



**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
User's Guide

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Introduction: Developing metrics for diversity, equity, and inclusion in clinical research

In late 2020, the MRCT Center convened representatives of professional, trade, academic, and patient advocacy organizations to formulate the Diversity, Equity, and Inclusion Roundtable (hereafter termed 'Roundtable'). The clinical research (CR) stakeholders have been justly charged with improving diversity, equity, and inclusion (DEI) in clinical trials for underrepresented populations (e.g., race, sex, gender, people with disabilities, people who speak languages other than English, people who are uninsured, etc.), and the goal of the Roundtable was to harmonize individual organizational efforts toward that end. Initial discussions highlighted the lack of any publicly available metrics that succinctly, accurately, and holistically capture DEI in clinical research. As such, the Roundtable met on a regular basis to develop metrics for evaluating progress, identifying gaps, facilitating benchmarking, strengthening accountability, and promoting collaboration for DEI in clinical research.

The Roundtable worked through an iterative process of defining identifying and streamlining key themes for DEI, qualitative and quantitative measures of actions within those themes, and approaches for configuration and communication. The draft framework was then reviewed by several organizations external to the Roundtable. The current structure is designed to provide a straightforward and engaging overview of DEI in clinical research, to orient user institutions/organizations toward potential entry and follow-up points (depending upon the maturity of their efforts in the process), and to propose metrics that can be tailored by different stakeholders across the clinical research spectrum. Because DEI success from the institutional/organizational and the study perspectives are interdependent, the EbD Metrics Framework is broadly designed to be useful for either, although some specific measures may be more applicable to one perspective. This framework is a living document, and its current structure is presented as:

- **A visual summary** (Figure 1 below) that can quickly familiarize users to: *Equity by Design in Clinical Research: The EbD Metrics Framework* (hereafter termed the EbD Metrics Framework) and illustrate the interdependent nature of the work;
- **A list of quantitative metrics**, organized by theme (where applicable), and inclusive of potential variables for disaggregation of data;
- **A list of qualitative metrics**, below the quantitative metrics in each theme, and organized by increasing level of detail.

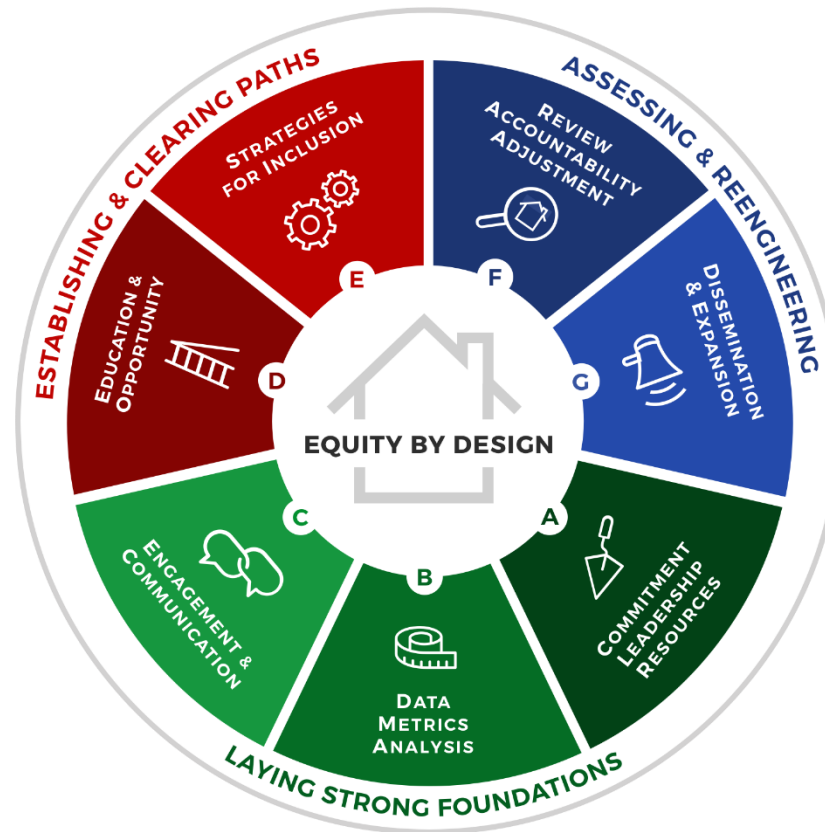
The framework is organized around SEVEN THEMES (each in italics designated by capital letters), divided into categories of effort:

- **Laying strong foundations** is inclusive of:
 - A. Commitment, leadership, and resources to support DEI in CR ("Commitment")**
 - B. Institutional and study metrics for DEI in CR, data collection, and analysis ("Data")**
 - C. 360-degree partnerships, communication, and engagement ("Engagement")**

- **Establishing and clearing paths** is inclusive of:
 - D. Educational and career opportunities to support DEI in CR (“Workforce”)
 - E. Strategies for inclusion of diverse participant populations in CR (“Inclusion strategies”)
- **Assessing and reengineering for success** is inclusive of:
 - F. Review, accountability, and course adjustment (“Review”)
 - G. Dissemination and expansion of work (“Dissemination”)

Figure 1. EbD Metrics Framework visual summary: Building inclusive clinical research processes and communities

The circular nature of the visual summary indicates that a given stakeholder may progress not only from one theme to the next but may also revisit themes as their efforts mature. Quantitative metrics, where applicable, align with the qualitative measures by theme.



How to utilize the metrics framework

Theme: Users may click (CTL+Enter) on any theme title in the table of contents to go directly to the theme that they wish to first engage with. There is a separate page of the framework for each theme to better enable simplified and viewing, with the theme title at the top highlighted in the color of the category of effort.

- Green highlight for the three themes under **Laying strong foundations:**

A. Commitment, leadership, and resources to support DEI in CR (“Commitment”)

B. Institutional and study metrics for DEI in CR, data collection, and analysis (“Data”)

C. 360-degree partnerships, communication, and engagement (“Engagement”)

- Red highlight for the two themes under **Establishing and clearing paths:**

D. Educational and career opportunities to support DEI in CR (“Workforce”)

E. Strategies for inclusion of diverse participant populations in CR (“Inclusion strategies”)

- Blue highlight for **Assessing and reengineering for success:**

F. Review, accountability, and course adjustment (“Review”)

G. Dissemination and expansion of work (“Dissemination”)

Theme description: Beneath the theme title is a section describing the theme scope and any specific terminology. For example:

D. Educational and career opportunities to support inclusivity in clinical research (“Workforce”)

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... (note: description continues in actual metrics framework)

Quantitative measures: Quantitative measures are listed below the theme title and description, and to the right of a horizontal italicized “Quantitative” header. They are currently available for the following themes:

- Commitment, leadership, and resources to support DEI in clinical research (“Commitment”)
- 360-degree partnerships, communication, and engagement (“Engagement”)
- Educational and career opportunities to support inclusivity in clinical research (“Workforce”)
- Strategies for inclusion of diverse participant populations in clinical research (“Inclusion strategies”)

Please note that the quantitative measures are not meant to be utilized as the quantitative outcome assessment of single qualitative measures. While it is true that some quantitative measures do relate closely to some specific qualitative measures, most quantitative measures assess the outcome of the combined processes involved in qualitative measures *across* the theme. For example, diversity in leadership positions depends not only on measures for recruitment and pipeline programs for underrepresented clinical research staff (D.1), but also upon measures for clinical research training and mentorship programs for underrepresented clinical research staff (D.2), and employee benefit packages (D.3).

Beside the quantitative measures are examples of variables that framework users may wish to utilize in disaggregating their quantitative data. They are categorized into regularly collected variables (e.g., age, race, sex, gender identity, ethnicity), and additional variables that are less commonly collected (e.g., language spoken, disability status, income level, etc.). The lists of variables provided are by no means exhaustive, and could include such variables as veteran status, immigration status, religion, and others. The variables utilized to disaggregate data will depend upon the institutional/organizational and/or study questions being asked and data availability. **Organizations could begin with a limited set of variables, collect baseline data, and set goal/s for progress. As the program plans and goals evolve, additional variables could be added, and then measured from baseline to assess performance.** Although the list of potential variables, and the potential values assigned to those variables (e.g., for gender identity: cis-male, cis-female, trans-male, trans-female, gender non-conforming, other), are not currently standardized, collaborative standardization in the future would engender comparability of data across organizations. **Please note that all measures are meant to be guideposts and can be utilized and or/tailored at the discretion of the user.**

The page layout for the section on quantitative variables looks similar to the following example from Theme D (Workforce):

