Abbott

ADVANCING DIVERSITY IN CLINICAL TRIALS

Designing a Diverse Clinical Trial Ecosystem

A Letter From the Founding Members of the Diversity in Research Office

Jennifer Jones-McMeans, Ph.D., Divisional Vice President, Global Clinical Affairs, Vascular, Abbott
Aparna Ahuja, M.D., Divisional Vice President, Medical, Clinical and Scientific Org, Rapid Diagnostics, Abbott

In "Advancing Diversity in Clinical Trials," we collate and contextualize contemporary thinking on the design and implementation of clinical trials with a specific focus on diversity — both in the population of clinical trial participants and the broader clinical research ecosystem. In focusing on this topic, we shine a light on how the historical lack of diversity in clinical trials has contributed to a lack of representation for diverse patient populations and exacerbated some of the existing inequalities in the U.S. healthcare system. We also examine the clinical implications of these limitations on driving insights into how varied populations will respond to the therapies and innovations examined within a clinical trial setting.

This document draws on experiences and insights from a diverse group of experts in the field, including academic researchers, physicians, advocacy groups and clinical trialists, as well as professionals within Abbott, an industry sponsor of hundreds of clinical trials and a company with decades of experience within the U.S. healthcare system.

In collecting and presenting a summary of these varied viewpoints, we hope to present a comprehensive overview of current thinking on diversity in clinical trials. Moreover, we hope that this document will serve as both an industry perspective and an actionable guide on how to increase diversity in clinical trials via site design, community partnership and education. Our goal is that this document helps provide useful commentary and guidance for community-based health systems, hospitals and academic researchers as they seek to diversify their own clinical research. As best practices and methodologies continue to evolve, we intend to adjust our recommendations accordingly to reflect new thinking in the field.

This document attempts to aggregate information and insights from dozens of international experts on trial diversity and health disparities alongside the views of industry experts that form Abbott's Diversity in Research Medical Advisory Board, but it is not intended to be definitive or curtail continued thinking. Rather, we hope the findings herein will be distributed and expanded upon to inspire other companies and organizations to invest in diverse clinical trials.

CONTENTS

DESIGNING FOR DIVERSITY

Introduction

Clinical trials are the foundation of modern medicine and the ultimate test of safety and effectiveness before healthcare products, medicines and medical devices are approved. Clinical research should help drive greater understanding of how innovations and breakthrough therapies could impact broad populations, and breakthrough healthcare technologies should be based on evidence that reflects the diversity of broad populations. However, in clinical research practice today, that is often not the case.[1]

Research shows systemic underrepresentation of women and people of color in clinical trials. Take heart disease, for example. It is the leading cause of death for women in the United States (roughly one in five women[2]), yet women only account for 38% of participants in cardiovascular clinical trials,[2] despite accounting for 50% of the U.S. population. The numbers are even worse for Black women; the age-adjusted rate of heart disease for Black women is 72% higher than for White women.[3] Black people accounted for only 2.9% of participants in clinical drug trials from 2006 to 2020,[4] despite representing more than 13.4% of the U.S. population.[5]

Why? How can we change these numbers? What organizations are already doing the work to increase diversity in clinical trials, and how can that work be elevated, supported, expanded and reproduced? Such questions are at the heart of this investigation.

"Diversity in clinical trials allows us to look at the scope of different populations and ask the question: Is this intervention impactful or effective on this particular population versus another? That will tell us if it works for everyone or only on this group."

— Dr. Hugh Mighty
Dean of the College of Medicine and Senior Vice President for Health Affairs at Howard University‡

Current Clinical Trial Environment in the United States

Clinical trials are foundational to the modern healthcare system in the United States, allowing for rigorous assessment and deeper understanding of newly developed therapies, treatments and medications. As of January 25, 2024, more than 169,000 clinical trials were registered in the United States (with more than 480,000 registered globally).[6] Most clinical trials are traditionally sponsored by healthcare companies, and clinical sites conduct the research to evaluate the efficacy of the medical intervention.

Clinical trials open the door to innovative new treatment options and insights that can further the understanding of diseases, including how to fight and prevent diseases. For some patients with complex health conditions, clinical trials can provide new ways to combat an illness that has not responded to other available treatments. In this way, clinical trials can offer hope to patients without alternatives while helping companies evaluate the efficacy of potentially life-saving treatments.

To maintain the integrity of data collected by clinical researchers, clinical trials must deploy strict protocols and involve a high level of both scientific and procedural rigor. Researchers often devise eligibility requirements (such as age, overall health and current disease state) to ensure the integrity of the trials. However, these requirements can inadvertently exclude individuals or limit access to trials in a way that further exacerbates existing inequalities in healthcare.

Historically, clinical trials in the United States have not been representative of the country's diverse population, and past injustices and mistreatment of underrepresented patient groups within the research system have caused significant distrust of clinical trials and the broader medical community. Addressing these issues requires systemic change, cooperation and a collective push for more diverse patient sets within clinical trials.

"The problem is distrust of the medical establishment, not mistrust. There's a big difference. Mistrust is having a hunch that something doesn't seem right. … Distrust means history. Something has happened. Personal experiences. So to overcome distrust, there has to be a stronger, more comprehensive effort. You have to demonstrate something."

