



Enhancing clinical trial diversity

Stakeholder perspectives on advancing research through representative clinical trials

About the Deloitte Center for Health Solutions

The Deloitte Center for Health Solutions (DCHS) is the research division of Deloitte LLP's Life Sciences and Health Care practice. The goal of DCHS is to inform stakeholders across the health care system about emerging trends, challenges, and opportunities. Using primary research and rigorous analysis, and providing unique perspectives, DCHS seeks to be a trusted source for relevant, timely, and reliable insights.

Our commitment to health equity: Through the Deloitte Health Equity Institute (DHEI), part of DCHS, the firm is expanding a long-standing commitment to helping align health care ecosystems to positively impact health outcomes. Grounded in its acknowledgement of racism as a public health crisis, the DHEI is dedicated to creating public good through community collaboration and investment, data and analytics expertise, and knowledge development. Our initiatives aim to help everyone achieve their full potential in all aspects of health, building a more equitable future for all.

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About the Pharmaceutical Research and Manufacturers of America (PhRMA)

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies. Our member companies are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives.

Diversity, equity and inclusion are essential to the development of new medicines, improving patient access and achieving health equity. At PhRMA, we believe that building a more just and equitable health care system must include a focus on health equity, enhancing clinical trial diversity, and opening new pathways to our industry for talent. Learn more about the PhRMA Equity Initiative at phrma.org/equity.

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Executive summary

Clinical trial diversity is an imperative for health equity

Racially and ethnically diverse clinical trial participants, representative of the intended patient population likely to use a medicine once approved, can help inform the safety and effectiveness evaluation of new medicines and the use of new medicines for patients. These outcomes can increase the understanding of certain diseases that can improve prevention and treatment for all populations, particularly racially and ethnically diverse communities. Members of underrepresented communities who participate in clinical trials not only help progress scientific discoveries, but their participation can also help improve public perceptions and build public confidence about drugs when others see and hear about clinical trial participants who look like them. Lastly, enhancing diverse participation in clinical trials may also help improve health equity by providing access to potentially lifesaving therapies and quality health care that might not otherwise be available. Clinical trials are the primary route by which patients may receive unapproved investigational drugs.¹

The COVID-19 pandemic and racial unrest in 2020 that grew following the tragic deaths of George Floyd, Breonna Taylor, and so many others illuminated long-existing health and social inequities in the United States. These inequities are particularly stark in health care and health outcomes, as demonstrated by the disproportionate impact of COVID-19 in Black and Latinx communities across the United States. Significant, quantifiable health disparities have been documented across many dimensions but are especially apparent along lines of race, with racially

and ethnically diverse communities experiencing barriers that can lead to poorer health overall than white populations. Systemic racism in health care is often a prime culprit. In the United States, racism has significantly influenced the way the health ecosystem is built, contributing to worse health outcomes for marginalized communities.² Enhancing diverse participation in clinical trials is one way to help foster better health outcomes and improve care for racially and ethnically diverse communities.

Lastly, enhancing diverse participation in clinical trials may also help improve health equity by providing access to potentially lifesaving therapies and quality health care that might not otherwise be available.

Industry and ecosystem efforts have increased to address the challenge

Enhancing meaningful representation of diverse participants in clinical trials would help provide information about drug response and measures of safety and efficacy in populations that have been historically underrepresented and understudied, Black and Latinx communities in particular. In response to the ongoing need to address health care disparities, stakeholders across the clinical

trial ecosystem, including members of academia, government, patient advocacy, community leaders, health care providers, technology experts, and clinical research organizations (CROs) have recently increased their diversity, equity, and inclusion (DE&I) efforts around clinical trials. These efforts include increasing clinical trial awareness and enhancing clinical trial representation, recognizing that none of the stakeholders can make sustainable change alone. Some examples include:

- The FDA issued draft guidance³ on enhancing the diversity of clinical trial populations in the summer of 2019 and finalized the guidance in November 2020.⁴
- The Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women’s Hospital and Harvard formed an MRCT Center Diversity Workgroup in February 2018 and published a guidance document⁵ in 2020 and a toolkit⁶ in early 2021.
- Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies published the first-ever industrywide principles on clinical trial diversity in November 2020, [“Principles on Conduct of Clinical Trials & Communication of Clinical Trial Results”](#). These principles became effective in April 2021.
- Last year, the American Medical Association partnered with the All of Us program to “gain better insights into the biological, environmental and behavioral influences on disease to enhance prevention and treatment.”⁷
- The National Academies of Sciences, Engineering, and Medicine also published a report titled “Strategies for ensuring diversity, inclusion, and meaningful participation in clinical trials.”⁸

PhRMA’s recently published principles on clinical trial diversity reinforce PhRMA member companies’ efforts and reflect their voluntary commitment to enhance diversity in future clinical trials.⁹ PhRMA’s principles state that sponsors and investigators should consider the incidence, prevalence, and severity of the condition or disease in various populations, as well as other prognostic factors that might influence the response to any intervention or outcome variable when designing clinical trials. Proactive science-driven strategies that are prospectively planned and designed into medical product development programs can help promote inclusion of diverse populations in clinical trials with an aim to understand the needs of those who are affected by the disease or condition being investigated. To support science-driven strategies for the conduct of clinical trials, it is important to identify sites where diverse patients with a particular disease or condition may be located, identify health care providers that treat underserved or underrepresented populations, and collaborate with investigators to address the goals of enrolling a diverse population in a clinical trial. Additionally, PhRMA’s principles recognize that broadening eligibility criteria for a clinical trial, when scientifically and clinically appropriate, maximizes the generalizability of trial results and the ability to understand the therapy’s benefit-risk profile across the patient population likely to use the drug in clinical practice, without jeopardizing patient safety. Patient-centric approaches can help improve the availability and quality of data that is representative of the population(s) most likely to use the drug. Study design, target enrollment population, endpoint selection, and recruitment and retention plans should be scientifically driven and responsive to the patient perspective.

PhRMA’s principles to enhance clinical trial diversity were a first step as the industry came together to address this important topic. Many PhRMA member companies are taking action to identify potential leading practices and implement strategies to increase clinical trial diversity. A

survey of and interviews with PhRMA member companies were conducted in January 2021 to identify current industry practices, inform potential leading practices and future opportunities to enhance clinical trial diversity, and better understand how to measure progress and success in enhancing clinical trial diversity. Surveyed PhRMA member companies are all committed to enhancing clinical trial diversity though currently they are approaching this goal in different ways. The approach that most companies reported as leading to increased enrollment or retention of patients from racially and ethnically diverse communities is identifying and engaging diverse sites or locations in underserved communities. Other strategies PhRMA member companies are pursuing include adapting protocol design (including feedback from patients), reducing barriers to access, increasing patient education and awareness, and pursuing partnerships with patient organizations and community leaders. Member company interviews and discussions conducted alongside the survey supported the conclusion that partnerships in the community are critical and that the industry cannot improve diversity in clinical trial participation alone or as individual companies.

Recognizing the need to bring stakeholders of the clinical trial ecosystem and underrepresented communities together, PhRMA convened a large, multistakeholder workshop dedicated to the topic of building partnerships to improve clinical trial diversity in June 2021, titled “Partnering for health equity: Advancing research through representative clinical trials.” During this two-day virtual workshop, over 500 stakeholders from 150 organizations interested in improving clinical trial diversity, including the FDA and other government officials, gathered to discuss the need to rebuild

trust in underrepresented communities; the root causes of health inequity; patient perspective in clinical trials; the community perception of clinical trials; the critical role of community-based providers and health systems; clinical trial digital innovations; and innovative efforts focused on diversity across the clinical trial ecosystem.

The approach that most companies reported as leading to increased enrollment or retention of patients from racially and ethnically diverse communities is identifying and engaging diverse sites or locations in underserved communities.

The workshop provided a forum to acknowledge the reality of the past and present experiences of racially and ethnically diverse communities, to have listening sessions with patients and community leaders, present recent research from stakeholders, and discuss cross-stakeholder solutions to drive change. The workshop concluded with a discussion on how these key stakeholders, along with trusted community leaders in the clinical trial ecosystem, can partner to build a sustainable community-based infrastructure focused on enhancing diversity in clinical trial participation in underserved communities.

FIGURE 1

PhRMA stakeholder workshop

Partnering for health equity: Advancing research through representative clinical trials



Including members of academia, government, patient advocacy, community leaders, health care providers, technology experts, and CROs

Gathered to discuss



The need for researchers and scientists to rebuild trust in underrepresented communities



The root causes of health inequity



Innovative efforts focused on diversity across the clinical trial ecosystem

Participants included

But were not limited to ...

- Dr. Marcella Nunez-Smith, Yale University
- Alexander Hardy, Genentech
- RADM Richardae Araojo, Food and Drug Administration
- Terri Carmichael Jackson, Women's National Basketball Players Association
- Robin Kelly, IL-2nd District Congresswomen
- Dr. Wayne A. I. Frederick, Howard University
- Ramona Sequiera, Takeda
- Dr. Freda Lewis-Hall, formerly at Pfizer
- Margaret Anderson, Deloitte

Source: PhRMA, "Partnering for health equity: Advancing research through representative clinical trials," June 8–9, 2021.

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Stakeholders identify opportunities to improve diversity in clinical trial participation

The workshop resulted from several months of joint research conducted collaboratively between PhRMA and Deloitte's Center for Health Solutions. This research included a literature review, a survey and interviews with PhRMA member companies, community focus groups and surveys, and interviews with patient advocates and clinical research stakeholders.

This research concluded that barriers to enhancing clinical trial diversity include lack of awareness of clinical trials, lack of access, and mistrust by underrepresented communities and populations.

Participants in the research and workshop pointed to the importance of meeting patients and caregivers where they live to improve awareness, access, and trust. Working with community leaders and networks to rebuild trust and trustworthiness and to allow bidirectional dialogue could make clinical trials more accessible to patients who want to participate. Stakeholders emphasized that it is critical to have a patient-centric approach by seeking patient input throughout the medical product development process.

Further, reliable information from trusted messengers in the community is critical to empower individuals to make decisions about participation in clinical trials. Communications should be culturally sensitive and consider unconscious/unintended bias. Partnering with community leaders for local engagement is necessary to build trust and trustworthiness. Many community leaders (e.g., faith-based organizations, civic leaders, educators, barbers, and beauty shops) and health care providers (e.g., nurses, pharmacists) can serve as trusted messengers for communicating health information. For example, nurses can engage with the communities in which

they live and can serve as advocates and educators on clinical trials. This is especially important in rural communities. Community health workers are community extenders for underserved populations and can be valuable resources to reach underrepresented populations.

