Equitable Breakthroughs in Medicine Development (EQBMED)

EQBMED Site Maturity Assessment: Maturity Model Rubric (Part 3 of 3)

Part 1: Team Guide

Part 2: Site Questionnaire

Part 3: Maturity Model Rubric

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EQBMED Site Maturity Assessment Model: Purpose & Overview

Purpose

The EQBMED Site Maturity Assessment 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 Center for Clinical Investigation, The Clinical Trials Transformation Initiative, The National Academy of Medicine, and Multi- Regional Clinical Trials Centers.

The Assessment consists of 11 components with 54 questions that address organizational level factors, community engagement factors and clinical trial operation capabilities. Taken together, these provide a comprehensive description of a site's maturity regarding clinical trial diversity. The 11 components are: 1) organizational leadership and governance, 2) bidirectional community partnerships, 3) programs to address barriers to recruitment and retention of diverse populations, 4) community input into trial design and implementation, 5) communications with community and clinical trial participants, 6) team science approach to clinical trial workforce diversity, 7) clinical trial workforce DEIA education, 8) site composition, 9) technical infrastructure, 10) physical infrastructure, and 11) research operations. Each component includes subcomponent questions and a rubric to capture a site's maturity level for each subcomponent question. Responses for each subcomponent question are then rolled up into a maturity classification for the full component. Please let the assessment team know if a particular question is not relevant to your site, and it will be marked not applicable. Responses will complement information which may have been provided in previous parts of the site application process to help characterize the site, typical patients, and capabilities.

The three levels of maturity for each component are Developing, Strengthening, and Leading:

Developing: Site is beginning to build capabilities for diverse clinical trials, but efforts are not yet sustained or scaled

Strengthening: Site has established capabilities for diverse clinical trials and is in a place to strengthen them further to enhance sustainability and scalability across trial efforts

Leading: Site has developed mature, sustainable capabilities for diverse clinical trials within their own institution and is in a place to be a mentor / trainer /resource to others

Maturity level at the component level is based on the criteria below. 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. Assignments are based on clinical trial & community engagement experts' experience, as few or no prior benchmarks exist. We fully expect that sites in the EQBMED program will have varying levels of maturity across components, resulting in unique goals for each site.

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.

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Organizational level factors					
Component	**Questions to ask site representative**	**Maturity Level**			**Optional supporting documentation**
		Developing	**Strengthening**	**Leading**	
1. Organizational leadership and governance specific to clinical trials	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 Black, Hispanic and 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)?	1. General interest in increasing clinical trial diversity, but no or limited specific initiatives underway or being discussed internally or externally 2. No dedicated leadership team for clinical trial diversity initiatives 3. No or limited dedicated funding for clinical trial diversity 4. No performance goals or measures for clinical trial diversity, but plans are in place to create them 5. Zero to few (<3) examples of shared governance and decision-making with Black, Hispanic & Latino community members 6. No/limited representation of Black, Hispanic & Latino community members in the governance structure, no formal charter, clinical trial diversity activities are not institutionalized	1. Formalized commitment to clinical trial diversity (e.g., inclusion in strategic plans), with opportunity and interest to become stronger. Leadership endorses clinical trial diversity programs in both internal and external communications 2. Leadership team for diversity initiatives in place, including dedicated leader (.5 FTE) and formal champion / research staff mentors within clinical trials / research 3. Dedicated funding for clinical trial diversity efforts is in place, but does not include long term investments or strategies for sustainability over time and between trials 4. Performance goals and measures for clinical trials diversity exist and data are used in limited ways 5. Some (3-5) examples of shared governance and decision-making with Black, Hispanic & Latino community members (e.g., community focus groups or other tools for strategic input and key decisions). Governance structures formally include Black, Hispanic & Latino community members to a moderate degree (e.g., limited authority), formal charter of community co-governance was recently established (<2 years) or is a priority for development. These elements of co-leadership might not be focused on clinical trials per se, but the potential for this is strong 6. Clinical trial diversity activities are part of the organization's mission/strategic plan and institutionalized to some degree	1. Long standing (>5 years) commitment to clinical trial diversity (e.g., dedicated funding, inclusion in strategic plans). Senior leadership frequently endorses clinical trial diversity programs in high level internal and external communications 2. Leadership team for diversity initiatives in place, including dedicated leader (>.5 FTE) and formal champion / research staff mentors within clinical trials /research. Leadership participates visibly and actively in programs and partnerships to support clinical trial diversity 3. Robust dedicated funding for clinical trial diversity efforts, well-coordinated internal and external budgets that can sustain clinical trial operations over time and between clinical trials 4. Performance goals and measures for clinical diversity are routinely tracked, and data are systematically used for accountability, decision-making, improvement efforts and resource allocation 5. Many (>5) examples of shared governance & decision-making with Black, Hispanic & Latino community members. Black, Hispanic & Latino community members are demonstrably engaged in co-leadership (e.g., community consultation processes). Governance structures formally include Black, Hispanic & Latino community members to a substantial degree (e.g., broad authority, input on institutional mission and policies, co-development of institutional-wide initiatives) and formal charter of community co-governance has been established (>2 years) 6. Clinical trial diversity activities are part of the organization's mission/strategic plan and fully institutionalized (e.g., integrated into the day-to-day workflow, fully aligned with organizational functions)	• 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 & statement of plan status

