CLINICAL TRIALS TRANSFORMATION INITIATIVE

June, 12, 2018

Issue, Project Overview, and Meeting Objectives

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Real World Evidence Project Team

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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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