Ecosystem stakeholders recommend a path forward

Shifting the paradigm will likely require substantial cross-stakeholder commitment and collaboration. Partnering to build scalable and sustainable relationships and solutions, embedded within underrepresented communities and that extend beyond any one clinical trial can be key elements to help ensure success. Patients can benefit from solutions cultivated by the clinical trial ecosystem coming together and developing long-term strategies across multiple disease areas. Some possible collaborations include:

- Partnering with stakeholders across the clinical trial ecosystem (patient groups, community members, clinical research sites, CROs, academia, nonprofit and advocacy organizations, federal and state agencies, industry, etc.) to establish a sustainable, community-based clinical trial infrastructure
- Establishing relationships with the target community through community leaders, Historically Black Colleges and Universities (HBCUs), other minority-serving institutions (e.g., Indian Health Service), Federally Qualified Health Centers (FQHCs), patients, and others to provide outreach, training and education, and mentorship/job pathways
- Adopting enhanced data collection capabilities to help support appropriate collection and sharing of racial and ethnic data and real-world data (RWD) through a cloud-based platform

- Utilizing a common source of disease incidence and prevalence by race and ethnicity to inform clinical trial design
- Developing patient-friendly resources that make it easier to identify and enroll in relevant clinical trials

Research participants as well as the multistakeholder workshop discussions emphasized the tremendous potential of supporting community-based clinical trial sites. The current clinical trial ecosystem depends on independent pharmaceutical companies or academic researchers preparing and training clinical research sites for individual trials. These disparate sites all have varying levels of capability and connectivity to the community and are most often driven by the design of the trial. It is not sustainable for any one company or researcher to adequately resource new potential sites focused on enhancing clinical trial diversity, if only one clinical trial will be conducted. On the other hand, dedicated resources supporting a network of clinical trial sites in the communities that serve underrepresented populations could over time create a sustainable national infrastructure focused on enhancing clinical trial diversity.

There can be several benefits to a community-based clinical trial infrastructure. First and foremost, the health care providers that serve those communities are often best positioned to engender trust and establish relationships with trusted messengers that live in those communities. Examples of some of these community health providers include Catholic health centers, Federally Qualified Health Centers (FQHCs), military health, HBCUs and other minority-serving institutions, pharmacies, or other academic centers with established, trusted relationships with the community. Using geotargeting techniques, other new site locations may be identified. Stakeholders that support this network could invest in increased training and education among investigators and

site staff, including supporting new sites in these underserved communities. Those participating in the network would be able to share potential leading practices and learn from each other. Industry members within this network may also provide access to a consistent pipeline of research studies to create opportunities for investigators and sustain the network of ready clinical trial sites over time.

Workshop participants and others who participated in our research identified steps the research clinical trial ecosystem should take to change the current paradigm and create a sustainable community-based infrastructure that is focused on clinical trial diversity, including:

- **Creating a network of clinical trial sites in underserved communities to make access easier so that those who want to participate can:** Infrastructure stakeholders should develop research sites that meet potential participants where they already receive care, including nontraditional locations such as FQHCs or Catholic health systems. These providers may be best positioned to engender trust and establish relationships with trusted messengers and leaders that are reflective of the cultural norms and demographics of the community, and with the right support and investment could be scaled into clinical trial sites in underserved communities. Infrastructure efforts should consider and leverage—to the extent possible—any existing networks or structures involved in the conduct of clinical trials. It is critical for clinical trial sponsors to provide necessary funding and resources to sites and nontraditional locations that serve underrepresented populations.
- **Developing a diverse pool of investigators and staff at sites in underserved communities:** Developing diverse staff to support clinical trials and serve as trusted sources of information requires good

clinical practice training as well as training in cultural competence and unconscious/implicit bias, mentoring, and opportunities and resources for investigators and site personnel to use when engaging with the community. Establishing a pipeline of clinical trial opportunities can also be critical to help ensure continued engagement and commitment.

- **Establishing long-term relationships and investing in the community:** It is critical to build long-lasting relationships rooted in a shared commitment to improve health equity in the communities being approached. These relationships should be established well before a clinical trial is proposed. Stakeholders of a community-based clinical trial infrastructure should invest in uplifting the community in ways that expand beyond their specific objectives. Investments could range from health education to donating buildings for educational programs or volunteering to help those in need. It is important to understand the diverse needs of the communities being served, including who the trusted messengers are. This could look different in each community and could, for example, include barber shops and beauty salons, church and ministerial staff, local food shops, consulates, and other community organizations. These community leaders and trusted messengers could serve as liaisons that can provide information about clinical trials and what participation means for patients.
- **Engaging the community in bidirectional conversations:** Educating the community on opportunities to improve health, including through clinical trials, can be a key component of sustainable relationships. Emphasis should be placed on improving patient health first. Education helps to build trust by empowering community leaders and other members of the community. Empowered patients and their

families are enabled to make informed choices about clinical trial participation. At the same time, sponsors should seek community input on clinical trial design, including endpoints of interest and elements of design that might impact patients' ability to participate (e.g., testing requirements). Sponsors should emphasize that without generous volunteer participation, the development of new medicines would not be possible. They should also share research findings with the participants once a trial is over and consider their research questions and needs in future trials. Sponsors of clinical research should engage in bidirectional conversations with the community to increase education, awareness, access, and enrollment into clinical trials in a way that is tailored for each individual community and made available to patients who want to participate. This includes offering information in various languages and taking into account varying levels of health literacy.

- **Providing sustainable support and standardized platforms:** Some community clinical trial sites may not have the technology platforms and databases in place to help identify patients for enrollment in clinical trials. Investigators who participated in the workshop pointed out that building a data infrastructure is a necessary first step to enable sites to participate in clinical trials. This type of infrastructure, leveraging real world data, could make it seamless for investigators to identify and engage with patients appropriate for clinical trials with minimal disruption to existing workflows. A community-based clinical trial infrastructure should include the development of standard data collection, baseline measurements to improve data on race and ethnicity, and measures of success for tracking progress on enhanced participation in clinical trials of diverse populations.

ELEMENTS OF A COMMUNITY-BASED INFRASTRUCTURE SUPPORTING CLINICAL TRIAL DIVERSITY WOULD INCLUDE:

- A network of clinical trial sites focused on diversity;
 - Communicating and increasing awareness about clinical trials;
 - Building community relationships;
 - Developing sites in underserved communities and diverse site staff; and
 - Sustainable support and standardized platforms and metrics.
-

Discussions at the multistakeholder workshop concluded with recognition across the clinical trial ecosystem that a partnership to address clinical trial diversity is needed. A sustainable community-based partnership that begins well before clinical trials start can be essential to both building trust and creating a successful infrastructure that serves underrepresented populations. Sustainability of the sites (e.g., a pipeline of clinical trials, consistent funding) can enable them to focus on building and maintaining community relationships. A toolbox of proven strategies can minimize the need to reinvent the wheel with each new study or the current one-and-done clinical trial approach that results when a site is trained for a particular study but does not

have a steady stream of additional studies following behind. Technology and data investments will be needed to measure and track progress moving forward. Many industry, health systems, academic institutions, government entities, patient advocacy, community leaders, technology experts, and CROs are working toward partnerships dedicated to enhancing clinical trial diversity through the formation of a sustainable community-based clinical trial infrastructure. Ultimately, investing in and supporting underserved communities can have a longer-term impact on the health and well-being of those communities beyond improving clinical trial diversity.

Introduction

A LONGSTANDING HISTORY OF systemic racism in the United States has contributed to health disparities that have disproportionately impacted racially and ethnically diverse communities. A recent study revealed that life expectancy in the United States plummeted by nearly 2 years from 2018 to 2020, the largest decline since 1943, with Black and Hispanic Americans disproportionately impacted.¹⁰ The murders of George Floyd, Breonna Taylor, and so many others that resulted in demonstrations against police violence across the country, alongside the COVID-19 pandemic, placed a spotlight on the deep inequalities and racial injustices in racially and ethnically diverse communities in the United States. Black individuals have been almost three times as likely to be hospitalized from COVID-19 compared to white persons and have been almost two times more likely to die. Those of American Indian or Alaskan Native descent, have been almost four times as likely to be hospitalized, and more than twice as likely to die from COVID-19.¹¹ The COVID-19 pandemic will cast a long shadow on American health, particularly for Black and Latinx Americans.

“This is our rallying call. This is our north star. I know it guides me; it guides all of us. How do we make sure that when we are talking about communities that have been minoritized and marginalized that they see themselves in clinical research and share ultimately in the benefit of new knowledge, of new technologies, of that scientific discovery?”

— Marcella Nunez-Smith, MD, MHS, Associate dean, Health Equity Research, Yale School of Medicine; C.N.H. Long professor of general internal medicine and public health; management director, Office for Health Equity Research, Equity Research and Innovation Center; deputy director, Yale Center for Clinical Investigation; associate director, Yale Cancer Center; chief health equity officer, Smilow Cancer Hospital; director, Pozen-Commonwealth Fund Fellowship in Health Equity Leadership, Yale University.¹²



According to Deloitte’s report [Activating health equity](#), health equity is defined as “the fair and just opportunity for every individual to achieve their full potential in all aspects of health and well-being.”

Health inequity is particularly apparent along lines of race, with racially and ethnically diverse communities experiencing barriers that lead to poorer health overall than white populations. Systemic racism is primarily responsible for these disparities, influencing the way the health ecosystem is built and creating barriers in drivers of health such as access to healthy food, affordable housing, a stable physical and social environment, and quality education, all of which can lead directly to poorer health among the disadvantaged.¹³ Some of the worst health outcomes brought about by these unjust systemic and social structures can and have persisted over generations.

Many pharmaceutical companies have undertaken specific efforts over the years to embed principles of DE&I into business practices, and build toward greater equity in opportunity and outcomes for patients. This progress is evident from a wide array of initiatives and programs within and across the industry including longstanding collaborations with entities such as the CEO Action for Diversity and Inclusion,¹⁴ Inclusion Index Company,¹⁵ Billion Dollar Roundtable,¹⁶ and the Lazarex Cancer Foundation’s Improving Patient Access to Cancer Clinical Trials (IMPACT) program.¹⁷ Additionally, in the past year, many pharmaceutical companies have made various public commitments to address health disparities and enhance health equity that can help foster diverse clinical trial representation. Examples include, but are not limited to:

- Amgen, Merck, Eli Lilly, and Gilead Sciences joined OneTen, a coalition with various leaders across industries aimed at hiring 1 million Black Americans over the next 10 years.¹⁸
- Bristol Myers Squibb dedicated \$300 million over the next 5 years to address disparities across several areas.¹⁹
- Genentech committed to \$1 billion in spending with diverse suppliers and a new strategic plan to double the number of Black and Latinx directors and officers in leadership by 2025.²⁰

Racially and ethnically diverse clinical trial participants are imperative to build the future of medicine. These outcomes can inform the understanding of certain diseases that can improve prevention and treatment for racially and ethnically diverse communities. Individuals identified as Black, American Indian or Alaska Native (AIAN), Asian American or Pacific Islander (AAPI), and those of Hispanic ethnicity are disproportionately underrepresented in clinical trials compared to white participants. For example, a study published in 2021 analyzed data from 230 US-based clinical trials for various vaccines, which revealed that adult white Americans were overrepresented (74%), compared to individuals identified as Black (13%), AIAN (1%), Asian (5%), Hawaiian or Pacific Islander (0.2%), and Hispanic or Latino (17%), who were underrepresented compared to US Census data.²¹ Additionally, studies reveal there is a general lack of patient diversity across many late-stage clinical trials and across therapeutic areas, and for diseases that affect racially and ethnically diverse communities disproportionately, such as cancer, cardiovascular disease, diabetes, and Alzheimer’s disease.²² Participation in clinical trials should reflect the demographics of the population affected by the disease. The demographics of the United States are also changing; in 2020, racially and ethnically diverse children made up 52.7% of all youth in the country.²³ And with a growing diverse population that can benefit from future novel medicines, it is more important than ever for the clinical trial

ecosystem to overcome the hurdles to achieving diversity in clinical trials.

