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.

Agenda

Time (EST)	Content	Presenter
12:00 PM	Welcome Remarks & Introduction to CTTI	Sara Calvert (CTTI)
12:05 PM	Trials in Clinical Practice Project Overview	Lindsay Kehoe (CTTI)
12:15 PM	Embedding Trials Feasibility Tool Overview	Lindsay Kehoe (CTTI)
12:25 PM	Stakeholder Perspectives	Suanna Bruinooge (ASCO) Daniel Larsen (AbbVie) Denise Snyder (Duke University) Henry Wei (Regeneron)
12:45 PM	Q&A	All Attendees
12:55 PM	Next Steps and Closing Comments	Lindsay Kehoe (CTTI)
1:00 PM	Adjourn	

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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.

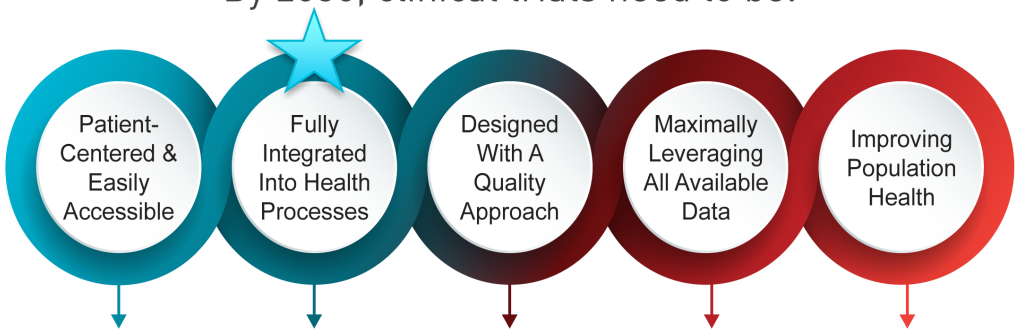
PUBLIC-PRIVATE PARTNERSHIP

- 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:



A critical part of the Evidence Generating System

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The Case for Embedding Clinical Trials into Practice

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

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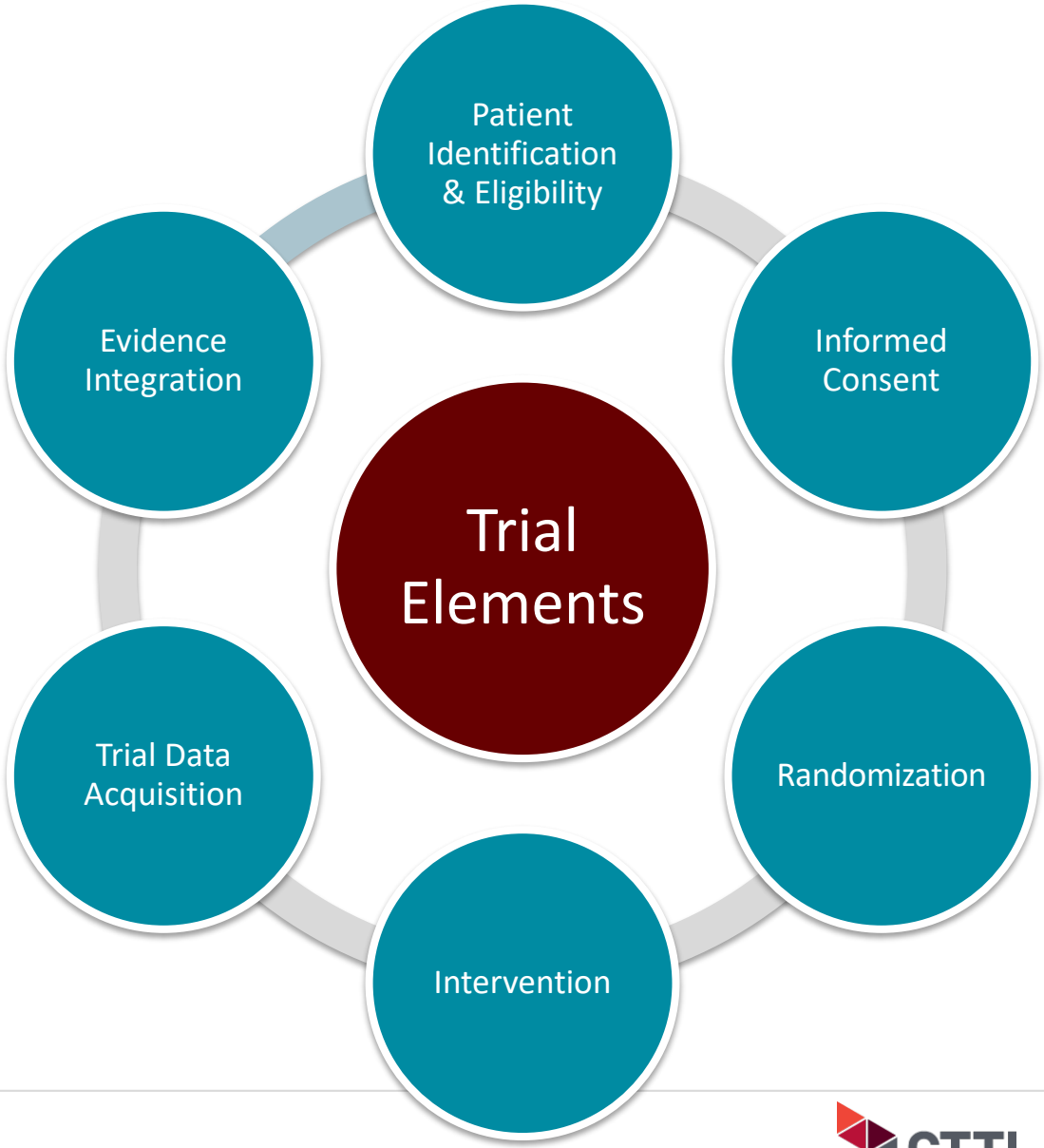
Trial Elements Amenable to Embedding

