

eBook

Increasing Diversity in Clinical Trials: A Comprehensive Guide for Pharma Companies

A comprehensive guide for increasing diversity in clinical trial research.

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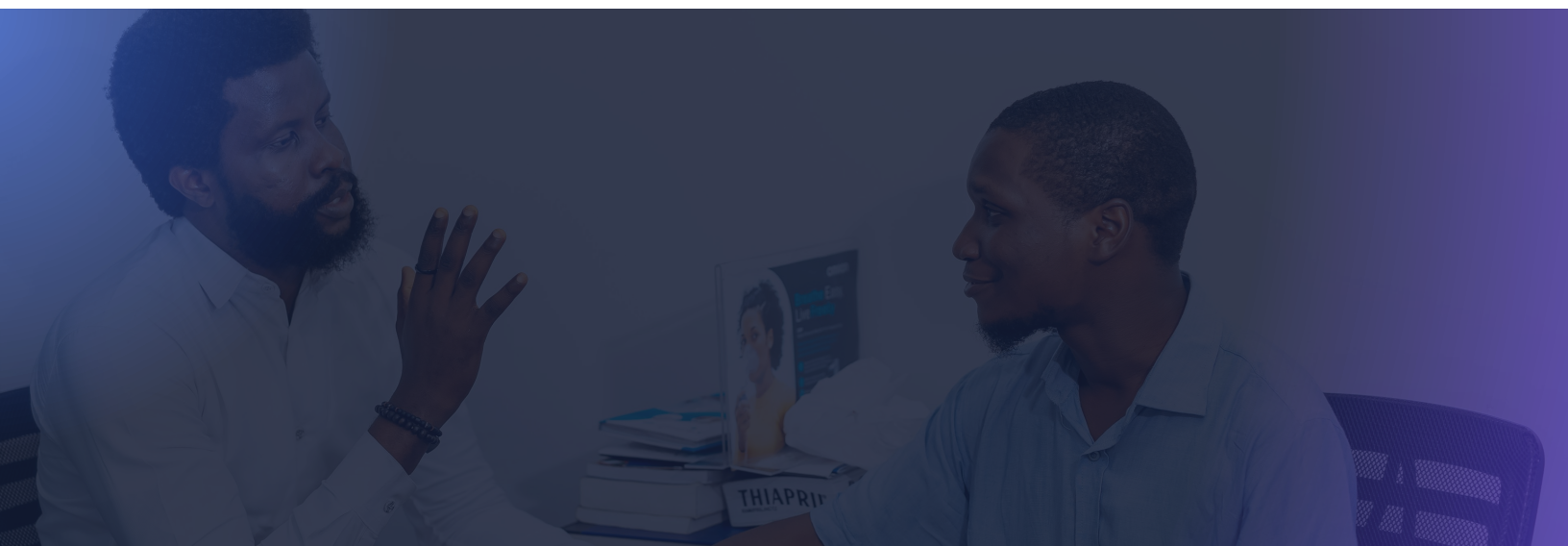
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INTRODUCTION

Clinical research serves as a cornerstone in evaluating the safety and effectiveness of medical interventions, guiding healthcare decisions for patients and providers alike. Yet, a persistent challenge plaguing healthcare is the lack of diversity among clinical trial participants, particularly within communities of color. Addressing this issue is not only a scientific imperative but also a moral and ethical obligation to ensure health equity for all individuals. The FDA took a significant step forward in 2022 by issuing guidance for pharmaceutical companies to submit diversity plans.

In this guide, we explore pivotal ways pharmaceutical companies can actively support the importance of diversity in clinical research as well as how to build the key component of affective trust – a nuanced, emotional connection that transcends surface-level assurances of participant protection – to overcome clinical trial recruitment challenges. Find out more about the profound impact of affective trust on clinical trial recruitment and participant engagement and the finer points of the FDA's latest guidance.

We'll also explore steps for building trust within communities of color, fostering genuine engagement, and leveraging innovative tools like clinical research software to drive diversity in clinical trials. Through proactive efforts to enhance representation and inclusivity, pharmaceutical companies can advance health equity, promote patient-centered research, and accelerate the development of effective treatments for all.



Chapter 1

Perspectives on Clinical Trial Diversity

Clinical research plays a vital role in assessing the safety and efficacy of medical devices and pharmaceutical products, aiding patients and healthcare providers in informed decision-making for managing health conditions.

However, a persistent issue in healthcare is the [lack of diversity in clinical trial participants](#), particularly among communities of color. This underrepresentation hampers researchers' and physicians' understanding of treatment effectiveness for diverse populations, highlighting the need for more inclusive trial recruitment strategies to improve clinical trial diversity.

Clinical Trial Diversity: What Does It Really Mean?

[The National Institute on Minority Health and Health Disparities \(NIMHD\) highlights](#) numerous factors that can influence individuals' disease development and treatment responses, such as age, biological sex, genetic variances, environmental factors, and comorbidities, among others. These factors can all be considered dimensions of diversity with potential relevance to health outcomes in both research settings and the real world.

The FDA reports that only

11%

of participants in new drug trials in 2020 were Hispanic, and only

8%

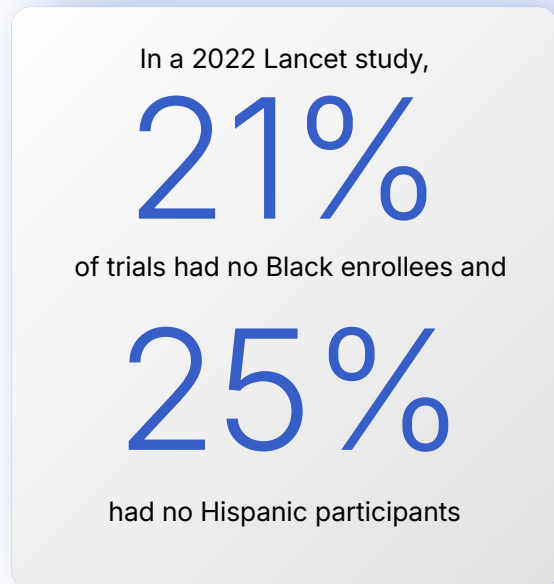
of participants were Black.

