



**Splash Clinical**  
Redefining Patient Recruitment

THE IMPACT OF UNDERREPRESENTATION

# How Lack of Diversity Influences Healthcare Outcomes

## THE IMPACT OF UNDERREPRESENTATION:

# How Lack of Diversity Influences Healthcare Outcomes

### OVERVIEW

Clinical trials are crucial in discovering how effective and safe new medical treatments are. However, there's a big problem- not everyone gets a fair chance to be part of these trials. The lack of diversity is a rapidly growing concern for doctors and scientists alike as they work to understand how vital treatments work for different people.

In an era where inclusivity is not just ethical but also methodologically imperative, the FDA has provided a [draft guidance](#) emphasizing the need for diverse enrollment in clinical trials. This document aligns with the FDA's recommendations, advocating for a strategic approach to ensure that clinical research reflects the demographics of the population that the medical products will serve.

Unfortunately, historical events and unjust practices have created a lack of trust between diverse groups toward clinical trials. Across the board, women and people from various racial and ethnic backgrounds are not adequately represented. As a result, this lack of representation makes it hard to know if treatments for various diseases and conditions will work equally well for all who need them.

The need for more diverse participation also stands in the way of personalized medicine — a healthcare approach that aims to tailor treatments to individual patient needs. Without diverse participation, we are slowing down progress in finding treatments that work well for everyone, no matter their background.

Ensuring diverse participation in clinical trials is not just about fairness; finding out how safe and effective treatments are for everyone is essential. All involved in clinical research need to work together to make trials more inclusive, leading to better healthcare for all.

### DIVERSITY AND TREATMENT OUTCOMES

The clinical research paradigm is a linchpin in the evolution of effective medical interventions, showing the path toward developing treatments tailored to diverse patient needs. However, the skewed representation in clinical trial enrollment casts a large shadow on the equity and effectiveness of the healthcare ecosystem. The narrative of diversity, or the lack thereof, intertwined with historical racism, paints a stark picture of the existing chasms in the [clinical trial landscape](#). Through the lens of comprehensive data, the correlation between diverse clinical trials and the enhanced efficacy and safety of medical interventions unveils the tangible impact of representation.

Historically, the lack of diversity has posed significant hurdles in the clinical trial landscape. The effects of unethical medical practices have fostered a climate of mistrust among minority populations toward clinical research. The landscape is further marred by the consistent underrepresentation of [women and people of color](#), specifically Black and Hispanic patients.

The risks and consequences of this underrepresentation create a scenario where

unforeseen side effects and less effective treatments for diverse populations become the norm rather than the exception. This lack of representation in clinical trials translates into a knowledge chasm regarding the efficacy and safety of new medical interventions across diverse demographic groups.

In 2021, a concerning fact was brought to the forefront of the clinical trial landscape: while people of color make up about 39% of the U.S. population, they only made up [2-16% of participants in clinical trials](#). This considerable gap furthers the urgent need to diversify clinical trial participation.

The ripple effects of underrepresentation extend to the heart of personalized medicine. The vision of personalized medical solutions tailored to meet the unique needs of different demographic groups hinges on the data derived from diverse clinical trials. The lack of diverse representation in clinical trials hinders progress toward personalized medicine and impedes potential advancements in [treatment outcomes](#).

## Representation of different racial and ethnic groups in clinical trials vs their percentage in the U.S. population in 2021

**75%**

of research participants are white, while white people are 60% of people in the U.S.

**8%**

of research participants are African-American/Black, while African-American/Black people are 13% of people in the U.S.

**11%**

of research participants are Latino/Hispanic, while Latino/Hispanic people are 18% of people in the U.S.

**6%**

of research participants are Asian, while Asian Americans are 6% of people in the U.S.

2020: U.S. Food and Drug Administration

Ensuring diversity in clinical trials is about promoting equity and ensuring the safety and effectiveness of medical treatments. All stakeholders in the clinical research ecosystem should work together to promote diversity in clinical trials, ultimately leading to more equitable healthcare outcomes.