- 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



Proposed trial elements identified by the project team

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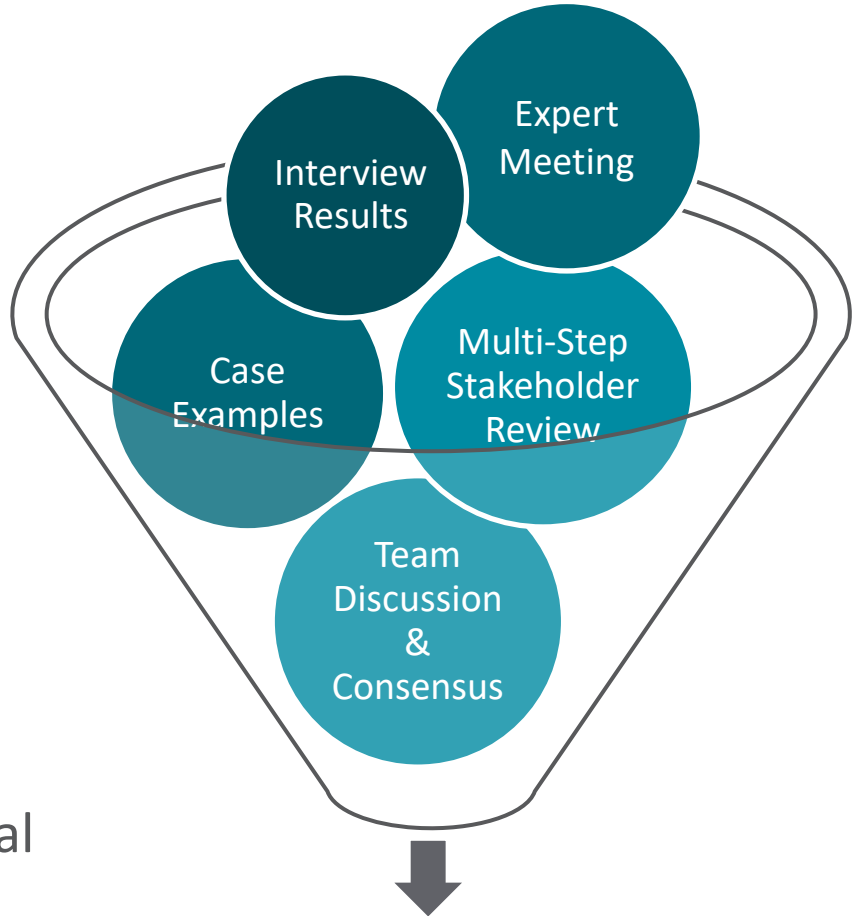
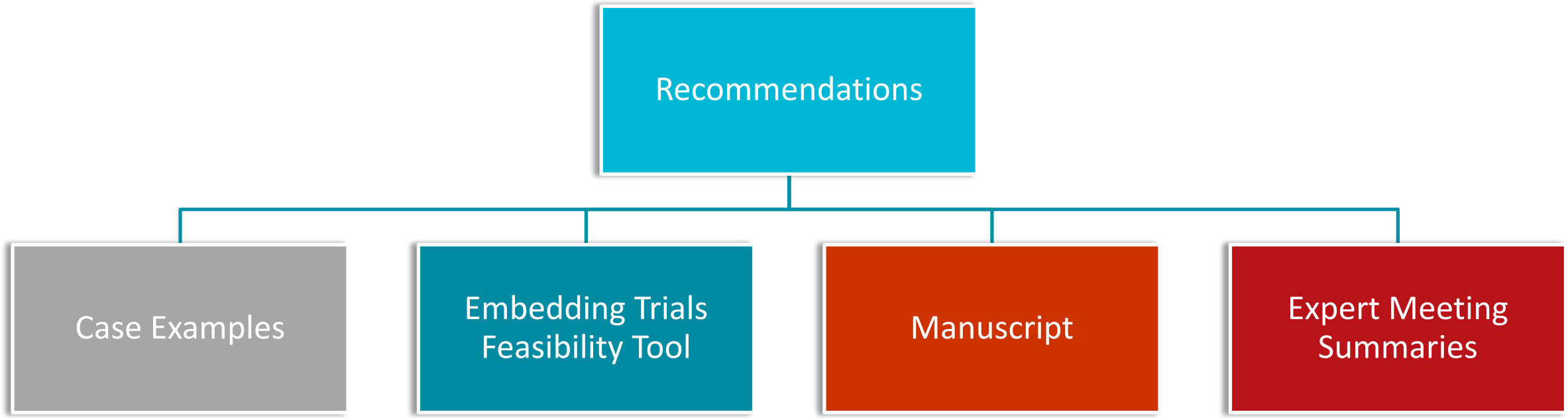
Trials in Clinical Practice (TCP)

