lyu

Xinyu (Sandra) Ye

Glossary Image Development



Source: pilot website

Sketch 1

Final rendering

Progress of the Illustration for “Infusion”

International Council for Harmonisation

of Technical Requirements for Pharmaceuticals for Human Use

International Council for Harmonisation

CAPACITY BUILDING

3 Principles of ICH E8(R1)

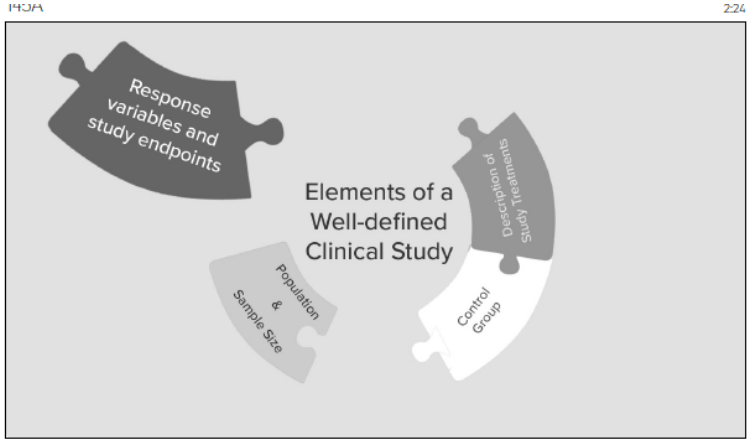
3. Patient Input into Drug Development.

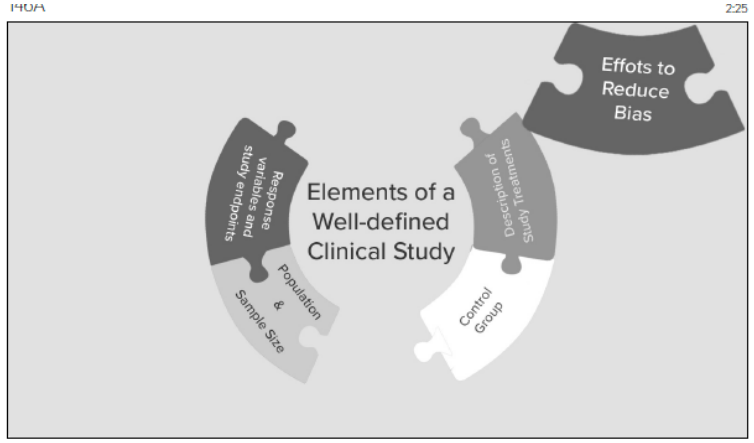
3 Principles of ICH E8(R1)

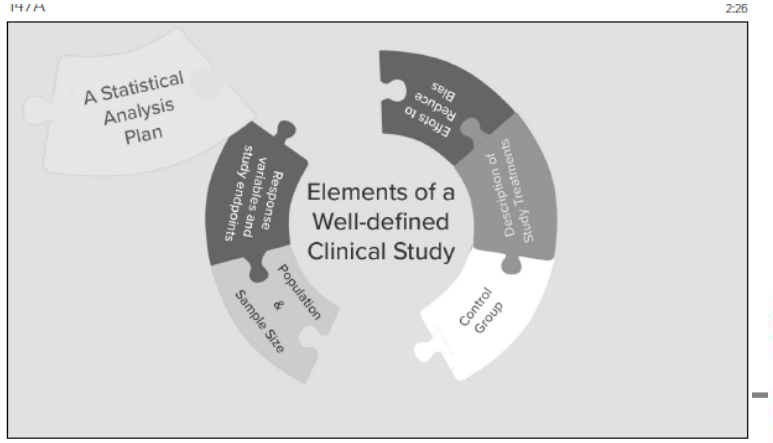
3. Patient Input into Drug Development.

3 Principles of ICH E8(R1)

3. Patient Input into Drug Development.







MULTI-REGIONAL CLINICAL TRIALS
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ABOUT US | OUR WORK | NEWS & EVENTS | RESOURCES | CONTACT

Defining and creating ethical, actionable, and practical solutions for global clinical trials.

HOW WE WORK

FEATURED HIGHLIGHTS FROM THE MRCT CENTER

Decentralized Clinical Trials ›

Join a webinar for the launch of tools, resources and best practices for ethical review of DCTs.

Accessibility by Design Toolkit ›

A comprehensive resource to support greater inclusion of people with disabilities in clinical research.

MRCT Center Glossary as Global Standard ›

Collaboration between MRCT Center

ABOUT THE MRCT CENTER

Our efforts have resulted in the implementation of best practices, greater transparency, and improved safety for

CLINICAL TRIALS & RESEARCH

Diversity, Inclusion, and Equity in Clinical Research

Health Literacy in Clinical Research

Oversight and Implementation of Decentralized Clinical Trials

Post-Trial Responsibilities

Promoting Global Clinical Research in Children

Protocol Ethics E-Learning

Real World Evidence

Return of Aggregate Results

Return of Individual Results

FOR PATIENTS & PARTICIPANTS

QUALITY & TRANSPARENCY

Advancing the Quality of Clinical Trial Enterprise

Data Sharing

Impact of Privacy Laws on Clinical Research

Proactive Safety Surveillance: A Global Approach

CAPACITY BUILDING

Global Regulatory Engagement

Joint Task Force for Clinical Trial Competency

Training & Education

BIOETHICS COLLABORATIVE

RESEARCH, DEVELOPMENT, & REGULATORY ROUNDTABLE (R3)

PROJECT-SPECIFIC WEBSITES

Clinical Research Glossary

Diversity, Inclusion, and Equity in Clinical Research

Health Literacy in Clinical Research

Joint Task Force for Clinical Trial Competency

Return of Individual Results

SEE ALL OUR WORK

Successful webinar with 792 registered!

