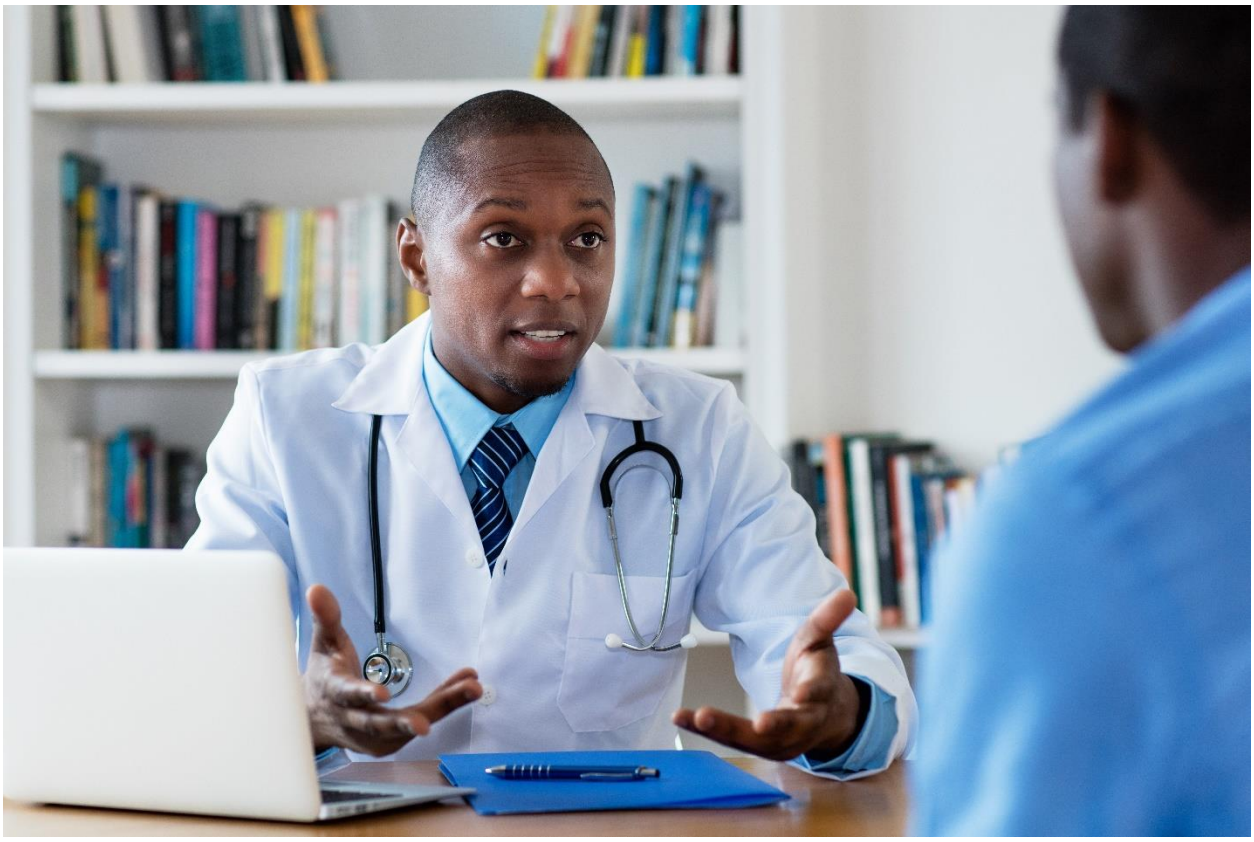

White Paper:

Achieving Diversity in Clinical Trials

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May 2021

JAVARA

Intentional and targeted strategies can promote trust, enhance diversity in participation.

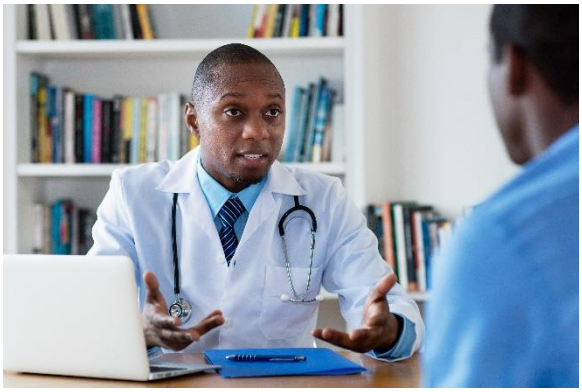
Diversity has long been an issue in clinical trial enrollment for several reasons, including the standard model of research with trials being conducted in the same areas, the same settings, with largely the same investigators and the same patients "recycled" from previous trials. Many of the types of organizations that participate in clinical trials are large groups that exclusively do research, in which there is little minority representation. Traditionally, these organizations get their patients from advertising, word of mouth, and collaborating with other physicians and healthcare practices.

