

Welcome to CTTI's Engaging Stakeholders in Trial Design Expert Meeting

- This meeting is being recorded for note taking purposes only
- Masks are recommended if you are experiencing cold-like symptoms
- Open discussion is encouraged and fostered by respect and collaboration
- Do you have a comment during the open discussion?
 - Please tip your name tent card and a microphone will be delivered

Here's to a great discussion!

Agenda

Time (EST)	Content	Presenter
8:30 AM	Welcome Remarks and Introduction to CTTI	Sally Okun (CTTI)
8:45 AM	Engaging Stakeholders Project Overview	Greg Vico (BMS)
9:00 AM	Model for Success (<i>Questions/Open Discussion and Break to Follow</i>)	Minetta Liu (Natera)
10:30 AM	Panel Discussion	May Mo (Amgen) Li Wang (AbbVie) James Donohue (Roche) Daniel Millar (Janssen) Stephanie Ann Christopher (Pfizer) Moderator: Naziah Lasi-Tejani (Roche)
11:35 PM	Introduction to Break Out Groups (<i>Lunch to follow</i>)	Kelly Franzetti (CTTI)
12:45 PM	Break Out Session	All Attendees
2:15 PM	Summarize Breakout Session: Open Discussion	May Mo (Amgen)
2:55 PM	Closing Comments and Adjourn	Robyn Bent (FDA)



April 4, 2023

Introduction to CTTI

Sally Okun, CTTI Executive Director



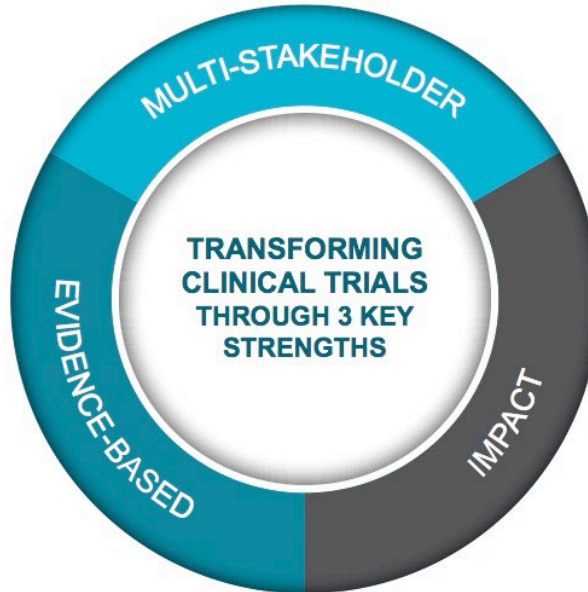
Clinical Trials Transformation Initiative

MISSION

To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials.

VISION

A high-quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options.



PUBLIC-PRIVATE PARTNERSHIP

- Co-founded in 2007 by FDA and Duke University
- Active collaboration with +500 individuals and groups
- Steering Committee with +80 member organizations

