


# Methodology to Improve Diversity and Representativeness in Clinical Trials

**General / overarching**  *Applies to all five stages of clinical trials*

## Methodology Strategies



- Build team with diversity and representativeness expertise
- Advocate for diversity and representativeness
- Analyze portfolio and identify gaps

**Define** **1** Analyze Portfolio Create Portfolio Strategy Propose Concept



- Develop preliminary forecast of subpopulations
- Discuss subpopulation barriers and brainstorm solutions

**Review** **2** Shape & Refine Concept Prioritize Concept Evaluate Proposal



- Build funding to bridge gaps for subpopulations
- Review inclusion and exclusion criteria

**Design** **3** Refine Protocol Refine Informed Consent Plan Accrual & Operations



- Review any new inclusion and exclusion criteria (refinement)
- Prepare final forecast (refinement)
- Develop accrual plan
- Select and solicit sites based on subpopulations
- Build supplemental funding to bridge gaps for study participants (refinement)

**Implement** **4** Activate Trial & Execute Accrual Plan Execute Protocol Operations Conduct Data & Safety Monitoring Modify Protocol as Needed



- Check accrual progress and develop countermeasures
- Reach out to experts

**Share** **5** Analyze Data Publish Results Develop Outreach Plan Disseminate Findings



- Determine audiences, media, and messaging for sharing
- Share results (with patient participants, survivor communities, clinicians, and general public)

This training applies the methodology above for improving diversity and representativeness in clinical trials. This methodology should be calibrated to the specific trial both in terms of the activities being applied and the rigor to which each activity is taken.

ADAPTED FROM THE NCI INFOGRAPHIC: *HOW ADVOCATES SUPPORT THE CLINICAL TRIAL LIFE CYCLE*