Equity by Design (EbD) in Clinical Research:
The EbD Metrics Framework

June 30, 2022
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Welcome to the EbD Metrics Framework Webinar

- Introduction to the MRCT Center:
  - Dr. Barbara Bierer - Faculty Director, Multi-Regional Clinical Trials (MRCT) Center

- Introduction to the EbD Metrics Framework:
  - Dr. Willyanne DeCormier Plosky - Program Manager, Multi-Regional Clinical Trials (MRCT) Center

- Panel discussion featuring:
  - Yasmeen Long - Director, Faster Cures, Milken Institute
    and
  - Dr. Rodrigo Garcia - Vice President Patient Solutions PPD, part of Thermo Fisher Scientific
Introduction:

The MRCT Center and Current Work in Diversity, Equity and Inclusion
Our Vision
Improve the integrity, safety, and rigor of global clinical trials.

Our Mission
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
The Work We’ve Done

EQUITY BY DESIGN IN CLINICAL RESEARCH: Cancer Trials

Building upon ethics and regulations, a six-part training course with practical guidance to increase inclusivity in cancer clinical research.

The American Journal of Bioethics

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/uajb30

Integrating Supported Decision-Making into the Clinical Research Process

Barbara E. Bierer, Ari Ne’eman, Willyanne DeCormier Plosky, David H. Strauss, Benjamin C. Silverman & Michael Ashley Stein

WATCH OUR CLINICAL RESEARCH VIDEO!

A helpful way to learn about clear communications and plain language in clinical research.

CHECK OUT THE MRCT CENTER CLINICAL RESEARCH Toolkit

Whether you are a patient, a researcher, a study sponsor, or a language glossary. It can support research understanding, etc.

Practical Approaches to Improving Diversity in Clinical Trials

Driving Inclusion in Clinical Research

Second Wednesday monthly

HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES

Tools and Resources

Information on techniques that are key to successful research communications.

Watch on: YouTube

PLAIN LANGUAGE Resources
NUMERACY Resources
CLEAR DESIGN Resources
USABILITY TESTING Resources
CULTURAL CONSIDERATIONS Resources
INTERACTIVE TECHNIQUES Resources
GLOSSARY Resources
CONSENT GUIDE Resources
Values that improve accountability, regardless of the stakeholder:

- Transparency
- Dialogue
- Measurement, tracking, and reporting (metrics)
Introduction:

The EbD Metrics Framework
Introduction: Origins of the EbD Metrics Framework

• Inequitable participation in clinical research (CR) -> Inequitable health outcomes


• Available at: https://mrctcenter.org/diversity-in-clinical-research/guidance/guidance-document/ OR on Amazon.

• Growing momentum to progress from: Conversation/guidance -> Action
• In late 2020, the MRCT Center convened representatives of professional, trade, academic, and patient advocacy organizations to formulate the Diversity, Equity, and Inclusion (DEI) Roundtable.

• Impetus:
  o Need for better planning and goal setting, understanding of processes, **accountability, and transparency**.
  o Metrics can provide *guideposts* for measurement and comparison of progress.

• Roundtable included members from:
  o Association of Clinical Research Organizations (ACRO)
  o Association of American Medical Colleges (AAMC)
  o Alliance of Multi-Cultural Physicians
  o Biotechnology Innovation Organization (BIO)
  o FasterCures
  o Food and Drug Administration (FDA)
  o Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center)
  o National Health Council (NCH)
  o National Institutes of Health (NIH)
  o PhRMA

* Please note, participation in the Roundtable does not imply endorsement of the EbD Metrics Framework or reflect the views or policies of the U.S. FDA, NIH, or any affiliated organization or entity
What do diversity, equity, inclusion (DEI), and justice mean?

Keep long-term goal in mind: move toward justice.


With thanks to Quincy Byrdsong and others
• MANY metrics were proposed. Some “forests”, some “trees”, some “leaves”.

• Quantitative outcome measures and qualitative process measures were necessary.

• Initial versions started with:
  o 4 domains + 3 areas within EACH domain + Quantitative and qualitative measures within EACH of those.

• Too much!