Improving health equity is more than providing access to care; however, enhancing clinical trial diversity can be a key mechanism to improving health equity for underrepresented populations.²⁴ For example, clinical trial participants are typically able to access quality health care, drugs and biologics, or other therapeutic interventions related to the illness or condition being studied.²⁵ Diverse representation of patient populations in clinical trials can also help build public confidence in tested therapies once available.²⁶

“Scientists and researchers need to rebuild trust with Black communities and communities of color more broadly. Enhancing representation in clinical trials is an important first step that can help provide more information on safety and efficacy in populations that have been historically underserved.”

— Congresswoman Robin Kelly, US Representative from Illinois’s 2nd congressional district²⁷

In response to the ongoing need to address the underrepresentation of minority patients in trials, many stakeholders across the clinical trial ecosystem who had been working in this space have recently increased their efforts around enhancing clinical trial diversity. Several of these resources were shared or presented at PhRMA’s [multistakeholder workshop](#), including:

- The FDA-issued draft guidance²⁸ on enhancing the diversity of clinical trial populations in the summer of 2019 and finalized the guidance in November 2020.²⁹
- The Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women’s Hospital and Harvard formed an MRCT Center Diversity Workgroup in February 2018 and published a

guidance document³⁰ in 2020 and a toolkit³¹ in early 2021.

- PhRMA and its member companies published the first-ever industrywide principles on clinical trial diversity in November 2020, “[Principles on conduct of clinical trials and communication of clinical trial results](#)”. These principles became effective in April 2021.
- Last year, the American Medical Association partnered with the All of Us program to “gain better insights into the biological, environmental and behavioral influences on disease to enhance prevention and treatment.”³²
- The National Academies of Sciences, Engineering, and Medicine also published a report titled “Strategies for Ensuring Diversity, Inclusion, and Meaningful Participation in Clinical Trials.”³³

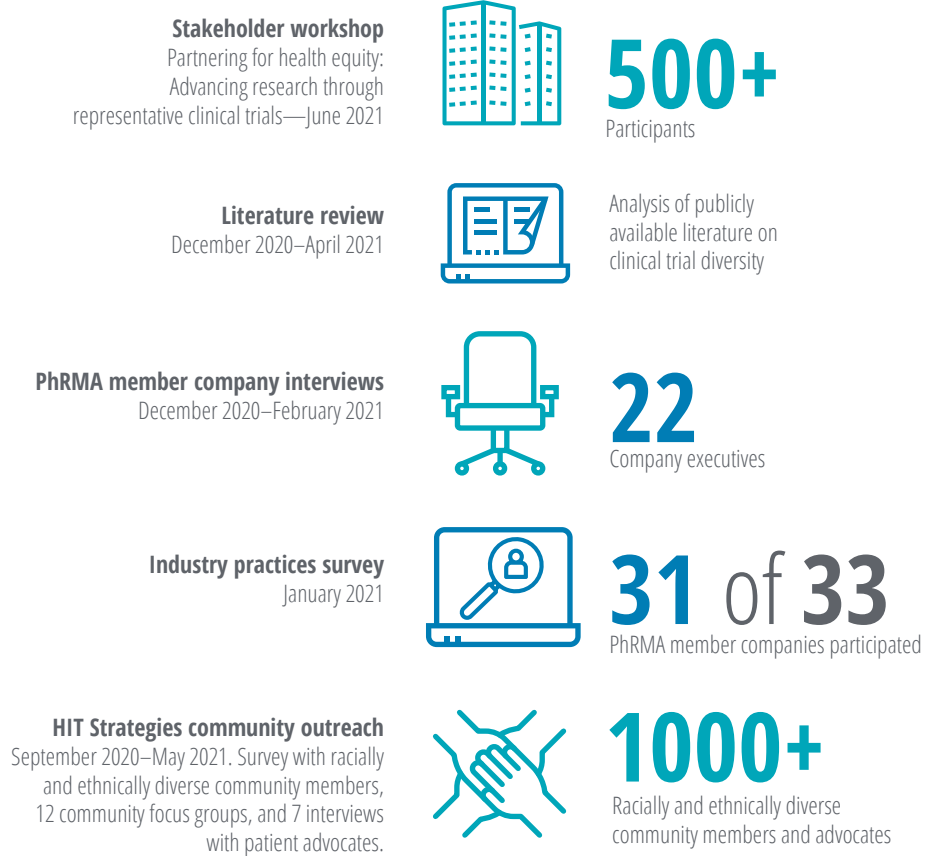
PhRMA’s recently published principles on clinical trial diversity reinforce efforts by PhRMA member companies in this space and reflect their voluntary commitment to enhance diversity in future clinical trials.³⁴ Many PhRMA member companies are taking action to identify potential leading practices and implement strategies to increase clinical trial diversity. PhRMA and the Deloitte Center for Health Solutions set out to understand the progress of efforts and what opportunities might exist to continue this momentum, including formation of a sustainable clinical trial infrastructure focused on addressing clinical trial diversity. This consisted of a literature search, a survey and interviews with PhRMA member companies, focus groups and surveys with community members³⁵ conducted by HIT Strategies, and interviews with other stakeholders in the clinical trial ecosystem (figure 2).

The culmination of this research was a large multistakeholder workshop, which brought together stakeholders from across industry, health systems, academic institutions, government entities, patient advocacy, community leaders, technology experts, CROs, and others to discuss

FIGURE 2

Methodology

Insights derived from multi-pronged research approach



Source: Deloitte.

the current clinical trial ecosystem and opportunities for collaboration to enhance clinical trial diversity. Discussions at the workshop included the root causes of health inequity, the patient perspective, the role of health systems and community networks, industry and stakeholder insights, clinical trial digital innovation, and

building a sustainable community-based infrastructure focused on clinical trial diversity. The workshop concluded with breakout sessions to discuss potential multistakeholder opportunities around the aspects of a sustainable community-based infrastructure and potential paths forward.

Stakeholders largely align on understanding the challenge

THE PAST YEAR has shown broad, general agreement on the barriers to clinical trial participation that primarily include trust, access, and awareness. HIT Strategies' focus groups with members from the Black community and a survey of racially and ethnically diverse community members suggest that the issue of trust is one of the most important and challenging barriers to overcome and is vital to clinical trial participation. HIT Strategies found that the top barrier preventing surveyed racially and ethnically diverse communities from participating in clinical trials was mistrust of those who run clinical trials (24%). The most trusted messengers to provide truthful information about health care were primary care doctors (66%), professional medical associations (49%), and federal agencies (46%); just over a quarter (28%) said biopharmaceutical companies.³⁶

"It's a Catch-22. If we're not participating, then how can we expect to be able to reap the benefits and change health care? But I think for that to change, there has to be a level of transparency in the trials and in companies, and in the approach. There really would have to be a very good public relations effort to be able to get the word out and to be able to establish some credibility for us to really be willing to participate."

— Black voter³⁷

While lack of awareness of clinical trials, lack of access, and mistrust were identified by both industry stakeholders and community members as

key barriers to diverse participation in clinical trials, there are several other barriers extensively outlined in literature. Some of these barriers include, but are not limited to, diversity and bias among investigators and site personnel, and protocol design or eligibility criteria.

Trust, mistrust, trustworthiness

The continuing effects of slavery and colonization at a systemic level have contributed to the ongoing health inequalities for racial/ethnic minorities in the United States and have led to substantial patient mistrust.³⁸ Some historic events reinforcing mistrust include:

- The US Public Health Service Syphilis Study at Tuskegee, 1932–1972, which allowed people in the trial with syphilis to go untreated after a treatment for the disease had been found to be effective³⁹
- Henrietta Lacks' cells used for decades of research without consent⁴⁰
- The US Air Force's former Arctic Aeromedical Laboratory (AAL) study to measure thyroid function under various conditions by administering a medical tracer—the radioisotope Iodine 131—to 102 Alaska Native subjects and 19 white military personnel⁴¹

While these historic events are often cited as examples of racism against Black and Indigenous or Native American communities, ongoing events continue to cause some to question the

trustworthiness of government, medical, and life sciences institutions. During the workshop, Dr. Terris King, senior pastor at Liberty Grace Church of God, emphasized this, stating “there is inequity in many of our cities as it relates to health care today. People don’t have to open a history book to understand that. All they have to do is look in the mirror, or look at their moms, or look at their dads and see how they are treated with insensitivity by the health care system today.” Clinical trial design aspects can exacerbate mistrust.

“Informed consent is an opportunity to build trust or squander trust.”

— Jason Resendez, executive director for UsAgainstAlzheimer’s Center for Brain Health Equity⁴²

“We have to acknowledge some hard truths. Our institutions are not universally viewed as trustworthy ... communities do not have to think back to the US public health service syphilis study at Tuskegee, or Henrietta Lacks, or James Marion Sims, or forced sterilization of Puerto Rican women to name injustice in the health care system. For all too many, the truth is they need only to reflect on their own experiences.”

— Marcella Nunez-Smith, MD, MHS, Associate dean, Health Equity Research, Yale School of Medicine; C.N.H. Long professor of general internal medicine and public health; management director, Office for Health Equity Research, Equity Research and Innovation Center; deputy director, Yale Center for Clinical Investigation; associate director, Yale Cancer Center; chief health equity officer, Smilow Cancer Hospital; director, Pozen-Commonwealth Fund Fellowship in Health Equity Leadership, Yale University.⁴³

Surveyed PhRMA member company respondents agree that trust is a top external barrier: Seventy-four percent of PhRMA member company survey

respondents selected lack of trust with underrepresented populations as an external barrier in achieving diverse clinical trial participation.

Awareness regarding clinical trials

Studies show that racially and ethnically diverse communities are willing to participate in clinical trials, but they are often not asked or made aware of participation opportunities.⁴⁴ Adrian Hernandez, vice dean and executive director of the Duke Clinical Research Institute, highlighted that “while 2–4% of the population participate in clinical trials, polls say 85% would like to participate.” Studies have shown that medical professionals, including clinical trial investigators, may have biases which could impact which patients they ask to participate in clinical trials. For example, researchers asked 222 medical students to rate the extent to which 15 biological differences between Blacks and whites are true or untrue, and 50% reported that at least one of the false belief items was possibly, probably, or definitely true.⁴⁵ These biases may lead clinical investigators to make mistaken assumptions about Black participants’ eligibility or ability to participate in trials.

