Equitable Breakthroughs in Medicine Development (EQBMED)

EQBMED Site Maturity Assessment:

Site Questionnaire (Part 2 of 3)

Part 1: Team Guide

Part 2: Site Questionnaire

Part 3: Maturity Model Rubric

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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.

Purpose of this document

This document is the guiding questionnaire for the EQBMED Site Maturity Assessment Model, including an overview of the assessment and questions for completion. The questions are intended to be completed by the site in collaboration with the EQBMED assessment team.

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 organizations 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 draws from and synthesizes substantial prior clinical trial diversity initiatives including those led by Yale Cultural Ambassadors Program, 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?

Although efforts to eliminate inequities in access to clinical trials began decades ago, clinical trial diversity was only recently defined as a national priority, with substantial investments from multiple sectors. Among the most powerful barriers to clinical trial diversity are structural 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 operational factors, 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?

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

1. Experience with the Yale Center for Clinical Investigation's successful maturity journey to promote diversity and inclusion in clinical research over the past 15 years. 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 Center of Brigham and Women's Hospital and Harvard[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 once 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) can 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 in person, on site. 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.

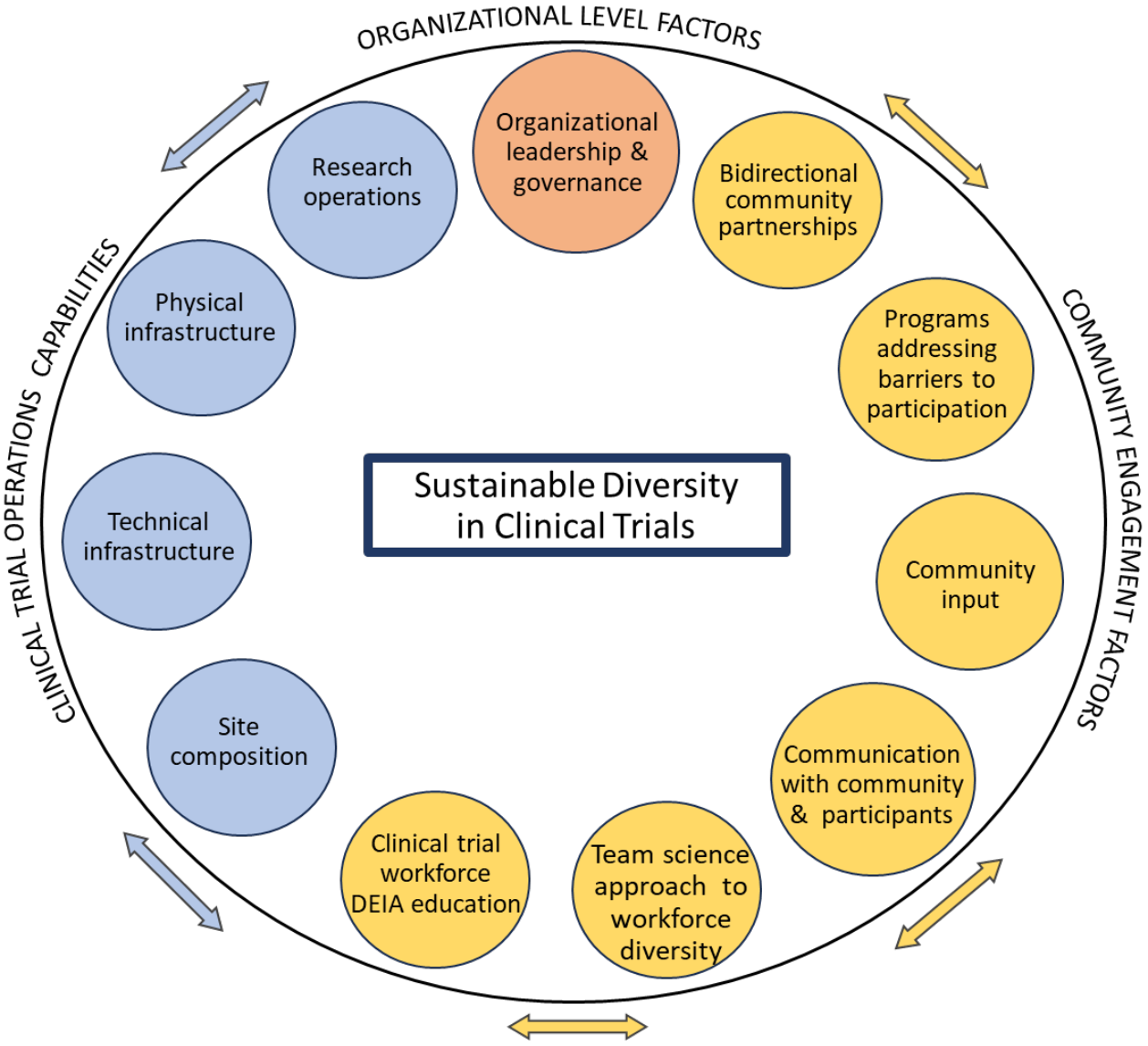
What is included in the EQBMED Site Maturity Assessment?

