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Bridging Gaps in Clinical Trials:

Strategies for Increasing Access and Representation

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Introduction

There is widespread recognition that despite high levels of spending on health care in the United States, almost double that of peer high-income countries, health outcomes continue to lag across a wide range of disease conditions. The differences in the incidence, prevalence, treatment course, and outcomes for various diseases, across populations, are stark. These differences are caused by myriad factors, such as social needs, geography, insurance coverage, and income, as well as variations in the underlying biology that affect the risk, onset, and severity of various chronic and acute diseases. They are exacerbated by a lack of access to basic health care and innovative treatments through clinical trials for many populations that are disproportionately impacted by the burden of disease.

Since the COVID-19 pandemic, the lack of access to clinical trials and of infrastructure to recruit populations across the US into clinical trials has become a major focus for researchers and clinical trial sponsors. This increased attention reflects a growing understanding that participation across populations strengthens the biomedical innovation ecosystem by improving the generalizability of research findings, boosting confidence in treatment safety and effectiveness, and building trust in the research enterprise. Clinical trial sponsors are developing action plans detailing the incidence and prevalence of the diseases under study and enrollment goals that reflect the underlying epidemiology and disease burden across populations. Accompanied by comprehensive strategies to achieve the enrollment goals, these plans aim to increase the participation of those who are most impacted by the diseases being studied in clinical trials and to collect data that better represent the intended users of the investigational medical product.

Considering the medical and scientific imperative for representative clinical trials, FasterCures sought to identify the actions by clinical trial sponsors, sites, and others in the research ecosystem to increase enrollment of representative populations in clinical research. We also interviewed community-serving and patient advocacy organizations about their perceptions of the effectiveness of these actions. From February 2024 to November 2024, we conducted a landscape review, analyzed publications, convened a roundtable, and interviewed representatives from pharmaceutical companies, clinical research organizations (CROs), clinical trial sites, community-serving organizations, and patient advocacy organizations. This report describes our findings.

Through this report, FasterCures seeks to highlight current practices and insights from organizations actively engaged in a range of efforts to build collective knowledge and to serve as a resource for stakeholders working toward increased access and representation in clinical trials across disease areas, geographies, and populations, within the constraints of the evolving research environment and acknowledging that one-size solutions do not fit all.

Background

In the context of persistent disparities in disease risk and burden across various populations, coupled with the diverse demographics in the US, there is growing recognition and appreciation that biomedical research, including clinical trials, should engage all populations impacted by the underlying biological factors and epidemiology of diseases under study and that barriers to participation should be addressed. This movement is also driven by the rapid discovery of new targeted treatments and precision medicine modalities that are often based on specific genetic variations, biomarkers, and other disease characteristics that vary widely within and across populations. Researchers and study sponsors are increasingly recognizing that developing new treatments based on a narrow range of participants results in new therapies that are not fit for purpose to treat all populations safely and effectively.

This issue of inadequate access to clinical trials extends to Americans across a wide range of groups and geographies. According to census data, in 2020, Americans living in rural areas comprised 20 percent of the US population (more than 62 million people), yet disparities in access to and enrollment in clinical trials between rural and urban populations persist, because geographic distance remains an obstacle to participation.

Clinical trials are more accessible and available in major metropolitan areas, large cities, coastal areas, and high-income regions, and less accessible in rural and remote areas.[1] Residents of rural areas are 77 percent less likely to receive an invitation to participate in a clinical trial compared to residents of urban and metropolitan areas.[2] In many cases, rural areas and other regions with limited access to health care and clinical trials for chronic diseases such as heart disease, cancer, diabetes, kidney disease, and neurological disorders are often the same areas with the highest incidence and prevalence of these diseases. For example, in the case of Alzheimer's disease, the uneven geographical distribution of research centers in rural areas is closely tied to the high burden of the disease in rural areas.[3]

