



Global Investigative Site Personnel Diversity and Its Relationship with Study Participant Diversity

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Abstract

Background There is little to no empirical data on the race and ethnicity of the global community of professionals conducting clinical trials funded by pharmaceutical and biotechnology companies and little empirical evidence on the relationship between the race and ethnicity of investigative site personnel and the overall and corresponding diversity of participants enrolled.

Methods A global online survey conducted in mid-2021 gathered responses from 3462 clinical research professionals representing approximately 3300 distinct investigative sites.

Results Worldwide, including all research settings, the majority (64%) of investigative site personnel are White, 20% are LatinX, 6% are Black, 7% are Asian and 3% are other races and ethnicities (e.g., indigenous peoples, Pacific Islander, Middle Eastern, etc.). The representation of non-white site personnel is significantly higher in North America and Rest of World (ROW) compared to Europe. The highest levels of personnel diversity are found in private community-based practices, investigative sites and site networks. A significant correlation ($p < 0.001$) was found between site personnel diversity and patient enrollment diversity worldwide. As the mix of site personnel by race and ethnicity increases, the diversity of patients enrolled—except for Asian patients in sites outside of North America—also increases. A significant relationship was also found between the proportion of a given race or ethnicity of investigative site personnel and the corresponding race and ethnicity of patients enrolled.

Conclusions An opportunity exists to address under-representation in clinical trials through identifying, hiring and supporting investigative site personnel to best reflect the patient communities that they serve.

Keywords Diversity, equity and inclusion · Under-representation in clinical research · Clinical trial diversity · Study volunteer disparities

Introduction

Stakeholders throughout the drug development enterprise are focusing attention on diversity, equity and inclusion (DEI) in clinical trials with renewed energy and commitment. There are several contributing factors including intensifying demand for more heterogeneous clinical and genetic data; growing pressure from regulatory agencies, health authorities, professionals, patients and the general public to address under-representation of demographic subgroups in clinical trials; and rising concern from health care providers and payers facing difficulties in translating clinical research findings of new medical therapies into clinical practice.

New guidance from the Food and Drug Administration (FDA), new requirements from journal editors and new

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frameworks from public–private partnerships, all within the past 18 months and partly in response to health disparities identified during the early stages of the COVID-19 pandemic, further punctuate enterprise-wide commitment. In August of 2020, for example, the Multi-Regional Clinical Trials (MRCT) Center at Harvard University—a public–private partnership—published a comprehensive document characterizing the importance of diversity in clinical research and the many factors and practices contributing to under-representation [1].

In November 2020, the FDA issued its final regulatory guidance to improve diversity in clinical trials and encourage inclusivity in drug development. The guidance satisfies the mandate under Section 610(a)(3) of the FDA Reauthorization Act (FDARA) and offers considerations for eligibility criteria that are more inclusive and representative, for clinical trial designs that facilitate more representative enrollment and targeted inclusion of select patient subpopulations, and for increased use of convenience- and access-enhancing practices and solutions for patients participating in clinical trials [2].

In September 2021, the editors of the *New England Journal of Medicine* announced new DEI requirements for manuscript submissions. Authors of manuscripts characterizing clinical research results will be required to provide supplementary information detailing the representativeness of the study volunteers enrolled. Journal editors plan to assess the diversity of the study population enrolled in relation to country-specific disease prevalence and demographic disparities [3].

Recent guidance, guidelines, recommendations and requirements add to a long and extensive body of work in the literature, and to a substantial collection of initiatives implemented during the past 30 years to understand and address the under-representation of patient demographic subgroups in clinical trials [4–6]. Stakeholder initiatives have focused on developing and implementing strategies and tactics to improve transparency, trust and disclosure; public awareness and education; geographic access; and patient recruitment communication effectiveness [7].

Decades of research in the literature has examined biologic variability by demographic subgroup and the impact of social determinants on health, disease burden and progression, and access to clinical trials [8–11]. Scholarly research has characterized the complex factors that affect minority community trust, perceived relevance and safety, and willingness to participate in clinical research [12–14].

A more recent and growing body of research in the literature has explored the important role played, and barriers erected, by research professionals seeking to attract, retain and engage with potential clinical trial participants in under-represented communities. Studies have shown, for example, that unconscious bias and stereotyping limits physician and

nurse referral and recruitment of minority participants [15, 16]. The authors of these studies recommend staff training and modified referral and recruitment processes and practices to address racial and ethnic disparities.