792 registrants
352 attendees

https://mrctcenter.org/project/oversight-and-implementation-of-decentralized-clinical-trials/

Horizon Scanning & Emerging Issues

International Framework for Specimen Sharing: The Seattle Principles

Background

- Collaborating organizations: Science Policy Think Tank, ISBER, Multi-Regional Clinical Trial Center of Brigham and Women's Hospital and Harvard (MRCT Center), Ropes & Gray, Riken Center for Integrative Medical Sciences
- Science Policy Think Tank Virtual Forum, December 2021
- ISBER Virtual Roundtable, June 2022
- Science Policy Think Tank Asia Pacific Virtual Forum, March 2023

Overview of Challenges to International Biospecimen and Data Sharing

- Multiplicity and patchwork of regulations
- Variations in regulations and policies
- Lack of clarity in regulations and guidelines
- Overly restrictive regulations
- Difficulties in obtaining current authoritative information on regulations and policies
- Evolving nature of the research and regulatory environment
- Lack of harmony in terminology
- Differing cultural perspectives
- Variable IRB/REC behavior
- Unresolved ethical issues
- Tracking and compliance
- Challenges with legacy collections

The Purpose of the Seattle Principles

- An international uniformity of regulations may be elusive, but more consistency could be gained through widespread acceptance of ethical principles in this area, which in turn could influence the making of policy and laws across national governments.

- At the same time, widely accepted principles in this area could promote better ethics in science itself.

- These principles are offered in this context and with these goals.

The Seattle Principles

1. Transparency to Donors
2. Respect for Broad Consent of Donors
3. Respecting the Scope of Consent
4. Respecting Withdrawal of Consent for Future Research
5. Safeguarding the Welfare of Specific Communities
6. Human Welfare Protection
7. Donor Privacy
8. Specific Consideration of Genetic/Genomic Research
9. Protecting Donors by Returning Clinical Actionable Research Results
10. Ensuring Responsible Use of Biospecimen Resources
11. Governance and Oversight

The Seattle Principles

Questions to consider:

- Are there additional principles that should be considered?
- Are there principles that should be taken out of the core set?
- Do you have specific recommendations on any of the principles?
- Are there additional aspects we should consider in the context of the aspired global relevance of these principles?

EC Feedback and Discussion

Diversity Convergence

Convergence Initiative: Diversity in Clinical Research

- Project aim: Achieve system-wide change and adoption of practices to promote DEI across the research enterprise.
- Founding organizations are uniquely positioned to strategically co-convene groups from across the clinical trials enterprise to advance a leadership-driven call to action that aligns shared goals and accountability to achieve racial and ethnic diversity in clinical trials.
- Domestic focus

Convening Organizations

CLINICAL TRIALS TRANSFORMATION INITIATIVE

MILKEN INSTITUTE

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

NATIONAL ACADEMIES Sciences Engineering Medicine

Convergence Initiative: Diversity in Clinical Research

Convening Organizations

CLINICAL TRIALS TRANSFORMATION INITIATIVE

MILKEN INSTITUTE FasterCures

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

NATIONAL ACADEMIES Sciences Engineering Medicine

Planned Meetings		**Hosted by**
June 12, 2023	Align on goals and accountability for driving system-level change	CTTI
September 22, 2023	Refine and set priorities for shared goals and accountability metrics	MRCT Center
Q4 2023	Establish an approach for monitoring, evaluating, and analyzing change	FasterCures
H1 2024	Present work plan for action-focused areas	National Academies

Convergence Initiative: Diversity in Clinical Research

Discussion with the EC:

How do we make significant progress related to DEI in the US? What are the system-level changes within the clinical research enterprise?

Diversity, Inclusion, and Equity in Clinical Research:
Diversity Action Plans (DAP) & Global DEI

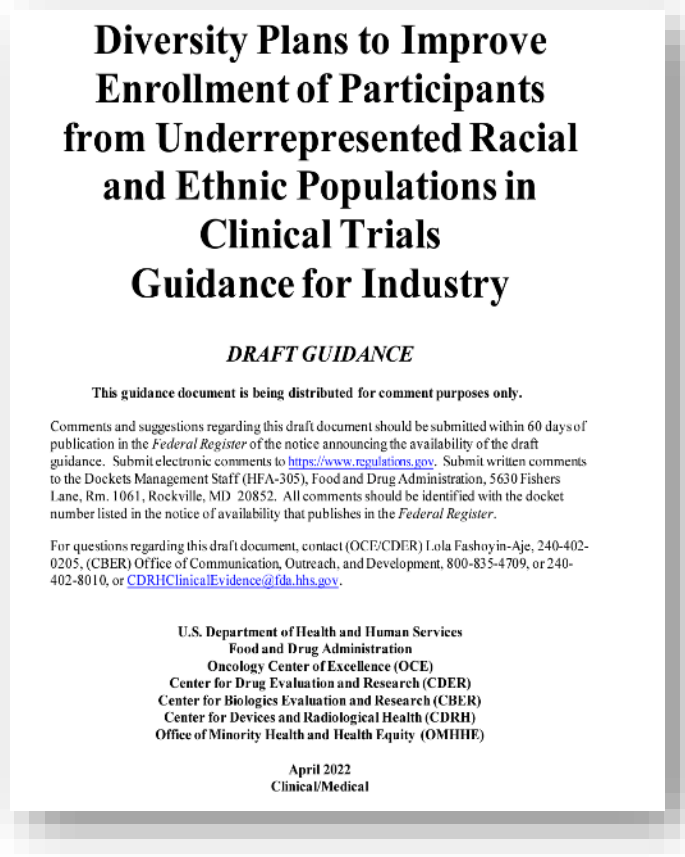
Global DEI

Update on ongoing work:

- Development of resources and prompts that organizations can use to develop a global DEI strategy.
  - Motivations for an organizational commitment to global DEI
  - Prompts to identify what aspects of diversity are relevant
  - Capacity-building resources
- A diversity action plan template designed as an internal document that provides detailed prompts for how to consider DEI considerations at all stages of research.
- Ethical principles and considerations to drive global DEI in clinical research.