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



Trials in Clinical Practice Recommendations

Trial Design/Methodology	Operational	Health Care & Research Culture
1. Recognize that embedding a trial into clinical practice is not all or nothing 2. Assess whether clinical trial elements should be embedded into clinical practice 3. Verify that data sources are fit for purpose –relevant and reliable 4. Streamline trial design to align with clinical workflows	5. Ensure site readiness to embed trial elements 6. Minimize participation burden for patients, providers, and research staff 7. Validate the quality of the clinical data for research purposes	8. Recognize and invest in research activities 9. Promote the basis for and ways to embed trial elements into clinical practice
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.

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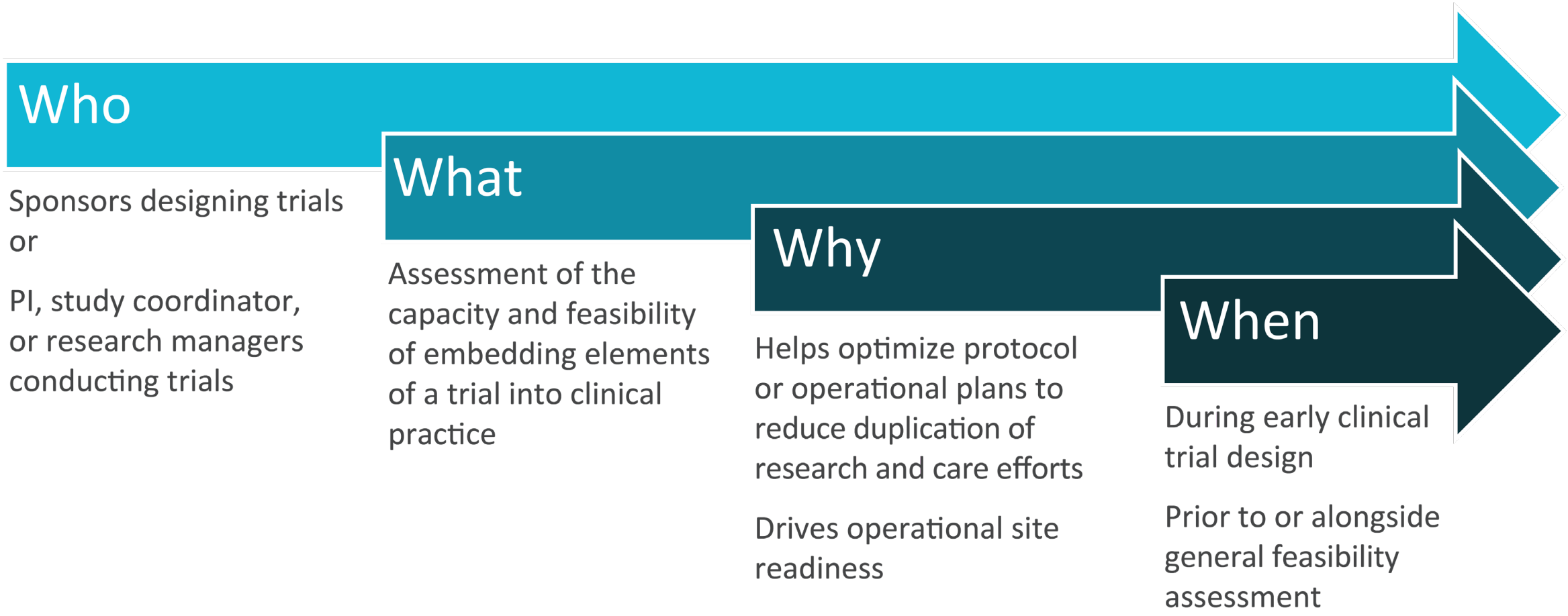
Embedding Clinical Trial Feasibility Survey



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

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Feasibility Survey User Flow

