

ENGAGING STAKEHOLDERS IN TRIAL DESIGN

Expert Meeting



MEETING SUMMARY | APRIL 4, 2023



BACKGROUND

Engaging all stakeholders during the earliest stages of clinical trial development is an important recommendation from CTTI's [Quality by Design](#) (QbD) project. In alignment with these recommendations, the Engaging All Stakeholders in Clinical Trial Design Project team is developing an engagement roadmap and recommendations to enable clinical trial designers to efficiently and effectively engage all stakeholders across the trial design process. The project team is also collating resources to facilitate meaningful engagement of all stakeholders and increase the efficiency of trial design.

The multi-stakeholder expert meeting was conducted to identify high-value approaches and situation-specific considerations for meaningful engagement of internal and external stakeholders. Experts from academia, clinical research organizations, patient advocacy groups, regulatory agencies, and the pharmaceutical industry discussed the challenges and opportunities, key strategies, and metrics for assessing holistic stakeholder engagement across the continuum of clinical trials.



MEETING OBJECTIVES

- Review two clinical trial 'models' where stakeholder engagement was well-executed
- Discuss and explore opportunities, barriers, and best practices for study designers to engage all stakeholders in trial design
- Identify situation-specific considerations for ensuring engagement is appropriately equitable, effective, and feasible



MEETING THEMES

Throughout the meeting, attendees discussed the timing of engaging internal and external stakeholders, operationalizing feedback to implement meaningful changes in the design and implementation of clinical trials, simplifying trial design, and measuring the impact of stakeholder engagement. The following key themes were emphasized during the meeting:

- It is important to engage key stakeholders – including patients, site staff, and regulatory agencies – very early in the design of clinical trials. When planning study timelines, identify all internal and external stakeholders and the appropriate time and approach to solicit their input.
- Stakeholder engagement should be an iterative process throughout the life cycle of clinical trials. Internal and external stakeholders should be engaged, as appropriate, from the beginning of clinical trial design through the dissemination of results.
- Bring stakeholders and functional groups together to identify gaps between teams and brainstorm solutions to increase the quality and efficiency of trials. Effective communication and collaboration across all stakeholder groups is crucial to create a community around designing high-quality studies that meet the needs of patients and that generate reliable evidence with fewer amendments.
- Advanced methodologies and tools, such as artificial intelligence and machine learning, can help study designers develop innovative, high-quality trials and streamline processes. With databases of real-world and clinical trial data, artificial intelligence and machine learning can be used to inform the design of trials, explore potential treatments for patient subgroups, assess feasibility of enrollment, and identify sites.
- A collection of resources for designing clinical trials, including recommendations on how and when to meaningfully engage all stakeholders, is needed to help study designers plan innovative clinical trials more efficiently and in alignment with regulatory guidance.



NEXT STEPS

The Engaging Stakeholders in Trial Design team will:

- Use feedback from this meeting to continue to expand the stakeholder engagement roadmap and develop recommendations and resources
- Organize a second virtual expert meeting to solicit feedback on the engagement roadmap, recommendations, and resources and troubleshoot remaining gaps
- Convene a Recommendations Advisory Committee to refine the recommendations
- Host a public webinar in 2024 to launch the recommendations and supporting tools



ADDITIONAL RESOURCES

- **Meeting materials**, including the agenda, participant list, and presentations
- Read more about CTTI's [**Engaging All Stakeholders in Clinical Trial Design 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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