Race and ethnicity are just one dimension but an important one in the clinical trial space as historically, communities of color historically have been underrepresented in the clinical research process. [The U.S. Food and Drug Administration \(FDA\)](#) reports that only 11% of participants in new drug trials in 2020 were Hispanic, and only 8% of participants were Black, despite these communities of color making up 19% and 14% of the U.S. population, respectively. In contrast, white Americans make up 60% of the population but 75% of clinical trial participants.

Examining the data from individual trials, the picture of representation is even worse.

In a [2022 Lancet study](#), 10% of clinical trials reported enrollment that was 100% white – while 21% of trials had no Black enrollees and 25% had no Hispanic participants.

Diversity in clinical trials means adequate participation from people of different races, ages, and other demographic criteria, such that participants provide an accurate representation of the real world.



The Importance of Diversity in Clinical Trials

Clinical trial diversity is important because the results of a clinical trial reflect the population that participated in the trial. As [Harvard Medical School](#) puts it, “If [trials] only include participants from a narrow demographic group, the results may not accurately represent the broader population.” This may result in treatments that are less effective – or even harmful – to certain segments of the population.

Enhancing inclusivity in clinical trials is essential for advancing medical understanding and fostering trust between the healthcare sector and communities of color. Today’s researchers must prioritize diversity in healthcare and the importance of representation, thereby promoting equitable access to healthcare innovations and improving health outcomes for all.

“If [trials] only include participants from a narrow demographic group, the results may not accurately represent the broader population.”

Harvard Medical School

Clinical Trial Diversity: **Healthcare and Medical Research Implications**

The under-representation of nonwhite participants in clinical trials is particularly concerning when you consider the research showing that over-representation of white participants is a “stark contrast” to the disease burden in communities of color. Data from the [Centers for Disease Control and Prevention \(CDC\)](#) revealed that communities of color have a higher prevalence of obesity and diabetes than white Americans. Moreover, members of communities of color are more likely to receive a late-stage cancer diagnosis, according to the Kaiser Family Foundation. This is significant because treating cancer in its advanced stages is typically more challenging and costly, with a higher likelihood of mortality compared to treating it in its early stages.

A 2022 Health Affairs paper concluded that less than

20%

of drug trials reported data on specific treatment benefits or side effects for Black patients.

The absence of clinical trial diversity presents numerous challenges. Without representation from communities of color, researchers lack insight into how treatments will impact these specific populations. For example, a [2022 Health Affairs](#) paper concluded that less than 20% of drug trials reported data on specific treatment benefits or side effects for Black patients.

Diversity in Healthcare and the Importance of **Representation**

The [Diverse and Equitable Participation in Clinical Trials \(DEPICT\)](#) and [Food and Drug Omnibus Reform \(FDORA\)](#) Acts ushered in a new era for Clinical Trial Diversity in 2022. FDORA required that research sponsors present diversity strategies to the agency before commencing pivotal studies and importantly gave the FDA the authority to mandate post-market studies if diversity enrollment targets are not met. As a part of FDORA, the FDA released [draft guidance](#) on clinical trial diversity with specific recommendations for developing race and ethnicity diversity plans.

The agency’s guidance stated researchers “should define enrollment goals for underrepresented racial and ethnic participants as early as practicable in clinical development for a given indication,” with an emphasis on differences in safety or effectiveness associated with race or ethnicity. It can be concluded that [enhancing clinical trial enrollment and diversity](#) is more than a regulatory push.

Benefits of Diversity in Clinical Trials

- ✓ **Establish and Regain Trust**
Demonstrating trial results from diverse participant groups enhances trust among patients, increasing the likelihood of benefiting from effective treatments.
- ✓ **Cultivate Fairness**
Simplifying participation for underrepresented groups can lead to a fairer distribution of medical knowledge gains. Strategies may include recruiting from community clinics, educating in-person visit requirements, and compensating participants for their time.
- ✓ **Improve Knowledge**
Enhancing diversity in clinical trials allows healthcare stakeholders to gain insights into disease burdens in underrepresented communities and evaluate the effectiveness of treatments tailored to these populations, guiding future research directions.

Diversity in Healthcare and Clinical Research: Challenges and Opportunities

The healthcare sector has a historical trend of insufficient representation from communities of color. It often begins with the clinical trial process, where [longstanding and well-established mistrust](#) of the industry makes it difficult to recruit Black participants. The consequences of the diversity gap in healthcare and medical research can include restricted treatment choices and unfavorable clinical results for communities of color.

While addressing the issue is overdue, there's a growing momentum, to so so in clinical research, where the absence of representation can significantly affect treatment effectiveness and the development of pharmaceuticals. It is critical that medical research companies cannot underestimate the importance of building trust within communities of color as they rethink how they engage and recruit with populations that have been left on the sidelines.

A History of **Exploitation** and a Legacy of **Mistrust**

Examples of unethical treatment of communities of color by medical professionals in the United States aren't hard to come by.