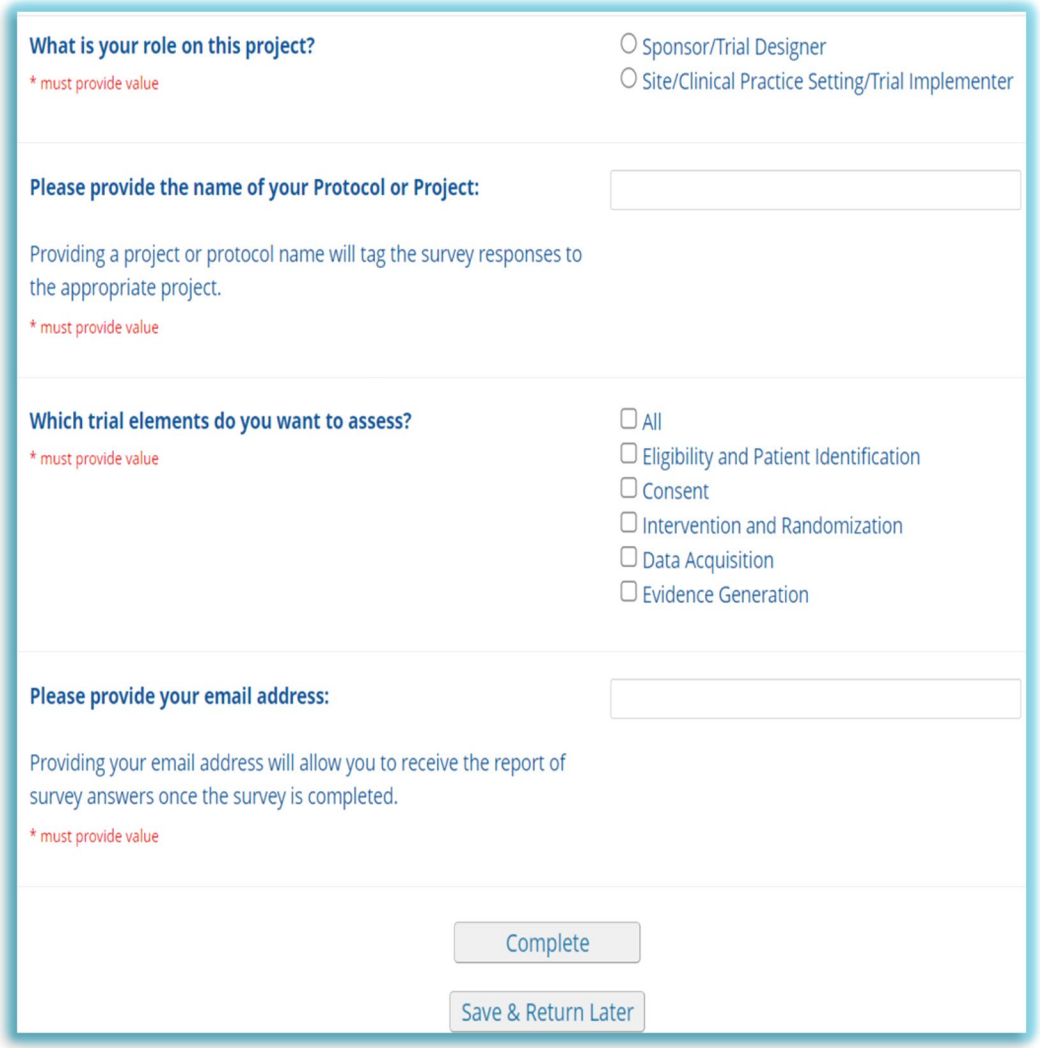
Scenario 1 Sponsor Trial Designer

Feasibility Survey User Flow

Scenario 2 Site Self Assessment

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

	Study Concept	Draft Protocol and Operational Plans	Refine Protocol & Ready Sites
WHO	Sponsor Trial Designers Project Leaders (PLs)	Sponsor: Trial Designers, Project Leaders, Site: PI, coordinators, Research Leads or Managers, IT, Patients	Sponsor: Trial Designers, Project Leaders, Site: PI, coordinators, Research Leads or Managers, Regulators
WHAT	**CTTI Resources:** 1. TCP Recommendations 2. TCP Case Examples 3. QbD Recommendations	**CTTI Resources:** 1. TCP Recommendations 2. Feasibility Assessment Tool	**CTTI Resources:** 1. TCP Recommendations
WHY	• Provide initial framework of thinking about trial design and operational plans	• Assess site capability and feasibility • Assess study feasibility: which trial elements are feasible to embed into practice	• Optimize protocol to incorporate embedded/point of care trial elements • Drive site readiness

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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

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Q&A

Thank You