Although these studies have examined clinical research professional attitudes and practices that influence, and even underlie, minority patient disparities in clinical trials, there is little to no empirical evidence on the relationship between the race and ethnicity of clinical research personnel and the overall and corresponding race and ethnicity of patients enrolled. Several widely referenced studies have quantified the distribution of NIH grant awards by applicant race and ethnicity as this demographic data is known and tracked routinely [17, 18]. Authors of these studies have suggested that the under-representation of minority grant awardees (researchers) is associated with patient recruitment disparities.

To our knowledge, there is little empirical data on the race and ethnicity of research professionals supporting clinical trials funded by pharmaceutical and biotechnology companies. In a 2008 study conducted by the Tufts Center for the Study of Drug Development, Tufts University School of Medicine (Tufts CSDD), 1376 United States-based investigators participating in industry-funded clinical trials were surveyed. The results showed significant racial and ethnic disparities among principal and co-investigators despite high and comparable interest in conducting clinical trials. We also suggested that investigator race and ethnicity may influence clinical trial volunteer participation rates and conveyed our interest in characterizing this relationship empirically in future research [19].

A follow-up empirical study has now been completed, and the results and their implications presented here. The purpose of this research was three-fold: (1) to expand our scope to include the broader, global community of professionals (e.g., study coordinators, administrative staff, investigators) who interact with study volunteers; (2) to gather a baseline measure of the distribution of this professional community by race and ethnicity; and (3) to empirically measure the relationship between site personnel diversity and patient enrollment diversity. It is our hope that the results of this study will inform efforts by research sponsors and other drug development stakeholders to improve diversity, equity and inclusion in clinical trial execution and participation.

Methods

A large working group of organizations participated in this study reflecting its high perceived importance. One professional association—the Association of Clinical Research Professionals (ACRP), five contract research organizations (Covance—now Labcorp Drug Development, ICON,

IQVIA, Parexel, Syneos Health) and 17 biopharmaceutical companies (AbbVie, Amgen, AstraZeneca, Biogen, Bristol Myers Squibb, CSL Behring, Eli Lilly and Company, EMD Serono, Janssen, Merck, Otsuka Pharmaceuticals, Pfizer, Genentech (a member of the Roche Group), Sanofi, Seagen, Takeda, UCB) participated. Working group members provided input into the survey design, assisted in implementing the survey among a global community of investigative sites and discussed the analysis of the results and their implications.

A global online survey was conducted between May and July 2021. Participating companies in the working group each distributed the survey directly to a convenience sample of investigative sites actively involved in their clinical trials. ACRP and another collaborating professional association, the Society for Clinical Research Sites, distributed the survey to their global members. The survey instrument was reviewed and approved by an ethical review committee and was deemed compliant with European General Data Protection Regulation (GDPR) by an independent data review committee at Tufts University.

Definitions of key terms provided to assist respondents in completing the online survey are summarized in Table 1 and informed by internationally recognized sources [20–28]. The race and ethnicity definitions included in our survey are consistent with those reported in a recent study looking at

the race and ethnicities of COVID-19 patients participating in 68 studies globally [29].

Raw data was stored in Microsoft Excel and data cleaning and analysis was conducted in SAS version 9.4. Analyses performed included descriptive statistics, frequency comparisons, coefficients of variation (defined as the ratio of standard deviation to the mean), comparisons of mean overall and subgroup response values, significance testing, correlations and multi-variate regression analyses.

Completed surveys were evaluated to remove duplicate responses from the same investigative site. Descriptive data (e.g., geographic location, site type, clinical trial volume) and data from several arbitrarily selected site-specific operating characteristics (e.g., type of standard operating procedures, communication and technology solutions used) were assessed to identify and remove duplicates and derive estimates for the total number of distinct investigative sites.

