

Figure 5: Process to complete the site maturity assessment

Illustrative example: Process to complete the site maturity assessment

Illustrative example
Community engagement: Site Maturity Assessment Results (3/6)

Illustrative example
Community engagement: Site Maturity Assessment Results (2/6)

Illustrative example
Community engagement factors: Site Maturity Assessment Results (1/6)

Programs addressing barriers to participation

Maturity level: Developing, Strengthening, Leading

Questions to ask site

Bi-directional community partnerships

Maturity level: Developing, Strengthening, Leading

Questions to ask site representative

Question	Developing	Strengthening	Leading	Summary of site responses
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?	Zero to few (<3) formal partnership with community organizations and / or patient advocacy groups for clinical trials research	Some (3-10) formal partnerships with community organizations and/or patient advocacy groups; may or may not be specific to clinical trials / research	Many (10+) robust, formal partnerships with community organizations and / or patient advocacy groups for clinical trials / research	Over 45 partnerships across organizations (e.g., regional community and public service, health and social services, faith-based, Black advocacy / service organizations, and others) with opportunity for partners to directly contact the site through a publicly-facing website form. However, not all are involved in clinical trials, so there is room to grow
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)?	Partners are rarely engaged	Community partners are routinely engaged in program planning, design, and delivery	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	Community engagement team regularly facilitates connections between researchers and community partners to ensure mutual fit with opportunities to increase activities across some partners
Do you have examples of bidirectional work that has had a measurable impact in some way?	Zero to few examples of bidirectional work with community partners	Some examples of bidirectional work with community partners	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	Frequent bi-directional engagement events with community partners, particularly events hosted by community partners where site is invited; opportunity for additional bi-directional relationships focused on clinical research



Illustrative example: Completed site maturity assessment

Maturity level: Developing, Strengthening, Leading

Factor	Component	Current state maturity level	Goals for discussion...
Organizational level factors	Organizational leadership & governance	Developing	Senior leadership voices commitment to increasing diversity in clinical trials; opportunity to formalize strategic initiatives and dedicate long-term funding
Community engagement factors	Bi-directional community partnerships	Strengthening	Has robust community partnerships and involves community members in advisory board, project-specific patient advisory groups. Opportunity to develop formal charter on community co-leadership and bi-directional partnership
	Programs addressing barriers to participation	Developing	Has some programming and supports to increase diverse participation in trials (e.g., transportation / time compensation); opportunity to establish formal trusted messenger models and expand participant supports (e.g., childcare)
	Community input	Strengthening	Has community members required on the IRB; community partnership group regularly gathers input on trial design; opportunity to establish formal policies for regular use of feedback and involve the community earlier on in research process
	Communication with community & participants	Developing	Spanish-speaking coordinators and recruitment materials available in Spanish; opportunity to expand translation capabilities and tailor with cultural framing in mind – especially sponsor-designed material
Clinical trial operations capabilities	Team science approach to workforce diversity	Strengthening	Informal mentorship of clinical research staff; limited examples of coes providing resources to researchers to protect time and ensure sustainability
	Clinical trial workforce DEIA education	Strengthening	Has HR-led cultural competency trainings for new coordinators and clinical trial staff participate in trial-specific community engagement events. Opportunity to bolster cultural humility and familiarity training offerings and expand requirements for staff
	Physical infrastructure	Developing	Has sufficient dedicated physical space for trials, adequate ancillary services, access to research equipment to support trials
	Technical infrastructure	Developing	Has no CTMS system in place for clinical research and limited ePRO/REMR use for patient recruitment
	Research operations	Developing	Has opportunities such as updating SOPs and training staff; establishing processes such as trial procurement and feasibility, patient retention; enhancing data management and regulatory processes; expanding types of trials; defining performance tracking & QA efforts
	Site composition	Strengthening	Conducts trials across several therapeutic areas, has multiple active and experienced investigators, multiple full and part time CRCs, staff with capacity for more trials, and emerging processes and supports (e.g., regulatory, financial). Opportunity to bolster clinical trial partnerships, expand satellite sites, and dedicate positions for data entry

