Action and Accountability: Equity by Design

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- I have no personal conflicts of interest with this presentation.
Our Vision
Improve the integrity, safety, and rigor of global clinical trials.

Our Mission
Engage diverse stakeholders to define emerging issues [across all stages of] global clinical trials and to create and implement ethical, actionable, and practical solutions.
Diversity, Equity, and Inclusion (DEI) in Clinical Research

- Race
- Ethnicity
- Sex
- Gender
- Ancestry
- Age
- Social Determinants of Health
- Environmental factors
- Genetics
- Co-morbidities
- Concurrent medications
- Other

Who me!? I thought you'd never ask.
MRCT Center’s DEI Guidance Document and Toolkit

https://mrctcenter.org/diversity-in-clinical-research/
MRCT Center’s DEI Guidance Document and Toolkit, cont.

https://mrctcenter.org/diversity-in-clinical-research/tools/toolkit/

• Audience: Sponsors, CROs, PIs and study teams
• Tools directed at different time points in the design and conduct of a clinical trial
  • Overview documents
  • Participant & Community Engagement
  • Participant awareness, knowledge, access
  • Workforce training and development
  • Data variables, collection and reporting
  • Study design, conduct, and implementation
  • Stakeholder commitments
  • Case studies (therapeutic and programmatic)

• Downloadable, editable → adaptable
DEI Toolkit Example Logic Model: Participant and Community Engagement

**INPUTS**
- Value for resources
- Staff time

**ACTIVITIES**
- Establish process for inclusion of target subpopulation(s) voice in trial design
- Create sustainable partnerships with patient advocacy and community organizations relevant to target subpopulation(s)
- Hold in-person meetings with patients of target subpopulation(s) to guide study design and recruitment planning
- Engage patients and advocates of target subpopulation(s) to review of all participant-facing materials
- Implement feedback process at end-of-study with participants of target subpopulation(s)
- Establish community advisory board(s) with target subpopulation(s) for consistent engagement across product development

**OUTPUTS**
- Process established for target subpopulation(s) voice inclusion during trial design
- Partnerships established with patient advocacy and community organizations relevant to target subpopulation(s)
- In-person meetings held with patients of target subpopulation(s) to guide study design and recruitment planning
- All participant-facing materials reviewed by patients and advocates of target subpopulation(s)
- Feedback process implemented at end-of-study with participants of target subpopulation(s)
- Community advisory board(s) established with target subpopulation(s)

**OUTCOMES**

**SHORT**
- Trial design and planning engages and integrates perspective of target subpopulation(s)
- Study protocol or recruitment materials adjusted based on patient engagement activities
- Patient input represented at company annual review

**MED/LONG**
- Clinical trial population representative of patient population
- Target subgroup community relationships and engagement materials sustained for future use
- Drug with efficacy and safety/risk evidence in representative populations

**IMPACT**
- Widespread understanding of heterogeneity of effect of marketed drug
- Decrease in health disparities for disease area (aspirational)
- Increased trust of clinical research within target subgroup (aspirational)
• Growing momentum to progress from guidance to action; Need for better planning and goal setting, understanding of processes, accountability, and transparency.

• MRCT DEI Roundtable: Convened individuals from representative professional, trade, academic, and patient advocacy organizations (including NIH).
Equity by Design in Clinical Research: The EbD Metrics Framework

About

In late 2020, the MRCT Center convened representatives of professional, trade, academic, and patient advocacy organizations and formed the Diversity, Equity, and Inclusion (DEI) Roundtable (hereafter termed Roundtable). To support burgeoning efforts in DEI and strengthen accountability, the Roundtable sought to develop metrics that succinctly, accurately, and holistically capture DEI in clinical research.

Structure

The EbD Metrics Framework is designed to provide a straightforward and engaging overview of DEI in clinical research, to prompt reflection for harmonized organizational DEI efforts, and to orient users toward potential entry and follow-up strategies. The framework is organized around seven key themes (see image). Quantitative and qualitative measures are proposed for each theme, which can be disaggregated into detailed measures and tailored by users. The level of detail explored will depend on the user’s purpose. For more information, please see the EbD Metrics Framework User Guide.
The Equity by Design Metrics Framework

- Consider overall DEI goals/targets
- Approach from a specific stakeholder perspective
- View DEI in clinical research holistically
- Enter the framework at any of the 7 key themes
- Map the goal-> Select metrics that measure progress in each theme contributing to overall DEI goals

Engage with successive layers of detail to plan for inclusion comprehensively

- For each theme in general:
  - Strategic, tactical, and operational levels
  - Operational level -> by whom, with whom, with which resources, how, what, and where
- For each theme: Consider unique issues for specific underrepresented populations
Continuing to build resources for action:

- **IRB/HRPP DEI Toolkit**
  - Points to Consider for IRB Reviewers to assess DEI factors at Initial and Continuing Review and other tools
  - Integrating DEI considerations in a Recruitment Strategy Document template
  - Revision ("call-outs") of NIH FDA protocol template(s) for inclusion

- **Related**
  - Health literacy resources, tools, and case studies
  - Best practices for return of aggregate and individual research results to participants and their communities

- **Inclusion of people with disabilities in clinical research**
  - Disability and protocol eligibility criteria; Supported decision-making
  - Forthcoming: Accessibility by Design Toolkit
Current MRCT DEI Work to Support Action, cont.

• Forthcoming:
  o Best Practices for Translation of Study Documents,
  o Revision of SBER NIH protocol template,
  o Model FDA diversity plan,
  o Consideration of SOGI issues in clinical research,
  o Global DEI in clinical research
Our work doesn’t end with greater inclusion.
Thank you