



MULTI-REGIONAL CLINICAL TRIALS

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

Action and Accountability: Equity by Design

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- I have no personal conflicts of interest with this presentation.



The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision

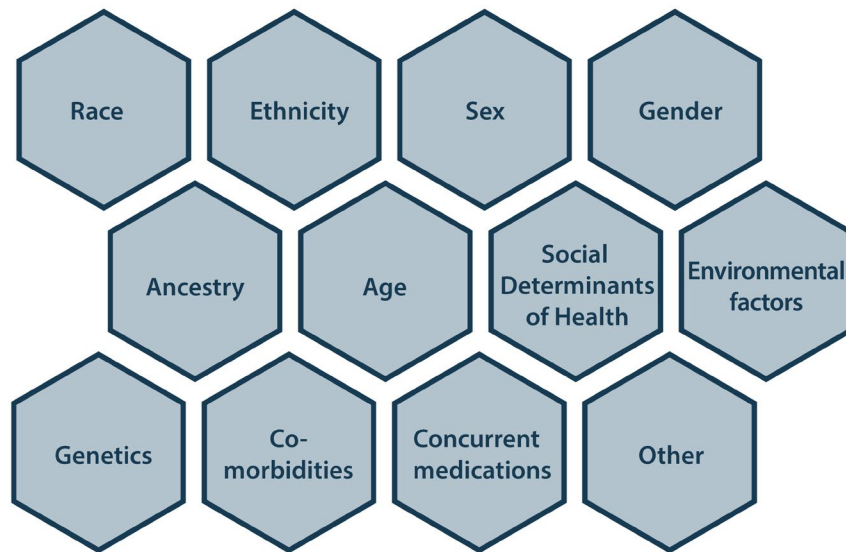
Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

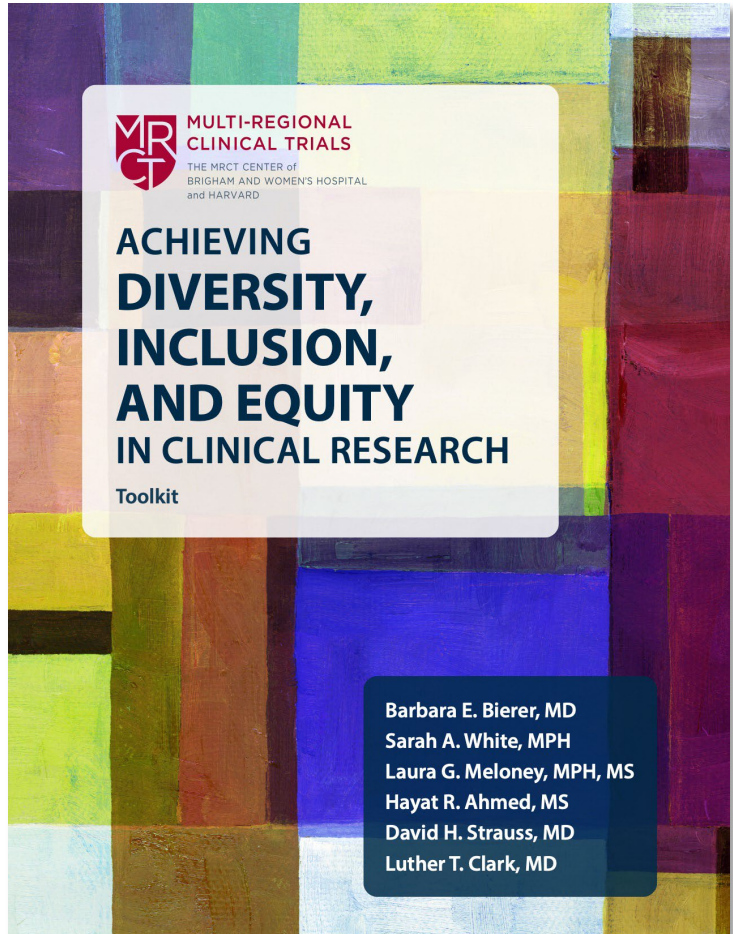
Engage diverse stakeholders to define emerging issues [across all stages of] global clinical trials and to create and implement ethical, actionable, and practical solutions.