— Reggie Ware
CEO of BlackDoctor.org[‡]

BEFORE THE CLINICAL TRIAL

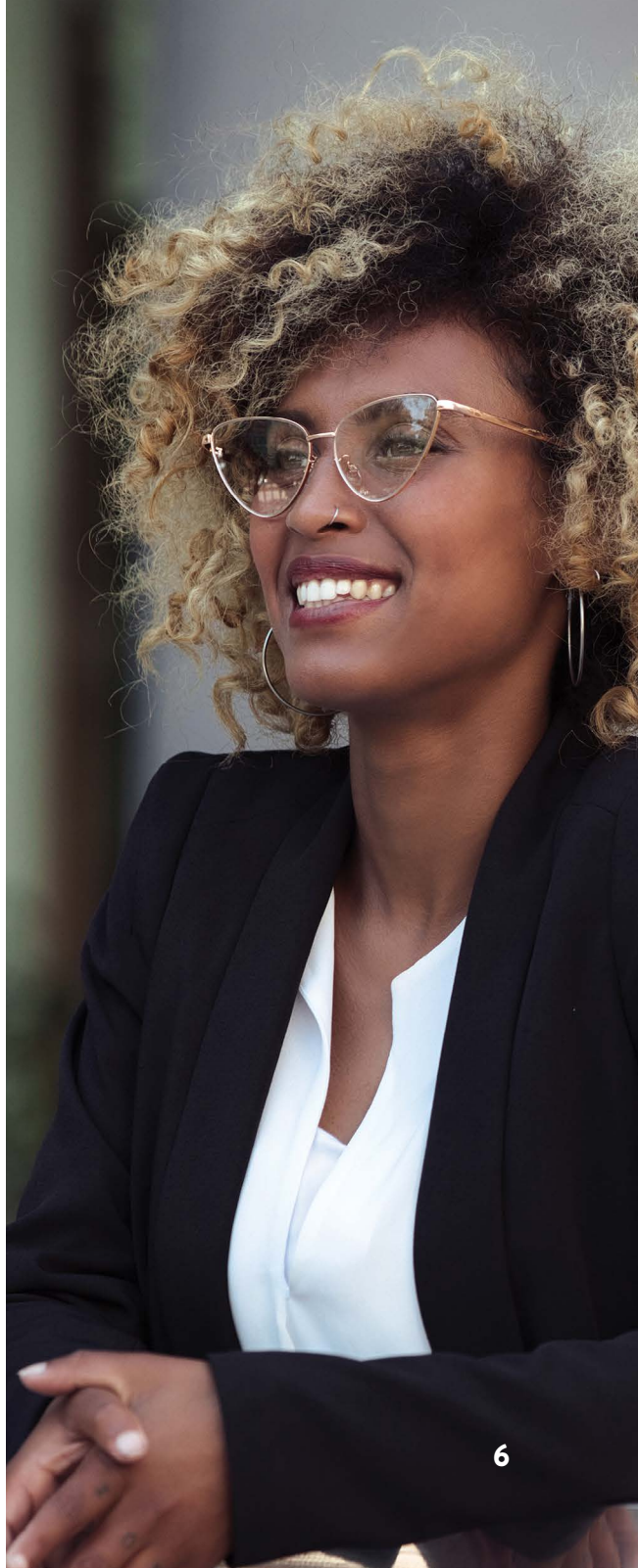
Much of the work to improve diversity in clinical trials must be undertaken before the clinical trial even begins.

The Role of Leadership for Clinical Trial Sponsors

Healthcare corporations have a significant role to play in focusing on diversity, equity and inclusion (DEI) goals, which are central to creating systemic change in the healthcare industry. Companies need the buy-in of the C-suite and other members of corporate leadership teams to ensure DEI is a focus in decision-making processes. Leadership can help clinical trial best practices and reinforce new standards of care.

Companies can make sustainable change by:

- Creating performance goals that tie to improving health equity.
- Empowering clinical teams to achieve key performance indicators through resource management.
- Understanding clinical trial needs and challenges for the organization in the coming years.



Forming a Network of Partners and Advocates

In a field as large and complex as healthcare, enacting change will require deep partnership and collaboration between stakeholders from all corners of the industry. However, meaningful engagement will take time and must occur well before a clinical trial begins, so it must be approached with intention, mutual understanding and a desire to improve patient outcomes in both the short and long term.

PAIRING ESTABLISHED AND NEWER CENTERS TOGETHER CAN ENSURE QUICKER KNOWLEDGE TRANSFER AND EXPANDED ACCESS TO CARE.

