Increasing Diversity in Clinical Trials Expert Meeting

Tuesday, October 12 & Thursday, October 21, 2021, 1:00 p.m. – 4:00 p.m. EDT

Pre-Meeting Materials – Day 1

MEETING OBJECTIVES:

- Present findings from project evidence generation: in-depth interviews with key decision-makers
- Refine a maturity model for organizational-level strategies to increase diversity in clinical trials
- Identify specific multi-stakeholder, portfolio-level strategies to increase the participation of underrepresented racial and ethnic minorities and women in clinical trials

OVERVIEW

In preparation for Day 1 of the virtual CTTI Expert Meeting on October 12, we ask that you review the material in this document. The meeting will include discussions about the development of a maturity model for organizational-level strategies to improve diversity in clinical trials. The CTTI Diversity in Clinical Trials work builds on previous CTTI work in Patient Engagement and Quality by Design. Below, you will find information about the CTTI Quality by Design Maturity Model as an example. In addition, an early draft of the diversity maturity model is included on the following pages and will be used to guide discussions during the meeting. Please review the content and see noted factors for breakout group discussion:

1) Scientific Disease Level Strategy, 2) Community and Patient Engagement, and 3) Measurement of Impact

Maturity Model Example: CTTI Quality by Design Maturity Model

A presentation on the CTTI QbD Maturity Model and the general purpose of maturity models can be viewed on CTTI's website. The maturity model section starts at the 23:04 mark in video, and starting on slide 18 of the slide set.

Draft Diversity Maturity Model for Organizational-Level Strategies

This draft diversity maturity model is intended to guide conversation at the October 12 & 21 CTTI expert meeting.

The final model's purpose will be to guide research organizations to assess their current organizational infrastructure for increasing diversity in clinical trials, as well as to identify a desired future state. This tool is primarily aimed at organizations that plan, conduct, and/or oversee clinical trials, including industry sponsors, CROs, academic research organizations, and patient groups. For this CTTI work and this document, the term "diverse patient populations" refers to racial minorities, ethnic minorities, and women.

Factors	**Level 1** Ad hoc	**Level 2** Early	**Level 3** Developing	**Level 4** Implementing	**Level 5** Optimizing
			CULTURE & LEADERSHIP		
Leadership Support & Accountability	Some awareness and recognition of importance. Ad hoc initiatives.	Leadership commitment to adopting organizational-level strategies. Organization has issued a statement of importance and planned commitments. Policies and strategies being developed.	Leadership supports and champions organization's philosophy, commitments, and organizational-level strategies through internal communication. Policies and strategies created and there is broad awareness and understanding of the necessity of diversity, equity, and inclusion (DEI) in clinical trials.	Priority of leadership and is clearly stated in internal and external communications. DEI are part of the organization's mission, core values, and/or strategic plan. Performance goals of leadership linked to DEI. Policies and strategies are publicly available and are implemented across organization.	Diversity & inclusion embedded in organizational culture and institutionalized, as demonstrated by: a) leadership is externally communicating activities, performance, and value of organizational-level strategies b) integrated into specific standard operating procedures (SOPs) for all departments c) implementation has spread to all associates across organization and part of day-to-day workload d) outcomes are measured and continuously improved (see last section)

Factors	Level 1 Ad hoc	Level 2 Early	Level 3 Developing	Level 4 Implementing	Level 5 Optimizing
Dedicated Personnel	No formal organizational structure for diversity, equity, and inclusion. No individuals responsible for driving practices to ensure representation of diverse patient populations in clinical trials.	Piloting task forces or workgroups; ad hoc training available.	Diversity, Equity, and Inclusion (DEI) in clinical trials team(s) formed. ● includes dedicated personnel assigned formal responsibilities with dedicated time	DEI teams are integrated into all functions of organization.	DEI teams include dedicated senior personnel reporting directly to leadership and integrated into organization. Strong cross functional coordination and collaboration with: ● Research team ● Patient Engagement team ● Clinical affairs ● Outreach and education team.
Investments	No specific budget for DEI activities.	Ad hoc funds available that can be requested for DEI activities.	Some dedicated DEI funds for personnel, external support, education, & materials. Starting to coordinate budgets for internal activities and external activities and/or support organizations.	Dedicated funding for personnel, external support, education, & materials. Internal and external budgets are coordinated.	Dedicated, adequate, budgets for personnel, external support, education, & materials. Internal and external budgets are well coordinated.

PORTFOLIO STRATEGY

The term "portfolio" may have different scope depending on an organization and its structure. For example, these analytical and operational strategies may refer to the full organization, therapeutic area, development stage, or compound level. "Portfolio Strategy" refers to assessing the portfolio level of interest and determining where and how to evaluate, improve, and optimize representativeness of diverse populations.