When participants in clinical trials fail to reflect the overall population or those most affected by the disease, it is less likely the results obtained will be applicable in the real world. This means interventions could be less effective in different groups of patients. In order to enhance diversity and develop intentional, targeted strategies to do so, there are multiple key factors and realities of the current clinical trial landscape that need to be illuminated and addressed.

SCOPE OF THE GAP

In a recent report from the U.S. Food and Drug Administration (FDA) on its 2018 Drug Trial Snapshots, whites make up 67% of the U.S. population, but are 83% of research participants.[1] Black patients comprise 13.4% of the US population, but only 5% of trial participants, while Hispanics and Latinos represent just over 18% of the population, but less than 1% of participants.[2]

A significant roadblock stems from the fact that, due to trust concerns, many patients choose to go to physicians who look like them or have a similar background. It stands to reason that the race of the physician will therefore influence the makeup of the clinical trial volunteers.[3] The percentage of minority physicians is, itself, a minority. This alone has an impact on patient participation in clinical trials, with further influences rooted in the reality that many of these physicians are often younger with limited access to clinical trial infrastructure.[3] Because historically minority providers have not participated in clinical trials at the same rate as nonminority providers, they are less likely to be recruited or have experience as clinical investigators.



IMPROVEMENT REQUIRES EDUCATION

To improve recruitment in clinical research so that it reflects the population as a whole, the industry must put forth mindful and intentional strategies—all with education at the core.

Address Trust

Medical mistrust is a major concern. Older people of color will undoubtedly bring up the Tuskegee study of syphilis in Black men that began in 1932, continued for 40 years, and was conducted without informed consent of the participants. Other individuals may reference the 19th century gynecologist J. Marion Sims, who conducted experimental surgery on enslaved Black women without their consent or anesthesia. Still others may recount the story of Henrietta Lacks, a Black woman who, in 1951, had cancer cells taken without her knowledge or consent by a doctor at Johns Hopkins Hospital. Since then, those cells have been used in research around the world.[4] All of these examples provide critical context behind minority distrust both in healthcare and, more specifically, in clinical research. Addressing this mistrust is vital and doing so requires communication and transparency that is culturally relevant. Talking openly about what has occurred in the past and engaging in intentional conversations surrounding the laws that have been enacted in the time since, are both essential actions we must take to ensure the highest ethical standards are adhered to with regard to research in human subjects.

Why Participation Matters

For clinical trials to succeed, it is critical that people from all different ethnic backgrounds – and age groups where appropriate – are included in studies. The reason for this is multifaceted, with one of the most prominent factors being the impact of participation on population health. Educating community members about the importance of participating in clinical research plays a central role when working to both increase and diversify participation. By providing informational resources that help illuminate how a patient's decision to participate in a clinical study not only has an impact on their own health but that of their entire community, a sense of pride as well as responsibility can become positive and influential factors in the equation that is clinical research.

Clinical Research as a Care Option

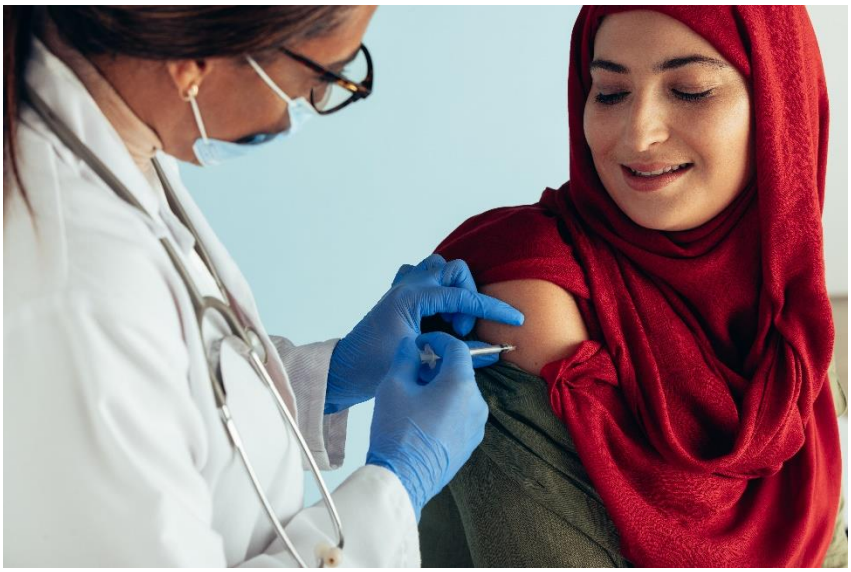
Many racial/ethnic minorities may delay obtaining health care due to a lack of access, information, and insurance. They are often unaware of treatment options available to them, including clinical research. For those who do not have access to insurance or are underinsured, clinical trials provide compensation for participation plus access to treatment that can improve their condition at no cost. With 10 visits in a clinical trial, for example, patients have more touchpoints with the healthcare system and more exposure to their physician and other healthcare staff. For many patients who feel they are out of options to improve or treat their condition, clinical research can provide a new avenue for care and hope.