The history of medical exploitation and unethical research practices has left a legacy of mistrust, particularly among communities of color. From [J. Marion Sims' experiments](#) on enslaved Black women without anesthesia to the [infamous Tuskegee experiment](#) withholding treatment from Black men with syphilis, and [Henrietta Lacks' unauthorized cell sampling](#), these instances highlight a pattern of disregard for consent and human rights. This history has led to a deep-seated mistrust among Black patients, who are more likely to fear undergoing treatment without consent or being prescribed experimental medications unknowingly. Consequently, recruiting individuals from these communities for clinical trials, which inherently involve experimentation, is often challenging.

Clinical Trial Representation: Where Do We Stand **Now?**

In 2020, the [U.S. Food and Drug Administration \(FDA\)](#) reported that only 11% of participants in new drug trials were Hispanic, and only 8% of participants were Black. These communities of color comprise 19% and 14% of the U.S. population, respectively.

The lack of representation in clinical trials contributes to health disparities, particularly in non-white populations, as practitioners lack sufficient data on effective treatment options for these groups. This is evident in the [higher prevalence of obesity and diabetes](#) among patients from communities of color compared to white Americans, as reported by the Centers for Disease Control and Prevention (CDC). Moreover, there are significant economic ramifications associated with chronic conditions, including decreased life expectancy, reduced work capacity, and increased healthcare costs. [Research from the University of Southern California](#) suggests that even a 1% improvement in clinical trial diversity could lead to substantial economic gains, estimated at \$40 billion for diabetes and \$60 billion overall. These findings underscore the urgent need to address the systemic barriers contributing to underrepresentation and to improve healthcare access and outcomes for communities of color.

Why Diversity Equity and Inclusion in Healthcare Is Vital

In recent years, there has been a notable increase in the emphasis on diversity, equity, and inclusion (DE&I) across all industries, including healthcare. This shift is not merely a business or regulatory obligation but also a moral imperative to ensure equitable care for patients of all races, ethnicities, genders, and sexual orientations. Recent events, such as the COVID-19 pandemic, have underscored the stark disparities in healthcare outcomes experienced by communities of color, who faced [higher mortality rates](#) and [lower vaccination rates](#) compared to white Americans. These disparities have brought longstanding gaps in medical services for communities of color to the forefront, particularly in clinical research where representation remains disproportionately low. Addressing these disparities requires a concerted effort across the healthcare ecosystem, spanning drug development, clinical assessment, and workforce diversity initiatives.

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The Importance of Diversity in Healthcare: **Disparities** in Clinical Outcomes

The enduring lack of diversity, equity, and inclusion in healthcare has resulted in disparate quality of services and clinical outcomes for communities of color. CDC data highlights the higher disease burden for preventable chronic conditions like [obesity and Type 2 diabetes](#) among these communities, along with elevated cancer mortality rates among Black patients due to late-stage diagnoses. Additional [CDC findings](#) reveal alarming maternal mortality rates among Black women compared to their white counterparts. These disparities are influenced by various factors, including [lower rates of cancer screenings](#), inadequate referrals for essential treatments, and [unmet needs in pain management](#), exacerbated by [barriers to accessing care](#) and pervasive bias and discrimination throughout healthcare processes. Implicit bias and racial essentialism further perpetuate disparities by impacting treatment decisions and risk assessments based on inaccurate beliefs about race-related biological differences.

Three Steps for Improving **Diversity** and **Inclusion** in Healthcare and Healthcare Research

The [American Medical Association \(AMA\)](#) has emphasized that diversity, equity, and inclusion should permeate all aspects of healthcare discourse, extending beyond frontline patient care to encompass medical education and the development of pharmaceutical products, among other areas. This includes but is not limited to frontline patient care, medical education, and pharmaceutical product development. While these conversations may be difficult, organizations can take practical steps aimed at steady and measurable improvement to affirm their understanding of the importance of diversity in healthcare and healthcare research.

1 Employ more physicians from communities of color.

The 2022 [Health Equity and Accountability Act](#) includes a provision aimed at enabling hospitals and health systems to recruit physicians from diverse backgrounds to better reflect the communities they serve. [Studies have shown](#) various benefits, including improved clinical outcomes and higher life expectancy among patients when they receive care from physicians of the same race or ethnicity.

2 Revamp clinical care pathways.

In November 2020, [the AMA](#) committed to combatting racial essentialism and proposed various strategies to promote diversity, equity, and inclusion in healthcare. These include revising clinical algorithms, collaborating with quality improvement organizations, and challenging the validity of race-based research. Disparities in access to clinical and technological resources highlight the need for nationwide advocacy efforts to ensure more equitable distribution of resources across institutions.

3 Enroll more diverse patient participants in clinical research.

A recent [paper in Health Affairs](#) found fewer than 20% of approved drugs included data on treatment benefits or side effects for Black patients, while a [Lancet literature review](#) found more than 20% of clinical trials had no enrollees from communities of color. Why is diversity in clinical trials important?

Regulatory mandates like the [Food and Drug Omnibus Reform Act of 2022 \(FDORA\)](#) underscore the importance of diversity action plans in late-stage trials. Additionally, informed prescribing decisions hinge on knowing a therapy's efficacy across diverse populations. Proactive recruitment from underrepresented communities ensures therapies meet regulatory standards and address overlooked patient needs.

Chapter 2

The Impacts of Clinical Trial Diversity on Health Equity

Health disparities persist in the U.S. For example, Black Americans face a [threefold higher risk of asthma-related death](#) than whites, partly due to ineffective asthma medications like albuterol. Similarly, drugs like warfarin and clopidogrel demonstrate varying effectiveness among different ethnic groups, highlighting the need for diverse clinical trials. However, historical underrepresentation of non-white participants in research exacerbates these disparities, underscoring the urgent need for more inclusive studies.