Several subgroups were created to organize our analysis and to aid in communicating the findings in the Results section. Personnel diversity subgroups were regionally defined. Outside of North America, the diversity of investigative site staff is based on the racial and ethnic category that comprises the highest proportion of the staff. As such, sites with HIGH personnel diversity are those with less than or equal to 40% of any single race or ethnicity making up the largest proportion; and sites with LOW personnel diversity

Table 1 Definitions of race & ethnicity; income level; and research location

<i>Race and ethnicity</i>	
Asian	A native, or person descending from the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam
Black (or of African Descent)	A native, or person descending from Africa
LatinX (Spanish Origin, Hispanic or Latino)	Persons of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race
White	A native, or person descending from Europe
Other	Includes ‘First Peoples of the Americas’ (those having origins in any of the original peoples of the Americas, including North America, Central America and South America); ‘Middle Eastern or North African’ (those having origins in any of the original peoples of the Middle East or North Africa); ‘Pacific Islander’ (those having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands); or ‘Other’ (any race or ethnicity not listed)
<i>Income level of community served</i>	
Low income	Communities where income is below the minimum level needed to secure the necessities of life (below the poverty line) or above the poverty line but below middle income
Middle income	Communities where income levels are at country-defined levels of middle income
High income	Communities where income levels are above country-defined levels of middle income or where income levels are defined as affluent
<i>Research location</i>	
Urban	City with a population of at least 50,000 inhabitants in contiguous dense areas (>1500 inhabitants per km ²)
Suburban	Town or semi-dense/suburban area with a population of at least 5000 inhabitants in contiguous areas with a density of at least 300 inhabitants per km ²
Rural	Consisting mostly of low-density areas (less than 300 inhabitants per km ²)

are those with any single race or ethnicity of the staff being equal to or greater than 60% of the total.

Within North America, the racial and ethnic diversity of investigative site staff is based on the proportion of White staff. Sites with HIGH personnel diversity are those that are equal to or greater than 60% minority staff (Non-White); and sites with LOW personnel diversity are those that are equal to or less than 40% minority staff.

Personnel race and ethnic diversity percentages are based on averages of survey respondents' perceptions of overall staff demographics. The race and ethnicity categories presented to respondents are outlined in Table 1. Respondents were instructed to select all race and ethnicity categories to which they identified and to select the 'Other' category if no other option applied. A small percentage of respondents selected multiple- categories and the 'Other' option. These respondents are all included within the 'Other' subgroup in our analyses. The race and ethnicity of patients enrolled was reported by investigative site personnel based on their review of historical data from their clinical study and patient recruitment management systems.

Two primary subgroups were created to characterize investigative site type: AMCs/HS includes investigative site personnel operating within academic medical centers, large health systems, regional and community hospitals and clinics. PRIVATE SITES/SITE NETWORKS includes investigative site personnel operating within community-based private practices, individual and networks of research centers that derive the majority of their income from industry-funded clinical study grants.

Results

In total, 3462 respondents consented to and participated in the online survey. Respondents had a mean tenure of 12 years at their respective investigative site. Respondent characteristics are summarized in Table 2.

There are an estimated 3300 distinct sites in the survey dataset representing approximately 40% of the total number of unique investigative site locations involved in FDA-regulated clinical trials in 2020 [30]. Fifty percent of the sites reflected in this study are operating in North America (US and Canada); 32% in Europe (including the UK); and 28% are operating in other parts of the world (10% in South and Central America (including Mexico), 4% in Asia and the Pacific, and 4% are operating in other regions including the Middle East and Africa).

These investigative sites focus on a wide range of therapeutic area specialties with the most common being cardiovascular disease, oncology, gastroenterology, neurology and pulmonary/respiratory diseases. Eight-out-of-ten (82%) global investigative sites are operating in urban settings, 15% in suburban and only 3% in rural settings. In addition, respondents report that investigative sites serve a mix

Table 2 Respondent characteristics

	<i>N</i>	Percent of total
Total respondents consenting	3462	100%
Role*		
Study coordinators and research nurses	466	25%
Principal investigators	756	40%
Site directors, managers and other administrative staff	676	36%
Sex*		
Female	1206	61%
Male	770	39%
Race & Ethnicity*		
White	1344	69%
LatinX	231	12%
Asian	146	8%
Black	69	4%
Other	159	8%

*Reflects only those respondents that chose to divulge this information. Includes all site types

of communities based on income level: 49% of sites are located in communities classified as middle income, 29% as high income and 22% as low income. About four-out-of-ten (43%) investigative sites comprise the Private Sites/Site Networks subgroup; and 50% make up the AMCs/HS (i.e., academic medical centers, large health systems, regional and community hospitals) subgroup. Six percent of sites were classified as government-sponsored or "Other" and are not included in subgroup analyses.