The following sections of this white paper will explore the interconnected themes of health disparities and equitable healthcare. They will then discuss Splash Clinical's innovative solutions for addressing the current disparities in clinical trial representation.

### Health Disparities and Equitable Healthcare

Cancer is a prime example of the disparity in clinical trial participation. Less than 20% of adults diagnosed with cancer participate in clinical trials with white middle-class men representing **around 85%**. On the other hand, Black Americans amount to 13.7% of participants enrolled in oncology clinical trials from **2010 to 2022** — participating at a rate of 10x less than white middle-class men, despite being at the **highest risk for cancer death**. This underrepresentation is not an isolated issue but reflects a broader narrative that transcends various diseases and conditions.

The same applies to diseases like asthma, disproportionately affecting marginalized racial and ethnic groups. The racial and ethnic disparity in clinical trials related to **asthma** is another example of the systemic issue pervading the clinical trial landscape.

Ensuring diversity in clinical trials is non-negotiable in pursuing a healthcare system that supports all individuals. Research studies focusing on **African American, Latino, and Native American** communities have provided valuable insights, highlighting the importance of inclusive trials in bridging healthcare disparities and promoting equitable outcomes.

The stark underrepresentation of certain racial and ethnic groups in clinical trials is not only a matter of equity but also one of scientific soundness and regulatory compliance. The **FDA's 2022 draft guidance** on the inclusion of diverse populations underscores the criticality of bridging these gaps. Splash Clinical supports the FDA's stance, advocating for concerted efforts to address and rectify health disparities through inclusive research designs.

Improving this systemic issue relies on policy-making and advocacy. The **Equity Action Plans, led by the Biden-Harris Administration**, demonstrate the political commitment and policy frameworks required to promote Diversity, Equity, and Inclusion (DEI) in clinical trials.

Promoting DEI is not only crucial ethically but also in terms of economic impact. Current **projections** indicate that if underrepresented populations in clinical trials continue to face decreased life expectancies, fewer years without disabilities, and reduced working years, the economic loss could amount to hundreds of billions of dollars over the coming 25 years.

**The Future Elderly Model (FEM) suggests that even a 1% improvement in health disparities through improved diversity in clinical trials could result in gains of over \$40 billion for diabetes and \$60 billion for heart disease.**

Percentage of Black American patients in oncology clinical trials with regard to race and ethnicity.

**13.7%** Black (6,912)  
**7.9%** Latinx (3,973)  
**78.4%** White (39,526)

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2807488>

The racial & ethnic distribution of asthma clinical trial participants alongside asthma prevalence rates among different demographic groups.

#### TRIAL PARTICIPANTS

**70.8%** White  
**10.4%** Black  
**0.2%** Hispanic

[https://www.jacionline.org/article/S0091-6749\(21\)02137-0/fulltext](https://www.jacionline.org/article/S0091-6749(21)02137-0/fulltext)

#### PREVALENCE RATES

**7.6%** White  
**10.9%** Black  
**6.4%** Hispanic

<https://www.cdc.gov/asthma/most-recent-national-asthma-data.htm>

The above statistics highlight the clear connection between diversity in clinical trials and equitable healthcare outcomes. To bridge the existing gaps, pave the way for a healthcare landscape characterized by equity and inclusivity, and optimize health outcomes, focusing on policy advocacy, strategic initiatives, and collective efforts to prioritize DEI in clinical trials is crucial.

## SPLASH CLINICAL'S INNOVATIVE SOLUTIONS

Achieving more representative and robust research outcomes requires diversification of patient enrollment. Splash Clinical is an innovative organization that fosters diversification through novel recruitment strategies. Collaboration is at the heart of Splash Clinical's initiatives, uniting various stakeholders to tackle underrepresentation in clinical trials. Real-world applications and case studies demonstrate Splash Clinical's solutions' tangible impact and effectiveness in augmenting diversity in clinical trials.

