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WHITE PAPER

Diversity in Clinical Trials

Life Sciences Initiatives and Challenges in Light of the FDA's Latest Guidance

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To date, life sciences' efforts towards driving equitable healthcare have centered around access to care, early identification and prevention. Meanwhile, less attention has been given to the impact of the racial and ethnic homogeneity in trial populations. Clinical trial diversity continues to be one of the greatest challenges pharmaceutical and biotech companies face in ensuring the delivery of medicines that are effective for all people. Diverse clinical trial populations are an integral step in achieving equitable healthcare treatment.

While we understand "diversity" to be more broadly inclusive of women, disabled persons, rural populations and racial minorities, when assessing the diversity of clinical trials, the FDA focuses mostly on racial and ethnic minorities, which will be the focus of this white paper.

While efforts to improve racial and ethnic diversity in trials have increased in the last decade, disparities still remain. Although over 40% of the United States (U.S.) population is currently comprised of ethnic and racial minorities[1], often only 5 to 10% of clinical trial participants represent any minority population. This disparity is striking and exposes the non-white population to harm as a result of an uncomfortable gap of knowledge around what is effective and ineffective (or even dangerous) in minority patients.

In 2022 the U.S. Food and Drug Administration (FDA) released draft guidance[2] for the pharmaceutical industry outlining tactics and plans to improve clinical trial participation from underrepresented racial and ethnic populations within the U.S. Clinical trial diversity is not a new topic for pharmaceutical companies who have implemented strategies to address it throughout the past decade. However, as the FDA's focus has shifted to this topic, with clearer guidelines coming into view, there has been a significant uptick in pharmaceutical engagement on the topic.

This paper is a follow up to Diversity in Clinical Trials Participation: A Life Sciences Perspective focused on understanding what is being done to recruit and retain diverse trial populations from the perspective of African American/Black and Hispanic/Latinx former clinical trial participants, clinical trial coordinators and principal investigators (physicians). From that research, we learned where the gaps are and provided some prescriptive guidance on what initiatives would help increase the number of diverse trial participants.

For this paper, our research sought to understand what initiatives are being undertaken at the corporate level to improve the diversity of trials, the effectiveness of those initiatives and the impact of the FDA's guidance to improve diversity now and in the future.

Read Now

[1] US Census QuickFacts, 2023

[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

Methodology

As a first step, we conducted a thorough review of company financial documents, investor presentations and public resources to assess the state and evolution of company activities based on what is available publicly. Documents from the healthcare sector generated between 2018 and 2023 were reviewed using public sources and investor databases.

Total mentions were assessed by keyword searches for combinations of "clinical trials" and "diversity," overall trends in documents and mentions were evaluated using AlphaSense's search metrics and advanced keyword criteria were used to identify relevant materials. Only primary company documents (e.g. press releases, presentations, ESGs[3], SEC[4] filings, public calls) were included in the overall trend analysis.

Following our literature review, primary market research was conducted using semi-structured qualitative interview methodology. One-on-one 45-minute telephone interviews were conducted with pharma and biotech executives in charge of clinical trial diversity initiative design and/or execution across the U.S. The sample included 15 executives from small to large pharma and biotech companies who have served as a clinical trial diversity leader within their organization for at least one year.

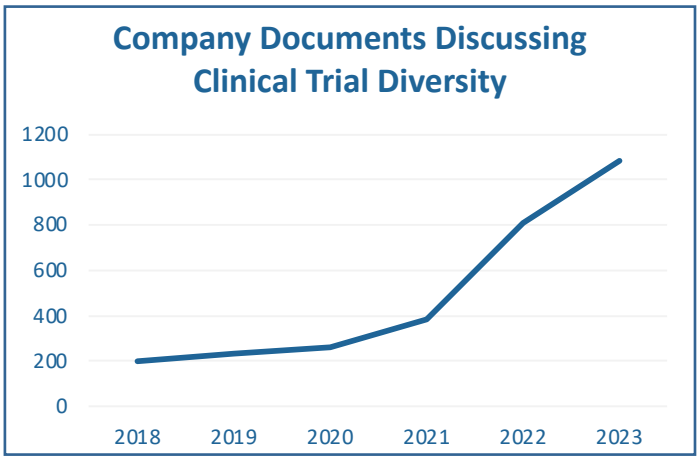
State of Industry Focus on Diversity in Clinical Trials

For our literature review we assessed company coverage of clinical trial diversity activities in the public domain and aimed to examine trends in current company engagement to understand how this landscape is evolving at an institutional level.

