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The Importance of a Diverse Research Staff and Its Potential Impact on the Enrollment of Racial and Ethnic Minorities in Clinical Research Studies

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Health care disparities may originate in clinical trials when particular members of the population (lower socioeconomic status, race, or gender) are not adequately represented for a specific drug, device, or procedure. In 2022, Abbott provided a \$1.5 million Diversity in Clinical Trials Initiative grant to the Institute for Health Equity at Norton Healthcare to encourage diversity in research. The Norton Healthcare Advancing Research through Inclusivity, Sustainability, and Equity (ARISE) Medical Research Internship Program was founded at Norton to foster and maintain a diverse and well-rounded research staff by building referral networks, providing internship opportunities, and empowering individuals. Through innovative strategies established at Norton Healthcare to promote and encourage diversity in research, the goal is to effectively serve and engage the communities from which participants are recruited from.

INTRODUCTION AND CONTEXT SETTING

Clinical trials have historically lacked representation, leading to gaps in understanding how treatments affect different populations. Lack of inclusivity has contributed to health disparities and has limited the effectiveness of interventions for underrepresented and marginalized communities. The Civil Rights Act of 1964 was the earliest occasion when legislators or regulators developed policies on racial diversity in clinical research.¹ In 1965, the National Institutes of Health (NIH) General Clinical Research Centers added new notices to grant applications stating that racial discrimination was illegal. Research can face numerous challenges pertaining to diversity, including cultural and linguistic barriers, socioeconomic factors, historical mistrust and ethical concerns, lack of awareness and understanding, unconscious bias, implicit bias, and lack of consensus.² Inclusivity is crucial for advancing healthcare equity. Tackling these challenges by implementing strategies focusing on understanding and overcoming barriers to inclusion is imperative. Several approaches include building trust, education and outreach, culturally and linguistically appropriate materials, and addressing socioeconomic barriers.²

RACIAL AND ETHNIC MINORITY REPRESENTATION IN CLINICAL RESEARCH STUDIES

BARRIERS TO PARTICIPATION

Health care disparity, specifically, “the increased burden of an adverse health outcome or health determinant within a specific subset of the population” poses a challenge in the U.S. health care system and exacerbates both morbidity and mortality in several traditionally underrepresented populations.³ Numerous factors interplay in health care disparities, including financial disadvantage, lack of access to medical delivery systems, cultural mistrust, unrecognized bias, and structural racism.³ Mistrust of the health care system is reportedly the primary barrier to participation in medical research studies among African-American adults.⁴ This mistrust stems not only from the Tuskegee syphilis study but is also reinforced by present-day health system discriminatory practices and institutional racism.⁴ More specifically, racial and ethnic disparities have been observed in cancer clinical trials,^{5,6} cardiovascular clinical trials,⁷ and vaccine clinical trials.⁸ Findings in these studies, have demonstrated the widening inequalities in access to trial sites, worsening of systemic biases, and uneven enrollment trends.⁵

Table 1. Perceptions and Barriers Proposed for Lack of Racial and Ethnic Minorities in Clinical Research Studies

- > Lack of representation, acceptance, and belonging
- > Negative community beliefs and attitude
- > Reluctance due to their religious faith
- > Lack of knowledge of the value of clinical research trials
- > Inadequate recruitment and retention efforts
- > Transportation difficulties
- > High frequency of study visits
- > Low health literacy

IMPACT OF UNDERREPRESENTATION

Disparities in health care may originate in clinical trials when certain members of the population (lower socioeconomic status, race, or gender) are not represented sufficiently for a particular drug, device, or procedure.^{3,5,7,9} This is important because efficacy and safety of new medicines, devices, and medical products are incompletely tested when the study population does not represent everyone who suffers from the targeted disease process. The reality is that racial and ethnic minorities along with women, are typically not accurately represented in clinical trials.⁷ Through a patient-centric lens, several reasons have been proposed to explain low minority participation in clinical research trials, including (1) lack of diversity in research staff and leadership, (2) mistrust influenced by historical instances of unethical research conduct, (3) structural racism producing systemic inequities in healthcare delivery, (4) lack of knowledge of potential benefits of clinical research trial participation, (5) inadequate focused recruitment and retention efforts, (6) transportation difficulties, (7) the burden of frequent study visits, and (8) limited health literacy (Table 1).^{6,7,10} Health illiteracy refers to the “inability to comprehend and use medical information that can affect access to and use of the healthcare system”.¹¹ Low health literacy exacerbates health inequity as most patients are elderly, poor, and minorities who are unable to participate in their own healthcare decisions.¹² Healthcare providers often do not realize the importance of health literacy and how limited health literacy worsens the disparities in health care.¹²

