



Association of Clinical Research Professionals' Response to FDA Draft Guidance on Diversity in Clinical Trials

Increased Diversity Should Be a Requirement, Not a Suggestion

by Otis Johnson, Diana Anderson Foster, Ruma Bhagat, Nadege T. Gunn, Marissa Hill, Ashley Moultrie, Aida Sabo & R'Kes Starling

Abstract

This article examines viewpoints from eight members of the Association of Clinical Research Professionals' (ACRP) diversity advisory council and industry stakeholders on FDA draft guidance on improving diversity in trials. This guidance is welcome amid heightened awareness of systematic and structural racial injustice. However, diversity should be a requirement rather than a recommendation. There are multiple ways for sites to advance diversity and for sponsors to support sites' diversity efforts. Next-generation protocols should be created jointly by sponsors, patients, and sites, building on advances in decentralized trials made during the COVID-19 pandemic, and ensuring that trials achieve the goals of the guidance.

Introduction

The need for action to improve the diversity of clinical trial participants is increasingly recognized against a backdrop where many trials have historically enrolled mainly white, and mainly male, participants.¹ At the clinical trial site level, pressure is already being felt, with sponsors increasingly requiring details of diversity in both the clinical research organization (CRO) workforce and clinical trial participant pool as early as the request-for-proposal (RFP) stage of an engagement.

"Industry as a whole will have to take action, supported by enterprise-level diversity teams. We have already seen mid-trial requests from FDA to increase diversity—requiring a costly rescue. Integration of all enterprises involved in clinical trials will be needed to plan for appropriate levels of diversity during protocol development, including relationship building with underrepresented communities."

– Diana Anderson Foster

“My fear is that we will not keep the learnings from COVID and we will go back to the way things were done before. This must not happen.

We have found that there is no regulatory barrier to DCT elements, which can be used without compromising patient safety. There is a robust appetite to continue, and active discussions are needed to make sure we continue to reap the benefits in support of improved diversity.”

– Ruma Bhagat

Improving diversity in trials is the subject of a recent draft guidance document from the U.S. Food and Drug Administration (FDA). Published in April 2022, the document is entitled, “Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry.”²² The latest guidance builds on FDA’s seminal guidance on clinical trial diversity, “Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry,” published in November 2022.

This paper provides viewpoints on the April 2022 draft guidance and on pathways forward from experts with extensive day-to-day experience of the realities of running clinical trials. In the authors’ views:

- *The new FDA draft guidance on diversity is welcome amid heightened awareness of systematic and structural racial injustice. However, clinical trial recruitment diversity should be*

a requirement, rather than a recommendation, to ensure that the stated goals of the draft guidance are fully realized.

- *While final FDA direction is awaited, sponsors can support sites in building on existing efforts to improve recruitment diversity; this will require financial support for sites in areas such as implementing new technology, decentralized trial elements, translation services, community outreach initiatives, patient navigators, and other patient-centric efforts.*
- *Sites should continue with activities that are positively linked to staff diversity—which in turn is associated with recruitment diversity—such as having standard operating procedures (SOPs) on unconscious bias and inclusive behavior.*
- *All clinical trial stakeholders should collaborate actively to rapidly improve recruitment of patients from underserved and underrepresented populations, based on early development of strategy during the RFP and protocol design stages. Next-generation protocols should be created jointly by sponsors, patients, and sites, building on advances in decentralized clinical trials (DCTs) made during the COVID-19 pandemic. This will help ensure that trials reflect the full spirit of the FDA draft guidance.*

Background

The longstanding issue of clinical trial diversity continues to be in the spotlight. As a recent *STAT* op-ed stated, “Increasing the racial and ethnic diversity of clinical trial participants is a scientific and ethical imperative emerging from differences in disease causality, presentation, and progression; in access to health care; and in drug safety and effectiveness across diverse populations.”²³

Pressure is mounting to address this issue in order to improve medical product safety and efficacy across the diverse populations living in the United States. The need for action is underscored by data from many sources.