Diversity, Equity, and Inclusion (DEI) in Clinical Research



MRCT Center's DEI Guidance Document and Toolkit



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DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

ABOUT | GUIDANCE | **RESOURCES** | CASE STUDIES | NEWS & EVENTS

GUIDANCE TOOLKIT & USER GUIDE

Guidance Toolkit & User Guide

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EBD METRICS FRAMEWORK & USER GUIDE

To accompany the [Guidance Document](#), the MRCT Center released a Toolkit to provide practical resources to improve diverse representation of participants in clinical research. The Toolkit contains logic models, checklists, example materials for participants, and more.

[Click here to download the full Toolkit](#). Otherwise, click on the sections below for the editable or PDF links to the individual tools relating to those topics.

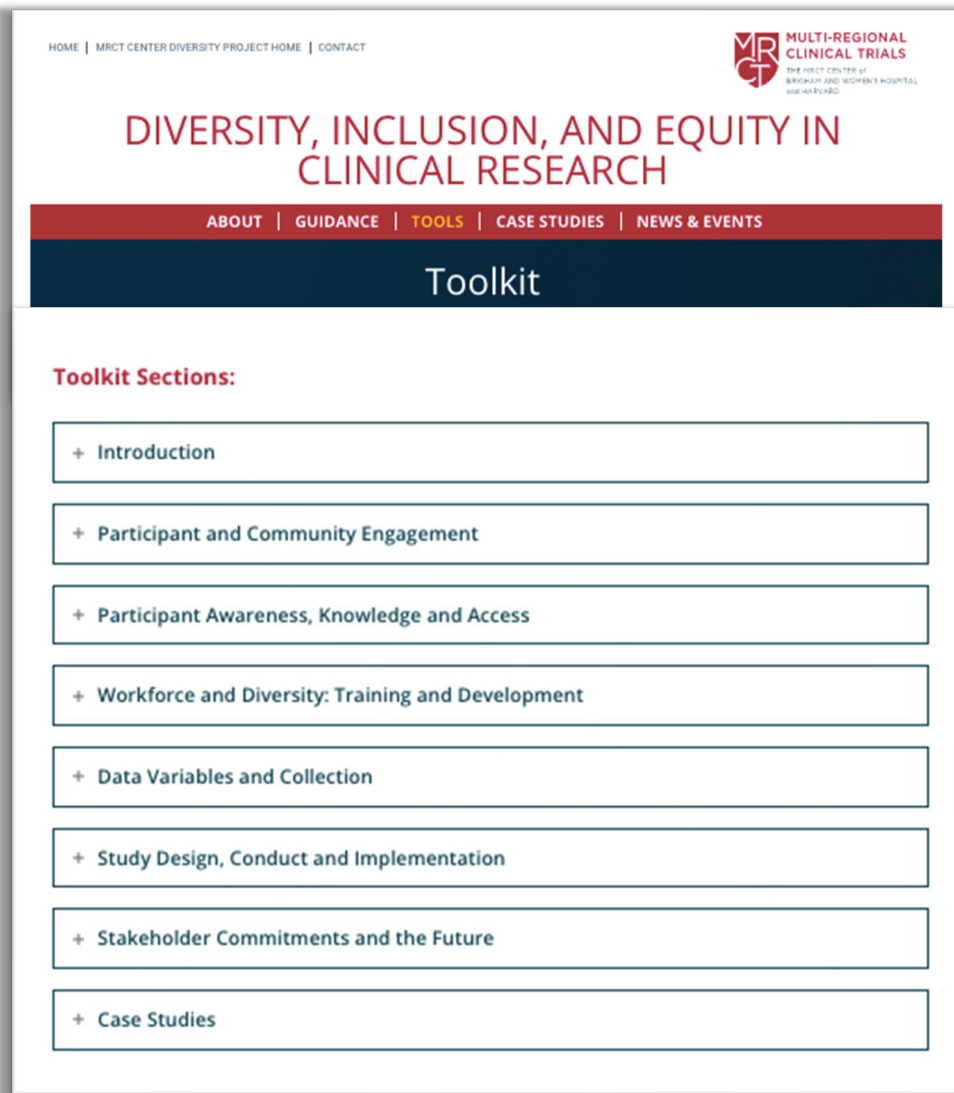
In-depth instructions are available for tools requiring explanation – if you need additional instruction, please feel free to contact the MRCT Center at MRCT@bwh.harvard.edu.

