

MEETING SUMMARY | OCTOBER 12 & 21, 2021



BACKGROUND

Underrepresentation of racial minorities, ethnic minorities, and women in U.S. clinical trials limits the knowledge of investigational products' safety and efficacy, reduces the availability of evidence-based treatment guidelines for underrepresented populations, and presents a serious human subject protection issue and broader public health threat.

In 2019, CTTI conducted an initial landscape scan on increasing diversity in clinical trials to determine where a new project would be most impactful. It identified the need for more consideration of diversity during protocol design and operational planning, more coordinated action across key system-level actors, more thorough efforts to scale and replicate diversity initiatives throughout and across institutions, and better resource allocation to these initiatives.

Since 2019, there has been increased awareness and calls for systemic change in clinical trials to ensure that they meet the needs of diverse populations. But there is still a continued need to share information and ensure sufficient resource allocation to diversity, equity, and inclusion programs and initiatives. A recent CTTI meeting, convening leaders and key stakeholders from across the clinical trials ecosystem, shed more light on the solutions required to meet this need.



MEETING OBJECTIVES

CTTI's diversity expert meeting aimed to:

- 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.



MEETING THEMES

- **The benefits are indisputable.** Including a diverse population in clinical trials improves the quality of science, enhances patient trust, increases patient recruitment and retention, and improves clinical care for all patients.
- **A culture shift is needed.** Organizations need to ingrain diversity, equity, and inclusion initiatives into their portfolio-level strategy and within their overall mission. They should foster bi-directional community partnerships and directly engage patients in the design and planning of clinical trials and diversity efforts from the very beginning.
- **This is a full group effort.** Increasing diversity in clinical trials is a multi-stakeholder effort that will take all groups working together to achieve goals of clinical trial populations representing the populations who are affected by disease.
- **There is important work ahead of us.** Meeting attendees provided feedback on CTTI's draft maturity model, helping to create a better public resource. Suggested additions included a focus on values and guidelines that are generalizable to a wide variety of stakeholders, not just industry stakeholders, and more guidance on how organizations can measure their progress through the maturity model.



NEXT STEPS

CTTI is currently working to:

- Develop recommendations & resources, including the final maturity model, for release in early 2022.
- Host additional webinars focusing on case studies and implementation of resources.



ADDITIONAL RESOURCES

- **Meeting materials**, including agenda, participant list, and presentations
- Read more about CTTI's **Diversity Project**



ABOUT THE CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI)

The Clinical Trials Transformation Initiative (**CTTI**), a public-private partnership co-founded by Duke University and the FDA, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Bringing together organizations and individuals from across the enterprise, CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges.



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