Reoriented into 7 key themes:

Laying strong foundations
1. Commitment, leadership, and resources to support DEI in CR (“Commitment”)
2. Institutional and study metrics for DEI in CR, data collection, and analysis (“Data”)
3. 360-degree partnerships, communication, and engagement (“Engagement”)

Establishing and clearing paths
4. Educational and career opportunities to support DEI in CR (“Workforce”)
5. Strategies for inclusion of diverse participant populations in CR (“Inclusion strategies”)

Assessing and reengineering for success
6. Review, accountability, and course adjustment (“Review”)
7. Dissemination and expansion of work (“Dissemination”)

June 30, 2022
Configure and communicate the EbD Metrics Framework:

- Layers
- Graphic representation
- User Guide
• **One theme per page**, with a brief description of each theme.

• **Quantitative measures** (QN) (4 themes completed to date)
  o Quantitative measures are not a 1:1 relationship to the qualitative measures.
  o Examples of quantitative variables given, to help disaggregating data.
    ▪ Regularly collected variables (e.g., age, race, sex, gender identity, ethnicity)
    ▪ Additional variables (e.g., language spoken, disability status, income level, etc.)

• **Qualitative metrics**: Strategic, Tactical, Operational
  o Intentionally broad to be useful to all stakeholders
  o Approach examples for the operational level metrics
E. Strategies for inclusion of diverse participant populations in CR (“Inclusion strategies”)

**Description:** Unlike the other themes in this framework that could be applicable to institutional/organizational, partnership, project, or study processes, Theme E is specific only to study processes. The measures under Theme E act in a way as a “backstop” to the measures in the other themes...(ctd. in actual EbD Metrics framework)

**Quantitative Measures**

- QN.E Participants screened
- QN.E Eligible participants
- QN.E Participants who declined study enrollment
- QN.E Participants withdrew / dropped out
- QN.E Participants lost to follow-up
- QN.E Participants retained and completed study

**Qualitative:**

- **Qualitative: Strategic level**
- **Qualitative: Tactical level**
- **Qualitative: Operational level (accessed through the hyperlink)**

**June 30, 2022**
Approach to detailed considerations standardized by prompts:

• **[By] Whom**: List whom within the organization is responsible for the metric
• **[With] Whom**: List with whom the people in “[By] Whom” should be collaborating
• **[With] Which [Micro/Project]**: List resources the people in “[By] Whom” should be utilizing at the micro/project (i.e. not institutional) level to accomplish the “how”, “what”, and “where”.
• **How**: List actions to support the development and/or positive impact of the process
• **What**: List “what” the metric is focused on
• **Where**: List where intended audience will engage with the “what”
Appendix 6: Operational Approach Example for E.1.3 “Eligibility criteria drafted for inclusivity”

**Quantitative Outcomes**
- Participants screened
- Eligible participants
- Participants who declined study enrollment
- Participants retained and completed study
- Participants withdrew/dropped out
- Participants lost to follow-up

**Qualitative Outcomes**

**Strategic**
- E.1 Study Protocol drafted to be as inclusive as possible

**Tactical**
- E.1.1 Study question/s identified based on relevance for intended populations
- E.2 Planning for feasibility, site selection
- E.3 Planning inclusive processes for recruitment and retention of participants
- E.1.2 Study designed to consider inclusion of intended populations (e.g., language, accessibility, frequency of visits, etc.)

**Outputs**

**What:**
- Inclusivity

**Where:**
- Inclusion Criteria
- Exclusion Criteria

**Activities/How**

- Consider demographic and non-demographic variables within the intended participant population
- Limiting exclusion only to when scientifically or ethically justified
- Use precise wording so that terms so that broad groups are not excluded
- Documenting scientific or ethical justification for exclusion, when necessary

**List supports (e.g., wheelchairs, sign language, supported decision-making) provided to facilitate inclusion; or reason why support can’t be provided**

**Inputs**

- [By/Whom]:
  - Sponsors
  - Principal investigators
  - DEI teams/positions
  - CROs
  - Sites

- [With/Whom]:
  - Study Coordinators
  - Nurse Navigators
  - Community organizations
  - Cultural Ambassador
  - Intended trial participants

- [With/Which/Micro/Project]:
  - Budget
  - Staffing time allocations
  - Software/hardware/infrastructure
• The MRCT Center EbD Metrics Framework and User Guide is posted at: https://mrctcenter.org/diversity-in-clinical-research/tools/ebd-metrics-framework-and-user-guide/

• We encourage testing of the EbD Metrics Framework, and submission of comments through the website.

• The MRCT Center is working to create an interactive web-based version of the EbD Metrics Framework.
Panel Discussion:

Yasmeen Long: Director, Faster Cures, Milken Institute

Rodrigo Garcia: Vice President Patient Solutions, PPD, part of Thermo Fisher Scientific