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Review Article

Key barriers against racial and ethnic minority participation in U.S. clinical trials

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ABSTRACT

Despite the United States' (U.S.) longstanding history of promoting a melting pot nation of people from diverse racial and ethnic backgrounds all capable of achieving the American Dream, it is argued that the U.S. is failing to deliver high quality healthcare to all of its constituents equally. The widely seen health disparities of ethnic minority groups endure has extended into the parallel field of clinical research and clinical trials. There is a staggering gap between the percentage of White clinical trial participants compared to clinical trial participants of racially and ethnically diverse minority groups in U.S. clinical trials. Underrepresentation of minority groups in clinical trials dismisses opportunities to identify potential serious sub-group safety or efficacy signals, open doors to access life-saving treatments, and ultimately improve the standard of evidence-based medicine in the United States. Current literature on this issue frequently reiterates the following five key barriers underrepresented minority groups face against clinical trial participation: mistrust, lack of awareness and access, cultural and language barriers, investigator and provider bias, and financial burdens. A deeper dive into understanding each barrier will be critical in implementing changes with actions and in perspectives in order to address the issue of poor racial and ethnic representation in clinical trial populations.

Keywords: Clinical trial participation, Barriers, Diversity, Underrepresented minorities, Race, Ethnicity

INTRODUCTION

The United States (U.S.), a long standing global beacon for diverse ethnic populations and a shining example of a melting pot country, continues to struggle translating the same concept of a diverse population in the field of clinical research. The 2020 United States Census showed the following total population breakdown: 61.6% White, 12.4% African-American, 1.1% American Indian and Alaska Native, 6% Asian, 0.2% Native Hawaiian and Pacific Islander, 8.4% Other Race, and 10.2% Multiracial.[1] At present, the US population retains a White majority, but experts predict the White population will decrease almost 10% by 2060, despite the total US population increasing an estimated 25% by 2060. All other population groups are expected to increase substantially with the Multiracial population estimated to increase 198% and the Asian population estimate to increase 101% by 2060.[2] Theoretically, in order to support the generalizability of results the clinical research population participating in clinical trials should represent the demographic breakdown seen in the actual population. Unfortunately, the current clinical trial population landscape underrepresents ethnic minorities, ultimately, limiting our understanding of varying drug responses and barring access to potentially beneficial experimental care.

The goal of achieving a more ethnically represented clinical trial population requires an in depth analysis of the barriers that limit clinical trial participation for underrepresented minority groups. The literature commonly states these five barriers limiting minority participation in clinical trials: mistrust, lack of awareness

and access, cultural and language barriers, investigator and provider bias, and financial burdens.[3-7] In addition to understanding the barriers, insight into the facilitators of minority clinical trial participation is imperative in developing the appropriate outreach, recruitment, and retention strategies in the minority communities.[6] It is important not to forget the underrepresented population is composed of various cultural, ethnic, racial, and socioeconomic groups, therefore, understanding the interaction between sub-groups and clinical trial participation will assist in strategic reform across clinical trial participation. The purpose of this paper is to spread awareness about the key barriers against racial and ethnic minority groups from clinical trial participation, so that steps towards addressing the barriers becomes the focus amongst the clinical research industry.

HISTORICAL BACKGROUND

The historical push toward increasing diversity kicked off with the National Institutes of Health (NIH) leading the way with the NIH Revitalization Act of 1993 (Figure 1). The act established guidelines on the inclusion of women and minority groups and their subpopulations in NIH funded clinical trials. The act strictly prohibits funding or costs as suitable reason for omitting women and minorities from participating in clinical trials. Additionally, the act requested rationale on whether clinically significant differences should be expected between sex, gender, race, and ethnicity groups in all proposed NIH Phase III clinical trials.8 Ultimately, asking investigators to think proactively and progressively on clinical trial inclusion from a diverse race and ethnicity perspective. Regardless of the NIH's actions toward increasing inclusion, the NIH Revitalization Act of 1993 has not been successful in addressing underrepresentation of ethnic minorities in clinical trials. In 2018, the NIH's National Cancer Institute reported an annual total of 1,245,905 subjects participated in their breast cancer studies.[9] It is important to note the total figure excludes participants from breast cancer studies focusing solely on a single race or ethnic group. The breakdown revealed White participants occupied the highest median percentage of 81%, whereas Black or African American participants only represented a median percentage of 7%, despite Black or African American women having a 40% more likelihood of dying from breast cancer compared to White women.[9,10] Again in 2018, the NIH reported White participants represented a median percentage of 66% in all NIH kidney disease studies, excluding single race studies, with Asian participants only comprising a median percentage of 2%, in spite of White and Asian individuals having the same 13% prevalence for chronic kidney disease in the United States.[9,11]

