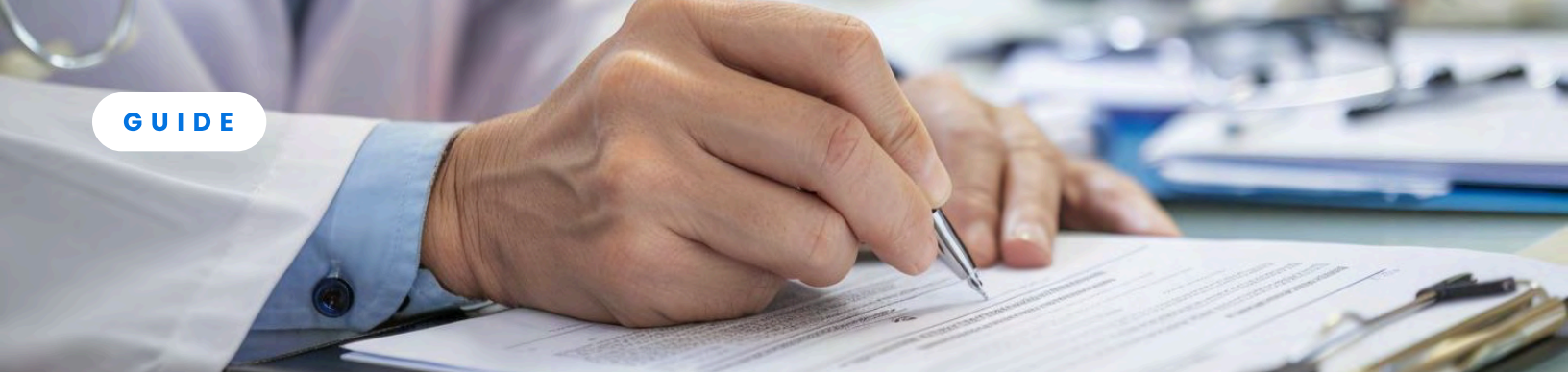
GUIDE

A Practical Approach to Building Diversity into Clinical Trials Using Purpose-Built Sites

Achieving diversity in clinical trials is critical to ensuring safe, effective therapies and equitable health outcomes, as well as fostering trust in healthcare research. Increasingly, planning for diversity is also a key component of regulatory compliance, as agencies such as the US Food and Drug Administration (FDA) issue guidance on ensuring that studies reflect the populations that will use the approved drugs and medical devices.

Strategic site selection is a key component of any plan to build diversity into a clinical trial. Partnering with sites that have proven diversity and implementing targeted interventions and communication strategies at the site level can help break down barriers to participation and create more inclusive trials.

In this guide, we explore the regulatory initiatives driving diversity in clinical trials and discuss strategies for building diversity with a focus on incorporating sites that have been purpose-built to encourage participation by underrepresented populations.



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Regulatory framework

While there are currently no regulatory mandates for diversity, there is strong encouragement and a growing body of guidance for enhancing representation.

US

The FDA has been working to address long-standing disparities in clinical trial representation since the FDA Modernization Act of 1997, which required demographic subgroup analyses for safety and efficacy in drug approvals. In 2020, the FDA issued guidance on Enhancing the Diversity of Clinical Trial Populations—Eligibility, Enrollment, and Trial Designs, providing sponsors with nonbinding recommendations to broaden trial participation by removing unnecessary exclusion criteria, using inclusive recruitment strategies, and partnering with community groups and healthcare providers to reach underrepresented populations.

Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA issued a draft guidance that would require sponsors to submit a Diversity Action Plan (DAP) for certain clinical trials. In June 2024, the FDA updated this draft guidance to better assist sponsors in meeting the requirements for DAP submission.[1] This current version places a strong emphasis on the role of the sponsor in meeting diversity goals and expands the focus of diversity to include more comprehensive measures such as socioeconomic status and geographic location. Release of the final guidance is expected in June 2025.

> "Many trial sites are geographically inaccessible to underrepresented populations, creating significant barriers to participation."

EU

While the FDA has been at the forefront of promoting clinical trial diversity, other regulatory agencies are also pushing for greater inclusion. The European Medicines Agency (EMA) has adopted regulations and guidelines which emphasize the need for inclusive enrollment strategies to ensure that study populations are representative of the broader patient demographic. In the UK, the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA) instituted a three-year strategy to promote diversity, equity, and inclusion (DEI). As part of this strategy, the agencies issued a draft guidance encouraging, but not mandating, consideration of diversity from the earliest stages of development with a plan similar to the FDA's DAP.

Challenges to achieving diversity

Achieving diversity in clinical trials presents several challenges. Many trial sites are geographically inaccessible to underrepresented populations, creating significant barriers to participation. Research has also shown that there is a racial gap in trust in medical research, and perceptions of unfair treatment in healthcare due to historical unethical medical practices, inequities in resource availability, and racial discrimination are increasing. In addition, socioeconomic factors, including lack of transportation, childcare, and scheduling flexibility, often prevent individuals from participating. Language and cultural differences further compound these challenges, as potential participants may find trial materials and communications inaccessible or alienating.

