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NO LONGER AN AFTERTHOUGHT

As Patients and Regulators Call for Greater Diversity and Inclusion in Clinical Trials, Sites and Sponsors Must Step Up

By Lori Abrams,
Executive Director of Patient Advocacy and Diversity at WCG

> "What are you doing from the beginning to ensure that you include those groups in your trial?"

Diane Carozza,
WCG Vice President for Clinical Strategic Solutions, Study Planning and Site Optimization, quoted in Applied Clinical Trials

Health equity is long overdue. For all the talk about diversifying clinical trials, aspirations have yet to become reality. We know drug safety and efficacy vary across demographic sub-groups, yet we fail to accurately represent those patients in clinical research. As the FDA wrote in the prologue to its 2020 guidance on the subject:

Over the past few decades, FDA has promoted enrollment practices that would lead to clinical trials that better reflect the population most likely to use the drug if the drug is approved, primarily through broadening eligibility criteria. Despite these efforts, challenges to participation in clinical trials remain, and certain groups continue to be under-represented in clinical trials.[1]

Consider the following:
Although 20% of the people living with multiple myeloma in the US are African Americans, they account for only 6% of patients in clinical trials.

As of 2018, approximately 78% of individuals included in genome-wide associated studies were of European descent. African Americans and Hispanics were 2% and 1%, respectively. All other ethnicities represent less than 1%.

These are just two of hundreds of examples. This persistent, distressing lack of diversity in clinical research means many therapies are never tested on the very patients for whom they are intended.

Various populations have been medically underserved and misunderstood for decades, perhaps even centuries. Until recently, health equity has been a largely futile battle with minimal movement, despite good intentions from a few. COVID-19 highlighted the disparities. New conversations are happening, and some organizations have increased spending on diversity and inclusion-spending that may or may not have long-term impact.

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[1]FDA guidance "Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry". November 2020.

[2]pharamaphorum.com | July 22, 2020

[3]Sirugo, G, et al. "The Missing Diversity in Human Genetic Studies," Cell, March 21, 2019.

One thing is certain: There is a consensus in the medical and scientific communities around the necessity for health justice, including equity in clinical trials.

I've been working in this area for years, and I've never seen more willingness among sponsors to take this seriously. But I also see confusion and uncertainty about how to implement solutions. I wonder why we don't treat diversifying clinical trials like we battled COVID-19 – together, organized, understanding the issues and the barriers, and inviting those who have been marginalized to sit at the table and help us find the solutions.

The federal government offers guidance, issues requirements and asks questions, but sponsors, sites, patient-advocacy groups, investigators and other stakeholders must do the heavy lifting, one trial at a time.
If we are going to be successful, we must begin by identifying barriers. What are the barriers to participation of diverse populations in clinical trials? How do we, the research community, begin to break down those barriers? Will we try to mitigate these barriers alone, or will we invite those who live with those barriers to join us?

IDENTIFY AND OVERCOME

Barriers to participation abound at every level from patients to data collection, from sponsor and sites to referring physicians.

The eligibility criteria are often too narrow. Sites and sponsors lack the necessary cultural competence and staff diversity. Sponsors fail to convey diversity expectations to the sites and investigators. Patients are often unaware of the ability to participate in clinical trials, and many distrust the system. And, amazingly, some investigators, sites and referring physicians fail to understand the scientific utility of inclusion. The list goes on, and sponsors must understand the barriers at all levels.

Almost every challenge can be overcome; here are a few recruitment-related examples:

- **Lack of referrer awareness and buy-in:** Encourage sites to create relationships with potential referring practices and physicians. Give them the resources to explain the scientific importance of diversity and emphasize their involvement over the life of the trial. Remember, healthcare providers are busy, and often are unaware of clinical trials in their neighborhoods. It's not enough to educate physicians about clinical trials, you must make them part of a holistic solution.

- **Lack of patient awareness:** Build relationships with advocacy groups and help sites to do the same. Encourage them to engage patients and caregivers, and to become an active part of the community. Such relationships need to be genuine, long-

term and not transactional. Health fairs are a great place to meet community leaders, medical and health professionals, as well as families in the area. This is where and how relationships are built. Continual visibility is key for trust building.