Five Ways Pharma Can Support the [Importance of Diversity in Healthcare](#)

The lack of diversity in clinical research not only jeopardizes patient safety by potentially prescribing incompatible drugs but also perpetuates systemic racism and neglects social determinants of health, leading to poorer healthcare outcomes for select populations in the U.S. Recognizing the significance of diversity, the FDA issued guidance in 2022, mandating pharmaceutical companies to [submit diversity plans](#). While historic barriers hinder participation from communities of color, pharmaceutical researchers can proactively dismantle these obstacles to demonstrate industry leadership. By [fostering workplace diversity](#) and implementing targeted strategies involving community partnerships and outreach, researchers can enhance inclusivity and accuracy in clinical trials, ultimately improving healthcare for diverse patient populations.

Here are five steps researchers can take to increase diversity among their clinical trial participants:

1 Partner with community organizations

[Deloitte's report](#) suggests that partnering with community organizations closely connected with communities of color is an effective strategy for enhancing diversity in clinical research. By collaborating with entities like historically black colleges or universities (HBCUs), federally qualified health centers (FQHCs), and community support organizations, pharmaceutical researchers can gain insights into community needs and preferences, facilitating more effective outreach efforts.

2 Interact with patient advocates

Engaging community organizations connects you with patient advocates, who are influential in communities of color. They address concerns and advocate research participation.

3 Develop patient-friendly educational resources

Creating clear, straightforward educational materials in languages spoken by underserved communities can help them understand the importance of participating in clinical research.

4 Implement support services for participants

Researchers can provide support services like transportation, flexible scheduling, childcare, and [fair compensation](#) to help members of underserved communities overcome logistical challenges in participating in clinical research.

5 Collect and report demographic data

Gathering and reporting demographic data is crucial for meeting diversity targets, adhering to the FDA diversity plan and [data collection guidelines](#), evaluating the success of efforts, and positioning the pharmaceutical industry as a leader in diverse research.

The Consequences of a [Lack of Diversity](#) in Clinical Trials

Successful clinical research hinges on meticulous preparation, particularly as pharmaceutical companies pivot towards prioritizing diversity in participant recruitment. Neglecting innovative strategies to enhance trial diversity could lead to delays and potential financial or reputational setbacks. Heightened awareness of the

consequences of inadequate diversity underscores the urgency for pharmaceutical firms to adapt their approaches accordingly.

As pharmaceutical companies begin to change their processes to prioritize diversity and inclusion when recruiting study participants, they must be equally thoughtful about finding innovative solutions to increase clinical trial diversity. Not doing so will put studies at risk of delay and could also cause companies to incur monetary or reputational damage.

✘ A Lack of Diversity Costs Money

Failure to adhere to FDA diversity guidance could result in potential delays or denials, incurring significant financial losses for pharmaceutical developers. Disregarding diversity action plans or failing to meet demographic enrollment targets may necessitate redoing research, leading to further financial setbacks and delays in product launches. Moreover, inadequate diversity may prompt the FDA to require additional post-market research, imposing additional costs on top of initial expenses. Despite short-term concerns about investment, prioritizing inclusive clinical trial participation proves more cost-effective in the long run.

✘ Homogenous Populations Lead to Skewed Data

With the growing diversity of the U.S. population, the validity of non-diverse study outcomes diminishes, potentially leading to skewed or limited applicability of findings. This lack of diversity in clinical trials has been linked to less effective medical interventions, exacerbated health inequities, substantial economic losses, and reputational risks for institutions failing to address diversity gaps in research populations.

✘ Non-inclusive Research Perpetuates Inequality

Lastly, a failure to consider diversity exacerbates the inequalities present in the U.S. healthcare system. Treatments developed without representative research have led to health inequities in pharmaceutical interventions, such as less effective asthma treatments for African Americans or Puerto Ricans and cardiovascular disease interventions primarily based on male-focused evidence despite its impact on black women. These disparities contribute to higher disease rates and mortality among various demographics, compounded by historical distrust of healthcare institutions and limited access.

Chapter 3

Overcoming Clinical Research Challenges: Why Affective Trust Matters

Inclusive clinical research populations are crucial for successful studies, with new laws now requiring diversity action plans to boost diversity in clinical trial enrollment. However, recruiting participants from communities of color poses challenges due to historical neglect and lingering mistrust of medical researchers and institutions.

Overcome Clinical Trial Recruitment Challenges: Start with **Affective Trust**

For clinical researchers who want to recruit more diverse research populations, acknowledgment of this history and establishing affective trust is key.

Surface-level assurances of participant protection are insufficient; researchers must cultivate affective trust, rooted in emotional connections and shared values, to engage underrepresented communities effectively. Affective trust, alongside cognitive trust based on logical reasoning, plays a vital role in enhancing patient engagement and participation in clinical trials.

How Researchers Can Cultivate Affective Trust

Building affective trust requires a proactive and patient-centric approach to outreach. Here are some guidelines for establishing affective trust with the communities you want to recruit from.



Proactively Engage with a Community

- Initiate contact with communities you wish to recruit from to establish affective trust.
- Participate in community events and form partnerships with local organizations like community centers and health centers.
- Connect with grassroots groups and volunteer organizations to demonstrate genuine respect for the community.



Create Clear and Transparent Communications

- Develop clear, transparent, and direct communication materials, avoiding medical jargon.
- Translate materials into languages spoken in the community and use imagery that resonates with them.
- Distribute materials in places where the community spends time, both in-person and online.



Involve Community Leaders

- Seek support from community leaders and influencers who already have trust within the community.
- Reach out to individuals involved in community organizations, healthcare clinics, and religious institutions.
- Participate in community-based groups to build connections with individuals from the target community.

