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Improving Diversity, Equity, and Inclusion in Clinical Trials

Based on a BIO Workshop & Expert Roundtable in January 2023

Executive Summary

Following the Biotechnology Innovation Organization's (BIO's) Clinical Trial Diversity Summit[1] in June 2021, dedicated to enhancing diversity in trials through strategies like data utilization, fostering trust, and community engagement, BIO organized another roundtable workshop ("Roundtable") on January 31, 2023 with the aim of advancing its Bioequality Agenda.[2] The Roundtable featured panel discussions from regulators and industry experts on the challenges faced and potential solutions to improving diversity and inclusion in various sectors, focusing on clinical trials. The discussions aimed to address the continuous evolution of systemic inequalities in underserved communities in the healthcare ecosystem.

There is great momentum to enhance diversity in clinical trials involving a wide range of stakeholders including the Food and Drug Administration (FDA), U.S. Congress, the industry, pharmaceutical companies, investigators and their institutions, healthcare providers, advocacy groups, patients, and caregivers. Addressing challenges and understanding diverse perspectives requires a collective effort driven by a moral imperative to progress toward diversity, inclusion, and equity in clinical trials. Legislative efforts, stakeholder collaboration, FDA guidances, company initiatives, and ongoing multi-stakeholder discussions have already increased awareness and established standards for inclusion and eliminating barriers to patient care. Ultimately, there is an ethical responsibility and scientific imperative in these endeavors, which will combat health disparities, systemic inequalities, injustice, and unfair treatment of underserved communities. This will enable more timely access to life-saving and life-sustaining medicines, promoting health equity for the broader global patient population.

During the workshop, panelists emphasized the need to reduce barriers to patient care through collaborative efforts and broad alignment among stakeholders, recognizing that no single entity can achieve this on its own. They discussed that a simple, yet effective approach involving patient-centered, physician-oriented, and system and policy-related changes is essential for addressing disparity and inequity within this space. They explored how solutions such as enhancing patient-family education, expanding peer-to-peer educational initiatives, promoting effective communication techniques to decrease barriers and foster trust, enforcing industry to engage patient advocacy organizations to better understand overall patient preferences, and support programs to facilitate greater engagement and participation from underrepresented populations all had the potential to advance the Bioequality Agenda.

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[1] *About – BIO Clinical Trial Diversity Summit.* BIO. (2021). https://www.bio.org/events/bios-clinical-trial-diversity-summit/about

[2] *Bioequality Agenda.* BIO. (2022). https://www.bio.org/bioequality-agenda

FDA representatives discussed their efforts in the areas of minority health and health equity, protecting and promoting the health of diverse populations. FDA's Center for Drug Evaluation and Research (CDER) expressed its commitment to increasing involvement of underrepresented populations in clinical trials through the establishment of the Diversity Plan Implementation Committee (DPIC), in addition to issuing guidances such as *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials.*[3]

In addition, panelists highlighted the significance of incorporating clear and replicable enrollment objectives into study designs, alongside ensuring accurate and relevant data – potentially through the utilization of data science and artificial intelligence methodologies. One panelist introduced a framework developed to quantify accountability and transparency. Presenters discussed that enrollment goals should extend beyond mere demographics such as race and ethnicity: it should incorporate an understanding of the strategies employed to assess and gauge the effectiveness of a specific strategy and its outcomes. Embracing a data-driven approach, encompassing both a qualitative and quantitative perspective, could leverage the improvement of diverse representation within clinical trials. However, it's imperative to recognize that "good" data should be good enough to allow the trial to progress and should not stall the process to advance.

The discussion also included viewpoints from Industry on inclusive research tactics aimed at improving patient diversity through a multi-channel approach. This approach entails strategies such as expanding site locations, optimizing communication, and enhancing data collection and utilization. Better planning to adjust programs and community engagement includes optimizing early-stage design, analyzing patient cohorts, incorporating patient voices, identifying suitable countries and sites, and incorporating site feedback. Additionally, emphasizing both patient and site diversity is critical, as "there is no patient diversity without site diversity." Ideally, these measures would contribute to narrowing health equity disparities.

Ultimately, BIO's intention for the Roundtable was to foster an honest, solution-driven discussion that illuminated the barriers to recruiting and retaining a more diverse patient base. It is a call to action to take forward-leaning strides toward embracing insights gained from the Roundtable, thereby advancing diversity in clinical trials.