For more details on the types of tools included in this kit and how to use or adapt them, explore our [Toolkit User Guide](#) to learn more.

[TOOLKIT USER GUIDE](#)

<https://mrctcenter.org/diversity-in-clinical-research/>

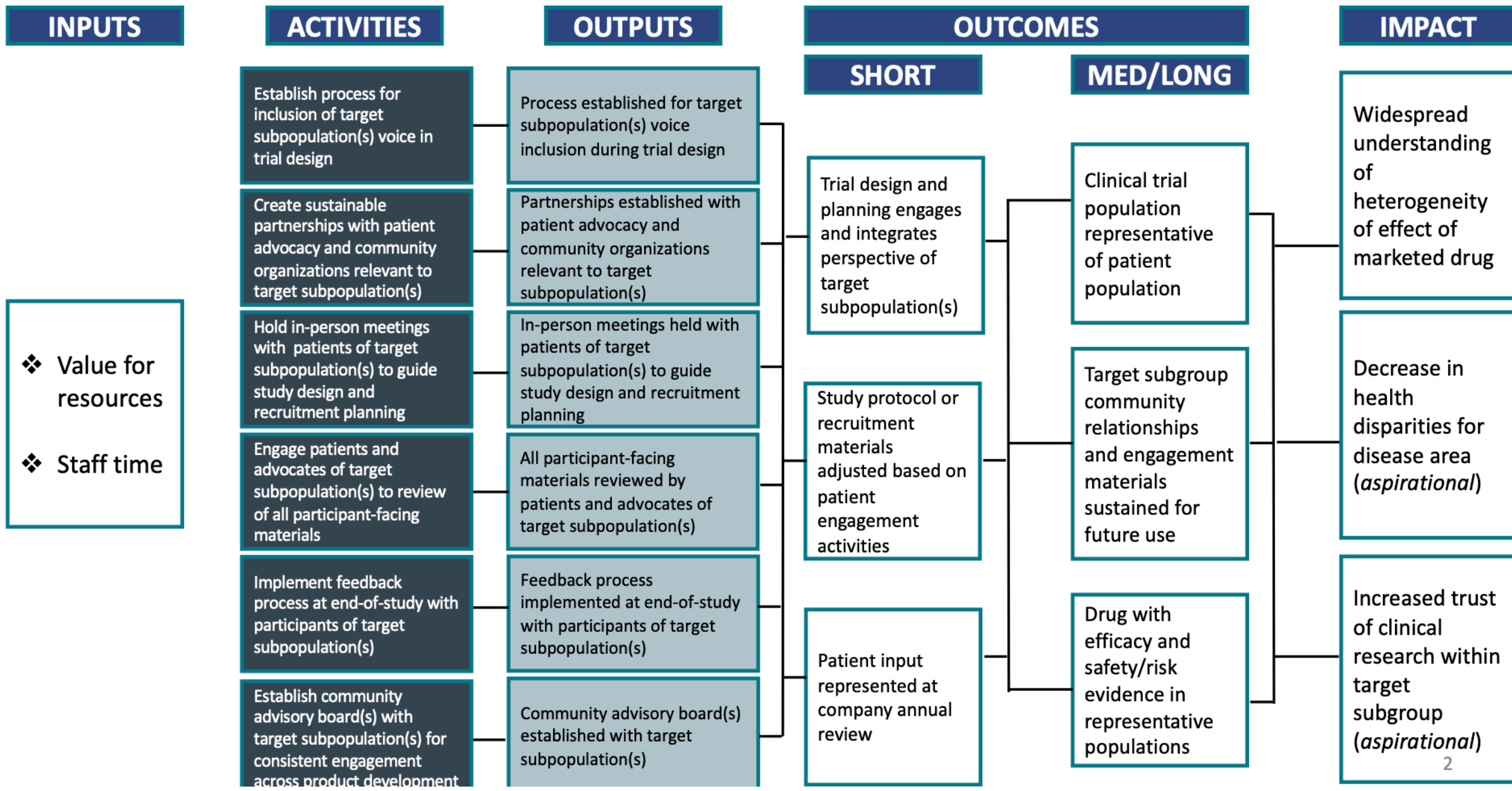
MRCT Center's DEI Guidance Document and Toolkit, cont.



