

# Registry Trials Project Overview and Scope

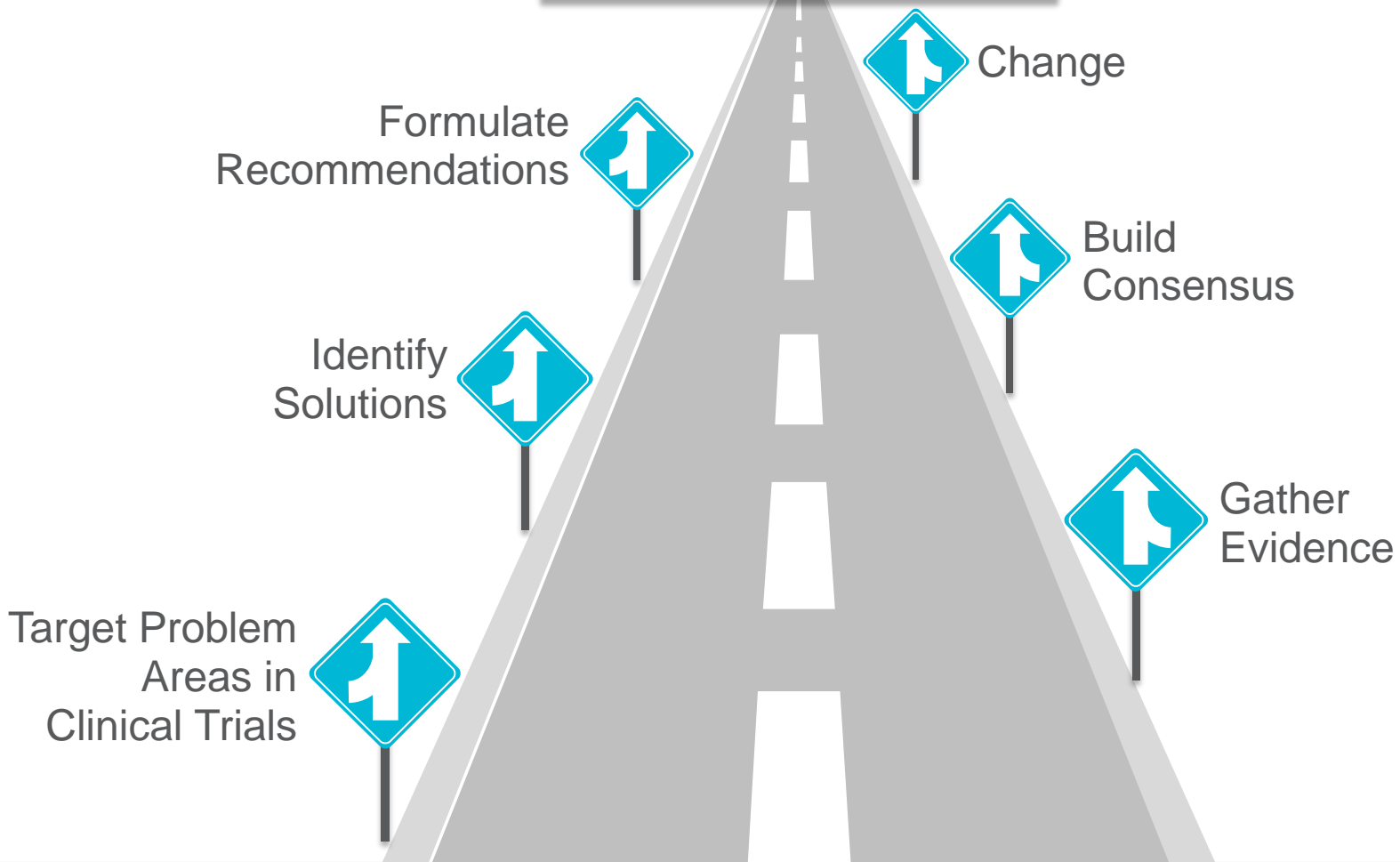
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# Best Practices to Increase Registry-Based Trials



Formulate Recommendations

Change

Build Consensus

Identify Solutions

Gather Evidence

Target Problem Areas in Clinical Trials

# 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.

# Definition of Registry

- ▶ 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.



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