



**MULTI-REGIONAL
CLINICAL TRIALS**

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



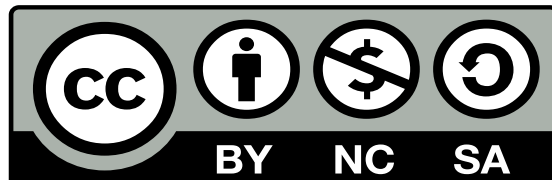
Equity by Design (EbD) in Clinical Research:

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





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Introduction:

The MRCT Center and Current Work in Diversity, Equity and Inclusion

The Multi-Regional Clinical Trials Center (MRCT Center)

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

Multi-Regional Clinical Trials
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD

ACHIEVING DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

HOME | MRCT CENTER DIVERSITY PROJECT HOME | CONTACT

DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

ABOUT | GUIDANCE | TOOLS | CASE STUDIES | NEWS & EVENTS

Toolkit

Practical Approaches to Improving Diversity in Clinical Trials

Driving Inclusion in Clinical Research

Second Wednesday monthly
11AM - 12PM ET

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.

HEALTH LITERACY HOME | CONTACT

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.

The American Journal of Bioethics

ISSN: (Print) (Online) Journal homepage: <https://www.tandfonline.com/loi/uajb20>

WATCH OUR CLINICAL RESEARCH VIDEO!

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

Watch on YouTube

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

CHECK OUT THE MRCT CENTER CLINICAL RESEARCH

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

VISIT NOW!

- PLAIN LANGUAGE Resources
- NUMERACY Resources
- CLEAR DESIGN Resources
- USABILITY TESTING Resources
- CULTURAL CONSIDERATIONS Resources
- INTERACTIVE TECHNIQUES Resources
- GLOSSARY Resources
- CONSENT GUIDE Resources

DEI: Who is responsible?

Values that improve accountability, regardless of the stakeholder:

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





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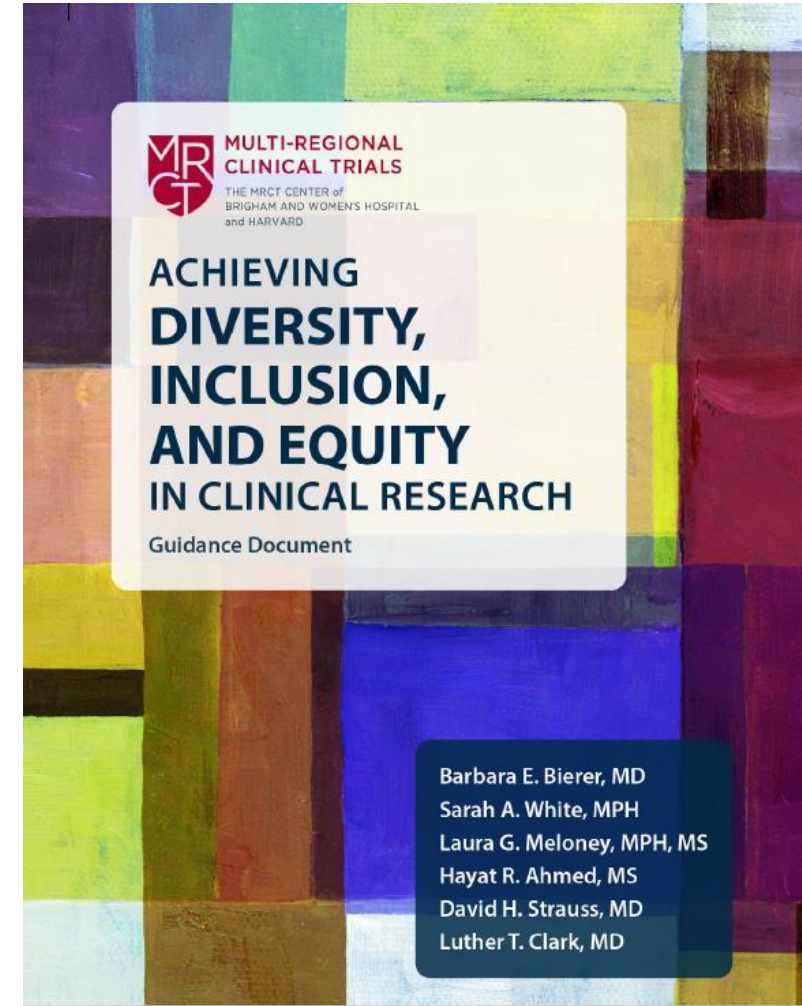
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Introduction:

The EbD Metrics Framework

Introduction: Origins of the EbD Metrics Framework

- Inequitable participation in clinical research (CR) -> Inequitable health outcomes
- Diversity, Inclusion, and Equity in Clinical Research Guidance Document and toolkit launched in 2020.
- Available at: <https://mrctcenter.org/diversity-in-clinical-research/guidance/guidance-document/> OR on Amazon.
- Growing momentum to progress from: Conversation/guidance -> Action



Introduction: Origins of the EbD Metrics Framework, ctd.