Clinical Trial Recruitment Strategies that Increase Diversity

[Joanice Thompson](#) spent 35 years at the University of Alabama at Birmingham (UAB). She started in a research interviewer role and retired as the Director of Community Engagement for the UAB Division of Preventive Medicine. After retirement, she continued her work as a consultant for UAB's Minority Health & Health Disparities Research Center.

Today, Thompson is Acclinate's Adviser for Community Engagement and Partnership Building. She discusses the primary clinical trial recruitment challenges, outlines strategies for improving diversity in clinical trials, and emphasizes the importance for trial sponsors to establish and sustain partnerships within communities.

In the Birmingham area where Thompson's career was focused, nearly 70% of the population is Black and located just a two-hour drive from Tuskegee, where the memory of the infamous Tuskegee study still lingers, making people defensive at the mention of "research." However, rather than avoiding the subject, Thompson stresses that it's crucial to openly discuss what made this study (and other ones) so egregious and highlight the differences in today's clinical trials.

Education plays a vital role in addressing the consequences of the lack of diversity in clinical research and developing successful clinical trial recruitment strategies. Before diving into recruitment efforts, trial sponsors must first address fundamental health issues and emphasize the importance of tested and approved therapies in improving health outcomes. Honest conversations about personal experiences with healthcare, including instances of untimely deaths or lack of access to medical care, can help contextualize the significance of clinical trials.

Subsequently, discussions about clinical trials should focus on their purpose and the importance of testing medications to ensure they work effectively for everyone, Thompson explains. This educational step is particularly crucial in communities of color, where awareness of clinical trial opportunities may be lower compared to white individuals. Finally, only after establishing trust and providing thorough education can sponsors effectively approach individuals about enrolling in a trial.

Thompson names two strategies to improve clinical trial participation in communities of color.

1 Reach out to anchor organizations to complement clinical trial recruitment strategies

In a 2021 [report](#), Deloitte and PhRMA highlighted the growing role of community relationships in health equity initiatives. Thompson echoes this approach in what she coins "boots on the ground." Thompson has seen firsthand how effective this approach is. She emphasizes the effectiveness of a hands-on approach in engaging with communities and advises trial sponsors to actively seek out community gatherings, whether it be at churches, schools, senior centers, or other venues, to connect with residents. Building relationships with community leaders and securing their support through signed letters is crucial to establishing effective clinical trial recruitment strategies.

Once rapport is established, sponsors have anchor organizations that endorse their efforts, facilitating access to community events where educational resources can be distributed. These anchor organizations also assist in identifying and addressing potential barriers to trial participation, such as transportation issues or scheduling conflicts, thus promoting health equity initiatives. Additionally, sponsors can leverage these relationships to connect with influential community members adept at outreach both offline and online.

This is especially valuable for trials leveraging access to communities of color through platforms such as [NOWINCLUDED](#), the community engagement arm of Acclinate. Through NOWINCLUDED, people of color interact and build relationships with supportive communities while also learning about the clinical trials and health resources available to them through both in-person events and digital avenues.

2 Establish a presence in the community, increase diversity in clinical research

Given the [historical underrepresentation of communities of color](#) in clinical trials, sponsors must prioritize short-term strategies aimed at achieving participation rates reflective of the broader population. However, Thompson emphasizes the greater significance of establishing a strong community presence to overcoming clinical trial recruitment challenges. Investing in breaking down barriers, fostering trust, and educating individuals yields long-term benefits by highlighting the value of clinical trial participation for both individuals and their communities. This sustained effort ultimately facilitates easier recruitment and underscores the impactful contributions of trials over time.

Chapter 4

Building a Strong Diversity Plan

As stated earlier, the U.S. Food and Drug Administration recently updated its [guidance document](#) on collecting race and ethnicity data in clinical trials. The document updates [previous guidance](#) released in 2016 and represents the latest step at the federal level to identify what the FDA calls “population-specific signals” in medical products.

Let’s examine what these updates mean for pharmaceutical companies today.

Unpacking FDA Guidance: Diversity in Clinical Trials for Pharma

The recent FDA recommendations on clinical trial diversity are influenced by a review conducted by the Office of Management and Budget (OMB) regarding its guidelines on standardized terminology concerning factors like race and ethnicity. While FDA guidance does not carry legal obligations, it offers trial sponsors explicit suggestions on gathering race and ethnicity information to meet diversity plan criteria and regulatory submissions, as well as determining suitable product labeling.

Updated FDA Guidance: Document Diversity in Clinical Trials in a Standard Format

The Office of Management and Budget (OMB) initiated a review of its 1997 policy directive concerning the collection and utilization of race and ethnicity data by federal agencies in January 2023, prompted by significant demographic changes over the past twenty-five years. The FDA, which had previously based its 2016 guidance on OMB’s “minimum standard categories,” had already begun updating its own guidance prior to the announcement of OMB’s review.

The FDA recommends a two-question format for self-reporting race and ethnicity in clinical trials, with the ethnicity question preceding the race question. For ethnicity, individuals are provided with at least two options: Hispanic or Latino, and Not Hispanic or Latino. For race, individuals are offered a minimum of five choices: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White, with the option to select multiple designations.

Additional detailed information beyond the baseline may be necessary to further delineate communities of color by geographic region. For ethnicity, sponsors may include additional options such as Mexican, Mexican American, Chicano, Puerto Rican, Cuban, and Other Hispanic or Latino. Similarly, for race, various selections may be provided for Asian, including Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, and Other Asian, as well as specific categories for Native Hawaiian, Guamanian or Chamorro, Samoan, or Other Pacific Islander, based on OMB standards.