FDA and Diversity Action Plans

- The Food and Drug Omnibus Reform Act of 2022 (FDORA) of December 29, 2022, included:
  - **Clinical Trial Diversity**: clinical trial sponsors must submit "***diversity action plans***" for certain late-stage drug trials, including all P3 trials and most device studies.
- MRCT Center has modified the Recruitment Strategy Document into a specific model template of a Diversity Action Plan ("DAP")
- Highlights FDA's 5 broad Categories
- Considers processes for implementation



Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

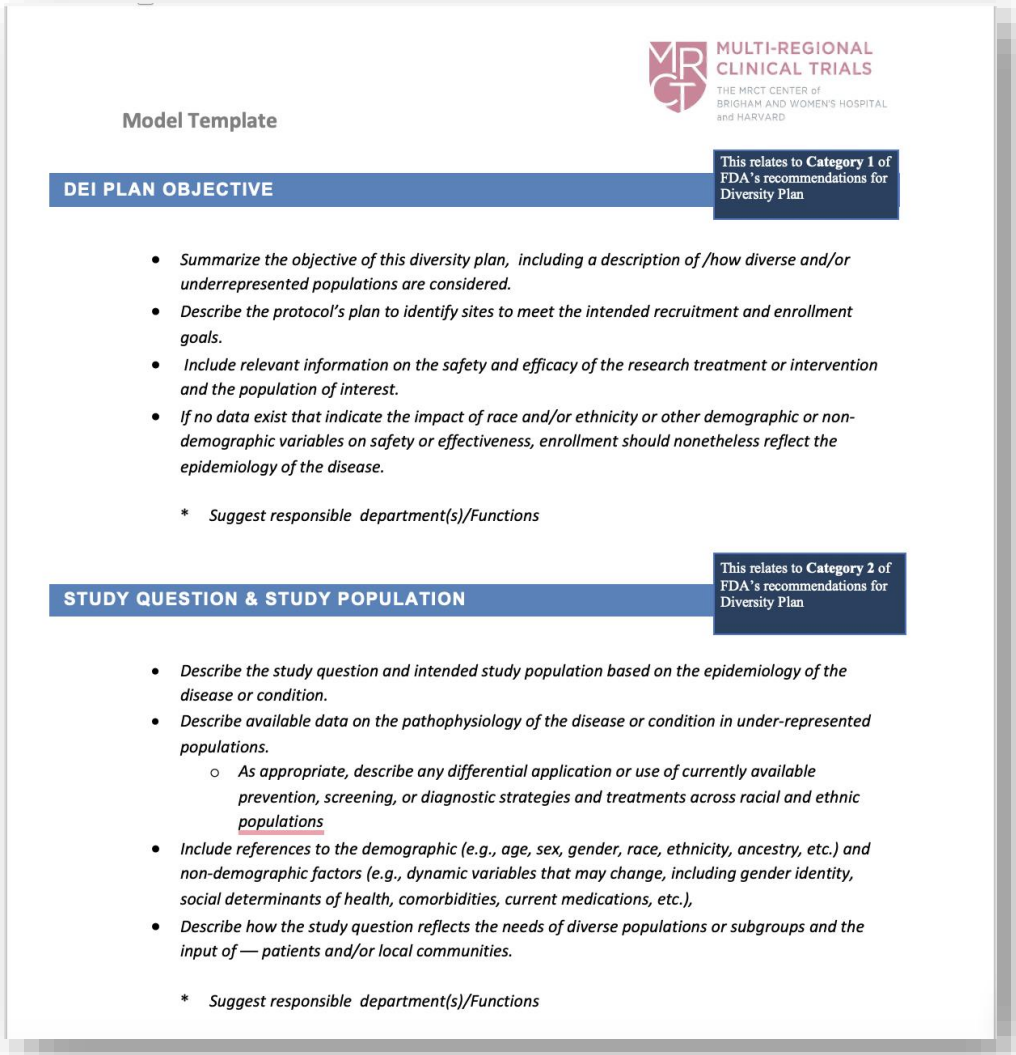
Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

April 2022
Clinical/Medical

Template Preview



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Model Template

DEI PLAN OBJECTIVE

This relates to **Category 1** of FDA's recommendations for Diversity Plan

- *Summarize the objective of this diversity plan, including a description of /how diverse and/or underrepresented populations are considered.*
- *Describe the protocol's plan to identify sites to meet the intended recruitment and enrollment goals.*
- *Include relevant information on the safety and efficacy of the research treatment or intervention and the population of interest.*
- *If no data exist that indicate the impact of race and/or ethnicity or other demographic or non-demographic variables on safety or effectiveness, enrollment should nonetheless reflect the epidemiology of the disease.*

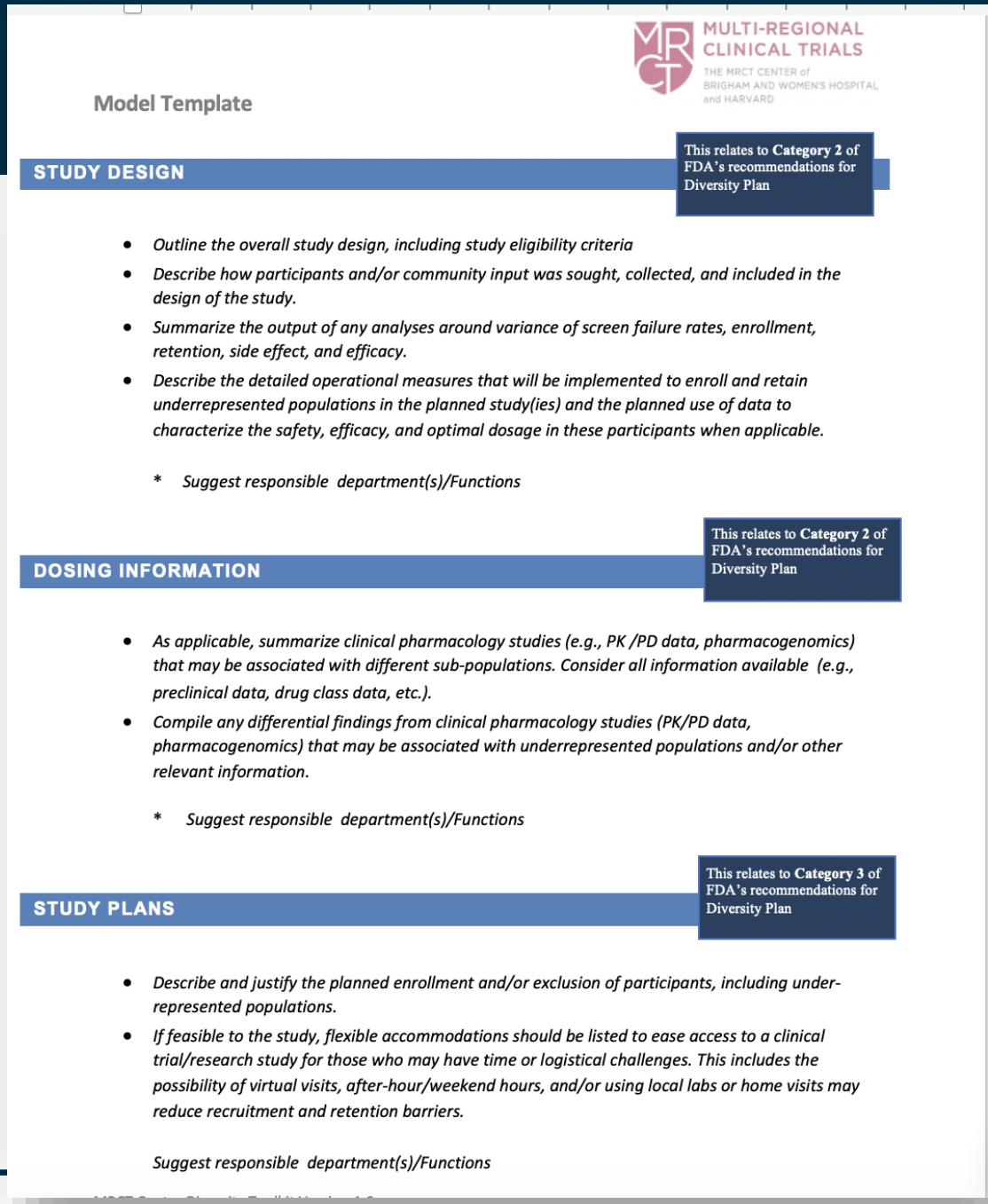
* *Suggest responsible department(s)/Functions*

