Equitable Breakthroughs in Medicine Development (EQBMED)

EQBMED Site Maturity Assessment Model:

Team Guide (Part 1 of 3)

Part 1: Team Guide

Part 2: Site Questionnaire

Part 3: Maturity Model Rubric

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Background Information

What is Equitable Breakthroughs in Medicine Development (EQBMED)?

Equitable Breakthroughs in Medicine Development (EQBMED) is a multi-stakeholder effort that aims to achieve equity in clinical research by providing community-facing clinical trial sites with robust support across community engagement and clinical trial operations capabilities. The program is funded by PhRMA and led by Yale School of Medicine, Morehouse School of Medicine, Research Centers in Minority Institutions (RCMI) Coordinating Center located at Morehouse School of Medicine, and Vanderbilt University Medical Center.

What is the EQBMED Site Maturity Assessment Model?

The EQBMED Site Maturity Assessment Model is a holistic, collaborative, site-driven, and formative assessment carried out with potential sites to catalogue their current capabilities and identify opportunities for growth in conducting industry-sponsored clinical trials and enriching diversity of those trials. It is not intended to be evaluative in nature, or to be used to compare sites in the EQBMED program or otherwise benchmark against others. The completed assessment will: 1) inform the site-specific roadmap for capability building during the Learning Phase (with the support of EQBMED infrastructure partners), 2) serve as a baseline for sites to track progress toward their maturity goals, and 3) create visibility into site capabilities to help trial sponsors assess interest in placing protocols at the site. Because the EQBMED Learning Phase is focused on increasing representation of Black, Hispanic, and Latino populations, the tool specifies these groups. However, the tool itself is agnostic to the nature of diversity goals and may be tailored for use accordingly. Importantly, this assessment model draws from and synthesizes substantial prior clinical trial diversity initiatives including those led by Yale Center for Clinical Investigation (YCCI), The Clinical Trials Transformation Initiative (CTTI), The National Academy of Medicine, and Multi-Regional Clinical Trials Centers (MRCT).

Why did we develop the EQBMED Site Maturity Assessment Model?

Although efforts to eliminate inequities in access to clinical trials have been underway for decades, only recently has clinical trial diversity been defined as a national priority, with substantial investments from multiple sectors. Among the most powerful barriers to clinical trial diversity are social determinants of health and trustworthiness of health care providers and research institutions, factors that underscore the need for substantive community engagement to improve access. Nevertheless, current tools to assess organizational capabilities for clinical trial diversity focus primarily on capacity for clinical trials operations in general, rely solely on quantitative self-reported data, and do not include meaningful assessment of capabilities related to community engagement. We sought to address these limitations by developing using a team-based, collaborative, mixed methods approach to develop a holistic maturity model and associated assessment approach for clinical trial diversity that captures organizational level factors, community level factors and research operations capabilities.

How did we develop the EQBMED Site Maturity Assessment Model?

In developing the model, we drew upon multiple sources of input, including:

1. Experience with the YCCI's successful maturity journey to promote diversity and inclusion in clinical research over the past 15 years[1]. Success is evidenced by increasing underrepresented communities of color participation in clinical trials from approximately 3% in 2010 to rates now close to 35%, with studies engaging the Cultural Ambassadors directly having rates averaging around 62% and retention rates averaging 97%

2. Review and synthesis of guidelines, principles, toolkits from the CTTI[2,3], National Academy of Sciences[4,5], Pharmaceutical Research and Manufacturers of America Pharmaceutical Research and Manufacturers of America (PhRMA)[6], Food and Drug Administration (FDA)[7], MRCT Centers[8,9], and others[10-13]

3. Iterative review by the EQBMED team and over a dozen additional content experts representing decades of expertise and experience in clinical trial operations, community engagement, organizational readiness, and maturity model building

4. Modified cognitive interviews to test content validity and feasibility at one trial site, and full field administration at two trial sites.

In total, there were 20 iterations on the model. The final version extends CTTI's foundational model by operationalizing measurement of core concepts and defining maturity levels for practical use by sites and partners seeking to improve clinical trial diversity.