In parallel, the FDA also published the Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs reversing historical precedence recommending women of childbearing potential be excluded from participating in clinical trials.[12] However, the FDA's 1993 guideline did not include guidance on the inclusion of minority groups and their subpopulations. Finally, almost two decades later, the FDA Safety and Innovation Act of 2012 (FDASIA) was passed by the U.S. Congress. The FDASIA required the FDA to draft a report for Congress on the extent demographic subgroups are included in clinical trial participation and if safety and efficacy data is available for subgroups. Additionally, Congress requested an action plan with recommendations to improve completeness and labeling of safety and efficacy reporting within demographic subgroups.[13] The final FDASIA report concluded Whites represented the majority of clinical trial participation for new drugs and biologics.[14] A fact still holding true after almost a decade. In November 2014, the FDA launched the Drug Trials Snapshots initiative with the first snapshot published in 2015, publicly disclosing the demographics of clinical trial participants.[15] The Drug Trials Snapshots increases public transparency on the industry's actions toward increasing racial and ethnic diverse clinical trial populations. Unfortunately, there are still blank fields in the snapshots demonstrating some sponsors do not include participant gender and ethnic demographic breakdowns in their market approval submissions. The snapshots continue to illustrate the incompleteness of data on clinical trial participant subpopulation demographics due to the FDA's New Drug Application (NDA) and Biologics License Application (BLA) nonexistent requirements for submitting such data. The 2020 study by Getz, Smith, and Peña highlighted out of all NDAs and BLAs approved between 2007 to 2017, only an estimated 37% of pivotal trials included data on participant ethnicities.

The majority of approved drugs and biologics during the defined time did not disclose any data on participant ethnicities, thus eliminating the opportunity for subgroup safety and efficacy analyses. Furthermore, only 13% of all clinical trials from approved NDAs and BLAs included data on participant ethnicities.[16] The FDA's lenient requirements on reporting participant demographics, specifically, race and ethnicity, and lack of accountability hinders the progression towards a more diverse clinical trial population. In 2017, the US Congress passed the FDA Reauthorization Act which required the FDA to conduct a public meeting with experts on clinical trial eligibility prior to developing industry guidance on the topic.[17] In late 2020, the FDA released the final guidance, Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry, outlining broadening eligibility criteria and inclusive study design considerations to achieve enhanced diversity in clinical trial participation.[18] The essence of the guidance is to move away from the standardized study design and protocol content by eliminating components and eligibility criteria that may unconsciously excluded clinical trial participants from both ethnic and socioeconomic minority groups.

Table 1: Ways to address or remove key barriers against minority participation in clinical trials.