We found a general lack of consistency in communication and transparency in company activities related to clinical trial activities. Some companies highlight their efforts—including new initiatives, educational activities, investment in programs and revised clinical trial design but others rarely (if ever) publish anything related to their efforts. Even for companies who publicize their initiatives, little is shared on the outcomes or impact of these efforts.

Trends in Focus

Since 2018, clinical trial diversity has seen increasing representation in company documents and communication – with significant jumps in 2022 and 2023. Companies have provided increasing coverage on their initiatives and investment in environmental, social and governance (ESG) reporting and investor presentations as well as at medical conferences.



[3] Environmental, social and governance reporting

[4] Securities and Exchange Commission

Across key pharma companies a number of activities and initiatives are consistently seen within three broad categories:

1

Collaboration

- Working with multicultural communities and establishing Clinical Trial Diversity Centers of Excellence to overcome barriers to appropriate representation in clinical trials.
- Collaborating with regulators, patients, other biopharma companies and the wider healthcare ecosystem to make meaningful progress on diverse participation in clinical trials.
- Making strategic collaborations with non-profits advancing health equity in core therapeutic areas.

2

Strategic realignment

- Reviewing and updating processes and systems to capture and analyze demographic parameters such as patient race and ethnicity.
- Committing to designing clinical trials that reflect the racial and ethnic diversity of the communities they serve.
- Establishing diversity goals informed by the epidemiology of the disease.

3

Investment

- Contributing to industry partnerships to advance clinical trial diversity initiatives.
- Developing and testing diversity measurement tools.
- Building inclusive community-based partnerships that serve underserved communities.

This activity is unsurprising, given the current sociopolitical climate and the FDA focus – supporting diversity in clinical trials is no longer optional. While the FDA guidelines have not gone into full effect, it appears that many companies are proactively implementing strategies to ensure compliance.

We see big pharma leading the charge with presentations and emphasis on company engagement in diversity. For example, in June 2023, GSK hosted an investor education event focused on clinical trial diversity – which appears to be the first public presentation focused solely on the topic by a major pharmaceutical company. Not only did GSK educate investors on the topic, it provided details on research and activities supporting clinical trial diversity and a roadmap for future work.

While this is the most significant example identified during our review, it is certainly not the only effort. Across big pharma, companies have launched education pages and reviews—either on their company websites or as dedicated pages, added a focus in corporate presentations throughout the year and continued to invest in education. The most notable educational investment is at medical congresses where diversity and inclusion is a consistent topic in company presentations and education activities.

Yet, despite these strong goals, initiatives and investment by many companies, the outcomes and tangible impact remain uncertain.

Lack of Data and Consistency

It is clear that the pharmaceutical industry as a whole has committed to increasing diversity, laying out plans and targets for their clinical trials and implementing new practices to increase diversity. These practices include decentralized clinical trial design, improved guidelines and standard operating procedures (SOPs) as well as overall investment in various initiatives. However, actual reporting on outcomes remains sparse.

GSK appears to be a leader on this front, reporting that 100% of its Phase 3 trials included a diversity plan at the end of 2022[5]. More importantly it is unique in the depth of coverage it provides on its activities and metrics. GSK remains an outlier in terms of company reporting – with most companies providing high level reviews of general activities.

In the current landscape, while companies appear focused on discussing DEI activities—including education campaigns and investment or commitment to DEI – the tangible outcomes remain hazy. Companies highlight efforts without clear measures of tangible outcomes and the outcomes and impact on clinical trials remain nascent. While some report specifics (such as GSK) or financial investments, most companies are more focused on general activities and planning.