The EQBMED Site Maturity Assessment Model consists of 11 components within three domains: 1) organizational level factors, 2) community engagement factors, and 3) clinical trial operations capabilities (see Figure 1). 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.

How can I share my feedback or ask questions about the tool?

Please contact EQBMED@yale.edu to share any feedback or ask any questions.

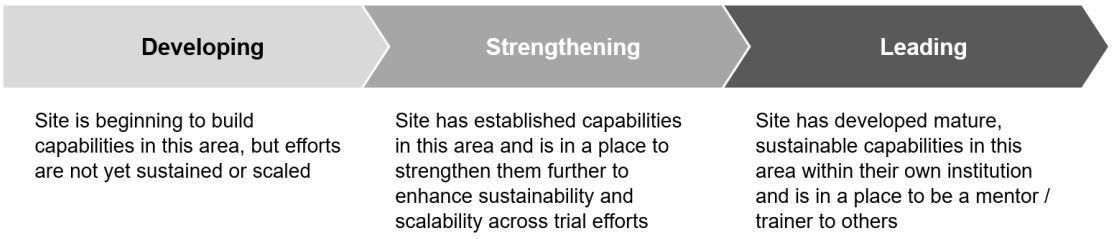
Figure 1: EQBMED Site Maturity Assessment Model



How is maturity defined?

The three levels of maturity 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. Maturity levels are determined by analysis of site responses to subcomponent questions and guided by the rubric, which is further described in part 3 of this series.

Figure 2: EQBMED Site Maturity Assessment Maturity Levels



Organizational level factors		
Component 1: Organizational leadership and governance specific to clinical trials		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Is clinical trial diversity a top priority of the organization? How is this communicated internally and externally? 2. Is there a dedicated leadership team to support clinical trial diversity initiatives, and if so, what does that look like? Does leadership actively participate in programs and partnerships to support clinical trial diversity? 3. Is there a dedicated budget for clinical trial diversity efforts? What does that look like? Can your organization sustain clinical trial operations over time and between clinical trials? 4. Are there performance goals and measures for clinical trial diversity and if so, can you describe how these data are used? 5. Do you engage diverse Black, Hispanic & Latino community members in shared governance for clinical trials/research? If so, what does that look like (e.g., representation, formal charter)? 6. Are clinical trial diversity activities institutionalized, meaning widely valued and embedded within the organization (e.g., standard operating procedures, part of the day-to-day workflow)?		• Internal or external communications (websites, memos) endorsing clinical trial diversity • Annual reports or other budget information • Organizational leadership chart • Written plan and/or communications about plan to enhance clinical trial diversity and statement of plan status

Community engagement factors		
Component 2: Bidirectional community partnerships (broad & specific to clinical trials)		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Does your organization partner with community organizations and/or patient advocacy groups? If so, about how many partnerships are in place? Are they focused on clinical trial activities? 2. How would you describe the level of engagement with community partners (e.g., is the work bidirectional, how long have the partnerships been in place, what types of programs do they run)? 3. Do you have examples of bidirectional work that has had a measurable impact in some way?		• Example(s) of engagement with community and patient advocacy partners • List of partnerships • Flyers, announcements and other media examples of bidirectional work done with partners

