Welcome

CTTI’s Embedding Trials Feasibility Tool Launch

- Thank you for joining us!
- This meeting is being recorded.
- All participants are muted upon entry.
- Questions will be taken via the chat box.
- The presentation and slides will be posted on the CTTI website.
<table>
<thead>
<tr>
<th>Time (EST)</th>
<th>Content</th>
<th>Presenter</th>
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<tbody>
<tr>
<td><strong>12:00 PM</strong></td>
<td>Welcome Remarks &amp; Introduction to CTTI</td>
<td>Sara Calvert (CTTI)</td>
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<tr>
<td><strong>12:05 PM</strong></td>
<td>Trials in Clinical Practice Project Overview</td>
<td>Lindsay Kehoe (CTTI)</td>
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<tr>
<td><strong>12:15 PM</strong></td>
<td>Embedding Trials Feasibility Tool Overview</td>
<td>Lindsay Kehoe (CTTI)</td>
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<td><strong>12:25 PM</strong></td>
<td>Stakeholder Perspectives</td>
<td>Suanna Bruinooge (ASCO)</td>
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<td>Daniel Larsen (AbbVie)</td>
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<td>Denise Snyder (Duke University)</td>
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<td>Henry Wei (Regeneron)</td>
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<td><strong>12:45 PM</strong></td>
<td>Q&amp;A</td>
<td>All Attendees</td>
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<tr>
<td><strong>12:55 PM</strong></td>
<td>Next Steps and Closing Comments</td>
<td>Lindsay Kehoe (CTTI)</td>
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<tr>
<td><strong>1:00 PM</strong></td>
<td>Adjourn</td>
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**Agenda**
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.

By 2030, clinical trials need to be:
- Patient-Centered & Easily Accessible
- Fully Integrated Into Health Processes
- Designed With A Quality Approach
- Maximally Leveraging All Available Data
- Improving Population Health

A critical part of the Evidence Generating System
# The Case for Embedding Clinical Trials into Practice

<table>
<thead>
<tr>
<th>Patients</th>
<th>Providers</th>
<th>Sponsors &amp; Investigators</th>
<th>Regulators</th>
<th>Payers</th>
<th>Health System Leaders</th>
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<tbody>
<tr>
<td>Research and care are better aligned</td>
<td>Potential to engage in research with minimal burden</td>
<td>Generalizable research populations and evidence</td>
<td>Sufficiently sized trials with diverse populations</td>
<td>More, diverse data for reimbursement decisions</td>
<td>A means to innovate and support quality care</td>
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<tr>
<td>Less burden to participate in research</td>
<td>Addresses clinically meaningful questions to improve care in a broad population</td>
<td>Insights into real-world implementation of interventions</td>
<td>Leverages power of randomization &amp; RWD in the context of regulatory decision-making</td>
<td>Better understanding of the effectiveness and safety of medical product interventions</td>
<td>Potential to attract new patients with research opportunities</td>
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<td>Greater trial diversity and inclusivity</td>
<td>Treatment optionality for patients</td>
<td>Potential for increased efficiency &amp; cost savings by reducing duplication of trial &amp; care activities</td>
<td>Generalizable evidence</td>
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<td>Uses health care data for research to represent more real life experiences</td>
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Trial Elements Amenable to Embedding

- Elements integrated into health care delivery
- Accessibility to patients at the point of care
- Close alignment with clinical workflows
- Ability to use clinical care data sources for research purposes
Trials in Clinical Practice (TCP)

Project Overview

**Purpose:** Facilitate the integration of clinical trials intended for, but not limited to, medical product review into clinical practice

**Focused on:**
- Trial design and operations
- Randomized trials with U.S. sites, global examples included

**Objectives:**
- Identify the barriers and potential solutions to incorporating interventional trials into clinical practice
- Identify when integration of clinical trial elements into clinical settings would be feasible
- Describe the operational approaches to incorporating interventional trials into clinical practice
Trials in Clinical Practice Project Deliverables

- Recommendations
  - Case Examples
  - Embedding Trials Feasibility Tool
  - Manuscript
  - Expert Meeting Summaries
### Trials in Clinical Practice Recommendations

<table>
<thead>
<tr>
<th>Trial Design/Methodology</th>
<th>Operational</th>
<th>Health Care &amp; Research Culture</th>
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<tr>
<td>1. Recognize that embedding a trial into clinical practice is not all or nothing</td>
<td>5. Ensure site readiness to embed trial elements</td>
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<tr>
<td>2. Assess whether clinical trial elements should be embedded into clinical practice</td>
<td>6. Minimize participation burden for patients, providers, and research staff</td>
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<td>3. Verify that data sources are fit for purpose – relevant and reliable</td>
<td>7. Validate the quality of the clinical data for research purposes</td>
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<td>4. Streamline trial design to align with clinical workflows</td>
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Recommendations 1-7 are particularly relevant for: sponsors, clinicians interested in conducting research, CROs, funders, health care settings, technology providers, patients/caregivers/patient advocacy groups, payers, and regulatory bodies.