Workshop participants further discussed the need for industry, health systems, academic institutions, government entities, patient advocacy, community leaders, technology experts, and CROs to consistently communicate with communities regarding clinical trial opportunities including before, during, and after completion of the trial. They highlighted that there is a lack of communication with community members regarding goals, metrics, and results of the trial.

In a survey of PhRMA’s member companies that was launched in January 2021, and in which 31 of 33 PhRMA members participated, 81% say that lack of patient awareness is a top external barrier

to improving clinical trial diversity. Black community members who took part in focus groups conducted by HIT Strategies agree that lack of information or awareness is a top barrier, and Black, Latino or Hispanic, AAPI, and AIAN surveyed community members say the top barrier to participation is lack of information (34%). HIT Strategies also found that 28% of Black, Latino or Hispanic, AAPI, and AIAN community members surveyed said the top barrier to clinical trial participation is that they have never been asked.

Access to clinical trials

Workshop discussions and our research make it clear that more needs to be done to address barriers around access. Access is defined as the extent to which clinical trials or research studies are made available to an individual and the ability of that person to then participate or contribute to the trial or study. Participants discussed the need to address the varying levels of health, economic and technology literacy, the lack of community feedback regarding technological tools used during trials, as well as meeting patients where they are by building and maintaining a sustainable, community-based clinical trial infrastructure focused on diversity.

Stakeholders largely agree on the need to meet patients where they are and build sustainable site infrastructure that is safe and welcoming for racially and ethnically diverse communities.

Eighty-one percent of PhRMA member company survey respondents ranked access to clinical trials as an issue. Secondary research reinforces and provides more detail around access barriers. These barriers include time away from work and lost wages, travel expenses, concerns around insurance coverage, caregiver responsibilities, and language gaps.⁴⁶ Studies reveal that patient populations with historically lower financial resources, including those who are uninsured and from racially and ethnically diverse communities, are often overrepresented in phase I trials where there is little therapeutic benefit expected, yet underrepresented in phase II and III trials. Dr. Elizabeth Ofili, professor of medicine with the Morehouse School of Medicine, said, “We have not perfected the situation where we actually get to have a location where we could help people with childcare, especially for trials that involve women. With that said, there are promising decentralized and remote monitoring approaches designed to ease the burden of participation for women.”⁴⁷

Language considerations with regard to outreach materials are also important. Nonnative English speakers may face challenges in reading and understanding signage or materials. How entities communicate about clinical trials in the community is vital, yet gaps exist in terms of tailoring messaging and sending the right individuals to deliver the message.

For trials leveraging personal devices for data collection, lack of access includes Wi-Fi connectivity and necessary technology and devices. Workshop participant Dr. Winston Price, chief information officer at W. Montague COBB/NMA Health Institute, stated, “When you think about the communities that are vulnerable, make sure they have adequate broadband access to the Wi-Fi and that their digital technology provides them with

the same degree of access to use any technology.” Dr. Price went on to state “I don’t think we have done enough in terms of digital marketing in communities at risk to make sure as we develop these apps to improve access to clinical trials and patient interaction, that we engage the community in the creation of some of these apps.”

Stakeholders largely agree on the need to meet patients where they are and build sustainable site infrastructure that is safe and welcoming for racially and ethnically diverse communities. HIT Strategies found during interviews with patient advocates who serve underrepresented communities that physical access to clinical trial sites was among the top barriers to diverse clinical trial participation. Patient advocates indicated that many clinical trials are held in university medical center settings, locations that can be miles from where patients live. PhRMA member company survey respondents pointed out that infrastructure

to enable patient access to clinical trials was also lacking. They specifically noted that external barriers to increasing clinical trial diversity include:

- Lack of existing site networks in underrepresented zip codes (77%);
- Lack of existing investigators to serve underrepresented populations (74%); and
- The inability to recruit sufficient participants at individual sites (68%).

“The challenge for systematic change is that we don’t have the infrastructure to reach into diverse communities in a structured and processed way ... We need a new model that embraces and reaches out to diverse communities that have historically been hesitant to participate.”

— Independent research and education organization⁴⁸



Clinical trial diversity is a priority for PhRMA member companies and many have enhanced their strategic efforts

DARRYL SLEEP, SENIOR vice president, global medical and chief medical office for Amgen, highlighted the commitment from the industry to enhance diversity in clinical trials and the industry's many efforts such as adapting protocol design, increasing patient education and awareness, identifying and engaging diverse sites, and pursuing partnerships. Other key takeaways are:

- Efforts that PhRMA member company survey respondents believe have increased enrollment and retention among underserved populations include identifying and engaging diverse sites, addressing patient support needs, looking at real-time enrollment and retention data, and pursuing partnerships.
- Of the surveyed PhRMA member companies pursuing strategies around partnerships, many have engaged with patient advocacy groups, clinical research organizations, academia, or other clinical trial experts.
- Most surveyed PhRMA member companies identified areas to address internally to enhance

clinical trial diversity, such as legacy processes and systems, data on demographics of disease by race/ethnicity, and protocol design flexibility.

- In addition to ongoing efforts, many PhRMA member company respondents would like to pursue several efforts in the future that require multistakeholder support such as collecting racial and ethnic data from real-world data; developing and implementing standardized procedures for collecting diversity data; offering training to minority medical students, clinical trial staff, and investigators; and engaging community stakeholders in underserved communities.

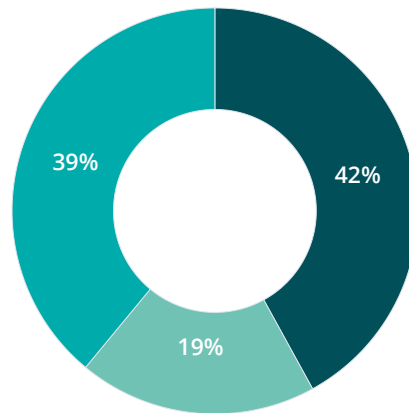
The PhRMA member survey showed that 61% of respondents have defined goals and objectives to enhance clinical trial diversity and 42% have begun incorporating potential leading practices across some trials. The remainder (39%) are working to define their goals and objectives (figure 3). Most PhRMA member company survey respondents indicated that the top reasons for improving clinical trial diversity are addressing health inequities (81%) and improving scientific rigor (71%).

FIGURE 3

PhRMA member company survey respondents have a strategy for increasing clinical trial diversity, although some are further along in their journey

Question: Which of the following statements best describes your current strategy for increasing clinical trial diversity?

- We have defined goals and objectives, identified best practices, and begun to incorporate these across some of our trials
- We have defined goals and objectives and are working to identify best practices
- We are working on defining our goals and objectives



Note: N = 31 PhRMA member companies.

Source: PhRMA member company clinical trial diversity industry survey, January 2021.

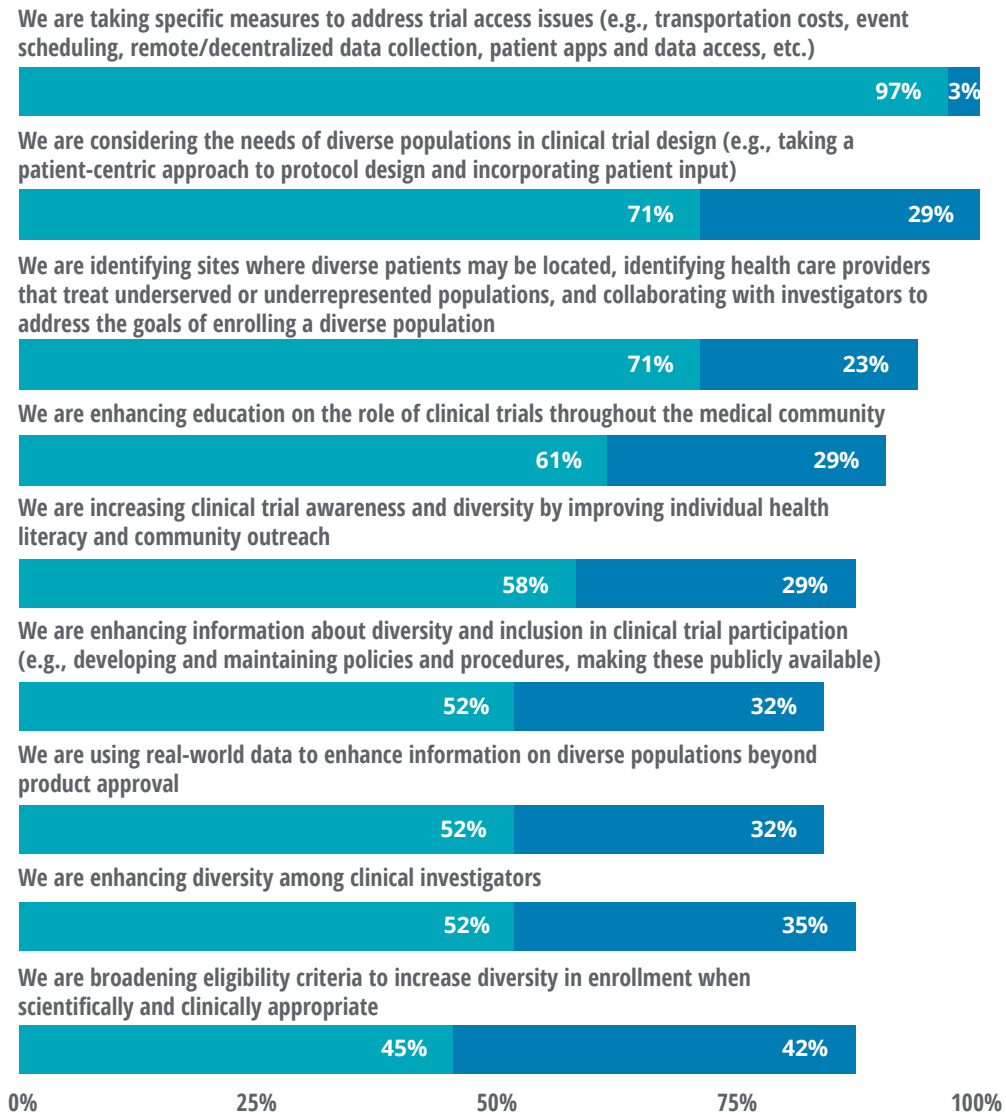
The PhRMA member survey showed that 61% of respondents have defined goals and objectives to enhance clinical trial diversity and 42% have begun incorporating potential leading practices across some trials

The PhRMA member survey showed that almost all respondent companies are taking specific measures to address access issues (97%), and 71% are considering the needs of diverse populations when designing clinical trial protocols, including incorporating patient input and identifying sites where diverse patients live (71%). In the next year, many companies say they plan to enhance diversity among clinical investigators and broaden eligibility criteria to help ensure inclusion of participants who may otherwise be excluded from trials without a justified scientific rationale (figure 4).

