Doing Better: Increasing Diversity in Clinical Trials

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Diversity in clinical trials is key to equitable health outcomes.

Increasingly, clinicians, researchers and patients are realizing that a lack of diversity in clinical trial participants may contribute to the stubborn persistence of health disparities, such as the fact that Black Americans are 30% more likely than whites to die prematurely of heart disease.1 After all, if a clinical trial for a new nonalcoholic steatohepatitis (NASH) drug doesn’t include an adequate number of Black participants, how can researchers be

reasonably sure that the drug will effectively combat fatty liver disease in Black patients?

Yet, historically, the industry has fallen short when it comes to ensuring that clinical trials adequately mirror the intended patient population. Many research studies didn't even report race or ethnicity data. In fact, a review of six early studies of COVID-19 treatments found that one-third of the studies didn't report race or ethnicity; one didn't even collect race data.2

It's time to do better.

A Commitment to Improve Representation in Clinical Trials

Maya Angelou, the famous writer, once said, "If you don't know where you've come from, you don't know where you're going."

An accurate understanding of the past – no matter how painful it might be – can help individuals and communities direct their efforts and move forward. That's why Pfizer Inc. recently conducted a vigorous, in-depth analysis of our U.S. clinical trials initiated between 2011 and 2020. The review, which was published as "Demographic diversity of participants in Pfizer sponsored clinical trials in the United States" in April 2021, included 213 clinical trials studying cancer, rare diseases, vaccines, inflammatory and autoimmune diseases and neurological conditions.3

"This is an industry first and we are proud to lead the way. We published these data to be transparent about our baseline, so we can track progress as we work to improve diversity in clinical trials," says Rod MacKenzie, Pfizer's Executive Vice President and Chief Development Officer.

One of the primary units of measurement that researchers applied was how many trials achieved racial and ethnic distribution levels that met or exceeded US census levels.

Researchers found that:

Participant levels above census were achieved in more than 50% of Pfizer trials for Black or African American participants, Hispanic or Latino participants and White participants. Participation was also above census for Asian participants, Native Hawaiian and Pacific Islander participants, and American Indian and Alaska Native participants in 16%, 14.2%, and 8.5% of trials, respectively.

More than half of Pfizer trials included Black participants at rates approximately equal to their representation in the overall population- but Black people were under-represented in cancer-related studies. Only about 16% of oncology studies included proportional representation of Black people.

Hispanic or Latino individuals are under-represented in clinical trials, particularly in cancer-related studies. Just 6.5% of oncology trials included proportional representation of Hispanic or Latino people.

White people are over-represented in therapeutic trials, or those in which the treatment under investigation is likely to benefit trial participants in some way. 78.6% of therapeutic trial participants were white; 17% were Black and just 2.2% were Asian.

Native Hawaiian, Pacific Islander and indigenous populations were under-represented. Some trials did not include any individuals from these demographic groups.

Pfizer initiated the review of our clinical trial demographics so we can better target our efforts to improve representation in drug and vaccine trials. Understanding our historic baseline points the way to necessary outreach and partnerships.4

“Volunteering to participate in a clinical trial – the foundation of medical research – is a selfless and personal choice that is often a challenge for many communities due to societal and economic factors,” says Dara Richardson-Heron, M.D., Pfizer’s former Chief Patient Officer. “Pfizer’s goal is to partner with patients’ and patient advocates to co-create solutions designed to lower many of the known barriers to clinical trial research such as financial challenges, lack of accessibility, the digital divide and many others. Pfizer must also do its part to increase awareness about the value and benefits of research and nurture relationships that will re-build trust in our nation’s healthcare system.”

With that in mind, Pfizer is taking decisive steps toward eliminating those barriers, including a company-wide commitment to diversity and knowledge-sharing. For clinical trials themselves, in some cases, researchers may cover participants' travel expenses and utilize available digital technology to minimize (or eliminate) onerous on-site visits. Pfizer will also emphasize partnering with local clinics and grassroots organizations, and listening to the needs and concerns of individuals in the community.

It will take time to achieve equitable representation in clinical trials. “Overcoming barriers and challenges to fair representation won’t happen overnight, nor can it be achieved by a single company,” says MacKenzie. “But it is the right thing to do for science, for public

health, and for patients who are waiting for the next breakthrough.”

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