Community engagement factors		
Component 3: Programs to address barriers to recruitment and retention of diverse populations		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Does your organization have programs and resources to address barriers to recruitment and retention of Black, Hispanic & Latino populations (e.g., trusted messenger models, targeted outreach campaigns, flexible scheduling, childcare, transportation)? If so, can you describe them? 2. What infrastructure (programs and/or procedures) does your organization have in place to support community-based activities or organizations that can help enhance representation of Black, Hispanic & Latino populations (e.g., funding, community-based clinical sites)?		• Documents describing formal strategies and activities to improve Black, Hispanic & Latino recruitment/ retention in clinical trials • Documents detailing programs, activities and procedures that demonstrate collaboration with community entities to focus on enhancing Black, Hispanic & Latino participation in clinical trials • Partnerships focused on research or clinical trial participation among target populations

Community engagement factors		
Component 4: Community input in trial design and implementation		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Does your organization provide Black, Hispanic & Latino community members with education around clinical trial design and operations, human subject protection, and IRB governance? 2. Does your organization have policies/protocols for Black, Hispanic & Latino community members to provide input to clinical trial design and implementation (e.g., recruitment and retention, informed consent, outreach materials)? 3. Is feedback gathered from study participants during and at the end of clinical trials? If so, can you describe how it works? 4. Is feedback used to make changes to clinical protocols or overall research approaches? 5. Do you have an ethics committee that can address issues related to recruitment of diverse populations (e.g., coercion, inadequate disclosures)? 6. Are community members on the IRB representative of Black, Hispanic & Latino populations?		• Flyers or meeting minutes of training sessions • Example(s) of guidance and training materials • Policies/protocols describing formal process of feedback loop with community members

Community engagement factors		
Component 5: Communication with community and clinical trial participants		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Do trial participants have access to translation and interpretation services at every point of contact (e.g., during informed consent processes, patient visits)? 2. How many languages in addition to English are available through certified translators or interpreters for clinical trial participants? 3. Are there dedicated resources to raise awareness / educate potential participants about clinical trials? 4. Are trial-related materials (e.g., informed consent, educational materials, marketing materials) available for trial participants of varying levels of literacy and numeracy? 5. Are trial-related materials (e.g., informed consent, educational materials, marketing materials) available for trial participants' most common language(s) in the primary service area? 6. Are trial-related materials developed using approaches for cultural framing to ensure they are meaningful and relevant? (e.g., cultural framing approaches or messaging developed and led by community)		• List of languages available from certified translation/ interpretation services • Example resources dedicated to patient clinical trial education

Community engagement factors		
Component 6: Team science approach to workforce and leadership diversity		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Are there any initiatives/programs (e.g., training, retention programs) in place to improve Black, Hispanic & Latino representation among clinical trial staff? Were they developed in collaboration with community partners? 2. Are there informal/formal or internal/external mentorship and training channels for diverse clinical research staff? 3. Are there defined career ladders for clinical research staff and clinical investigators, and any defined supports for diverse staff? 4. Are there community-based team members (not employed by the institution, such as trained community ambassadors, navigators, community health workers) embedded as part of the overall team?		• List of activities to improve Black, Hispanic & Latino representation/ retention in the workforce • Workforce development approach for hiring and training of Black, Hispanic & Latino community members • Documented career ladders/career tracks for Black, Hispanic & Latino research staff

Community engagement factors		
Component 7: Clinical trial workforce DEIA education		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Does the clinical trial staff have time to dedicate to trainings on DEIA / Equity in trials? How often do they refresh that knowledge, and are there opportunities for continued education (e.g., grand rounds, lectures, conferences)? 2. Are clinical trial staff required to receive DEIA/cultural competency training, with specific content on clinical trials? 3. Do clinical trial staff have dedicated time for community engagement? (e.g., volunteering) 4. Does your organization measure self-reported implicit bias and other DEIA/cultural competency training domains for staff and investigators?		• Required curriculum and hours for clinical research staff DEIA training • Agendas/programs relevant to DEIA provided by the site or community organizations