FIGURE 4

All PhRMA member company survey respondents have or are planning to address trial access issues and are considering the needs of diverse populations in clinical trial design

■ Yes ■ In progress



Note: N = 31 PhRMA member companies.

Source: PhRMA member clinical trial diversity industry survey, January 2021.

PhRMA member companies have pursued many strategies to improve clinical trial diversity

WORKSHOP DISCUSSIONS HIGHLIGHTED the importance of developing a thoughtful site strategy to make access to clinical trials easier for underrepresented populations. They affirmed that setting up trials at care providers that serve underrepresented populations has helped to enhance diverse recruitment in clinical trials. Further, assessing processes at existing clinical trial sites can help elucidate what works to improve diversity. Diana Foster, VP, strategy and development, at the Society of Clinical Research Sites (SCRS), noted that SCRS launched a diversity site assessment tool and benchmarked site processes. Through that work, SCRS found that understanding clinical trial participant challenges in transportation and lodging, ensuring phone prompts were available in different languages, and making the referral process easier within each

community were relatively simple ways that improved clinical trial diversity for sites.

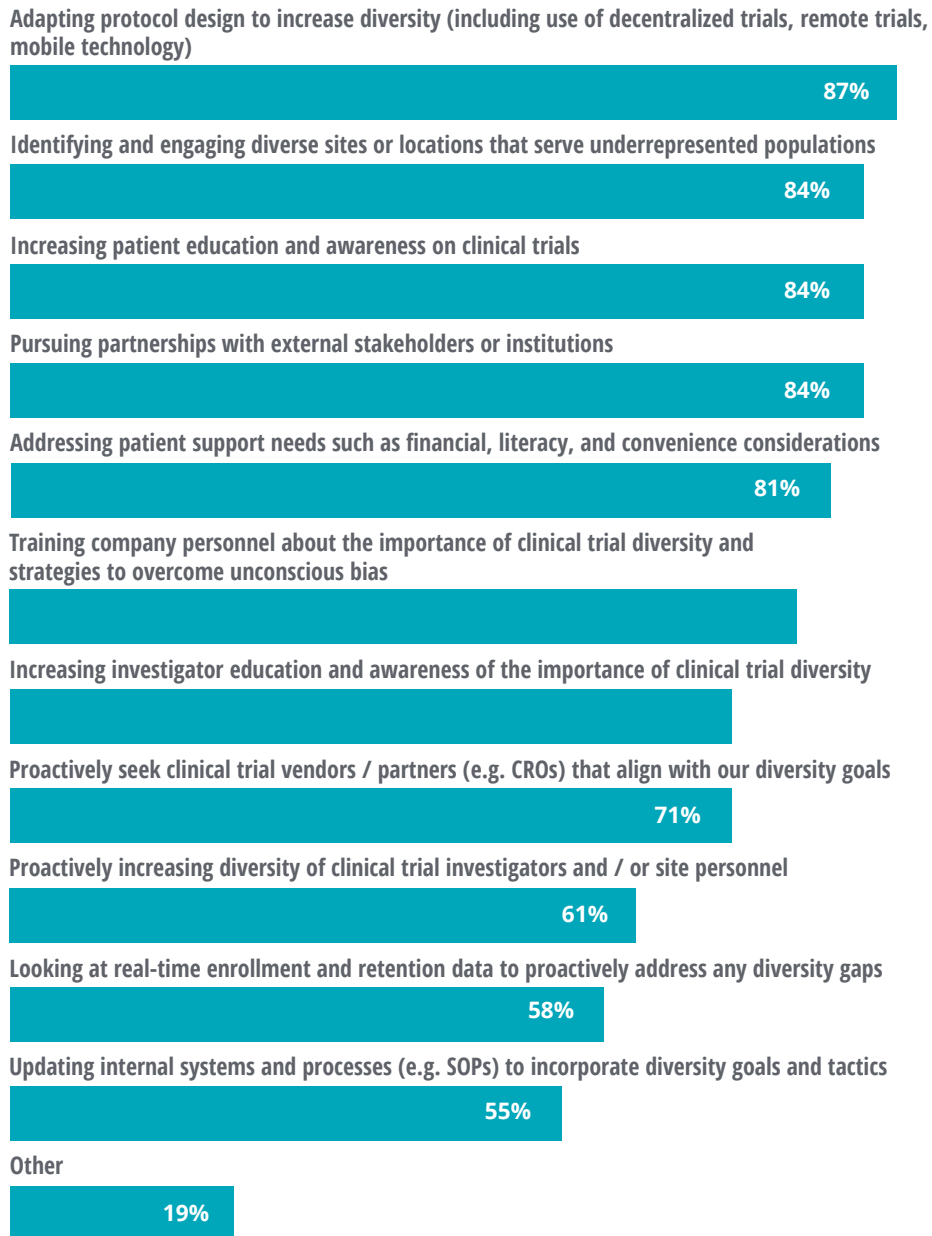
A majority of PhRMA member company survey respondents identified that so far one strategy has definitively led to increased enrollment and retention of patients from underrepresented populations: identifying and engaging diverse sites or locations that serve underrepresented populations (according to 69% of the 84% of respondents who are pursuing this strategy). In addition to site strategy, PhRMA member company survey respondents are pursuing a multitude of different strategies and approaches to improve clinical trial diversity (figure 5), ranging from adapting clinical trial protocol design (87%), to increasing patient education and awareness (84%), to pursuing partnerships (84%). But they believed it was too soon to say if other strategies being pursued would lead to increased enrollment and retention.

Workshop participants affirmed that setting up trials at care providers that serve underrepresented populations has helped to enhance diverse recruitment in clinical trials.

FIGURE 5

Most PhRMA member company survey respondents are pursuing strategies around protocol design, identifying and engaging diverse sites, increasing patient awareness, and pursuing partnerships

Question: What strategies are your company pursuing to improve diversity in clinical trial participation? Select all that apply.



Note: N=31 PhRMA member companies.

Source: PhRMA member company clinical trial diversity industry survey, January 2021.

Areas of recent success

Data-driven approaches to identify potential clinical trial sites have proved especially beneficial for some PhRMA member companies. Researchers can identify appropriate sites for specific studies by identifying those locations where incidence rates are highest, and where care is typically provided (see sidebar, “Case study”). One PhRMA member company interviewed is working with vendors to use geomapping and geotargeting to understand where different populations are located and where potential outreach sites are/should be located. Staffing these sites with trained personnel, representative of the target population, providing unconscious bias and cultural competency training, and addressing patient support needs were also suggested as ways to improve patient recruitment and retention.

Several workshop participants and interviewed PhRMA member company executives also cited success in improving clinical trial diversity through building long-standing, trusted, community relationships. Engaging key members of these communities and establishing community advisory boards that can serve as patient representatives

can also help build trust. Workshop participant Dr. Elizabeth Ofili stated that the Morehouse School of Medicine’s original model was to go out in the community and invite members to participate. They learned the importance of community engagement and pivoted their strategy by creating community advisory boards with members of the community such as pastors or nurses to serve as reviewers for things such as consent language. One industry executive suggested that companies should start their community outreach with public health initiatives and health education. Once these local relationships have been established, the topic of clinical trial participation should be broached. And when the clinical trial is complete, the public health initiatives and health education should continue so that the relationships can be sustained beyond the clinical trial itself. Working with already established, trusted partners can provide another route: One company partnered with a consortium of community pharmacists to disseminate information about COVID-19 broadly during the pandemic. Other clinical research executives interviewed commented on successes achieved by meeting patients where they are on social media through trusted platforms such as BlackDoctor.org and Black Health Matters.



CASE STUDY

Genentech's EMPACTA study⁴⁹ is the first global phase III study focused on enrolling largely underserved and minority patients, which showed the efficacy of a medicine, Actemra, in COVID-19-associated pneumonia. Approximately 85% of the 389 patients were from minority racial and ethnic groups. Most of the patients were Hispanic, with significant representation of Native American and Black populations. Genentech recruited a diverse and representative group of patients by first identifying COVID-19 "hotspots," geographic areas that had higher incidence of COVID-19, and then used epidemiology data to identify communities and hospitals where underrepresented patients lived and were being treated to find study sites. For example, they went to areas in New Orleans, New Mexico, and Arizona as well as hospitals in the Bronx where the disease burden was high for underserved populations. After the study sites were identified, enrollment was the fastest among all studies in the history of Genentech, disproving the notion that it takes more time to recruit diverse participants. During an interview, Genentech representatives discussed using data to further debunk myths about increased time and cost, stating, "We've created our own myths that diverse populations will slow us down, make it slow to enroll trials. We are stretching teams to think and behave differently, tracking milestones and measures that we can focus on. We are rewarding teams in different ways."

Source: PhRMA and the Deloitte Center for Health Solutions member company interview, February 2021.

"We've created our own myths that diverse populations will slow us down, make it slow to enroll trials. We are stretching teams to think and behave differently, tracking milestones and measures that we can focus on. We are rewarding teams in different ways."

Current challenges and areas of opportunity

During the workshop, several participants discussed challenges with lack of sustainable community outreach. Alexander Hardy, CEO of Genentech, indicated that industry members have partnered or engaged community organizations, community health care providers, and new sites, but there has to be a mechanism to make this engagement sustainable across the clinical trial ecosystem. He said these partnerships were vital focus area for the industry and that it starts with ensuring that DE&I is an “enterprise priority.”

Several workshop participants and industry stakeholders emphasized the need to consider diversity an objective early on in the planning process. Efforts to improve diversity in clinical trials should occur across the entire process of drug development and start as early as designing studies. Community relationships should extend beyond

any one particular trial aimed at elevating the health of the community.

Stakeholders also mentioned the need to provide sufficient budget, training, and incentives to personnel at sites that serve underrepresented communities. For example, companies looking to partner with FQHCs and HBCUs should support the staff at these locations with appropriate resourcing. Community workers, particularly those from underrepresented populations, should be fairly compensated for trial-related activities such as recruitment support. Further, participants in the multistakeholder workshop pointed out that expectations around compensation may differ between sponsors and potential partners. Clinical research is an additional obligation for partner organizations, and often sponsors are looking for help to educate them on how to engage diverse populations, creating additional work.

Potential opportunities to address these challenges are outlined in the next section.

Deep dive into specific tactics

Areas of progress and opportunity

THE WORKSHOP AND other elements of our research identified concrete steps that the clinical trial ecosystem can take to increase accessibility to diverse communities, promote accountability, track progress, ensure durability and sustainability, and identify key stakeholders that should be connected in this space. Identifying and developing sites that treat underrepresented patients where they already receive care can help to not only improve access but also trust by offering trials through trusted providers. Community relationships can further build trust and increase awareness of clinical trials. Measuring success can help to build sustainable solutions that can be scaled over time.