For example, among the total of 53 new molecular entities and biologics approved by FDA in 2020, 75% of the 32,000 clinical trial participants were white, 8% African American, 6% Asian, and 11% Hispanic.⁴ Only 37% of pivotal trials for the 371 drugs and biologics approved in the United States from 2007–2017 provided data on ethnicity, according to the Tufts Center for the Study of Drug Development (CSD-D).⁵ African Americans were the most under-represented, with participation rates registering 65% below their levels in general census and disease populations. Various examples of the impact of the lack of diversity in clinical trials are provided in the Additional Information section.

The April 2022 FDA draft diversity plans guidance has the stated purpose of giving recommendations on how

“The new draft guidance is refreshing in paying attention to the detail of improving diversity. This will require a full understanding of diverse patient populations in rural areas, who may be uninsured, socio-economically disadvantaged, and with transportation insecurity. Making appropriate accommodations is a complex endeavor, much of which can be mitigated at the protocol development stage.”

– Nadege T. Gunn

The burden of advancing diversity does not fall only on the sponsor. Clinical trial sites are also eager to advance diversity, which will require additional budget resources, education, and training.”

– Marissa Hill

sponsors should develop a plan to “enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States, such as Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and Other Pacific Islanders, and other persons of color, in clinical trials.” FDA notes that individuals from these underrepresented populations may have a disproportionate disease burden for certain diseases, and that their adequate representation in trials will ensure sufficient data and may identify effects on safety or efficacy outcomes in these populations.⁶

A May 2022 report titled, “Improving Representation in Clinical Trials and Research,”⁷ from the National Academies of Sciences, Engineering and Medicine, also represents an important step forward in recognizing the need for diversity. The report’s authors describe the urgent need to move away from trials that focus largely on white men.⁸

Steps to Meet the Goals of the FDA Draft Guidance

The new draft diversity plans guidance is welcome amid heightened awareness of systematic and structural racial injustice. It is also helpful that the draft guidance includes medical devices. While FDA’s guidance documents are nonbinding,⁹ anecdotal reports strongly suggest that life science industry scientists follow

FDA guidance as if it were legally binding. This makes the guidance highly influential. As a result, it is important for improved diversity to be a requirement as part of FDA policy, rather than simply a suggestion. This would address the potential risk of “passive resistance” or non-compliance with the draft guidance due to lack of a “fear factor,” which could tempt stakeholders to do the minimum required to comply with the draft guidance, falling short of achieving its full intent. However, such a policy change would entail administrative hurdles that would require drafting of new regulations.

The new draft guidance on diversity could potentially benefit from incentives and consequences, provided care is taken to avoid an undue burden for sites, such as excessive increases in infrastructure costs or complex rules around management and enforcement. FDA could offer expedited review for studies with diversity information; this would create a structure to support change. The agency could give public recognition to companies whose trials recruit diverse populations, thereby offering an incentive by boosting corporate reputation. Additional communications resources should be provided by the agency to complement the guidance. In addition, FDA should reconsider a suggestion in the draft guidance that enrollment of additional participants would be required if a difference in response is found between various ethnic groups; this additional burden could discourage moves to increase diversity in enrollment.

There remains a need to clearly identify how best to implement proposals to boost diversity. Potential steps include:

- *Considering making it a requirement to provide FDA with details of*

how diversity plans will be implemented, helping ensure that the planning exercise does not simply become “a box to be checked.” This requirement to execute the plans would help maintain momentum for improvements.

- *Ensuring that trial participant diversity adequately reflects real-world populations affected by the disease of interest. The “gold standard” would be to have this proportion represented at all stages of development. Statisticians should be engaged in planning for appropriate levels of enrollment to achieve study goals.*
- *Building trust among underrepresented communities by fully acknowledging the damage done in the past by initiatives such as the unethical Tuskegee syphilis study¹⁰ and harms that continue today, including African American females dying in childbirth at three times the rate of white women.¹¹ This will require enhanced efforts and education to resolve medical and structural biases and improve access to healthcare for marginalized populations.*
- *Widening eligibility criteria for potential trial participants if scientifically*

“The guidance is a helpful step towards identifying the longstanding problem of diversity in clinical trials, but there’s been little conversation about the ‘how.’ Requirements should go beyond simply ‘checking the box’ by submitting a plan. Clear recruitment goals and implementation strategies should also be required to maintain momentum.”