Investigative Site Personnel Race & Ethnicity

Across all research settings, nearly two-thirds (64%) of investigative site personnel were reported as White; 6% as Black or of African Descent; 20% as LatinX; 7% as Asian and 3% as other races and ethnicities. Nearly three-out-of-four (71%) investigative site personnel were identified as female. Table 3 shows the racial and ethnic diversity of investigative site personnel by geographic area and research setting.

The vast majority of investigative site personnel in Europe are White with only 7–8% of the total representing other races and ethnicities. Site personnel based in North America and Rest of World have much higher levels of proportional representation by race and ethnicity. Personnel diversity is much higher in private investigative site settings in North America and Rest of World (ROW).

The distribution of investigative site personnel by race and ethnicity varies considerably by reported therapeutic areas of specialty. Investigative sites conducting clinical trials focusing on infectious diseases, vaccines and endocrine disorders have the most diverse site personnel. Oncology

Table 3 Distribution of investigative site personnel by geographic region and investigative site type

	Overall	Europe	North America	ROW
AMC/HS				
Asian	9.2%	1.5%	8.8%	28.9%
Black	4.5%	0.8%	10.1%	3.0%
LatinX	10.5%	4.4%	9.2%	28.5%
Other	3.1%	1.1%	6.0%	2.8%
White	73.6%	91.7%	66.8%	39.3%
Private sites/ site networks				
Asian	5.3%	0.5%	8.0%	3.0%
Black	7.8%	0.4%	11.1%	5.7%
LatinX	27.6%	1.8%	21.0%	67.2%
Other	3.8%	0.4%	4.6%	4.6%
White	56.5%	93.2%	57.5%	20.6%

Table 4 Distribution of site personnel* by race and ethnicity and clinical trial therapeutic area focus

	Asian	Black	LatinX	Other	White
Cardiology	8.5%	6.9%	22.3%	4.0%	59.7%
Dermatology	7.6%	5.3%	24.6%	3.0%	59.5%
Endocrinology	8.4%	7.7%	24.9%	4.2%	55.4%
Hepatology	9.8%	7.2%	23.5%	4.2%	57.2%
Infectious diseases and immunology	9.7%	9.1%	20.3%	4.4%	58.2%
Nephrology	12.1%	6.4%	25.5%	4.8%	53.4%
Oncology	8.7%	5.2%	19.1%	4.5%	63.2%
Ophthalmology	14.8%	6.5%	24.2%	4.6%	52.8%
Pediatrics/neonatology	10.4%	8.4%	17.5%	4.7%	59.6%
Psychiatry	8.5%	7.1%	21.6%	3.9%	59.5%
Rheumatology	7.7%	5.9%	25.1%	3.6%	57.1%
Vaccines	7.4%	10.0%	24.6%	4.6%	54.4%

*Includes all site types

and dermatology have significantly lower relative representation of Black investigative site personnel. Table 4 presents this distribution for the most common reported clinical trial areas of therapeutic focus.

Diversity of Patients Enrolled

Across all research settings and geographies, investigative sites report that 64.2% of enrolled patients are White; 9.9% are Black or of African Descent; 19.3% are LatinX; 5.2% are Asian and 2.3% are reported as other races and ethnicities.

In industry-sponsored clinical trials performed in AMC/HS settings, 73.6% of patients enrolled are White. This compares to 56.5% of enrolled patients in private settings. In turn, Private

Table 5 Site reported distribution of patients enrolled overall and by site type

	All Global Investigative sites*	AMC/HS	Private Sites/ Site Networks
Asian	5.2%	7.7%	2.5%
Black	9.9%	6.6%	12.2%
LatinX	19.3%	10.4%	25.4%
Other	2.3%	2.3%	2.4%
White	64.2%	73.9%	57.9%

*“All Global Investigative Sites” includes all site types

Sites/Site Networks enroll significantly higher proportions of Black and LatinX patients. Table 5 shows the distribution of diversity of patients enrolled overall and by research setting.

Worldwide, and in North America specifically, site personnel diversity is correlated and predictive of patient enrollment diversity. As personnel diversity in global sites increases, the proportional races and ethnicities of patients enrolled at those sites also increases. This association is significant for all races and ethnicities except for Asian patients who were enrolled in clinical trials conducted by sites that tended to have substantially higher relative representation of Asian personnel. In North America specifically, the race and ethnicity of all patients enrolled—including Asian patients—is correlated with site personnel diversity. As noted earlier, in this region higher representation of site personnel by race and ethnicity is observed.