Clinical trial operations capabiities		
Component 8: Site composition		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. How many PIs conduct clinical trials, and what is their average experience? Do investigators have dedicated time, motivation, and engagement? In what therapeutic areas are clinical trials conducted? 2. Does the site have a research operational and leadership structure? (e.g.,Clinical Trials Office, clinical research center, Director of Clinical Trials Office, Director of Research, Director of Human Subject Protections) 3. Does the site have personnel in place to meet the needs of clinical trials operations? (e.g., research coordinators, project managers, clinical research nurses) 4. Do research personnel have onboarding training and time to dedicate to ongoing training/continuing education? 5. Does the site use satellite/secondary sites? 6. Does the site have existing clinical trial partnerships or relationships with other healthcare organizations such as AMCs, FQHCs, or health systems?		• Organizational diagram of clinical research operational and leadership structure • Financial management policies (coverage analysis, budgets, contracting • List of trials and enrollment for 2 years (incl. phase and therapeutic area) • List of priority therapeutic areas and number of experienced investigators in each • Evidence of staffing levels and competencies

Clinical trial operations capabiities		
Component 9: Technical infrastructure		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Are there electronic systems for the management of clinical research? Do the systems to support the real-time management of clinical research lifecycle? (CTMS, eReg, eSource or other management systems) 2. Does the site have experience with EDC systems or platforms? Are they optimized to support clinical research? Can they be used to report, track, and complete trend analyses of clinical research impact measures? (used to screen, recruit patients in clinical trials, manage research billing) 3. Are EHR/EMR systems in place? Are they capable of integrating across sites and with sponsor provided EDC platforms? 4. Are there systems to support regulatory compliance in research (IRB system, QA and CAPA management, regulatory committee management)? 5. Are there systems for the management of investigational product and device management? 6. Are there systems supporting contract and financial/budget development and ongoing management?		• List of systems used and names (CTMS, eReg, EHR, and EDC) • List of interfaces and functionality active in support of clinical research • Documents demonstrating ability to oversee multi-site trials as research lead (e.g., active and accurate tracking and reporting functions; Collection of target variables for reporting such as screening and screen failures, enrollment rates, participant demographics, data management timeliness)

Clinical trial operations capabiities		
Component 10: Physical infrastructure		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Is there adequate physical space to conduct clinical trials (e.g., space for monitors, private rooms for consent, storage of study supplies, for research team)? 2. Are there adequate ancillary services to support clinical trials (laboratory, imaging, pharmacy) 3. Is there access to research equipment with current documentation of maintenance / calibration to support clinical trials (e.g., centrifuge, weight & height scale, refrigerator, freezer)?		• Floorplans or photos of research area and equipment

Clinical trial operations capabiities		
Component 11: Research operations		
Questions	**Site Responses**	**Supplemental materials (optional)**
1. Does the site have an SOP manual in place for clinical trial operations and how are SOPs maintained? 2. Does the site have a trial procurement and feasibility review process? How is it tracked and reported? 3. Does the site have a trial procurement and feasibility review process? How is it tracked and reported? 4. What is the site's current clinical trials portfolio composition? (e.g., How many trials? What types (e.g., Phase, non-therapeutic [blood draw, QOL], etc.)? How many patients have been enrolled annually for the past 2 years? 5. What research operations systems are utilized to track and report key indicators (e.g., screening rates & failures, enrollment, participant demographics, completion rates, data management, regulatory processing, compliance maintenance, etc.)? 6. Please describe any patient retention strategies. 7. What is the quality assurance and process improvement approach at site? Is there an audit schedule/process?		• SOP System Manual (table of contents) • SOP training process & documentation • Descriptive portfolio report of clinical trials composition, including annual enrollment for last 2 years • Examples of audit reports

8. Does the site have a local Institutional Review Board (IRB) and if so, can you describe it (e.g., meeting frequency, review times)		