CLINICAL TRIALS TRANSFORMATION INITIATIVE

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Paving the Way for Embedded Trials

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CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Multi-stakeholder,
public-private partnership
co-founded by Duke University & FDA

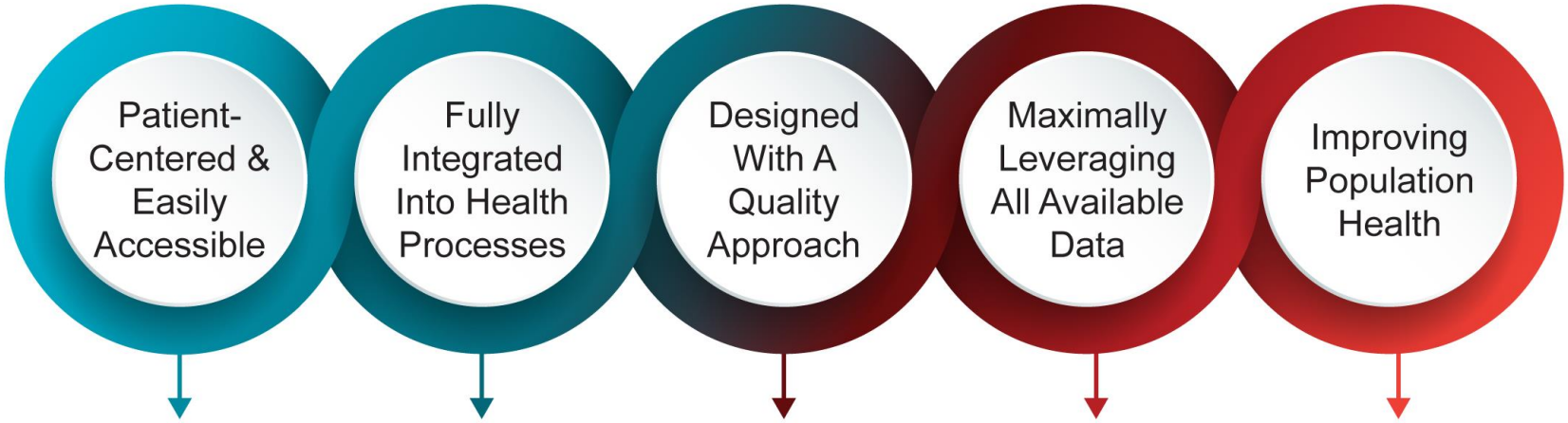
Participation of 500+ more orgs and ±80 member organizations

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

CTTI

TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System

CTTI

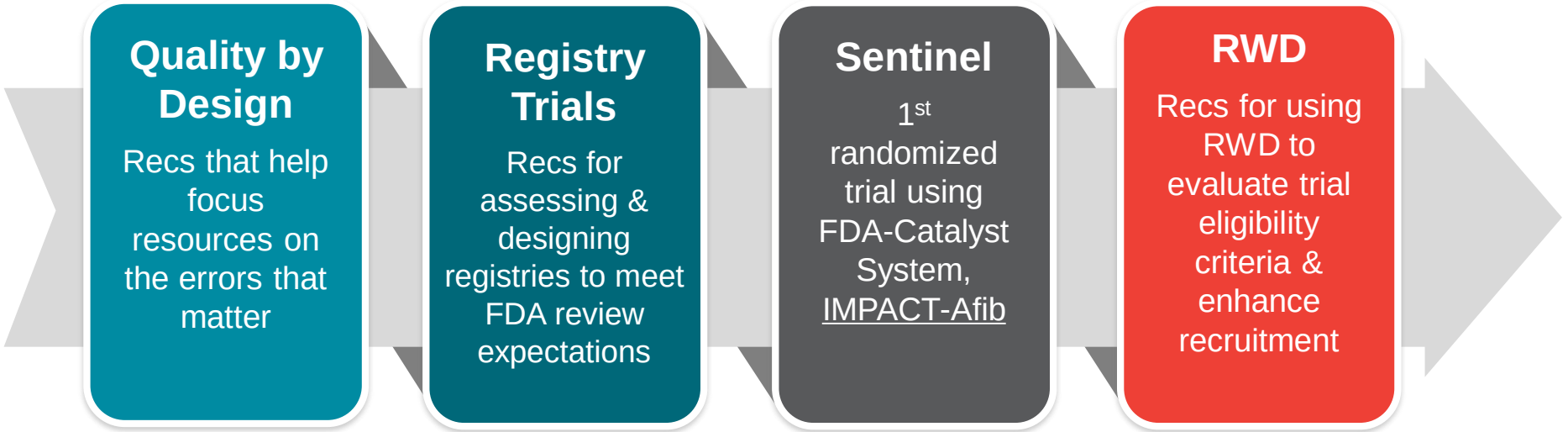
Embedded trials are:

- Integrated within health care settings
- Conducted with patients where they get their medical care
- Streamlined with clinical work flows
- Use health care data capturing systems, such as EHRs, to collect trial data

Ultimately, what is the trial purpose? What is the question to be answered?

Paving the Way for Embedded Trials

- FDA RWE Framework, NIH Collaboratory, PCORI, VA, ACTA, AHRQ
- Existing CTTI work



New CTTI Project: Embedding Trials into Healthcare Settings

The Issue:

- Traditional RCTs:
  - Typically don't collect data through integration w/clinical care
  - May not reflect the real world performance of medical products in the populations that will use them
  - May be inefficient, and expensive when they duplicate activities that already occur in clinical care
- Integrating research components into clinical care can overcome these limitations
- Clarity around how to operationalize this integration is needed.

Embedding Trials into Health Care Settings: Project Overview

- **Purpose:** Facilitate the fit-for-purpose integration of clinical trials intended for medical product review into clinical care
- **Objectives:**
  - Identify when elements of interventional clinical trial integration into clinical settings would be feasible and the associated benefits and risks
  - Identify the barriers and potential solutions to incorporating interventional trials into clinical care settings
  - Describe the operational approaches to incorporating interventional trials into clinical care settings

Project Scope

Interventional Trials

Interventional studies of drugs, devices, & biologics

Trials Meant for Regulatory Review

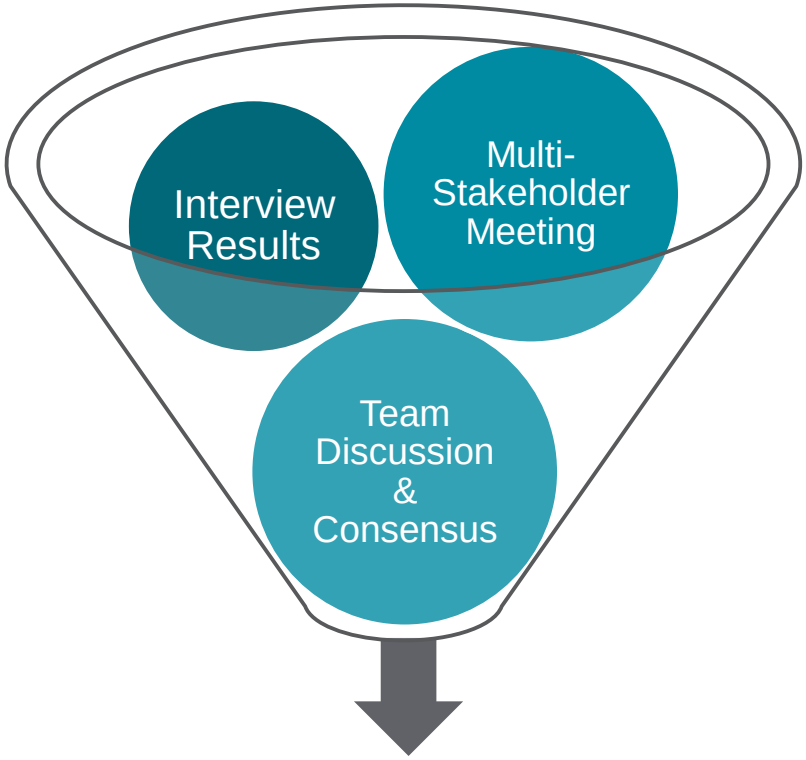
Investigational products

Products intended for a new indication

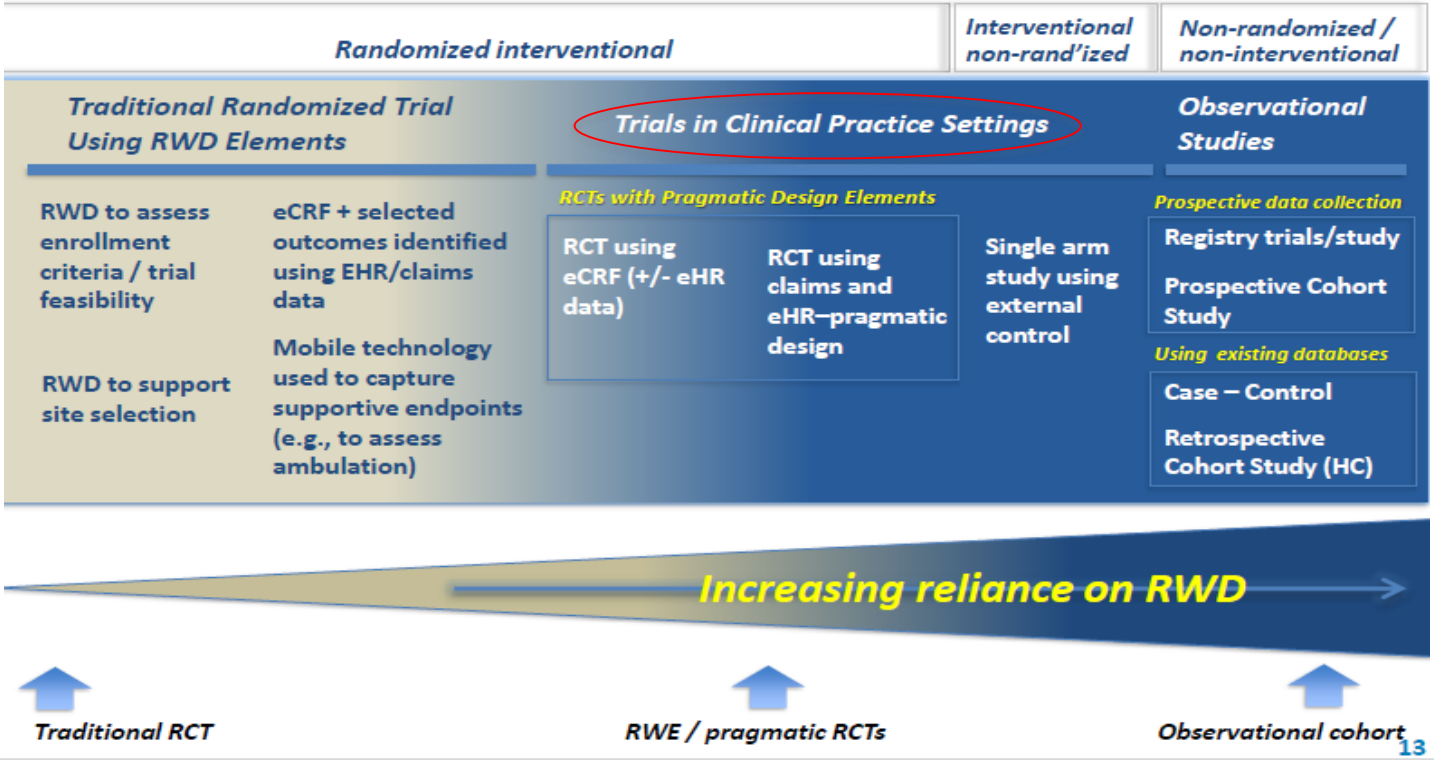
Global Perspective

Particular focus on trials with U.S. sites

Project Deliverables



Wide Spectrum of Potential Uses of RWD / RWE in Clinical Studies



https://www.fda.gov/media/123160/download | Courtesy of Peter Stein OND

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THANK YOU

www.ctti-clinicaltrials.org