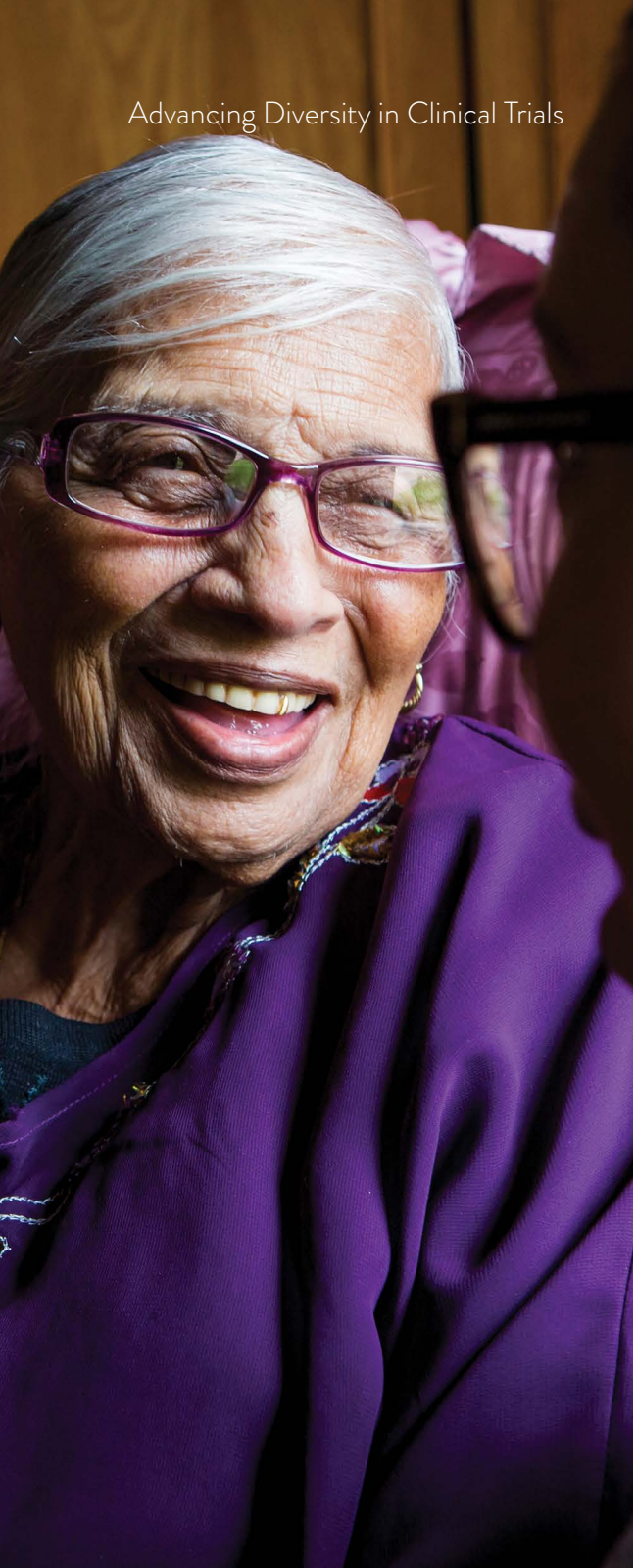
Forging Partnerships With Universities and Institutions

Most clinical researchers begin their careers in research at medical universities and institutions, where the researchers receive professional training and hands-on experience with clinical trials. Greater diversity in the student population can help increase the pool of researchers who come from diverse backgrounds. However, these individuals face other barriers when entering the profession.

For clinical research to be more attractive to diverse students, there need to be incentives for these students to pursue research. As one example, Abbott has partnered with historically Black colleges and universities (HBCU) and minority-serving institutions to fund scholarships for medical students. We believe that this will help strengthen the researcher pipeline in the years to come.

Not all partnerships must be financial, however. Sharing information, resources, connections or opportunities can also be extremely valuable and can help break down the silos in clinical research.

For example, in spring 2021, Stand Up To Cancer‡ awarded a $6 million grant to fund Project DISRUPT (Diversity and IncluSion in Research Underpinning Prevention and Therapy Trials),[7] a project about DEI in cancer clinical trials. In addition, since 1999, the National Medical Association‡ has been managing Project I.M.P.A.C.T. (Increase Minority Participation and Awareness of Clinical Trials),[8] a project dedicated to increasing the number of Black people in all areas of clinical research — from participating in a study to running one. By tapping into these existing initiatives and sharing resources, other organizations interested in increasing diversity can elevate the work that has already been done and continue to build on it in the future.



Leveraging Community and Patient Advocates

In some communities, the most effective way for researchers to reach out to patients is to work with third-party individuals and organizations, such as community leaders and patient advocates, who have already established rapport with community members.

Patient advocates can also serve as connectors between clinical trial participants, researchers, and other medical facilities and resources. Dr. Jay Vadgama, Vice President for Research and Health Affairs at Charles R. Drew University of Medicine and Science[‡], always leverages patient advocates in his clinical trials. He related how, early in his career, he met a trial participant who was a single mother with young children, trying to balance work, transportation and caregiving duties with the clinical trial. He realized then that this patient and others like her needed help to participate in that trial, and that is why patient advocates exist: to help connect patients to resources, navigate insurance and the healthcare ecosystem, and ensure that barriers like lack of access to a car should not prevent individuals from participating in a clinical trial.

Accounting for Cultural, Regional and Local Differences

Just as no two cities are the same, no two communities are the same. Researchers should take into account cultural, regional and local differences in communities when designing their clinical trials and selecting sites. Otherwise, researchers may make erroneous assumptions, which can alienate potential participants and jeopardize enrollment. For example, though some Latinx communities do have promotores (community health workers), not all do. Local partners and community advocates can help researchers understand and account for those differences.

Building Trust Through Communication and Education

In addition to building trust through a network of partners and advocates, the sponsors and organizers of clinical trials can demonstrate their commitment to increasing health equity and diversity in the field through thoughtfully prepared, patient-centric communications and educational campaigns. A strategic communications campaign might include digital and physical materials in multiple languages, an explainer about informed consent, collateral about the medical intervention being tested with the trial, success stories and experiences from past trial participants, and general information about clinical trials.

Awareness and understanding of exactly what clinical trials are and their benefits remain relatively low, according to surveys.[9] To increase patients' baseline understanding of clinical trials, researchers should focus on educating patients about the basics of clinical research and the terms they might encounter during a clinical trial, which will enable deeper understanding and greater potential for informed consent.

For example, efforts to improve health literacy about trials must be tailored to individual community and patient needs. Demonstrating sensitivity to and understanding of the patient's circumstances, as well as the community's history with the healthcare system, has the potential to improve the enrollment and retention of trial participants.[10]

Creating a Diversity Advisory Board

Understanding and learning from the experiences of the physicians, researchers, academics, administrators and patients from diverse backgrounds who have been a part of the clinical trial ecosystem is vital to the success of clinical trials that have diversity. A diversity advisory board made up of industry experts can help improve that understanding while also informing continued work. This board can provide clinical trial sponsors with guidance on how to design future clinical trials to be more inclusive, advice on evolving health policies and regulations, and insight into topics such as health equity and patient privacy.

