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#ClinicalTrialsSoWhite: How Drug Makers Are Using COVID-19 To Improve Trial Diversity

Pandemic Highlights Trials' Minority Underrepresentation

by **Alaric DeArment**

Efforts to improve trial diversity predate COVID-19, but the pandemic's disproportionate effects on minority communities have brought the issue to the forefront.

The COVID-19 pandemic has highlighted a number of deficiencies within the US health care system, chief among them the vast gulf of inequality between different ethnic groups and geographic areas, a gulf that has resulted in the virus causing significant disease and death among Black, Latino and Native American communities. A consequence of that inequality is that the populations enrolled into clinical trials have historically often not properly reflected the ethnic makeup of the country.

The pandemic has drawn significant attention to the issue of clinical trial diversity, and as a result, several drug makers have sought to address the problem as they develop vaccines and therapeutics to combat COVID-19. Some, like Moderna and Pfizer – the first companies to win emergency use authorizations from the US Food and Drug Administration for vaccines against the SARS-CoV-2 virus – have made particularly well-publicized efforts to include diverse populations in their studies. (Also see "[Reducing Clinical Trial Burdens Brings Greater Participant Diversity – PhRMA](#)" - Pink Sheet, 17 Nov, 2020.)

[Editor's note: For more on diversity in clinical trials, [sign up](#) for our complimentary webinar on 21 April, part of a two-day event on clinical trial trends.]

Meanwhile, industry organizations like the Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO) have increased their efforts on the issue in the past year, including PhRMA's clinical trial diversity principles and the BIOEquality Agenda. Race and equality issues also took the stage at the BIO annual meeting, prompted by the Black Lives Matter protests in the summer of 2020, and industry's role in diversity and inclusion has remained a common topic at its biggest meetings. (Also see "[Leading A Diverse Company: Biopharma Executives Offer Ways Forward](#)" - Scrip, 12 Jun, 2020.)

Q&A: BIO CEO Michelle McMurry-Heath Outlines Diversity Goals

By [Mandy Jackson](#)

10 Aug 2020

Expanding on difficult conversations during the recent BIO Digital meeting, the group aims to take actions that will increase diversity and inclusion in health care, science and industry.

[Read the full article here](#)

Looking outside company walls, the biggest way industry plays a part is in clinical trial enrollment – and the pandemic's disproportionate effects on minority communities have brought an unprecedented degree of focus on inclusion in clinical research.

During a panel discussion on investing in diversity at the Biotech Showcase meeting in January, Lucy Abreu, who leads diversity and inclusion efforts at [Syneos Health](#), noted that “We could not have gotten to even fathom the idea of having the vaccine ready for distribution if we did not work together across industries and look at that from an inclusive lens.”

Recognizing The Issue

An analysis published in the *Journal of the American Medical Association* on 19 February looked at 230 pre-pandemic vaccine trials in the US that took place from July 2011-June 2020. It found that white participants accounted for 78% of all the nearly 220,000 participants, while Black people, Latinos and Native American/Alaska Natives were all underrepresented, accounting respectively for 11%, 12% and 0.4% of participants. Conversely, adult women were overrepresented, at 56%, while Asians and Pacific Islanders were equitably represented.

An article on racial disproportionality in COVID clinical trials, published 27 August 2020 in *The New England Journal of Medicine*, illustrated the problem, pointing out that although Black, Latino and Native American communities were hit especially hard by COVID-19, those groups made up comparatively small shares of participants in the Phase III studies that led to the FDA's EUA for [Gilead Sciences, Inc.](#)'s Veklury (remdesivir).

Indeed, hospitalization and mortality among those three groups is multiple times higher than

among white and Asian populations in the US, according to the Centers for Disease Control and Prevention. An analogous – but often overlooked – situation exists in Europe, with Sinti, Roma and Traveler populations also at high risk of morbidity and mortality from the pandemic due to underlying health issues and lack of engagement with health systems, according to an August 2020 paper in the journal *Public Health*.

The disproportionality in the Veklury studies was emblematic of a larger problem, one that Quita Highsmith, chief diversity officer at *Roche Holding AG*'s *Genentech, Inc.*, came across when the company was planning a patient summit but couldn't find any trial participants who were Black or Latino.

"So let me give you the first hashtag: 'Clinical trials so white,'" she said in a panel discussion during the Milken Institute's health summit in December 2020.

Insufficient data on diverse groups leaves physicians and industry in the dark about a medicine's risk-benefit profile in various populations and how genetics, environment and social determinants of health can affect it.

To illustrate, Carol Horowitz, director of the Institute for Health Equity Research at New York's Mount Sinai Hospital, said during the Milken Institute panel that it was crucial to look at multiple determinants of health.

"We are looking at gene variants in people of African ancestry because of their ancestral genetic makeup," she said. "At the same time, we're looking at the fact that these are intersecting with air pollution – people have this gene variant and are also exposed to air pollution [and] get even more kidney failure."

In a 14 April panel sponsored by PhRMA and the US Black Chambers to discuss building confidence in COVID-19 vaccines among African-American communities, B. Cameron Webb, a physician and senior policy adviser for equity on the White House COVID-19 Response Team, said much of the media attention on mistrust in vaccines focuses on the infamous Tuskegee syphilis experiment, but this often misses the broader issue of rebuilding trust.