FDA Guidance on Uses for Data on Diversity in Clinical Trials

The FDA, echoing OMB's directive, highlights ethnicity and race as social constructs rather than scientifically defined biological distinctions, marking an overdue acknowledgment. This recognition is significant as the longstanding notion of [race as a social construct](#) has perpetuated systemic racism, particularly in medical research, clinical diagnosis, and disease treatment, among other areas.

Furthermore, the FDA underscores that both intrinsic and extrinsic factors can influence the efficacy of therapeutics and treatments across different population subsets. Intrinsic factors encompass genetic variations, skin pigmentation, and pharmacokinetics, while extrinsic factors encompass environmental conditions, dietary habits, cultural influences, and other social determinants of health.

Along these lines, when it comes to reporting diversity in clinical trials, FDA guidance offers three recommendations.



It's crucial to provide individuals with the opportunity to personally report their ethnicity and race. Researchers should refrain from reporting this data on behalf of patients, and they should not solely depend on electronic health records to obtain this information.

- ✓ The use of “non-white” is discouraged when presenting federal government data, according to FDA guidelines. Instead, it’s advised to provide detailed breakdowns of ethnicity, single-choice race, and multiple-choice race responses separately. Although distinguishing between these categories may pose challenges, it allows trial sponsors to gain comprehensive insight into the demographics of study participants.
- ✓ Trial sponsors are advised to include demographic data in their submissions for drugs and devices, as well as in product labels and prescribing information, particularly in sections concerning Clinical Studies and Adverse Reactions. While it’s probable that trial sponsors already adhere to this practice, the FDA now recommends aligning with OMB standards for capturing race and ethnicity data to ensure consistency.

The Impacts of FDORA

The FDA’s guidance on clinical trial diversity marks a significant step toward promoting representative clinical trials. This initiative builds upon historical efforts like the [NIH Revitalization Act of 1993](#) and the [DEPICT Act](#), which aimed to enhance diversity in clinical trials. [The Food and Drug Omnibus Reform Act \(FDORA Act\)](#) further reinforces these principles by requiring sponsors to submit diversity action plans and enrollment targets, with the FDA empowered to [mandate post-market studies](#) if diversity goals are not met. The introduction of FDORA and updated FDA guidance signals a shift in addressing the consequences of limited diversity in clinical trials, with potential for more severe financial penalties for non-compliance in the future.

Using Clinical Trial Services to Connect with Communities of Color

To overcome these challenges, researchers need to first reach the Black community to proactively rebuild trust.

Building an effective diversity strategy for clinical researchers hinges on establishing affective trust within communities. This necessitates direct engagement with community members, demonstrating respect, and a collaborative approach to foster trust. Connecting with respected

community organizations like the aforementioned Acclinate's [NOWINCLUDED](#) and leveraging their support to disseminate patient resources and education is crucial. Additionally, clear, honest, and transparent communication is vital, along with partnering with community leaders who can educate patients about clinical trial participation, ultimately fostering affective trust and promoting patient engagement in the pharmaceutical industry.

NOWINCLUDED Ambassadors: From the Community and For the Community

[NOWINCLUDED](#) serves as a vital resource for connecting clinical research organizations with Black community leaders, saving them time, dedication, and resources. Beyond being a digital community hub, NOWINCLUDED offers educational resources, community groups, and information on clinical research opportunities for patients from communities of color. Its ambassadors, who share their healthcare journeys and experiences with clinical research, play a crucial role in fostering affective trust through various channels such as 1:1 interactions, videos, webinars, Q&As, and in-person events.

Tamara Mobley a NOWINCLUDED ambassador, was diagnosed with [multiple myeloma](#) 14 years ago. Now, she gives back by sharing her treatment journey with members of NOWINCLUDED support community.

"I really wanted to provide hope, provide a space for people to see themselves," Mobley says, explaining why she chose to become a NOWINCLUDED ambassador. She shares her experiences via videos, question-and-answer sessions, and personal discussions with other individuals coping with multiple myeloma.

Through discussing her story, Mobley assists individuals similar to herself in comprehending how to manage this condition, which has a disproportionate impact on Black patients. This includes furnishing them with resource materials and educational insights.

Growing Clinical Trial Enrollment with Authentic Relationships

Mobley's journey exemplifies the transformative power of building affective trust for clinical trial services. She emphasizes the profound impact of shared experiences in fostering genuine trust among individuals. Leveraging this trust, Mobley offers invaluable insights into managing multiple myeloma to a receptive audience that

resonates with her background and challenges. "There really is something about shared experiences that lends to a level of trust," she says.

A significant aspect of Mobley's guidance addresses the unique challenges faced by younger Black women coping with multiple myeloma, a perspective often overlooked in conventional medical resources dominated by older, predominantly white patients. Through NOWINCLUDED, Mobley recounts forming a meaningful friendship with another woman who reached out to her after watching a video on the platform. "Someone saw my video on the NOWINCLUDED page and reached out to me directly to have a conversation," Mobley says. This connection evolved into regular conversations where they exchange information and support, underscoring how Acclinate facilitates real-life connections beyond mere educational content. "It's one thing to watch a video, but I think Acclinate actually connects the dots in real life," Mobley adds.

With the support of NOWINCLUDED and Acclinate ambassadors like Mobley, barriers to clinical trial participation within communities of color are being dismantled. These initiatives not only facilitate greater diversity in clinical trials but also empower individuals to navigate healthcare with confidence and advocate for their needs effectively.

Improving Your Diversity Strategy and Action Plan with Acclinate

Patient communities come together through NOWINCLUDED around genuine desires to share healthcare-related support.