[3] Draft *Guidance on Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials.* https://www.fda.gov/media/157635/download

Introduction

Background (1990-2020)

Clinical research has been extensively documented to exhibit inadequate representation of women, elderly individuals, and ethnic and racial minority groups.[4] In 2011, the FDA and the Society for Women's Health Research published a white paper revealing a stark discrepancy that while African Americans account for 12% of the U.S. population, they represent only 5% of trial participants.[5] An investigation into active trials for new molecular entities (NMEs) and biologics reviewed by CDER from 2013 to 2015 further revealed imbalances with white participants accounting for 77.2% of trial subjects, while Asians, Latin Americans, and African Americans represented 12.2%, 13.3%, and 6.4%, respectively.[6] In addition, a recent analysis of 230 vaccine trials conducted between 2011 and 2020 underscored the overrepresentation of white participants and the underrepresentation of minority groups, thus exacerbating the issue of diverse enrollment.[7]

The reasons for these disparities are manifold, including a lack of trust in medical research among minority groups, geographical distance from treatment centers, inadequate transportation to such facilities, limited awareness of ongoing trials within specific communities, inadequate patient understanding and preferences, challenges with timely enrollment in clinical trials, insufficiencies in education from both the clinician and patient perspectives, time constraints, biases from healthcare providers, and industry efforts lacking inclusivity toward underrepresented patients.

To encourage diversity in clinical trials, the FDA has issued a series of guidelines and regulations regarding demographic reporting. One of their earliest actions included the issuance of the *Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs*[8] guidance in 1993, mandating sponsors to include males and females in clinical trials to detect potential significant differences. In 1998, FDA amended 21 CFR part 312 and 314, stipulating that sponsors must analyze and report safety and efficacy data by age, gender, and race.[9]

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[4] Chen et al. "Representation of Women and Minorities in Clinical Trials for New Molecular Entities and Original Therapeutic Biologics Approved by FDA CDER from 2013 to 2015," J Women's Health (Larchmt). 2018 Apr 1; 27(4), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7001461/.

[5] The Society for Women's Health Research and U.S. Food and Drug Administration (FDA), "Dialogues on Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials." 22 September 2011, https://www.fda.gov/media/84982/download.

[6] Chen et al. "Representation of Women and Minorities in Clinical Trials for New Molecular Entities and Original Therapeutic Biologics Approved by FDA CDER from 2013 to 2015," J Women's Health (Larchmt). 2018 Apr 1; 27 (4), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7001461/.

[7] National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Bibbins-Domingo K, Helman A, editors. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington (DC): National Academies Press (US); 2022 May 17. Appendix B, Key Trends in Demographic Diversity in Clinical Trials. Available from: https://www.ncbi.nlm.nih.gov/books/NBK584392/.

[8] *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs; Notice.* U.S. Food and Drug Administration. (1997, February). https://www.fda.gov/media/71107/download https://www.fda.gov/media/71107/download

[9] *Investigational New Drug Applications and New Drug Applications.* Department of Health and Human Services. (1998, January). https://www.govinfo.gov/content/pkg/FR-1998-02-11/pdf/98-3422.pdf

In 2012, Congress directed the FDA to revisit representation and diversity in clinical trials, leading to the formation of a task force that investigated and reported on demographic subgroups in medical product applications.[10] Although the FDA concluded that the regulatory framework provided sufficient guidance, they published the "*FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data"*, concentrating on improving the quality of such data, identifying barriers to subgroup enrollment, and increasing the transparency and accessibility of demographic subgroup information.[11]

To fulfill their objectives of improving the quality of demographic data, the FDA issued the *Collection of Race and Ethnicity Data in Clinical Trials*[12] guidance in 2016. This guidance recommends that the trial population accurately reflects the clinically relevant racial and ethnic composition. FDA also committed to publicly posting demographic information from pivotal studies for newly approved NMEs and biologics, launching the Drug Trials Snapshot program.[13]

Legislative provisions to increase diversity in clinical trials were also included in the 21st Century Cures Act (Public Law 114-255), signed into law in 2016. This legislation required FDA to revise their report and action plan, addressing the scope of clinical trial participation and the inclusion of safety and efficacy data by demographic subgroups in applications submitted to the Agency. Furthermore, the Government Accountability Office (GAO) was directed to report on how the Department of Health and Human Services (HHS) addresses barriers to participation by underrepresented populations in conducting or supporting clinical trials. Additionally, HHS was directed to carry out a public campaign to increase awareness and understanding of ongoing clinical trials and provide resources relevant for enrollment, with a focus on minority communities. HHS was also mandated to establish a task force to enhance the user-friendliness of the FDA'S publicly accessible clinicaltrials.gov webpage.

In 2017, the FDA Reauthorization Act (FDARA)[14] required the FDA to examine how clinical eligibility criteria hinder broader trial participation. This resulted in the development of the *Enhancing the Diversity of Clinical Trial Populations*[15] guidance in 2020. This guidance provides sponsors with recommendations on avoiding unnecessary exclusions and improving trial recruitment. The FDA suggests that eligibility criteria should be broadened as safety data accumulates, and that adaptive trial designs can be employed to modify the trial population. Furthermore, the FDA recommends reducing the participation burden and fostering inclusiveness through strategies such as situating trial sites in regions with a higher concentration of racial and ethnic minority patients and providing cultural competency training for clinical investigators and research personnel.