Recent reviews of clinical trial participation in therapeutic areas such as cancer and heart disease show a continued lack of representation proportional to burden of disease. One review concluded that although greater than 60 percent of cancer patients are older adults, only 25 percent of cancer clinical trial participants are over age 65.[4] Another review concluded that clinical trials for cardiovascular disease did not reflect the disease burden among women.[5]

In addition, an analysis of clinical trial participation from 2000 through 2020 found that only 41 percent of cardiology clinical trial participants were women.[6] Yet, heart disease is the number one cause of death among women in the US.[7] Pregnant and lactating people, people with disabilities, and older adults are also largely not represented in clinical trials.[8]

Recruitment efforts across populations have faced many challenges, including a lack of trust in biomedical researchers and health-care providers. Although hesitancy to participate in clinical trials does persist within some populations, overly strict inclusion/exclusion criteria, complex

protocol designs, and extensively long informed consents are among the persistent reasons for historical underrepresentation across various populations, even when they are willing participants. Bringing clinical trials closer to all populations is both an ethical and a scientific imperative in order to:[9]

- **Improve generalizability of scientific findings.** Clinical trials that include representative populations help ensure that the findings apply to populations that are most impacted by disease and those who will potentially benefit from the treatments under study. Differences in underlying disease biology and response to treatment can arise from differences in demographic factors. For example, genetic predispositions may cause individuals of different genders and ancestry to metabolize drugs at different rates, leading to variations in efficacy and adverse effects. Socioeconomic factors, such as rurality, built environments, nutrition, education, access to care, and income level, can also influence treatment outcomes by affecting individuals' baseline health; for example, studies have found that lower socioeconomic status is associated with elevated blood pressure and cardiovascular risk and with exposure to different environmental factors.[10]

- **Accelerate innovation.** Exploring the effects of treatments in different populations can also help identify new biological processes that could lead to new scientific discoveries. The discovery of PCSK9 (proprotein convertase subtilisin/kexin type 9) exemplifies how more representative clinical trials can foster innovation.[11] Insights into PCSK9's role in cholesterol homeostasis, given the role of ethnicity as a proxy indicator of genetic variance, spurred the development of PCSK9 inhibitors, a class of drugs now used worldwide to reduce low-density lipoprotein cholesterol and prevent cardiovascular disease. With representative participation in the earlier clinical trial phases, sponsors can glean key information about pharmacokinetics, pharmacodynamics, safety, and tolerability across a broad population. They can then use this information to anticipate and potentially avoid the emergence of new adverse events in the later phases that can harm subpopulations of study participants and delay drug approvals.

- **Enhance participant recruitment.** Insufficient enrollment is a leading cause of clinical trial failure. Low accrual rates were responsible for 55 percent of terminated Phase I–IV trials from 2008 to 2017, according to a 2021 analysis by GlobalData. In oncology trials alone, low accrual accounts for up to 20 percent of trial failures.[12] Improving representation in clinical trials and eliminating barriers to access can expand the pool of eligible participants and thereby increase accrual, which has implications for the speed of trial completion and clinical trial costs.

- **Develop evidence to support access to new therapies.** Clinical trial results inform drug approval, health coverage policies, and clinical guidelines. Without adequate representation, approval and marketing authorization may be limited to the population represented in clinical trials, which would carry over into coverage policies. Insurers may make additional efforts to refine the eligible population even further than the label based on study findings.[13]

Insights

Through 2024, FasterCures interviewed representatives of pharmaceutical companies, CROs, and clinical trial sites to understand their strategies to increase access and representativeness in clinical trials. We also interviewed community-serving organizations and patient advocacy organizations to understand how they see research participation changing on the ground. This section describes the findings from this research.