Key barrier	Stakeholders	Ways to address or remove the barrier
Mistrust	• Drug Development Sponsors • Investigators	• Partner with advocacy groups on building trust in minority communities[22] • Include patient feedbacks and advisory boards early and throughout the drug development process[22] • Provide participants with routine updates about the clinical trial and trial progress[34]
Lack of access and awareness	• Drug Development Sponsors • Investigators • Health Care Providers	• Partner with community health care providers and clinics to educate the community on clinical trials and health literacy • Partner with local advocacy groups on spreading information about clinical trials • Select clinical sites and investigators in diverse ethnic and socioeconomic locations[34]
Cultural and language barrier	• Drug Development Sponsors • Investigators	• Consent and study documents should be translated into various languages prior to the start of a clinical trial[27] • Hire company personnel or site staff from diverse racial and ethnic backgrounds[3] • Customize the informed consent process to be compatible with different cultures and ethnic backgrounds[6]
Investigator and health care provider bias	• Drug Development Sponsors • Investigators • Health Care Providers	• Educational seminars for health care providers and new investigators on basic clinical trial knowledge and benefits of participating in clinical research[34] • Diversity and inclusion training for investigators and site staff[31] • Review inclusion and exclusion criteria for criteria that may exclude specific ethnic groups unconsciously[34]
Financial burdens	• Drug Development Sponsors • Investigators	• Cover costs of indirect clinical trial participation costs (childcare, time taken off work or school)[3] • Cover trials costs health insurances will not pay[32,33] • Provide flexible clinic hours for patient study visits[34] • Cover meal, transportation, and lodging costs associated with clinical trial participation[3]

Only just recently, in December 2020, the U.S. Congress passed the Clinical Treatment Act requiring state Medicaid programs to cover routine patient care costs for patients enrolled in applicable clinical trials for cancer or life-threatening conditions.[19]

The FDA's industry guidance, NIH's institutional policies, nor government legislation have succeeded in opening the door for underrepresented minority groups to learn and participate in clinical trials.

The road towards inclusive and true representation in clinical trials is long and marked with potholes waiting for failure.

THE IMPORTANCE OF A DIVERSE SUBJECT POPULATION

Drug research and development benefits when clinical trials are conducted on a comprehensive sampling representative of the affected disease group and ethnic sub-populations. Health care physicians and providers are taught to practice evidence-based medicine (EBM) using the best and most relevant data in patient care decisions.

The best and most relevant data is commonly referenced from randomized controlled trials (RCT), also known as the gold standard of clinical research.[20]

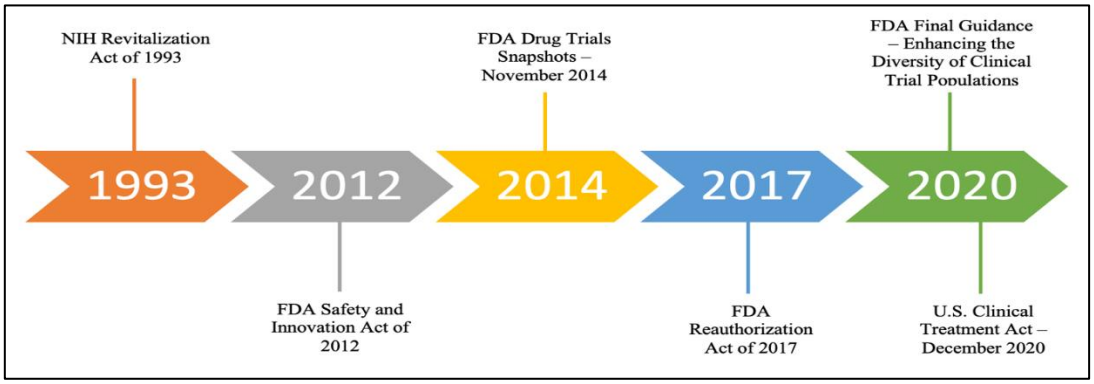

Figure 1: Historical timeline of key regulations towards increasing diversity in clinical trial populations.

The problem arises when the industry's gold standard of utilizing a homogenous subject population is actually preventing opportunities to expand the application of EBM in various minority populations that traditionally are not part of the homogenous subject population. The nature of a randomized controlled trial is to, in fact, control or limit internal variability in order to produce valid results. Homogeneity in clinical trials is stressed and even promoted as a requirement in producing reliable and valid results, but the truth is it is reducing generalizability of clinical trial outcomes. In the process of promoting homogeneity, we miss out on opportunities to learn about potential varied drug responses in different racial, ethnic, genetic, sociocultural, and socioeconomics sub-populations.[3,20] The global population is not a homogenous group and never will be, therefore, the diverging idea of clinical trials with a heterogenous participant group is the true golden standard in producing real EBM for real world application.