"You want to do things to impact your community, and Acclinate makes it easy for me to do that because they already have a built-in audience, a platform," Mobley shares. "I have a voice to empower and to help people be advocates for their own health. I'm so appreciative of the NOWINCLUDED community."

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Tamara Mobley | NOWINCLUDED ambassador

The collaborative harmony between various components drives Acclinate's efforts in enhancing diversity within clinical research. Essentially, the journey towards better health equity in pharmaceuticals initiates well before clinical trials commence.

Building trust is the foundational step in diversifying clinical research that can support other efforts, such as leveraging clinical research software and predictive analytics.

How Can Clinical Research Software Improve DEI for Clinical Trials

Despite the life sciences industry's efforts to enhance diversity in clinical trials, there's still progress needed, especially evident in [cases like childhood asthma](#). Clinical trials for widely used drugs like albuterol have shown poor performance in children of African and Puerto Rican descent due to limited research in these communities.

However, advancements in clinical research software are aiding in analyzing digital engagement efforts. Bryan Saxon, Head of Product and Technology for Acclinate, explains how these tools help identify potential trial participants based on online interactions and determine the most engaging content, crucial for building trust with underrepresented communities.

Illuminate Clinical Research Analytics

Clinical researchers are actively working to diversify clinical trials, using strategies like targeted outreach to communities of color and leveraging technology for engagement. Acclinate's e-DICT analytics platform plays a pivotal role, providing real-time insights into community engagement activities and potential trial participants. Through a proprietary participation probability index (PPI) algorithm, e-DICT assigns individuals a score indicating their likelihood to participate in a trial. This enables researchers to prioritize outreach efforts, focusing on individuals who are more inclined to participate, thus streamlining the recruitment process and ensuring a more strategic, data-driven approach to trial enrollment.

"We create more of a [funnel] so that researchers more readily know who's willing to participate, and then it's less about trying to get 1,000,000 people to get one participant, Saxon says. In other words, e-DICT's proprietary PPI score is an efficiency enabler.

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Bryan Saxon | Head of Product and Technology, Acclinate

Clinical Trial Software's Valuable Impacts

In a recent article, [pharmaphorum highlighted](#) various technological advancements aimed at enhancing access to and diversity within clinical trials. While these innovations, such as expedited patient assessments and provisions for remote participation, offer valuable support, they often overlook a critical initial phase: the identification, engagement, and mobilization of trial participants from diverse communities, particularly those of color.

Clinical research software like e-DICT provides organizations with invaluable insights to not only execute but also strategically plan more inclusive trials. By leveraging such software, sponsors can identify specific population subsets in various geographic areas that may be receptive to trial participation. Additionally, they can discern which content resonates most effectively with individuals within these populations. The implications of achieving greater diversity in clinical trial populations extend beyond mere compliance with FDA diversity action plan requirements.

Indeed, a more diverse trial population directly addresses regulatory guidelines, potentially averting the need for additional reviews or supplementary studies, which could otherwise delay drug approval timelines or jeopardize clearance. Research indicates that increased trial diversity can also lead to higher drug development costs and prolonged market entry, as additional trials and clinic visits may be required.

Furthermore, diverse trial populations offer researchers invaluable insights into how treatments impact traditionally underrepresented communities. This is particularly significant for communities of color disproportionately affected by conditions like asthma, Type 2 diabetes, obesity, and certain cancers. By including these populations in clinical trials, researchers can gather direct evidence to improve clinical outcomes and mitigate longstanding barriers to health equity.

Chapter 5

Dispelling 5 Myths About Recent FDA Guidance

In June 2024, the FDA introduced [updated guidance on Diversity Action Plans in clinical trials](#). This announcement underscores the agency's proactive stance on fostering health equity and broadening inclusivity in clinical research.

To clarify these clinical trial FDA recommendations and dispel common misconceptions, we consulted our own Chief Medical Lead, Camille Pope, PharmD, RPh.

Myth 1

The guidance focuses solely on recruitment diversity

While improving participant diversity is central, recent FDA guidance extends beyond recruitment. It emphasizes sustained community engagement, diverse trial sites, and cultural competency training.

Dr. Pope reflects, "If you look at the differences between [\[the draft guidance in\] 2022](#) and [the updated recommendations in] 2024, the 'how-to' section talks about sustained community engagement and diversity of clinical trial sites — including cultural competency training for the sites that you do engage or wish to consider for your clinical trials."

She adds, "It's important for different groups who haven't been included in clinical research in the past to be included. There may be differences in genetics, biology, and metabolism that can make it so that drugs work differently in various groups of people

Myth 2**Race and ethnicity are the only factors addressed**

The FDA's guidance expands the lens of diversity to include age, gender identity, socioeconomic status, and more. The goal is to ensure trials reflect the diverse populations likely to use a medical product.

"That's why this guidance is important. It's a reinforcement of what has been strongly recommended in the past — still highlighting race and ethnicity, but also talking about the other dimensions of diversity that should be considered."

Camille Pope, PharmD, RPh | Chief Medical Lead, Acclinate

Myth 3**Non-compliance has minimal consequences**

Though they're not binding clinical research regulations, recent recommendations significantly impact pharmaceutical research. Sponsors that fail to develop or submit Diversity Action Plans may face additional FDA requirements during the review process.

Dr. Pope remarks, "It's guidance. It's a strong recommendation. It strongly recommends that you not only [aim to improve diversity], but also create a Diversity Action Plan that you submit outlining how you'll go about including these historically marginalized races and ethnic groups that you haven't intentionally considered including in the past."