Move from 'Templates to Process'

Clinical trial sponsors recognize the importance of a holistic approach to biomedical research, that is, scientific evidence and disease burden are considered at every stage—from drug development to Phase III and beyond, and, in terms of individual study conduct, from protocol development and investigator and site selection to recruitment and retention. Some sponsors and sites have revisited their approach to protocol development, as representation based on epidemiological data, scientific evidence, real-world data, and disease burden has become a higher priority. Their more intentional approach includes revisions to inclusion/exclusion criteria for characteristics such as age, performance status, lab value ranges, concomitant hormonal therapies, and other criteria that have repeatedly excluded older adults, people with disabilities, and other groups.

> **"There were a lot of things that [were a] carryover from protocol to protocol, and there was no scientific rationale … there needs to be a scientific rationale for why we are excluding certain populations."**
>
> ***—Digital health and retail clinical trials leader***

For example, clinical trials for hematologic malignancies (blood cancers), such as multiple myeloma, often exclude patients with low absolute neutrophil counts (ANC) because of safety concerns, such as chemotherapy-induced low white blood cell counts leading to increased risks of fever and infections. However, researchers recently identified a genetic variation that causes significantly lower baseline ANC in nearly 80 percent of people of sub-Saharan African ancestry, referred to as the "Duffy-null" phenotype. This lower baseline ANC has led many oncology clinical trials to exclude people of sub-Saharan African ancestry because they did not meet protocol-mandated cutoffs for this lab value.

Upon further study, researchers determined that patients and study participants with the Duffy-null phenotype did not have an elevated risk for worsened neutropenia, fever, and infections compared to those with higher baseline ANC counts. Some sponsors have broadened the acceptable range for this lab value to mitigate unnecessary exclusion of this population.[14] This example highlights the importance of genetic data collection for multiple populations and how

the use of templated exclusion criteria in the absence of population-specific data can hamper recruitment and enrollment of potentially eligible participants.

Sponsors are taking a more proactive approach to determining when exclusion criteria should be maintained for reasons of safety or scientific rationale and when these criteria can be potentially broadened to make trials more accessible.

> **"If we see that [trial criteria will] impact a certain patient population, then we may need to over-index in terms of trying to recruit and engage that population."**
>
> ***—Pharmaceutical industry sponsor***

Leverage Data-Driven Recruitment Strategies

Sponsors and CROs are leveraging multiple sources of data (e.g., epidemiological, electronic health record [EHR], and pharmacy data) to identify optimal trial sites and to pinpoint geographic areas with high incidences of the conditions under study.

> **"Electronic health records are an untapped tool. We've worked with [EHR company] to optimize messaging tailored to different cultural and linguistic groups. Many academic centers still don't leverage this capability."**
>
> ***—Academic clinical trial director***

An interviewee provided an example of using heat mapping and epidemiological data to identify areas where specific diseases are most prevalent. In the US, geographic location has become an increasingly important determinant of disease burden, incidence, prevalence, access to health care, and treatment outcomes. Focusing recruitment efforts on specific regions where disease burden is highest can not only save time and resources but also enable tailored outreach and community engagement efforts.

Another important source of information is community health needs assessments (CHNAs). CHNAs examine the factors that contribute to the health and wellness of all people within a hospital's service area.[15] The CHNA must be conducted with input from the community about their health concerns. Information in the assessments guides decisions about where to invest resources to address unmet health and social needs. An interviewee noted that the CHNA can provide insight into the major health-care needs within a community and enable a more strategic allocation of resources to develop effective recruitment programs.

Remove Logistical Barriers to Trial Participation

Removing barriers to participation requires a comprehensive understanding of the social, financial, and logistical challenges different populations face. Many sponsors and sites stress that a successful recruitment campaign cannot be launched without first addressing the factors that discourage or exclude potential participants, so that "in parallel to [their] recruitment campaign, [they can] have a pre-engagement plan in order to address these barriers before recruitment starts."