"When we go in, we have a tendency to be prescriptive: 'You should take this because it's good for you. Trust me because I'm the expert.' That doesn't engender trust. You need to ask: 'Who is the trust agent in that community?'"

— **Dr. Hugh Mighty**
Dean of the College of Medicine and Senior Vice President for Health Affairs at Howard University‡

BARRIERS TO CLINICAL TRIAL PARTICIPATION

Before we can break down barriers to clinical trial participation, we must first understand what the barriers are and why they exist. In a 2022 paper on the subject by the External Council for Advancing Inclusive Research‡,[11] these barriers are grouped into three categories.

The System Level: A barrier that exists because of a systemic issue in healthcare, the clinical trial landscape or our society.

The Study Level: A barrier introduced or reproduced by the study and its design, which can often be solved through inclusive study design practices.

The Patient Level: A barrier, such as distrust of the medical system, that exists within the patient but may be a symptom of a broader systemic issue.

Understanding Barriers at the Patient Level

Individual circumstances, often far beyond a person's control, are collectively known as social determinants of health (SDH). The World Health Organization defines SDH as the "conditions in which people are born, grow, work, live, and age," as well as the often complex, interrelated social structures and economic systems[12] that can determine a person's ability not only to participate in a clinical trial but also to access basic healthcare.[13]

In almost all cases, the onus for addressing patient-level barriers falls on study designers, the clinical trial ecosystem and healthcare at large. We have identified four key areas of deficiency where increased focus on DEI can make a substantial difference in breaking down these barriers. They are lack of trust, lack of transparency, lack of access and lack of a common language.

Barrier: Lack of Trust

1 **Issue:** Distrust of the healthcare system often stems from historical cases that eroded trust among minority patient groups, such as the Tuskegee syphilis study and ethical debates related to the origins of the Henrietta Lacks cell line.

Recommendation: This kind of distrust should be addressed at the system level by establishing DEI practices, guidelines and accountability metrics to help ensure such injustices are not repeated.

2 **Issue:** Lack of diverse representation among investigators and research coordinators affects patient buy-in. If patients do not see themselves reflected in the care team or are unable to communicate with researchers, they will be hesitant to enroll.

Recommendation: Researchers should implement inclusive hiring and study design practices to mitigate this issue and increase diversity among the staff running clinical trials. For more information, see "Selecting an Inclusive Research Team" on pages 18–21.

3 **Issue:** Unconscious bias in research teams can lead to researchers not offering participation to certain patients due to age, race, ethnicity or immigration/citizenship status, etc., under the false assumption compliance will be low or patients will withdraw.

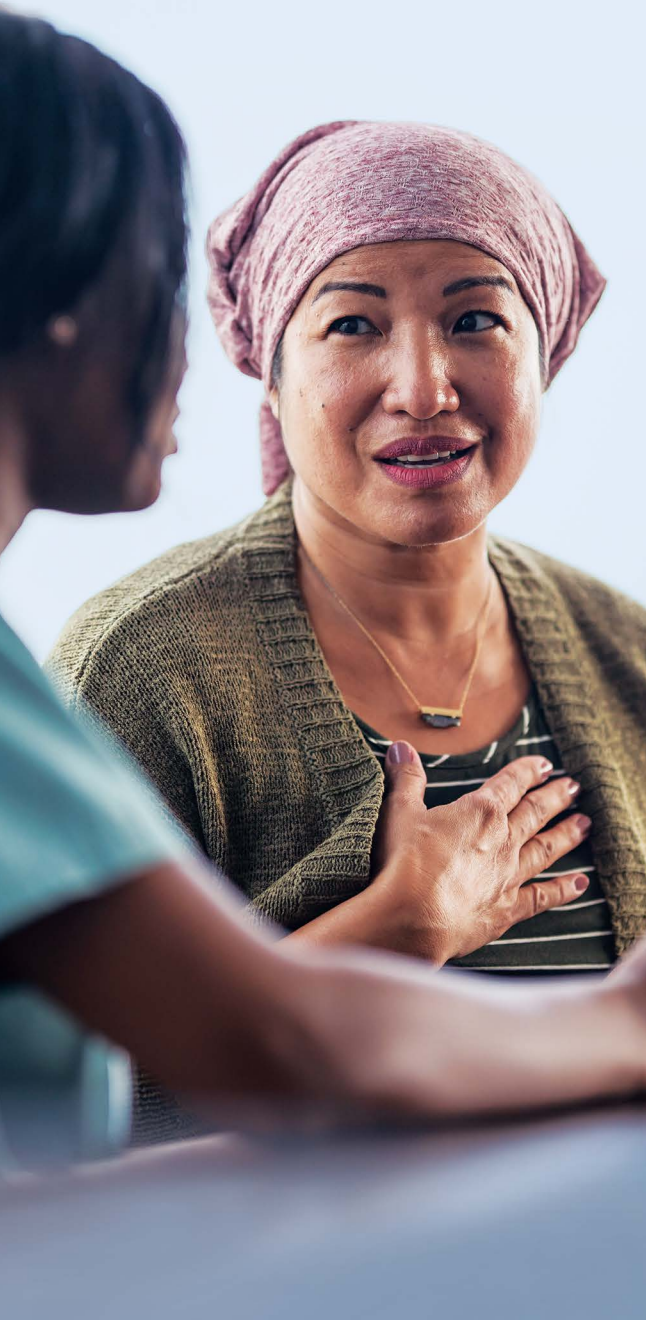
Recommendation: Unconscious bias is a problem in our society, not just within the clinical trial ecosystem, and as such no one team can solve this problem. However, there are steps we should take to help eliminate unconscious bias in clinical trials — for example, by leveraging inclusive practices. For more information on this, see "Designing Inclusive Clinical Trials" on pages 15–21.