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Community engagement factors					
Component	**Questions to ask site representative**	**Maturity Level**			**Optional supporting documentation**
		Developing	**Strengthening**	**Leading**	
2. Bidirectional community partnerships (broad and specific to clinical trials)	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 measurable impact in some way?	1. Zero to few (<3) formal partnerships with community organizations and / or patient advocacy groups for clinical trials / research 2. Partners are rarely engaged 3. Zero to few examples of bidirectional work with community partners	1. Some (3-10) formal partnerships with community organizations and/or patient advocacy groups; may or may not be specific to clinical trials / research 2. Community partners are routinely engaged in program planning, design, and delivery 3. Some examples of bidirectional work with community partners	1. Many (10+) robust, formal partnerships with community organizations and / or patient advocacy groups for clinical trials / research 2. Actively engages community partners in program planning, strategic growth, and advising on research priorities. Showcases community-led efforts within clinical trials to address their unique perspectives and needs. 3. Demonstrates bidirectional work with community partners, including measurable impact (e.g., trial enrollment rates for Black, Hispanic & Latino participants, vaccination rates, access to diagnostic tests). Highlights community influence on the research agenda, fostering more inclusive and responsive clinical trials.	• Example (s) of engagement with community and patient advocacy partners (e.g., list of partnerships, examples of bidirectional work done with partners)

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3. Programs to address barriers to recruitment and retention of diverse populations	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)?	1. No or limited 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) 2. No or ad hoc infrastructure to support community-based activities or organizations that can help enhance representation of Black, Hispanic & Latino populations in trials.	1. Some programs and resources to address barriers to recruitment and retention of Black, Hispanic, & Latino populations are tangible and ongoing (e.g., trusted messenger models, targeted outreach campaigns, flexible scheduling, childcare, transportation) 2. Some infrastructure to support community-based activities or organizations that can help enhance representation of Black, Hispanic & Latino populations in trials. (i.e., ensuring participant stipends for travel and meal costs are part of the clinical trial budget).	1. Multiple, substantial programs to address barriers to recruitment and retention of Black, Hispanic, & Latino populations are well established (e.g., trusted messenger models, targeted outreach campaigns, minority recruitment plans) 2. Significant infrastructure to support community-based activities or organizations that can help enhance representation of Black, Hispanic & Latino populations in trials (i.e., engaging family and care partners for added support, leveraging community health workers, and navigators, contractual partnerships with community-based organizations to address social needs.)	• Formal strategies, programs and activities to improve Black, Hispanic & Latino recruitment / retention in clinical trials • Programs and/or procedures that support community-based activities and organizations that facilitate and sustain research/trial participation among Black, Hispanic & Latino populations. • Partnerships focused on research or clinical trial participation among target populations.