"The question I get most often – different iterations of it – is, 'Do you trust this vaccine?'" Webb said. "My answer usually starts with, my momma got this shot ... that's how much I trust the science and how much I trust the work that's gone into this, the researchers, the real nuance that went into making these safe and effective vaccines."

Another panelist, University of Virginia-Charlottesville physician Ebony Hilton, said that what is often called vaccine hesitancy among Black Americans is really just people – including her own family and friends – being "vaccine curious."

“They really just want to know, how do these vaccines work, and what will it do to our bodies,” she said.

Biopharma Spurred To Action

PhRMA’s clinical trial diversity principles do not specifically mention COVID-19, but PhRMA CEO Steve Uhl noted at the STAT Summit in last November that the announcement was happening in the context of the pandemic.

“I think COVID has certainly laid bare the health inequities that plague our system and broader society,” he said. “The vaccine companies have done really good work to reach into Black and Brown communities to ensure that they are representative of the broader population. That gives us some momentum to build on.”

Meanwhile, individual companies have been making pushes of their own.

[*Pfizer Inc.*](#) is one company that has been particularly active in this regard, including in its development of the BNT162b2 vaccine.

“COVID-19 gave us the opportunity to do more,” the company told *Scrip*. “We obviously want to make sure the vaccine works for everybody, especially people who are disproportionately affected. These are lessons we will implement going forward for every trial we do.”

The company said the effort to increase diversity in its Phase III trial of the vaccine happened in a number of ways. First, there was addressing access, which meant selecting easily accessible sites in diverse communities, by means such as data from the CDC and Johns Hopkins University. Next, there was raising awareness, which meant outreach through media and advocacy groups as well as printing materials for patients in a variety of languages – particularly Spanish, Haitian Creole, Tagalog, Japanese and Simplified Chinese. The third issue to overcome was mistrust in minority communities, which meant doing outreach through groups like the National Black Nurses Association and National Hispanic Caucus.

“It’s about building those long-term relationships because we have a lot of work to do when it comes to restoring faith and credibility with certain communities,” Abreu said during the Biotech Showcase panel.

Although it is not a member of PhRMA, [*Regeneron Pharmaceuticals, Inc.*](#) – which introduced the COVID-19 antibody cocktail casivirimab/imdevimab – told *Scrip* the pandemic has likewise been a learning experience, on top of its existing diversity and inclusion programs. (Also see [*"Regeneron COVID-19 Cocktail's Flame To Burn Brightly But Unclear For How Long"*](#) - *Scrip*, 23 Nov, 2020.)

“With respect to our clinical trials for COVID-19, our approach to site selection has been and continues to be to follow the virus,” the company said. “That has led us to locales hardest hit and has resulted in the recruitment of a diverse population of patients.”

Genentech has paid similarly close attention to ensuring diversity in its studies. In the EMPACTA trial of its IL-6 inhibitor Actemra (tocilizumab) as a treatment for COVID-19 pneumonia, 85% of the study’s 389 patients were from racial and ethnic minority groups, mostly Latino, with “significant representation” among Black and Native American populations. That was thanks to the study’s focus on recruiting from among minority groups that are often underrepresented in trials, Genentech global head for global health equity and population science Nicole Richie told *Scrip*.

“We believe this trial will become foundational for future inclusive research trials at Genentech and Roche, and we hope the industry as well,” she said.

Lessons from that experience include the importance of trial site locations to ensuring access, engagement and enrollment of underrepresented groups and what Richie called “a hyper-local approach at a global scale”; asking investigators to be more intentional about recruiting diverse populations; and financial support for participant needs like travel and childcare. That goes for diverse populations outside the US as well, she added.

“We deeply recognize that health is multifaceted and that achieving better outcomes for more patients globally means we must consider all aspects of a person’s health, particularly those who have been affected by adversity, such as Sinti and Roma populations,” she said.

Meanwhile, [*Johnson & Johnson*](#) has enlisted Black celebrities such as Debbie Allen, a cast member and executive producer of “Grey’s Anatomy,” to encourage African-American enrollment in the Phase III ENSEMBLE trial of its COVID-19 vaccine.

Other companies have sought to improve diversity under broader programs through their nonprofit arms.

For example, [*Novartis AG*](#)’s Novartis US Foundation has added to more than \$10m in ongoing program funding a \$15m commitment to address lack of diversity in clinical trials as a driver of health inequities, Novartis US president Tom Kendris told *Scrip*. The pandemic, he said, has also highlighted how technology can play a role in preparing health care systems to predict, prevent, respond to and recover from future health crises.

“A key learning from the crisis is how the digital preparedness of health care systems has influenced their ability to respond,” he said.

Bristol Myers Squibb Company's philanthropic arm has done the same – in November it announced a \$100m push to include diversity in trials, as well as a \$300m investment over the next five years toward the effort. That program includes training 250 diverse clinical trial investigators to serve underrepresented patient populations.

BIO specifically cited COVID-19 and its effects on minority communities in announcing BIOEquality. Its program includes enhancing use of minority- and women-owned businesses in biotech supply chains to promote economic development of marginalized communities, especially those hit hard by the pandemic and promoting access to vaccines and therapeutics for uninsured and underserved populations.

“Included in that initiative is equitable access to therapies and equitable representation of women and people of color in clinical trials,” BIO CEO Michelle McMurry-Heath told *Scrip*. “We agree that clinical trials should reflect the people that they’re eventually going to serve, and we will continue to work with our members to effect this systemic change.”