4 **Issue:** Adhering to traditional practices can lead clinical trial sponsors to go back to the same sites and investigators rather than explore other options. Often, sponsors make this choice under the assumption that new or unfamiliar researchers do not have the qualifications necessary to conduct a clinical trial. This false assumption centralizes resources and research infrastructure in the hands of a few.

Recommendation: Trial sponsors should cultivate relationships with new principal investigators and research centers better connected to the populations that would most directly benefit from the trial. This is especially true with underserved and underrepresented populations, where a lack of access and/or of a common language could make it impossible for those unfamiliar with the community to run an effective study.

"When I go into healthcare settings, I'm already at a disadvantage because I'm a woman and I'm Black. When it comes to my cardiovascular health, I'm not believed. When it comes to pain management, I'm not believed."

— Dr. Akilah Cadet
Founder and CEO of Change Cadet and a patient advocate



Barrier: Lack of Transparency

1 **Issue:** Information about clinical trials often fails to answer simple questions for participants about the goals of the trial, what researchers hope a medication or treatment will do, and even what the final outcome could be, leaving participants in the dark about the true impact of their contribution.

Recommendation: Standard practice for clinical trials should be for researchers and patient advocates to provide information without patients having to ask, and readily answer questions that do come up at any point during the process. This will help patients understand the importance of the study.

2 **Issue:** It is often unclear if patients need to have insurance or pay to participate in clinical trials. Many patients with Medicare‡ coverage can be reimbursed for clinical trial procedures or treatments. However, private insurers do not always provide the same benefits.

Recommendation: Industry sponsors, researchers and patient advocates should work with clinical trial participants to navigate insurance, mitigate costs and understand the financial implications of a trial. Note that trial stipends may be considered income, meaning low-income participants may lose their public benefits if stipends are offered.

Barrier: Lack of Access

1 **Issue:** Inconvenient study locations make it more difficult for patients to participate in a study due to conflicts with work schedules, traffic, childcare and the cost of travel. For example, primary caregivers must schedule around the daycare, school and/or after-school options available to them.

Recommendation: During the site selection phase of designing a study, researchers should take care to select sites that maximize access for members of the target community. Where possible, companies should build the cost of transportation vouchers or other travel arrangements into the trial budget to support patient access. For more information, see "Site Selection" on page 16.

2 **Issue:** A high frequency of follow-up visits can be challenging for participants balancing work, family and other responsibilities and may be a significant deterrent to enrollment. Hourly employees and shift workers often cannot afford to lose wages to participate in a trial.

Recommendation: Researchers should consider designing the study to minimize the number of follow-up visits where the patient must travel. At-home wearable or monitoring devices provided by researchers can allow patients to log data remotely when possible.

3 **Issue:** The digital divide prevents many patients from being in frequent contact with the clinical trial team. Some patients do not have access to high-speed internet or the use of a laptop, tablet or smartphone. The clinical trial team should not assume that they will be able to easily communicate with all patients via a single method, such as email.

Recommendation: Researchers should design their trials so that they are prepared to engage with patients using multiple methods of communication.

Barrier: Lack of a Common Language

1 **Issue:** In many cases, clinical trial information is only available in one language (English), and yet the trial participants may not speak English or may be more comfortable in their own language.

Recommendation: Multilingual materials and translation services should be available to all prospective patients. Family members may help the participants to communicate with researchers, but the trial should not be designed with the assumption that family members will be available for translation services.

2 **Issue:** Scientific jargon can be confusing. Often, the terminology used to enroll patients into clinical trials and confirm consent is technical, complex and difficult for people without a medical background to comprehend, leaving the patient unsure about what exactly they have been asked to agree to and sign.

Recommendation: Wherever possible, scientific and legal jargon should be simplified and restated to improve comprehension. Additionally, researchers should be available to answer any questions about the trial and associated forms, and the potential participants should be given ample time to review the documents.

DESIGNING INCLUSIVE CLINICAL TRIALS

Clinical trials should be designed to recognize and account for differences, not assume a homogenous patient population. Age, race, ethnicity, gender identity and geography are all important factors in the research and development of healthcare products, new therapies and medical devices. Inclusive clinical trials must take these factors into account at the design stage. In this section, we outline best practices for designing for inclusivity during site selection, patient selection and team selection.

