

Building A Clinical Trial Diversity Plan

Explore the 5 steps:

Step 1



Overview the Disease or Condition

- Assess the pathophysiology of a disease across different populations
- Evaluate any varying use of available prevention, screening, diagnostics, or treatments

Step 2



Describe the Development Program

- Assess how study design, population, eligibility criteria, endpoints, and geographic locations may impact inclusion of underrepresented populations
- Identify any differential pharmacologic findings associated with certain populations

Step 3



Set Enrollment Goals

- Specify goals for enrollment of underrepresented participants
- Justify planned enrollment goals

Step 4



Build an Action Plan

- Identify operational measures to enroll and retain underrepresented participants
- Define planned use of data to characterize safety, efficacy and dose
- Define metrics to ensure goals are being met
- Define what actions will be taken if planned enrollment goals aren't met

Step 5



Update Status

- Discuss the status of meeting enrollment goals
- If enrollment goals are not met, discuss the plan and justification for collecting data in the post-marketing setting