Although this trend still represents growth and a shift over the past 5 years – there remains a gap in the current reporting of actual efforts. Given the focus on these efforts and public perception of these issues, the onus should be on pharmaceutical companies to proactively share results. As we look to the future, we hope to see greater transparency from the pharmaceutical industry on their DEI activities as well as the impact on clinical trials and data. There is an opportunity for companies to catalyze change and evolve the dynamics of clinical development, but the industry must acknowledge historic challenges and approach this new environment with greater transparency and proactive engagement. We hope to see increasing depth of coverage, especially from industry leaders, to build confidence in these efforts and demonstrate commitment to increasing diversity in clinical trials.

[5] GSK ESG Performance Report 2022

Barriers to Clinical Trial Diversity

Using the findings from the literature review as the basis for the areas to explore during the qualitative interviews, we sought to interview executives from large pharma to smaller biotech's who could speak in depth to the conversations happening internally within the highest levels of their organization around clinical trial diversity efforts. We wanted to understand from their perspective not only what their organizations are doing in the name of clinical trial diversity, but also what they see as the current barriers to having diverse trial populations. What we found largely reinforced what our initial paper, Diversity in Clinical Trials Participation: A Life Sciences Perspective had shown.

Geographic Proximity and Financial Burden

The geographical landscape of both clinicians and patients plays a significant role in the level of treatment and the capacity to conduct effective clinical research. Researchers in rural areas may face challenges in accessing the same resources as those in more urban or well-established research centers. This can include limited access to funding, specialized equipment, infrastructure and potential difficulties in recruiting and retaining diverse trial populations. Additionally, rural areas may have limited access to healthcare facilities and expertise, which can impact the ability to conduct clinical trials effectively. Therefore, researchers in rural areas may need to go the extra mile to find and engage with underserved populations, often relying on community hospitals and local medical associations, with a much more limited patient population to choose from.

Trial sponsors provide an array of financial support to those who wish to participate in clinical trials to help alleviate some of the barriers to participation. These options may cover expenses like transportation, hotel stays, meals and even compensation for travel to clinical trial sites. To further support patients, especially those from underserved and diverse populations, some initiatives minimize the financial burden by reducing the number of required clinic visits and shipping medication directly to patients. The primary goal of these initiatives is to make clinical trials more accessible to patients who want to participate but may not be able to due to work and family obligations.

Focus on Diseases Impacting Specific Groups

Diversity is prioritized most in clinical trials when the disease has a disproportionate impact on a specific minority group, such as sickle cell disease, obesity and diabetes. With other conditions that impact races and ethnicities similarly there is less effort put forth to ensure diverse trial populations. Diversity quickly becomes a secondary or tertiary objective in the trial design and unless deemed "clinically relevant" (Medical Affairs, 2023). In this context, "clinically relevant" means that there would be a potential impact on efficacy and safety endpoints. This approach leads to a narrow focus on specific diseases and populations that disproportionately affect minorities, neglecting the broader need for diversity across clinical trials. Executives do recognize that diversity should not be limited to diseases that affect specific minority groups but should encompass a wide range of diseases and conditions that affect diverse populations.

As greater emphasis is being placed on diversity and inclusion in the clinical trial space, executives are becoming more cognizant of this issue, where attention to diversity was not a point of emphasis within all studies, no matter the treatment area. This broader perspective is crucial for ensuring that clinical trial results are applicable and beneficial to a diverse patient population. Including a diverse population in clinical trials ensures results are representative of the general global population, leading to more accurate and applicable findings.

Mistrust of healthcare as an institution remains a barrier

From our research, 5 out of 15 executives explicitly mention that mistrust in the healthcare system remains a significant barrier to diverse enrollment in clinical trials due to several factors. These factors include historical abuses in clinical trials and negative experiences patients may have experienced with their own medical care. There is reluctance within communities, particularly among those of lower socioeconomic status, to participate in trials due to concerns about the care they will receive and fears based on past abuses.

