DATA ECOSYSTEM

Clinical Trial Diversity: Solutions for Underrepresentation

Racial diversity in clinical trial populations has been a prominent challenge for years, but most recently the inequality of ethnic representation in COVID-19 vaccine development trials has once again brought the issue to the forefront.

Geographical regions and patient groups that have been hit the hardest by the pandemic have been largely unaccounted for during these trials and are therefore not a fair representation of how the virus has affected the population. Diseases do not impact all races and ethnicities equally, so collecting and accounting for this patient information is critical to creating an effective treatment. According to the Center for Disease Control and Prevention data, people of color make up about 60% of COVID-19 cases and about 50% of the deaths, yet Black Americans have been severely underrepresented in the studies to treat and develop a vaccine for COVID-19. Without diversity amongst clinical trials the results cannot be truly representative of the entire patient population the therapy is designed to treat. It is therefore vital that clinical trial sponsors utilize every available resource to rectify this disparity to uphold societal equity in healthcare.

The COVID-19 trials are not an anomaly in underrepresentation of one or more minority groups; prior to the pandemic, this disparity could be seen perhaps most notably in multiple Myeloma, a cancer that disproportionately affects Black males over the age of 65. Statistics show that **Black Americans are twice as likely** as white Americans to be diagnosed with this disease, yet between 2003 and 2018 only 4.5% of participants in multiple myeloma trials were Black American. Despite these diseases having a large impact amongst this population, Black Americans are significantly underrepresented in clinical trials of therapies aimed at treating them. The reasons behind this disparity are complex and efforts to lessen the gap have made few strides over the years.

While clinical trials are vital to medical advancements and often save many lives, sponsors have historically struggled with accruing and retaining patients to fill their study cohorts. Factors such as financial impacts for out of pocket costs and general accessibility issues like transportation are often barriers to patient participation. The burden of these additional costs of participating creates a bias to those in higher socioeconomic levels [1]. As racial equity is a critical topic of conversation right now, specifically in healthcare, many are revisiting the **draft guidance the FDA issued** last year that highlights ways to create more diversity amongst clinical trials. Their recommendations have led to a trend towards **virtual clinical trials** aimed at alleviating some of these accessibility issues raised by transportation and economic factors to ultimately enable participation from more diverse populations.

Study design and patient eligibility criteria are also cited as barriers that prevent the accrual of an optimal patient cohort. While eligibility criteria is important to narrow the focus of the study and create clear goals of trials, these strict measures can make trials very exclusive and difficult for patients to get into. The FDA published additional guidelines urging sponsors to determine eligibility criteria that will allow the clinical trial population to reflect the diversity of the patients who will be using the drug if it is approved. These suggested practices include the following considerations:

- In early clinical development characterize drug metabolism and clearance across populations that may metabolize or clear the drug differently
- Using adaptive clinical trials, which allow for pre-specified trial design changes during the trial, including altering the trial population
- Including a broader participant group in the trial as part of the secondary efficacy and safety analyses, even when the primary analysis population is narrowed

While traditional solutions like broadening eligibility criteria and removing accessibility barriers are a step in the right direction, they do not solve the core issue of having access to a more diverse group of patients to recruit from. Pharmaceutical sponsors and Clinical Research Organizations (CROs) need a way to gain access to ethnically diverse patient populations to fully implement these solutions while upholding clinical trial ethics, privacy, and HIPAA regulations.