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[10] 2012 Food and Drug Administration Safety and Innovation Act (FDASIA), Sec 907 https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf

[11] FDA, "FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data," August 2014, https://www.fda.gov/media/89307/download.

[12] FDA, Guidance for Industry, "Collection of Race and Ethnicity Data in Clinical Trials," October 2016, https://www.fda.gov/media/75453/download.

[13] FDA, "Drug Trial Snapshots," Accessed May 2021, https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots.

[14] FDARA https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf.

[15] FDA, Guidance for Industry, "Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs," November 2020, https://www.fda.gov/media/127712/download.

While there are no regulations requiring industry sponsors to include specific populations in clinical trials, FDA regulations necessitate that product developers analyze clinical trial data by sex, age, and race. This said, the FDA acknowledges that in certain instances, other factors may take precedence, particularly when sponsors involve participants representing certain populations (e.g., patients with rare diseases).[16]

Regulatory Activities – Improving Representation in Clinical Trials (2020-Present)

FDA Guidance

In April 2022, the FDA issued a draft guidance entitled *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials*.[17] This guidance's primary objective is to outline the prerequisites for sponsors of medical products to develop a Diversity Plan aimed at improving the enrollment of underrepresented racial and ethnic populations in clinical trials. The guidance recommends that sponsors submit a Diversity Plan for all medical products within Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications. For drugs, the Diversity Plan should be submitted at the earliest stages of drug development, while for devices, it is recommended to be submitted as part of the investigational plan in the IDE application. The Diversity Plan should comprehensively outline potential strategies to enlist and retain a diversified trial population, strategies for selecting trial sites and ensuring accessibility (including language assistance), sustained community engagement initiatives, and methods to alleviate challenges related to trial/study design/conduct.

FDA Office of Minority Health and Health Equity

FDA's Office of Minority Health and Health Equity (OMHHE) is responsible for the administration of programs aimed at fostering diversity within clinical trials and raising awareness about medical product development among minority groups. OMHHE oversees both the Agency's extramural and intramural research initiatives centered around diversity and inclusion, actively engaging stakeholders in the medical community to diversify the medical product development enterprise. To this end, OMHHE has signed a collaborative Memorandum of Understanding (MOU) with the Alliance of Multicultural Physicians, aimed at jointly creating educational and training initiatives for physicians to advance health equity. OMHHE is also involved in the Multi-Regional Clinical Trials Center (MRCT Center) initiative *Achieving Diversity Inclusion and Equity in Clinical Research*[18] and the Clinical Trials Transformation Initiative (CTTI) Diversity Project, both of which are dedicated to increasing diversity within clinical trials, thereby enriching research outcomes that are relevant to broader patient populations.[19]

Establishing Post-Marketing Requirements for Demographic Reporting

To enhance diversity within clinical trials, the FDA has initiated measures within the post-market arena, encouraging sponsors to carry out studies that better reflect both the demographic composition of the

[16] Ibid.

[17] FDA, "Diversity Plans to Improve Enrollment of Participants from Underrepresented racial and Ethnic populations in Clinical Trials," https://www.fda.gov/media/157635/download

[18] Bierer BE, White SA, Meloney LG, Ahmed HR, Strauss DH, Clark LT, (2021). *Achieving Diversity, Inclusion, and Equity in Clinical Research* Guidance Document Version 1.2. Cambridge and Boston, MA: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Available at: https://mrctcenter.org/diversity-in-clinical-trials/

[19] *Diversity.* CTTI. (2023, March 1). https://ctti-clinicaltrials.org/our-work/quality/diversity/

U.S. and the targeted patient population[20]. To date, the FDA has provided demographic insights from clinical trials through the Drug Trials Snapshot program.[21] The Snapshot program, established in 2015, enables healthcare professionals and the public to learn of the diversity of participation in clinical trials for drugs approved by CDER. However, no such data are available for post-market trials. Nevertheless, in accordance with the Consolidated Appropriations Act[22], the FDA will provide annual reports detailing clinical results stemming from new diversity initiatives.

Congressional Actions

In recent years, Congress has been actively championing diversity in clinical trials. The Diverse and Equitable Participation in Clinical Trials (DEPICT) Act,[23] introduced in February 2022, aimed to strengthen diversity in clinical trials by requiring enhanced data reporting on the demographic composition of clinical trial participants. It proposed the allocation of resources to underrepresented communities to improve access and participation in trials. It further required IND and IDE applicants to report clinical trial enrollment targets by demographic subgroups, encompassing age, race, ethnicity, and sex, along with providing a rationale behind these targets and a diversity action plan for meeting such targets. Provisions of the DEPICT Act and other provisions related to clinical trial diversity were incorporated in the 2023 Omnibus Spending Bill, passed in December 2022[24], marking the establishment of the first statutory requirement for diversity in clinical trials. Beginning in 2024, the law requires the FDA to publish an annual aggregate report of action plans received by the agency.