Quantitative	QN.D CR workforce representation/demographic & non-demographic data	}	Regularly collected variables	Additional variables (examples)
	QN.D Leadership/management; funding/decision-making committees		<input type="checkbox"/> Age	<input type="checkbox"/> Language
	QN.D CR workforce hiring: applicants/interviews/offers/accepted offers		<input type="checkbox"/> Sex assigned at birth	<input type="checkbox"/> Person with a disability
	QN.D CR workforce training: types/applications for/completion rates of trainings/certifications achieved		<input type="checkbox"/> Gender Identity	<input type="checkbox"/> Educational level
	QN.D CR workforce opportunities: promotions/support groups		<input type="checkbox"/> Race	<input type="checkbox"/> Veteran
	QN.D CR workforce satisfaction/retention		<input type="checkbox"/> Ethnicity	

Qualitative measures: The Roundtable recognized that users of the metrics framework will likely differ in the level of detail with which they wish to engage. Therefore, **the qualitative metrics have been separated into three successive levels of specificity: STRATEGIC, TACTICAL, and OPERATIONAL.** Please note that that all suggested qualitative metrics are guideposts and are intentionally non-specific to any given stakeholder within the clinical research enterprise. Users of the metrics framework can adapt them to the specific nature of their organization and work.

- **STRATEGIC:** Some users may wish to look only at the 3-4 strategic “must have” qualitative metrics per theme, which are in bold font/grey highlight, and designated by the theme letter and strategic metric number (e.g., D.1).
- **TACTICAL:** Other users may wish to go beyond the strategic level “must have” qualitative metrics and look additionally at the 2-3 suggested tactical level qualitative metrics. These are listed under each strategic metric with the theme letter, the strategic metric number, and the tactical metric number (e.g., D.1.1).
- **OPERATIONAL:** Operational level metrics are not listed directly under the tactical metrics, because it is anticipated that users who wish to consider in more detail how to measure efforts on the tactical qualitative metrics would create their own operational level metrics. **However, to assist those wishing to develop operational level metrics, *approach examples* in the format of logic model flowcharts have been included in the framework Appendix. These are available for 1-2 tactical level metrics for each theme and can be accessed by clicking on the “see Appendix [#]” that is in blue underlined font next to the tactical measure, or by scrolling to the Appendix section.**

The page layout for qualitative measures will resemble the following example from Theme D (Workforce):

Qualitative	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
	D.1.2 Vacancies for professional/volunteer positions in CR accessible to diverse audiences and applications fairly assessed
	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 1)
	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
	D.3.1 Required training for all employees on cultural humility, implicit bias, and accessibility by design
	D.3.2 Equitable and targeted benefits, flexible work policies, and opportunities to create/participate in support groups
	D.3.3 Retention strategies, individualized plans, and support available through human resources

The approach examples for operational level metrics follow a suggested format using a logic model flowchart. The idea is to flow conceptually deeper from intended quantitative outcomes/goals, to the qualitative measures needed to achieve those quantitative outcomes, and further on (for stakeholders tasked with operational detail) to the specific outputs, activities and inputs underpinning the qualitative measures. Specific prompts are provided to support conceptualizing initial and progressive outputs, activities and inputs.

Outputs

- **What:** List “what” the metric is focused on.
- **Where:** List where intended audience will engage with the “what”.

Activities

- **How:** List actions to support the development and/or positive impact of the process.