Recommendations 8 & 9 are particularly relevant for: health care system leaders, regulatory bodies, funders, patient advocacy groups, and policy makers.
Embedding Clinical Trial Feasibility Survey

**Who**

Sponsors designing trials or PI, study coordinator, or research managers conducting trials

**What**

Assessment of the capacity and feasibility of embedding elements of a trial into clinical practice

**Why**

Helps optimize protocol or operational plans to reduce duplication of research and care efforts Drives operational site readiness

**When**

During early clinical trial design Prior to or alongside general feasibility assessment

Note: The tool does not rank questions by risk. A quality by design approach should always be considered when designing a trial.
Feasibility Survey User Flow

Scenario 1 Sponsor Trial Designer

**Sponsor/Trial Designer**
- Send protocol to sites of interest
- Send survey to same sites of interest

**Site/Clinical Practice Setting**
- Review protocol
- Answer survey questions
- Submit back to sponsor

**Sponsor/Trial Designer**
- Evaluate survey report
- Refine protocol and operational plans based on feasibility
- Prepare site
Feasibility Survey User Flow
Scenario 2 Site Self Assessment

1. **Site/Clinical Practice Setting**
   - Send survey to self
   - If relevant, review a point of care protocol of interest

2. **Clinical Practice Setting/Site**
   - Answer relevant survey questions

3. **Clinical Practice Setting/Site**
   - Evaluate survey report
   - Identify what is needed to support your site readiness
Tool Options & Benefits

- Relatively Short Survey
  - Not all trial elements need to be assessed
  - Less than 10 questions for the majority of trial elements
- Assesses level of site capability
- Opportunity for standardization
- Opportunity for you to help us shape it
  - At the end of survey there’s a link to provide voluntary feedback and to help CTTI appreciate future use of the tool
Putting it all together

Implementation of CTTI TCP Recommendations & Tool

<table>
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<tr>
<th>WHO</th>
<th>WHAT</th>
<th>WHY</th>
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| Sponsor Trial Designers, Project Leaders (PLs) | CTTI Resources:  
  1. TCP Recommendations  
  2. TCP Case Examples  
  3. QbD Recommendations | • Provide initial framework of thinking about trial design and operational plans |
| Sponsor: Trial Designers, Project Leaders, Site: PI, coordinators, Research Leads or Managers, IT, Patients | CTTI Resources:  
  1. TCP Recommendations  
  2. Feasibility Assessment Tool | • Assess site capability and feasibility  
  • Assess study feasibility: which trial elements are feasible to embed into practice |
| Sponsor: Trial Designers, Project Leaders, Site: PI, coordinators, Research Leads or Managers, Regulators | CTTI Resources:  
  1. TCP Recommendations | • Optimize protocol to incorporate embedded/point of care trial elements  
  • Drive site readiness |
Stakeholder Perspectives

Suanna Bruinooge
American Society of Clinical Oncology

Daniel Larsen
AbbVie

Denise Snyder
Duke University School of Medicine

Henry Wei
Regeneron

Moderator: Lindsay Kehoe, CTTI
Q&A
Thank You

- Research Participants
- Expert Meeting Attendees
- Recommendation Advisory Committee
- Tool Beta Testers & Designers
THANK YOU Trials in Clinical Practice Project Contributors

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Mark Stewart (Friends of Cancer Research)

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James Riddle (Advarra)
Jeffrey Roberts* (FDA/CBER)
Daniel Rose (Pulmonary Fibrosis Foundation)
Heather Stone (FDA/CDER)
David Thompson* (Open Health)
Alandra Weaver (Crohn’s &Colitis)

Project Manager
Lindsay Kehoe (CTTI)

*former team lead or member
Questions/Comments?

• Technical help with the tool: [CTTI’s Contact Us Page](#)
• General Feedback: On the survey at [Contact us Page](#)
• Contact [Lindsay.Kehoe@duke.edu](mailto:Lindsay.Kehoe@duke.edu)

THANK YOU

[www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org)