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KICKSTARTING HEALTHCARE CONVERSATIONS

THE WHOLE WORLD IN OUR HANDS

Clinical trial redesign must be defined by diversity

Shape-shifting: How pharma is moving with the times

Pixel prowess: The digital era is finally gaining traction

Different dynamic: Inclusivity can truly ignite medicine

A design for life

Obtaining the right mix of patients from different ethnic, racial and demographic backgrounds requires a strategic approach leveraging community-based resources and patient-friendly technologies

Improving diversity among clinical trial participants is a critical component for ensuring that research data accurately represents the population among which the intervention is intended to treat.

Championed by both regulators and industry, many initiatives and technological innovations aimed at improving the diversity of clinical trial participants have been reasonably successful, but there's still much more. Ultimately, all clinical studies must be accessible to a broader and more diverse mix of patients from different ethnic, racial and demographic backgrounds.

Connecting with community

Part of that shortcoming can be attributed to an overall lack of diversity among investigators and site staff that still exists in clinics and hospitals nationwide.

Even though we've seen significant momentum over the past decade on efforts to improve diversity among healthcare providers and clinical research professionals, these efforts have not yet translated into a more inclusive research environment that increases minority representation in clinical trials.

One tactic that could help increase minority representation in trials is to fully leverage community engagement as a clinical trial recruiting and retention strategy to help improve diversity and to obtain valuable, subgroup specific data that might otherwise be missed.

We have seen a large increase in the number of health advisory boards, advocacy groups and community health workers operating on the ground to help increase access to healthcare – including research opportunities – and these should be applauded and supported.

Nevertheless, initiatives still seem to operate in isolation, as most contract research organisations (CROs) don't have established relationships with these groups and lack the ability to gather patient-centred insights that will help them better design studies to include people from diverse backgrounds.

Issue of trust

There's still an understandable lack of trust and stigma associated with medical research among some racial and ethnic groups. Therefore, sponsors and CROs should work to establish relationships with these boots-on-the-ground community-based healthcare groups and turn them into advocates for clinical research participation.

This mirrors regulator recommendations for developing a research framework that includes sustained community engagement.

Regulators have long recognised diversity as a barrier to conducting clinical research with subjects more representative of real-world patients, and a US Food and Drug Administration (FDA) guidance document published in April 2022 intended to provide some clarity to sponsors by focusing its recommendations on creating a Race and Ethnicity Diversity Plan.

While previous FDA guidance from 2016 covered how to collect and present race and ethnicity data, last year's document detailed to sponsors what elements to collect as part of a proper diversity plan.

In addition to timelines for planned assessments of race and ethnicity among participants, the guidance encourages sponsors to detail recruitment and retention strategies in three key areas: engaging with community leaders, improving access to clinical research sites and reducing the patient burden.

'A lack of transportation, potential lost wages and time associated with study visits are common reasons frequently given for not participating in a clinical trial'

Although there is still plenty of work left to do to better engage community leaders and community-based providers to help improve diversity in clinical research, there has certainly been notable, positive momentum. There have also been successes when it comes to utilising technologies and virtual trial designs in order to expand patient access to clinical trials and improve the patient experience.

Patient-focused technologies

The global COVID-19 pandemic showed us that in many cases clinical research could be conducted remotely, as more and more companies embraced decentralised clinical trial (DCT) models and methods to continue their studies.

It was an unforeseen solution to an age-old problem, as companies were forced to adopt technological alternatives to the traditional site-based model of clinical research; ushering in new ways to engage with patients and providers remotely.

As 70% of trial-eligible patients live more than two hours away from the nearest research site, DCT models and technologies that include elements such as telehealth visits and remote monitoring create more research opportunities to a much wider segment of the population, without any geographical limitations.

By enabling trial participation from the comfort of patients' own homes, these tools help eliminate many barriers to research participation – particularly for patients of racial and ethnic groups who are influenced by these barriers disproportionately.

A lack of transportation, potential lost wages and time associated with study visits are common reasons frequently given for not participating in a clinical trial. With this in mind, DCT technologies help solve many of obstacles those by leveraging technologies, systems and people to make trials more patient-friendly, more diverse and more reflective of the real-world target population.

Bring us all together – strategically

In a similar way to the early engagement with community-based leaders and outreach groups, DCT technologies are most effective when part of a holistic, top-down strategy in which diversity is made a priority from the start. From the very beginning stages of trial planning, we need to:

- Start writing protocols that are more inclusive
- Ensure that diversity is part of the criteria for site selection
- Employ and apply specific technologies that will help broaden trial access
- Further engage community-based resources to help educate patients on the clinical research process to expand opportunities for all those eligible.

The final analysis

For as far as we've come in making clinical research more accessible to all through technology, face-to-face human interactions are still the critical element in retaining and recruiting clinical trial participants from racial and ethnic minority groups.

Doing so properly requires a committed and unified approach that consolidates mindful community-based engagement with DCT models alongside technologies to widen patient access to research.

People from every area of society should feel empowered by the opportunity to be part of a life-transforming clinical trial, and that requires our industry to reduce the burden of participating in them.

Tracy Parker, Vice President, Biometrics at Advanced Clinical.
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Note from the Editor: God, I hate the expression 'no-brainer'. I do, however, believe that when applied to clinical trials and the need for diversity therein, we have a 'no-brainer' situation on our hands.

The nuance of disease is as complex as our communities, our backgrounds, our identities and our individuality. We cannot just aim an arsenal of scientific wizardry at the conditions that conspire to defeat us – we need an army of clinical trial participants that represent every facet of society to back it up.

Furthermore, these individuals need to feel as though they are credible stakeholders in the future of their health and the wider treatment landscape. The days of a 'typical' clinical trial profile must give way to an accurate representation of the real people involved – and that requires a pharma-wide reality check. John Pinching