Methodology to Improve Diversity and Representativeness in Clinical Trials

<table>
<thead>
<tr>
<th>General / overarching</th>
<th>Applies to all five stages of clinical trials</th>
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<tbody>
<tr>
<td>Define</td>
<td>Analyze Portfolio</td>
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<tr>
<td>Review</td>
<td>Shape &amp; Refine Concept</td>
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<tr>
<td>Design</td>
<td>Refine Protocol</td>
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<tr>
<td>Implement</td>
<td>Activate Trial &amp; Execute Accrual Plan</td>
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<tr>
<td>Share</td>
<td>Analyze Data</td>
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**Methodology Strategies**

- Build team with diversity and representativeness expertise
- Advocate for diversity and representativeness
- Analyze portfolio and identify gaps
- Develop preliminary forecast of subpopulations
- Discuss subpopulation barriers and brainstorm solutions
- Build funding to bridge gaps for subpopulations
- Review inclusion and exclusion criteria
- 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)
- Check accrual progress and develop countermeasures
- Reach out to experts
- 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