

BIO Clinical Trial Diversity Roundtable: Analyzing the Data We Have Today, Enhancing Data Sources and Infrastructure for the Future and Building a Diverse Workforce

The Equity by Design Metrics Framework

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Disclaimer

- The views and findings expressed today are those of the individuals, serving in their individual capacity, and do not imply endorsement or reflect the views or policies of the U.S. FDA, NIH, or any affiliated organization or entity.
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The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision

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

Our Mission

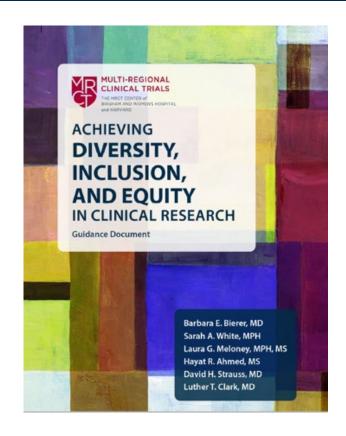
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.





The EbD Metrics Framework: History

- Diversity, Inclusion, and Equity in Clinical Research Guidance Document and print/online toolkit launched in 2020.
- Growing momentum to progress from:
 Guidance -> 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 BIO).
- Equity by Design (EbD) Metrics Framework developed and launched in June 2022.



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

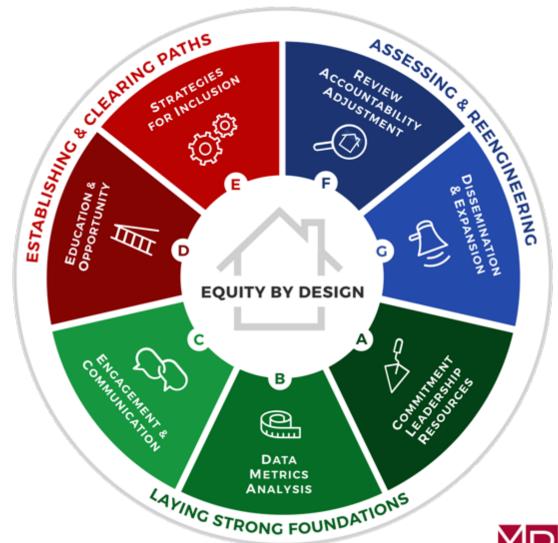


The EbD Metrics Framework: Overview



The Equity by Design Metrics Framework:

- Holistic look at DEI in clinical research
- Built in layers
 - o 7 key themes
 - Quantitative and qualitative metrics
 - Each metric has levels of detail that can be accessed
- Graphics representing the themes, the interconnectedness of the themes, and stakeholders (house)



EbD Metrics Framework: Example page (abbreviated)



Theme	D. Educational and career opportunities to support DEI in CR ("Workforce")
Description of the theme	Description: Theme D focuses on actions to recruit and retain a diverse workforce that is representative of participant populations. It begins with recruitment, pipeline, and cohort programs for underrepresented clinical research staff, then moves to training and mentorships to support new hires. Finally, workforce retention also involves workplace environments, benefits, resources and support plans that enable all employees to remain physically and mentally healthy,
Quantitative Measures — Quantitative Variables —	QN.D CR workforce representation/demographic & non-demographic data QN.D Leadership/management; funding/decision-making committees QN.D CR workforce hiring: applicants/interviews/offers/accepted offers QN.D CR workforce training: types/applications for/completion rates of trainings/certifications achieved Regularly collected variables Additional variables (examples) Age Sex assigned at birth Educational level Gender Identity O Veteran
	QN.D CR workforce opportunities: promotions/support groups
Qualitative: Strategic level—	D.1 Recruitment and pipeline programs for underrepresented CR staff D.1.1 Equitable and targeted opportunities to access institutionally supported pipeline/recruitment/cohort programs such as CR leadership development, internships/fellowships, or CR workforce training programs
Qualitative: Tactical level –	D.1.2 Vacancies for professional/volunteer positions in CR accessible to diverse audiences and applications fairly assessed
Qualitative: Operational level (accessed through —	D.2 Clinical research training, development, mentorship programs for underrepresented CR staff D.2.1 Equitable and targeted opportunities for training in clinical research, grant applications, and professional development (see Appendix 5)
the hyperlink)	D.2.2 Equitable and targeted opportunities for mentorship programs, training partnerships, or networking D.3 Workplace environment supports the well-being and retention of employees from diverse backgrounds



Appendix 5: : Operational Approach Example for D.2.1 "Equitable and targeted opportunities for trainings in clinical research, grant applications, and professional development"

Quant. Outcomes

CR workforce representation (demographic & non-demographic)

Leadership positions, funding /decision making committees, & management

CR workforce
hiring: applicants
/interviews /offers
/accepted offers

CR workforce training: types, applications for /completion rates of trainings, certifications

CR workforce opportunities: promotions/ support groups

CR workforce satisfaction/retention

Qualitative Outcomes

D.1 Recruitment and pipeline programs for underrepresented CR staff

Strategic

D.2 Clinical research training, development, mentorship programs for underrepresented CR staff

D.3
Workplace
environment
supports the well
being and retention
of employees from
diverse
backgrounds

D.2.1
Equitable
and targeted
opportunities for
trainings in clinical
research, grant
applications, and
professional
development

Tactical

D.2.2 Equitable and targeted opportunities for mentorship programs, training partnerships, or networking

Outputs

What:

- Training in design and conduct of clinical trials
- Data management training
- Training in writing a good research proposal
- Boilerplates to improve access to applying, conducting, and executing research grants
- Implicit bias training
- Cultural humility training
- DEI training

Where:

- Institutions
- Clinical research sites

Activities/How

- Define staff continuing education paths and skill/learning objective profiles
- Allocate equitable time for learning
- Reimburse tuition if applicable

Assess the DEI

- training and engagements that clinical research staff, community members, and patient advocates feel have been the most helpful
- Document the opportunities presented and those pursued

Inputs

- [By] Whom:
- Human
 Resources
- CITI Program
- Training consultants /partners

[With] Whom:

- Institutional Leadership
- IRBs
- Principal Investigators
- Study Coordinators
- Nurse Navigators
- Additional employees of organizations that work in CR

[With] Which [Micro/Project]:

- Budget
- Staffing time allocations
- Software/ hardware/ infrastructure

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- 1. When can we/should we ask for sensitive demographic data?
 - E.g., clinical research applicants, interviewees, hires; clinical research participants
 - Asking about race and ethnicity, gender identity, sexual orientation, disability status, educational level, income level
- 2. How can we structure navigation to support different stakeholders and different goals/purposes?
- 3. How do we create gold-standard measures that would also be applicable outside the US?
 - Data sources may be different
 - Values for demographic variables may be different
 - Foci for work in DEI may vary (e.g., race and ethnicity may not be a priority for DEI efforts in some countries)



Thank you