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4. Community input in trial design and implementation	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 in 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?	1. No or limited community education around clinical trials 2. No policies/protocols for Black, Hispanic & Latino community members to provide input to inform clinical trial design and implementation 3. No or limited mechanisms to gather participant feedback during and at the completion of clinical trials 4. No formal policies and limited examples of use of feedback to make concrete changes to clinical trial protocols 5. No established ethics committee to address issues related to recruitment of diverse populations (e.g., coercion, inadequate disclosures) 6. IRB has limited representation of Black, Hispanic & Latino populations	1. Some recent examples of community education around clinical trials (e.g., small group meetings, education sessions, brochures, or flyers) 2. Some recent (< 5 years) systematic process or protocols exist for Black, Hispanic & Latino community members to provide input to clinical trial design and implementation (ad hoc review determined by individual investigators, no formal policies, or procedures) 3. Mechanisms exist for study participants to provide feedback during and at the completion of clinical trials 4. No formal policies but some examples of use of feedback to make concrete changes to clinical trial protocols 5. Established ethics committee in place to address issues related to recruitment of diverse populations (e.g., coercion, inadequate disclosures) 6. IRB includes Black, Hispanic & Latino population community members to a moderate degree	1. Well-established ongoing community education programming around clinical trials design and operations, human subjects protection, and IRB governance 2. Multiple policies/protocols/procedures exist (>5 years) for Black, Hispanic & Latino community members to provide ongoing substantial input to inform study review, design, recruitment, and retention (including identification of patient reported outcomes, development of endpoints), for all studies 3. Multiple mechanisms exist for study participants to provide feedback during and at the completion of clinical trials 4. Formal policies for regular use of study participant feedback to make concrete changes to clinical trial protocols and/or overall research approaches 5. Established ethics committee in place to address issues related to recruitment of diverse populations (e.g., coercion, inadequate disclosures). Committee includes community representation 6. IRB includes Black, Hispanic & Latino community members to a substantial degree (equal to or greater than representation in the community's population)	• Flyers or meeting minutes of training sessions • Example(s) of guidance and training materials • Policies/protocols detailing feedback loop with community members

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5. Communications with community and clinical trial participants	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 tools to ensure they are meaningful and relevant? (e.g., cultural framing approaches or messaging developed and led by community)	1. No defined language access plan and no or few translation and interpretation services 2. No languages other than English are available through certified translators or interpreters for clinical trial participants 3. Limited or no dedicated resources to raise awareness / educate potential participants about clinical trials 4. No trial-related materials are available for trial participants of varying levels of literacy and numeracy 5. No trial-related materials are available in trial participants' most common languages in the service area 6. Trial-related materials are not developed using tools to ensure they are meaningful and relevant for all community members	1. Defined language access plan and some translation and interpretation services 2. Limited number of languages other than English are available through certified translators or interpreters for clinical trial participants 3. Some dedicated resources to raise awareness / educate potential participants about clinical trials 4. Some trial-related materials are made available to support trial participants with varying levels of literacy and numeracy 5. Some trial-related materials are made available for trial participants' most common languages in the service area 6. Some trial-related materials are developed using tools to ensure they are meaningful and relevant, but this capacity is not robust and consistently used	1. Site has a robust language access plan and extensive translation and interpretation services available at every point of contact 2. Extensive number of languages other than English are available through certified translators or interpreters for clinical trial participants 3. Extensive dedicated resources to raise awareness / educate potential participants about clinical trials (e.g., line item in budget) 4. All trial-related materials are made available to support trial participants varying levels of literacy & numeracy 5. All trial-related materials are made available for trial participants' most common languages in the service area 6. All trial-related materials are developed using tools and approaches to ensure they are meaningful and relevant	• List of languages available from certified translation / interpretation services • Example resources dedicated to patient clinical trial education

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		Developing	**Strengthening**	**Leading**	
6. Team science approach to clinical trial workforce and leadership diversity	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 Black, Hispanic & Latino 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?	1. No initiatives/programs in place to improve Black, Hispanic & Latino representation among clinical trial staff 2. Limited or no mentorship and training available within the organization for Black, Hispanic & Latino clinical research staff 3. No career ladder for clinical research staff and investigators, and no defined supports for Black, Hispanic & Latino staff are available 4. No community members embedded in the team	1. Some programs are in place to improve Black, Hispanic, & Latino representation among clinical trial staff, from grade school through postgraduate. Programs are developed and implemented in collaboration with community partners 2. Some mentorship and training available within the organization for Black, Hispanic & Latino clinical research staff 3. Limited career ladder for clinical research staff and investigators, and some supports for Black, Hispanic & Latino staff are available 4. Community members are engaged for clinical trials advising or other work with community members on an ad hoc basis	1. Multiple (>3), longstanding comprehensive programs are in place to improve Black, Hispanic, & Latino representation among clinical trial staff, from grade school through postgraduate. Programs are developed and implemented in collaboration with community partners 2. Formal mentoring, training, and other resource supports are available within the organization for Black, Hispanic & Latino clinical research staff 3. Clearly defined career ladder for Black, Hispanic & Latino clinical research staff and clinical investigators 4. Well-informed/trained community members are deeply embedded in the site's overall clinical trials 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

