Registry Trials Project Overview and Scope

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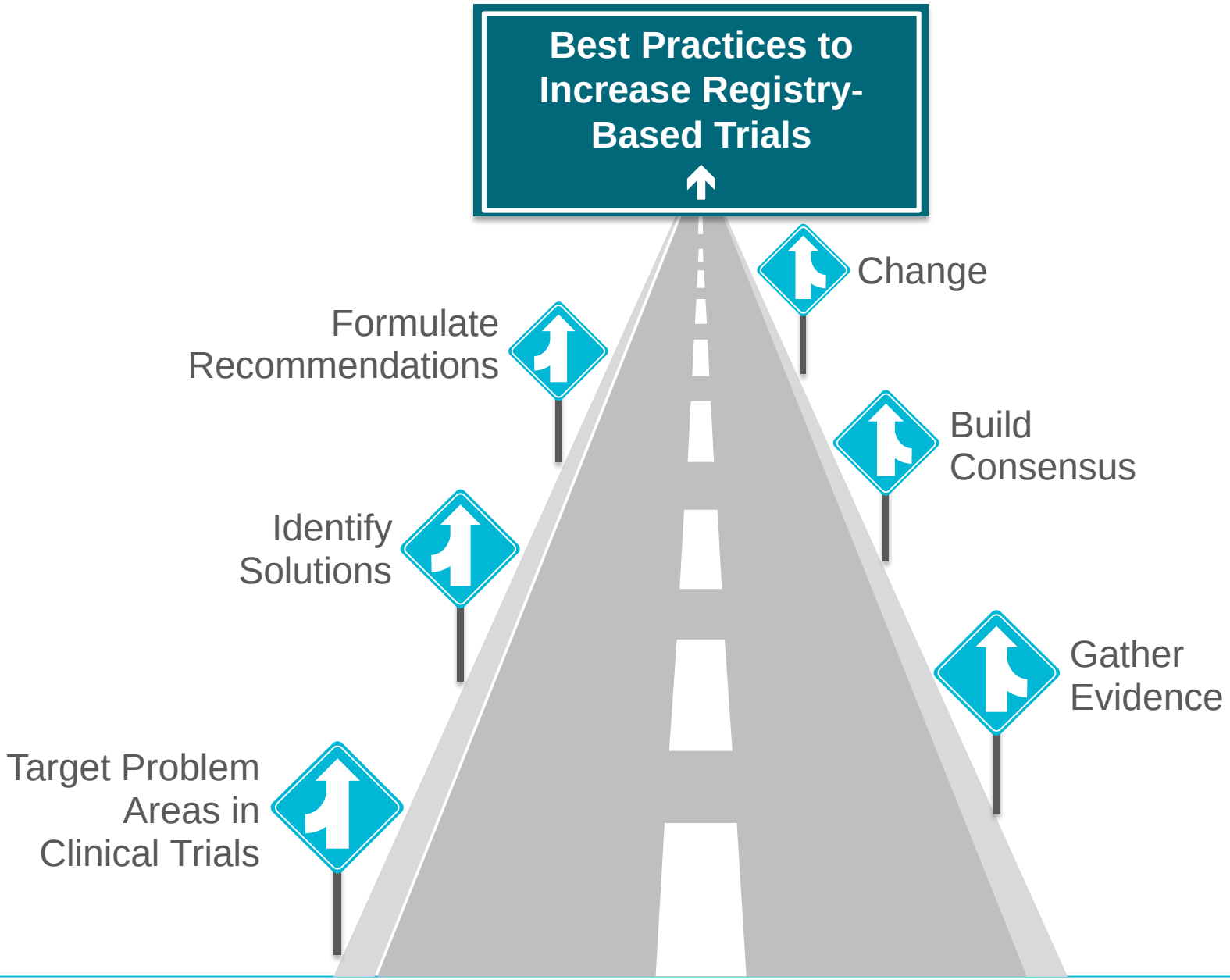
CLINICAL TRIALS **TRANSFORMATION** INITIATIVE


Best Practices to Increase Registry-Based Trials
Change
Formulate Recommendations
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

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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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