– Ashley C. Moultrie

and clinically appropriate and partnering with research-naïve sites, which may provide access to broader populations. However, care must be taken not to negatively affect studies' scientific integrity if eligibility criteria are widened.

"The draft guidance is definitely a step in the right direction. It touches a lot of key areas where action is needed. However, it does not go far enough. Throughout the guidance, there are reminders that these are nonbinding recommendations. In other words, they are optional and it is OK if you choose not to follow them. There are no consequences and no incentives. These should be requirements."

– Otis Johnson

Considerations for Rural and Underserved Populations

Improving access to clinical trials for those who live in rural areas and other underserved areas will be central to improving participant diversity. Currently, sites tend to be located in areas that are predominantly white and urban, posing an accessibility challenge for people from other populations and locations.

Rural access is not fully covered by the draft guidance. Complexities may arise outside of metropolitan areas, including transportation challenges, and lack of availability of imaging modalities such as MRI and ultrasound, and limited internet access. Many underserved patients may be uninsured or undocumented. To help overcome these hurdles, protocol

development should include input from patient advocates, enabling any necessary accommodations to be included in trial design.¹² Given that transportation remains a leading barrier to recruiting a more diverse patient population, this should be included in the budget for any patient-centric study. Providing access to imaging may require a hotel stay, which must also be taken into account in budgeting. Any out-of-pocket costs should be paid upfront to meet the needs of low-income participants—rather than requiring an expense submission—and packaging for investigational products should be tailored for the participant population, such as being suitable to be carried on public transportation.

Role of DCTs in Improving Diversity

Decentralized clinical trials (DCTs) have potential to support a more patient-centered approach by reducing long-standing barriers to participation such as transportation, logistics, and geographical location. Such trials can also positively impact access for underrepresented populations. For example, a recent study at the University of Rochester Medical Center found that telemedicine can make care more accessible for the most vulnerable patients.¹³ However, trust and technology skills must be built before any remote trial features are introduced.

During recent, rapid advances in implementing DCTs during the COVID-19 pandemic, sites have tended to be left out of stakeholder discussions and have, in some cases, been unprepared to manage these approaches. Sites may be cautious about DCTs due to the fact that site personnel lose direct control over elements of the trial, including oversight of procedures that are performed remotely or by third party vendors. To address this, sites may need additional support

to implement new technology. Sites may also be under-resourced from the perspectives of both workforce and capital; engagement with underserved communities requires significant investment and needs to be included in trial budgets. Budget needs will vary by geographic location, depending on local populations.

Benefits of Increased Site Staff Diversity

Diversity of site staff is strongly associated with diversity of clinical participants, according to a Tufts Center for the Study of Drug Development study of more than 3,000 sites, one-half of which were in the United States.¹⁴ Sites with high staff diversity are more likely to be in urban settings with larger proportions of low income patients and fewer staff; these sites are also more likely to perceive value in staff diversity, according to the study. SOPs on topics such as unconscious bias and inclusive behavior are associated with higher staff diversity.

There is also a need to increase the diversity of principal investigators (PIs). Out of 8,350 principal investigators in the United States, only 9.8% are Black¹⁵ and few belong to other minorities.¹⁶ Promoting diversity among PIs is being increasingly recognized as a priority.¹⁷

Approaches to further build site diversity—and hence support study recruitment diversity—could include extending outreach to potential clinical researchers to younger populations, helping promote clinical research as a vibrant career path

"It's not enough simply to want to improve diversity in clinical trials and in the workforce—action and commitment are required."

– Aida Sabo

to students at historically Black colleges and universities, community colleges, and other schools. In addition, as site workforces evolve, efforts to increase diversity should go beyond race and ethnicity to include disability, gender identification, age, sexual orientation, religion, and other factors.

A Sponsor Perspective

From a life science industry perspective, the new draft guidance is very welcome, solidifying the FDA position in this area and providing a foundation for a universal blueprint on how to collect race/ethnicity data, and generally advancing the conversation on diversity. There have been increasing indications from the agency that diversity is a high priority, including requirements for post-marketing studies where such data are lacking, as part of efforts to improve health equity and address disparities in care. The draft guidance will help standardize efforts for future trials and provides insights into likely FDA requirements for submission packages based on trials that are already underway. More clarity would be helpful on exactly how to set appropriate targets for enrollment, including U.S. and global studies.