Several important assumptions underpin the guiding model. First, organizational readiness to engage in authentic, sustainable clinical trial diversity initiatives is a highly complex, multifaceted phenomenon including both technical and relational dimensions. As such, assessment of organizational readiness requires a mixed methods approach using both quantitative and qualitative measures. Robust quantitative measures (e.g., number and types of trials, enrollment, and retention data) are needed to develop key performance indicators to track progress along the model levels. Qualitative data (e.g., notes and transcripts of interviews) characterize other essential capabilities to achieve clinical trial diversity such as the nature of community partnerships and the commitment of senior leadership. Second, the process of assessment must be collaborative in nature. Productive, meaningful collaboration requires trust among partners. Trust is facilitated by investing time and good will in relationship building, creating conditions that encourage candid reflection and exchange by both parties, and deferring to the site representative team to define their aspirational goals. While perhaps not feasible within the current EQBMED Learning Phase, ideally assessments would take place on site, in person. Requiring supporting 'evidence' of various site capabilities does not engender trust and should be done only if the assessment team has a justification and has developed a clear process for appraising supportive documentation. Finally, the model is fundamentally unified since sustainable clinical trial diversity cannot be achieved when research operations and community engagement operate in silos. Accordingly, the assessment must have input from

a range of organizational representatives, including clinical trial staff, investigators, and senior leadership across operations and community engagement.

How is this different from other assessment model tools?

The development of a readiness assessment to gauge organizational commitment and capacity for execution of a sustainable model for increasing representation of diverse populations in clinical research must be conceptualized and implemented as a site-partnered process, with engagement from sites themselves as well as other stakeholders from the clinical research ecosystem. Intentional, structured engagement with sites, applying established principles of participatory research, is the only approach that will elicit a comprehensive set of considerations known to be important to sites caring for underrepresented populations of color. Assets, challenges, and opportunities identified by the assessment can guide implementation solutions most relevant and appropriate for the proposed trial context. Thus, this assessment model was developed as a collaborative effort among community-based sites; EQBMED leaders with decades of experience spanning industry, academia, and the full clinical research ecosystem; experts in clinical trial diversity assessments; scientists specialized in the development of maturity model tools; and scientists specialized in clinical trials, partnership development, social determinants of health, and community engagement.

Has this assessment been validated?

Although there is no single 'ideal' method of validating a maturity model,[2] the EQBMED model development used common methods of validation including iterative review by over 20 domain experts, 2 waves of modified cognitive interviews[3,14] to assess content validity[15] (clarity, comprehensiveness) and feasibility (ability to assemble artifacts, supporting evidence, time required to complete), and piloting in 'real environments' to test applicability and inform refinements[16]. Iteration is key in the development and validation process. There have been 20 iterations on the model to date. It is our hope that by sharing this model with the broader clinical trial ecosystem beyond EQBMED stakeholders, further iterations can be developed with improvements based on a broader set of real-world learnings.

Can this tool be used as part of a site visit approach?

While site visits were not feasible during initial months of the EQBMED Learning Phase, ideally assessments would take place on site, in person. A collaborative process of assessment fosters trust among partners, enhances validity of the assessment, and supports local ownership of results. Authentic collaboration is facilitated by investing time and good will in relationship building, creating conditions for dialogue that encourages candid reflection and exchange by both parties, and deferring to the site representative team to define their aspirational goals. The holistic nature of the assessment requires inputs from a range of organizational representatives, including trial staff, investigators, and senior leadership.

What are the limitations of the tool?

There are several limitations of the tool. First, while taxonomy categories should be mutually exclusive and substantively exhaustive as feasible, interrelatedness is unavoidable given the complexity of organizational capacity for achieving clinical trial diversity. Second, it is possible that an important aspect of organizational readiness has not been included. However, the model was developed following design thinking principles, including input of end users, other experts, iterative refinement, and field testing,[2] along with learnings from YCCI's maturity journey, in order to ensure a comprehensive diverse set of inputs into content domains to the greatest extent possible.

How might the assessment results be used?

The model is intended to be used as a diagnostic tool to determine current capacity across specified domains, prioritize areas for improvement and growth, and serve as a benchmark for organizational to track progress toward their maturity goals.[4-6] Importantly, it is descriptive in nature (rather than prescriptive or comparative). Assigned maturity levels can be shared with internal and external stakeholders to guide strategic planning and investments.[4,7] In the context of clinical trials, this maturity model will identify needs and assets across highly varied types of trials sites and inform peer mentoring approaches in which sites share complementary strengths in order to progress toward their defined maturity goals.