Identifying and developing sites focused on treating underrepresented populations

The majority of PhRMA member company survey respondents (84%) are pursuing strategies on identifying or engaging sites that serve underrepresented populations. This strategy was selected by most of PhRMA member company survey respondents who have pursued this strategy (69%) to have an impact on increased enrollment and retention of diverse populations. Workshop participants sought to build off of this success by exploring opportunities for sites in nontraditional locations and recognizing the need for funding and resources for sites.

Nontraditional site locations, such as pharmacies, are highly accessible and are often designated as trusted sources within the community.⁵⁰

Pharmacies were successfully utilized by sponsors and other industry partners to find potential COVID-19 trial participants. One pharmacy chain successfully engaged more than 300,000 prescreened volunteers.⁵¹ Some stakeholders also recommended partnering with care delivery sites, particularly those that serve diverse populations such as FQHCs, HBCUs, military health, and mission-driven health care organizations. One CRO recently partnered with an organization that helps create fully equipped, high-performing sites that serve underrepresented populations.

Decentralized clinical trials (DCTs) can help improve access for patients by reducing the requirements to visit sites. Decentralized trials, which encompass a range of solutions that include digital apps, in-home testing, remote monitoring and diagnostics, and the use of other technologies, are tools that may help improve diversity when coupled with other efforts and resourced appropriately. For example, one workshop participant stated they conducted a fully decentralized trial that took place in the patients' home, and people used smartphones. However, in some instances, technology has hindered participation if people do not have access to Wi-Fi, do not feel comfortable entering in their personal information digitally, or when an entire family shares one device.

Stakeholders suggested that CROs and investigators can help achieve diversity in clinical trials.

“That was part of our vendor decision-making. Not just who has the cheapest and best organization but who’s going to be respectful of the population we are going to be working with.”

— Moupali Das, M.D., M.P.H. executive director, HIV Clinical Development, Virology Therapeutic Area, Gilead Sciences⁵²

KEY OPPORTUNITIES AS IDENTIFIED BY INTERVIEW AND WORKSHOP PARTICIPANTS

- **Create a sustainable, community-based clinical trial infrastructure focused on diversity:** Stakeholders indicated that sites within a network can help foster information sharing on potential leading practices and key learnings that other sites can benefit from. They also discussed that an effective site network takes a federated approach with a shared, multistakeholder governance structure, and common principles established on the outset. They recommended that any site network have a common set of expectations to join but few restrictions to allow for a way to upscale new sites and groups through training, staffing, mentoring, etc.
 - **Provide funding and resources to sites:** Stakeholders indicated that it takes a lot of money, technology, training, documentation, and equipment for a site to be able to execute clinical research. This includes developing protocols and standards to be compliant with good clinical practices (GCPs).
 - **Explore and utilize nontraditional locations for clinical trial sites:** Stakeholders expressed that nontraditional site locations such as pharmacies are highly accessible and are often designated as trusted sources within the community. Some stakeholders also recommended partnering with care delivery sites, particularly those that serve diverse populations such as FQHCs, HBCUs, military health, and mission-driven health care organizations. Some PhRMA member company executives said their companies provide support to those types of organizations through funding or resourcing—this can be particularly important for underfunded study sites.
 - **Hold CROs accountable for meeting diversity metrics:** Stakeholders suggested that CROs and investigators can help achieve diversity in clinical trials. One PhRMA member company executive explained that the company reevaluated its CRO relationships and refocused its selection on which CRO was most open to understanding the nuances of improving clinical trial diversity and respectfully working with specific populations. Some companies have found that if planned in advance, increased diversity can be achieved efficiently and cost-effectively.
 - **Utilize institutional review boards:** Academic researchers see institutional review boards (IRBs) as untapped resources. Those interviewed stated that the IRBs themselves should have more diversity not only in terms of race and ethnicity, but also community membership. Including more community leaders in the IRB process could help build trust between researchers and community members. IRBs could also play a meaningful role in helping to reduce some of the perceived barriers that make it difficult for underrepresented populations to enroll.
-

CASE STUDY

One academic stakeholder has seen success in its trials by aligning sites to where they take care of a large group of traditionally underserved populations. In a stroke-prevention trial, they selected sites that have more diversity and more trust with the investigator group, for example safety net hospitals (that treat patients regardless of insurance status or ability to pay) in underrepresented areas. They also focused on language, particularly for the Hispanic population. They were able to track enrollment and provide feedback to sites. They also eased restrictions on only medical doctors (MDs) being the principal investigator (PI), and instead incorporated clinical pharmacists, nurses, or physician assistants (PAs) as PIs.

Source: The Deloitte Center for Health Solutions industry stakeholder interview, January 2021

Developing and training diverse investigators and site staff

Our research suggests there are opportunities to enhance efforts in recruiting and retaining diverse investigators and site staff, providing sufficient training to existing site staff and evaluating

progress. PhRMA member companies and stakeholders interviewed noted the importance of having participants see themselves in the people who are recruiting and designing research to build trust in the clinical trial process. While one interviewee noted that while it is possible to recruit diverse patients with a less diverse staff, the staff should be trained appropriately.

KEY OPPORTUNITIES AS IDENTIFIED BY INTERVIEW AND WORKSHOP PARTICIPANTS:

- ***Come together as an ecosystem to collaborate on training materials:*** Participants discussed the importance of collaborating across the clinical trial ecosystem to produce training packages and other materials or develop a shared platform accessible to stakeholders to help train investigators and site staff. They noted this can reduce the burden on each individual entity while also standardizing training at the site level. One PhRMA member company is focused extensively on creating training for anyone who interacts with a patient, including CRO staff and nonclinical staff such as security guards. The training covers antiracism and focuses on the specific language to use when speaking with patients.
 - ***Provide ongoing opportunities and mentorship to investigators and site personnel:*** Participants indicated the need for ongoing support to investigators and site personnel, particularly for new investigators. Dr. Sandoval, CEO and research director of Emerson Clinical Research Institute Inc., stated, “We don’t want to see one and done [investigators]. We want to make sure that these investigators can continue to do work.” He went on to say that sites “should never start a study without having an infrastructure in place. But we need to give [them] a chance. We need to train them; we need to educate them because they want to do it.” Many universities, government agencies, and patient advocacy organizations offer internships to undergraduates and opportunities to graduate students from underrepresented populations to conduct clinical research and learn about clinical trials. Some interviewed PhRMA member companies also have similar programs, partnering with HBCUs to increase the number of diverse investigators. These efforts to improve the future pipeline of investigators take time but are important for improving clinical trial diversity.
-

Building community relationships

Workshop participants highlighted the importance of community engagement in enhancing clinical trial diversity and increasing awareness of clinical trials. Diana Foster, VP, Strategy and Development at SCRS, said, “If we’re able to engage in grassroots community-oriented efforts that are very big in a rollout, in a large way bringing industry together, I

think that would be an ideal scenario.” They discussed various aspects of community engagement to include building sustainable relationships, consistently communicating with communities, partnering with community organizations, and engaging communities during the trial design. PhRMA member companies and other stakeholders interviewed also repeatedly emphasized the importance of establishing and sustaining relationships in the communities where underrepresented participants live and work.

KEY OPPORTUNITIES AS IDENTIFIED BY INTERVIEW AND WORKSHOP PARTICIPANTS:

- **Build sustainable relationships with the community:** Stakeholders indicated the need for a “plan of sustainability” when engaging with the community, and emphasized the importance of trusted messengers who are continually engaging and fostering relationships with community members. One equity researcher noted that the most effective community leader is not always the one who might be expected; it may be a church leader, a barber shop worker, and sometimes it may be a grandmother who knows everyone in the community. Approaching community leaders with genuine interest and an intent to maintain relationships after a clinical trial has completed is key. Research from HIT Strategies also found that patient advocates cite the most effective long-term way to increase diversity in clinical trials is, at minimum, to understand nuances of different racially and ethnically diverse communities, forging and sustaining relationships with community advocates, having resources to conduct massive outreach to patients in communities, and prioritizing and incentivizing racially and ethnically diverse communities.
 - **Communicate with the community consistently and clearly:** Stakeholders emphasized the importance of communicating with the community before, during, and after a trial takes place to increase awareness of clinical trials. Communication regarding clinical trials should be bidirectional and should start with general knowledge about health and more broad clinical trial information. Workshop participants also recommended that communication remain throughout the trial and after completion, and the industry should empower those who have firsthand knowledge of the disease or trials to serve as the messenger.
 - **Partner with community organizations:** Stakeholders indicated that organizations such as pharmacies can be helpful in educating communities about clinical trials and can also help foster recruitment for clinical trials. Eighty-four percent of PhRMA member company survey respondents are pursuing at least one partnership with external stakeholders or institutions to support efforts around clinical trial diversity and have been doing so for some time—and 65% of those companies are doing so with at least one community group such as HBCUs, community leaders, social media influencers, and religious organizations.
 - **Engage with community members on the clinical trial design:** Stakeholders highlighted the need for community members to review protocols and provide input into clinical trial design, including endpoints that matter to improving their conditions. Community members should also review any materials containing health or clinical trial information prior to release to ensure it accurately represents and is inclusive of the target community. One solution mentioned was utilizing advisory boards that represent the diversity and voice of the target community to gather this feedback. Research from HIT Strategies found that for surveyed racially and ethnically diverse community members, 72% said to get input from people like them.
-

“Patients of color respond to trusted messengers. That is an extremely important issue. They will not just show up when there is a crisis, you want people to be there in the community developing relationships long term and if more effort is put into educating people about clinical trials long before they have an opportunity to participate, we will see a lot more traction.”

— Dr. Wayne A. I. Frederick, president,
Howard University⁵³

Eighty-four percent of PhRMA member company survey respondents are pursuing at least one partnership with external stakeholders or institutions (including patient advocacy groups, CROs, and industry expert groups/consortia) to support efforts around clinical trial diversity and have been doing so for some time. Sixty-five percent of PhRMA member company survey respondents that are pursuing partnerships to increase diversity are doing so with at least one community group such as HBCUs, community leaders, social media influencers, religious organizations, etc. Over a third of this group (32%) are working with three or more community groups. PhRMA member company survey respondents were more likely to be partnering with academic institutions serving underrepresented populations (e.g., HBCUs) and community leaders as compared to other community groups. Several PhRMA member company survey respondents acknowledged that they are in the early stages of establishing these partnerships.

There are still opportunities to partner with Indian Health Services, FQHCs, and fraternities and sororities. Interviewees emphasized that funding and support for public health initiatives as well as education and training on clinical trial execution will be needed for these stakeholders, particularly FQHCs. When working with Native American tribes, workshop speakers noted differences between tribes; the nuances and history of health inequity

and trauma in the tribal community should be acknowledged. According to stakeholder interviews, fraternities and sororities have longstanding relationships in the community and could offer sponsorship opportunities for corporate partners.