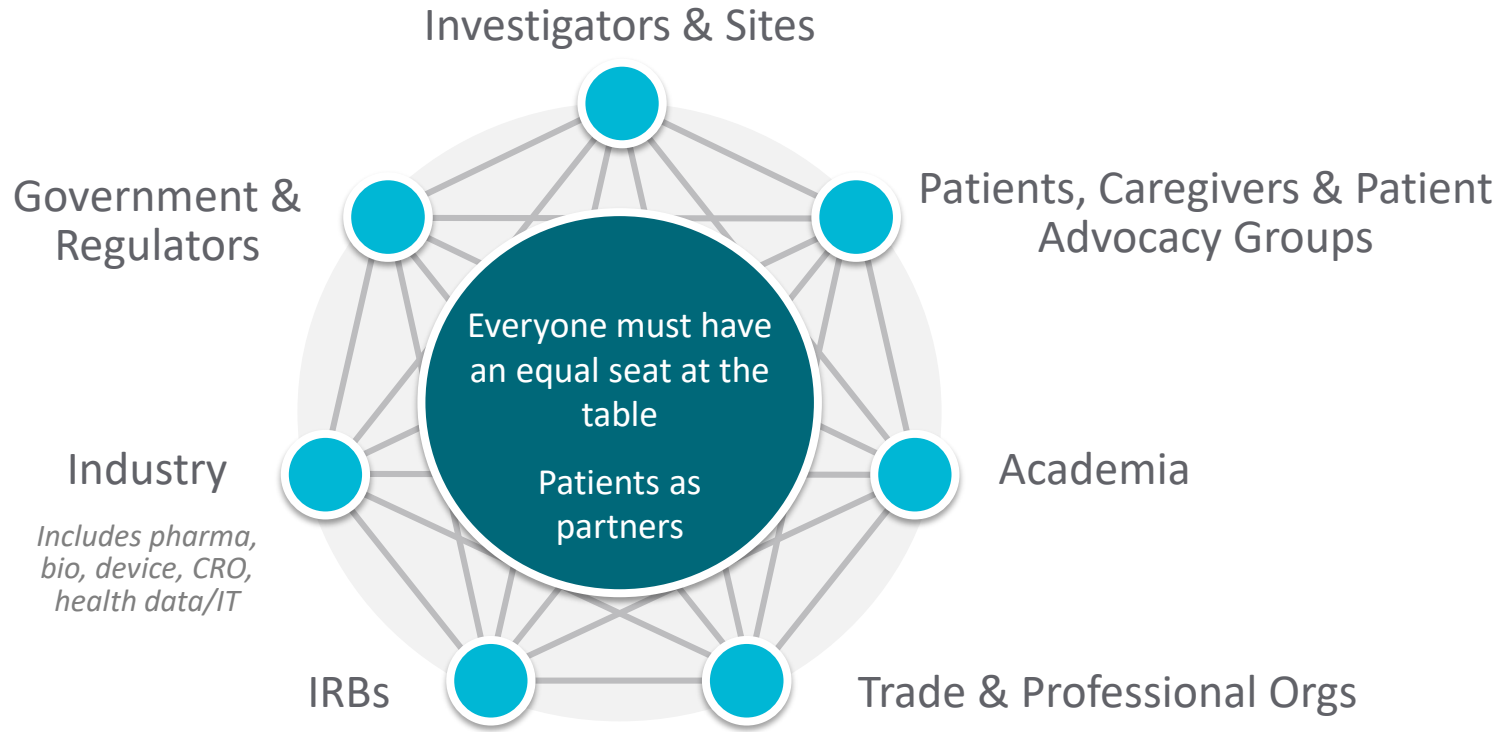
SCOPE

Focus on clinical trials of FDA-regulated medical products, recognizing that clinical trials are international and acting as a collaborative global citizen.

CTTI Membership



Multi-Stakeholder



CTTI Products



Recommendations

Evidence-based and actionable results from a CTTI project that are approved by the CTTI Executive Committee



Tools

Supportive resources developed by a CTTI project team to assist with the implementation and adoption of project recommendations



Publications



Reports



Case Studies



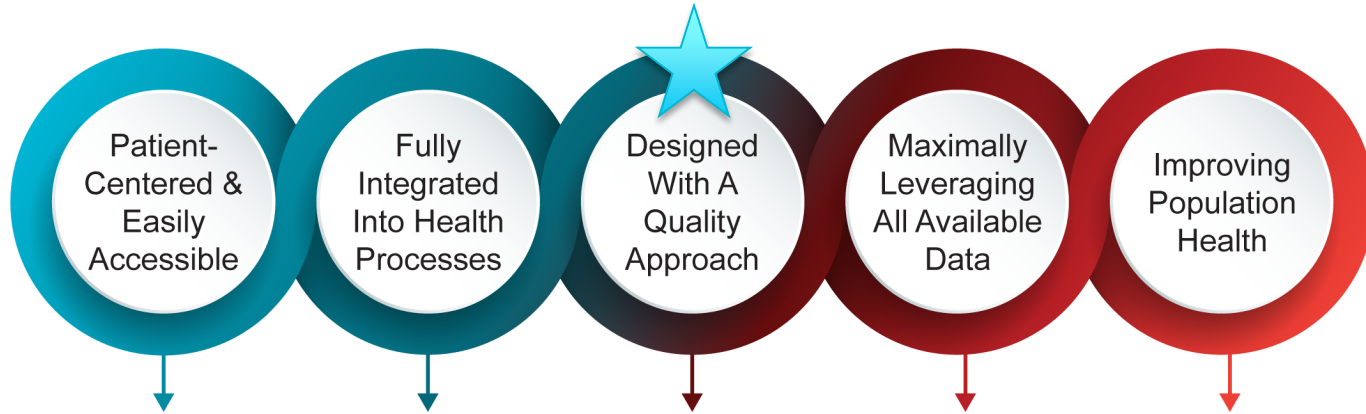
Webinars



Presentations

TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System

Continuation of CTTI Quality by Design Work



Quality by Design (Qbd) - an approach that focuses resources on the errors that matter to decision making during a trial. Includes:

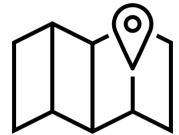
- **Create a culture** that values & rewards critical thinking & open dialogue about quality
- **Involve the broad range of stakeholders** in protocol development & discussions around study quality
- Prospectively identify & periodically review the **critical to quality factors**
- **Focus effort** on activities that are essential to the credibility of the study outcome

 CTTI has developed a suite of QbD resources:

<https://ctti-clinicaltrials.org/our-work/quality/quality-by-design/>

Engaging All Stakeholders in Clinical Trial Design

-  Create resources that will enable clinical trial designers to efficiently & effectively engage all stakeholders across the trial design process
-  Drafting engagement roadmap
 - Patients & Caregivers
 - Investigators & Sites
 - Regulators
 - Institutional Review Boards
 - Technology
 - Payers





April 4, 2023

Engaging Stakeholders in Trial Design

Project Overview

Greg Vico, BMS



Project Premise: Engagement Increases Quality



- ▶ **CTTI QbD Recommendations**: “Engaging all stakeholders with study development is an important feature of quality by design.”
- ▶ **ICH E8(R1) Draft**: “Clinical study design is best informed by input from a broad range of stakeholders...”
- ▶ **CDRH/CBER Draft Guidance**: “FDA believes medical device clinical investigations prospectively designed with input from patient advisors may help to address common challenges...”

Engaging Stakeholders in Trial Design Project Overview

Purpose:

Provide details and logistics for engaging all stakeholders in the design of clinical trials

Objectives:

- Identify specific opportunities and high value approaches for study designers to engage with stakeholders
- Identify situation-specific considerations for ensuring engagement is appropriately equitable, effective, and feasible
- Assess the extent to which draft products address stakeholder needs and incorporate

Anticipated Impact:

- Increase meaningful engagement
- Produce high quality efficient clinical trials

Project Scope



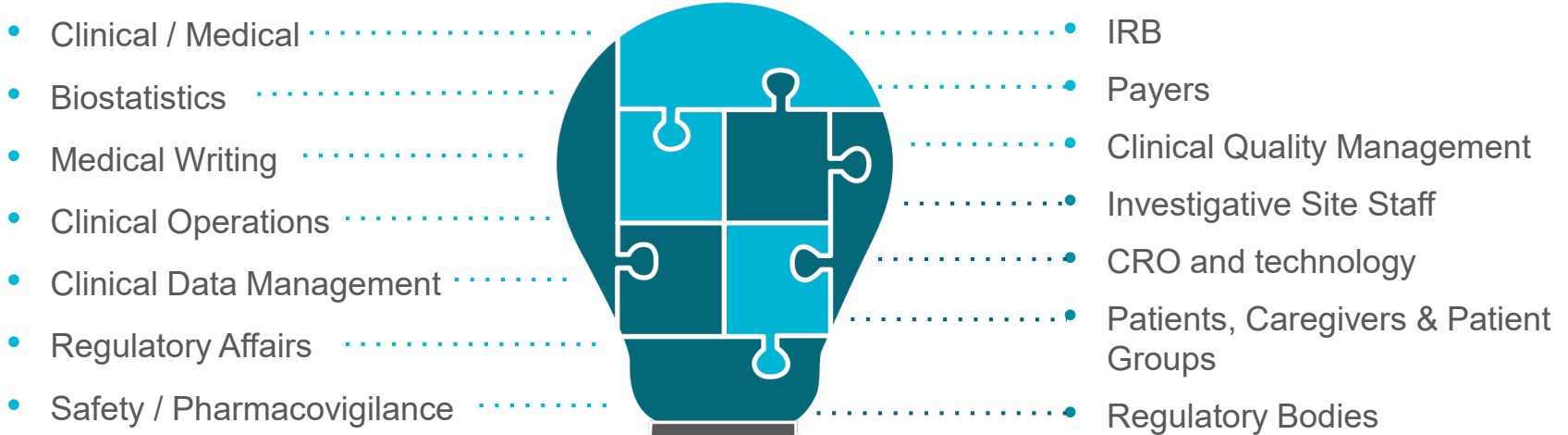
Engage all stakeholders to...

