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Opinion: Patient Advocacy Organizations Play a Key Role in Cultivating Diversity for Clinical Trials

by Andrew Barnhill

The future of clinical innovation depends on increasing trial enrollment from underserved populations. In this *Medtech Insight* exclusive, IQVIA experts explore steps industry, regulators and other stakeholders must take towards this goal.

One of the biggest concerns in the clinical research space is lack of diversity in study participants across historically underrepresented demographic subgroups. A *2021 study* uncovered that more than 40% of 230 US-based trials didn't report the race of participants -- and of those that did report race, 78% of participants were white. (By contrast, 2020 census data shows that the country is about 60% white.) The pandemic further illustrated these inequities, with COVID-19 hospitalization rates *2.2 times higher* for Black Americans compared to white Americans.

Lack of diversity presents both ethical and scientific issues. Not only does underrepresentation deny patients access to promising therapies, but it also hinders the scientific research process as some approved therapies may only be effective for subsets of patient disease. Effective research is diverse, and when populations that are often most vulnerable and predisposed to health challenges are not adequately represented in clinical trials, researchers lack the comprehensive data needed to accelerate drug delivery and breakthrough, life-saving therapies.

The future of clinical innovation depends on increasing enrollment in these underserved populations.
Accomplishing this requires three key components:

1. Advanced data technologies that identify and match the right patients to the right clinical trials;

2. Organizations that assist in trial awareness and patient advocacy; and

3. Technologies that break down participation barriers and ease the patient burden, especially in underserved populations

Addressing Enrollment Barriers

Industry, academia, non-profits and the federal government have worked toward representative enrollment in clinical research for well over a decade. However, enrollment to date in clinical research does not generally align with the diversity of the population. In fact, data shows that clinical trial enrollment of racial/ethnic minorities has actually *decreased* over the past 14 years. There are several recurring areas that create barriers to clinical trial enrollment by racial and ethnic minorities, including:

- Awareness and knowledge of clinical trials. Patients with ties to academic research institutions have a built-in advantage when it comes to clinical trials, as providers often have more information surrounding existing trials and more connections to point patients in the direction of enrollment. Too often, the clinical research industry fails to reach community providers who typically comprise the regular source of care for racial and ethnic minorities. This perpetuates distrust in the clinical research process and misunderstandings about what clinical trial participation entails.

- Financial burden of participation. The cost of participating in a clinical trial can be significantly burdensome. Clinical trial site locations are often outside of the patient's immediate area – and could be hours away, meaning patients potentially incur travel costs, hospital expenses and parking fees for each on-site visit. On top of that, participants must account for time off, childcare and additional cost risks for their caregivers.

- Issues with access, coverage and overall trust of medical establishments. Health insurance coverage plays a critical role in providing access to life-saving care and protecting families from high medical costs. When measuring for health coverage, access, health status, outcomes, behaviors and social determinants of health, people of color *fare far worse* than their white counterparts. Given the historic discrimination of people of color in medical research and the healthcare system, it comes as no surprise that these patients are *more likely* than their white counterparts to mistrust healthcare organizations and less likely to take medical advice, keep follow-up appointments or fill prescriptions.

Leveraging Patient Advocacy Organizations To Cultivate Diversity

Addressing these barriers will require all stakeholders – lawmakers, medtech companies, clinical research organizations, healthcare providers and leaders for racial and ethnic minority communities – to come together to create opportunities for participation and establish trust. In this context, Patient Advocacy Organizations act as a critical liaison. By empowering patients through providing the necessary tools, resources, education and guidance to advocate for themselves, Patient Advocacy Organizations build trust between patients and the medical

system. Equipping patients with key talking points to discuss with their providers and resources to expand their awareness of clinical trial opportunities brings the clinical research industry one step closer to addressing diversity challenges.

Another important barrier to consider for diversity in clinical trials is the patient burden. In addition to financial strain, surveys that are rigid and repetitive can be a hindrance to trial participation. Patients who may already be experiencing uncomfortable or painful symptoms related to their illness need efficient methods of data collection to minimize repetitive action and required on-site visits. Nowadays, most health data is generated outside of a clinical setting, meaning that patient-reported and patient-generated data are increasingly necessary to improve care.

Patient Advocacy Organizations are a key solution to these barriers by opening the door to more advanced data technologies that ease the patient burden. These technologies can be used to create “health wallets” that provide patients easy access to their data, supporting joint decision making with providers. In the clinical research process, Patient Advocacy Organizations not only streamline touchpoints between patients and investigators, but also ensure patient data is effectively leveraged to accelerate breakthrough treatment options.

In addition to easing the patient burden, advanced data technologies address diversity by identifying trial matches. With the right clinical health data registry platform, stakeholders can accelerate and improve the process of matching candidates based on inclusion criteria to align with the diversity of the overall population. Following trial enrollment, patients and physicians can leverage this advanced technology for simplified, compliant data sharing to better inform care and treatment decisions. In addition to trial matching, patient registries allow those who might not be able to participate in a traditional on-site clinical trial to share their data for research. Capturing these insights helps address financial, geographic and exclusion criteria barriers to participation. Investigators are also able to track these population groups over time, meeting patients where they are through virtual follow-ups and touchpoints. Ultimately, the collection, storage and analysis of these diverse data types drives innovation and saves lives.

The challenges ahead begin with advanced data technologies and patient advocacy

All stakeholders share a common goal of enrolling clinical trial participants to represent the diversity of the entire patient population. Clinical innovation depends on addressing inequities surrounding clinical trial awareness, the patient burden and overall trust of the medical research system. These challenges present a unique opportunity for Patient Advocacy Organizations to leverage advanced data technologies for clinical trial matching and cultivating relationships with historically underrepresented patients.

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companies and a diverse set of healthcare coalitions and political campaigns at the state and federal level. Named by The Hill *as a 2022 Top Lobbyist, Andrew currently serves as Head of Policy at IQVIA. He was the 2016 Democratic Nominee for North Carolina Senate in the 9th District in a competitive race that garnered national attention by multiple national news outlets when he was endorsed by President Obama. A graduate of Furman, Duke, and the University of North Carolina, Andrew is a native of the North Carolina coast and lives in Washington while commuting to Manhattan for his service on the faculty of NYU's Wagner School.*

Alexandra Weiss has an extensive background in patient advocacy and is a patient and caregiver advocate herself. She currently serves as Director of Strategic Operations for Patient Advocacy Organizations at IQVIA. Prior to joining IQVIA, Alexandra spent over six years leading industry relations and engagement for an oncology patient advocacy organization. While there, she worked closely on their Scientific & Medical Initiatives, raised funds to drive progress, and represented the patient voice for industry-hosted initiatives. Alexandra has spent over a decade in philanthropic leadership roles most recently as chair of her local hospital's cancer institute board.