Registry Trials Project Overview and Scope

Stephen Mikita, JD
Project Manager

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Best Practices to Increase Registry-Based Trials

- Target Problem Areas in Clinical Trials
- Identify Solutions
- Formulate Recommendations
- Gather Evidence
- Build Consensus
- Change
The Issue—Registry Trials Project Plan

Demographic, disease and outcome data collected in clinical observational registries at times may overlap with data needed to support traditional clinical trials.

As a result, integrating clinical trials within observational data registries could offer valuable opportunities to:

1. avoid duplicate data collection,
2. increase operational efficiencies and
3. decrease clinical trial costs.

However, questions exist about how to:

1. identify appropriate registries,
2. ensure data quality/comparability,
3. meet regulatory/legal requirements,
4. protect privacy/security, and
5. clarify the processes needed for implementation.
Scope of Project

- The Registry Trials Project focuses on using clinical registries in the context of prospective registry-embedded trials to support traditional pre- and post-marketing trials.

- Other large data sets (e.g., EHRs, and Comparative Effective Research) fall outside the scope of this project.
For the purposes of Registry Trials Project, an adapted version of the EMA’s definition of registry is being used:

- “An organized system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition or exposure. A registry can be used as a data source within which studies can be performed. Entry in a registry is generally defined either by diagnosis of a disease (disease registry) or prescription of a drug, device, or other treatment (exposure registry).”

  - Source: EMA: Guideline on good pharmacovigilance practices (GVP).
Project Objectives

1. Identify **essential elements** of registries needed to successfully embed and conduct registry based clinical trials

2. Determine **requirements** to utilize a registry for a clinical trial

3. Identify **regulatory requirements** for using registry data for regulatory purpose

4. Describe **barriers** to the conduct of registry-based trials and leverage learning from **successful trials**

5. Recommend **best practices** for conducting registry-based trials
Why are we doing this?

ANTICIPATED IMPACT OF THIS PROJECT

Increase the use of registries to facilitate high quality clinical trials at lower costs!
Thank you.

Steve Mikita
steve.mikita@duke.edu