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One example is the impact of the Tuskegee experiments, a series of unethical clinical studies where African American male patients were not informed of their diagnosis and were not provided with appropriate treatment, even after penicillin became widely available as an effective treatment for syphilis. The lack of informed consent and withholding of treatment led to severe health consequences for participants and sparked widespread mistrust of clinical research with the African American community.

The Tuskegee experiments have left a legacy of skepticism and reluctance to participate in clinical trial research, especially among the African American community. The stories of Tuskegee live on and are still very salient in the minds of many minorities who are now several generations removed from the atrocities. Investigators will need to put in significant work to overcome the justified medical mistrust amongst minority populations.

> "There's a fundamental lack of trust in clinical research that is higher in non-white populations, particularly African American populations. The whole history of the Tuskegee trial related to syphilis has left a fundamental lack of trust, particularly among older African American individuals to participate in clinical research. So, overcoming that and overcoming other issues related to trust, takes a lot of work and effort."
>
> VP Medical Affairs, 2023

Language Barriers

Language barriers often play a significant role in the lack of clinical trial participation amongst ethnic participants. Inability to communicate naturally leads to skepticism and uncertainty. Research organizations are actively addressing language barrier concerns through translation support, geographic inclusion and developing diversity plans targeting the enrollment of diverse language-speaking populations. This includes efforts such as external recruitment with advertisements and informed consent forms in different languages and a focus on language matching for retaining patients in the trial.

> "We're ensuring that the sites that we choose have diverse principal investigators. The Hispanic grandmother that's like 80 years old, she's not going to go to a white doctor and principal investigator and feel like she trusts him if he's asking her, do you want to enroll this trial? She's going to trust in the doctor that looks like her nephew or grandson, speaks her language and understands her culture."
>
> VP Clinical Development, 2023

Tactics to Improve Clinical Trial Diversity

Companies have been employing a variety of tactics to improve the racial diversity of their trials on both macro and micro levels with various levels of success. While each strategy employed is an incremental step in the right direction, there are challenges with consistent execution that are driven by human and financial capital constraints.

To ensure successful enrollment of subjects in different regions, certain regulatory requirements must be met. Investigators are educated on the study's operational aspects and therapeutic area to ensure alignment and understanding of the goals and objectives for the intended study and its participants. Feasibility assessments are also performed to determine realistic enrollment expectations for each investigator and ongoing communication is maintained to monitor recruitment and address any under-recruitment issues.

Creation of Senior Leadership Roles in Charge of Trial Diversity

One of the clearest efforts on the part of organizations is the creation of senior level roles responsible for diversity, equity and inclusion (DEI) initiatives within trials. Individuals with titles such as Director of Clinical Trials Diversity, Senior Medical Directors and Senior Clinical Trials Managers, are directly involved in contributing to diversity and inclusion initiatives within their organizations and are at the forefront of implementing diversity in clinical trials.

These individuals serve as internal consultants, providing input and contributing to the development of diversity and inclusion policies for clinical research programs. Typically, efforts to address diversity and inclusion are not the role of a single employee but involve teams to create and execute diversity plans. There are a few major clinical research organizations that have developed internal teams of diverse staff members from different ethnic and cultural backgrounds that brainstorm ideas to increase recruitment and participation from hard-to-reach patient demographics. These initiatives underline the importance of not only the role and responsibilities of senior leadership, but entire research organizations to ensure the success of diversity and inclusion practices.

> "I have a friend who was brought into a company to help; they tried to enroll a Hispanic population with one Hispanic investigator, but they were in all the wrong areas, all the wrong cities and all the wrong states and that was number one."
>
> Senior Director Clinical Trials Management, 2023

Telehealth Visits

Using telehealth visits whenever possible for trial follow ups is one of the most common (and reasonably easy) tactics biopharma has implemented.