Viewing the draft guidance through a compliance lens, life science companies will likely comply as early as possible. If it ultimately receives FDA approval, there are clear benefits to having trial participants reflect the population that will receive the drug. Indications are that improvements in diversity are expected as early as phase 1, which will help support decision-making in later development and could potentially avoid the need for phase 4 post-marketing commitments. Improving the inclusivity of research can uncover potential variations in outcomes between subgroups, as well as

enabling unique or specific responses to be identified.¹⁸ Choosing not to comply would involve a calculated compliance risk that could negatively affect future filings, since, anecdotally, there is a trend that FDA does not look favorably on companies that ignore guidances.

Sponsors can support sites' efforts to improve study recruitment diversity in ways that extend beyond budgets. Examples include early provision of patient-focused materials and consent forms in relevant languages for the target population, tailored to health literacy levels. Sponsors can also provide grants for patient navigators, who play a key role in overcoming logistical challenges to trial participation, and can help improve patient engagement and retention across therapeutic areas. Stipends can be built into study budgets to support patient centricity, for example, compensating participants for costs such as childcare or time taken by a caregiver to accompany the participant to a study visit.

Where appropriate, sponsors can use technology to help ease the burden of travel for patients and to help sites respond to current staffing challenges while accommodating more patients. Inclusion-by-design in all components of clinical trials will underpin successful studies built on the learnings from COVID.

In addition to implementing the draft guidance in future protocols, it will be important to take a hard look at the protocols for studies that are already underway. For those at an early stage, it may still be possible to comply with the draft guidance, while later stage trials could be supplemented by a phase 4 study or real-world data.

"I applaud FDA for issuing this draft guidance. As part of a more comprehensive approach, decentralized clinical trials can improve trial diversity. Sites will need to be fully equipped with technology and training, along with budgetary resources for community engagement and recruitment."

– R'Kes Starling

Emphasizing the Importance of Diversity Guidance

There remains a need for FDA to emphasize the importance of the latest diversity plan guidance. For example, each page of the guidance contains a statement that these are non-binding requirements—a fact that may be stressed less often in guidances on developing drugs for specific indications. The repetition of the term “non-binding” gives the impression that diversity efforts are optional and possibly carry less weight than the indication guidances. As noted earlier, sponsors typically take FDA indication guidances very seriously and follow these closely to avoid perceived risks to marketing approvals. FDA should consider moves to indicate that the diversity plan guidance is as important as indication guidelines.

There is increasing evidence that clinical trial diversity will be taken even more seriously in the future, as specified in the fiscal year 2023 omnibus spending bill package signed by President Biden in December 2022. The bill's passage means that FDA “will make mandatory its current recommendation that sponsors file

diversity action plans alongside phase 3 trials submitted to the agency,” according to CenterWatch;¹⁹ “the new law does give the FDA some flexibility to exempt certain trials from this requirement, such as trials of rare diseases for which diversity plans may be unrealistic.”

Conclusion

The clinical trial enterprise must act rapidly to further improve recruitment of diverse patients. There are anecdotal reports of FDA requesting additional recruitment diversity from sponsors in trials that were already underway. This type of “diversity rescue” places an unanticipated burden on sites and budgets and could cause significant delays. Diversity targets for enrollment should be established upfront in the protocol to avoid such challenges. Sponsors should

be encouraged to consider their strategy for recruiting diverse populations before beginning trial design, as early as the RFP stage. This planning should start at the enterprise level and reflect a thorough understanding of disease epidemiology and patient population characteristics.

Looking ahead, a collaborative effort between all stakeholders will be needed to increase diversity in clinical trials.²⁰ There remains a need to boost awareness, understanding, and trust of the clinical trials enterprise among potential participants, particularly those in underrepresented populations. Clinical trial stakeholder companies should have clear diversity goals, with employees receiving mandatory training in diversity, equity, and inclusion-related topics. Data transparency is also essential, including disclosing diversity metrics at all

organizational levels and at sites.