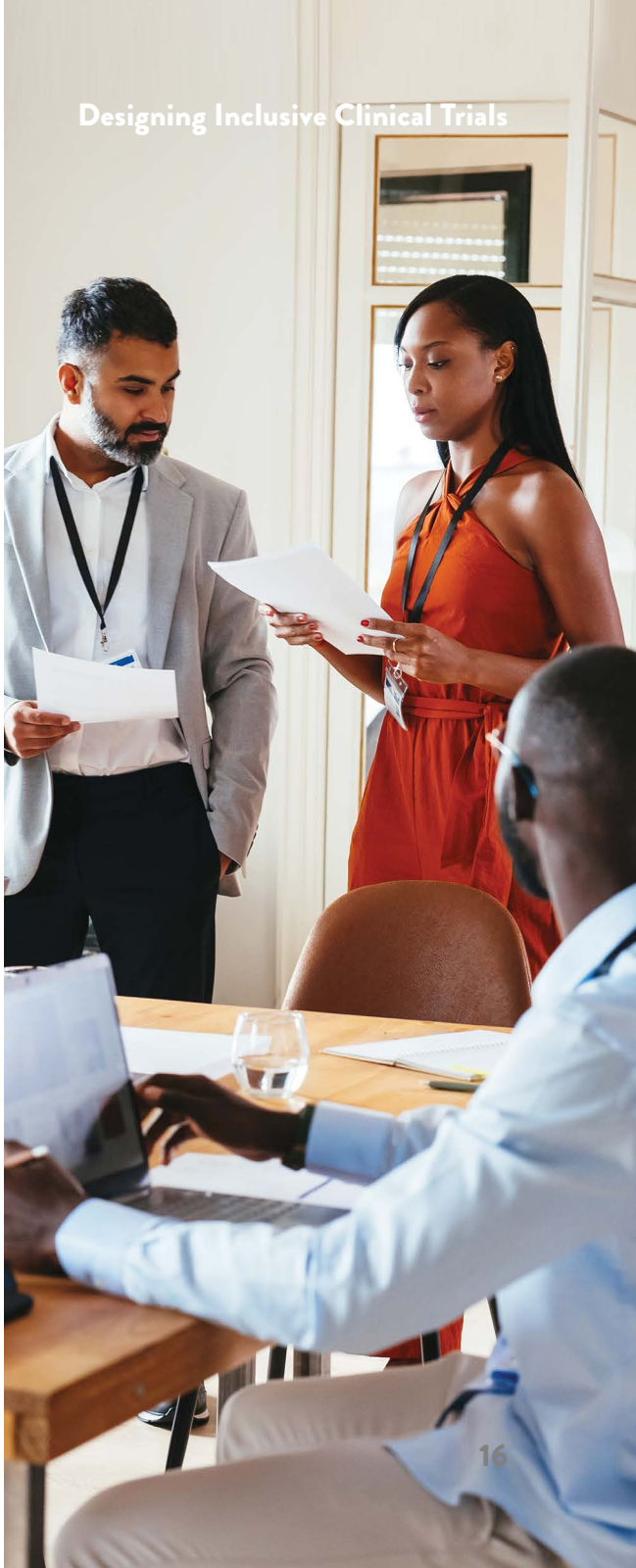
1

SITE SELECTION

Site Selection

Mindful site selection is integral to diversity in clinical trials. Often, industry sponsors will only work with medical centers and researchers that have experience running clinical trials or already have the resources to do so. This limits opportunities for new or less experienced sites, as well as sites in rural settings or without the resources and infrastructure of a large medical center. Only running clinical trials in urban centers or with established sites limits access for both the participants and researchers, resulting in less diversity on both sides of the clinical trial. Sponsors should actively recruit more women and people of color for research teams, as well as work with a mix of urban and rural sites.

SPONSORS SHOULD ACTIVELY RECRUIT MORE WOMEN AND PEOPLE OF COLOR FOR RESEARCH TEAMS, AS WELL AS WORK WITH A MIX OF URBAN AND RURAL SITES WHEN POSSIBLE.



2

PATIENT SELECTION

Patient Selection and Participation

Building accessibility throughout the clinical trial design will foster a more diverse patient population. Where researchers choose to run the trial will impact who can participate, making site selection just as critical to increasing diversity in clinical trials as intentional patient selection. When more accessible sites are available, patient demographics shift, meaning that more people, including people of color and economically disadvantaged patients, are able to participate in clinical trials.

Clinical trial sponsors and researchers can further increase accessibility by working with patients and advocates to set up transportation, translation or other services. For example, vouchers for ride-sharing can help patients travel between the trial site and their homes or jobs, removing a transportation barrier. When measures like this are built into the trial design, more diverse patients are able to participate in the clinical trial, increasing the quality of the data that comes from the trial.

3

TEAM SELECTION

Selecting an Inclusive Research Team

The Role of Investigators

Investigators are the physicians responsible for conducting a clinical trial. Principal investigators generally lead teams of researchers who work together to coordinate and complete their trial. In this leadership position, investigators play an integral role in forming teams, setting expectations for individual team members and representing the clinical trial to potential participants. Patients are also more likely to participate in clinical trials if a physician looks and speaks like them. This relatability factor helps build trust between the patient and the clinician.[14]

Building a robust and diverse registry of physicians who participate in clinical trials is key to the success of diversity in clinical trials. This registry should include diversity within age, gender, race, ethnicity and geography to increase the likelihood of enrolling patients from underrepresented groups, such as non-English speakers or women of color. Women often do not see themselves reflected in the medical establishment, and it might not occur to them that they could be a candidate for a clinical trial.

BUILDING A ROBUST AND DIVERSE REGISTRY OF PHYSICIANS WHO PARTICIPATE IN CLINICAL TRIALS IS KEY TO THE SUCCESS OF DIVERSITY IN CLINICAL TRIALS.

The Importance of the Research Coordinator

This role is integral to the clinical trial's overall success and is primarily responsible for running a clinical trial. Oftentimes, the research coordinator has the closest relationship with the patient. The research coordinator's responsibilities are wide-ranging and include:

- Performing project management tasks and coordinating with patients and colleagues.
- Enrolling/consenting patients into the trial and providing information to patients.
- Ensuring compliance with regulatory requirements and FDA audits and inspections.
- Tracking and monitoring patients during the study and follow-up visits.
- Entering data and maintaining the integrity of that data.

Due to the essential nature of this role, one of the major barriers for new sites hoping to conduct clinical trials is the requirement to have a trained research coordinator. Community-based clinics without a research coordinator already on staff are at a disadvantage and, as a result, will often be passed up by sponsors seeking sites with teams ready to start work immediately.

A RESEARCH COORDINATOR IS CRITICAL TO THE SUCCESS OF COMMUNITY-BASED CLINICS.

Partnering With Contract Research Organizations (CROs)

Many sponsors partner with CROs to complete multicenter clinical studies. CROs provide full-service support from the pretrial phase through FDA approval. When screening CROs, it is vital to ensure diversity is a key part of their business practices. If not, they should be willing and able to incorporate diversity into their research methodologies. Additionally, sponsors should be mindful of considering all possible sites and researchers for a given clinical trial — not just returning to the same CROs as a matter of course. Returning to previous CROs may limit opportunities for researchers from diverse backgrounds to engage in clinical research.