EFFECTIVE STRATEGIES TO ENHANCE DIVERSITY IN CLINICAL TRIALS

Factors associated with successful racial and ethnic minority recruitment include increasing diversity of research site personnel and leadership who conduct trials, previous participation in a clinical trial by friends or relatives, and encouragement by trusted health care providers (Table 2).⁶

From an institutional standpoint, Adamson and colleagues recently reported that demographics of Centers for Medicare and Medicaid Services beneficiaries hospitalized with heart failure varied regionally by age and gender, stressing the importance of developing a clinical site and recruitment strategy based on an understanding of where patients with specific disease processes live.³ Research in-

stitutions, sponsors, and funding agencies are now strongly encouraged to prioritize the representation of all demographic groups by providing specific methods used in their proposals and notices of awards to achieve appropriate representation of all people with the disease process being studied.⁹ There are several reasons to elevate the importance of developing a priori methods to achieve adequate representation, as described in a recent systematic review focusing on research with socially disadvantaged groups.⁷ It seems clear that medical research data often fails to reflect the whole population which leads to numerous shortcomings, including (1) lack of external validity and ability to generalize results of a trial to all who may safely benefit from the innovation being tested, (2) preventing excluded groups from any health benefits of trial participation, (3) inability to confirm the safety of health innovations with population subgroups, (4) failing to identify groups that have the highest burden of illness, and (5) inability to determine if pathophysiologic or therapeutic differences exist within the population.⁹ Health inequity starts with clinical trial enrollment when new therapies are not sufficiently tested in all people with a particular disease which prevents generalizability of results.^{3,13} Identifying physiological differences in efficacy and safety can only be ascertained if all patients with the studied disease are reflected in clinical trials.³

Three goals have been proposed to enhance diversity in clinical trials, including building trust in medical research and institutions, promoting fairness for potential participants and their communities, and increasing health literacy (Table 2).¹⁴ Strategies to enhance involvement of minorities in clinical trials require inclusion of several key stakeholders in the clinical trial ecosystem. The physicians primarily caring for the patient often have a long-term trusting relationship with the patient. These physicians may be less aware of research programs or processes which may impact their desire to remember inclusion criteria or take the time to recruit patients. This offers an opportunity for community outreach and education. Local site principle scientific investigators are well-positioned to develop local strategies specifically designed for successful diverse and appropriate recruitment of underrepresented populations. Successful strategies must identify and solve hurdles and barriers minority patients may face in the catchment of the investigator’s practice. Coordinators and clinical trial teams are the main contact for participants in clinical trials and significantly influence recruiting efforts and protocol adherence. It is very important to include coordinators when developing strategies for diverse enrollment. In addition to setting clear expectations with personnel involved in the clinical trial ecosystem, it is important to establish effective communication between clinical trial participants and coordinators to ensure trust, impart knowledge, and offer support. Sustainable solutions require open, transparent, and carefully designed communication strategies which should include engaging community health workers, faith leaders, and community partner organizations. The goals of outreach communications must include public education efforts focusing on the nature and conduct of clin-

Table 2. Strategies to Increase Participation of Racial and Ethnic Minorities in Clinical Research Studies