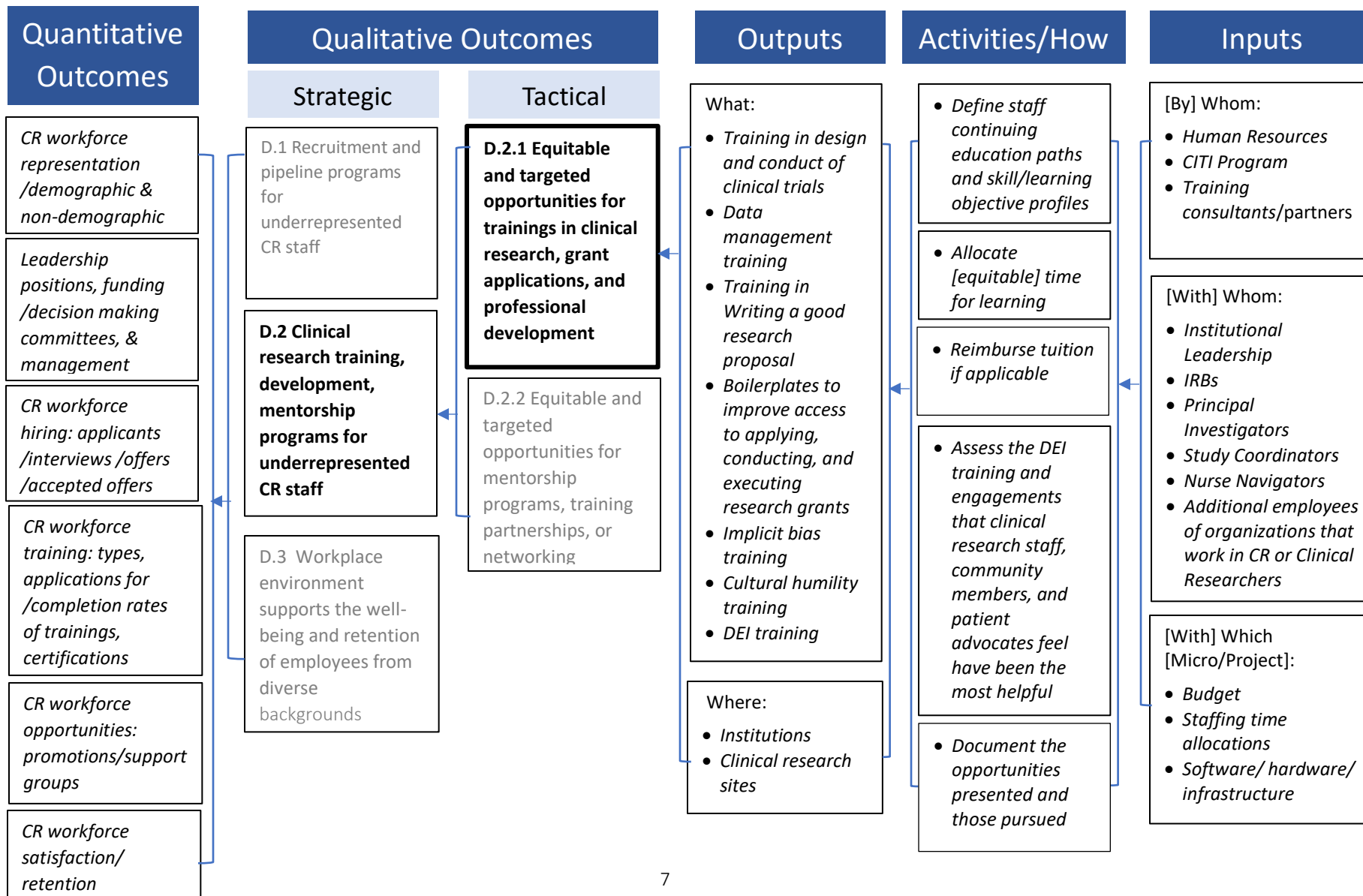
Inputs:

- **[By] Whom:** List whom within the organization is responsible for the metric;
- **[With/to/for] Whom:** List with whom the people in “[By] Whom” should be collaborating;
- **[With] Which [Micro/Project]:** List the resources needed at the micro/project level (i.e., not the organizational level) to accomplish the “How”, “What” and “Where”.

The operational approach logic models provided in the EbD Metrics Framework are intended only to be *examples* of how users of the framework make may conceptualize the operational level. One example is provided below in Figure 2. Please note that an editable PDF of a “blank” operational approach logic model, containing only the flowchart scaffolding and prompts listed above, is also available for download on the EbD Metrics Framework website. **Users of the EbD Metrics Framework are advised to generate operational level approach details for their specific environment, focus, program and project. They can add additional detail under each of the prompts as their goals and plans evolve.** For example, for the tactical metric of [D.2.1] “Equitable and targeted opportunities for trainings in clinical research, grant applications, and professional development”, an organization may wish to start with listing under “what”: training in the conduct of clinical trials and training in writing a good research proposal. As the organizational capabilities and goals for progress on DEI evolve, they could then add in additional “what/s” such as: boilerplates to improve access to applying, conducting, and executing research grants; implicit bias training; and cultural humility training. Similarly, for the “how” prompt the user could initially put in measures such as: define staff continuing education paths and skill/learning objective profiles and/or allocate [equitable] time for learning. As goals evolve, the EbD Metrics Framework user may then add under “how” measures such as: 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; and/or document the opportunities presented and those pursued.