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



Introduction: Origins of the EbD Metrics Framework, ctd.



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

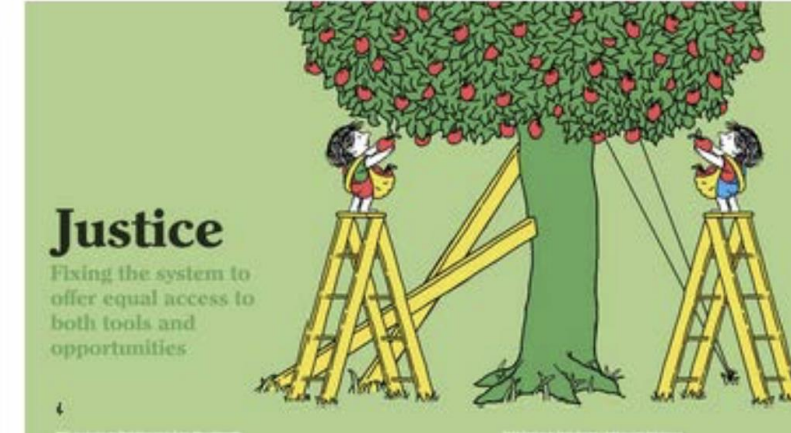
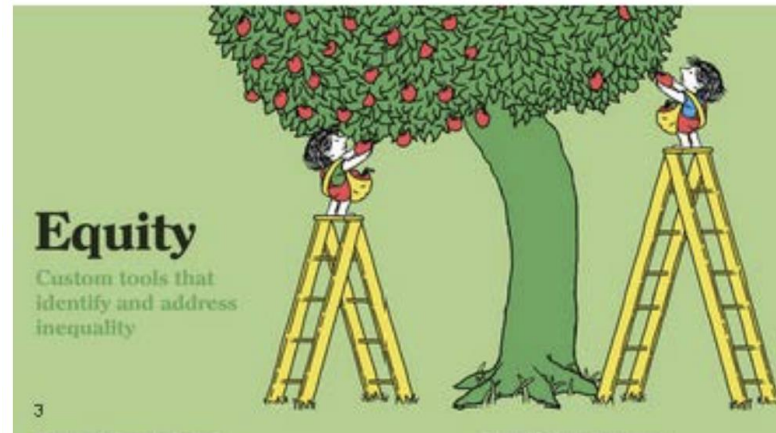
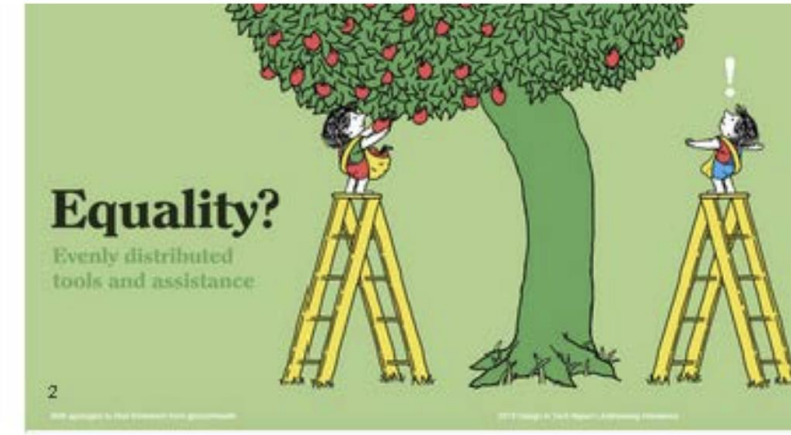
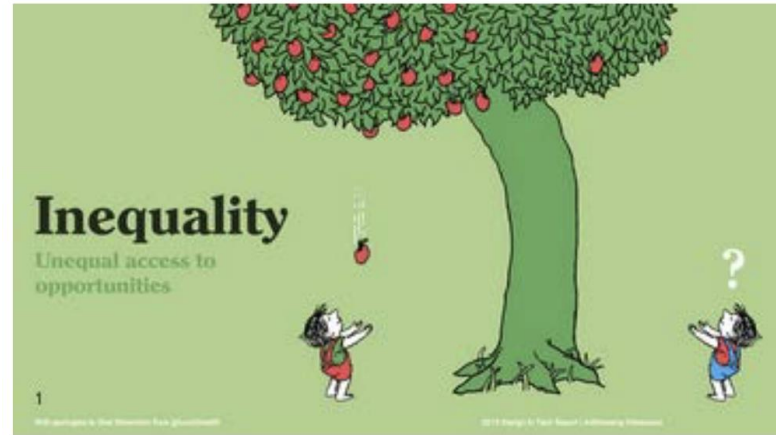