<ul style="list-style-type: none"> > Increase diversity of research site personnel > Previous participation in a clinical trial by friends or relatives > Encouragement by health care providers > Building trust in medical research and institutions > Promoting fairness for potential participants and their communities > Increasing health literacy > Effective communication between research staff and minority clinical trial participants > Engaging community members through strategic partnerships with community health workers, faith leaders, and community organizations > Utilizing multimedia (television, radio, newspapers, posters, pamphlets) to advertise for clinical research trials using sensitive and culturally competent materials > Providing transportation and childcare

ical trials along with opportunities to participate at local research centers. Many centers also consult local community leaders and organizations for input in the design of recruitment strategies that focus on typically underrepresented populations. These efforts improve the development and implementation of clinical trials and enhance minority enrollment by fostering trust through a community-based participatory approach. In some areas, culturally tailored multimedia (television, radio, newspapers, posters, pamphlets) advertising may enhance community education and improve recruitment success. Consulting with local institutional review boards will ensure appropriate content and methodology for general community communication. Practical considerations of providing transportation and childcare options may overcome hurdles that discourage some minority patients' participation in trials that require frequent in-office follow-up visits.^{6,7,15} Finally, there is a significant correlation between site personnel diversity and patient enrollment diversity worldwide. This underscores the need for recruiting study personnel who may "look like" patients who are traditionally underrepresented. As the mix of research site personnel by race and ethnicity increases, the diversity of patients enrolled also increases.

NIH AND U.S. FDA APPROACHES TO PROMOTE DIVERSITY IN CLINICAL TRIALS

To encourage greater diversity in clinical trials, the NIH Revitalization Act of 1993 mandated inclusion of women and racial/ethnic minority groups in publicly sponsored clinical trials, however, diverse participation continues to remain low.^{8,16} These findings underscore the need for practical and effective recruitment strategies beyond simply making the community aware of the problem. The U.S. Food and Drug Administration (FDA) was recently empowered with several tools to improve clinical trial representation, including a standardized approach for collecting and reporting race and ethnicity data for clinical trials for FDA regulated medical products.¹⁶ The FDA established the Reauthorization Act of 2017 (FDARA) that included broadening subject eligibility criteria and avoiding unnecessary exclusions for clinical trials and established a requirement for trial sponsors to provide specific methodology to adequately represent the population with the target disorder for which the innovation being tested will likely be prescribed after approval.^{10,17,18} On April 13, 2022, the FDA

issued new guidance for "developing plans to enroll more participants from underrepresented racial and ethnic populations in the U.S. into clinical trials".⁸ Other acts such as the Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act and Diverse and Equitable Participation in Clinical Trials (DEPICT) Act have strived to promote greater diversity in clinical trials research by offering incentives and educational programs.^{10, 19,20} Enrollment in vaccine trials should target the patient population who are most at risk for infection, serious morbidity, or mortality.⁸ Certain viruses such as SARS-CoV-2 reportedly infect older adults and certain minority groups at greater rates, therefore, requiring their involvement in vaccine trials against this virus.⁸

RACIAL AND ETHNIC MINORITIES IN CLINICAL RESEARCH STUDIES AT NORTON HEALTHCARE

In early 2022, the medical device company Abbott announced a series of new programs within its multi-million-dollar initiatives to increase diversity in clinical trials and enhance care among underrepresented populations.²¹ As part of this initiative, Abbott provided a \$1.5 million Diversity in Clinical Trials Initiative grant to the Institute for Health Equity at Norton Healthcare to promote diversity in research, with a focus on enhancing the diversity of research staff and developing effective systems to improve diversity in clinical trial enrollment within an already established research infrastructure. The goal was to assist community-based health systems in creating clinical trial research centers of excellence to serve diverse populations. A pilot project that arose following the Abbott funding was to increase access of African-Americans from underrepresented communities to medical school and other medical professions. This pilot program was launched by Kelly McCants, MD, a cardiologist at Norton Healthcare and Executive Director of the Norton Heart & Vascular Institute Advanced Heart Failure & Recovery Program and Executive Director of the Institute for Health Equity at Norton Healthcare. This pilot program resulted in a partnership with Simmons College of Kentucky (an historically black colleges and universities [HBCU] in Louisville, KY), supported by Norton Healthcare, where students may embark on a Master of Science in Medical Sciences (MSMS) graduate program.²² This program helps students prepare with a

course of study that aligns with the traditional first year of medical school courses.²²