STUDY QUESTION & STUDY POPULATION

This relates to **Category 2** of FDA's recommendations for Diversity Plan

- *Describe the study question and intended study population based on the epidemiology of the disease or condition.*
- *Describe available data on the pathophysiology of the disease or condition in under-represented populations.*
  - *As appropriate, describe any differential application or use of currently available prevention, screening, or diagnostic strategies and treatments across racial and ethnic populations*
- *Include references to the demographic (e.g., age, sex, gender, race, ethnicity, ancestry, etc.) and non-demographic factors (e.g., dynamic variables that may change, including gender identity, social determinants of health, comorbidities, current medications, etc.),*
- *Describe how the study question reflects the needs of diverse populations or subgroups and the input of — patients and/or local communities.*

* *Suggest responsible department(s)/Functions*



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Model Template

STUDY DESIGN

This relates to **Category 2** of FDA's recommendations for Diversity Plan

- *Outline the overall study design, including study eligibility criteria*
- *Describe how participants and/or community input was sought, collected, and included in the design of the study.*
- *Summarize the output of any analyses around variance of screen failure rates, enrollment, retention, side effect, and efficacy.*
- *Describe the detailed operational measures that will be implemented to enroll and retain underrepresented populations in the planned study(ies) and the planned use of data to characterize the safety, efficacy, and optimal dosage in these participants when applicable.*

* *Suggest responsible department(s)/Functions*

DOSING INFORMATION

This relates to **Category 2** of FDA's recommendations for Diversity Plan

- *As applicable, summarize clinical pharmacology studies (e.g., PK /PD data, pharmacogenomics) that may be associated with different sub-populations. Consider all information available (e.g., preclinical data, drug class data, etc.).*
- *Compile any differential findings from clinical pharmacology studies (PK/PD data, pharmacogenomics) that may be associated with underrepresented populations and/or other relevant information.*

* *Suggest responsible department(s)/Functions*

STUDY PLANS

This relates to **Category 3** of FDA's recommendations for Diversity Plan

- *Describe and justify the planned enrollment and/or exclusion of participants, including under-represented populations.*
- *If feasible to the study, flexible accommodations should be listed to ease access to a clinical trial/research study for those who may have time or logistical challenges. This includes the possibility of virtual visits, after-hour/weekend hours, and/or using local labs or home visits may reduce recruitment and retention barriers.*

Suggest responsible department(s)/Functions

Discussion/ Key Questions

- How have your organizations responded to the DAP, and what progress has been made in its implementation?
  - What specific initiatives or actions has your company implemented to align with the FDA diversity action plan?
  - Are there any gaps or areas where your organization needs to improve its operations in order to align with the FDA diversity action plan? If so, what are they, and how are you addressing them?
  - Are there any specific resources or tools that you have found helpful in supporting your organization's efforts to implement the FDA diversity action plan? If so, could you provide recommendations or examples?
  - How are global considerations considered in and incorporated into the plan?
- What would be most helpful to include in the template we're developing?

TIME FOR LUNCH

International Capacity Building for Regulatory and Ethics Committee Review

Global Capacity Building and Training

RECENTLY COMPLETED COURSES

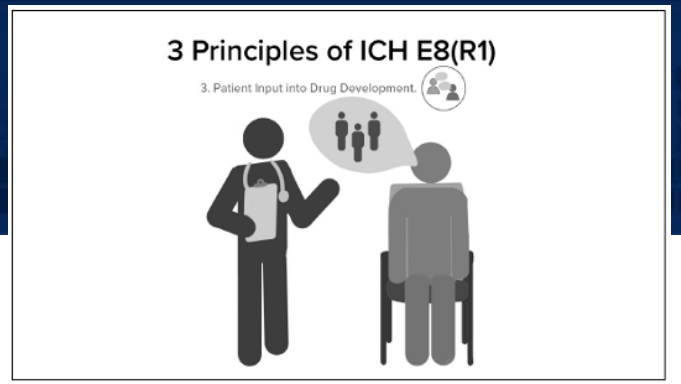
- MRCT Center – AVAREF: Training in Ethics Review of Clinical Research
- Equity By Design in Clinical Research: Cancer Trials
- Health Literacy Training for IRBs
- National Institutes of Health at the University of the Philippines: Training on Data Monitoring Committees
- Pfizer Indonesia: Advanced lectures in Indonesian undergrad/grad biotechnology programs