A significant relationship was observed between the races and ethnicities of site personnel and the corresponding races and ethnicities of patients enrolled in clinical trials at that investigative site. Tables 6 and 7 present the results of linear regressions analyses.

Sites with higher relative representation of personnel by race and ethnicity are more likely to strongly agree that diversity is a critical success factor and to have developed policies and standard operating procedures (SOPs) to encourage and support diversity, equity and inclusion in the workplace and in their patient recruitment practices. This trend is statistically significant for Private Sites/Site Networks in North America. A higher percentage of sites with ‘High’ personnel diversity reported achieving their patient enrollment goals. Table 8 presents comparisons between ‘High’ and ‘Low’ personnel diversity sites in Europe and North America by research setting.

Discussion

The results of this study present a first-of-its-kind empirical assessment of the distribution, by race and ethnicity, of the global investigative site landscape involved in industry-funded clinical trial activity. The study found that worldwide, including all research settings, most investigative

Table 6 Linear regression showing that as the mix of site personnel diversity increases, the mix of race and ethnicity of patients enrolled (with the exception of Asian patients) also increases

	Coefficient	Adjusted R^2	p -value
Worldwide*			
Asian	−0.004	−0.002	0.862
Black	0.273	0.173	<0.001
LatinX	0.162	0.018	<0.001
Other	0.053	0.051	<0.001
White	−0.499	0.138	<0.001
North America*			
Asian	0.038	0.027	0.005
Black	0.138	0.051	<0.001
LatinX	0.395	0.342	<0.001
Other	0.029	0.023	0.011
White	−0.614	0.501	<0.001

*Includes all site types

Table 7 Linear regression showing that as the proportion of any given race or ethnicity of site personnel increases, the corresponding race and ethnicity of patients enrolled also increases

	Coefficient	Adjusted R^2	p -value
Worldwide*			
Asian	0.692	0.647	<0.001
Black	0.857	0.443	<0.001
LatinX	0.873	0.866	<0.001
Other	0.393	0.746	<0.001
White	0.826	0.246	<0.001
North America*			
Asian	0.121	0.097	<0.001
Black	0.531	0.181	<0.001
LatinX	0.616	0.578	<0.001
Other	0.226	0.152	<0.001
White	0.619	0.516	<0.001

*Includes all site types

site personnel were reported as White, 6% as Black or of African Descent; 20% as LatinX; 7% as Asian and 3% as other races and ethnicities (e.g., indigenous peoples, Middle Eastern, Pacific Islander, or other). The results also indicate that the representation of site personnel by race and ethnicity is significantly higher in North America and Rest of World compared to that in Europe and that the highest levels of personnel diversity are found in private community-based practices, investigative sites and site networks. Less than 10% of site personnel in Europe are representative of minority populations compared to almost one-third of North American site personnel conducting clinical trials in academic medical centers, regional and

community health systems and nearly half of site personnel conducting clinical trials in private settings.

Numerous factors contribute to variation in the levels of racial and ethnic under-representation among site personnel by geographic region and investigative site type. The physical location of research centers and their associated pool of minority-trained professionals may be limited. Variation in staffing practices and hiring biases may be partial explanations. Competition for trained minority clinicians and clinical researchers may be a contributing factor given the low relative attractiveness of industry-funded clinical trials to academic center- and hospital-based professionals. The competition for trained minority personnel may also be higher in large health systems as they offer more job opportunities and upward mobility not only in clinical research but also in clinical care and care administration.

The study findings indicate variation in site personnel diversity by therapeutic area. Infectious diseases, vaccines and endocrine disorders have the most diverse clinical trial personnel. Dermatology and oncology—the most active therapeutic areas—had significantly lower relative representation of personnel who identify as Black or of African Descent. These results mirror recent research characterizing racial and ethnic disparities in patients enrolled in pivotal trials of new drugs and biologics recently approved by the FDA [31]. In that study, nearly all pivotal trials of drugs and biologics approved for cancer-related and dermatologic diseases had high levels of under-representation of Black patients.

