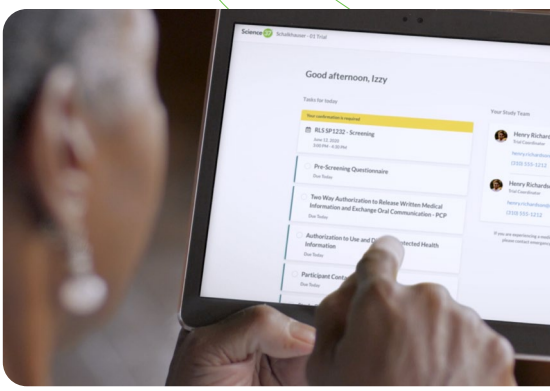
Science37

WHITE PAPER

How to Meet the FDA's Diversity Guidance—Improving Diversity in Clinical Trial Recruitment and Retention



Clinical trials are the hub of therapeutic innovation. The data they generate provides evidence critical to the efficacy and safety assessment. Regardless of the condition the research industry continually struggles to recruit and retain adequate patient representation resulting in sampling bias. Despite efforts to be more inclusive, most models fail to yield an adequate representation of diversity. One oncology study, published by JAMA, found that Participation to Prevalence (PPR) was below acceptable ranges for Black people, women, and older adults.[1]

In April 2022, the FDA released draft guidance entitled *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials*[2]. It offers recommendations to the industry on developing plans to enroll more racially and ethnically diverse participants into their trials. Specifically, the document includes recommendations for sponsors developing medical products (human drugs and medical devices) on approaches for developing and submitting a Race and Ethnicity Diversity Plan to the Agency early in their clinical development process.

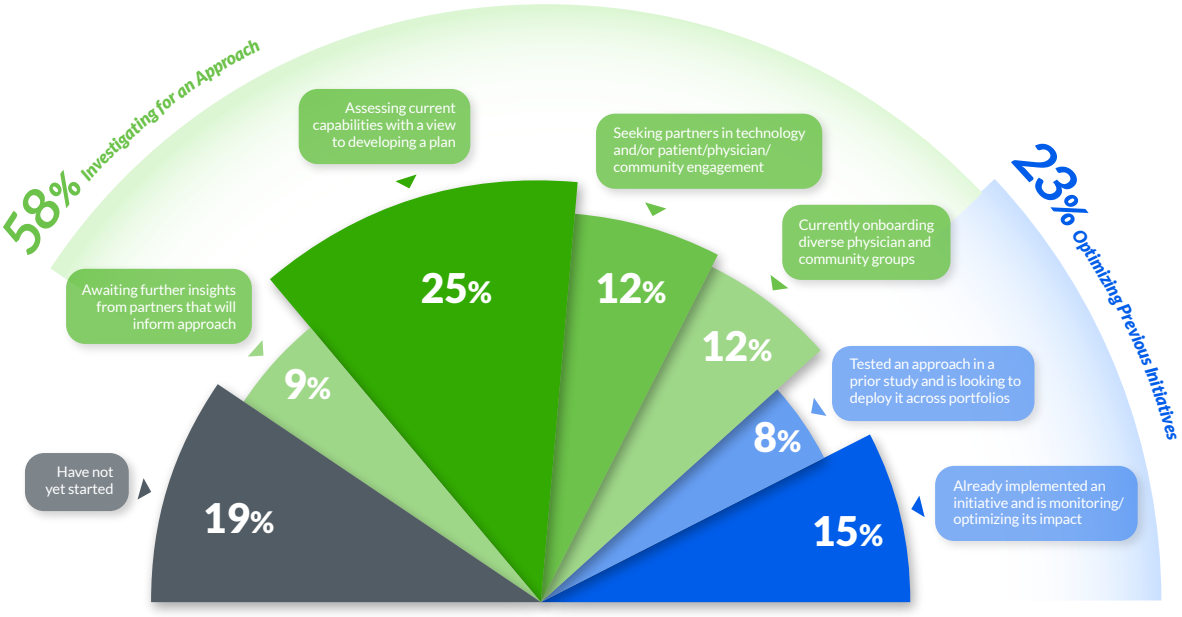
Furthermore, in June 2022, the U.S. House of Representatives passed by a vote of 392-28 the Food and Drug Amendment of 2022 (H.R.7667)[3], title V- Improving Diversity in Clinical Studies- sets up clear requirements for diversity actions plans and timelines for finalizing and/or creating supporting guidance, evaluates the need for FDA authority to mandate post-approval studies or postmarket surveillance due to insufficient demographic subgroup data as well as creating public workshops to enhance clinical study diversity. In addition, this legislation set timelines for creating draft guidance that addresses considerations for decentralized clinical studies, enrollment, and retention of a meaningfully diverse population.