She adds, "More and more pharmaceutical companies are being asked by the FDA to conduct post-marketing studies because they don't have diverse populations in their initial clinical trials; this requires spending more money. They've already spent millions of dollars doing this big pivotal phase-three clinical trial and the FDA says 'Well, great data. We're going to approve the drug, however, you need to do additional trials now in the Black [or other underrepresented] participants who you didn't include the first time.'"

Myth 4

Diversity Action Plans drive up costs

While inclusive strategies may introduce initial costs, they can reduce expenses in the long term by avoiding additional studies and improving trial generalizability.

"If you build in the correct way early on to include historically underrepresented patients in your trials, you may not have to spend budget later proving to the FDA that the drugs are safe and efficacious across a broad range of diverse populations or maybe working backwards."

Camille Pope, PharmD, RPh | Chief Medical Lead, Acclinate

Myth 5

Diversity planning is only necessary for late-stage trials

The FDA urges sponsors to integrate diversity considerations early in the trial design process, well before phase-three trials. Early engagement fosters trust and improves compliance with clinical trial FDA standards.

Dr. Pope states, "Updated guidance recommends that companies submit their plans to the FDA for review prior to starting a big phase-three or pivotal clinical trial, which is important because it takes time to build affective trust and truly engage in a genuine fashion with people you haven't engaged with before."

Chapter 6

FDA Diversity in Clinical Trials: A 5-Step Template for Effective Action

The FDA's updated guidance on Diversity Action Plans, announced in June 2024, underscores the importance of achieving representation in clinical trials. These recommendations expand on existing frameworks to enhance health equity by promoting greater inclusion across all stages of research.

Creating a Diversity Action Plan that aligns with [FDA diversity in clinical trials recommendations](#) can be challenging, but these five essential components provide a practical framework.

1 Build a solid foundation

The cornerstone of a Diversity Action Plan is a clear explanation of your strategy for addressing representation goals. Start by defining your target demographics, key metrics, and alignment with the FDA's priorities. Include how your plan supports every research phase, from pre-Phase III trials to post-market evaluations.

Keep your Diversity Action Plan concise — no longer than 10 pages — and emphasize transparency in data collection while safeguarding participants' privacy and confidentiality.

Acclinate's tools, combining AI analytics with community engagement, help sponsors establish robust Diversity Action Plans that meet clinical trial requirements.

2 Define target demographics

A critical feature of the latest FDA diversity in clinical trials guidance is its focus on intersectionality. Beyond race and ethnicity, it considers age, gender identity, socioeconomic status, geographic location, and other factors.

Illustrate how your plan addresses these dimensions by referencing demographic data and enrollment trends. For example, provide prevalence rates for the condition under study and set measurable targets for diversity in clinical trial participants, such as percentages for specific populations. Align these goals with the broader scientific benefits of improving representation.

3 Outline comprehensive recruitment and retention plans

Recruitment and retention strategies must reflect the Diversity Action Plan's goals. Engage directly with communities by forming partnerships with local organizations, advocacy groups, and trusted leaders. Include culturally tailored outreach programs to address historical mistrust of medical research.

Leverage digital recruitment tools, such as targeted social media and pre-screening platforms, designed for specific populations. Outline support measures—like transportation and flexible scheduling—that reduce barriers to participation. Highlight ongoing communication strategies that maintain participants' trust throughout the trial.

Acclinate's NOWINCLUDED platform facilitates inclusive community engagement, effectively mobilizing underrepresented populations to participate in clinical trials.

4 Select sites and investigators strategically

Selecting trial sites and investigators is integral to achieving diversity in clinical trials. The FDA emphasizes the need for trial locations accessible to underrepresented communities and investigators equipped with cultural competence.

Outline criteria for site selection, ensuring the inclusion of rural, urban, and suburban locations. Include plans to train investigators and staff on cultural sensitivity and unconscious bias, fostering a welcoming environment for diverse participants.

Acclinate's e-DICT tool supports clinical trial sponsors with predictive analytics, helping them identify optimal sites and strategies for participant diversity.

5 Monitor progress and adapt strategies

The FDA's guidance encourages ongoing evaluation and improvement. Include mechanisms to monitor enrollment and retention data, address challenges, and report progress to stakeholders. Use analytics to assess whether specific demographic goals are being met and adjust strategies as needed.

Incorporate staff training on topics like social determinants of health and effective communication with diverse populations. Offer opportunities for continuous learning, ensuring your team remains equipped to meet FDA diversity in clinical trials expectations.

Get Support for Increasing Diversity in Clinical Research

[NOWINCLUDED](#), Acclinate's community engagement initiative, fosters connections with individuals of color through both digital platforms and face-to-face interactions. Its mission is twofold: to establish supportive community relationships and to educate individuals about available clinical trials and healthcare resources. Grounded in Acclinate's [Affective Trust Framework](#), NOWINCLUDED prioritizes authenticity and inclusivity in its approach.

Integrated with Acclinate's mission, the e-DICT clinical trial software offers valuable features that support this mission. By assessing individuals' likelihood of trial participation through a Probability Participation Index (PPI) score and identifying engaging activities for prospective participants, researchers can strategically tailor outreach efforts to enhance trial diversity efficiently.

Achieve greater trial inclusivity and sustained diversity by pinpointing underserved populations. Acclinate provides access to communities of color, facilitates engagement surrounding your trials, and employs data analytics to predict and plan future outreach endeavors.

[Schedule a personalized meeting](#) to discover more about our approach.

BEFORE RECRUITMENT, BUILD REPRESENTATION

Connect better with communities of color and increase diversity in clinical research through community engagement and predictive insights.

Acclinate turns trust and data into better representation.

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