Post COVID, the involvement of technology and remote healthcare connections has been brought to the forefront of patient and clinician interaction. Rural communities often lack the capabilities of much larger urban populations when it comes to health equity, highlighting the importance of telehealth visits and follow-ups to a more widespread audience. While technology can be beneficial in reaching more distant areas, there are technological barriers that must also be considered:

- Unequal access to devices, as well as challenges related to training individuals on using devices such as smartphones or tablets, can further impact healthcare follow-ups
  - In the event that a research organization must provide a device such as a tablet or phone to ensure participation, device security and potential loss of devices often become a concern. These concerns can act as deterrents for research organizations recruiting populations that lack access to participation, especially in low-income communities
- Disparities in broadband service and internet access itself
- Technology literacy

Broadening Eligibility Criteria

In the U.S., the FDA and other government bodies closely examine the percentages of subjects from different racial and ethnic categories and require demographic breakdowns of clinical trial populations to ensure diversity and representation. The manner in which organizations meet racial and ethnic quotas varies depending on the treatment being studied, its prevalence in certain populations and the budget allocated to get trial participants.

In the U.S., clinical trial researchers often find it is easier to go to other nations (usually third world) to meet their diversity quotas rather than attempt to find individuals in the U.S. who are of the ethnic group. From our primary research we learned CROs recruit participants from countries like Uganda, Kenya, Tunisia, Thailand and Brazil to gather the pharmacogenomic diversity they need across certain studies. It is often easier and cheaper to find participants in third world regions to participate in clinical trials. The degree to which this practice is monitored and the ethics of it may be questionable in some circumstances, but it is just another manifestation of the limitation of human and financial capital to get diverse trial participants.

With the implementation of the FDA Clinical Trial Guidelines, clinical research organizations are being challenged to expand efforts to recruit a diverse trial population, but that does not mean they are looking solely within the U.S. population for trial diversity.

Metrics for Success of Diversity Initiatives

The success of DEI initiatives in clinical trials is broadly measured by the categorization of subjects enrolled in the trial, particularly in terms of racial and ethnic diversity. Regulatory bodies such as the FDA closely examine the percentages of African American, Native American Indian, Hispanic, Asian American and other demographic groups in clinical trial populations to measure inclusion. These agencies demand specific data on subset analyses to demonstrate safety and efficacy across different subgroups, including by race and ethnicity (VP Clinical Development, 2023). The demographic breakdown of the clinical trial population is a key metric included in all regulatory filings.

Since the development of the FDA guidelines for DEI in Clinical Trials, many organizations have taken an active role in developing their own DEI rubric to further seek more diverse populations. However, gauging the efficacy of both current and past initiatives remains a challenge. Metrics for measuring the improvement of DEI initiatives are crucial in understanding the direction in which companies are moving to impart change within clinical trials. Currently, it does not appear that companies are doing any retrospective, micro-level cost-benefit analysis to determine the payoff of their trial diversity efforts.

When asked, nearly all executives mentioned that there are currently no set measures in place to gauge the progress of all diversity and inclusive practices in their clinical trials. Although, "success" is broadly measured by the percent of minority subjects enrolled. Companies are broadly looking at the totality of their efforts but have not yet started looking more granularly at what is working and what is not.

In our conversations with executives, we found that they suspect the following types of outreach efforts yield the most success, but a lot of these initiatives require a lot of human capital (that they do not have) to execute consistently.

Grassroots Patient Outreach Efforts

Recruiting diverse populations for clinical trials requires strong relationships with local communities from collaboration with healthcare providers, community leaders and other relevant entities to educate and engage potential participants. This approach involves implementing strategic measures such as creating executive positions within research organizations and forming partnerships with academic and advocacy organizations.

Apart from the crucial role played by the executive and organizational level efforts, it is equally important to engage in grassroots initiatives that specifically target cultural events, organizations, community hot spots, social clubs and advertising through television and web-based platforms. These initiatives can significantly aid in reaching and engaging a diverse audience in clinical trials and serve as an effective way to enhance diversity and inclusion.