<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



DEI: Guidance to Action

- 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).



MRCT Center's Equity by Design (EbD) Metrics Framework: Overview

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EbD Metrics Framework & User Guide

GUIDANCE TOOLKIT & USER GUIDE

IRB AND HRPP TOOLKIT

EBD METRICS FRAMEWORK & USER

GUIDE

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EbD Metrics Framework & User Guide

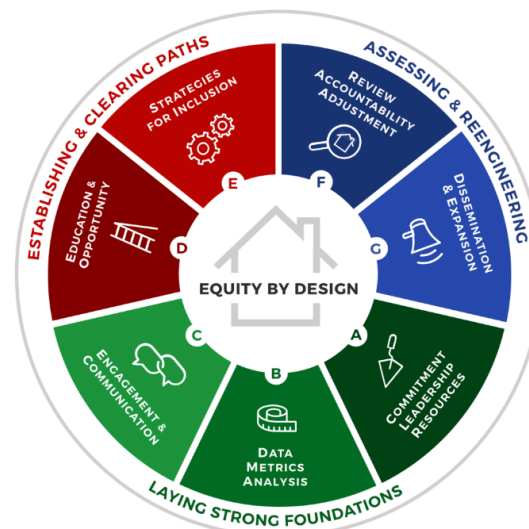
Equity by Design in Clinical Research: The EbD Metrics Framework

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**.