Research Participants

Expert Meeting Attendees

Recommendation Advisory Committee

Tool Beta Testers & Designers

THANK YOU Trials in Clinical Practice Project Contributors

Team Leads

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Matthew Roe (AstraZeneca)

Mark Stewart (Friends of Cancer Research)

Executive Committee Champion

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David Thompson* (Open Health)

Alandra Weaver (Crohn's &Colitis)

Project Manager

Lindsay Kehoe (CTTI)

*former team lead or member

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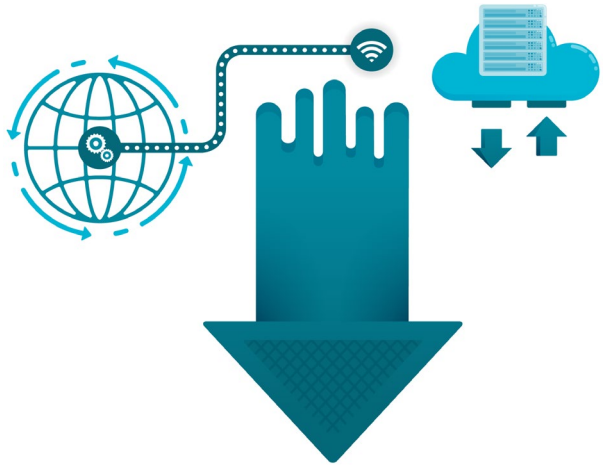
Download the Recommendations & Tool



Available Now on the CTTI website:

https://ctti-clinicaltrials.org/our-work/novel-clinical-trial-designs/integrating-clinical-care/

Share and Learn How Others Implement CTTI Resources

CTTI CASE STUDY EXCHANGE

Available Now through the CTTI website:

https://connects.ctti-clinicaltrials.org/case_study_exchange

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

@CTTI_Trials

Questions/Comments?

- Technical help with the tool: CTTI's Contact Us Page
- General Feedback: On the survey at on Contact us Page
- Contact Lindsay.Kehoe@duke.edu

THANK YOU

www.ctti-clinicaltrials.org