



MULTI-REGIONAL CLINICAL TRIALS

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

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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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.

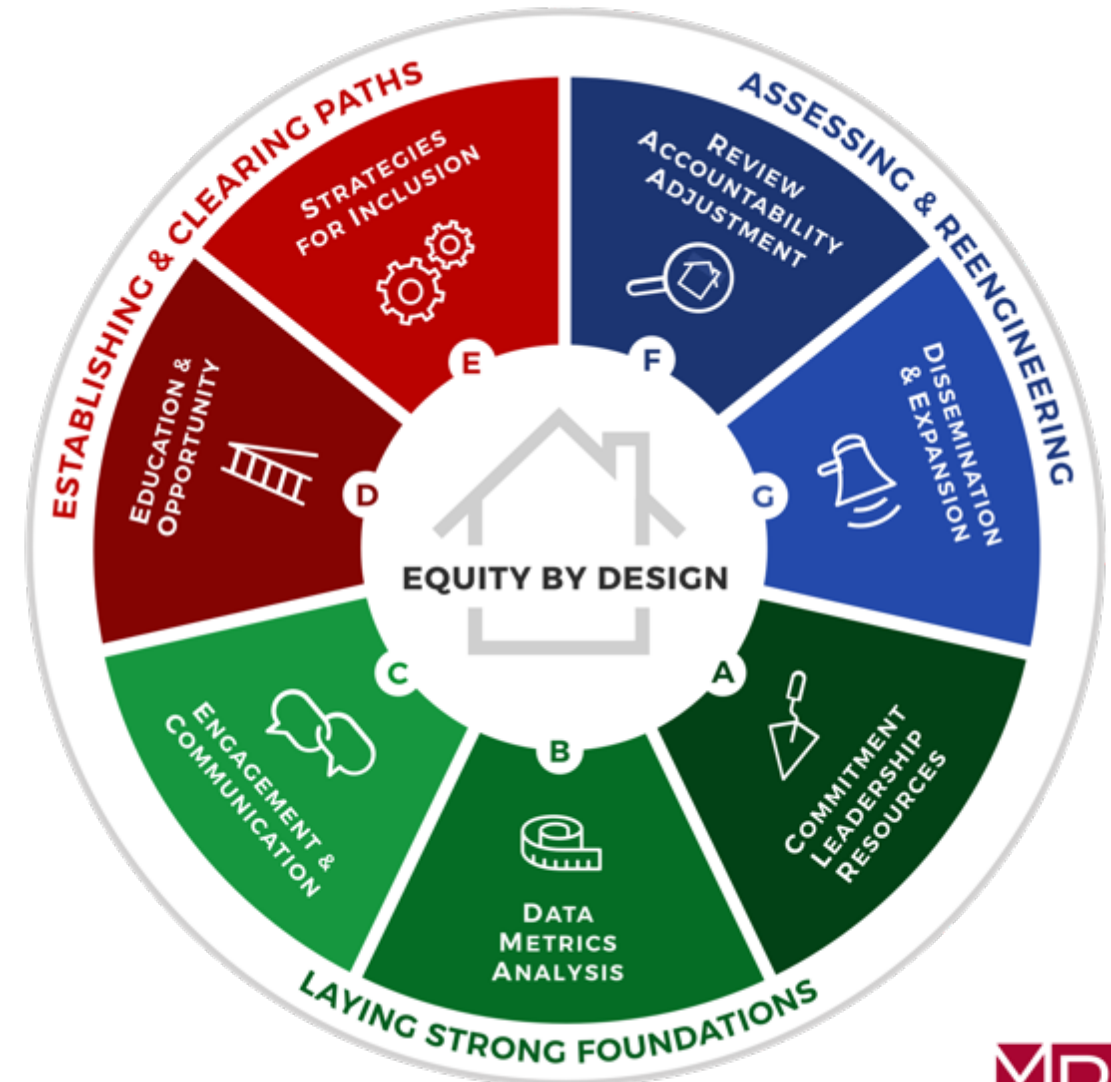


<https://mrctcenter.org/diversity-in-clinical-research/>



The Equity by Design Metrics Framework:

- Holistic look at DEI in clinical research
- Built in layers
 - 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)