Stakeholder and Industry Engagement

Stakeholder Organizations

Several organizations, spanning both industry and nonprofit sectors, are spearheading initiatives to promote diversity within clinical trials. For instance, the Clinical Trials Transformation Initiative (CTTI) launched a diversity project in July 2020 with the objective of emphasizing the critical engagement of women and racial and ethnic minorities in clinical trials.[25] Through interviews with key stakeholders, CTTI aims to identify optimal practices and incentives to encourage decision-makers to prioritize diversity. Another noteworthy effort comes from TransCelerate BioPharma, which established "*The Diversity of Participants in Clinical Trials Initiative".* This initiative encompasses the creation of a hub for sharing best practices and a dashboard for identifying priority diseases displaying disparities in trial populations.[26]

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[20] *Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products*. U.S. Food and Drug Administration. (2023, August 8). https://www.fda.gov/media/170899/download

[21] Center for Drug Evaluation and Research. (2023, October 12). *Drug Trials Snapshots*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

[22] *Consolidated Appropriations Act, 2023.* Congress.gov. (2022, January). https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf

[23] *H.R.6584 – 117th Congress (2021-2022): DEPICT act.* Congress.gov. (2022, February 3). https://www.congress.gov/bill/117th-congress/house-bill/6584/text

[24] *Consolidated Appropriations Act, 2023.* Congress.gov. (2022, January). https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf

[25] *Diversity.* CTTI. (2023, March 1). https://ctti-clinicaltrials.org/our-work/quality/diversity/

[26] *Diversity of Participants in Clinical Trials.* TransCelerate. (2023, March 29). https://www.transceleratebiopharmainc.com/initiatives/diversity-of-participants/

The American Association for Cancer Research (AACR) has championed governmental guidelines pertaining to trial diversity while advocating for more stringent enforcement mechanisms to ensure representation. This involves requiring the reporting of criteria leading to the exclusion of minority patients and offering priority review vouchers to sponsors meeting inclusion benchmarks.[27] Additionally, AACR recommends broadening access to clinical trial sites through supplemental funding and support for patient navigation services, alongside requiring Medicaid programs to cover clinical trial participation.[28]

At Brigham and Women's Hospital of Harvard Medical School, the Multi-Regional Clinical Trials Center (MRCT Center) stands as a research and policy center concentrating on the ethical conduct, oversight, and regulatory environment of multi-site, multi-national clinical trials. Following a three-year collaborative endeavor involving over 50 representatives from sectors including industry, academia, regulatory agencies, patient advocacy organizations, and more, the MRCT Center published, "Achieving Diversity, Inclusion, and Equity in Clinical Research" guidance document and an accompanying Supplementary Toolkit in 2020.[29] To transform this guidance into tangible action, the MRCT collaborated with members of a DEI Roundtable to contribute to the development of an "*Equity by Design in Clinical Research Metrics Framework,*" introduced in 2022.[30] This framework provides a holistic outlook on DEI in clinical research, encompassing seven key themes that span data/ metrics and workforce development. It reinforces accountability by providing guidepost quantitative and qualitative measures of progress. Most recently, the MRCT Center has published a toolkit designed to encourage the inclusion of individuals with disabilities in research.[31]

Industry Organizations

In response to the underrepresentation of racial and ethnic minority groups in COVID-19 vaccine trials,[32] several trade organizations launched initiatives to enhance trial diversity. In November 2020, the Pharmaceutical Research and Manufacturers of America (PhRMA) updated their industry-wide principles for trial conduct, incorporating a commitment to enhancing diversity in clinical trials.[33] This commitment involves acknowledging historical inequities and reducing participation barriers, though it does not endorse mandatory demographic reporting. Instead, companies are encouraged to share information about their policies and practices aimed at boosting trial diversity. In August 2020, BIO issued their

[27] Ibid., 123.

[28] Ibid., 123-124.

[29] Bierer BE, White SA, Meloney LG, Ahmed HR, Strauss DH, Clark LT, (2021). *Achieving Diversity, Inclusion, and Equity in Clinical Research* Guidance Document Version 1.2. Cambridge and Boston, MA: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Available at: https://mrctcenter.org/diversity-in-clinical-trials/

[30] *Equity by Design Metrics Framework*, MRCT Center (2022) https://mrctcenter.org/diversity-in-clinical-research/tools/ebd-metrics-framework-and-user-guide/

[31] Accessibility by Design (AbD) Framework. MRCT Center (2023) https://mrctcenter.org/diversity-in-clinical-research/tools/abd_toolkit/

[32] Chastain, Daniel, et al. "Racial Disproportionality in Covid Clinical Trials," *NEJM* 383, 27 Aug 2020; https://www.nejm.org/doi/10.1056/NEJMp2021971

[33] PhRMA, "Principles on Conduct of Clinical Trials," October 14, 2020, https://www.phrma.org/cost-and-value/phrma-principles-on-conduct-of-clinical-trials

Bioequity Agenda,[34] which focuses on three pillars: promoting health equity, investing in scientists and entrepreneurs, and expanding opportunities for underrepresented populations. As part of their endeavors to improve trial diversity, BIO has pledged to collaborate with contract research organizations and minority-serving institutions through educational initiatives, partnerships, and advocacy efforts. It has sought to foster discussion on the barriers to the recruitment and retention of patients from diverse communities and to promote diversity in clinical trials [See Appendix A – Roundtable Agenda].

