

Phase III Trial Diversity Plan

The FDA now requires phase III clinical trials to have a diversity plan but as yet, the requirements are vague. This framework can serve as a resource to build out a plan for diverse patient recruitment.

Goal Setting

Diversity goals should be specific to per-population incidence and mortality. In many cases, these goals may not necessarily reflect census demographic numbers.

Protocol design

Understand whether the protocol unintentionally excludes minority groups. Part of this budget can go toward a patient board for feedback.

Ensure you are asking:

- Do the I/E criteria preferentially exclude people from minority groups?*
- Does the trial methodology make it more difficult for people from minority groups to participate?*
- How would a decentralized or hybrid trial approach affect accessibility for underrepresented groups?*

Site Selection and Startup

Find sites that are primed to recruit diverse participants by taking a portfolio management approach to diversity goals. It's unrealistic to expect every site to have the same patient mix. Forecast demographics across your sites as you conduct site selection.

To set up your sites for success, consider:

- Neighborhoods that reflect disease demographics.*
- The diversity of their existing patient population.*
- The diversity of their research staff.*
- Whether they exist in a hub and spoke ecosystem with access to other populations.*
- Whether they operate outside of 9-5 hours.*
- Whether they are equipped for telehealth appointments.*
- Implicit bias training.*

Recruitment

Build a recruitment strategy based on access for underserved populations.

Your toolkit should include:

- Community engagement and outreach.*
- Relationship building with racialized patient advocacy groups.*
- Data analytics to understand which recruitment partners connect with diverse patients.*
- Online platforms that improve patient access (withpower.com is one option).*

Lifestyle Barriers

Invisible lifestyle barriers can be unexpectedly exclusionary. Broaden reimbursement tools to include:

- Reimbursement for distance traveled and time spent traveling.*
- Travel booking assistance.*
- Childcare stipends.*
- Increased coverage of medical costs for participants without insurance.*
- Emphasis on ease of physician/hospital system transfer for research participation purposes.*

Ongoing Monitoring and Analytics

- Audit which sites are on track to meet diversity goals, and which need more assistance.*
- Provide additional assistance to sites that are not on track to meet diversity goals.*