Sixty-five percent of PhRMA member company survey respondents that are pursuing partnerships to increase diversity are doing so with at least one community group such as HBCUs, community leaders, social media influencers, religious organizations, etc.

Additionally, a few PhRMA member companies, patient advocates, and professional organizations interviewed are engaging pharmacists, particularly for community education. For example, one member company partnered with a consortium of community pharmacists regarding COVID-19–related education and clinical trial awareness. Integrating clinical trials into health care delivery settings, whether at pharmacies or physician offices and local hospitals, was cited by academic and nonprofit research stakeholders interviewed as one way to make clinical trials more accessible to more patients. The patient advocates interviewed mentioned partnering with local health care providers who can recommend patients for trials and even administer trials at the local level as a primary way to increase diversity. Workshop participants also indicated that community members should be involved in the review of materials containing health or clinical trial information prior to release to help ensure it accurately represents and is inclusive of the target

community. According to HIT Strategies, 72% of community members surveyed also said that opportunities where they can provide input would help increase awareness about clinical trials in their community, and 52% said having more information would very likely motivate them to participate in clinical trials.

One solution discussed by stakeholders was utilizing advisory boards that represent the diversity and voice of the target community to gather this feedback. According to academic and government stakeholders interviewed, creating community advisory boards or stakeholder committees comprised of diverse community members, from various racial, ethnic, and education levels, to help serve as the interface between the community and the organization conducting the clinical trial has been effective. Including these members early in the clinical trial process and ensuring that they are comfortable and

willing to speak about their questions and concerns can be key. According to HIT Strategies, Black, Latino or Hispanic, AAPI, and AIAN community members surveyed said having more information (52%) and having someone to answer questions (51%) were top motivators for participating in clinical trials.

“I think they can ... make a concerted effort to invest in communities by partnering with community-based organizations, investing in community-based organizations ... Like folks that are not going in to ask you to, strictly asking about recruiting into research, but giving back to the community ... having a bigger presence in the communities as an investor in communities I think is really critical. And that means investing in research in communities.”

— Patient advocate⁵⁴

Integrating clinical trials into health care delivery settings, whether at pharmacies or physician offices and local hospitals, was cited by academic and nonprofit research stakeholders interviewed as one way to make clinical trials more accessible to more patients.

CASE STUDY

The Yale Center for Clinical Investigation (YCCI) created a cultural ambassador program comprising community-based partnerships with the African Methodist Episcopal Zion (AME Zion) Churches of Connecticut and several Hispanic or Latinx leaders in the area including the Junta for Progressive Action.⁵⁵ These relationships were formed after candid discussions regarding the need for more diverse participants and the benefit to both the individuals and the community.

Key features of cultural ambassadors include:

- Engaging in advocacy and education efforts in the community, driving awareness of the importance of clinical research;
- Serving as bidirectional partners appointed by community leaders;
- Focusing on building trust-based relationships, increasing health system engagement, and contributing to improved overall health;
- Being committed to the organization, not to a specific trial; and
- Compensating for training and engagement with a minimum training requirement of 40 hours; most members train over 200 hours and community health care worker certification.

The cultural ambassadors meet monthly with clinical trial researchers who explain the research and are receptive to feedback from the ambassadors. Because these ambassadors are respected leaders in their communities, when they reach out to individuals who they think would be good candidates for a study, they have a higher rate of success in recruiting and retaining them in the study. The cultural ambassadors program has enabled success over the past 10 plus years. In fiscal year 2020, the Yale School of Medicine sponsored more than 2,111 active trials, with approximately 27,800 participants, including approximately 31% underrepresented minorities. In some individual studies, with direct support of the cultural ambassadors, underrepresented minorities represent more than 90% of total enrollment. Workshop participant Tesheia Johnson, deputy director and chief operating officer of YCCI, stated, "The cultural ambassadors enabled us to be highly successful in not only connecting with the needs of the community and understanding the priorities of the community and bringing that insight into our research and projects, but also helped us to think very sensitively about the cultural and language aspects of what we are doing in our research enterprise."

Source: The Deloitte Center for Health Solutions industry stakeholder interview conducted in February 2021; PhRMA, "Partnering for health equity: Advancing research through representative clinical trials", June 8–9, 2021.

Establishing measures and metrics for success

Many stakeholders have discussed the need to establish a data baseline to measure success, utilize scorecards with modern capabilities, and develop shared platforms. They noted that data is essential to understanding where the industry is today and how it will measure its progress moving forward. Per FDA regulations, pharmaceutical companies

must collect race and ethnicity data in US clinical trials. These data comprise two ethnic categories, and five race categories. Barbara Bierer, faculty director of the Multi-Regional Clinical Trials Center of Harvard, indicated that there currently is no common way of collecting data. Most PhRMA member company survey respondents would like to collect more in-depth race and ethnic data for participation rates in clinical trials (figure 6) but are limited in part by the lack of data standardization.

KEY OPPORTUNITIES:

- Establish companywide and industrywide data collection procedures on race and ethnicity:** Stakeholders acknowledge that there is no common way of collecting data and no data on why individuals decline to participate in a trial. Most PhRMA member company survey respondents would like to collect more in-depth race and ethnic data for participation rates in clinical trials—from screen failure to dropping out. PhRMA member company executives interviewed found they could leverage recruitment and retention data in real time, improving the number of participants from traditionally underrepresented populations, rather than waiting until the trial was over to see the final data. Dashboards display real-time data measures on recruitment and help make the data actionable.
 - Improve access to RWD:** RWD that includes race and ethnicity would be helpful for all clinical trial ecosystem stakeholders, but there may be challenges comparing RWD across different settings. Some PhRMA member company executives interviewed discussed partnering with hospitals and EHR companies to increase access to this data and use EHRs to find and recruit patients. Additionally, it is important that patient privacy is appropriately protected.
 - Develop new scorecards to drive site accountability and measure progress:** Workshop participants also discussed that old performance measurements have been applied to new sites. They indicated that scorecards need to be innovative and thoughtful. Racquel Racadio, senior manager, Diversity and Representation in Clinical Research at Amgen said, “Do we have different scorecards for brand new sites versus ones that are established, are the scorecards different depending on their potential capacity based on their patient population versus just the ability to enroll?” She stated, “We are in that place where we can turn our traditional scorecards on their head when we start talking about potential capacity to enroll patients from historically excluded groups.” Others indicated the importance of gaining insight from site personnel as to what data and measurements would be useful and meaningful for them as well as providing resources.
 - Develop shared platforms:** Workshop participants discussed the need for a shared platform that enables interactions between sites, study sponsors, CROs, and with each other. Some warned that sites are already overwhelmed with various platforms, but that there may be opportunities to utilize current systems to embed a centralized platform.
-

CASE STUDY

Pfizer conducted an in-depth analysis of its own US clinical trials between 2011 and 2020 to better understand the demographic diversity of participants and focus representation in drug and vaccine trials.⁵⁶ The analysis comprised 213 clinical trials studying cancer, rare diseases, vaccines, inflammatory and autoimmune diseases, and neurological conditions.

They found:

- Participant levels above census were achieved in more than 50% of Pfizer trials for Black participants, Hispanic or Latino participants, and white participants. Participation was also above census for Asian participants, Native Hawaiian and Pacific Islander participants, and American Indian and Alaska Native participants in 16%, 14.2%, and 8.5% of trials, respectively.
- Black, and Hispanic or Latino individuals are underrepresented, particularly in cancer-related studies.
- White individuals are overrepresented in therapeutic trials or trials in which the treatment under investigation is likely to benefit trial participants.
- Native Hawaiian, Pacific Islander, and indigenous populations were underrepresented. Some trials did not include any individuals from these demographic groups.

“This is an industry first and we’re proud to lead the way. We published these data to be transparent about our baseline, so we can track progress as we work to improve diversity in clinical trials,” said Rod MacKenzie, Pfizer’s executive vice president and chief development officer. “Ensuring diversity of volunteers in clinical trials is a matter of equity and good science. We understand that overcoming barriers and challenges to fair representation in clinical trials won’t happen overnight nor can it be achieved by a single company, but we are committed to doing our part. Pfizer is committed to achieving racially and ethnically diverse participation at or above US census or disease prevalence levels (as appropriate) in all of our US trials, and is taking decisive steps towards meeting this goal.” said Rod MacKenzie, Pfizer’s executive vice president and chief development officer.

CASE STUDY

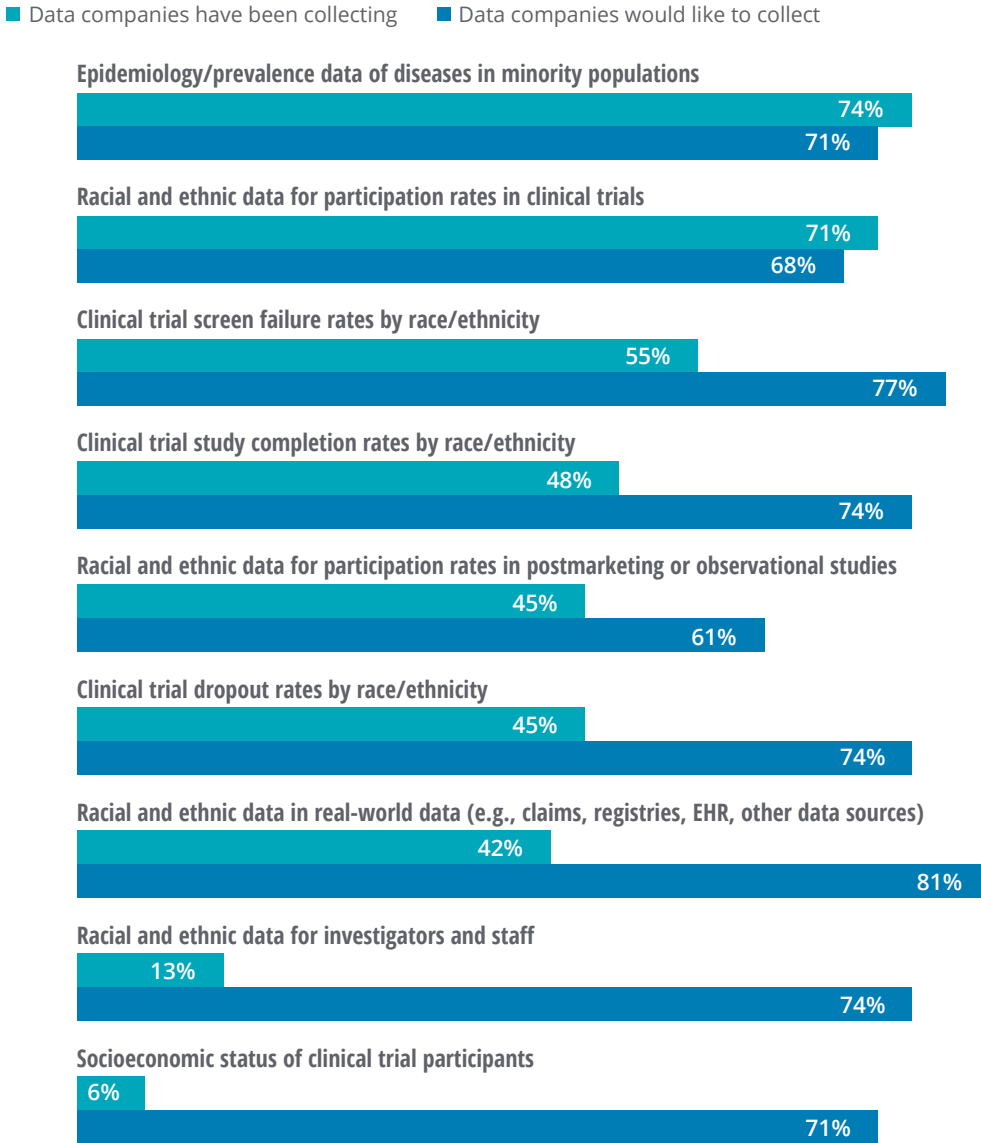
Having access to the right data can make recruitment of underserved clinical trial participants easier. One interviewed nonprofit organization has been collecting health data at the zip code level over the past 20 years. The data set consists of 5 billion patients, covering 72 conditions including cancer, diabetes, and HIV/AIDS, and can be segmented by race/ethnicity and gender. This database shows not only where patients are, but also which providers are treating them. With this data, the organization has partnered with pharmaceutical companies to quickly pinpoint where specific populations are located and to focus clinical trial recruitment in those areas. It is also able to evaluate interventions and see differences in health services and status over time.