In February 2023, a group of Norton Healthcare research scientists developed two projects to address Abbott's dual initiative geared towards promoting diverse enrollment of research participants and improving research staff diversity. The first project utilizes a mixed methods approach leveraging research enrollment data from the Norton electronic medical record EPIC to provide the data-driven foundation, coupled with customized qualitative interviews used to explore the barriers and facilitators to diverse enrollment with key stakeholders. The second project was an innovative internship and scholar program through a joint collaboration between the Institute for Health Equity and Norton Research Institute (NRI) that will provide sustainable inflows of future staff members who represent and mirror the communities they serve. The goal is to establish a more diverse research staff to encourage diverse enrollment in research studies. By allowing the potential participants to identify with the research staff, they may be more likely to trust, embrace, and feel a sense of belonging when participating in a clinical trial at Norton Healthcare.

THE NORTON HEALTHCARE ARISE PROGRAM

The Norton Healthcare Advancing Research through Inclusivity, Sustainability, and Equity (ARISE) Medical Research Internship Program was founded at Norton to support and maintain a diverse and well-rounded research staff by building referral networks, providing internship opportunities, and empowering individuals (Fig. 1). The goal was to develop an interdisciplinary Internship and Scholar Program to recruit undergraduate students and post-graduates for inclusion in the program. Table 3 depicts the details of each of the two tracts. The objectives of this program were the following: (1) cultivate diversity (recruit from underrepresented minority groups), (2) empower emerging scholars (participate in immersive experiences with mentors), and (3) build sustainable pipelines (partnerships with HBCUs, minority-serving institutions, state and local universities, and community organizations). The learning curriculum is presented in Table 4.

To support Abbott's initiative of establishing a program to enhance diversity in research staff, two individuals (Edward Brown, MS, MBA, CCRP with the NRI and Valenchia Brown, DNP, MSN, APRN, FNP-C, CIC with the Institute for Health Equity) are guiding this effort. Dr. Brown holds the esteemed title of being named the inaugural Abbott Research Scholar in February of 2024. She serves as a postdoctoral research fellow and a Clinical Research Advanced Practice Provider with the Institute for Health Equity at Norton Healthcare. Dr. Brown has been enthusiastic about her postdoctoral position, stating that it has been an "engaging experience" where she continues to implement innovative programs and spearhead clinical research studies with a keen awareness of the importance of diversity and representation in research". She persists in "deepening her expertise in the intricate mechanisms of research studies and clinical trials while ensuring that her work is inclusive and characterized by equitable practices".

INITIATIVES TO IMPROVE DIVERSITY IN HEALTH SCIENCE RESEARCH

In the 2015 Kelly Report's examination of racial and ethnic health disparities in the United States, the need for a diverse healthcare workforce was noted.²³ It was proposed that public health and healthcare workforce training programs geared towards diversity could increase the likelihood that underrepresented patients would interact and be treated by providers who share a common race, ethnicity, culture, or language. Given the changing racial and ethnic demographic trends and projections for the U.S. population, medical systems and research institutions should evolve their workforces to increase their cultural and linguistic diversity to match the changing needs of their patients. The Centers for Disease Control and Prevention currently hosts many pipeline diversity training programs sponsored by the Office of Minority Health and Health Equity (OMHHE) that have shown to be effective at increasing staff diversity.²⁴ Implementation of the ARISE program is central to reaching this goal at the NRI. The ARISE program actively fosters a diverse research staff. The varied backgrounds of the research staff provide a wide range of perspectives and valuable experiences which enhance the quality and relevance of research projects. Interns and mentors from different cultural and linguistic backgrounds offer unique insights into health disparities and patient care, leading to inclusive and effective research outcomes.