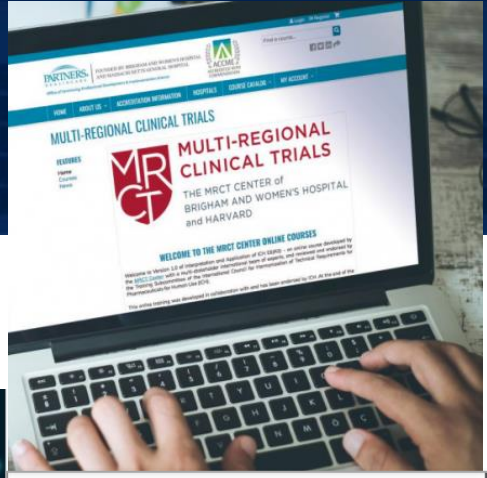
ONGOING

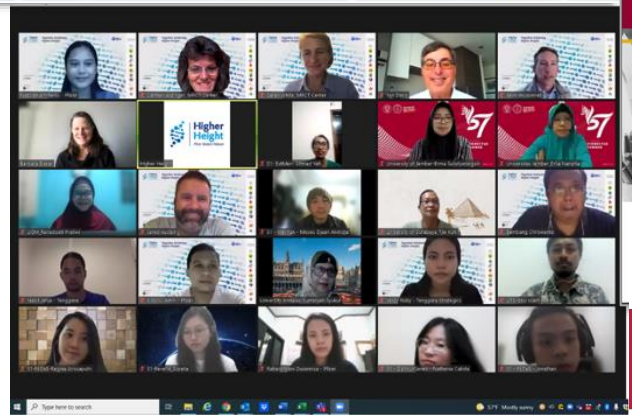
- Interpretation and Application of ICH GCP E6(R2)
- **Ethics Committee capacity through operational understanding and process development across Africa (Funded by BMGF)**
- ICH Training Associate: creating training videos and modules to introduce, enhance, and apply the following ICH guidelines: E6(R3), E8, E17

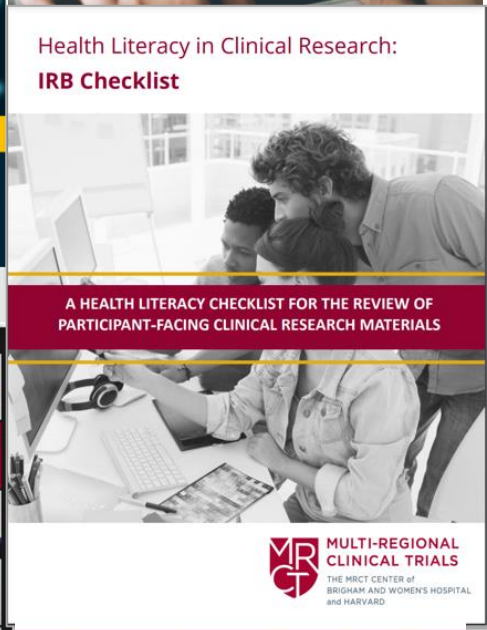
UNDER CONTRACT NEGOTIATIONS:

- WHO: Introduction to Ethics Review of International Research
- Equitable Breakthroughs in Medicine Development (EQBMED). The MRCT Center will act as an education and training partner to support the EQBMED sites









BILL & MELINDA GATES foundation

World Health Organization
REGIONAL OFFICE FOR Africa

AVAREF
African Vaccine Regulatory Forum

Higher Height
Pfizer Biotech Fellows

B-Imtiyaz

2023-2025: Building Capacity for Ethics Review of Clinical Research Across Africa

Funding from BMGF and WHO

Goal: support competent, efficient, and independent ethics review of clinical research across Africa

1. Capacity Building & Training:
   - Redesign current course into online, on demand training course
   - Accessible and sustainable training course
   - Interactive case studies, pre/post test assessments
2. Capacity Building through Operational Understanding and Process Development (in collaboration with WHO)
   - Understand current operational capacity, processes, and potential of EC
   - Benchmark Ethics Committee oversight
3. Integration and Harmonization
   - Establishing Centers of Excellence in Regulatory Science and Ethics

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BILL & MELINDA GATES foundation

World Health Organization
REGIONAL OFFICE FOR Africa

AVAREF
African Vaccine Regulatory Forum

Course	Module	Unit
Fundamentals I	Introduction to Ethics Review of Interventional Research	I. Recap of Introductory Course
		II. Research Ethics Committee (REC) Roles and Responsibilities
		III. Clinical Trial Stakeholders
	Product Development Pathway	I. Pre-Clinical Drug Development
		II. Clinical Development
		III. Development Pathway for Vaccines, Biologics, and Devices
		IV. Informed Consent throughout the Drug Development Pathway
	Considerations in Study Design	I. Elements of Study Design 1
		II. Elements of Study Design 2
		III. Specific Study Designs 1
		IV. Specific Study Designs 2
Fundamentals II	Operations and Processes of RECs	I. Unanticipated Problems: Adverse Events and Protocol D
		II. Protocol Amendments and Continuing Review
		III. End of Study Considerations
	Ensuring Research Integrity	I. Research Integrity
		II. Study Monitoring, Inspections, and Oversight
		III. Responsibilities of the DSMB and Interactions with RECs
	Data Sharing, Biospecimens, and Genetic & Genomic Research	I. Genetic and Genomic Research
		II. Data Sharing and Biospecimens
		III. Cultural Considerations for Genomic Research and Res Involving Biospecimens
	REC Application of Regulations and Guidances	I. Overview of Regulations and Guidances
		II. General Principles for Multi-Regional Clinical Trials
		III. AVAREF Processes and Reliance
Further Topics	Special Populations	I. Children
		II. Pregnant and Lactating Persons
		III. People with Disabilities
	Other Topics	I. Ethics Review of Vaccine Trials
		II. Research Ethics in Emergency Environments
		III. Traditional Medicine Trials

Capacity Building and Training: An online, on-demand training course

YEAR 1:

Course	Module	Unit
Fundamentals I	Introduction to Ethics Review of Interventional Research	I. Recap of Introductory Course
		II. Research Ethics Committee (REC) Roles and Responsibilities
		III. Clinical Trial Stakeholders
	Product Development Pathway	I. Pre-Clinical Drug Development
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		IV. Informed Consent throughout the Drug Development Pathway
	Considerations in Study Design	I. Elements of Study Design 1
		II. Elements of Study Design 2
		III. Specific Study Designs 1
		IV. Specific Study Designs 2