> **"You can't parachute into a community and say 'Alzheimer's is what matters,' and expect people to engage when their concerns might be clean water or access to healthy food. True engagement means meeting people where they are—partnering with trusted local organizations and addressing what's meaningful to them."**
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> ***—Health-care provider***

Strategies to address these barriers include financial and transportation support (for both trial participants and caregivers), childcare, and translation assistance. In addition, concerns such as food insecurity or access to clean water may need to be addressed to build a foundation of trust.

> **"We know, for example, there are rural populations where there may be unique unmet needs. There are physician shortages in rural populations. There are hospital closures … If we are envisioning clinical research as the care option, we've [got to] think about where a patient is learning what a clinical trial is in the context of their care, and if the hospital has closed and if the physicians are moving away to other geographies."**
>
> ***—Digital health and retail clinical trials leader***

Interviewees discussed the role of decentralized clinical trial models and modalities, including technology-based solutions such as telehealth and biometric devices, to enable participants to engage in clinical trials from their own homes. These models and modalities can reduce the logistical burdens associated with traditional site-based trials, such as travel, time commitment, or navigation of caregiving responsibilities. Options such as at-home blood draws, telemedicine consultations, and remote monitoring via wearable devices can increase participant-centricity and align clinical trials with the day-to-day reality of diverse populations.

> **"Patients have the option of going to a brick-and-mortar facility if that's the most convenient location for the study visit or coming to the private health room where there's a health-care professional who is trained to do clinical trials where that study visit can be done there or if the study warrants, a patient can have that study visit done at home. And so, the option of having blood drawn at home is something that patients in a clinical trial can opt for versus having them come somewhere else."**
>
> ***—Digital health and retail clinical trials leader***

Deploy Digital Solutions Strategically as an Enabler

Digital solutions offer promise to streamline clinical trial processes and expand access for underrepresented and underserved populations by reducing traditional barriers such as geography, mobility, and access to health care. Technology-enabled approaches have been particularly beneficial for populations with limited mobility, such as older adults or those living in areas with limited access to health-care facilities.

However, clinical trial sites and researchers quickly noted that they have been overwhelmed by offers of "free" digital solutions. The utility of digital solutions in this setting depends critically on whether they are genuine enablers that can address the specific needs of participants. In addition, digital solutions and technology-enabled tools should be one component of a comprehensive approach that also includes the strategies described above. These tools cannot replace human interactions and direct patient and participant engagement or be treated as a shortcut; rather, they should complement a well-supported and participant-centered engagement approach.

Although the integration of digital solutions offers a range of benefits, interviewees noted that it is not without challenges. Successful deployment of digital solutions requires addressing technical complexities such as connectivity, ensuring robust data privacy and security, and providing adequate support to participants who may have less experience with digital tools. Some interviewees also cautioned against over-relying on technology, which can inadvertently exclude people without reliable internet access or digital literacy.

> **"The incorporation of technology into trials brings opportunities to simplify, streamline … broaden potential subjects for enrollment. But it also comes with its complexity … I think as we've discovered over the last few years, you know [it's] easier to say [decentralized clinical trial] than to actually deliver [a decentralized clinical trial]."**
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> ***—CRO leader***

Hire a Clinical Trial Site Workforce That Is Concordant with the Population

Clinical trial sites are taking great care to hire personnel who understand the needs and norms of the populations they serve. This deliberate alignment, referred to as workforce concordance, is seen as a pathway to enhance trust, communication, and participation rates among diverse communities. The workforce has been shown to play a significant role in shaping the success of efforts to increase representation in clinical trials. Despite the benefits, several barriers impact the ability of sites to build and maintain a workforce that is concordant with the community.

Interviewees described barriers such as staff turnover and retention, resource limitations, and training gaps as factors that impact a site's ability to engage, recruit, and retain clinical trial participants. High turnover rates among site-level staff disrupt trial continuity and weaken relationships with community participants. Limited resources and insufficient training further exacerbate these challenges, particularly in areas where experienced personnel are in short supply.