Introduction: EbD Metrics Framework Evolution



What do diversity, equity, inclusion (DEI), and justice mean?

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



<https://www.paperpinecone.com/blog/teaching-difference-between-equality-equity-and-justice-preschool>

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:
 - 4 domains + 3 areas within EACH domain + Quantitative and qualitative measures within EACH of those.
- Too much!



Introduction: EbD Metrics Framework Evolution, ctd.



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")

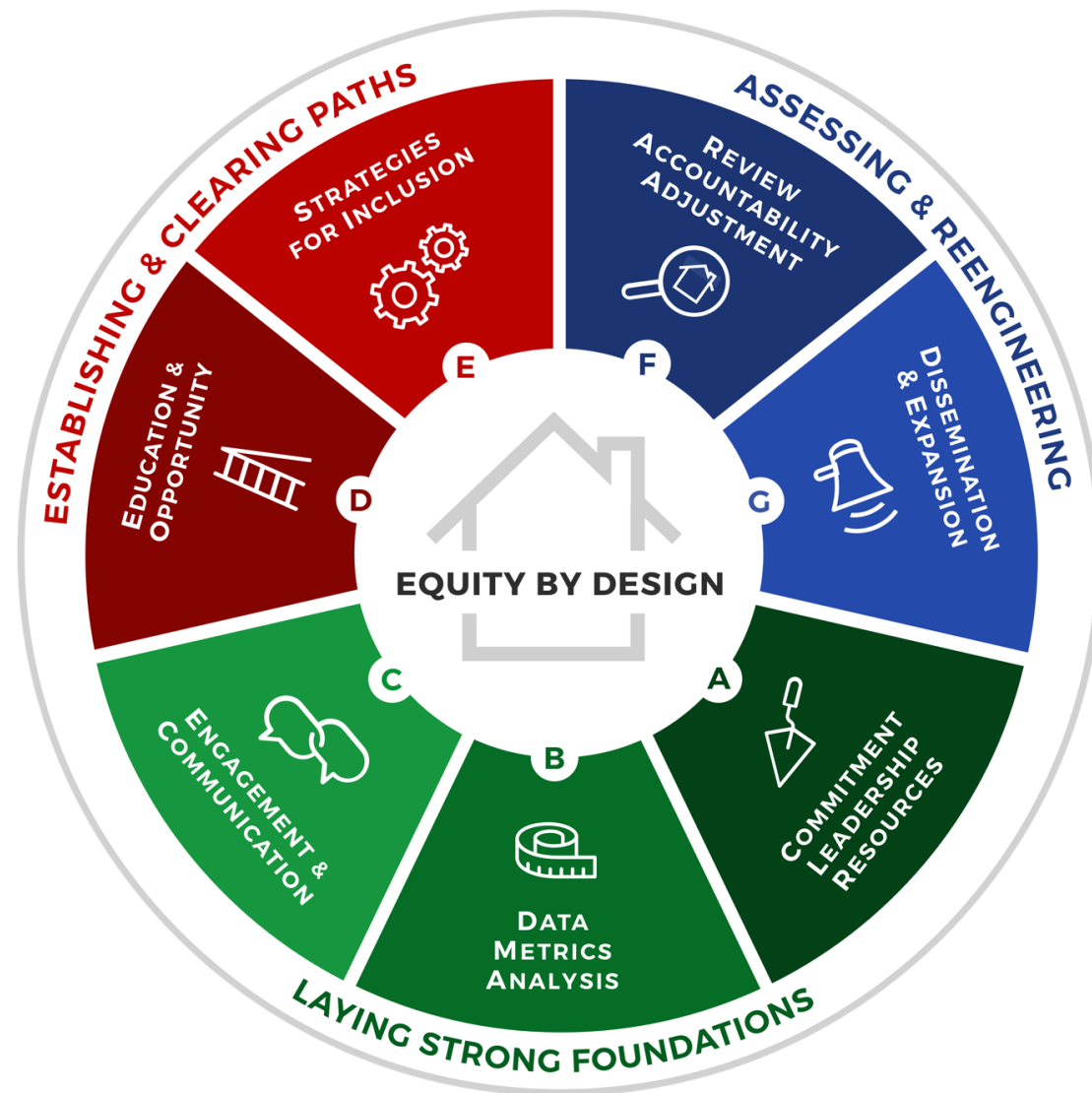


Introduction: EbD Metrics Framework Evolution, ctd.