Source: The Deloitte Center for Health Solutions stakeholder interview, February 2021.

FIGURE 6

Most PhRMA member company survey respondents have been collecting epidemiology/prevalence data of diseases in minority populations, and racial and ethnic data for participation rates in clinical trials, but would like to collect racial and ethnic data in real-world data

Questions: Which of the following data elements has your organization been collecting/accessing to assess clinical trial diversity? Which of the following data elements would you like to collect/access in the future to assess clinical trial diversity? Select all that apply.



Note: N = 31 PhRMA member companies.

Source: PhRMA member company clinical trial diversity industry survey, January 2021.

The path forward

THE MULTISTAKEHOLDER WORKSHOP made it clear that PhRMA member companies and stakeholders are committed to increasing diversity in clinical trials, and that no one entity can fully address the issue alone. Some possible collaborations could include:

- Partnering with stakeholders across the clinical trial ecosystem (patient groups, community members, clinical research sites, CROs, academia, nonprofit and advocacy organizations, federal and state agencies, industry, etc.) to establish a sustainable, community-based clinical trial infrastructure;
- Establishing relationships with the target community through community leaders, HBCUs, other minority-serving institutions, FQHCs, patients, and others to provide outreach, training and education, and mentorship/job pathways;
- Adopting enhanced data collection capabilities to help support appropriate collection and sharing of racial and ethnic data and RWD through a cloud-based platform;
- Utilizing a common source of disease incidence and prevalence by race and ethnicity to inform clinical trial design; and
- Developing patient-friendly resources that make it easier to identify and enroll in relevant clinical trials.

Research participants as well as the multistakeholder workshop discussions emphasized the tremendous potential of a

community-based clinical trial site infrastructure. The current clinical trial infrastructure depends on independent pharmaceutical companies or academic researchers preparing and training clinical research sites for individual trials. These disparate sites all have varying levels of capability and connectivity to the community, depending on the needs of the trials and communities they serve. This current state is likely not sustainable for any one company or researcher to upskill and adequately resource a new potential site, if only one clinical trial will be conducted. On the other hand, dedicated resources supporting a network of clinical trial sites in the communities that serve underrepresented populations could create sustainable, national infrastructure.

This current state is likely not sustainable for any one company or researcher to upskill and adequately resource a new potential site, if only one clinical trial will be conducted.

There are several benefits to a community-based clinical trial infrastructure. First and foremost, the health care providers that serve those communities are typically best positioned to engender trust and establish relationships with trusted messengers that live in those communities. Stakeholders could invest in increased training and education among investigators and site staff, including at new sites. Those participating in the network would be able to

share potential leading practices and learn from each other. Industry members within this network would also be able to help ensure a consistent pipeline of research studies to create opportunities for investigators and sustain the network over time.

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Workshop participants and others who participated in our research identified steps the research clinical trial ecosystem could take to change the current paradigm and create a sustainable community-based infrastructure that is focused on clinical trial diversity, including:

- **Creating a network of clinical trial sites in underserved communities to make access easier so that those who want to participate can:** Stakeholders of the infrastructure should develop research sites that meet potential participants where they already receive care, including nontraditional locations such as FQHCs or Catholic health systems. These providers may be best positioned to engender trust and establish relationships with trusted messengers and leaders that are reflective of the cultural norms and demographics of the community, and with

the right support and investment could be scaled into clinical trial sites in underserved communities. Stakeholders could start by partnering with sites that serve these communities and have an established track record. Clinical trial sponsors may need to provide additional funding and resources clinical trial sponsors to provide necessary funding and resources to sites and nontraditional locations that serve underrepresented populations.

- **Developing a diverse pool of investigators and staff at sites in underserved communities:** Developing diverse staff to support clinical trials and serve as trusted sources of information requires good clinical practice training, as well as training on cultural competence and unconscious/implicit bias, mentoring, and opportunities and resources that can be used by investigators and site personnel when engaging with the community. Establishing a pipeline of clinical trial opportunities can also be critical to help ensure continued engagement and commitment.
- **Establishing long-term relationships and investing in the community:** It is critical to build long-lasting relationships, rooted in a shared commitment to improve health equity in the communities being approached. These relationships should be established well before a clinical trial is being proposed. Stakeholders of a community-based clinical trial infrastructure should invest in uplifting the community in ways that expand beyond their specific trial. Investments could range from health education, to donating buildings for educational programs, or volunteering to help those in need. It is important to understand the

diverse needs of the communities being served, including who the trusted messengers are. This could look different in each community and could, for example, include barber shops and beauty salons, church and ministerial staff, local food shops, consulates, and other community organizations. These community leaders and trusted messengers could serve as liaisons that can provide information on clinical trials and what participation means for patients.

- **Engaging the community in bidirectional conversations:** Educating the community on opportunities to improve health, including through clinical trials, is a key component of sustainable relationships. Emphasis should be placed on improving patient health first and foremost. Education helps to build trust by empowering community leaders and other members of the community. Empowered patients and their families are enabled to make informed choices about clinical trial participation. At the same time, sponsors should seek community input on clinical trial design, including endpoints of interest and elements of design that might impact patients' ability to participate (e.g., testing requirements). Sponsors should emphasize that without generous volunteer participation, the development of new medicines would not be possible. They should also share research findings with them once a trial is over and consider their research questions and needs in future trials. Sponsors of clinical research should engage in bidirectional conversations with the community to increase education, awareness, access, and enrollment into clinical trials that are tailored for each individual community and made available to patients who want to participate. This includes offering information in various languages and taking into account varying levels of health literacy.

- **Providing sustainable support and standardized platforms:** Some community clinical trial sites may not have the technology platforms and databases in place to help identify patients for enrollment in clinical trials. Investigators who participated in the workshop pointed out that building a data infrastructure is a necessary first step to enable sites to participate in clinical trials. This type of infrastructure, leveraging RWD, could make it seamless for investigators to identify and engage with patients who may be appropriate for clinical trials, with minimal disruption to existing workflows. A community-based clinical trial infrastructure should include the development of standard data collection, baseline measurements to improve data on race and ethnicity, and measures of success for tracking progress on enhanced participation in clinical trials of diverse populations.

Shifting the paradigm will likely require substantial cross-stakeholder commitment and collaboration. Partnering to build scalable and sustainable relationships and solutions, embedded within underrepresented communities, and that extend beyond any one clinical trial are key elements to help ensure success.

Ultimately, improving clinical trial diversity can help improve health equity by increasing patient access to clinical trials, educating them about the potential benefits and risks associated with these studies, and improving the scientific rigor and applicability of research. A community-based clinical trial infrastructure may be the most effective way to sustainably accomplish the goal of enhancing access to clinical trials for diverse patient populations.

Appendix

FIGURE 7

Methodology

Stakeholder workshop: Partnering for health equity: Advancing research through representative clinical trials June 2021

PhRMA hosted a workshop “Partnering for Health Equity: Advancing Research through Representative Clinical Trials,” conducted on June 8th and 9th 2021, convening more than 500 patients, practitioners, and community and industry stakeholders to collaboratively identify strategies for enhancing diversity in clinical trials. The workshop added to the foundational research conducted under a collaboration between PhRMA and Deloitte’s Center for Health Solutions as outlined below.

Literature review

December 2020–April 2021

Analysis of publicly available literature from primary, secondary, and tertiary sources to understand the challenges to enhancing clinical trial diversity, examples of opportunities to address these challenges, and pharmaceutical company initiatives in this space.

PhRMA member company interviews

December 2020–February 2021

Pre survey: Conducted interviews with 10 company representatives from four PhRMA member companies in December 2020 to understand where companies are in the clinical trial diversity space to help inform survey development.

Post survey: Conducted interviews with 15 company representatives from six PhRMA member companies in January–February 2021 to gather additional data based on each company’s survey results.

Industry practices survey

January 2021

Conducted a survey with PhRMA member companies (which included 31 company respondents) to understand where member companies are already making progress and seeing early successes in relation to achieving PhRMA’s newly published principles committing to diversity in clinical trial participation; and to understand current industry practices, gaps, opportunities, what has worked, what failed, why, etc., with a focus on clinical trials conducted in the United States.

Industry stakeholder interview

January–March 2021

Conducted interviews with 26 executives from 22 organization ranging from academic organizations, advocacy groups, CROs, government agencies, industry consortia, and others to explore how to make clinical trials more diverse. Areas of focus during the discussion included barriers to improve clinical trial diversity, strategies, specific initiatives that have succeeded or failed, data collection, and future perspectives.

HIT Strategies community outreach

August–September 2020; January–February 2021; May–April 2021

HIT Strategies, a public opinion research firm, conducted 12 online focus groups with Black or African American (AA), Latino or Hispanic, white, Asian American and Pacific Islander (AAPI) voters, policy influencers, and health care workers from August–September 2020 and January–February 2021. It also conducted seven in-depth interviews with patient advocates who serve Black or AA, AAPI, and American Indian and Alaska Native (AIAN) populations in April 2021. And HIT Strategies conducted a survey with 1,000 community members (700 AA or Black, Hispanic or Latino, AAPI, and AIAN populations, and 300 white) across the United States in May 2021. Research was also conducted with those of varying ages/generations and those living with disabilities.

Source: Deloitte analysis.

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