Elements of DCTs will continue to play a vital role in engaging patients. Many studies have taken a hybrid approach, enabling some in-person visits, with other visits or tests taking place remotely, greatly reducing the patient burden, while enabling the study PI to retain full oversight of patient safety. For the next generation of protocols, it will be important that advances in decentralized elements made during the COVID-19 pandemic are retained in future trials. Future protocols should be jointly created by sponsors, patients, and sites, ensuring that needs of all stakeholders are taken into account.

Taken together, these efforts can help ensure that the entire spirit of the FDA draft guidance—and not just the suggestion to make a plan—comes to fruition. **▲**

Additional Information

Potential Racial bias in Pulse Oximetry

A recent study published in *JAMA Internal Medicine*²¹ suggests that COVID-19 care was delayed for some Black and Hispanic patients due to inaccurate oxygen measurements from pulse oximeters. These measure oxygen based on the color of the blood, and may overestimate blood oxygen levels in people with dark skin. “The finding may be one reason much higher COVID-19 mortality rates have been seen in communities of color across the United States,” writes STAT (May 31, 2022).²² An FDA safety communication issued on June 21, 2022, cites ongoing concerns that pulse oximeters “may be less accurate in individuals with darker skin pigmentation.”²³

A study published in the *NEJM* in 2020 found that in two large cohorts, Black patients had almost three times the frequency of occult hypoxemia—defined as arterial oxygen saturation of <88% despite an oxygen saturation of 92–96% on pulse oximetry—that was not detected by pulse oximetry than White patients.²⁴ The *NEJM* study authors wrote that “the variation in risk according to race necessitates the integration of pulse oximetry with other clinical and patient-reported data.”

In addition to impacts during the COVID-19 pandemic, a study published in the *British Medical Journal*²⁵ found that in general care, shortcomings in pulse oximeter measurements “could limit access to supplemental oxygen and other more intensive support and treatments for Black patients.”

Routine Racial Adjustments in Spirometry

Certain medical tools and measures correct for race based on historical decisions. One example is in spirometry, used to measure lung function. As noted in a paper in *The Lancet Respiratory Medicine*, “[s]pirometers use a race-based correction or a so-called ethnic adjustment, which assumes a 10–15% smaller lung capacity for Black patients and 4–6% smaller lung capacity for Asian patients compared with their White counterparts. . . . The notion that Black lungs are inherently inferior dates back to 1785, when the US President Thomas Jefferson described ‘a difference of structure in the pulmonary apparatus’ between slaves and White Americans.”²⁶ The paper continues, “Race-based corrections are likely biasing clinical reports of COVID-19 recovery, severity of lung damage, and subsequent recovery treatment plans. Further, race corrections reinforce assumptions about innate biological differences between races, which is a pervasive problem across medical practice.”

Perceptions of Black Patients’ Pain

“Myths, disparities, and pervasive systemic inequities in health care have fostered bias and distorted perceptions of Black people’s pain, leading to catastrophic outcomes,” notes a 2020 *New England Journal of Medicine* article.²⁷ Titled, “Taking Black Pain Seriously,” the article points out that “[a] 2016 study details the ludicrous yet common belief among medical trainees that Black people have a higher pain tolerance than Whites, perpetuating 19th-century slaveowner Dr. Thomas Hamilton’s fallacy that our [Black people’s] skin is ‘thicker,’ made up of fewer nerve endings, and hence less sensitive.”

COVID-19 Vaccine Trial Recruitment Slowed to Help Improve Diversity

In October 2020, Moderna announced that it had slowed enrollment of its phase 3 COVID-19 vaccine trial due to challenges recruiting enough Black, Latino, and Native American participants.²⁸ “The late-stage 30,000-person study has been filled with mostly White volunteers, despite the fact that COVID-19 infects the Black community in the U.S. at almost three times the rate as the White community,” wrote *CenterWatch* (October 12, 2020). To increase enrollment of minorities, Moderna said it planned to collaborate with academic researchers who have existing relationships with minority community organizations.