> **"If we have a site that has a great relationship with the community … but doesn't have the clinical research coordinator on site … that is a huge part of what's needed. [What's needed] is the workforce staffing and the dollars to help those sites stay connected in the community [and] be able to do clinical trials."**
>
> ***—CRO leader***

Interviewees noted that retaining a skilled workforce that reflects the needs and characteristics of every community requires competitive pay, professional development opportunities, and supportive work environments. To achieve longer-term success, sponsors are approaching workforce congruence as a strategic priority that involves funding additional staff positions and providing resources to ensure that research teams remain connected to their communities.

Sponsors can invest in efforts to enhance the clinical trial workforce, such as clinical research training programs launched in partnership with pharmacy, nursing, and allied health and bioscience programs at colleges and universities. Multiple industry sponsors recently initiated programs and partnerships specific to representation in clinical trials.

Building a workforce that reflects and serves the community is not just about hiring. It is also about creating lasting relationships and embedding research teams within the fabric of the community. Interviewees mentioned the importance of ongoing support from sponsors to ensure that sites have the necessary funding, training, and infrastructure to maintain these connections.

Actionable Strategies for Study Sponsors to Increase Representation in Clinical Trials

Move beyond the "cut-and-paste" approach to protocol development. Proactively identify which inclusion/exclusion criteria should be maintained due to safety or scientific rationale and which criteria can be broadened to make trials more accessible. Leverage population-specific data to inform protocol inclusion/exclusion criteria, with a goal to avoid unnecessary exclusion of older adults, people with disabilities, and other groups.

Leverage various data sources and tools, such as epidemiological data, EHRs, pharmacy data, CHNAs, and heat mapping, to guide site selection, focus recruitment efforts, and deploy customized, community-informed engagement strategies to ensure that trials include the populations most impacted by the diseases under study.

Offer decentralized trial options, including technology-enabled solutions such as telehealth visits and remote biometric monitoring, to expand clinical trial access for people living in rural and underserved areas with limited access to health-care facilities. Wherever possible, address issues such as broadband internet access and support digital literacy training to ensure equitable access to digital trial solutions.

Invest the time in data gathering and resource allocation required to increase representation. Be intentional about the data-driven enrollment goals for each study and communicate these goals to trial stakeholders early and often. Embed disease-specific data and access-informed processes across the drug development life cycle and at every stage of individual study conduct, from trial and site-level feasibility to protocol development, investigator and site selection, recruitment, and retention.

Identify and seek to overcome barriers to trial access and participation due to social, financial, and logistical barriers, and infrastructure challenges. Conduct early assessments and pre-engagement plans to address factors such as transportation scarcity, food insecurity, lack of social services, and limited family and caregiver support. Provide financial support for site-specific travel assistance and other logistical support within each protocol to help address these barriers.

Provide funding and infrastructure support for clinical trial training and upstaffing directly to sites. Invest in efforts to enhance the clinical trial workforce through long-term partnerships with community organizations, professional schools, allied health and bioscience programs at colleges and universities, and both individual sponsor and multi-sponsor-based apprenticeships, internships, and training programs.

Conclusion

FasterCures' research is intended to add to the current dialogue around how to bring more populations into the clinical research ecosystem. This report aims to share strategies that can be readily implemented by clinical trial sponsors, CROs, and sites working within the current research landscape. The interview series primarily engaged mid- to large-sized organizations and companies with relatively well-established initiatives and long-standing community partnerships. As a result, the strategies and insights gathered here may vary in relevance and feasibility for organizations with different levels of resources, experience, and history with initiatives centering on representation and access.

Through this report, FasterCures seeks to offer practical strategies for enhancing representation in and access to clinical trials. The knowledge and learnings shared can help the biomedical research ecosystem to develop treatments that are more relevant to the real-world population with a goal to deliver trials that are accessible to people who shoulder the greatest disease burden in the US and, in turn, lead to more effective, equitable, and safer health-care solutions for all.

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