



Unlock Diversity in Clinical Trials: Top 10 Tips for Crafting a Successful Action Plan

June 2024 saw updated guidance released by the FDA in relation to diversity in clinical trials. In accordance with the latest FDA guidance, Diversity Action Plans **must**:

- Specify the sponsor's rationale and goals for clinical study enrollment (separated by the age group, ethnicity, sex, and race of clinically relevant study populations)
- Describe how the sponsor intends to meet those goals

The latest guidance also urges sponsors and investigators to consider the many dimensions of clinical trial diversity, even those that extend beyond age, ethnicity, sex, and race to enroll populations that represent the patients who will be treated if the product is approved.

Top tips for building a diversity action plan



1

Plan early and fully integrate:

Integrate diversity considerations early in the clinical development process. Define enrollment goals for underrepresented populations at the beginning of the study design phase.

Understand disease epidemiology:

Analyze the disease's epidemiology across different racial and ethnic groups. Use this data to set realistic and meaningful enrollment targets that reflect the disease's impact on these populations.

2



3

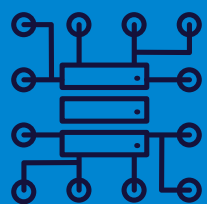
Support inclusive study designs:

Ensure that your study designs, eligibility criteria, and endpoints support the inclusion of diverse populations. Consider geographic locations and community engagement strategies to enhance participation.

Utilize diverse data sources:

Leverage various data sources, such as published literature, real-world data (RWD), and social determinants of health (SDOH), to inform and justify your enrollment goals. This helps address potential challenges in setting goals based on limited epidemiological data and race and ethnicity categories following the Office of Management and Budget (OMB) standards.

4



5

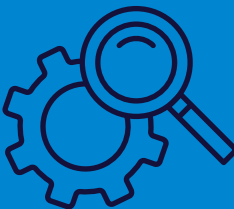
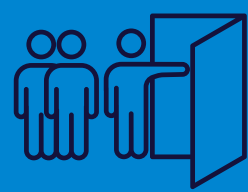
Provide accessible study locations:

Select study sites that are accessible to diverse populations. Ensure the sites are located in areas with high concentrations of underrepresented racial and ethnic groups.

Address potential barriers to participation:

Identify and mitigate barriers to participation, such as cultural differences, mistrust of the medical system, and logistical challenges. Tailor your recruitment and retention strategies to address these specific issues.

6



7

Monitor and adjust recruitment efforts:

Establish metrics to track enrollment progress and be prepared to adjust strategies if goals are not being met. Continuous monitoring and proactive problem solving are crucial to maintaining diversity in participant enrollment.

Engage with the FDA early and often:

Discuss your diversity plans with the FDA early in the development process and seek feedback during milestone meetings. Keep the FDA informed of your progress and any adjustments to your plan.

8



9

Practice transparency and encourage feedback:

Communicate with participants about the study's goals and progress. Provide regular updates and seek feedback from the community to improve ongoing and future recruitment efforts.

Partner with expert data providers and consultants:

Form strategic partnerships with reputable data providers and consulting services specializing in epidemiology, demographic analysis, and clinical trial diversity. These experts can offer valuable insights, advanced analytics, and tailored strategies to enhance your diversity action plan. They can help identify underrepresented populations, refine recruitment tactics, and ensure compliance with regulatory requirements. Leveraging their expertise will not only streamline the execution of your plan but also increase the likelihood of achieving diverse and representative clinical trial enrollment.

10



Learn more about how Citeline can help you identify and reach a diverse patient population for your clinical trial at Citeline.com

LEARN MORE