Effects of Statins Vary Between Western and Asian Populations

Large-scale genetic studies and multiple trials show the varying effects of statin medications on Western and Asian populations, which includes side effects such as myopathy and hepatotoxicity.²⁹ These are attributed to pharmacokinetic differences, which are partially explained by genetic factors.³⁰

SCRS Focuses on Diverse Enrollment Training for Sites

The Society for Clinical Research Sites (SCRS)³¹ recently held a Diversity Site Solutions Summit on May 20, 2022 in Austin, Texas.³² At the summit, 300+ participants discussed the need to prioritize site training and improve engagement of diverse communities, with sponsors including outreach funds for sites in study budgets. As part of its diversity awareness program, SCRS has also developed a Diversity Site Assessment Tool to quantify the competence of a clinical research site to execute clinical trials with a diverse subject population.³³ The tool is designed to allow a self-assessment of sites’ capacities for recruiting and meeting the needs of diverse patient populations.³⁴

1. Patrick Boyle, *Clinical Trials Seek to Fix Their Lack of Racial Mix*, AAMC NEWS (Aug. 20, 2021), <https://www.aamc.org/news-insights/clinical-trials-look-to-fix-their-lack-racial-mix>.
2. U.S. Food & Drug Admin., *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry: DRAFT GUIDANCE* (Apr. 2022), <https://www.fda.gov/media/157635/download>; U.S. Food & Drug Admin., *Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability* (Apr. 2022), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations>; Press Release, U.S. Food & Drug Admin., *FDA Takes Important Steps to Increase Racial and Ethnic Diversity in Clinical Trials* (Apr. 13, 2022), <https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-increase-racial-and-ethnic-diversity-clinical-trials>.
3. Nicholas Kenny, Keri McDonough & Stephen Keith, *6 Ways to Bolster FDA's Guidance for Diversifying Participation in Clinical Trials*, STAT NEWS (July 22, 2021), <https://www.statnews.com/2022/07/21/6-ways-to-bolster-fdas-guidance-for-diversifying-participation-in-clinical-trials/>.
4. Patrizia Cavazzoni, Eleni Agnostiadis & Milena Lolic, U.S. Food & Drug Admin., *2020 Drug Trials Snapshots Summary Report* (Feb. 2021), <https://www.fda.gov/media/145718/download>.
5. Press Release, *Tufts Center for the Study of Drug Development Establishes Demographic Benchmarks for Pivotal Clinical Trials, Showing Areas of Under-Representation* (May 12, 2020), <https://www.globenewswire.com/en/news-release/2020/05/12/2031952/0/en/Tufts-Center-for-the-Study-of-Drug-Development-Establishes-Demographic-Benchmarks-for-Pivotal-Clinical-Trials-Showing-Areas-of-Under-Representation.html>.
6. U.S. Food & Drug Admin., *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry: DRAFT GUIDANCE* (Apr. 2022), <https://www.fda.gov/media/157635/download>.
7. National Academies of Sciences, Engineering & Medicine, Consensus Study Report, *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups* (2022), <https://nap.nationalacademies.org/catalog/26479/improving-representation-in-clinical-trials-and-research-building-research-equity>.
8. Usha Lee McFarling, *National Academies Report Cites 'Urgent' Need to Recruit More Diverse Participants for Clinical Trials*, STAT NEWS (May 17, 2022), <https://www.statnews.com/2022/05/17/diverse-clinical-trials-urgent-need-national-academies-report/>.
9. U.S. Food & Drug Admin., *Guidances* (Jan. 24, 2022), <https://www.fda.gov/industry/fda-basics-industry/guidances>.
10. Centers for Disease Control & Prevention, *The U.S. Public Health Service Syphilis Study at Tuskegee Timeline* (page last reviewed, Apr. 22, 2021), <https://www.cdc.gov/tuskegee/timeline.htm>.
11. Office of Minority Health & Health Equity (OMHHE), Centers for Disease Control & Prevention, *Health Equity: Working Together to Reduce Black Maternal Mortality* (Apr. 6, 2022), <https://www.cdc.gov/health-equity/features/maternal-mortality/index.html>.
12. Nadege T. Gunn, *Diversify the Clinical Trial Workforce to Drive Patient Population Diversity*, ACRP BLOG (Feb. 3, 2022), <https://acrpnet.org/2022/02/03/diversify-the-clinical-trial-workforce-to-drive-patient-population-diversity/>.
13. Kathleen Fear, Carly Hochreiter & Michael J. Hasselberg, *Busting Three Myths About the Impact of Telemedicine Parity*, NEJM CATALYST (Sept. 21, 2022), <https://catalyst.nejm.org/doi/full/10.1056/CAT.22.0086>.
14. Press Release, *Diversity of Investigative Site Staff Highly Associated with the Diversity of Patients Enrolled in Clinical Trials, According to Tufts Center for the Study of Drug Development* (Nov. 2, 2021), <https://www.globenewswire.com/news-release/2021/11/02/2325455/0/en/Diversity-of-Investigative-Site-Staff-Highly-Associated-with-the-Diversity-of-Patients-Enrolled-in-Clinical-Trials-According-to-Tufts-Center-for-the-Study-of-Drug-Development.html>.
15. Awawu Igbinalolor, Suvi Gross & Benjamin Karsai, *A Conundrum of Trust: Addressing the Diversity Gap in Clinical Research*, ACRP CLINICAL RESEARCHER (Feb. 15, 2022), <https://acrpnet.org/2022/02/15/a-conundrum-of-trust-addressing-the-diversity-gap-in-clinical-research/>.
16. R'Kes Starling, *Lack of Minority PIs Hinders Clinical Trial Diversity Efforts*, ACRP BLOG (Aug. 21, 2019), <https://acrpnet.org/2019/08/21/lack-of-minority-pis-hinders-clinical-trial-diversity-efforts/>.
17. JoAnn Lindenfeld, Mona Fiuzat & Christopher O'Connor, *Promoting Diversity in Clinical Trial Leadership: A Call to Action*, 9 JACC HEART FAILURE 401 (May 2021), <https://www.jacc.org/doi/full/10.1016/j.jchf.2021.03.005>.
18. Mohammed Suhail Chaudhry, Jessica Spahn, Shilpen Patel, Charles S. Fuchs, Jennifer Lauchle, Nikheel Kolatkar, Nicole Richie, Quita Highsmith, Meghan McKenzie & Ruma Bhagat, *Myths About Diversity in Clinical Trials Reduce Return on Investment for Industry*, 28 NATURE MED. 1520 (June 6, 2022), <https://www.nature.com/articles/s41591-022-01858-4>.
19. CenterWatch, *Omnibus Spending Package Makes FDA Diversity Plans, Confirmatory Trials Mandatory* (Jan. 2, 2023), <https://cms.centerwatch.com/articles/26402-omnibus-spending-package-makes-fda-diversity-plans-confirmatory-trials-mandatory>.
20. Ed Miseta, *SCRS Puts a Spotlight on Diversity*, CLINICAL LEADER (June 9, 2022), <https://www.clinicalleader.com/doc/scrs-puts-a-spotlight-on-diversity-0001>.
21. Ashraf Fawzy, Tianshi David Wu, Kunbo Wang, Matthew L. Robinson, Jad Farha, Amanda Bradke, Sherita H. Golden, Yanxun Xu & Brian T. Garibaldi, *Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility*