A significant correlation ($p < 0.001$) was found between site personnel and patient enrollment diversity. Worldwide, regardless of geographic region, as the mix of site personnel by race and ethnicity increases, the diversity of patients enrolled—except for Asian patients in sites outside of North America—also increases. Moreover, a significant relationship was found between the proportion of a given race or ethnicity of investigative site personnel and the corresponding proportion of patients enrolled. As the number of Black or LatinX investigative site personnel involved in conducting a clinical trial increases, the corresponding proportion of Black or LatinX patients enrolled also increases. Stakeholders throughout the clinical research enterprise have long suspected, based on direct personal experience and anecdotal evidence, that this important relationship exists. This study presents compelling and affirming empirical evidence.

Significant variation was also observed in site personnel and patient enrollment diversity by research setting. Academic medical centers, regional and community health systems and centers worldwide enroll a disproportionately high percentage of White patients into industry-funded clinical trials. Private sites and site networks enroll much more diverse patient populations. Further, sites with more diverse personnel are more likely to view diversity as an important

Table 8 Perceived importance, commitment to diversity and enrollment achievement by site type

Percent of total	Europe AMC/HS		North America AMC/HS		North America Private Sites/Site Networks
	Low (n = 212)	High (n = 30)	Low (n = 111)	High (n = 116)	Low (n = 153)
Personnel diversity level					
‘Strongly agree’ that Diversity is a Critical Success Factor	35.3%	41.2%	26.3%	40.5% α	23.5% α
Offer Patient Diversity Mentorship Training	59.6%	63.2%	44.6%	59.8% α	37.7% α
Have a Mission Statement that Includes Diversity and Inclusion	62.7%	76.5%	58.3%	62.1% α	41.8% α
Have Diversity and Inclusion SOPs	56.1%	70.0%	54.9%	59.8% α	40.9% α
Have Unconscious Bias SOPs	46.9%	57.9%	48.8%	54.2% α	35.7% α
Have Inclusive Behaviors SOPs	50.0%	58.8%	45.7%	51.6% α	36.5% α
Report Achieving Enrollment Goals	97.8%	86.7%	86.5%	98.7%	94.3%

* α indicates statistically significant ($p < 0.05$)

success factor and to have developed proactive policies to encourage and support diverse enrollment.

The results of this study highlight a major opportunity to address under-representation in clinical trials through not only training professionals and supporting clinical trial execution but also through hiring diverse investigative site personnel who share perspectives, cultural views and experiences with the corresponding race and ethnicity of their patients. The study results strongly suggest that research sponsors and CROs reassess use of site selection criteria beyond identifying physical site locations within a geographic area known to have a higher relative concentration of minority communities. As clinical trials increasingly transition to remote and virtual approaches (e.g., telehealth, wearable devices, smartphones, and home visits), where the geographic location of the investigative site becomes less defining, the diversity and cultural competency of the clinical research workforce and its ability to connect with a diverse patient population will become even more important.

This study received a strong global response despite challenges presented by the pandemic. The methodology, however, had several limitations. Data on personnel and patient enrollment diversity are based on self-report from respondents. Future research will look to gather more patient-reported data including their perceived importance of, and willingness to enroll based on, the corresponding race and ethnicity of site personnel. Additionally, bias may have been introduced by the methods used to reach and encourage respondents to participate in an online survey.

The Tufts CSDD team is planning several future studies to understand, overall and by geographic region, how clinical research professionals are first exposed to and gain experience conducting clinical trials. Future research will also look at investigative site personnel diversity, operating infrastructure and its relationship with measurable clinical trial performance outcomes

Conclusions

This study establishes an important baseline measure of the global distribution of investigative site personnel by race and ethnicity that can be used to monitor and track improvements in personnel diversity over time. Most importantly, the results of this study identify a critical opportunity to improve clinical trial participant diversity, equity and inclusion through encouraging and supporting investigative site personnel to best reflect the patient communities that they serve.

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Author Contributions

KG contributed to all four aspects (substantial contribution to conception, design, analysis, interpretation; drafting and revising the work; final approval of the version to be published; agreement to be accountable for all aspects in ensuring accuracy and integrity of the work). MF, EB contributed to all four aspects. KR, GG, LR, OA made substantial contribution to conception, design, analysis, interpretation; and assisted in drafting and revising the work.

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Declarations

Conflict of interest

Kenneth Getz, Maria Florez, Emily Botto declare that they have no conflict of interest. Kim Ribeiro, Gretchen Goller, LaShell Robinson, Omer Abdullah declare that they are an employee and have financial holdings in the company.

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