If the industry can improve communities' understanding of these key concepts, more minorities will be encouraged to participate and at the same time, morbidity and mortality in these groups can be reduced.

GOING BEYOND

Communications should break clinical research down to its basics to connect with patients, particularly in communities of color. This is not about oversimplifying or relying inappropriately on laymen's terms when discussing clinical research. Rather, the fundamental goal when breaking down communications should be ensuring potential participants understand exactly what will take place during their participation. Physicians cannot simply hand a patient an informed consent document and say, "read this and my office will be in touch." There must be thoughtful conversations about details, what will happen to them and why. To gain that trust, healthcare providers need to take the time to make patients comfortable with their participation. Any materials should promote clear understanding of the research questions, study design, participant protections, and potential community benefit.[5]

By addressing concerns up front, emphasizing the benefits to them including gaining access to expert medical care, learning more about their condition, and playing an active role in their own personal healthcare, the industry will be able to overcome barriers and achieve greater diversity, encouraging participation among underrepresented populations.



FDA SEEKS TO INCREASE DIVERSITY

Attempts to include participants from more ethnic backgrounds in studies through regulations have not been successful; 48% of the adult trials did not meet the target recruitment goal for including underrepresented populations.[6]

Last year the FDA released nonbinding guidance for industry, "Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs."[7] The issue was front and center throughout this past year with clinical trials for COVID-19 vaccines. It is believed FDA may soon add requirements for minority participants. Those goals should be realistic, however, balancing inclusivity with the ability to bring new drugs to market. In addition, Acting FDA Commissioner Janet Woodcock has recently shared a vision to create a new clinical trial infrastructure using the nation's hospitals and healthcare systems. By creating community research networks to forge relationships with local care providers, broader and more diverse patient populations could be included in clinical trials.[8]

HOW INTEGRATED RESEARCH ENABLES DIVERSITY

As an integrated research organization (IRO), Javara's model delivers on this shared goal. Through partnerships with healthcare organizations at the community level, we are able to reach a broader and more diverse patient population with clinical research as a care option. Javara's expert research staff are embedded within practices for a seamless integration of clinical trials. A seasoned and experienced team supports the physician so there is no additional burden. Using a variety of media approaches from video to brochures that break down clinical research and provide additional information, Javara empowers physicians to educate and inform their patients.

By engaging physicians at the healthcare practice level, Javara can support and encourage minority physicians and new physicians in general to participate in clinical research. Javara helps to facilitate conversations about the value of clinical research—its importance and benefits and how the process works—between physicians and their patients.

PART OF THE SOLUTION

Javara seeks to increase diversity in clinical research by removing barriers to minority recruitment and participation. In order to do so, the first step is to improve awareness of and access to clinical trials. IMPACT, Improve Minority Participation and Awareness in Clinical Trials, is Javara's strategic plan intended to make advancements for minorities and underrepresented communities, particularly those who experience significant health disparities. The goal of IMPACT is to enable minority communities with health and medical research to be able to make informed decisions about participating in clinical research.

Part of IMPACT is establishing trust and education in local communities. Javara partners with Greater Gift, a non-profit organization who reaches out into ethnic minority communities to connect with groups like the Hispanic League and faith-based organizations to provide clinical research education to local populations. These partnerships open the doors of understanding so that when presented with specific study opportunities, hopefully by their healthcare provider or healthcare organization, patients are in a better place to understand information and make an educated decision about whether or not participation is right for them.

It is also important to be involved in industry organizations advocating for change. Javara CEO Jennifer Byrne co-chairs the Racial Equity Task Force at Wake Forest Baptist Health, and I personally serve as a member of the ACRP Diversity Advisory Council focusing on policy change. Javara also strives to encourage historically Black colleges' involvement with clinical research programs. With this concerted effort under IMPACT, we aim to make great strides to bring more diverse populations of physicians and patients into clinical research.

CONCLUSION

The COVID-19 pandemic has brought clinical trials and medical research into the day-to-day conversations of Americans nation-wide, and in a positive manner. Because of this, awareness is at an all-time high and there is great reason to be optimistic. Through continued education and intentional communications to increase trust among minority populations, the industry is set up to build upon the present momentum and bring more diversity into clinical trials.

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