- Among Patients With COVID-19*, 182 *JAMA INTERNAL MED.* 730 (2022), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653>.
22. Usha Lee McFarling, *Faulty Oxygen Readings Delayed Covid Treatments for Darker-Skinned Patients, Study Finds*, STAT NEWS (May 31, 2022), <https://www.statnews.com/2022/05/31/faulty-oxygen-readings-delayed-covid-treatments-darker-skin-patients/>.
 23. U.S. Food & Drug Admin., *Pulse Oximeter Accuracy and Limitations: FDA Safety Communication* (June 21, 2022), <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>.
 24. Michael W. Sjoding, Robert P. Dickson, Theodore J. Iwashyna, Steven E. Gay & Thomas S. Valley, *Racial Bias in Pulse Oximetry Measurement*, 383 *NEW ENG. J. MED.* 2477 (2020), <https://www.nejm.org/doi/full/10.1056/nejmc2029240>.
 25. Valeria S. M. Valbuena, Sarah Seelye, Michael W. Sjoding, Thomas S. Valley, Robert P. Dickson, Steven E. Gay, Dru Claar, Hallie C. Prescott & Theodore J. Iwashyna, *Racial Bias and Reproducibility in Pulse Oximetry Among Medical and Surgical Inpatients in General Care in the Veterans Health Administration 2013-19: Multicenter, Retrospective Cohort Study*, 378 *BMJ* e069775 (2022), <https://www.bmj.com/content/378/bmj-2021-069775>.
 26. Meredith A. Anderson, Atul Malhotra & Amy L. Non, *Could Routine Race-Adjustment of Spirometers Exacerbate Racial Disparities in COVID-19 Recovery?* 9 *LANCET: RESPIRATORY MED.* 124 (2021), [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30571-3/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30571-3/fulltext).
 27. Oluwafunmilayo Akinlade, *Taking Black Pain Seriously*. 383 *NEW ENG. J. MED.* e68 (2020), <https://www.nejm.org/doi/full/10.1056/NEJMp2024759>.
 28. CenterWatch, *Diversity Challenges Slow Enrollment of Moderna's Late-Stage COVID-19 Vaccine Trial* (Oct. 12, 2020), <https://www.centerwatch.com/articles/25050-diversity-challenges-slow-enrollment-of-modernas-late-stage-covid-19-vaccine-trial>.
 29. Waqas Haque, *Lack of Diversity in Clinical Trials*, HOPKINS BIOTECH NETWORK (2020), website currently down 9/7/22 and 9/29/22, <https://hopkinsbio.org/academic/diversity-in-clinical-trials/>.
 30. Ryo Naito, Katsumi Miyauchi & Hiroyuki Daida, *Racial Differences in the Cholesterol-Lowering Effect of Statin*, 24 *J. ATHEROSCLEROSIS & THROMBOSIS* 19 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5225129/>.
 31. Society for Clinical Research Sites (SCRS) website, <https://myscrs.org>.
 32. SCRS Diversity Site Solutions Summit website, <https://diversitysitesolutions-summit.com>; Ed Miseta, *SCRS Puts a Spotlight on Diversity*, *CLINICAL LEADER* (June 9, 2022), <https://www.clinical-leader.com/doc/scrs-puts-a-spotlight-on-diversity-0001>.
 33. Press Release, *SRS Announces Release of the Diversity Site Assessment Tool*-<https://myscrs.org/press/press-releases/scrs-announces-release-of-the-diversity-site-assessment-tool-dsat/>.
 34. SCRS website survey, <https://myscrs.org/dsat/>.