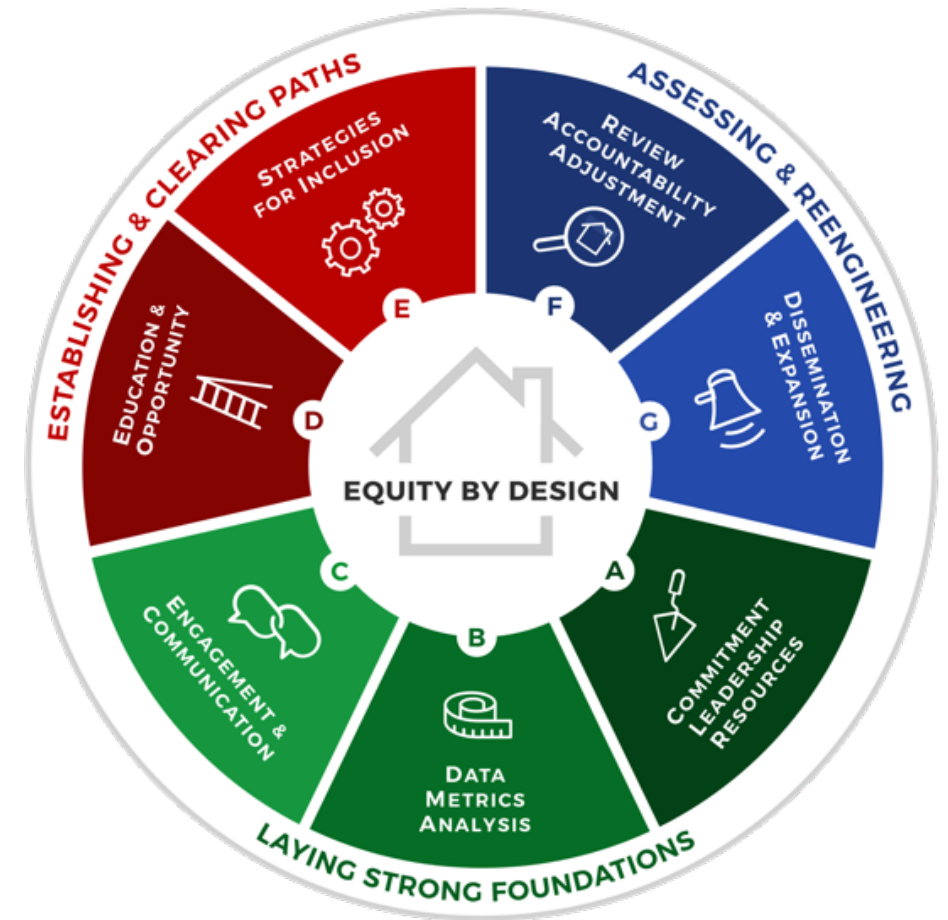
Equity by Design (EbD) in Clinical Research: The EbD Metrics Framework *User's Guide*



MRCT Center's Equity by Design (EbD) Metrics Framework: Overview, cont.

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



<https://mrctcenter.org/diversity-in-clinical-research/tools/ebd-metrics-framework-and-user-guide/>

MRCT Center's EbD Metrics Framework: Getting Into the Details for Action

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



Current MRCT DEI Work to Support Action

- 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
 - <https://mrctcenter.org/diversity-in-clinical-research/tools/irb-and-hrpp-toolkit/>
 - 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