These efforts to reform reveal that diversity is an urgent priority for regulators, patient advocates, key opinion leaders, and payers attempting to address unmet medical needs. To address these concerns, the clinical trial ecosystem must become increasingly adaptable and responsive to all patients' needs.

One viable option to improve access is Decentralized Clinical Trials (DCT). In the summer of 2022, Science 37 surveyed over 150 Sponsors/CROs. Data showed that 95% of those that had utilized DCT/Hybrid agreed that it can enable better diversity and started their diversity initiatives.

Sponsor State of Diversity

Source:
2022 Science 37
DCT Sponsor Survey



6 Steps to Achieving Diversity in Clinical Trials

Many sponsors mistakenly believe that diverse recruiting will add time and cost to the process. This assumption is valid only when they add diversity goals mid-stream, without reinventing the trial design or recruiting strategies. Added costs can be avoided by making diversity a part of the planning process. Sponsors must choose trial designs and recruitment methods that will help achieve those goals. A simple way to begin is by reviewing the diversity needs in your portfolios, assessing your capabilities, establishing partnerships, and continually working to improve performance.

01

Make diversity part of the culture.

Achieving diversity in clinical trials isn't a check-the-box activity. It has to impact every decision—from protocol design and inclusion/exclusion criteria, to site selection, community outreach, and the incorporation of decentralized clinical trial (DCT) elements that reduce the burden of participation. When sponsors make diversity part of study culture, they are more likely to meet goals without spending extra time or money. For sponsors who opt to outsource these activities, working with vendors that have demonstrated success in diverse recruiting can accelerate the path to success.

02

Lower the burden of participation.

For many sponsors, the approaches for improving participant convenience will involve leveraging technology. Borrowing from a consumer model, decentralizing a clinical trial empowers participants with decision-making. Remote nursing and wearable devices remove travel burden and ensure seamless participation, empowering participants to join trials with no concern of geographical limitations.

03

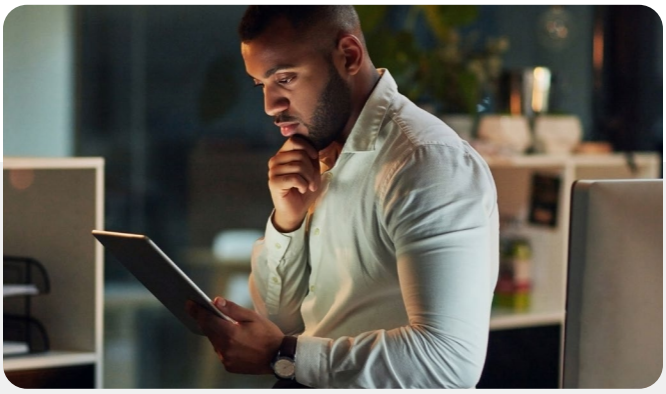
Engage the community – before recruiting begins.

Building trust and awareness is key to recruiting diverse populations. To win trust, sponsors should begin outreach efforts early to raise awareness about clinical research as a treatment option by empathetically answering questions and addressing concerns. When vetting sites, identify investigators and recruiters who understand the local culture and healthcare concerns with established partnerships in the community. Early engagement takes time up-front, but it can accelerate recruiting and build a foundation of trust in the community that will lead to better retention.

04

Make representation part of the protocol.

Establishing specific protocol requirements based on representation, incidence, and other diverse criteria makes it easier to attract and retain the right participants—providing the ability to adjust recruiting resources in response to results. For example, suppose the trial requires that Hispanic patients make up 20% of the population and that specific demographic is under-enrolling; in that case, sponsors can stop recruiting other populations to meet that 20% target.



05

Monitor and adapt.

