MULTI-REGIONAL CLINICAL TRIALS

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

Executive Committee Meeting

January 23, 2024
Virtual meeting

Today's Agenda

- Welcome to new EC members
- DEI: Reflecting on organization efforts; how to ensure active engagement with the patient and community
- MRCT Center Brief Updates
  - Projects in flight

Welcome to our new Executive Committee Members

New Organization

- **Bristol Myers Squibb** – Jean Sposaro & Moke Sharma

New Representatives

- **Alexion**: Christina Archer
- **AstraZeneca:** Barbara Valastro

DEI
Reflecting on organization efforts; how to ensure active engagement with the patient and community

DEI Reflecting on Organizational Efforts

During the Annual Meeting, several EC/SC members voiced concerns that DEI efforts at a central level were challenging to implement and coordinate at other levels. We would like to understand these challenges better.

- Are the efforts of central DEI teams successfully disseminated to therapeutic areas and then to sites?
- If not, where are the gaps (e.g., operations, specific therapeutic areas, sites, push-back from the business side, complexity, cost)?
- Is there a system of feedback from TAs and sites/investigators back to the central teams?
- If yes, and trials are becoming more diverse, how are you assessing with participants and communities whether participation has been worthwhile?
- What collaborative efforts are in place (within an organization) to address these persistent challenges?

MRCT Center Brief Updates

MRCT Center Projects in flight

- MRCT Center Brief Updates
  - Environmental Impact of Research
  - Post-Trial/Continued Access Task Force: Medical Devices Conference
  - Pediatric Platform Trials Conference
  - Pediatrics Website Launch
  - Topics for Research, Development, & Regulatory Roundtable (R3)
  - Diversity Convergence Update

Environmental Sustainability and Clinical Trials

In response to EC/SC, we have held several conference calls to begin to scope the issues:

- Many issues to consider when assessing environmental sustainability and the clinical trial enterprise
- Global efforts are underway to mitigate the environmental impacts, including in healthcare. A few recent efforts focusing on clinical trials exist (e.g., Medical Research Council - Greener Trials; Medical Research Council in South Africa; The Nordic Pharmaceutical Forum (NPF)).

- Is there a role for the MRCT Center to play in this set of interrelated and complex issues?
- Initial scoping effort is underway:
  - Conducted 4 group scoping calls with an average of 6 participants each, representing UK, Europe, US, South Africa
  - Stakeholders included: academic administration and researchers, clinical trialists, industry, environmentalists, CROs, and others

Environmental Sustainability of Clinical Trials:
Preliminary Findings

- The work is localized, and not well coordinated across large regions
- No single US-based institution or organization is leading a sustainability in clinical trials effort
- All stakeholders, at all stages along the clinical research lifecycle, represent opportunities for improvement
- No one entity can tackle this successfully
- There is an appetite for multi-stakeholder discussion forums and a project plan

Environmental Sustainability of Clinical Trials:
Impact Opportunities

- Trial design, conduct and necessity
- Role of ethics committees, including evaluation of redundant trials, carbon footprint calculators, expectation to hold protocol writers to present the carbon footprint at each stage in a trial
- Manufacturing processes
- Supply chain choice
- Procurement processes
- Patient, family, and investigator-related--travel
- Decentralized Clinical Trials (DCTs): a modest adaptation
- Packaging/ single-use items/waste
- Energy sources, consumption, and calculation at all points along the way
- Considerations for and by regulators
- Patient and participant input

Post-trial, Continued Access to Investigational Medicines and Devices Taskforce: *Device Conference*

- Turning attention to challenges of post-trial, continued access to and maintenance of investigational devices
- Planning ½ day (or full-day) conference in 2024: *TBD*
- Current scope: Implanted/attached devices (something that is not transient)
- Planning Committee:
  - Interested members of the task force
  - Others: **Need recommendations for med-tech contacts and experts!**
  - Scope of the Planning Committee: (1) Pre-work to prepare for the conference; (2) Review of current principles and framework of responsibility
  - Planning committee meetings: 1st Thursday of each month

- Please email sawhite@bwh.Harvard.edu with contacts and recommendations. Thanks!