The Impact of CRO Make-Up on Trial Diversity

The underrepresentation of diverse healthcare professionals and researchers may also impede patients' willingness to take part in studies or clinical trials. While having clinical trial staff of the same racial or ethnic background as trial participants is seen as important for encouraging participation, clinical research organizations do not hire trial coordinators based on matching ethnic backgrounds with trial participants. Although, in our research we did find that in site selection, clinical trial staff tend to match the demographic of trial participants when the geography of the study is considered. It is easier to pre-select a region containing your target demographic of both trial participants and trial staff, than if you specifically recruit both intended samples.

However, recruiting diverse trial populations is not currently a major consideration in CRO selection and may be a limiting factor in getting diverse trial participants. Some CROs may tout their ability to recruit diverse trial populations, but some consistently fall short. Organizations often fall short because of limited understanding for the specific diversity criteria expected by the FDA, limited financial and human capital, as well as having no current criteria for measuring the success of DEI initiatives. It is expected that this ability will become more heavily weighted in CRO selection in the future given the FDA's guidance.

> "The majority of our physicians to this day are still Caucasian. We do need African Americans, Hispanics and others within our trials, because you need to have a generalizability of the disease of the drug, especially when it goes out into the market. We ask sites those questions very early on and then actually have one-to-one conversations with each of those sites prior to selection."
>
> Sr. Director Clinical Trials Management, 2023

Counselling and Education on Clinical Trials

Participating in clinical trials can be intimidating and daunting for patients who may not fully understand the process and the pivotal role of their participation. Accordingly, initiatives are being undertaken to provide education and training in targeted areas about the therapeutic area and investigational compounds. Efforts include educating underrepresented communities about the potential benefits of participating in clinical trials, providing materials approved for patient use and gaining support from local practitioners and community organizations. These efforts aim to address the lack of awareness and understanding of clinical trials and the importance of research within underrepresented populations. Within many African American and Hispanic communities, researchers are connecting directly with practitioners, social worker and patient advocacy groups bridging the gap of minority participation in clinical trials through education.

> "Patient advocacy groups have the knowledge, the reach and the insight that drug sponsors don't, and they're able to make good partners for drug sponsors to enroll studies with DEI in mind."
>
> Director Clinical Development, 2023

Perceptions & Impact of the FDA Guidance

Once we had a thorough understanding of what companies are currently doing to promote trial diversity and the challenges faced, we broached the topic of awareness and perceptions of the FDA clinical trial diversity draft guidance. What we found was that the level of familiarity with the impending FDA guidance varied, depending on whether the company's leadership has made adherence to the guidance a priority. Companies that prioritize adherence are considering the guidance's impact on trial design, by reviewing current policies and having regular discussions to ensure trials align with the guidance. Based on the current clinical trial landscape, companies that have started to prioritize clinical trial diversity are outliers, with very few companies making the conscious effort to both implement and measure diversity efforts. Companies who have not discussed the guidance at all state, they do plan to have these conversations in the future.

Macro- and micro- level concerns were found to be some of the greatest challenges in implementing diversity initiatives, including the preference for non-academic clinical trial sites, difficulty in recruiting non-white subjects and the need for resources, training and infrastructure to support diversity initiatives. Regulatory concerns and the need to meet FDA requirements for diversity in trial populations also pose challenges.

> Resources, both human and financial, were cited by 100% of executives as the biggest barriers to implementing trial diversity initiatives.

Overall, there is general uneasiness about what the guidance will be for pharma once finalized. The questions circulating among those in charge of executing these strategies are:

- Will this guidance eventually be an unspoken or formal mandate?
- How closely will companies be required to adhere to it?
- What will the impact be on the ability to bring the drugs to market?
- What will this mean in terms of resource allocation?