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Community engagement factors					
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		Developing	**Strengthening**	**Leading**	
7. Clinical trial workforce DEIA education	1. Does the clinical trial staff have time to dedicate to trainings on DEIA (Diversity, Equity, Inclusion and Accessibility) in trials? How often do they refresh that knowledge, and are there opportunities for continued education (e.g., community events, 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 time to dedicated to 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?	1. Staff does not have time to dedicate to training 2. No training requirements focused on DEIA / cultural competency for site staff or investigators 3. Limited or no staff capacity for community engagement (e.g., volunteering) 4. Does not measure self-reported implicit bias and other DEIA/cultural competency training domains for staff and investigators	1. Staff have capacity to spend time in training and refresh the knowledge sometimes with limited opportunities for continued education 2. Some training, education requirements focused on DEIA / cultural competency for site staff and investigators 3. Some staff capacity/time dedicated for community engagement (e.g., volunteering) 4. Measures self-reported implicit bias and other DEIA/cultural competency training domains for staff and investigators but does not actively apply the findings into strategies and initiatives	1. Staff have capacity to spend time in training and frequently refresh the knowledge with many opportunities for continued education 2. Staff required to receive training in DEIA/cultural competency, with specific content on clinical trials 3. Broader staff capacity/time dedicated for community engagement exists within the organization (e.g., volunteering) 4. Measures self-reported implicit bias and other DEI/cultural competency training domains for staff and investigators. Regularly uses information for coaching and professional development and actively applies findings into strategies and initiatives	• Required curriculum and hours for clinical research staff DEIA training • Agendas/programs relevant to DEIA provided by the site or community organizations

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Clinical trial operations capabilities					
Component	**Questions to ask site representative**	**Maturity Level**			**Optional supporting documentation**
		Developing	**Strengthening**	**Leading**	
8. Site composition	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?	1. Zero-1 clinical trials conducted (Note: *if the site has not conducted any clinical trials, some questions are not applicable)* 2. No clinical research operational leadership structure 3. Lacks adequate research personnel 4. No research onboarding training and time to dedicate to ongoing training/continuing education 5. Zero-1 satellite sites exist 6. No or limited connections to academic medical centers, federal qualified health centers (FQHCs), or other organizations	1. Site has 2 PIs 2. Have some 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, dedicated research staff) 3. Has adequate basic research personnel for current clinical trials (e.g., research coordinators, project managers, clinical research nurses) 4. Some research onboarding training and time to dedicate to ongoing training/continuing education 5. Some satellite sites are operational 6. Some connections with other academic medical centers, FQHCs and other health care organizations	1. >2 PIs and clinical trials conducted in >2 therapeutic areas 2. Has robust research operational, leadership and staff structures in place (e.g., Clinical Trials Office, Clinical Research Center, Director of Clinical Trials Office, Director of Research, Director of Human Subject Protections) 3. Has adequate research personnel to meet current and projected needs for clinical trials (e.g., research coordinators, project managers, clinical research nurses, onsite clinical pharmacist/s, ITS professionals and quality assurance and compliance professionals) 4. Has a well-developed and evolving onboarding/training program for research personnel and personnel are given time to dedicate to ongoing training/continuing education 5. Has multiple clinical outlets and may uses satellite sites 6. Well established, formal, organizational-level relationships with other AMCs, FQHCs and other health organizations, with formal / informal MOUs or other written agreements	• 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

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Clinical trial operations capabilities					
Component	**Questions to ask site representative**	**Maturity Level**			**Optional supporting documentation**
		Developing	**Leading**	**Leading**	
9. Technical infrastructure	1. Are there electronic systems for the management of clinical research? Do the systems support the real-time management of clinical research lifecycle? (CTMS, eReg, eSource or other systems in the management of clinical trials) 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? 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?	1. No electronic clinical trial management systems are in place 2. Limited or no experience working with an EDC 3. EHR systems are not in place or are underdeveloped 4. No electronic systems to support regulatory compliance in research 5. No platform dedicated to medication and clinical device management and dispensation system in place 6. No electronic systems to support clinical research contracts and finances/budgets	1. Key clinical research admin systems are in place (e.g., eReg document management; clinical trial management system (CTMS)) 2. Has experience working with a variety of sponsor-provided EDC platforms 3. EHR systems in place but not integrated across sites (capability for integration may exist) 4. Some systems to support regulatory compliance in research (IRB system, QA and CAPA management, regulatory committee management) but are not integrated across platforms 5. Has a platform dedicated to medication and clinical device management, but it is not used in clinical trials 6. Has electronic systems to support clinical research contract and financial/budget development and ongoing management	1. Robust clinical research admin systems are in place and are fully integrated to support the real-time management of clinical research along the lifecycle (e.g., eReg document management; clinical trial management system (CTMS)) 2. A variety of EDC systems are used and are fully operational with established capability to track by race/ethnicity and SES across multiple domains: clinical trial screen failure rates, completion rates, post-trial participation rates, clinical trial investigators and staff 3. EHR systems highly integrated across sites and with EDC systems 4. Has systems to support regulatory compliance in research (IRB system, QA and CAPA management, regulatory committee management) that are fully integrated across platforms and are audit ready at all times 5. Has a highly functional electronic platform or system dedicated to investigational product management, including necessary oversight for scheduled medications 6. Has well established electronic systems to support clinical research contract and financial/budget development and ongoing management (may be integrated with electronic regulatory systems)	• 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)

