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Does your **Clinical Trial Enrollment** Meet Today's **Diversity Standards?**

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To say that 2020 was a year of disruption may downplay the facts. Yet, the events also helped illuminate long-standing issues, raising them in the public consciousness in ways that now demand action. As the inter-relationship of race, socioeconomic status and healthcare outcomes began making international headlines, achieving clinical trial diversity has surfaced as a priority in successful trial conduct. Fortunately, there are readily available technological solutions that help ensure compliance.

Why Aren't Clinical Trial Populations More Diverse?

The fundamental premise of diversity in clinical trials seems obvious on the surface: If a prospective therapy, diagnostic, vaccine, or medical procedure is meant to be used on everyone suffering with a certain disease, then its safety and efficacy should be proven in a correspondingly diverse population. Yet, historically, clinical trials have not employed that breadth of inclusion. Among the myriad reasons:

- Standardized eligibility criteria used as a template across trials may exclude certain populations from trials without strong clinical or scientific justification.

- Relying on a consistent group of lead investigators and Centers of Excellence, sponsors inadvertently limit access to trial participation.

- Many minorities have a deep mistrust of the healthcare system due to historical mis-steps, which leads to recruitment challenges.

Despite these challenges, experts agree that the pandemic could mark a turning point for diversity in clinical trials. Our trial participants deserve it; regulatory bodies are demanding it; technology is enabling it.

US Regulatory and Industry Bodies are Looking for Diversity in Trials

In November 2020, the U.S. Food and Drug Administration published some new recommendations: Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry. They state that broadening eligibility criteria and adopting more-inclusive enrollment practices should improve study quality in three critical ways:

- Ensure that the study population is more representative of the population that will use the drug if the drug is approved
- Facilitate the discovery of important safety information about use of the investigational drug in patients who will take the drug post-approval
- Increase the ability to understand the therapy's benefit-risk profile in phase 3 drug development across the patient population likely to use the drug in clinical practice

The Pharmaceutical Research and Manufacturers of America followed suit with a four-point set of principles on clinical trial diversity:

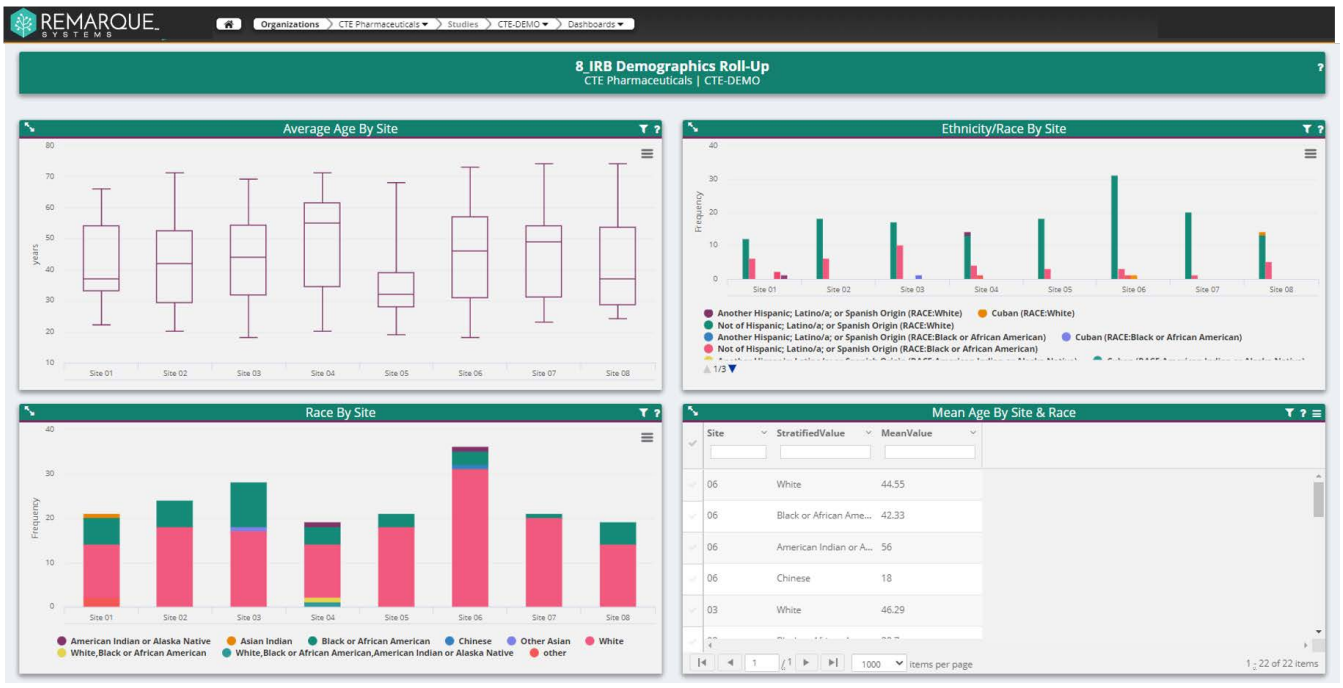
- Build trust and acknowledge the historic mistrust of clinical trials within BIPOC communities
- Reduce barriers to clinical trial access
- Use real-world data to enhance information on diverse populations
- Enhance information about diversity and inclusion in clinical trial participation

While both sets of guidance are recommendations, not legally enforceable responsibilities, they emphatically point the way for the industry.

Concrete Steps for Overcoming Homogeneity in Trial Populations

Clearly, sponsors and CROs need to attack this issue on multiple fronts; casting a wider net for potential recruits is not an overnight process. New metrics must be woven into studies from the very beginning, broadening eligibility criteria and targeting study sites in areas with diverse populations—even when that requires training new investigators. Concurrently, Centers need to rebuild trust among potential trial participants; one way is through patient-centric groups that engage the stakeholder community, helping them understand that their trial participation advances the overall research into that particular disease.

Yet, no matter which strategies are employed, study personnel also need to understand and track how successful their efforts to diversify enrollment are—not just anecdotally but in real numbers. Technology can help.



Consider Remarque's Demographic Roll-up. A single screen centralizes up-to-the-minute reports, detailing patient age and ethnicity by site, geography, study, or even CRA. The study team can program the desired levels of diversity—for instance, 50% minorities and 25% >65 years old—then assess their success in achieving those percentages at a glance. Critically, this technology also alerts the team when the desired level of diversity is not being met, so that they can take action to address the situation.

The first step in moving forward is to know where you stand. This technology provides absolute insight.

Taking a Stand: Making Certain that Trial Populations Reflect the Total Population

As the crucial importance of diversity in clinical trial populations rises to the fore of public consciousness, the industry itself is taking a stand. Urged by the expectations of regulatory bodies and their own moral compasses, pharmaceutical companies are seeking ways to ensure that the population in their studies mirrors the entire population who hope to benefit from those studies. With technology, they are able to measure and monitor their success.

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