Anticipated Challenges with the FDA Guidance

According to our research with executives that will be tasked with being in alignment with the FDA guidance, the biggest anticipated challenges will be:

- Difficulties in obtaining pharmacokinetic-pharmacodynamic (PK/PD) data and making summarizations for underrepresented populations
  - Executives expect that summarizing differential findings from clinical pharmacology studies (PK/PD data, pharmacogenomics) that may be associated with certain racial and ethnic populations will be challenging given these studies tend to be smaller and less representative of the general population. There is not a lot of PK/PD data available in many less common disease states and/or disease states where a condition is not very common in a particular ethnic group. In more common conditions such as diabetes, obesity and heart disease this data is easy to obtain for minority populations. For more rare conditions and a lot of cancers, the data just is not there
  - The focus for the trial is on primary and secondary endpoints rather than exploratory endpoints, which include the pharmacogenomic analysis. This analysis often does not get done, or the data stays in house, so there is a lack of publicly available data around PK and pharmacogenomic studies
- Strategy implementation to educate and engage diverse populations, including efforts to address the challenges of accessing patients and the need for community-based approaches
- Meeting enrollment goals for underrepresented populations, especially when dealing with limited available data on the pathophysiology of diseases in underrepresented ethnic populations
- Repercussions for not making best efforts to meet diversity and inclusion goals, such as issues with filing and approval of clinical trials

Looking Ahead to the Future

The FDA has emphasized the need for best efforts to achieve diversity goals, but there is uncertainty about the specific repercussions if the targets are not reached. The lack of clarity has left mixed perceptions on potential impact of not adhering to the guidance ranging from no real enforcement to delays in getting drugs to market.

In summary, the FDA has made efforts to improve DEI in clinical trials through the release of guidance documents and initiatives to increase transparency and accountability. However, as currently written guidelines may be too vague and without clear penalties for non-compliance adherence will vary. Pharmaceutical companies hope for clear penalties, guidelines or standard practices outlining inclusion of diverse populations that are measurable to measure past and present diversity initiatives and improve accordingly. Without this, CROs lack the motivation to make any additional changes to DEI initiatives, unless they already emphasize diversity within their internal framework.

Looking to the future, promoting diversity in clinical trials will require continued collaboration and effort from all stakeholders involved. As the landscape prepares for the FDA guidance to become final, company investment in trial diversity initiatives will continue to be an area of focus. Our research findings make it clear that companies are thinking about how to reach diverse populations, but many are also watching and waiting to understand the FDA's enforcement.

Ultimately, the goal of diversity in clinical trials should be to ensure that all patients have access to the latest medical treatments and that health disparities are reduced. While there is still work to be done to achieve this goal, the efforts of the FDA and other stakeholders are an important step forward. By continuing to collaborate and invest in diversity efforts, we can help to ensure that clinical trials are truly inclusive and representative of all populations, leading to better health outcomes for all.

In our prior white paper (based on trial participant feedback) we recommended increasing minority representation through various means such as advertisement, media campaigns and diversifying pharmaceutical boardrooms.

While these recommendations remain relevant, from this research we would:

- Add that CROs start to play a larger role in facilitating diverse trial recruitment
- Double down on our prior assertion that community engagement (such as with churches, barbershops and social clubs) has the potential to be very successful in recruiting more minorities for clinical trials.

If companies can surmount the people and financial barriers to executing these on-the-ground recruitment tactics, there is the potential to increase minority participation in clinical trials--and also to educate these populations on trials so that we can start to overcome the still existing participation barriers.

Authors

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Monique is an experienced qualitative researcher and moderator who co-leads Trinity's Marketing Communications (MarComms) Center of Excellence. She specializes in using projective techniques and novel interview approaches to mine insights across stakeholder groups. Her 15+ years of designing and implementing domestic and global market research projects for pharmaceutical and biotech companies has enabled her to develop expertise in opportunity assessment, positioning, patient journey, and marketing communications testing. Her research interests include women's health, DEI, and cell and gene therapy.

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Lisa has partnered with life sciences clients to glean actionable insights from market research for over 15 years. As the head of the qualitative research center of excellence, she has helmed numerous insights engagements with a variety of stakeholders and across multiple TAs including novel Oncology, infectious diseases, women's health and CNS products. Patient centric work and addressing health disparities are also passions for Lisa and during her tenure at Trinity she has worked to develop innovative offerings to better understand the emotional underpinnings of the patient experience, especially those from diverse backgrounds.

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