World Health Organization OpenWHO.org About Courses

COURSES WILL BE AVAILABLE ON

OpenWHO.org

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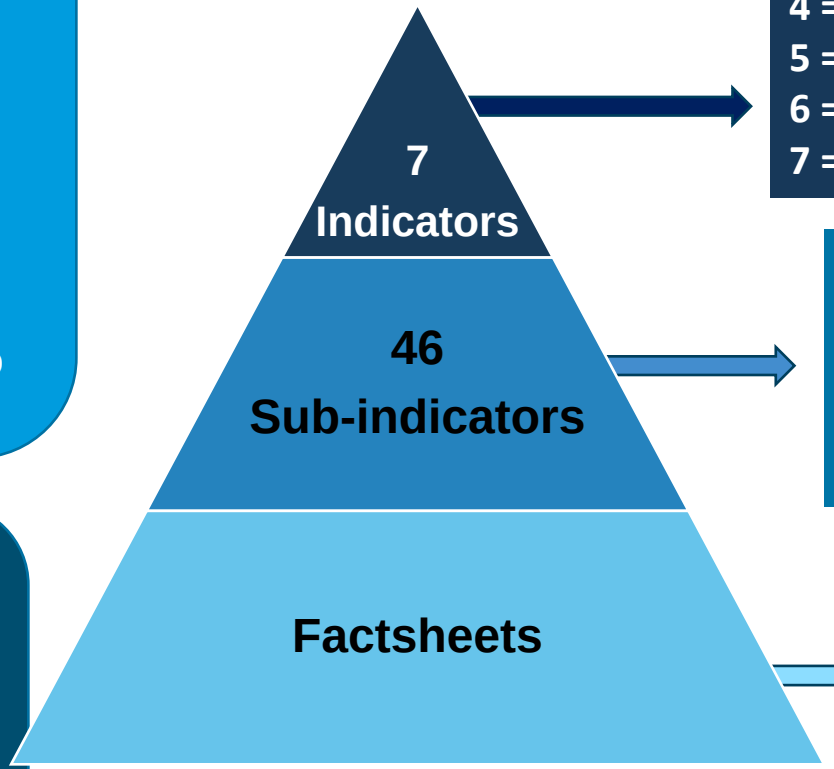
WHO TOOL - BENCHMARKING ETHICS OVERSIGHT OF HEALTH-RELATED RESEARCH

World Health Organization

Objectives:

- To assist in evaluating the existing capacity to provide appropriate ethical oversight
- To guide the development of recommendations to address the identified gaps
- To assist in capacity-building efforts
- To promote policy convergence and best practices in research ethics oversight and to enhance public trust in health research.

Scope:
Designed for all entities involved in the ethical oversight of health-related research involving humans, including research ethics committees (RECs) at the national, sub-national, or institutional levels, and institutions whose employees or agents conduct health-related research involving humans.



1 = Legal provisions
2 = Structure and composition
3 = Resources
4 = Procedures
5 = Transparency
6 = Performance
7 = Responsible research institutions

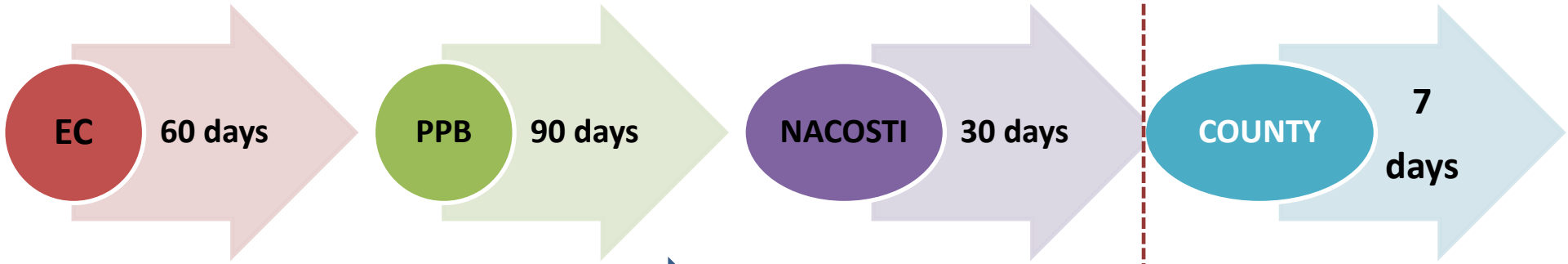
Example: Indicator 1 = Legal provisions
Sub-indicator 1.1: Legal provision requiring health-related research with humans to be reviewed and approved by RECs.

- **Description**
- **Objective**
- **Evidence to review**
- **Framework**
- **Rating scale**
- **Remarks**
- **References**