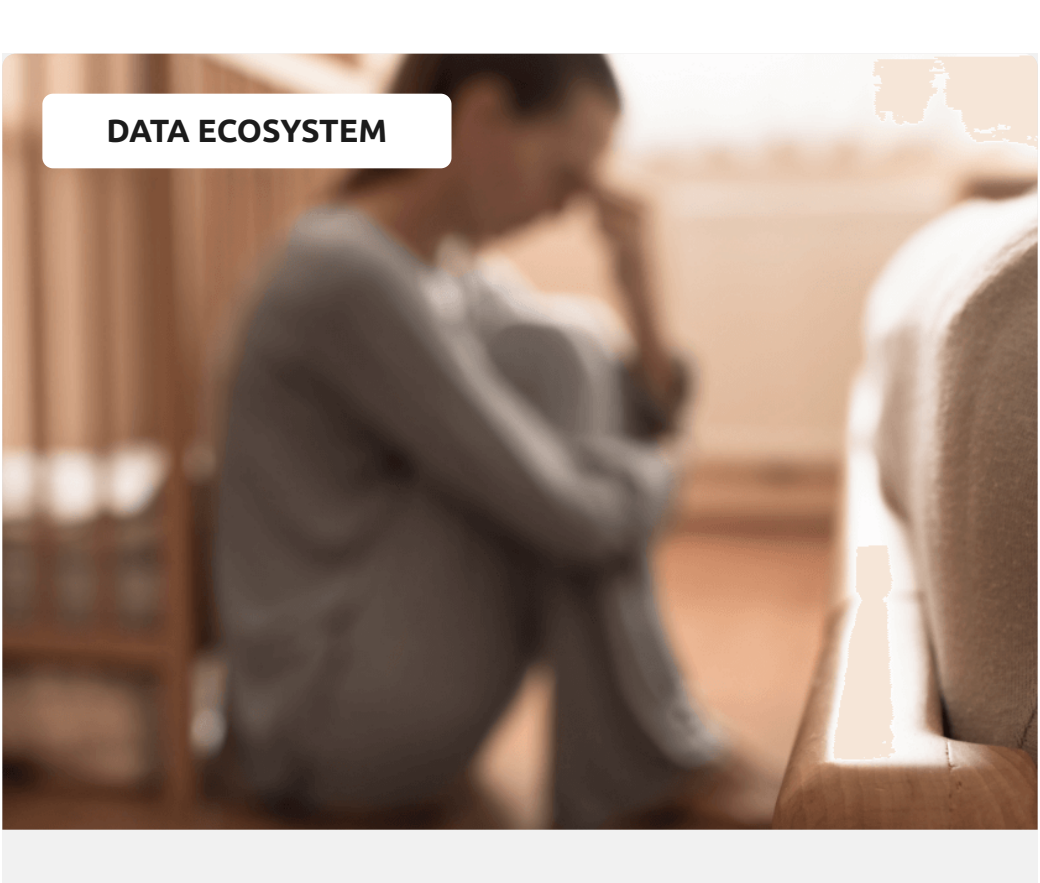
With this in mind, HealthVerity has created a solution that allows pharmaceutical companies and CROs to gain greater visibility into the racial makeup of patient populations seen by each provider. The HealthVerity **Provider Diversity Index** will accelerate recruitment of minority groups by providing access to 330 million US patients and the vast majority of healthcare providers represented in the nation's largest healthcare data ecosystem. Gaining access to a physician's patient demographic will give sponsors an opportunity to better direct their recruitment efforts to accrue a well-rounded patient cohort. Having the ability to work with physicians who are better positioned to inform and educate the optimal mix of clinical trial subjects will yield a more accurate representation of the patient population.

It is imperative that clinical trials become more representative of the actual patient population the therapy aims to treat. The HealthVerity **Provider Diversity Index** eases the burden of patient accrual by providing an opportunity for sponsors to recruit from the broadest possible patient set and provides a solution for sponsors that can have a profound impact on clinical trial participation. These efforts towards creating more diversity amongst clinical trials and rectifying the ethnic disparity seen in clinical research will improve the efficacy of new therapies and ultimately save more patient lives.

Article Sources

[1] Journal of Clinical Oncology. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. Retrieved from https://pubmed.ncbi.nlm.nih.gov/11956272/

Related Post:



DATA ECOSYSTEM

Maternal mental health matters

Mental health treatment for women who are pregnant or lactating is crucial to ensure positive mental and physical health...

Read more >

DATA ECOSYSTEM

A Path Plagued by Progression: The Chronic Kidney Disease Journey

Chronic kidney disease (CKD) is known as a "silent disease" because as many as 90% of patients don't realize they have t...

Read more >

DATA ECOSYSTEM

How to Target the Right Physicians Using Trigger Programs

As therapies become increasingly complex and personalized, it is imperative that physicians prescribe the right patient ...

Read more >

Subscribe to the HealthVerity blog

Business Email

Submit

Contact us

First name

Last name

Email

Job title

Company name

Message

Send