How to Boost Racial, Ethnic and Gender Diversity in Clinical Research

Why All Stakeholders Must OWN The Mission: An Executive Summary

Healthcare transformations take time—and the time lag has consequences.

It has been 25 years since Congress passed the NIH Revitalization Act requiring federally funded clinical research programs to prioritize inclusion of women and minorities. Since then, both the NIH and the FDA have mounted numerous initiatives, including regulatory guidance aimed at shoring up the law’s intent.

Despite parallel efforts by biopharmaceutical innovators, the demographics of clinical trials today still do not reflect the racial, ethnic or gender diversity of target patient populations around the world. This is true for trial participants, of whom an estimated 83 percent are white. And it’s true for the race/ethnicity/gender representation of investigators at many trial sites as well.

As advanced health systems around the world enter an era of genomic and precision medicine, lack of diversity across the clinical research landscape is an encumbrance. As of 2018, some 78 percent of individuals included in genome-wide association studies were of European descent, while those of African or Hispanic ancestry made up just 2 percent and 1 percent, respectively, according to a report in the journal Cell. The bias in the data harms our understanding of genetic and environmental causes of disease and impedes both individualized and population-wide efforts in prevention and treatment.

Even as the challenges persist, however, education and outreach efforts by agencies, industry organizations, patient groups and private companies are accelerating.

- The NIH maintains a Scientific Workforce Diversity website with toolkits to improve recruitment of talented researchers from minority racial/ethnic communities.
- Through the FDA’s Drug Trials Snapshots program—a consumer-facing website—visitors can download summaries showing percentages of race/ethnicity/gender representation in clinical trials for every new FDA approved drug in a given year. Consumers can now learn if researchers have found any differences in safety or efficacy relevant to their demographic subgroups.
- Noting that Blacks and Hispanics make up just 2 percent and 3 percent of all practicing oncologists in the U.S., the American Society for Clinical Oncologists (ASCO) has launched funding and mentoring programs aimed at medical students from underrepresented groups. Other associations have started similar programs.
- Patient organizations such as African Americans Against Alzheimer’s and the Lazarex Cancer Foundation are tackling the diversity challenge from multiple angles—educating minority communities on the benefits of trial participation, helping cover travel and other costs, and working with companies to upgrade education and outreach materials.

Amidst these efforts, many organizations still worry that population trends will magnify the negative impact of racial/ethnic imbalances in clinical research. After all, in the U.S., the percentage of minority participants in studies rarely exceeds low double digits at a time when racial and ethnic minorities make up nearly 40 percent of the population overall. The picture will be far more complicated in 2060, when the number climbs to 56 percent, based on current census trends. In short, there’s an intrinsic bias issue when results are generalized from a white European subject base, and we must tackle that issue now to build for the 21st century.

Consider the fast-growing therapeutic category of cancer immunotherapies. A review published by ASCO last month showed that black participants made up less than 4 percent of patients in trials for checkpoint inhibitors targeting lung cancer, and similar underrepresentation affected trials in renal cell carcinoma and other tumor types. This can perpetuate outcome disparities, the authors note, because “the unique biology of the host and the tumors from this subpopulation is not accounted for as new treatment algorithms to guide optimal use of immunotherapy are developed for use in the real world.”

The issues raised in oncology are a harbinger for precision medicine as a whole. Nonetheless many researchers are hopeful. With robust federal initiatives in place, transparency on channels such as Drug Trials Snapshots, and collaborative education and outreach programs on the ground, it should be possible to build trust in demographic subgroups that are chronically underrepresented in clinical research.

Trust, after all, is the gateway to the healthcare transformation everyone desires.
About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Learn how we help customers shorten the distance from lab to life® at syneoshealth.com.

© 2019 Syneos Health™. All rights reserved.