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21 Feb 2023 | **Analysis**

Trials In Focus: A Call For Incentives To Help Drive Trial Diversity

by Alaric DeArment

Panelists at the BIO CEO & Investor meeting talked about ways to improve trial diversity. Also, GSK and Pfizer released retrospective analyses of diversity in their trials, while J&J is working to improve diversity with Stand Up To Cancer.

The Food and Drug Omnibus Reform Act, signed at the end of 2022 amid heightened attention to the importance of clinical trials enrolling diverse populations, requires clinical trial sponsors to submit "diversity action plans" for late-stage drug and device studies. But panelists at the recent BIO CEO & Investor Conference suggested more needs to happen for diversity to become the norm, including an effort by the entire health care sector and incentives to encourage diversity.

"I think a lot of this is going to come back to what are the economic incentives that we'll try to sustain commitment to representation in trials," Decentralized Trials & Research Alliance co-chair Craig Lipset said on the 6 February panel. "It's one thing to say you have to show the regulators a plan, it'll be another thing to say, 'Can I command a period of extended exclusivity if my study is designed to have the power to show efficacy and safety in representative populations,' or what's the stick that might be needed in this space."

He suggested that existing incentives for rewarding companies that develop drugs in indications that are challenging or don't offer big payouts could serve as models. The orphan drug incentives offered in the US have helped build a case for other high-need areas, such as anti-infective drug development.

"Personally, I think carrots work just fine: When you look at pediatric drug development, rare disease drug development, incentives have worked. And I think that, quite honestly, can drive a dramatic change here," he said. "This is a good first step, but I think it's really just the first step."

Syneos Health CEO Michelle Keefe said that in order to drive diversity in trials, "the whole

ecosystem" has to change, and there have to be incentives around that ecosystem-level change, which would have to include health systems and support from the broader health care industry rather than depending just on pharma and biotech companies. She acknowledged longstanding distrust of the health care system among various populations and the need to be aware of where that comes from.

"But then there are tons of surveys done that there's a lot of underrepresented populations that want to be involved in clinical trials – they just don't know how to access them," she said. "Or they tend to see physicians that either … don't do clinical trials or don't even know how to get access to them."

There is a lot of competing information about what the real challenges are, which makes it important to use data to understand where the patients are, Keefe added. She said there is a lot that industry can do to open opportunities for health care systems, clinics and other places in urban areas that tend to treat diverse patients and help them become able to run clinical trials or help them use decentralized capabilities to be able to participate.

Lipset still emphasized the importance of trust as a bridge to decentralization, which in turn can be an aid to improving diversity, but which he said is not a silver bullet.

"Diversity efforts have to start with trust, which means working in local communities to be understood, and it has to start with asking. So many individuals in underrepresented communities tell us they were never asked to participate," Lipset told *Scrip*. "Once we get trust and an invitation, then the challenge that we need to focus on is access, and that's where decentralized trials come in – how can we help to mitigate some of the access challenges that affect all patients but can disproportionately affect patients from underserved communities because of the burden of travel or work or childcare or other responsibilities."

And once decentralization can happen, particularly with the aid of technology, it opens up frontiers of diversity that can extend beyond borders. Simon Burns, CEO of the digital technology-focused CRO Vial, pointed out how the firm is running a trial in El Salvador, Honduras and Guatemala entirely on its electronic platform, with digital onboarding and remote monitoring instead of using the traditional methods of paper reporting and sending in trial monitors. But when the company started, Burns said a lot of people were insisting that trials would happen the old-fashioned way.

"I think those types of conversations happen a lot, and a lot of those types of conversations result in not going after new sites, not going to populations that would help drive the diversity of the trial," he said. "And that's part of the problem in the industry – we keep going back to the exact same sites … back to the academic medical centers."

Big Pharma Taking Stock Of Trial Diversity

- GSK plc recently published a paper in *Clinical Trials: Journal of the Society for Clinical Trials* examining trial diversity across 495 of its studies, involving more than 100,000 participants between 2002 and 2019. The British drug maker used real-world disease epidemiology data rather than the traditional benchmark of US Census Bureau race and ethnicity data to ensure trial enrollment reflected the populations affected by different diseases, focusing on asthma, chronic obstructive pulmonary disease, HIV and influenza. It found that in GSK's trials, enrollment of Black participants in asthma studies, at 22.6%, exceeded both their 13.5% share of the overall US population and their 17% share of people living with the condition. By contrast, Black enrollment in HIV studies, at 35.1%, was higher than the 13.5% Census figure, but lower than the 55.3% of people living with HIV who are Black. In a 6 February statement, the company said making meaningful progress on diversity required efforts by the wider health care ecosystem.

- A similar analysis by Pfizer Inc. roughly coincided with GSK's, as the New York-based drug maker conducted a study of 213 clinical trials initiated between 2011 and 2020 in cancer, rare diseases, vaccines, inflammatory and autoimmune diseases and neurological conditions. Pfizer's study found that the percentage of Black participants, 14.3%, slightly exceeded the percentage of the US population that is Black, while Native American and Alaska Native participants, who make up 1.3% of the US population, made up only 0.6% of trial participants. White participants also exceeded their share of the US population – 80.4% in the trials versus 76.3% of the population – while Asian participants made up 3.1% of trial participants despite constituting 5.9% of the US population, and 15.9% of participants were Hispanic or Latino despite their making up 18.5% of the US population. Only in the case of Native Hawaiians and Pacific Islanders did the percentage of trial participants equal their share of the US population, at 0.2%. Measured by age, the percentage of trial participants who were 65 and older, 31.7%, far exceeded their 16.5% share of the population, while percentages of male and female participants were roughly in line with their respective shares of the population.

- The Janssen Pharmaceutical Cos. of Johnson & Johnson are supporting efforts by the oncology research charity Stand Up To Cancer (SU2C) to improve diversity in oncology trials. The group announced 13 February that it is launching four teams tasked with increasing diversity in early-phase oncology clinical trials, particularly Phase I and Phase II studies, with a focus on Chicago, Dallas, Los Angeles and Philadelphia. The teams will work with stakeholders in underrepresented communities, address local and regional needs and help the development of new treatments.