Factors	**Level 1** Ad hoc	**Level 2** Early	**Level 3** Developing	**Level 4** Implementing	**Level 5** Optimizing
Scientific Disease Level Strategy Each level (column) has two parts: 1) obtain necessary data, 2) applying data	No or limited processes are in place to formally evaluate the impact of the disease on diverse populations. Clinical development strategies only consider population demographics.	Some processes exist to evaluate the impact of disease on diverse populations* based on epidemiologic incidence of disease, known intrinsic and extrinsic factors, and other data (e.g., real word data and previous clinical trial data), but these processes are not consistently applied across indications and have limited impact on clinical development strategies. *when the disease occurs in the diverse population(s)	Organization has an understanding of the impact of the disease on diverse populations based on epidemiologic incidence of disease and has evaluated areas of largest need due to disproportionate impact on diverse populations. Data is applied to clinical development strategy on a limited basis.	Epidemiological analysis is available for every clinical trial and: • DEI strategies applied proactively for every trial where indicated. • Pre-specified subgroups are selected based on the populations disproportionately affected by the disease.	Robust analytical strategy in place to generate adequate data • for sufficient analysis of safety and efficacy in **pre-specified** subgroups to support labeling in all populations affected by the disease. Development programs are de-risked early by looking at epidemiological data and known intrinsic and extrinsic factors. Goals are set based on data, progress monitored, and if early trials do not hit targets (issue), make necessary adjustments (issue management).
Breakout Group #1	Example discussion question: What sources of data are needed to determine if there is a disproportionate impact of disease and if there are differences in treatment effect?				

Community & Patient Engagement Each level (column) has two parts: 1) Determining who the key stakeholders are to be engaged, 2) What are the diverse patients'/populations' needs and interests? How are needs and interests informing strategy?	Portfolio strategy includes input primarily from company leadership. No comprehensive engagement strategy and no input from diverse patients, patient groups, or community stakeholders.	Portfolio strategy identifies and obtains some input from some, but not all, key patient and community stakeholder needs. Input is not routinely incorporated into development strategy.	Portfolio strategy identifies and considers most key stakeholders' needs. Input is incorporated into development strategy in some but not all cases and not at all levels of development.	Portfolio strategy includes direct engagement with key stakeholders from earliest stages of study planning. Engagement is an embedded strategy at all stages of development.	Portfolio strategy collaboratively considers needs of key stakeholders, inclusive of diverse patients and community stakeholders. Strategy periodically updates understanding of who the stakeholders are across the research enterprise, and their current needs. Transparency and feedback loop present -- provide feedback to the groups about how input is used and results of strategies and programs.
Breakout Group #2	Example discussion questions: Should community engagement and patient engagement be separate rows? What are the levels of maturity of an organization's strategy to engage with the community?				

Additional Portfolio Level Strategy rows will be added, including **Site Feasibility and Investigator & Site Development and Training**

Factors	**Level 1** Ad hoc	**Level 2** Early	**Level 3** Developing	**Level 4** Implementing	**Level 5** Optimizing
			MEASUREMENT		
Lessons Learned	Informal review and dissemination of lessons learned at end of study.	Study 'after-action' reviews of representation of diverse patient populations. Lessons learned do not consistently inform future studies.	Lessons learned often inform future studies, but substantial barriers remain (e.g., data incomplete, siloed or difficult to access).	Lessons learned are systematically and collaboratively captured and shared across stakeholders. Study design consistently incorporates lessons learned.	Organizational culture, technology, and systems fully support rapid incorporation of lessons learned into quality planning of all future trials.
Continuous Improvement Metrics	No organization-wide measurement of inclusion diverse patient populations.	Evaluation of inclusion in past studies is underway.	Range of appropriate metrics tracked, though output not consistently used.	Metrics routinely viewed, evaluated, and changes made as needed.	Metrics regularly reviewed and updated in alignment with evolving strategic plan for DEI infrastructure implementation. Consistent quality improvements over long term.
Measurement of value and impact	Support and momentum to create systemic change in clinical trial diversity, equity, and inclusion has increased since CTTI began this work in late 2019. However, there is a continued need for sharing of information about the clinical, scientific, and economic value and impact of initiatives to increase diversity in clinical trials in order to ensure necessary resources are allocated and the needs of diverse patient populations are met.				
Breakout Group #3	Example discussion question: What dimensions of value and impact of organizational level-strategies are/will be most impactful to measure and share to create continued change?				