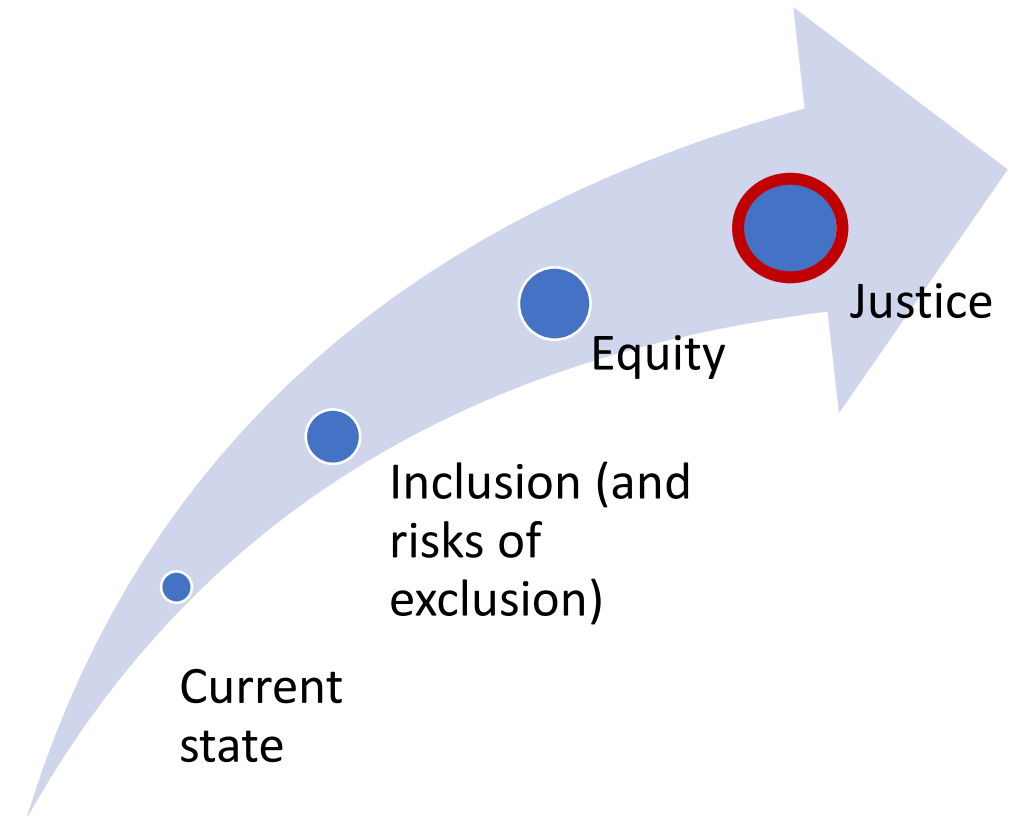
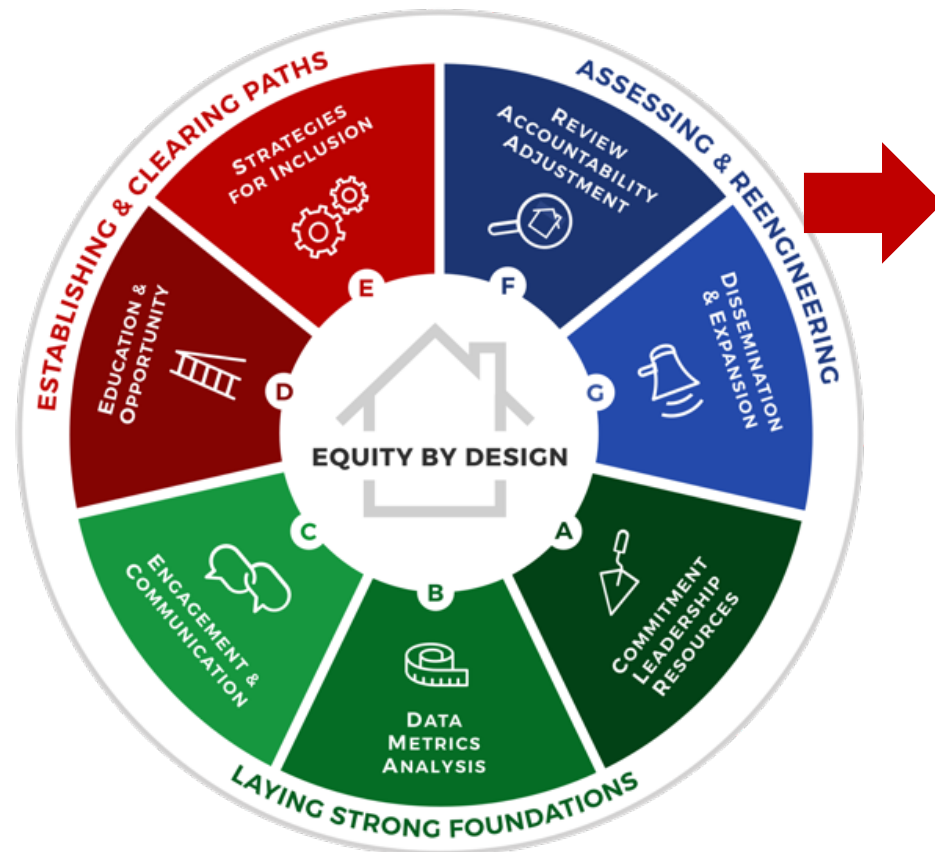
Current MRCT DEI Work to Support Action, cont.

- Forthcoming:
 - Best Practices for Translation of Study Documents,
 - Revision of SBER NIH protocol template,
 - Model FDA diversity plan,
 - Consideration of SOGI issues in clinical research,
 - Global DEI in clinical research



Accountability for Inclusion, Equity, and Justice

Our work doesn't end with greater inclusion.



Thank you