Individual Company Level Engagement

Several companies have launched their own initiatives to support the shared commitment of PhRMA and BIO in advancing diversity within clinical trials. In 2018, Amgen sponsored the IMPACT Program, a three-year pilot study led by the Lazarex Cancer Foundation. The program aimed to increase minority enrollment and retention in clinical trials by offering participant reimbursement and implementing comprehensive outreach and educational programming.[35]

Genentech is collaborating with external partners to establish new internal benchmarks and principles for inclusive research as a component of their *Advancing Inclusive Research* agenda. Concurrently, Genentech is conducting three pilot studies in the U.S., designed to identify optimal practices in study screening and recruitment strategies.[36]

AbbVie has committed to using a data-driven approach to improve diversity in clinical research. This involves regular evaluations of trial protocols against real-world datasets to identify diversity gaps, ensuring that regional demographics and internal resources are accessible to product teams to address these diversity gaps.[37]

In addition, Bristol Myers Squibb (BMS) and the BMS Foundation have committed $300 million towards initiatives centered on diversity and inclusion. The BMS Foundation plans to train and develop 250 diverse clinical investigators in underserved patient communities. Simultaneously, BMS will continue to advocate for policies that foster health equity on both the federal and state levels.[38]

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[34] BIO, Press Release, "Ensuring Scientific Justice by Building Bridges to Minority Communities is Centerpiece of BIO Equality," August 6, 2020, https://www.bio.org/press-release/ensuring-scientific-justice-building-bridges-minority-communities-centerpiece

[35] Amgen, "Amgen's Commitment to Clinical Trial Diversity," https://www.amgen.com/science/clinical-trials/clinical-trial-diversity/amgens-commitment-to-clinical-trial-diversity ; Lazarex Cancer Foundation, "IMPACT Program," https://lazarex.org/impact/

[36] Genentech, "Advancing Inclusive Research," https://www.gene.com/patients/advancing-inclusive-research#position-statemen

[37] AbbVie, "AbbVie's Commitment to Racial Justice," https://www.abbvie.com/who-we-are/equity-equality-inclusion-diversity/commitment-to-racial-justice.html#:~:text=In%202020%2C%20we%20donated%20%245,communities%20across%20the%20United%20States.

[38] Bristol Myers Squibb, "Bristol Myers Squibb and the Bristol Myers Squibb Foundation Commit $300 Million to Accelerate and Expand Health Equity and Diversity and Inclusion Efforts," https://news.bms.com/news/details/2020/Bristol-Myers-Squibb-and-the-Bristol-Myers-Squibb-Foundation-Commit-300-Million-to-Accelerate-and-Expand-Health-Equity-and-Diversity-and-Inclusion-Efforts/default.aspx

Panelist Discussion & Next Steps for Advancing Clinical Trial Diversity

At the beginning of the Roundtable, Dr. Joy Buie of the Lupus Foundation of America stated that the importance of diversity in clinical trials lies in their ability to be inclusive and representative of the population living with a particular disease. Inclusivity promotes equitable outcomes and social benefits by accounting for various social and medical experiences, environmental factors, and responses to medications, which ultimately helps in informing real-world clinical utility and guidelines. However, there are several challenges to achieving diversity in clinical trials, including issues related to access to care, patient-physician communication and mistrust, transportation barriers, and job inflexibility. Patient-related challenges, such as low health literacy and misconceptions, also play a role, as do physician-related challenges like a lack of knowledge about clinical trials and implicit biases. System and policy-related challenges include centralized trials and a lack of focus on patient preferences.

Dr. Buie proposed several patient-focused solutions to address these challenges, including educating patients and families about clinical trials, designing trials that consider negative social determinants of health, involving patients in trial design, and adequately compensating them for their participation. Provider-focused solutions involve shared decision-making between patients and physicians, educating healthcare workers about clinical trials, and improving culturally congruent care. Policy-focused solutions include issuance of FDA guidance on diversity action plans, implementing decentralized trials, incentivizing training for diverse clinical trialists, and engaging patient advocacy organizations to capture preferences from underrepresented populations. These solutions collectively aim to enhance diversity in clinical trials, ensuring their relevance and impact on a wider spectrum of patients, including those from diverse backgrounds and underserved areas.