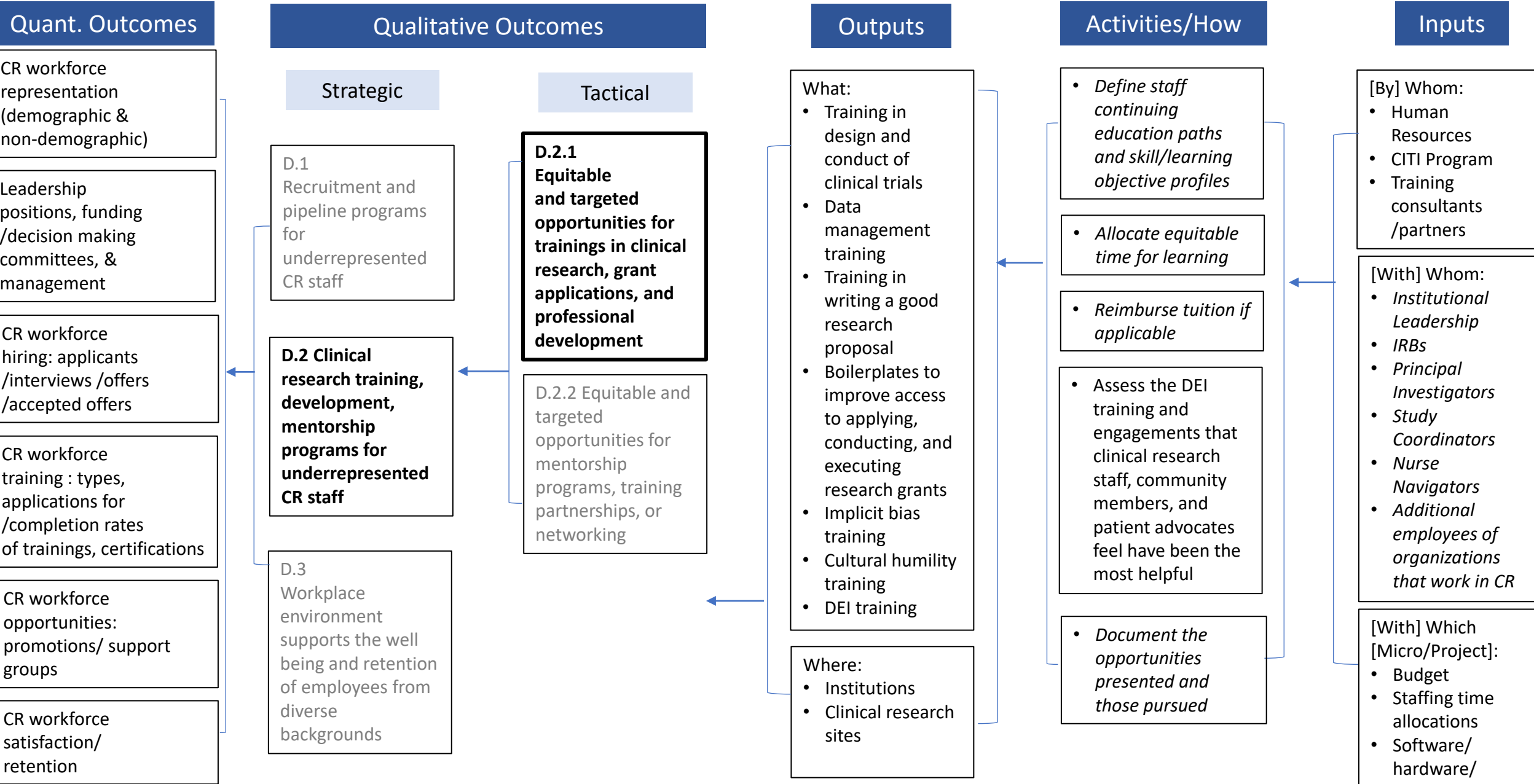


EbD Metrics Framework: Example page (abbreviated)

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	<p>QN.D CR workforce representation/demographic & non-demographic data</p> <p>QN.D Leadership/management; funding/decision-making committees</p> <p>QN.D CR workforce hiring: applicants/interviews/offers/accepted offers</p>	Regularly collected variables	Additional variables (examples)
Quantitative Variables	<p>QN.D CR workforce training: types/applications for/completion rates of trainings/certifications achieved</p> <p>QN.D CR workforce opportunities: promotions/support groups</p>	<input type="checkbox"/> Age <input type="checkbox"/> Sex assigned at birth <input checked="" type="checkbox"/> Gender Identity <input type="checkbox"/> Race	<input type="checkbox"/> Language <input type="checkbox"/> Person with a disability <input type="checkbox"/> Educational level <input type="checkbox"/> Veteran
Qualitative: Strategic level	D.1 Recruitment and pipeline programs for underrepresented CR staff		
Qualitative: Tactical level	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 D.1.2 Vacancies for professional/volunteer positions in CR accessible to diverse audiences and applications fairly assessed		
Qualitative: Operational level (accessed through the hyperlink)	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) 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”





EbD Metrics Framework: Continuing questions

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