Pediatric Platform Trials (*An opportunity to explore*)

- Platform studies that evaluate more than one investigational product simultaneously can offer substantial efficiencies if companies collaborate, speeding the delivery of safe and effective medicines to children.

- We need to understand the challenges in developing platform studies—and master protocols—for pediatrics, and the parameters of study design, eligibility, outcome measures, and endpoints would be helpful.

- Discussions are needed to operationalize how data and information sharing, and company confidential information, can be handled.

Current working plans

- Host a 2-day in-person workshop (Fall 2024 in Washington DC area) to explore how multi-sponsor pediatric platform trials can be leveraged to speed delivery of innovative therapies to children.
- Goals of such an effort:
  - Develop the principles, ethical foundation, and operational considerations upon which platform trials can be pursued for regulated studies of pediatric investigational products
  - Identify knowledge gaps that impact clinical trial planning
  - Recommend actionable approaches to address these gaps
- Workshop potential output
  - Construct a framework that can be used by investigators, funding agencies, and sponsors to support further advancement of platform trials in pediatric product development
- Discussion

Promoting Global Clinical Research in Children:
Dissemination Update

Updated webpage coming soon!

Deliverables include:

- Foundational Principles
- Including Young People in Clinical Research Toolkit
- Publications
  - Establishing a global regulatory floor for children's decisions about participation in clinical research
  - The Parent's Dilemma: Pediatric Assent in Research
  - Additional forthcoming publications
- Webinar recordings
- Patient-facing information materials, including education brochures and videos

2024 Sessions Announced

Research, Development, & Regulatory Roundtable

UPCOMING MEETINGS

March 21, 2024, 1:30-4:00 PM ET
- *Expanded Access (Compassionate Use) for Drugs and Devices*

May 2024: TBD
- *Recent Developments in FDA Guidance on Real-World Evidence*
- *Subject-Directed Recruitment Materials and Testimonials*

October 10, 2024, 1:00-3:30 PM ET
- *Laboratory Developed Tests*

December 12, 2024, 1:00-3:30 PM ET
- *TBD*

Diversity Convergence Update

- National Framework to Improve Diversity and Inclusion in Clinical Trials (V.1.0) to be released in March 2024.

- **Save the date**: April 23, 2024.
  - Diversity Convergence Meeting #4.
  - https://www.nationalacademies.org/event/41856_04-2024_toward-a-framework-to-improve-diversity-and-inclusion-in-clinical-trials-a-workshop
  - Location: NASEM, Keck Center, 500 5th St. NW, Washington DC
  - A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize a public workshop to explore opportunities to improve racial and ethnic diversity in clinical trials with a focus on system-level change and collective efforts across organizations and sectors that no one entity can effectively take on alone.

2024 Executive & Steering Committee Meetings

2024 Executive and Steering Committee Meetings (virtual meeting)

- February 27, 11-12 PM
- April 9, 11-12 PM
- September 17, 11-12 PM
- December: TBD

Executive Committee Meetings (virtual meeting)

- January 23, 11-12 PM
- May 30, 9 AM -2 PM (hybrid, in person preferred)
- June 25, 11-12 PM
- October 22, 11-12 PM

MULTI-REGIONAL CLINICAL TRIALS
BIOETHICS COLLABORATIVE

Research, Development, & Regulatory Roundtable

UPCOMING MEETINGS

March 8, 2024, 11 AM – 2 PM
- Advancing Inclusion: Integrating Pregnant and Lactating People in Clinical Research

June 14, 2024, 12:30-3:00 PM ET

September 10, 2024, 10:00-12:30 PM ET

November 14, 2024, 1:00-3:30 PM ET

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Please follow the MRCT Center:

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Thank you for your support and collaboration

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