### Splash's DEI Checklist

A proactive approach toward enhancing DEI in clinical trials is fundamental to reshaping the clinical research landscape. By considering factors like location, community engagement, and trial design, we aim to mirror the FDA's guidelines and ensure equitable participation across all racial and ethnic groups. Splash's DEI Checklist serves as a practical guide for embedding DEI principles at every stage of the clinical trial process. By following this checklist, stakeholders can work towards more inclusive and representative clinical research, which is essential for improving healthcare outcomes for all.

#### DEI Checklist

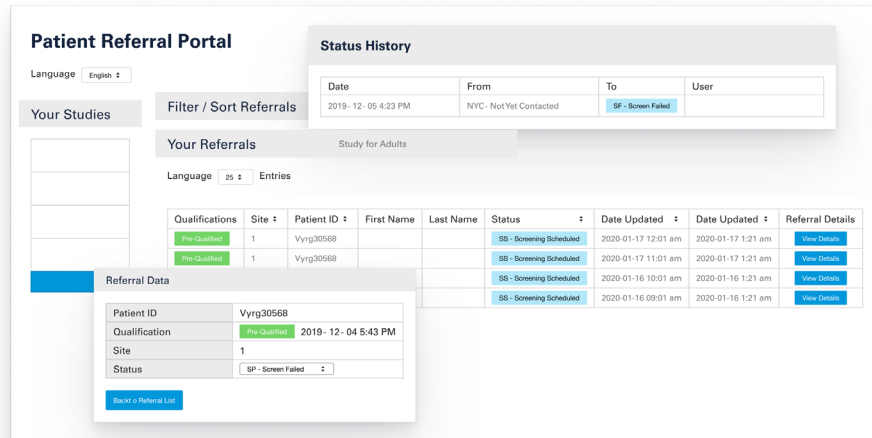
- **Using Data to Drive DEI:** Using census data to target areas with higher concentrations of demographic groups needed for study. This, in turn, informs study site selection.
- **Study Materials for All:** Provide diverse study materials to ensure that languages, ad images, and localizations appeal to individuals regardless of age, race, nationality, gender, sexuality, etc.
- **Supportive Staff:** Staff should be equipped with the materials and skillsets to support individuals from all walks of life.
- **Set Goals:** Establish and monitor enrollment targets based on diversity goals.
- **Mobile-Friendly Marketing:** Ensure that the study website and other digital materials are optimized for mobile usage.
- **Know Your Facts:** Consider things such as historic racism in the medical field, epidemiology and its relationship to diversity, etc., that may impact the ways in which participants feel, navigate, and trust in the clinical trial landscape
- **Community Engagement:** Foster relationships with community organizations to build trust and increase awareness about clinical trials among underrepresented populations.
- **Engage with Advocacy and Diversity Groups:** Establish connections with patient advocacy groups and larger diversity organizations like BlackDoctors.org, National Hispanic Medical Association, etc., to broaden outreach and foster a more inclusive environment for clinical trial participation.
- **Accessible Locations:** Select study sites that are easily accessible to a diverse range of participants, considering factors like public transportation and proximity to communities with diverse socio-economic profiles.
- **Flexible Scheduling:** Offer flexible scheduling options to accommodate the varied availability of participants, making it easier for a diverse population to engage.
- **Transparent Communication:** Maintain clear and open communication about the study's purpose, process, and potential impact, ensuring participants are well-informed.

With a solid framework for DEI in place, as outlined by the DEI Checklist, the pathway to implementing tangible solutions becomes clearer and more structured. The checklist lays the groundwork for acknowledging and addressing the disparities in clinical trial representation.