The chance to better address the growing health disparities and disease burdens underrepresented minorities face is another reason increased patient diversity is a necessity. Clinical trial participation provides an opportunity for underrepresented individuals, who usually identify as an ethnic minority and from a low socioeconomic status, to receive potentially life-saving treatments that can improve quality of life and survival rates.[3] The underrepresentation of minorities in drug development only perpetuates the cycle of health disparities by stunting society's understanding of medical science and blocking avenues to address the disparities that disproportionately impact minority groups. A call for deeper insights into the barriers stopping and facilitators encouraging minority research participation is warranted.

KEY BARRIERS

The barriers underrepresented minority groups face most frequently can be categorized into one of five categories: mistrust, lack of awareness and access, cultural and language barriers, investigator and provider bias, and financial burdens.

Mistrust

Mistrust is a shared barrier against clinical trial participation across African Americans, Latinos, Asian Americans, and Pacific Islanders.[6] After a long and repetitive history of unethical medical practices against minority groups at the hands of the United States government, many are skeptical or suspicious of participating in a clinical trial. The U.S. Public Health Services Syphilis Study at Tuskegee, markedly the most notable violation against ethical medical and clinical research conduct, is a prime example of how past abuses created a cloud of mistrust around clinical research for African Americans today.[21] The mistrust of medical or clinical research stems from a deep rooted history of mistrust of a health care system that continues to marginalize and discriminate against African Americans and other minority groups across all socioeconomic levels. There is a general consensus underrepresented minority groups rarely benefit from the successes of clinical trials, especially, when historically White Americans were awarded all the benefits.[5,22]

Lack of access and awareness

The health disparities faced by underrepresented minorities and people of color translates over into the clinical research system as well. Historically in the U.S., the non-White population have received poor access to health care.[23] The geographic accessibility of a clinical trial site plays a large role in underrepresented minority groups lack access to clinical trials. For example, oncology clinical trials are usually conducted at large academic cancer centers with the appropriate research infrastructure, but African Americans are more likely to receive care at an under-resourced community hospital.[24] The limited engagement with community health care settings and community physicians in clinical research results in less referrals for patient participation in clinical research trials and the continued lack of awareness about clinical trials.[25] Evidence shows physicians are less likely to adopt findings from research at academic medical centers than community health care settings.[26]

Cultural and language barriers

Communication is a vital part of any clinical trial participant's journey through a clinical trial starting at the time of invitation when they are first approached regarding the trial. As previously stated, the majority of clinical trial participants in the U.S. are White Americans.[14] This fact translates to the majority of clinical trial participants communicating primarily in English, therefore, clinical trial materials, such as the informed consent form and recruitment materials, are again primarily formatted in the English language. One of the main reasons individuals from diverse ethnic backgrounds are underrepresented in clinical trials is due to the fact research opportunities and related documents are not presented in a comprehensible language or appropriate literacy level.[27] Underrepresented ethnic minorities, usually non-English speaking, are then immediately excluded from the opportunity to participate in a clinical trial. Despite the majority of the U.S. identifying as English speakers, the U.S. Census Bureau estimates over 350 different languages are spoken in the United States.[28] English may be the majority spoken language and heard across the country, but it is important to remember it is not the only language. As racial and ethnic minority populations continue to grow it only makes sense to standardize translating clinical trial documents and materials into languages other than English. The University of Utah's Office of Research Participant Advocacy (RPA) implemented a translation library with short forms and parental permission forms in 29 different languages, as well as audio and videos recordings for individuals with low literacy levels and visual impairments. The RPA's preparedness was heavily regarded as a factor in streamlining the increased volume of translation requests during the COVID-19 pandemic.[27]

Communication styles and methods are not identical across the United States, largely in part due to the many cultures that accompany the many racial and ethnic minority groups found in the United States. The current practice of recruiting a clinical trial participant, which mainly consists of speaking with a potential participant alone at the start of the clinical trial to obtain consent, is a "one size fits all" mindset that has not been successful in enrolling diverse subject populations. In the Asian American culture, the endorsement from family is an important facilitator in clinical trial participation. Similarly in the Pacific Islander culture, elder involvement, and community mediation, or engaging with the community for input on how the results with be reported and applied within the community, is important for clinical trial participation.[6] In some cases, the individual subject is not the only party consenting to participate and a wider perspective on community buy in is warranted.