When sponsors work with partners who can capture recruiting data in near real-time, they can track which sites are meeting goals—observing where they are falling short. Data-driven monitoring helps sponsors effectively focus their recruiting resources in ways that maximize outcomes, and proactively address shortcomings in the recruiting plan. Without such specifications, adapting recruitment to attract specific demographics becomes increasingly complicated.

06

Collaboration is key.

As a community, we encourage changing the term 'research naive' to 'research-limited' when referring to sites and providers that have historically been excluded from clinical trial participation. Research-limited institutions and providers often have trusted relationships with critical patient populations that should be included in clinical trials. To help overcome the challenge of onboarding, DCT partners often provide support and training to assist providers navigating the process. Science 37, as an example, regularly supports community-based providers by delivering the appropriate GCP training and guidance from a board-certified Primary Investigator to facilitate the shift in clinical trial conduct.

The Time for Diversity Planning is Now

When sponsors plan for diversity from the outset and make it part of every decision in the trial design and recruiting, they can meet these goals with the same budget and effort they apply to traditional recruiting efforts. Current FDA guidance may remain preferential, but it suggests sponsors will face growing pressure to demonstrate diversity in clinical research. Pioneering sponsors who adopt best practices today, and partner with experts who have a history of prioritizing diversity in clinical trials, can prove to regulators that they are ready to meet these goals.

To learn more about Science 37's approach to diverse recruiting,
visit **www.science37.com/diversity**
or email **science37@email.science37.com**

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Ryan Brown leads Science 37's Diversity in Clinical Trials business unit and also serves as a strategic advisor to the industry's first Diversity in Clinical Trials Foundation. Ryan brings more than a decade of clinical research experience from PRA, PPD and Worldwide Clinical Trials across clinical operations, business development, and strategic commercial leadership roles.

Ryan has also spent more than 15 years driving diversity and high-priority initiatives for cross-functional organizations in academia, grassroots communities and clinical research, including of CISCRP, ACRO and WOCIP (Women of Color in Pharma.)

Fritz Sevrain
Director, Diversity in Clinical Trials
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Fritz Sevrain, Science 37 Director of Marketing for Diversity in Clinical Trials, most recently comes from Clario where he served as the Director of Marketing for Imaging and Business Intelligence. Fritz has over 20 years of experience at infusing the customer voice into solution design, integrating marketing communication, and elevating the corporation's market presence. In his effort, he is partnering across the healthcare ecosystem with industry leaders and advocacy groups to elevate the underrepresented patient voices through Science 37's efforts - enhancing clinical trial diversity.

Silvia Chia
Senior Director, Regulatory Affairs
Science 37

Silvia Chia started her professional career in clinical research in 1998 before embarking upon regulatory affairs in 2000. Since then, she has worked for a variety of CROs and established a successful regulatory affairs consultancy business, providing specialized support for clinical trials covering operational and strategic regulatory affairs activities.

Silvia's clinical research experience includes phase I-IV studies with successful management of start up for large global studies in various therapeutic areas including, CNS, Oncology, Immunology, Infectious Diseases, Rheumatology as well as Paediatric Studies, NIS, Post Registry studies, Medical Devices and Decentralized Clinical Trials.

With a passion for innovation, creating new pathways in clinical research and participant-focus, Silvia has successfully managed strategic communication with global regulatory authorities, regulatory intelligence and operations supporting decentralized clinical trials.

Sources

[1] Reporting of Study Participant Demographic Characteristics and Demographic Representation in Premarketing and Postmarketing Studies of Novel Cancer Therapeutics. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8058642/

[2] Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

[3] H.R.7667 - Food and Drug Amendments of 2022. https://www.congress.gov/bill/117th-congress/house-bill/7667

About Science 37

Science 37, Inc.'s (Nasdaq: SNCE) mission is to enable universal access to clinical research, making it easier for patients and providers to participate from anywhere. Since 2014, we've pioneered decentralized and agile clinical trial approaches and having conducted more than 125 agile clinical trials, we're helping forge the future of research. The Science 37 Operating System (OS) supports today's more agile clinical research design, enabling up to 21x faster enrollment, 28% better retention, and 3x more diverse patient population. To learn more about our solutions, and how we can help you implement Agile and Decentralized Trials, visit www.science37.com, or email science37@science37.com.