Working With User Experience Experts

Due to ethical, regulatory and legal requirements around clinical trials, industry sponsors are prevented from having direct contact with patients enrolled in their trials, which means that even though industry sponsors are aware of the barriers participants face, they cannot work directly with participants to break down those barriers. In instances like these, the expertise of a patient engagement specialist or patient experience researcher could be a viable solution.

Traditionally, clinical trials were executed with a focus on what clinical sites needed to run a trial. There has been a shift to focus on patient experience and education on participation. Clinical trial user experience research is the study of how potential recipients access clinical trials and participate in the trial process, as well as the motivations behind people's interest in participating in clinical research. User experience researchers can provide counsel to companies leading clinical trials around how the companies can make their trials more accessible by working with patients, principal investigators and research coordinators. With this feedback and insight from user experience researchers, companies can break down barriers and make the research process more patient-centric.

Key Recommendations

Without an experienced research coordinator, sites are not usually considered for selection in a sponsor-led clinical trial. To address this weak link in the clinical trial ecosystem, sponsors can:

- Develop a pipeline of qualified research coordinators.
- Create a grant program for investigators to train and hire a research coordinator.
- Create a shared network of research coordinators across sites.
- Provide training and development opportunities for research coordinators.
- Initiate a mentoring program for research coordinators.

Pretrial Checklist

- Is the site new to clinical trials? If yes, do they have appropriate training? Is it a trusted source of medical advice and care in the community?
- How will the inclusion of this site reflect the needs of the real-world population and make the results of the trial better?
- Are the principal investigators and their team committed to including a diverse population?
- What kinds of support and training can be provided to the research team to set the site up for sustainable success?
- Are the eligibility requirements limiting participation of patients from diverse backgrounds?
- Have materials been developed to meet the needs of patients with different levels of comfort with and access to technology? Have materials been translated into multiple languages?
- Have other resources been provided to participants to make the trial more accessible?

CONCLUSION

Health equity issues cut across all areas of the healthcare spectrum. Making incremental but meaningful changes to industry practices signals to the medical community, the patient community and society at large that there is willingness to truly make **healthcare products** for all **by including diverse populations** in the research and development of new medical interventions. Having already increased representation of diverse doctors and communities of color, the industry is working to ensure we continue to evolve our clinical trials to be more representative of more diverse communities. Setting a new standard for clinical trials is possible with intentionality and partnerships across the healthcare ecosystem.

List of Contributors

Philip Adamson, Former Divisional Vice President and Chief Medical Officer, Heart Failure, Abbott

Aparna Ahuja, M.D., Divisional Vice President, Medical, Clinical and Scientific Org, Rapid Diagnostics, Abbott

Shridara Alva, Sr. Director and Clinical Affairs Associate Research Fellow, Diabetes Care, Abbott

Dr. Danielle Bajakian, Vascular Surgeon, Columbia University‡ Irving Medical Center

Dr. Akilah Cadet, Founder and CEO, Change Cadet

Jessie Coe, Global Project Director of Global Clinical Operations, Vascular, Abbott

Jeffrey Dressler, Divisional Vice President, Global Clinical Operations, Abbott

John Frels, Vice President, Research and Development, Diagnostics, Abbott

Melissa Gonzales, Board Member, National Association of Latino Healthcare Executives

Kelly Greer, Director, Clinical Site Management, Global Clinical Operations, Abbott

Chananit Hutson, Senior Manager, Global Clinical Affairs, Vascular, Abbott

Jennifer Jones-McMeans Ph.D., Divisional Vice President, Global Clinical Affairs, Vascular, Abbott

Dr. Yolanda Lawson, Board Chair, National Medical Association‡, and an Associate Attending, Baylor University Medical Center‡

Yen Ling Low, Divisional Vice President Scientific and Medical Affairs, Nutrition, Abbott

Jon Marion, Associate Director of Clinical Quality, Quality and Regulatory, and Clinical Research Council, Abbott

Beth McQuiston, Medical Director of Research and Development, Diagnostics – Neuroscience Research, Abbott

Dr. Hugh Mighty, Dean of the College of Medicine and Senior Vice President for Health Affairs, Howard University‡

Dr. Lyssa Ochoa, Vascular Surgeon, The San Antonio Vascular and Endovascular Clinic

Dr. Ki Park, Vascular Surgeon, University of Florida‡ Health

Richard Rapoza, Divisional Vice President Global Product Development, Vascular, Abbott

Dr. Joseph Ravenell, Internal Medicine Physician, NYU Langone Health‡, and Associate Professor in the Departments of Population Health and Medicine, New York University‡

Dr. Elena Rios, President and CEO, National Hispanic Medical Association‡

Dr. Uzma Samadani, Neurosurgeon, Minneapolis Veterans Affairs Medical Center, and Associate Professor of Bioinformatics and Computational Biology, University of Minnesota‡

Erica Sethi, Director of Regulatory Affairs, Diagnostics, Abbott

Barathi Sethuramen, Divisional Vice President Global Clinical Affairs, Structural Heart, Abbott

Jason Staples, Senior Counsel, Corporate Legal, Abbott

Christine Steele, Director of Clinical Development and Scientific and Medical Affairs, Nutrition, Abbott

Kartik Sundareswaran, Sr. Clinical Program Director, Structural Heart, Abbott

Alicia Swanson, Director Public Affairs, Cardiac Rhythm Management and Vascular, Abbott

Dr. Jay Vadgama, Vice President for Research and Health Affairs, Charles R. Drew University of Medicine and Science‡