- **Identify critical to quality aspects** of trial design and potential challenges
- **Tailor design** to avoid errors that could undermine evaluability or safety
- **Streamline** trial where feasible
- **Verify** proposed design consistent with scientific question
- **Highlight and evaluate** residual risks

Issues To Be Addressed

- ▶ Lack of comprehensive resources for engaging all stakeholders in trial design
- ▶ Most approaches assume patients and other stakeholders will be engaged separately, rather than having all stakeholders 'at the table,' as emphasized by Quality by Design
- ▶ The clinical trials enterprise lacks a unifying framework, especially one tied to regulatory guidance, delineating how the various existing engagement methods can be used collectively and coherently across the trial design process

Stakeholders to Engage



INTERNAL PERSPECTIVE



EXTERNAL PERSPECTIVE

Initial Project Outputs

- Engagement Roadmap identifying detailed, ‘nuts and bolts’ considerations for who and how to engage at each stage of trial planning
 - Covers all phases of development – though may not address all in equal depth or detail
 - Identifies all major stakeholders, though may not address engagement approaches for all stakeholders in equal depth or detail
 - Serves as a ‘one-stop shop,’ linking to existing tools/resources
 - Visual and easy to follow, likely structured as a timeline or flowchart
 - Flexible, helping to identify the best engagement approach given particular situation
 - Outlines engagement approach that is effective and efficient (e.g., with respect to time, cost, minimizing repetition)

Multi-Stakeholder Project Team

Team Leads

Lorri Wiggins (FDA)
Naziah Lasi-Tejani (Roche)
Durga Borkar (VeranaHealth)
Karlin Schroeder
(Parkinson's Foundation)*
Whitney Bondurant
(University of Mississippi)*
Michael Howland (Genentech)*

Team Members

Robyn Bent (FDA)
David Borasky (WCG IRB)
Suanna Bruinooge
(American Society of Clinical Oncology)
Patrick Frey (Amgen)
Courtney Granville
(Drug Information Association)
Heather Kim (WCG IRB)
David Leventhal (Pfizer)
Renee Leverty (Duke)
May Mo (Amgen)
Xinyi Ng (FDA)
Nuru Noor (Patient/Caregiver)
Gregory Pennock (EMD Serano)
Jamil Rivers (Patient/Caregiver)
Jeanine Salamone
(American Society of Clinical Oncology)
Theresa Strong
(Foundation for Prader-Willi Research)
Pujita Vaidaya (Amgen)*
Greg Vico (Bristol-Myers Squibb)
Glendon Zinser (Susan G. Komen)

Writer

Alexis McCloskey (Duke)

Communications Lead

Rae Holliday (CTTI)

Project Manager

Kelly Franzetti (CTTI)

Event Planner

Susan Morris (CTTI)

*former team lead or member



Today's 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

Model for Success

Session I Objectives:

- Explore trials in which stakeholders were well engaged
- Identify key milestones/interactions that supported this success



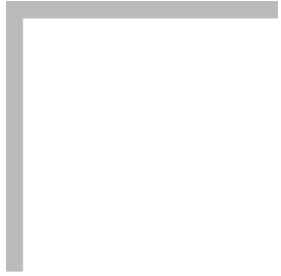
April 4, 2023

Models for Success

Minetta Liu, Natera



 INSERT MINETTA'S SLIDES



Q & A



BREAK

Return at 10:30 am



April 4, 2023

Challenges and Opportunities

Panel Discussion

Naziah Lasi-Tejani, Roche



Session Objectives

- 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

Topics Overview

- Building the Value Proposition of Engaging Stakeholders in Trial Design
- Timing of Stakeholder Engagement
- Operationalizing Stakeholder Feedback
- Simplifying the Process
- Measuring the Impact

Panel: Challenges and Opportunities to Engagement



*Stephanie Ann
Christopher,
Pfizer*



*James Donohue,
Roche*



*Daniel Millar,
Janssen*

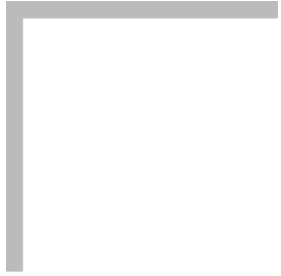


*May Mo,
Amgen*



*Li Wang,
AbbVie*

Moderator: Naziah Lasi-Tejani, Roche



Q & A

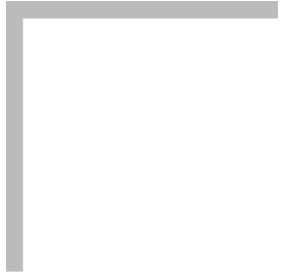
Breakout Topics Overview

- Timing of Stakeholder Engagement
- Operationalizing Stakeholder Feedback
- Simplifying the Process
- Measuring the Impact

Breakout Group Instructions

- Check badge for dot color
- Duration: 90 minutes
- Refreshments available in foyer throughout the session
- Please enjoy lunch and then go directly to your breakout session location

Group	Dot Color	Location	Moderator
1	Green	Lincoln	Glendon Zinser
2	Yellow	Declaration A	Renee Leverty
3	Red	Banneker	Suanna Bruinooge
4	Blue	Declaration B	Courtney Granville



BREAK

Go to Breakout Session at 12:45 pm



Breakout Sessions

Return to Main Session at 2:15 pm



April 4, 2023

Breakout Summary with Discussion

May Mo, Amgen



Welcome Back!