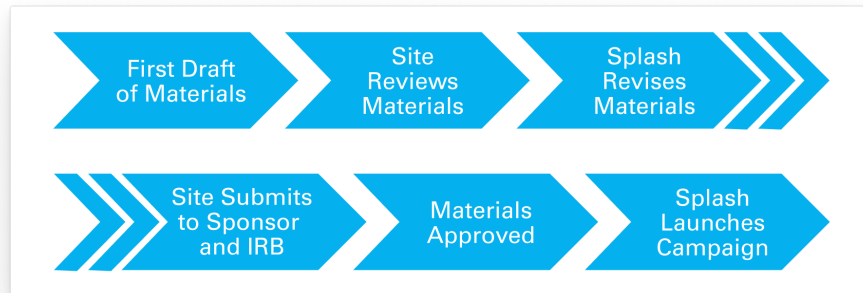
However, real progress begins when these guidelines are combined with innovative solutions. The solutions from Splash Clinical offer our clients comprehensive tools to help them enroll diverse groups for clinical trials. These solutions show how using technology and working together can help overcome the challenges in today's clinical trial landscape. These are some of the tools and methods developed by Splash Clinical to address these challenges while also offering the flexibility to tailor our DEI services to meet the unique needs of each client.



The PRP enables real-time analytics tracking and study-specific patient-facing websites. Secure patient portals provide prequalified patient referrals to selected study sites, while robust websites support tailored prescreeners.



SSS is designed to provide study sites with a digital patient recruitment campaign tailored to their unique needs. With secure software, Single Site Solutions campaigns accelerate referral speed and engagement, reaching out to qualified individuals based on specific demographics like location, age, and gender.



We go beyond recruitment, offering a lens into campaign performance and progress through in-depth analytics. The real-time tracking facilitates an ongoing assessment against stated objectives, empowering a proactive approach to addressing any hurdles promptly.



In the digital age, social media is a powerful tool for engagement, yet it comes with challenges. The Comment Manager App, approved by Facebook, meticulously manages comments on social media ads and pages, reducing the risk of adverse events while keeping a detailed record of deleted comments.



SES is crafted to enhance campaign site engagement, leading to enhanced outcomes and faster enrollment. It's an easy-to-use platform bundled with onboarding, training, and support, allowing a close watch on the progress of prequalified referrals and enrollment rates per study site.



vWR amplifies the enrollment funnel by supplementing patient follow-up. It ensures a continuous engagement with referrals throughout the recruitment funnel, ensuring prospective patients stay caught up. vWR is part of our call center, which has contributed to a remarkable 69% increase in screening rates for participating trial sites.

As we advance towards a future where clinical trials are as diverse as the populations they aim to benefit, adherence to the FDA's draft guidance on participant inclusion becomes paramount. Splash Clinical is committed to this vision, ensuring that our practices not only meet but exceed the expectations set forth by regulatory bodies, paving the way for truly equitable healthcare solutions.

The pursuit of DEI in clinical trials cannot be confined to ethical obligations. It is crucial for improving healthcare outcomes and tackling health disparities that affect our societies. The inadequate representation of diverse populations in clinical trials has been a persistent issue that limits clinical research findings' universal applicability and effectiveness. Nevertheless, the current landscape is ripe for change thanks to innovative patient recruitment strategies and a culture of cooperation that bridges gaps between stakeholders.

Splash Clinical's efforts highlight the potential and promise of such innovative approaches. By developing cutting-edge recruitment platforms and strategies, Splash Clinical has set an example of how the clinical research field can become more inclusive and representative. The combination of technology and cooperation, as demonstrated by Splash Clinical, signals a new era where clinical research reflects the diverse makeup of our populations and leads to equitable healthcare outcomes.

Through collective and collaborative efforts, the clinical research industry can overcome traditional barriers and usher in a new era where research is as diverse as the populations it hopes to serve. By creating a space where each demographic group sees itself reflected in clinical research, we move closer to a healthcare paradigm that is inclusive, equitable, and capable of meeting the unique health needs of all community members.



If you're looking to harness the power of precision targeting to drive diversity in clinical trials visit [\*\*splashclinical.com\*\*](https://www.splashclinical.com).