Configure and communicate the EbD Metrics Framework:

- Layers
- Graphic representation
- User Guide

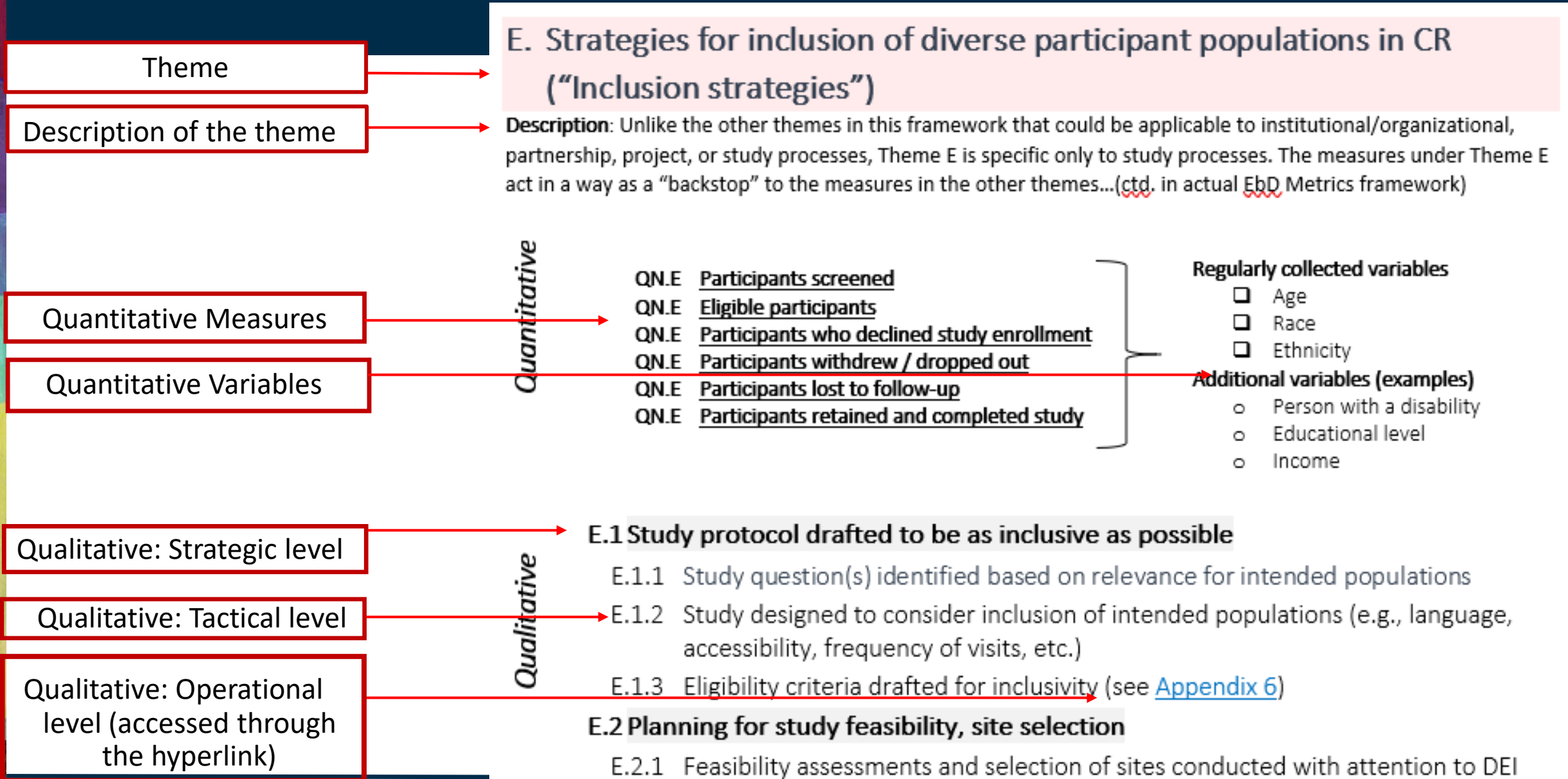




- **One theme per page**, with a brief description of each theme.
- **Quantitative measures (QN)** (4 themes completed to date)
 - Quantitative measures are not a 1:1 relationship to the qualitative measures.
 - Examples of quantitative variables given, to help disaggregating data.
 - Regularly collected 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
 - Intentionally broad to be useful to all stakeholders
 - Approach examples for the operational level metrics



EbD Metrics Framework: Structure, ctd.