Detailed deep dives of maturity assessment by question

Example synthesis of completed maturity assessment by component, for discussion with site to co-develop goals

Illustrative example: Completed site maturity assessment

Developing
 Strengthening
 Leading

Factor	Component	Current state maturity level	Goals for discussion...
Organizational level factors	Organizational leadership & governance	 Senior leadership voices commitment to increasing diversity in clinical trials; opportunity to formalize strategic initiatives and dedicate long-term funding	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; border-radius: 50%; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center; margin-right: 10px;"> > </div> <div> <ul style="list-style-type: none"> • Co-develop with the site... </div> </div>
	Bi-directional community partnerships	 Has robust community partnership and involves community members in advisory board, project-specific patient advisory groups; Opportunity to develop formal charter on community co-leadership and bi-directional partnership	
	Programs addressing barriers to participation	 Has some programming and supports to increase diverse participation in trials the importance of community engagement in research (e.g., transportation / time compensation); opportunity to establish formal trusted messenger models and expand participant supports (e.g., childcare)	
	Community input	 Has community members required on the IRB; community partnership group regularly gathers input on trial design; opportunity to establish formal policies for regular use of feedback and involve the community earlier on in research process	
	Communication with community & participants	 Spanish-speaking coordinators and recruitment materials available in Spanish; opportunity to expand translation capabilities and tailor with cultural framing in mind – especially sponsor-designed material	
	Team science approach to workforce diversity	 Informal mentorship of clinical research staff; limited examples of cores providing resources to researchers to protect time and ensure sustainability	
Community engagement factors	Clinical trial workforce DEIA education	 Has HR-led cultural competency trainings for new coordinators and clinical trial staff participate in trial-specific community engagement events. Opportunity to bolster cultural humility and familiarity training offerings and expand requirements for staff	<ul style="list-style-type: none"> • Co-develop with the site...
	Physical infrastructure	 Has sufficient dedicated physical space for trials, adequate ancillary services, access to research equipment to support trials	
	Technical infrastructure	 Has no CTMS system in place for clinical research and limited EHR/EMR use for patient recruitment	
	Research operations	 Has opportunities such as updating SOPs and training staff; establishing processes such as trial procurement and feasibility, patient retention; enhancing data management and regulatory processes; expanding types of trials; defining performance tracking & QA efforts	
Clinical trial operations capabilities	Site composition	 Conducts trials across several therapeutic areas, has multiple active and experienced investigators, multiple full and part time CRCs, staff with capacity for more trials, and emerging processes and supports (e.g., regulatory, finance). Opportunity to bolster clinical trial partnerships, expand satellite sites, and dedicate positions for data entry	<ul style="list-style-type: none"> • Co-develop with the site...

Illustrative example: Completed site maturity assessment

Developing
 Strengthening
 Leading

Factor	Component	Maturity level	Goals co-developed with the site
Organizational level factors	Organizational leadership & governance		<ul style="list-style-type: none"> Expand leadership capacity to develop an organization-wide strategic plan to advance diversity in clinical trials
Community engagement factors	Bi-directional community partnerships		<ul style="list-style-type: none"> Create opportunities community partners to shape research priorities from the outset Create formal mentorship and training opportunities for Black, Hispanic & Latino clinical research staff Consider opportunities to mentor other organizations on community engagement and partnership
	Programs addressing barriers to participation		
	Community input		
	Communication with community & participants		
	Team science approach to workforce diversity		
	Clinical trial workforce DEIA education		
Clinical trial operations capabilities	Physical infrastructure		<ul style="list-style-type: none"> Integrate clinical research technology into provider workflows to streamline management of clinical research Formalize research SOPs and establish a streamlined process to manage and update these as needed
	Technical infrastructure		
	Research operations		
	Site composition		