How can I share my feedback about the tool? Please contact EQBMED@yale.edu to share any feedback or ask any questions.

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INTRODUCTION: WHAT IS THE EQBMED SITE MATURITY ASSESSMENT MODEL?

Overview and purpose

The EQBMED Site Maturity Assessment Model is a holistic, collaborative, site-driven, and formative assessment carried out with sites to catalogue their current capabilities and identify opportunities for growth in conducting industry-sponsored clinical trials and enriching diversity of those trials. It is not meant to be evaluative in nature, or to be used to compare or benchmark sites against others. This document describes the assessment and the steps to complete the process. It should be used in conjunction with the EQBMED Site Questionnaire.

Key components

The EQBMED Site Maturity Assessment Model is shown in Figure 1. The model consists of 11 components within three domains: 1) organizational level factors, 2) community engagement capabilities, and 3) clinical trial operations capabilities. When taken together, these components provide a comprehensive description of a site's maturity in terms of clinical trial diversity. Each component includes 2-7 questions (54 questions in total) and a rubric to capture maturity for each question and component. Detailed definitions of each component appear in Table 1.

Figure 1: EQBMED Site Maturity Assessment Model

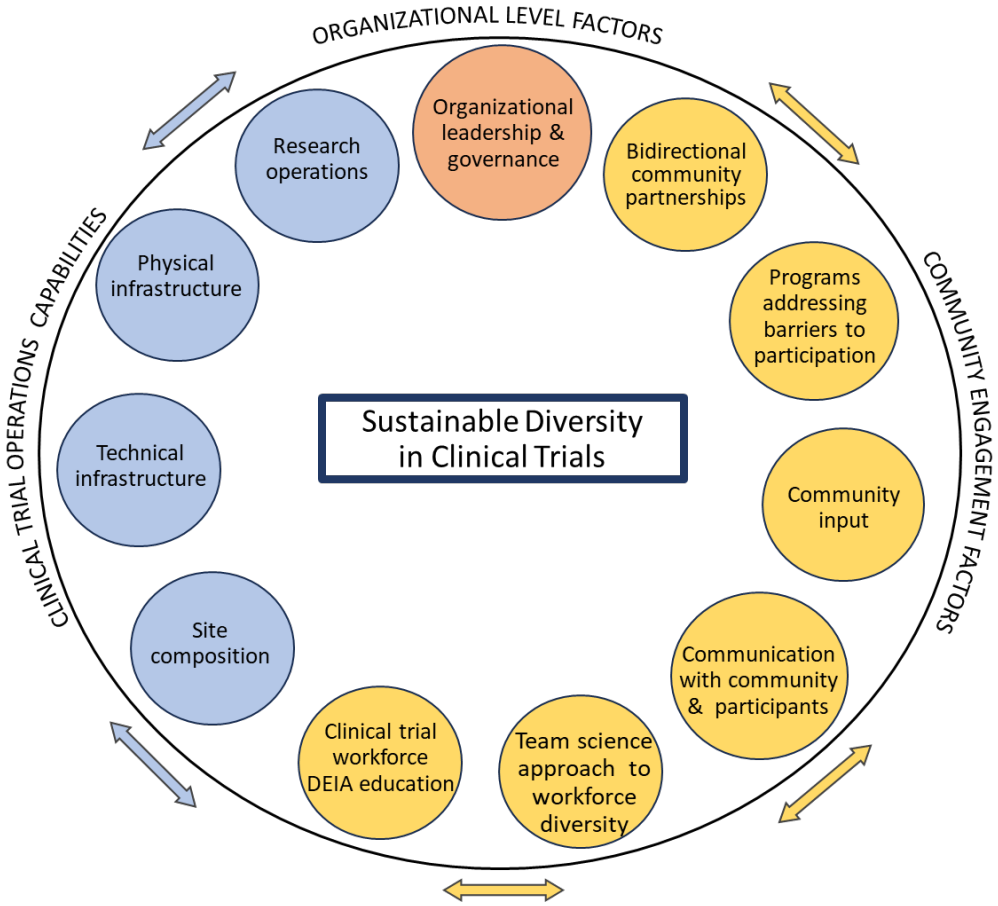


Table 1: Component definitions

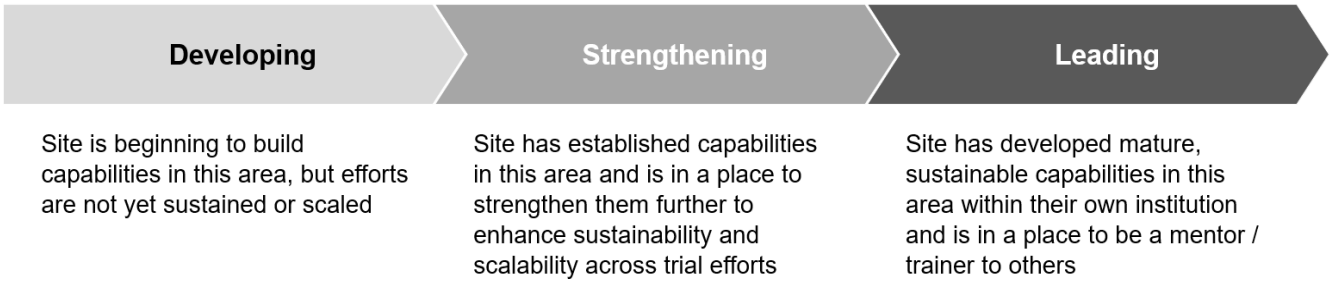
Organizational level factors	
Organizational leadership and governance	Senior leadership commitment to enhancing diversity in clinical trials, as demonstrated by: diversity and inclusion-focused organizational values; allocation of resources aligned with these organizational values; structures and policies that support goal setting, performance management tracking and accountability for clinical trial diversity; strategic planning to ensure long term sustainability of trial diversity efforts; visible endorsement and participation in programs and activities directed at trial diversity
Community engagement factors	
Bi-directional community partnerships	Active collaborations in which all partners have some share of ownership, decision-making, development, and promotion of programs to support clinical trial diversity. [Note: partnerships may address broader organizational goals rather than clinical trials diversity per se]
Programs to address barriers to recruitment and retention	Programs and resources that address economic barriers to participation in clinical trials (e.g., insurance, housing, employment benefits, childcare, transportation, nutritional supports), as well as social and cultural barriers to engagement (e.g., distrust of the healthcare system, lack of cultural humility of staff and investigators)
