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INSIGHT BRIEF

Five Ways to Be More Inclusive in Clinical Research: Perspectives from a Multi-Stakeholder Panel

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Introduction

The global pandemic put a spotlight on a problem that has existed in healthcare and clinical research for years: communities of color face higher rates of illness and death due to insufficient access to quality care. Trends supported by decades of data show that clinical trials are still made up of predominantly white participants, even when a condition largely impacts diverse populations.

In the most recent annual Drug Trial Snapshot report from the US Food and Drug Administration, African Americans represented just nine percent of trial populations, and Hispanics 18%, while white people represented 72% of these populations.

This lack of diversity in research makes it difficult to conduct a robust analysis of drug safety and efficacy. That puts Sponsors at risk of making assumptions about drug effect based on the majority, with not enough analysis across diverse populations.

This problem requires attention, innovation, and collaboration across the life sciences industry.

In a recent virtual panel sponsored by Advanced Clinical entitled Improving Health Equity Through Diversified Trials, we were joined by a panel of experts to discuss the key barriers to diversity in clinical research and how we can overcome these barriers to create more inclusive clinical trials.

Through our discussion, we agreed that the lack of diversity in trials has not gone unnoticed. Regulators have been pushing Sponsors to improve trial diversity for years, and Sponsors have been trying to meet those demands.

But setting diversity goals is not enough. Unless Sponsors and CROs are willing to reexamine their entire clinical research process to find the problems in their design that are alienating diverse populations, they are never going to be able to attract and retain these communities to participate in their research.

We identified five strategies that will help Sponsors bring greater diversity to future research:

1. Make diversity a priority from the start.

Diversity is not a “check the box” activity, or a goal that can be tacked on at the end of trial planning. If it’s not a goal from the outset, many of the design decisions a Sponsor makes can unintentionally skew the trial population toward predominantly white participants and make it much more difficult to meet diversity goals.

To ensure diversity is a priority from the outset, panelist Julian Jenkins, Group VP of Development Operations and Project Management for Incyte, noted that his company requires study teams to create a diversity plan as part of every project. “We want to see their strategy for representative diversity against the census for the disease,” he said.

These plans inform every decision about the trial design, and can also inspire innovative ideas, like buying a mini-bus to promote clinical research education in certain communities and provide transportation to patients in communities of interest. “When you set the tone, you create an intent from the start.”

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2. Make diversity a part of the criteria for site selection

Site selection, and the associated subject enrollment, can make or break a Sponsor's diversity efforts. Yet few Sponsors consider this challenge with sites when making selections.

"Sponsors tend to go to the same sites over and over again because they have a track record of success with those investigators," said panelist Sheila Thorne, President and CEO of Multicultural Healthcare Marketing Group. But if these sites have entirely white staff who only speak English, if they are located in predominantly white communities, and/or if they lack the networks, outreach strategies and training to effectively engage diverse communities, they become a significant barrier to diversity.

She advises Sponsors to make diversity part of the evaluation criteria. This includes choosing sites located in diverse communities, evaluating a site's past track record in recruiting and engaging diverse populations, and reviewing diversity on their internal teams.

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She also suggested talking to Investigators about why they may be falling short to determine if the problem can be addressed. She noted that some PIs have an unconscious bias against certain populations because they assume they don't have the language skills, education, or interest to participate in a trial, or that their co-morbidities will make them ineligible. Others claim to be "open to all patients" but fail to enact recruiting strategies that engage communities of color.

Understanding why a site is failing to meet diversity goals can help them make better choices. In these cases, Sponsors can either choose sites with more enlightened and diverse teams or provide training to their preferred sites on how to communicate with, and respectfully engage with communities of color, and how to find the patients in these communities who fit the trial criteria.

3. Use technology to reduce patient burden.

Sponsors have a habit of designing clinical trial plans with only the science in mind. They choose endpoints and protocols to meet their exact data needs (and then some); they select sites based on the Primary Investigator's (PI) scientific expertise in a treatment category, and they set requirements for site visits and procedures to best support the research.

These are all relevant decisions, but when Sponsors fail to consider how those decisions affect the patient experience, they may be unintentionally driving participants away. These burdens increase for patients who live farther away, and who need to juggle work, childcare, and transportation issues.

Decentralized Clinical Trial (DCT) models can play a significant role to address this issue. The pandemic proved that it is possible to engage clinical trial participants virtually without compromising their safety or data quality. Incorporating telehealth, wearable devices, electronic consent, direct-to-patient drug delivery services, and home health support as part of the trial design can reduce the number of site visits required and minimize the burden on patients without sacrificing data. In fact, many of these tools can increase the quantity and quality of data gathered by capturing it in real time from automated devices that transmit data directly to the trial team.

To make the most of these tools, DCT elements should be factored into the trial plan from the beginning, and their selection should be based on patient and advocate feedback about what they think would make a trial more accessible.

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4. Write protocols to be more inclusive.

Protocols are not typically written to be culturally appropriate or inclusive, which can inadvertently make certain populations ineligible. For example, if a neurology study requires a participant to be diagnosed clinically depressed, and/or to have a family member who was diagnosed clinically depressed, it may alienate communities that lack access to mental healthcare. That reduces the potential for trial diversity and makes recruiting challenging and more costly.

Sponsors should work with their CROs to identify unconscious bias in protocol designs and consider how they can be written to be more inclusive. Ensuring diversity is represented during protocol development will allow for improvements in diversity considerations overall. It can also help Sponsors avoid costly protocol amendments later on down the road.

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5. Engage community leaders.

It's not enough to tell sites to recruit diverse populations. They need guidance on where to find them, which key opinion leaders and physicians to engage in the recruiting process, and what messaging, education, and channels will have the biggest impact.

Thorne referred to this as "evidence-based clinical trial recruitment." "You need to engage with organizations that have a relevant voice in the community," she said.

Those organizations should align with the demographics of the population being recruited—not just their skin tone. While Black churches and senior centers may be ideal for engaging older patients, Black fraternities and sororities will be more relevant for a younger age span, Thorne noted. "The more thoughtful you are about these engagements the better it works."

Technology should be a key part of outreach efforts to amplify the impact. Leveraging social media platforms and online communities can be a great way to connect with diverse communities. Though these early engagements need to encourage real-time, one-on-one conversations where potential candidates can ask questions and learn more about the trial. "High tech gets their attention," Thorne said. "But high touch makes it work."

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Conclusion

It can be difficult to get stakeholders to think about diversity, and to acknowledge how their own unconscious biases are getting in the way. To make these conversations more productive, "focus on the science," Thorne said. "Think about the health of people from diverse groups who we can help to live better longer lives from this research."

When Sponsors are intentional about implementing effective, impactful change, they will be able to meet their diversity goals, while gaining access to larger patient populations for their studies. That will result in faster studies and more comprehensive and inclusive data, which benefits everyone.

About Advanced Clinical

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