▶ Session III Objectives:

- Session moderators share highlights of each breakout
- Q&A/Discussion



Breakout Session Summaries

- ▶ **Breakout Moderators:** Group 3: Suanna Bruinooge, American Society of Clinical Oncology
Group 4: Courtney Granville, Drug Information Association

- ▶ **Simplifying the Process**

- Challenges when planning for and executing stakeholder engagement
- When and how to engage with stakeholders
- What role will technology play and how will it complement or augment stakeholder engagement
- Soliciting structured feedback from each stakeholder group
- How can the stages or timing of stakeholder engagement be classified

- ▶ **Measuring the Impact**

- How can Sponsors measure the impact of stakeholder engagement in their drug development efforts?
- What role can organizations like CTTI play in the development of measurable KPIs for stakeholder engagement in the design of clinical trials?



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

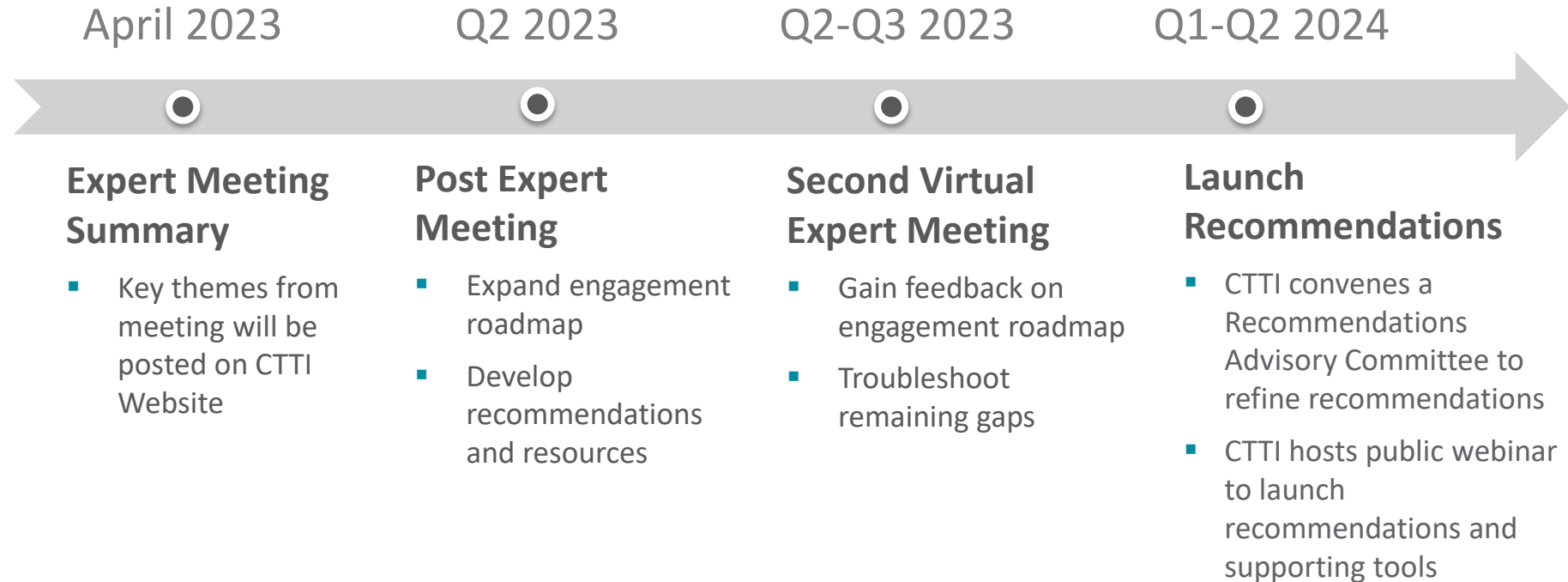
April 4, 2023

Closing Comments

Robyn Bent, FDA



Next Steps & Potential Timeline





CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE



@CTTI_Trials

THANK YOU

www.ctti-clinicaltrials.org