



Engaging Stakeholders in Trial Design

Multi-Stakeholder Expert Meeting Overview

April 4, 2023

8:30 a.m. – 3:00 p.m. EDT

Grand Hyatt Washington

1000 H Street, NW, Washington, D.C.

CTTI MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

- ▶ 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
- ▶ Review a clinical trial 'model' where stakeholder engagement was well-executed

APRIL 4, 2023

7:30 a.m. **Breakfast** (*Provided*)

8:30 a.m. **Welcoming Remarks and Opening Comments**

8:30 a.m. Introduction to the Clinical Trials Transformation Initiative (CTTI)
Sally Okun, CTTI

8:45 a.m. **Project Introduction**

8:45 a.m. Project Overview and Meeting Objectives
Greg Vico, Bristol Myers Squibb

9:00 a.m. **Session I: Model for Success**

Session Facilitator/Moderator: *Jeannine Salamone, ASCO*

Session Objectives:

- ▶ Explore a well-executed trial
- ▶ Identify key milestones/interactions that supported success

9:00 a.m. What Does a Well-Engaged Trial Look Like

- Methods and milestones
- Roadblocks to engagement?

Minetta Liu, Natera

9:30 a.m. *Open Discussion - Q&A*

10:20 a.m. **Break** (*Refreshments Provided*)

10:30 a.m. **Session II: Challenges and Solutions**

Session Facilitator/Moderator: *Naziah Lasi-Tejani, Genentech*

Session Objective:

- ▶ Discuss and explore opportunities, barriers, and best practices for engaging all stakeholders in trial design
- ▶ Identify specific opportunities and approaches for study designers to engage with internal and external stakeholders across the clinical trial design and planning process

10:30 a.m. Introduction to Session II – Industry Challenges and Solutions Discussion
Naziah Lasi-Tejani, Genentech

10:35 a.m. Panelists:

- ▶ *Stephanie Christopher, Pfizer*
- ▶ *James Donahue, Roche*
- ▶ *Daniel Millar, Janssen*
- ▶ *May Mo, Amgen*
- ▶ *Li Wang, AbbVie*

11:15 a.m. Q&A

11:35 a.m. Introduction to Break Out Groups – Challenges and Solutions Discussion
Kelly Franzetti, CTTI

11:45 a.m. **Lunch** (*Provided*)

12:45 p.m. Session III: Break Out Sessions

- 12:45 p.m. Break Out Groups
- *Challenges and Solutions: How are they addressed in early, mid, and late stage protocol development?*
 - *Identify situation-specific considerations for ensuring engagement is appropriately equitable, effective, and feasible*
 - o *Potential to relate to specific trial phases and disease areas*
- 2:15 p.m. (Return to Main Session)
Report Back/Summarize then Open Discussion
May Mo, Amgen

2:55 p.m. Closing Comments

2:55 p.m. Highlights and Next Steps
Robyn Bent, FDA

3:00 p.m. Adjourn

For more information, contact the Engaging Stakeholders in Trial Design Project Manager, Kelly Franzetti at Kelly.Franzetti@duke.edu, or visit <http://www.ctti-clinicaltrials.org>.