Example: total timelines for Clinical Trials Approvals in Kenya

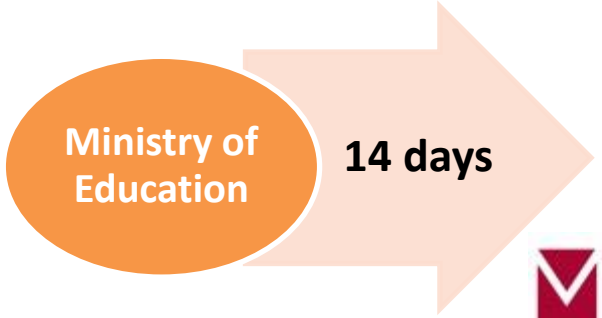
National level

County level



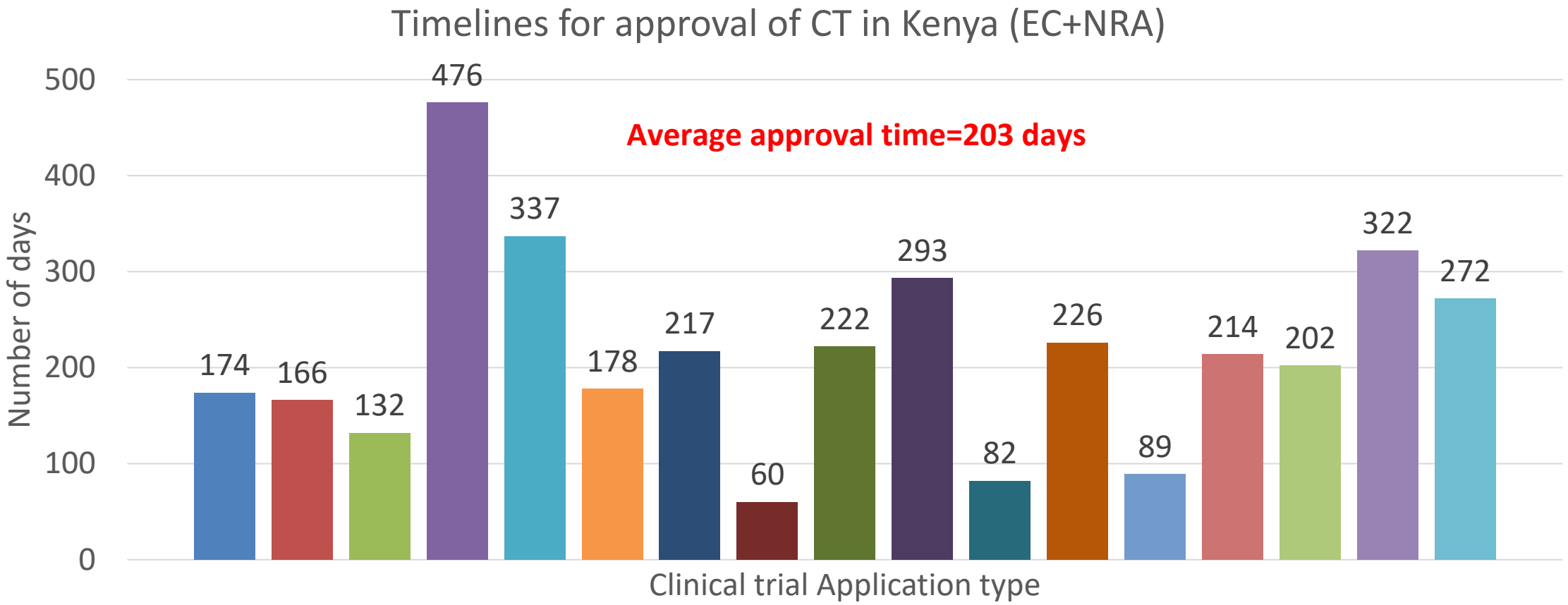
Total time 180 days

For clinical trials involving participants from schools



PPB: Pharmacy and Poisons Board
NACOSTI: National Commission for Science, Technology and Innovation

Overall approval times from EC to PPB (2022)

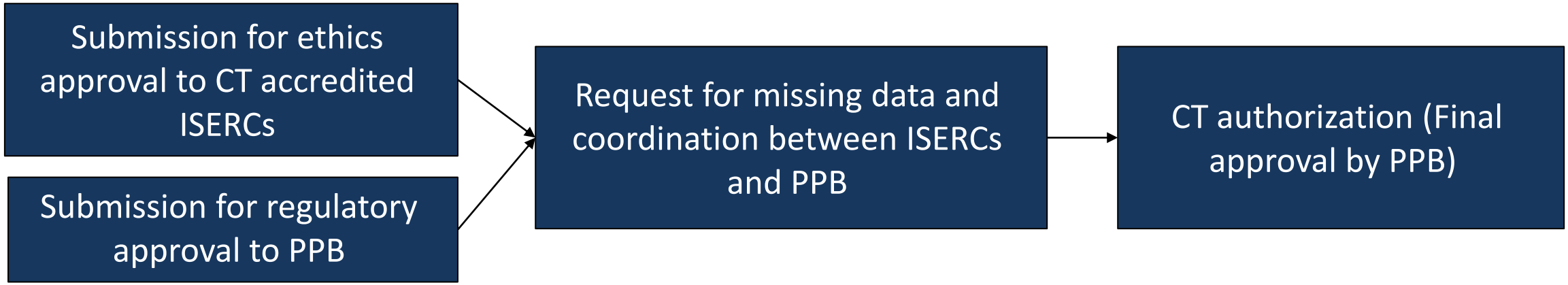


Clinical Trial Review & Approval Process

Current Process

Submission to ISERCs for ethics review and approval → Submission to PPB for regulatory authorization → Submission to NACOSTI for research license → Submission to counties for approval

Proposed Process



International Capacity Building for Regulatory and Ethics Committee Review

- Our current work will inform Year 3 of our BMGF grant: **Integration and Harmonization**: Establishing Centers of Excellence in Regulatory Science and Ethics

Discussion:

We would like to engage the EC to understand current investments in clinical trial infrastructure that are ongoing in Africa and/or other LMICs

MRCT Center Executive and Steering Committees

Executive & Steering Committee Members

EXECUTIVE COMMITTEE

Alexion Pharmaceuticals

Amgen, Inc.

AstraZeneca

Bill & Melinda Gates Foundation

Eli Lilly and Co.

Gilead

Johnson and Johnson

Mayo Clinic

Merck & Co., Inc.

Microsoft, Life Sciences Innovation

Pfizer

PhRMA

Ropes and Gray LLP

Takeda Pharmaceuticals U.S.A., Inc.

STEERING COMMITTEE

Advarra

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)

Association of Clinical Research Professionals (ACRP)

Biogen Inc.

Biotechnology Innovation Organization (BIO)

Clinical Data Interchange Standards Consortium, Inc. (CDISC)

Clinical Research Initiative for Global Health (CRIGH)

Comprehensive and Integrative Medicine Institute (CIMI)

Daegu Catholic University Medical Center (DCUMC)

European Clinical Research Infrastructure Network (ECRIN)

Genentech – a member of the Roche Group

Headlands Research

Indian Society for Clinical Research

IQVIA

Kowa Research Institute

Medable, Inc

Novartis

PPD, part of Thermo Fisher Scientific

PRAXIS Australia

PRIM&R

RIKEN, Center for Integrative Medical Sciences

Sanofi

Syneos Health

Veristat

WCG IRB

Distinguishing the MRCT Center Executive Committee

GOAL:

- Increase participation
- Increase # of individuals working across our projects
- Increase the value proposition of EC sponsorship to EC organization

Proposal for discussion: Distinguishing the EC

STEERING COMMITTEE

- 3 virtual meetings + 1 in-person / year (All in collaboration with the EC)
- Participate in review and prioritization of potential MRCT Center projects

EXECUTIVE COMMITTEE

- 6 virtual meetings + 2 in-person (Currently 5 virtual meetings + 2 in-person / year)
- The June in-person meeting overlaps with annual EAB meeting
- R3 membership included in EC sponsorship
- Private project launch presentations with internal teams
- EC sponsors to serve on MRCT Center conference/meeting planning committees
- Participate in the identification, review, and prioritization of potential MRCT Center projects

Additional Discussion, Questions & Thoughts

MULTI-REGIONAL CLINICAL TRIALS
BIOETHICS COLLABORATIVE

UPCOMING MEETINGS:

June 27, 2023, 1 PM – 3:30 PM ET

- *Blurring boundaries: Revisiting the distinction between research and care*

October 10, 2023, 1 PM – 3:30 PM ET

- *The chat is out of the bag: The future of AI in clinical research*

December 12, 2023, 9 AM – 3 PM ET

- *When good is more than good enough: The ethics of de-escalation trials*

Research, Development, & Regulatory Roundtable

UPCOMING MEETINGS:

June 1, 2023, 11AM - 3:00PM ET

- *The Revolution in Online Behavioral Advertising – What it Means for the Research Enterprise*
- *Challenges in Decentralized Clinical Trials – Open Discussion Forum*

This meeting took place at the Ropes & Gray Boston offices (in-person attendance preferred)

September 12, 2023, 1:30PM - 4PM ET

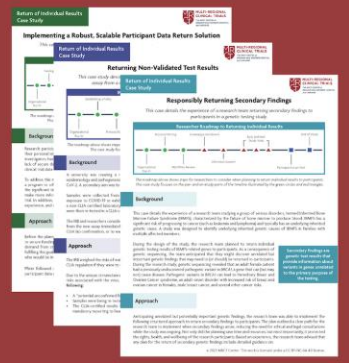
- *Research Collaboration with China*

November 13, 2023, 1:30PM - 4PM ET

- *TBD*

MRCT Center 2023 Upcoming Events

Returning Individual Research Results and Data: Digging Deeper



A 3-part webinar series about the specific ethical, operational, and technical challenges to returning individual research and results to participants.

Pfizer's Participant Data Return Solution – Thursday, July 27, 12-1pm EDT
IRB and HRPP Responsibility – Thursday, August 17, 12-1pm EDT
Genetic Testing – Thursday, September 21, 12-1pm EDT

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REGISTER NOW!

Convening Organizations

CLINICAL TRIALS TRANSFORMATION INITIATIVE
MILKEN INSTITUTE FasterCures
MULTI-REGIONAL CLINICAL TRIALS THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD
NATIONAL ACADEMIES Sciences Engineering Medicine

Convergence: Diversity in Clinical Research

September 22, 2023 (time TBD)

Hybrid event

National Academies, Washington DC

2023 Executive & Steering Committee Meetings

2023 Executive and Steering Committee Meetings

- January 31, 11-12 PM
- April 25, 11-12 PM (virtual)
- September 12, 11-12 PM (virtual)
- December 13, 8 AM-5 PM including Annual Meeting (preferred in-person, hybrid planned)

Executive Committee Meetings

- March 21, 11-12 PM
- June 22, 9 AM-2 PM (preferred in-person, hybrid planned)
- October 24, 11-12 PM

Please follow the MRCT Center:

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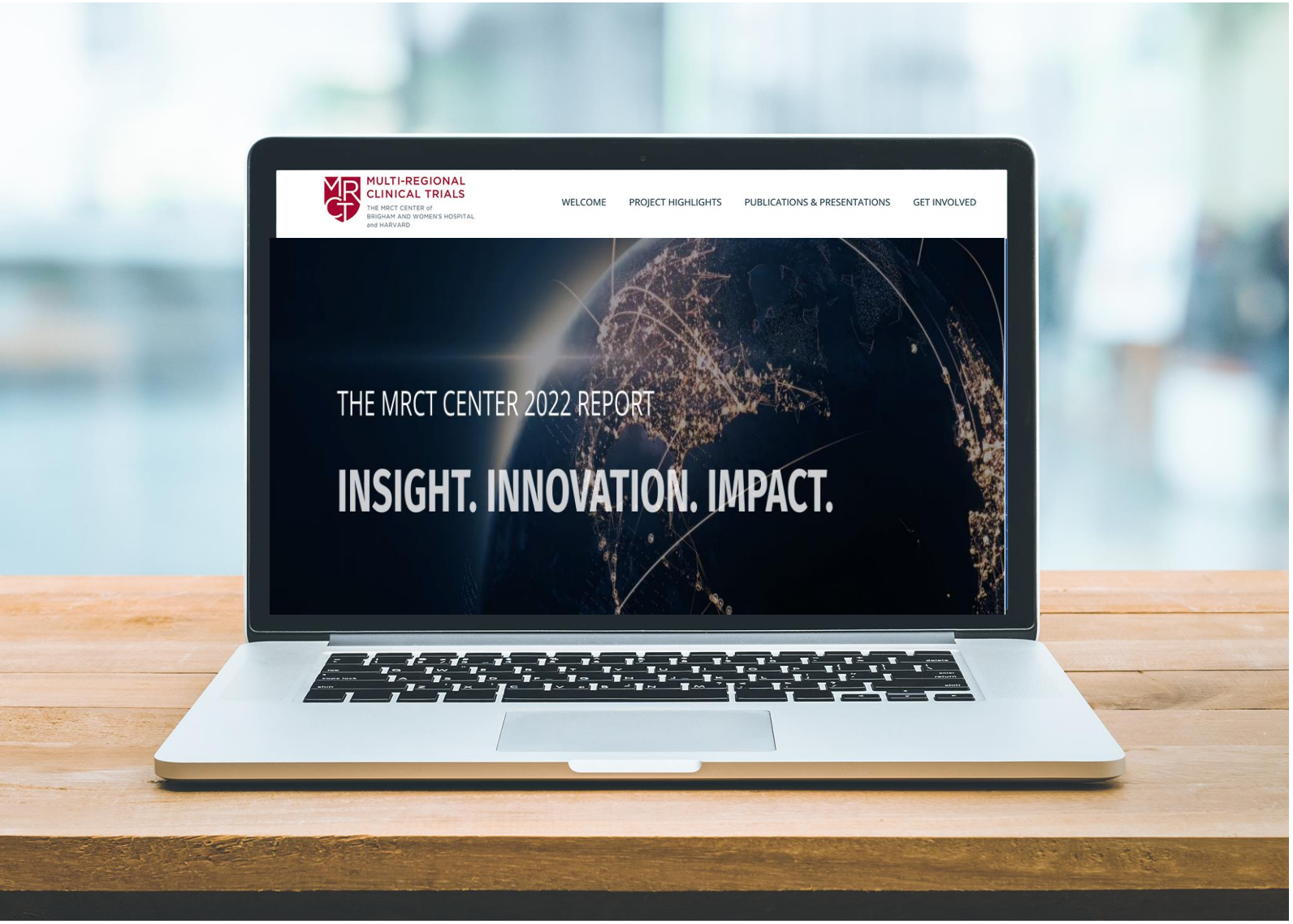
MRCTCenter.org



Thank you for your support and collaboration

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