Community input to trial design and implementation	Policies and practices that empower community members to provide input to trial design, recruitment, and retention as well as research engagement approaches. Mechanisms may include ethics committees that are prepared to address issues related to recruitment of diverse populations (e.g., coercion, inadequate disclosures), community representation on Institutional Review Boards and community studios
Communications with community and clinical trial participants	Capabilities that ensure accurate, culturally tailored, meaningful written and verbal communications between investigators, community members and trial participants. Translation, interpretation, and communication services provide all trial-related materials in participants' preferred language, using standard techniques for addressing literacy, numeracy, cultural framing at every point of contact
Organizational leadership and clinical trial workforce diversity	Programs to improve Black, Hispanic, & Latino representation among clinical trial staff, developed and implemented in collaboration with community partners. Formal mentoring, training, and other resource supports are available within the organization for diverse staff, with clearly defined career ladders and opportunities for professional advancement
Clinical trial workforce DEIA education	Education and training for staff and investigators that enable them to understand and apply principles and practices of DEIA and cultural competency. Programs may include specific content on clinical trials, and community experiences for (e.g., volunteering). Organizations may measure DEIA/cultural competency/humility and use this information for coaching and professional development

Clinical trial operations capabilities	
Site composition	A broad array of features of the trial site including overall structure (e.g., secondary sites, partnerships with healthcare organizations), focal therapeutic areas, trial workforce size and experience, finance management and regulatory capabilities, investments in staff training
Technical infrastructure	Information technology to support the conduct of clinical trials (e.g., trial management systems), electronic data capture, electronic health record access for recruitment and retention
Physical infrastructure	Physical space and facilities to support the conduct of clinical trials (e.g., storage, for research team), ancillary services (e.g., laboratory, imaging, pharmacy) and equipment (e.g., centrifuge, weight & height scale, refrigerator, freezer)
Research operations	A broad array of capabilities to support the conduct of clinical trials (e.g., human resource functions, SOPs, IRB, performance monitoring, etc.)