Regulatory & Industry Perspectives

The first panel focused on regulatory perspectives for improving representation in clinical trials. Dr. Richardae Araojo discussed the Office of Minority Health and Health Equity's mission to address disparities through research and communication, with FDA prioritizing diverse clinical trial populations. She emphasized their aim to reduce disparities and enhance equity through initiatives like diversity campaigns and funding opportunities. Dr. Lola Fashoyin-Aje emphasized FDA's draft guidance for diversity plans, encouraging early submissions and open sharing of solutions. Specifically, she emphasized that sponsors should be considering their research strategy as early as possible, inclusive of the feasibility of enrolling diverse populations during site selection. FDA acknowledges that plans evolve over the study period and will accept amendments as needed. Sponsors of multi-regional trials should note regions that share similar demographics to the US, designing them so that FDA can assess commonalities and differences in demographics across regions to fulfill US CTD requirements. Ultimately, Dr. Fashoyin-Aje emphasized that diversity plans are meant to be a learning tool and a way to document progress towards improving diversity, and sponsors are not expected to have all the answers but are expected to consider what reasonable steps can be taken to improve inclusivity. Dr. Karen Hicks highlighted CDER's commitment to increasing underrepresented participation, including cross-center collaboration through the Diversity Plans Implementation Committee (DPIC), and implementing diversity plans. Overall, CBER's Ms. Diane Maloney reiterated FDA's dedication to trial diversity and involvement of multiple agency centers.

The second panel featured industry perspectives on improvement in representation. Dr. Alexandra Goodyear discussed her company's strategies collection to address multiple sclerosis trial underrepresentation by operating additional sites. Meanwhile, Dr. Leo Russo highlighted setting transparent enrollment goals and leveraging real-world data (RWD)[39] while Ms. Leah Peters discussed inclusive research tactics (e.g., expanding eligibility criteria, use of mobile nursing and telemedicine, translation of informed consent and other patient documents into multiple languages, and reimbursement of expenses) and emphasized the importance of diverse site representation. Broadly, the panel underscored the outsized impact of site diversity on patient diversity.

In the third panel, Dr. Denise Bronner from J&J discussed the "Race to Health Equity" initiative which pursues goals to expand reach, ensure cultural competency, and achieve diversity goals in clinical studies. Ms. Kim Ribeiro emphasized the link between patient and site diversity and introduced training programs for research-limited sites. Ms. Brittany Gerald shared Moderna's commitment to diversity, with examples like the COVE Study for COVID-19 vaccines. During the question and answer (Q&A) portion, panelists addressed hesitations in diverse communities, championing diversity in management, and accessing diversity and inclusion data outside the US.

Overall, the discussion highlighted the importance of transparent goal-setting, improving access, and increasing workforce diversity to achieve meaningful representation.

Improving Representation in Clinical Trials

The final two panels discussed strategies for overcoming challenges in improving representation in clinical trials. In the fourth panel, Dr. Camille Pope presented an effective trust framework focused on inclusive study design, sustained community engagement, and trust-enabling technology to enhance trial diversity. Ms. Heather Pierce discussed health equity and health justice as a path toward ultimate goals, emphasizing trustworthiness, data for health equity, maternal health equity, and environmental justice. Dr. Gary Puckrein highlighted the National Minority Quality Forum (NMQF)'s initiatives focused on community engagement, transparent communication, cultural sensitivity, and workforce diversity to raise health awareness in underserved populations. He mentioned the Alliance for Representative Clinical Trials (ARC) and its efforts to diversify and integrate clinical trials into routine care.

In the final panel, Mr. Laurent Grosvenor emphasized the importance of accurate and relevant data for trials to reflect patient populations to achieve global health equity. Mr. Arnaub Chatterjee highlighted the role of artificial intelligence in using historical clinical trial data for diverse patient recruitment, focusing on trust, authenticity, and methodology. Ms. Rachael Fones stressed the need for better planning, setting goals early, accepting imperfections, and maintaining momentum for lasting change. Dr. Willyanne DeComier Plosky introduced the Equity by Design Framework (EbD) for ethical solutions, focusing on commitment, leadership, engagement, education, inclusion, accountability, and dissemination. During the Q&A session, panelists discussed strategies for building trust, engaging communities, managing diversity in enrollment, standardization, and global recruitment challenges.

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[39] Rottas, M., Thadeio, P., Simons, R., Houck, R., Gruben, D., Keller, D., Scholfield, D., Soma, K., Corrigan, B., Schettino, A., McCann III, P. J., Hellio, M.-P., Natarajan, K., Goodwin, R., Sewards, J., Honig, P., & MacKenzie, R. (2021, April 30). *Demographic diversity of participants in Pfizer sponsored clinical trials in the United States*. Contemporary Clinical Trials. https://www.sciencedirect.com/science/article/pii/S1551714421001579?via%3Dihub

In summary, these panels reviewed strategies for building trust, utilizing data and AI, addressing challenges in clinical trial planning and recruitment, and implementing frameworks to enhance representation and diversity in clinical trials.