- **Patient burden:** We already know this starts at the protocol level. Be less rigid. Allow for flexibility in scheduling and logistics. Include remote options, including telemedicine and home visits. Consider providing transportation and childcare, as well as pre-paid cards for reimbursement. If you really want to understand and mitigate patient burden, ask patients and patient advocates what would ease the patient burden, and ensure that your sites ask the same of patients and caregivers. Once you have the answers, act on them: It is critical that these groups realize that they have been heard.

- **Patient fear and distrust:** Both sites and sponsors must cultivate relationships with patients and patient groups and be transparent about the research process. Acknowledge past atrocities and describe current safeguards that protect research participants. Keep in mind the patient isn't the only one with such fears. Educate caregivers and include them in the process. Enlist trust bearers, who can reach patients in ways you never can.

- **Language barriers:** Provide study materials in multiple languages and allow sites to enlist interpreters as needed.

- **Data privacy concerns:** Develop clear, easy-to-understand data protection policies that explain how data will and will not be used.

Understanding and addressing barriers is essential, but sponsors must be strategic, not reactive. Addressing each problem as it emerges, whack-a-mole fashion, is beyond futile: It's counterproductive.

We've been helping clients improve diverse patient representation in trials, and what we've learned is this: Sponsors need a strategic, integrated approach. So we came up with one.

BUILDING A SUSTAINABLE D&I PROGRAM: FOUR PILLARS

We identified four key elements to any successful diversity and inclusivity initiative.

- **Diversity strategy:** Develop a diversity strategy as early as possible. Don't do it in a vacuum; make sure that diverse community members, patients, care providers and others as appropriate have a seat at the table; their insights are critical. This strategy can be modified as needed throughout the life of the protocol and/or program. Formalize the strategy because

the FDA may ask to see it. Communicate diversity expectations to the sites and hold them accountable. If the sites have issues, be prepared to help them mitigate or try another tactic.

- **Patient identification and engagement:** Build trust. Begin building relationships with the community and patient-advocacy organizations and identify areas of alignment. Truly engage: Nobody likes to be "talked at." As you learn from these relationships, refine the protocol to further enhance its design and execution. Use their insights to develop culturally appropriate materials in multiple languages.

- **Site identification:** Identify investigators and site networks with access to representative patient populations. Implement targeted referral support mechanisms. Once a site is chosen, begin implementing a site level diversity strategy.

As my WCG colleague Diane Carozza explains, any site feasibility strategy must explicitly call for ethnic diversity and inclusiveness. She made such a case in a recent issue of Applied Clinical Trials, where she asked, "What are you doing from the beginning to ensure that you include those groups in your trial?" It's a question the FDA expects you to answer. (Diane is vice president for clinical strategic solutions, study planning and site optimization).

- **Site support:** Provide D&I training to the sites that need it; you'll find many do. Recruiting, enrolling and retaining diverse populations may represent a significant change in the way they do business. Because that could result in increased site burden, we encourage clients to supply sites with pre-screened patient referrals and provide supplemental staff-such as Clinical Research Coordinators-to support enrollment efforts.

This is an integrated, collaborative approach, one that listens to and acts on the patient voice.

BE STRATEGIC. STAY COMPLIANT. KEEP MOVING FORWARD.

The FDA's recent guidance on the topic is extensive, and the agency is taking it seriously, and it expects sponsors to do so as well.

Diversity and inclusion can no longer be an afterthought or a series of tactics. Sponsors need an integrated strategy that includes all the stakeholders-patients, families, sites, investigators, referring physicians and the community.

We must do a better job as an industry, and we are moving in the right direction. In the past 18 months, several sponsors announced initiatives to diversify both patients and clinical investigators. However, the longstanding

issues related to a lack of diversity and representation will not be resolved by a few sponsors or sites changing how they work. It requires us as an industry to move in the same direction - together.

BUILD A COMPREHENSIVE D&I STRATEGY WITH WCG

WCG has been working in this area for years, and we've developed a framework and tools to help sponsors:

- Implement a diversity, equity and inclusion strategy at all levels across the trial, clinical program and enterprise.
- Identify and mitigate barriers to participation in their clinical trials.
- Build relationships with patient advocacy groups so that they can be part of the overall solution.
- Establish and administer participant boards so the voices of the patients, caregivers and healthcare providers can be heard and incorporated before, during and after the trial.
- Find clinical trial sites willing and able to seek out and enroll the mix of patients appropriate for your trial. We also help support sites in their endeavors.

609.945.0101
www.wcgclinical.com