Originating in 2021, the North Carolina Center for AIDS Research (NC CFAR) developed a pipeline program to improve diversity in health sciences research called the North Carolina Diversity and Inclusion Pathway Program (NC-DIPP).²⁵ NC CFAR leveraged its relationships with North Carolina's 11 HBCUs and established collaborations with North Carolina Central University and North Carolina Agricultural and Technical State University. NC-DIPP is a 12-month paid research internship for undergraduate students who are paired with experienced faculty members. Interns are assigned to a project in either basic science, clinical, or population-based research and are asked to present the results of their project to NC CFAR faculty at the end of their term. After two full terms, the 8 participating interns reported an average of 8.3 when asked to rate their overall experience and an average of 9 when asked if they would participate in programs like this again, on a 10-point likert scale.²⁵ Most interns reported having a positive experience and that the program helped them gain tangible research skills, grow their professional networks, and receive useful career development. Consequently, some barriers and challenges were identified. The main identified challenges were 1) logistical challenges with onboarding, 2) varying knowledge and skillsets between interns causing challenges for mentors, 3) and breakdowns in communication between interns, mentors, and program leadership.²⁵ Some of the proposed solutions for these challenges were 1) standardization of the intern onboarding process, 2) formulation of a detailed program handbook, 3) centralized program management and activity coordination, and 4) more frequent communication and check-ins between interns, mentors, and program leaders.²⁵

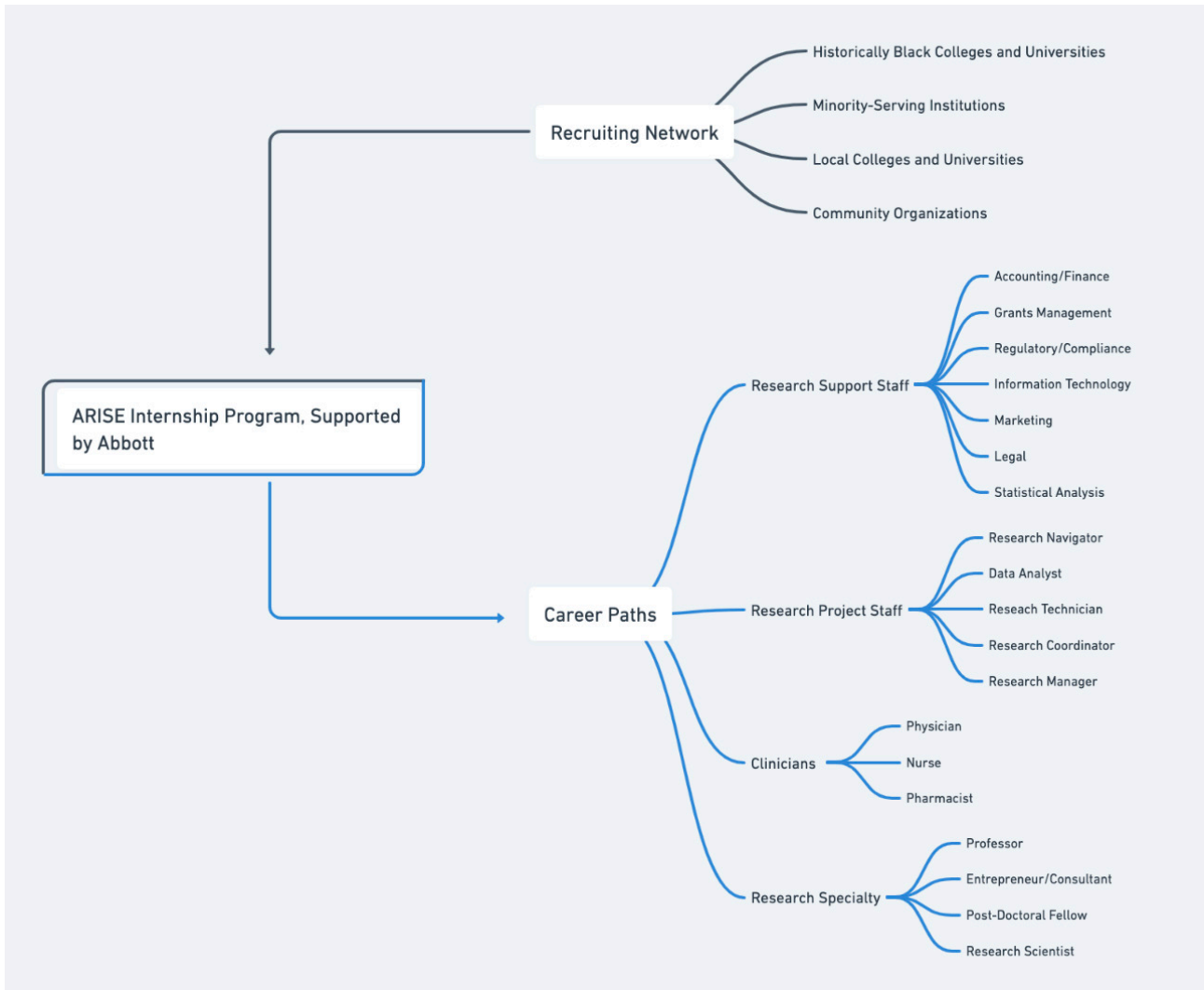


Figure 1. The ARISE Program at Norton Healthcare, supported by Abbott

Table 3. Two Tracks of the Norton Research Institute’s ARISE Internship and Scholar Program

