Issue, Project Overview, and Meeting Objectives

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Issues to Solve

We need to:

- Support evaluation of new medical products, indications, and label changes at lower cost and participant burden than is possible with traditional randomized clinical trials (RCTs).

- Answer important questions about the benefits and risks of medical products that we can’t answer following traditional methodologies.

- Determine the use of RWD in RCTs and prospective trials
Project Overview

**Purpose:** Issue recommendations that will foster awareness and appropriate use of RWD sources incorporated into RCTs to help produce RWE.

- Initial project focus: Identify RWD/RWE opportunities in support of regulatory decision making

**Data Sources:** EHRs and payment claims
Project Methods

Dec 2017/Jan 2018: Qualitative Interviews with industry (drug sponsors and CROs), academic investigators, health systems and payers.

TODAY!!! Expert meeting with diverse stakeholders to:
- Present findings from evidence-gathering activities;
- Identify barriers and potential solutions to generating RWE for regulatory submission from RWD sources; and
- Describe what recommendations and resources CTTI should develop to equip change agents to increase appropriate use of RWD in RCTs, including to support regulatory submissions.
Anticipated Resources

- Recommendations
- Conceptual framework
- Manuscript(s)
- Considerations document for engaging regulators
THANK YOU.

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