EbD Metrics Framework: Operational level qualitative approach

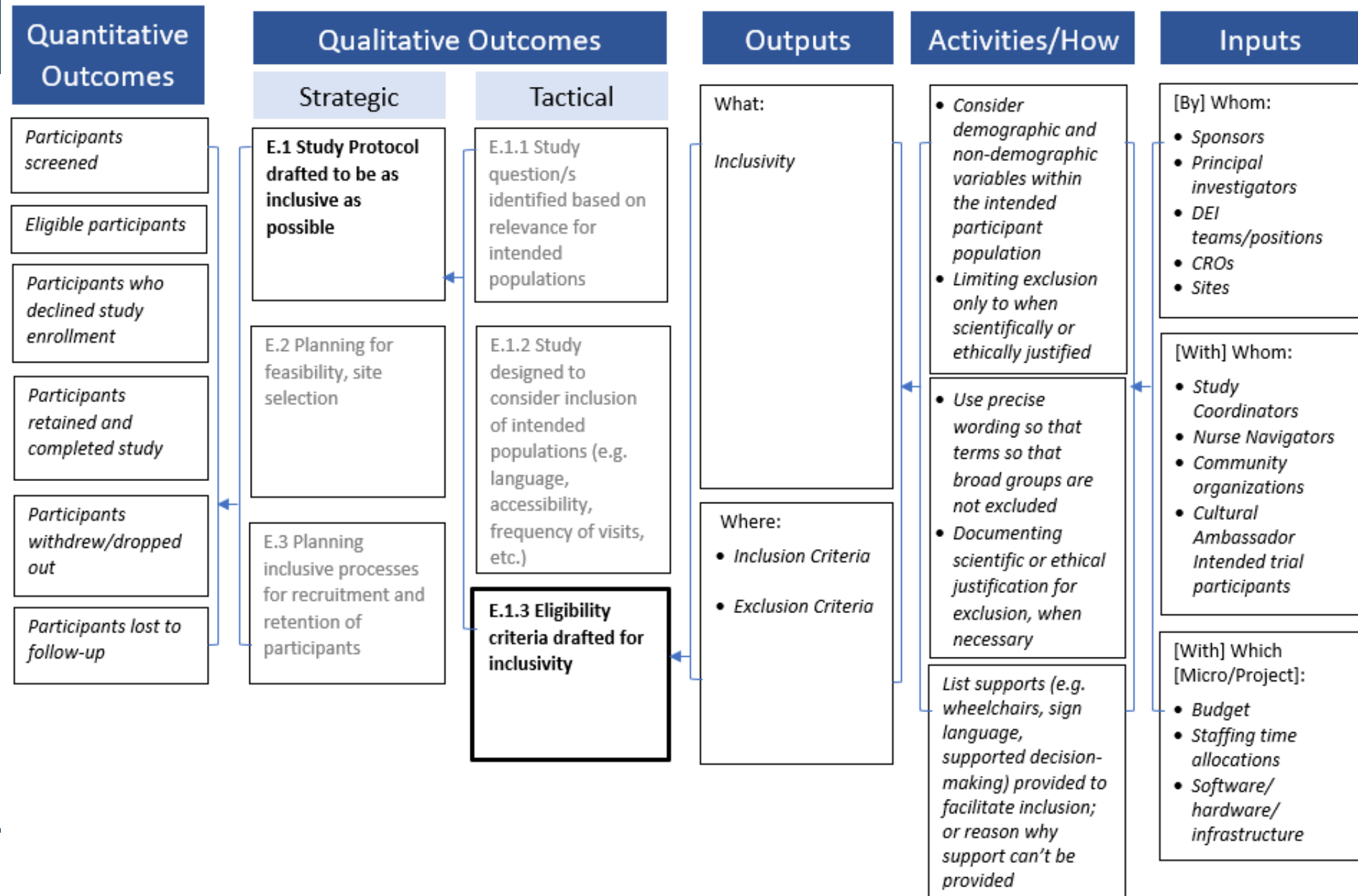


Approach to detailed considerations standardized by prompts:

- **[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"





- 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.





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