Otis Johnson is the Chief Diversity, Inclusion and Sustainability Officer at Clario, a founding member of the patient recruitment team at Merck, and former Head of Feasibility and Clinical Informatics at ICON and Syneos Health. Johnson is an accomplished clinical research professional and award-winning diversity, equity, and inclusion (DEI) leader.



Marissa Hill is the Communications Manager for the Society for Clinical Research Sites (SCRS), where Hill handles the society's marketing initiatives and publications.



Diana Foster is the CEO of Total Diversity Clinical Trial Management. Since its inception in 2016, Foster has led the Society for Clinical Research Site Diversity Awareness Program and has been integral in developing the program's Diversity Site Assessment Tool (DSAT).



Ashley Moultrie is the Director of Clinical Operations at Javara. Moultrie currently leads strategic planning, administration, and operation efforts for all clinical research activities conducted within Javara healthcare partner organizations.



Ruma Bhagat is principal science leader in the Health Equity and Population Science team at Genentech, Inc. Bhagat leads cross organization efforts that advance health equity and inclusive research by broadening scientifically driven representation of understudied patients in clinical trials.



Aida Sabo is the Senior Vice President of Diversity/Inclusion (D/I) at PAREXEL. Sabo is responsible for the Global Diversity & Inclusion Strategy and for finding creative ways to execute the strategy.



Nadege Gunn is Medical Director of Gastroenterology/Hepatology at the Impact Research Institute and a gastroenterologist and hepatologist who focuses mainly on finding therapies for liver related illnesses. Gunn is passionate about the management of chronic liver disease and is committed to providing world class care for patients.



R'Kes Starling is the Chief Executive Office and President at Reveles Clinical Services and a versatile, innovative, and results-oriented senior executive leader with extensive experience in clinical research and specialty pharmacies and has a proven track record of building profitable new business lines during times of extensive growth.