To enhance diversity and transparency in clinical trials, the workshop emphasized the responsibility of Industry and its stakeholders to take the lead. Sponsors were encouraged to develop their own diversity and inclusion initiatives, establishing internal targets for participant diversity. For instance, sponsors were encouraged to incorporate diversity enrollment metrics in contracts with clinical research organizations and incentivize greater trial diversity through internal dashboards that rank investigators based on the enrollment of diverse populations. A data-centric approach is crucial in achieving these objectives.

However, patient enrollment in clinical trials remains a rate-limiting factor that results in delays.[40] [41] Innovative approaches are imperative for recruiting and enrolling diverse study populations, with transparency and trust being essential to participant retention. While industry and its partners can drive greater diversity and enrollment, they may balk at new regulations that could introduce uncertainties, potentially leading to trial delays and increased costs. Moreover, mandated reporting of diversity and inclusion metrics may not be embraced by the industry, as it could signal a lack of comfort with mandatory transparency.

Building Trust

The workshop participants noted that the improving and retaining participant involvement in clinical trials hinges on the foundation of trust, as it is key in fostering sustainable community engagement and establishing relationship between trial sites and communities. Without trust, these connections cannot be established on a sustainable basis.

Organizations such as the Alliance for Representative Clinical Trials (ARC), a multi-sponsor public/private program of community clinicians, strive to diversify and extend clinical trials to communities of color and other historically underrepresented groups. This initiative focuses on recruiting community and minority physicians, building trust with transparent communication, demonstrating cultural sensitivity, raising health awareness in underserved populations, and actively engaging communities throughout the ecosystem can greatly benefit the landscape of clinical trials.

The Importance of Diversity in the Workforce

Throughout the workshop, panelists noted the need for diversity among those running clinical trials. Panels discussed that addressing this requires a comprehensive approach. This involves actively recruiting and training a diverse workforce, including principal investigators, research staff, study coordinators, and data managers. Outreach to diverse communities and partnerships with minority-serving institutions is essential, as well as implementing training programs that prioritize diversity and cultural competency. Sensitivity and cultural competency training for research staff is crucial to build trust with participants from diverse backgrounds.

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[40] Tufts CISCRP, Tufts CISCRP 2013 International Survey on Public and Patient Attitudes About, and Experiences with Clinical Research Studies, https://www.ciscrp.org/new-ciscrp-study-reveals-improvements-in-public-perceptions-of-clinical-research-and-insights-into-patient-participation-experiences/

[41] Lamberti, *State of Clinical Trials Industry*, CenterWatch, 2018, 29.

Collaborating with organizations, community groups, and healthcare providers that serve diverse populations is important for effective recruitment strategies and cultural relevance of clinical trials. Establishing mentorship programs and career development opportunities for underrepresented individuals interested in clinical trial research can create a diverse pipeline of future researchers. Promoting diversity and inclusion in leadership positions within research institutions, pharmaceutical companies, regulatory agencies, and funding organizations can drive policy changes and research practices that enhance trial diversity. Public awareness campaigns, especially targeted at underrepresented communities, play a vital role in educating the public about clinical trials, dispelling myths, and fostering trust and participation.

When combined with strategies focused on participant engagement, trial design, and community involvement, these actions can collectively increase diversity in clinical trials and enhance the applicability of research findings for broader patient populations. Many of these concepts are further defined in the MRCT EbD Metrics Framework[42].

Conclusion

The workshop was successful in identifying many overarching principles to guide further progress:

- Diversity encompasses more than race; it includes ethnicity, sexual orientation, gender, age, and disability communities, among others
- Everyone, including patients, can contribute to making progress towards clinical trial diversity
- It is imperative not only to develop strategies but to implement them
- It is important to engage communities in clinical research with respect to, and recognition of, their perspectives and values. Collaboration should be a core feature of such engagement.
- Engagement should be as broad as possible because assisting one community does not ensure all communities are helped
- Transparency, reproducibility, and consistency is critical
- Change will take time

It is imperative to promote diversity in clinical trials to ensure that all patients can access safe and effective treatment options. The Roundtable's intention was to explore the obstacles surrounding the recruitment and retention of diverse patient cohorts in clinical trials, including decreasing the barriers to participating and fostering trust. Many of the Roundtable panelists echoed the shared belief that, "*in the absence of action, there is an impact of inaction*". Participants concluded that making progress in increasing diversity in clinical trials will require collaboration on many fronts that involves the U.S. Congress, FDA, industry, and others. Ultimately, success in this collective effort will ensure enhanced access to health care and health equity for all.