Maturity levels

There are three levels of maturity defined in the model. These are: 1) Developing, 2) Strengthening, and 3) Leading. Maturity levels are dynamic and are intended to be tracked over time as sites build and strengthen various capabilities.

Figure 2: Maturity levels



HOW DO WE COMPLETE THE SITE MATURITY ASSESSMENT MODEL?

Guiding principles

The assessment was designed with several principles in mind, with the intent to: 1) encourage small group collaboration and open discussions, 2) streamline the process to ease site burden in completing the assessment, and 3) generate information related to a site's maturity in specific areas that support clinical trial diversity.

Steps for completion

There are 3 major steps in completing the site maturity assessment, beginning with a detailed inventory of all site capabilities, and moving through maturity level assignment and finalization.

Each of these steps is described below, with guidance for the types of site representatives best suited to provide insights and information.

Step 1: Inventory site capabilities

We have found small groups are most helpful to engage throughout the process, rather than an exhaustive list of site representatives. For instance, a core team of 2-3 may be in the meetings, and then reach out to others for information as needed. The core team might include:

- Site representative(s) able to speak at a high level about all site activities and programming which includes community engagement, ongoing trials, and clinical trial governance and organizational leadership. Example roles may be Director of Research Administration, or Senior Director of Clinical Operations.

- Site representative(s) able speak to clinical trial operations capabilities. Example roles may be Director of Clinical Research, or Clinical Research Manager.

- Site representative(s) able speak to community engagement capabilities. Example roles may be Clinical Trial Diversity Specialist or Director of Diversity, Equity, Inclusion & accessibilities in Clinical Trials.

We suggest site representatives and the assessment team convene for 2 types of meetings with defined agendas and attendance for each:

1. **Introductory meeting**: Initial introduction to share an overview of the purpose of the assessment and what to expect with sites (e.g., content, process). This may take ~30 minutes and should involve all representatives who will be engaged in the Site Maturity Assessment process.

2. **Facilitated questionnaire meetings**: Meetings to complete the facilitated assessment exploring: 1) organizational level factors, 2) community engagement capabilities, and 3) clinical trial operations capabilities. This may require ~3 hours in total and may be organized based on site and assessment team preference, availability and pre- or offline work. In these meetings the assessment team supports site representatives in completing the maturity assessment tool, answering all questions for each component, and noting if a specific question is not applicable to the site and the rationale for why it is not relevant. The assessment team and site representatives work together to determine if any supplemental information or documents are needed or would be helpful in developing the site roadmap (e.g., annual reports, budget information, list of community partnerships, table of contents from SOP manual, and list of trials for the last 2 years).

Step 2: Assign maturity levels

The assessment team aggregates question-level results into a component-level score according to these criteria. The criteria are intended to 1) set a very high bar for ‘leading’ classification,

and 2) be highly sensitive to 'developing' responses so that capacity needs are not underestimated.