Undergraduate Internship Track	Post-Graduate Scholar Track
<ul style="list-style-type: none"> > Semester/summer-term-based (4 months) > Paired with internship mentor > Didactic learning modules > Plan and implement a customized internship project. > Deliver a comprehensive presentation of their experience to the NRI 	<ul style="list-style-type: none"> > 1-year appointment > Collaborate with research faculty member > Didactic learning modules > Actively contribute to ongoing or new projects > Produce final report or draft for publication > Receive certificate of program completion

NRI: Norton Research Institute

The ARISE program will not start until the Spring of 2025 when we will be welcoming our first cohort of undergraduate interns. While similar programs to the ARISE program such as the NC-DIPP have been successful, they have also faced challenges.²⁵ We have incorporated these lessons into our program design by ensuring a robust onboarding experience and clear communication pathways among interns, mentors, and leaders. We have developed a detailed program handbook and implemented weekly check-ins with mentors. ARISE leadership will evaluate the program by assessing feedback from interns, mentors, and program leadership. ARISE leadership will implement a mixed methods

data collection approach to analyze feedback from program stakeholders. Each intern will be invited to participate in a semi-structured interview near the end of their internship term to provide feedback on overall program impressions as well as experiences with specific program components. A survey will then be distributed to each intern for up to 5-years annually after program completion to follow-up on career progression. ARISE leadership and ARISE mentors will be asked to complete a short survey to provide feedback and ratings related to their specific cohort or intern. To enhance the robustness of the evaluation, ARISE leadership will use this evaluation data to create annual reports which

Table 4. Learning Curriculum for Interns and Scholars in the Norton Research Institute’s Internship and Scholar Program

Benefits of the scientific methods and rigorous procedures
<p>Staff Training Topics</p> <ul style="list-style-type: none"> • Diversity in Clinical Research • Human Subjects Protection • Clinical Trial Phases • Implicit Bias Training
<p>Didactic Learning Modules</p> <ul style="list-style-type: none"> • Proposal Planning • Obtaining Funding • Regulatory Compliance • Financial and Budget Management • Teamwork and Project Management • Reporting to Sponsors • Dissemination Efforts
<p>Roles and Responsibilities of Research Positions</p> <ul style="list-style-type: none"> • Scientific Investigators • Project Team • Support Staff
<p>Career Opportunities and Mentoring</p> <ul style="list-style-type: none"> • Undergraduate Possibilities • Graduate School Possibilities • Academia vs Industry vs Hospital System

will be shared with stakeholders to demonstrate the program’s impact and effectiveness. These reports will include key metrics, success stories, and actionable recommendations for future program iterations. This approach allows

for continuous improvement and excellence of the ARISE program.

ADDITIONAL PROGRAMS DEVELOPED BY NORTON HEALTHCARE TO STIMULATE DIVERSITY IN RESEARCH

In addition to the ARISE program, Norton also plans to develop strategies to enhance diversity in research studies by understanding representation at each phase of the research enrollment process, outlining an annual program evaluation with performance metrics, performing geospatial mapping studies used for targeted recruiting efforts, matching disease-specific demographics to study populations, and creating dashboard tools for use by study investigators.

CONCLUSION

Diversity in research staff improves the engagement, enrollment, and retention of a diverse population of study participants. To overcome the pervasive medical mistrust held by minorities and marginalized communities, we have strived to perform outreach education and trust building within the community. Through the myriad innovative approaches developed at Norton Healthcare to stimulate diversity in clinical research, we aim to continually meet the needs of the communities we serve and recruit from.

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