Figure 2: Operational Approach Example for Tactical Measure D.2.1 under Theme D (Workforce)

Appendix 1: Operational Approach Example for D.2.1 “Equitable and targeted opportunities for trainings in clinical research, grant applications, and professional development”



It is possible that metrics lists could also be used for each level of the qualitative metrics to quickly view snapshots of the framework. **However, the vision for the EbD Metrics Framework is not simply a “checklist”** and will likely evolve into an interactive web format that could involve a built-in dashboard with visuals for tracking progress on the metrics. Example snapshots are illustrated below:

Figure 3: STRATEGIC Level Metrics Snapshot

A. Commitment, leadership, and resources to support DEI in CR
A.1. Statement of commitment to DEI in clinical research by the President, Executives, and Board
A.2. Resource commitment to support DEI in CR across institution
A.3. Executive leadership team and board action on commitment for DEI in CR
A.4. Dedicated teams, committees, positions and specific roles with identified institutional structure
B. Metrics for diversity in clinical research trials, data collection, and analysis
B.1. Defined set of necessary metrics for evaluating institutional or study performance on DEI in CR
B.2. Identification of existing and/or needed data, variables, and data sources
B.3 Standardization of data collection practices
C. 360-degree partnerships, communication, and engagement
C.1. Partnerships with community sites, community organizations and community members developed and sustained
C.2. Respectful and accessible communication platforms and materials
C.3. Opportunities for safe, respectful, and open engagement
D. Educational and career opportunities to support inclusivity in clinical research
D.1. Recruitment and pipeline programs for underrepresented CR staff
D.2. Clinical research training, development, mentorship programs for underrepresented CR staff
D.3. Employee benefit packages, flexible work policies, and resource groups
E. Strategies for inclusion of diverse participant populations in clinical research
E.1. Study protocol drafted to be as inclusive as possible
E.2. Planning for feasibility, site selection
E.3. Planning inclusive processes for recruitment and retention of participants
F. Review, accountability, and course adjustment
F.1. Cleaning and analysis of data and review of results
F.2. Periodic review of goals and performance criteria
F.3. Accountability and course adjustment
G. Dissemination and expansion of work
G.1. Mechanisms to solicit diverse views in assessment, authorship, and advocacy of DEI efforts for CR
G.2. Transparent and broad communication of results, analyses, and plans
G.3. Institutional advocacy for reducing disparities and improving health equity

Figure 4. TACTICAL Level Metrics Snapshot (example)

A. Commitment, leadership, and resources to support DEI in CR
A.1. Statement of commitment to DEI in clinical research by the President, Executives, and Board
A.1.2 Internal communication of commitment to DEI
A.1.2 Public communication of commitment to DEI
A.2. Resource commitment to support DEI in CR across institution
A.2.1 Assessments of the institution's financial, human, and physical resources to support DEI in CR
A.2.2 Processes to generate/re-allocate financial, human, and physical resources to support DEI in CR
A.2.3 Criteria for vendor selection and contracting to support DEI in CR
A.3. Executive leadership team and board action on commitment for DEI in CR
A.3.1 Institutional partnerships with external advisors that coordinate or conduct CR
A.3.2 Goals, processes for monitoring of institutional performance
A.4. Processes for monitoring of team, committee, and individual position performance
A.4.1 Dedicated teams, committees, and positions for DEI in CR
A.4.2 Demarcated roles, tasks, and supervisory/reporting structures for teams, committees and positions for DEI in CR
A.4.3 Processes for monitoring of team, committee, and individual position performance

Conclusion and next steps

In conclusion, the EbD Metrics Framework is designed to be utilized by stakeholders across the clinical research community (e.g., institutional/organizational/company leadership, DEI teams, Principal Investigators and research teams, etc.) to plan for and measure progress on diversity, equity, and inclusion in clinical research. For some users and purposes, such as for advocacy or for a quick review, an overview of the measures may be most useful in the form of the EbD Metrics Framework visual graphic or in the snapshots of the strategic or tactical qualitative measures (see Figures 3 and 4 above). Other users may wish to look at the quantitative measures by theme in combination with the strategic and tactical qualitative measures. They would then go to the table of contents in the EbD Metrics Framework and click on the theme that they first wish to look at or scroll to the page for that theme. For users that wish to delve into the finer planning details, they can click on the example operational approaches or scroll to the Appendix. These operational approach examples give some idea of what could be listed in the logic models for each tactical measure. However, the entries users make into their own operational approaches will certainly be different depending upon the stakeholder and the purpose for which the EbD Metrics Framework is being utilized. Where users feel comfortable doing so, they are invited to share back with the MRCT Center any operational approach examples that they have created, and feel would be useful to others. The EbD Metrics Framework is a living document and will be improved through the commentary and suggestions of readers. As revisions are incorporated, we will post updated versions to the website.

Although the EbD Metrics Framework is currently in print format, we do envision creating an interactive web-based version. We look forward to, with your feedback, creating improved versions of the EbD Metrics Framework and to working together to build more inclusive clinical research processes and communities.