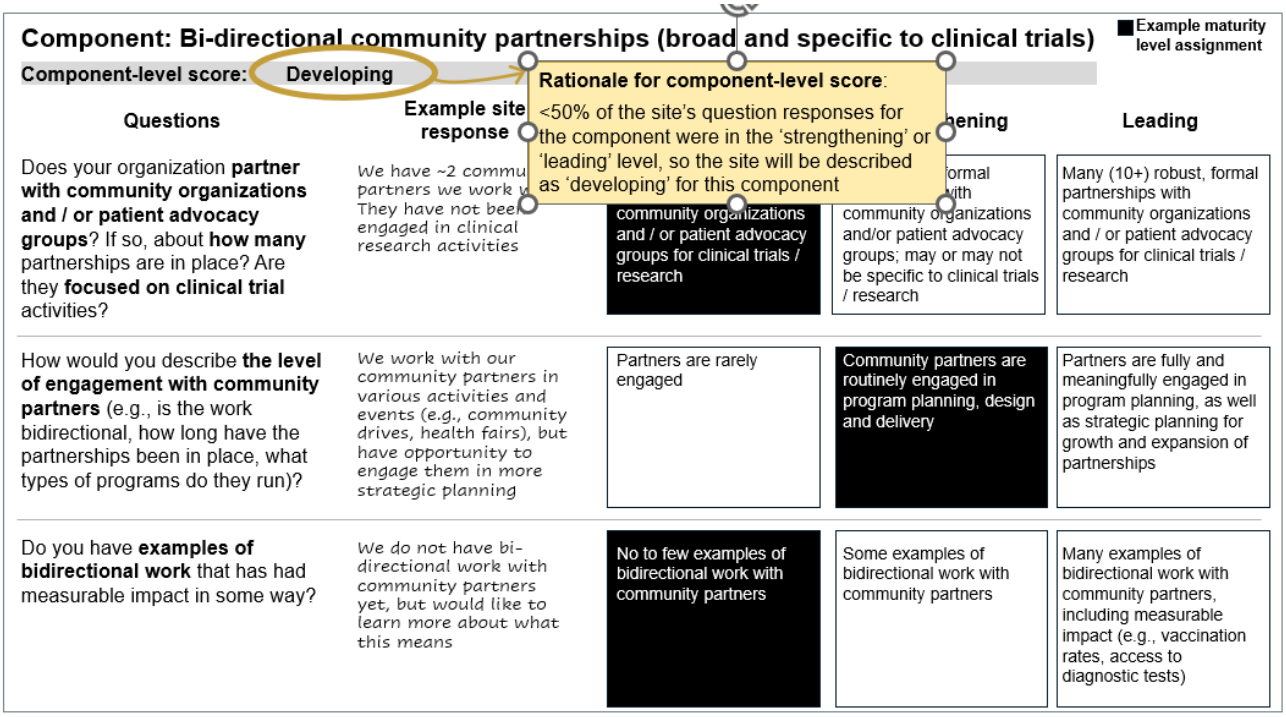
- If 100% of the responses are in the 'leading' level, the site will be described as 'leading' for that component.

- If 50-99% of the responses are in the 'strengthening' or 'leading' level, the site will be described as 'strengthening' for that component.

- If less than 50% of the responses are in the 'strengthening' or 'leading' level, the site will be described as 'developing' for that component.

Assessment team assigns a maturity level to each question based on site responses (see Figure 3 example below).

Figure 3: Illustrative question-level maturity scoring



Step 3: Refine and align results with sites

Following the completion of the Site Maturity Assessment, a collaborative review should take place with the assessment team and site representatives to review and refine the results together. This will likely require at least 1 hour. This may also present the assessment team and site an opportunity to identify growth opportunities and brainstorm goals.

HOW MIGHT WE USE THE SITE MATURITY ASSESSMENT RESULTS?

The Site Maturity Assessment results are intended to serve as a tool for sites to identify growth opportunities across key capabilities in advancing clinical trial diversity. The process is likely to be iterative over time, as sites grow and seek new areas of opportunity for strengthening capacity (Figure 4). Findings can be used to inform:

- **Goal setting**: These growth opportunities may be translated into action-oriented goals specific to each site. Goals may range in focus and scope (e.g., increase staff to expand trial capacity, develop mechanisms to receive and act on community and patient feedback, develop community advisory boards to co-develop site priorities), and will be unique to each site, even for those with similar maturity levels. Goal setting might also include identifying needed resources and supports.

- **Impact metrics**: Once goals are developed, sites may consider developing impact measures to track progress and change over time (e.g., near-term (6-12 months) and long-term (1+ year) measures).

- **Roadmap**: To achieve these goals and impact measures, sites may consider developing a ~6-12-month roadmap of key milestones and activities.

- **Re-assessment**: The assessment and these goals should not be static, but rather should be revisited over time as the site achieves goals and matures.

Figure 4: Site Maturity Assessment next steps

CONCLUSION

We consider the assessment of site capabilities to engage in meaningful clinical trial diversity efforts to be a deeply site-partnered and inclusive process following established principles of participatory research. In addition, organizational readiness to engage in authentic, sustainable clinical trial diversity initiatives is a highly complex, multifaceted phenomenon including both technical and relational dimensions. Ideally this assessment could take place in-person, on the site location over a several days period in order to cultivate trust and collaborative relationships that are essential for sustainable success.

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