Investigator and health care provider bias

Individuals frequently report that their health care providers as the primary source for clinical trial information.[29] Our health care providers play an important role in all potential clinical trial participants consenting to participate in a clinical trial just by sharing their own views on clinical trials. Health care providers' attitudes toward clinical trials is a known influential barrier to increasing underrepresented racial and ethnic minority participation, meaning if a provider possesses a negatively skewed opinion of clinical trials, usually believing clinical trials lack benefits for their patients, they will most likely not recommend patients participate in clinical trials. In many instances, health care providers are not aware of clinical trials or do not possess the full knowledge of clinical trials and research to feel confident in referring their patients.[30] Some providers display an implicit bias against minority patients believing them to be untrustworthy and lack the capability to comprehend the many nuances of participating in a clinical trial.[5] These negative views harm the patient-provider relationship, increasing the mistrust underrepresented minority groups have towards the health care system and clinical trials.

Even the investigators conducting the clinical trials are known barriers stopping ethnically diverse populations from participating in clinical trials. Some investigators lack the knowledge and understanding about the importance of including racially and diverse participants in clinical trials. Without understanding the importance of diversity in clinical trials investigators are less likely to possess skills and training to recruit a diverse subject population. Educational courses and modules on enhancing the recruitment of minorities in clinical trials can increase an investigator's knowledge and subsequently influence change to their recruitment practices.[31]

Financial burdens

The indirect and direct costs associated with participating in a clinical trial limit underrepresented minority groups from participating in clinical trials. Indirect costs include lost wages from taking time off of work or school in order to participate.[4,18] Direct costs associated with clinical trial participation include out of pocket expenses for meals, travel, and lodging on top of deductibles, copayments, and clinical trial specific procedural costs insurances do not cover.[32,33] Individuals from higher socioeconomic backgrounds are more likely to enroll in clinical trials because they have the financial resources to cover any additional expenditures related to the clinical trial.[32] Minorities, who are more likely to be of a lower socioeconomic status, do not have the same financial security to participate in clinical trials.[33] The high price tag on clinical trial participation prevents minority groups from buying into clinical research.

THE FIRST STEP TOWARDS A SOLUTION

The industry's acknowledgement that underrepresentation of racial and ethnic minorities in clinical trials is an issue is the first step in addressing the

issue. Acknowledgement cannot be the only step the industry takes because the problem will not fix itself. The path towards resolution is long and requires all industry stakeholders, from the drug development sponsors to the clinical investigators, to put forth efforts towards change. The industry-wide goal and theme to keep in mind should be to remove the barriers and burdens underrepresented minorities groups face when presented with an opportunity to participate in a clinical trial. Some examples of removing burdens include covering the costs of transportation to and from the research clinics, providing clinic hours in the evening and weekends, and implementing translated consent and study documents at the start of the trial before being requested.[34] There are various ways to address each of the five key barriers that minority groups encounter (Table 1).

Change is usually first seen with apprehension and hesitation, but the motivation for change reveals itself and in turn promotes the push for change. As the industry and its stakeholders learn and understand the reasons for change, a positive momentum will ignite a greater force to tackle the issue of underrepresentation of minority groups in clinical trials.

CONCLUSION

Increasing racial and ethnic minority representation in clinical trials is not an overnight fix, but a long process that requires an industry-wide shift in thinking about inclusion and heterogeneity in clinical trials. The industry needs to move away from believing homogenous clinical trial populations are the best standard and start asking questions about how variances within a population affect the safety and efficacy of a new investigational drug. The current industry perspective is unconsciously excluding clinical trial access from underrepresented minority groups. The social and health impacts of continued exclusion of racial and ethnic minority participation will include increases in health disparities for minority groups, growing mistrust of the U.S. health care system, and widening of the quality and standards of health care between the majority and minority population groups.

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