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Clinical trial operations capabilities					
Component	**Questions to ask site representative**	**Maturity Level**			**Optional supporting documentation**
		Developing	**Strengthening**	**Leading**	
10. Physical infrastructure	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 (e.g., 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)?	1. Limited or no physical space available for conducting clinical trials 2. Limited or no ancillary services available for conducting trials 3. Limited or no supplies and equipment for conducting clinical trials	1. Dedicated physical space for conducting clinical trials 2. Adequate ancillary services (e.g., lab, imaging, pharmacy) for supporting clinical trials 3. Dedicated adequate supplies & equipment for conducting clinical trials (e.g., centrifuge, weight & height scale, refrigerator, freezer)	1. Dedicated physical space with room for expansion for conducting clinical trials 2. Ancillary services support research as part of their mission, potentially with a dedicated research lab and pharmacy 3. Dedicated adequate supplies and equipment (e.g., centrifuge, weight & height scale, refrigerator, freezer), with room for expansion	• Floorplans or photos of research area and equipment

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11. Research operations	1. Does the site have an established SOP system for clinical trial operations, SOP training and documentation? 2. Does the site have a trial procurement and feasibility review process? How is it tracked and reported? 3. 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? 4. 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.) 5. Do operations support specific patient retention strategies? If so, can you describe them? 6. What is the quality assurance and process improvement approach at site? Is there an audit schedule/process? 7. Does the site have a local Institutional Review Board (IRB) and if so, can you describe it (e.g., meeting frequency, review times)	1. No clinical trial SOP system exists 2. No trial procurement & feasibility process 3. Not currently conducting clinical trials 4. No established tracking and reporting systems for performance management, manual tracking of site/trial performance metrics 5. Operations do not support patient retention strategies 6. No/limited capability for quality assurance/process improvement/internal audit improvement approach 7. No local IRB	1. Has some research-related SOPs for key activities and a process to maintain the SOPs 2. Some process for trial procurement & feasibility, but not fully established or robust 3. Currently conducting 1-25 trials including Ph II-III therapeutic trials and maintains an updated portfolio of portfolio composition and meets enrollment targets within 60% 4. Some process for tracking and reporting key indicators across one or more electronic systems and tracks some metrics for compliance and/or work unit metrics 5. Operations may support patient retention strategies (e.g., automated text messaging reminders) 6. Some capability for quality assurance/process improvement/internal audit, but limited in scope (range of data, timeliness of data). Site does not conduct formal internal audits on clinical trial compliance, but rather relies on site monitors to review and provide feedback 7. Has local IRB but does not require all protocols to be reviewed or site makes use of an external IRB	1. Robust internal SOP system in place that are managed effectively and evolve with the site capacity (e.g., SOP manual, documentation of training, tracking evolution of procedures) 2. Established process for trial procurement & feasibility assessment with functional tracking and reporting capacity 3. Conducting >25 trials, has a robust and diverse clinical trial portfolio, including Ph II-IV therapeutic trials, and meets enrollment targets within 80% 4. Has well-established and documented process for tracking and reporting key indicators across one or more electronic systems including a report of clinical trials enrollment for the last 2 years, and has robust systems in place for performance management including high functioning capability to track site/trial performance metrics 5. Operations support retention in multiple ways using electronic retention solutions, such as apps and ePROs (electronic patient reported outcome tools) 6. Established capability for quality assurance/process improvement/internal audit and performs regular audits for clinical trial compliance 7. Has local IRB and requires review and approval of all protocols, meets frequently and has rapid review times	• SOP Manual (table of contents), perhaps evidence of evolution (treating SOP as a living document) • SOP training process & documentation • Descriptive portfolio report of clinical trials composition, including annual enrollment for last 2 years • Examples of audit reports