[42] *Equity by Design Metrics Framework*, MRCT Center (2022) https://mrctcenter.org/diversity-in-clinical-research/tools/ebd-metrics-framework-and-user-guide/

Appendix A

Roundtable Agenda

BIO Clinical Trial Diversity Roundtable:
Analyzing the Data We Have Today, Enhancing Data Sources and Infrastructure for the Future, and Building a Diverse Workforce

The Biotechnology Innovation Organization (BIO) Clinical Trial Diversity Workgroup will hold a one-day, virtual roundtable on ***Analyzing the Data We Have Today, Enhancing Data Sources and Infrastructure for the Future, and Building a Diverse Workforce*** on **Tuesday, January 31, 2023**.

As a follow up to our BIO Clinical Trial Diversity Summit in June 2021, this important January event will feature solution-oriented perspectives from FDA, patient groups, industry, health technology organizations and other stakeholders. Registration for the workshop is free.

AGENDA

Moderator: Winston Kirton, JD, Partner, BakerHostetler

Welcome

—Cartier Esham, PhD, Chief Scientific Officer, Biotechnology Innovation Organization (BIO)

Introductions & Call to Action

"Call to Action"
—Eric Dube, PhD, President and Chief Executive Officer and a Director of Travere Therapeutics (on the Board of Directors and Executive Committee for BIO)

"Legislative Perspective"
—Aisling McDonough, Chief of Staff, U.S. Rep. Anna G. Eshoo (CA-16)

"Patient Perspective"
—Joy Buie, PhD, MSCR, RN, Lupus Foundation of America

Panel 1: Regulatory Perspectives on Improving Representation in Clinical Trials

"Regulatory Perspectives: OMHHE"
—RDML Richardae Araojo, PharmD, MS, Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity (OMHHE), FDA

"FDA Draft Guidance on Diversity Plans"
—Lola Fashoyin-Aje, MD, MPH, Deputy Director, Division of Oncology, Gastrointestinal, Cutaneous Sarcoma; Associate Director, Science and

Policy to Address Heal Disparities, Oncology Center of Excellence, FDA

"Regulatory Perspectives: CDER"
—Karen Hicks, MD, FACC, Deputy Director, Office of Medical Policy, CDER, FDA

"Regulatory Perspectives: CBER"
—Diane Maloney, JD, Associate Director for Policy, Office of the

Center Director, CBER, FDA Q&A

Panel 2: Industry Perspectives on Improving Representation

"Inclusive Research Tactics to Improve Patient Diversity"
—Alexandra Goodyear, MD, MS, Global Development Lead, Roche-Genentech

"Building a Framework for Setting Enrollment Goals to Ensure Trial Participant Diversity: Insights & Challenges"
—Leo Russo, PhD, Vice President and Head of Global Medical Epidemiology, Pfizer Inc.

"Challenges to Defining and Achieving Enrollment Goals"
—Leah Peters, BS, Senior Clinical Operations Lead, Patient Access & Inclusive Research Community/Clinical Operations, Roche-Genentech

Q&A

Panel 3: Industry Perspectives on Improving Representation

"Leveraging a Data-Centric Approach (qual & quant) to Improving Representation in Clinical Studies"
—Denise Bronner, PhD, Director, Diversity, Equity & Inclusion in Clinical Trials, Johnson & Johnson

"AbbVie Workforce Diversification"
—Kim Ribeiro, MLS (ASCP)CM, MS, Head of Diversity & Patient Inclusion, AbbVie

"Achieving Diverse Representation in the Covid-19 COVE Trial"
—Brittany Gerald, BS, Senior Manager, Clinical Trial

Diversity and Inclusion, Moderna Q&A

Panel 4: Overcoming Challenges to Improve Representation

"Case Study: Leveraging an Affective Trust Framework to Enhance Clinical Trial Diversity"
—Camille Pope, PharmD, Chief Medical Lead, Acclinate

"Perspectives from AAMC"
—Heather Pierce, JD, MPH, Director of Policy, Center for Health Justice, Association of American Medical Colleges (AAMC)

"Training Community Clinicals to be Principal Investigators"
—Gary Puckrein, PhD, President and Chief Executive Officer, National Minority Quality Forum (NMQF)

Q&A

Panel 5: Overcoming Challenges to Improve Representation

"Rethinking Clinical Trials: How Better Data Can Improve Health Equity"
—Laurent Grosvenor, Chief Diversity Officer, Institute for Health Metrics and Evaluation (IHME)

"How AI is meaningfully moving the needle in improving diversity in clinical trials"
—Arnaub Chatterjee, BS, MHA, MPA, Senior Vice President, Medidata AI, a Dassault Systèmes company; Alliance for Artificial Intelligence in Healthcare (AAIH)

"Setting Diversity Goals and Measuring Success—Lessons learned and the path forward"
—Rachael Fones, Director, Government & Public Affairs, IQVIA; Chair, Diversity & Inclusion in Clinical Trials Committee, Association of Clinical Research Organizations (ACRO)

"Perspectives from MRCT"
— Willyanne DeCormier Plosky, DrPH, Program Manager, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Q&A

Closing Remarks