April Veoukas, Director of Regulatory Affairs, Quality and Regulatory, Abbott

Reggie Ware, CEO, BlackDoctor.org‡

References

1. Clark LT, Watkins L, Piña IL, et al. Increasing diversity in clinical trials: overcoming critical barriers [published correction appears in *Curr Probl Cardiol*. 2021;46(3):100647]. *Curr Probl Cardiol*. 2019;44(5):148-172. doi:10.1016/j.cpcardiol.2018.11.002
2. Jin X, Chandramouli C, Allocco B, Gong E, Lam CSP, Yan LL. Women's participation in cardiovascular clinical trials from 2010 to 2017. *Circulation*. 2020;141:540-548. doi:10.1161/CIRCULATIONAHA.119.043594
3. Women's Heart Foundation. Women and Heart Disease Facts. Accessed February 2023. http://www.womensheart.org/content/heartdisease/heart_disease_facts.asp
4. Chen S, Li J. Participation of Black US residents in clinical trials of 24 cardiovascular drugs granted FDA approval, 2006-2020. *JAMA Netw Open*. 2021;4(3):e212640. doi:10.1001/jamanetworkopen.2021.2640
5. United States Census Bureau. Quick Facts. Accessed February 2023. https://www.census.gov/quickfacts/US
6. ClinicalTrials.gov. U.S. National Library of Medicine. Trends, Charts, and Maps. Accessed February 2023. https://clinicaltrials.gov/ct2/resources/trends
7. Stand Up To Cancer‡. Increasing Diversity in Clinical Trials the Focus of New Stand Up To Cancer Team. Updated March 23, 2021. Accessed February 2023. https://standuptocancer.org/press/increasing-diversity-in-clinical-trials-the-focus-of-new-stand-up-to-cancer-team/
8. National Medical Association‡. Project I.M.P.A.C.T. Accessed February 2023. https://impact.nmanet.org/#:~:text=Project%20I.M.P.A.C.T.,biomedical%20research%20and%20clinical%20trials
9. National Institutes of Health. Opportunities for Education and Awareness. Updated February 13, 2017. Accessed February 2023. https://www.nih.gov/health-information/nih-clinical-research-trials-you/opportunities-education-awareness
10. Otado J, Kwagyan J, Edwards D, Ukaegbu A, Rockcliffe F, Osafo N. Culturally competent strategies for recruitment and retention of African American populations into clinical trials. *Clin Transl Sci*. 2015;8(5):460-466. doi:10.1111/cts.12285
11. Garrick O, Mesa R, Ferris A, et al. Advancing inclusive research: establishing collaborative strategies to improve diversity in clinical trials. *Ethn Dis*. 2022;32(1):61-68. doi:10.18865/ed.32.1.61
12. World Health Organization. Social Determinants of Health. Accessed February 2023. https://www.who.int/teams/social-determinants-of-health
13. diaTribe‡. Masto L, Oxenreiter M, Kotsalidis N. Why Social Determinants of Health Matter in Clinical Care. Updated August 13, 2021. Accessed February 2023. https://diatribe.org/why-social-determinants-health-matter-clinical-care
14. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *Am J Public Health*. 2014;104(2):e16-e31. doi:10.2105/AJPH.2013.301706

Abbott Diversity in Research Initiatives

2021

- **Abbott launched a new initiative** to drive diversity in medical research and improve care among underrepresented populations.
- Through **partnerships with four HBCU medical schools** — the Charles R. Drew University of Medicine and Science‡, Howard University‡ College of Medicine, Meharry Medical College‡ and Morehouse School of Medicine‡ — alongside the National Black Nurses Association‡ and National Association of Hispanic Nurses‡, **Abbott dedicated $5 million to fund nearly 300 scholarships over the next 5 years** to support the next generation of ethnically diverse nurses, doctors and researchers who will lead and support future clinical trials.
- Abbott created a **Diversity in Research Medical Advisory Board**, made up of external experts and an internal steering committee of leading independent doctors, trialists and health advocates, to provide counsel on methods to reduce barriers to access within underrepresented populations and communities of color and provide feedback on how Abbott can continue to drive diversity enrollment within select company clinical trials.
- Abbott dedicated **internal funding** to improve access for women and underrepresented communities within Abbott trials. This funding supports additional trial sites for select Abbott trials, new investigator training opportunities and trial components to eliminate barriers to participation, such as transportation vouchers and interpreters where needed.
- Abbott demonstrated its commitment to recruiting diverse participants during clinical trials in its **LIFE-BTK trial**, which tested a new therapy to treat peripheral artery disease. This approach to increasing diversity in the clinical trial served as a model for future clinical trial blueprints.

2022

- Abbott partnered with **Women as One** to help more underrepresented physicians lead clinical trials.
- In partnership with Barnett International‡, **Abbott launched a comprehensive education program to support the training of new coordinators** who are from diverse backgrounds and will work with underrepresented communities.
- Abbott launched **a new initiative with the Norton‡ Healthcare Foundation to build and implement new models of sustainable clinical research** alongside the Institute for Health Equity, a part of Norton Healthcare‡ in Louisville, Kentucky.

2023

- Abbott created a new **Diversity in Research Office**, which is responsible for ensuring that research efforts include diversity plans and key performance goals and foster collaboration across the company, the industry and regulatory bodies.

2024

- Abbott convened patient advocates, industry experts, trialists and a diverse set of physician thought leaders to develop and publish **an open-source perspective to highlight key learnings** around increasing clinical trial diversity across the health tech industry.
- Abbott created **a public website** to inform and educate people about advancing diversity in clinical trials.

Abbott
100 Abbott Park Road, Abbott Park, IL 60064-6048
Abbott.com

Abbott