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Building diversity into clinical trials

Ensuring diversity, equity, and inclusion in clinical trials requires a multifaceted approach:

1 | Strategic site selection

Site selection is a critical determinant of success in any clinical trial. Purpose-built study sites offer a solution to achieving diversity. Strategically locating sites in diverse and underserved communities ensures that participants can access them more easily. Employing culturally competent staff trained in sensitivity and inclusiveness creates a welcoming environment for participants from various backgrounds.

2 | Proactive community engagement

Proactively engaging with local communities to build trust and awareness about clinical research expands the pool of patients who are informed about—and interested in—participating in studies. Partnering with established community and religious leaders or healthcare providers who are already trusted by underrepresented populations can help to establish standing and open minds to the opportunities of study participation.

3 | Tailored recruitment strategies

Recruitment must be intentional and tailored. Outreach campaigns should be designed to resonate with underrepresented populations and address their specific concerns. This involves not only translating materials into multiple languages but also adapting them to be culturally relevant and sensitive. Recruitment incentives, such as stipends or transportation support, can be offered to ease participation burdens, provided they adhere to ethical guidelines.

4 | Participant support

Removing barriers to participation is essential for retention. Offering free transportation to trial sites, on-site childcare, and flexible visit hours ensures that participants can take part without undue disruption to their daily lives. Community health workers or patient navigators can also play a critical role by guiding participants through the process and addressing their concerns.

5 | Staff training

Rigorous training in cultural competency, unconscious bias, and effective communication enables site staff to connect with potential clinical trial participants. This includes simplifying medical jargon and providing clear explanations about the purpose, procedures, and potential risks and benefits of a clinical trial to make it more accessible. Diverse teams that reflect the participant population can also help to create a more inclusive environment and improve trust.

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CASE STUDY:

Enhancing access and diversity with purpose-built sites

Background

To evaluate whether establishing de novo sites in communities with underrepresented populations would impact clinical trial diversity, Alliance Clinical built a database of individuals with an interest in participating in clinical research, with a focus on underserved groups. This database was used to narrow down potential geographies for establishing de novo sites in racially diverse metropolitan areas. Locations with existing clinical research sites were excluded. Feasibility of the remaining areas was assessed based on proximity to a local hospital and confirmation of population demographics.

Seven sites were established in California, Nevada, and Texas, with the purpose of multiple measures of demographic diversity, including race, ethnicity, and age. Following establishment, specific media targeting and communications channel strategies were used to recruit African American, Hispanic/Latino, and other diverse audiences to participate in Phase 1-4 clinical trials across multiple therapeutic indications.

Racial demographic information is collected for all studies that these sites participate in. On an ongoing basis, Alliance Clinical's in-house call center makes over 1,000 outbound calls per day and more than 700 patients are prescreened per month.

In Alliance Clinical's participant database, more than **85%** are from underrepresented populations.

Results

Alliance Clinical's database includes more than 250,000 consented, prescreened participants. Within this database, more than 85% of participants are from underrepresented populations and over 20% are aged 65 and older.

Alliance Clinical sites have participated in 50 vaccine studies in 5 years. Across these studies, the racial demographic breakdown among enrolled participants was 50% African American and 30% Hispanic/Latino.

Five of Alliance Clinical's sites are participating in an ongoing study of diabetic peripheral neuropathic pain. As of August 8, 2024, these sites have been responsible for 37% of total enrollment. Across the entire study, approximately 20% of participants are Black or African American. In contrast, among the participants enrolled by Alliance Clinical sites, over 40% are Black or African American.

Conclusion

Increasing diversity in clinical trials is critical for enhancing representation and ensuring the generalizability of study results. However, effective diversification often remains elusive. At Alliance Clinical, we have found that intentionally establishing de novo study sites in communities with underrepresented can positively impact clinical trial diversity. Recognizing that study participation remains relatively low among underrepresented groups that carry a disproportionately high burden of chronic diseases, it is essential for sponsors to strategically select site locations to maximize racial, ethnic, and age diversity. It is also important to implement initiatives designed to increase study awareness and access among groups that have historically been underrepresented in—or alienated from—clinical research.

It is expected that, by June 2025, diversity action plans (DAPs) will be mandatory for all phase 3 and pivotal clinical trials and sites will be the cornerstones of delivering diversity in the role as hubs for study recruitment and participation. Intentionally establishing sites in strategic locations with underrepresented populations can increase participation by specified racial and ethnic populations and may help improve the strength and generalizability of clinical trial evidence.

To learn more about how Alliance Clinical sites can support your clinical trial, contact us.