

# Strategies for increasing patient diversity in trials

## Sponsors look to improve racial, ethnic recruitment without going overseas

**T**he problem has plagued the industry for many years: how do you get more minorities to participate in clinical trials?

The task of increasing diversity among trial participants is seeing renewed interest because of a growing U.S. minority population—along with the ability to target drugs to more specific groups and the need to tap these narrower patient populations.

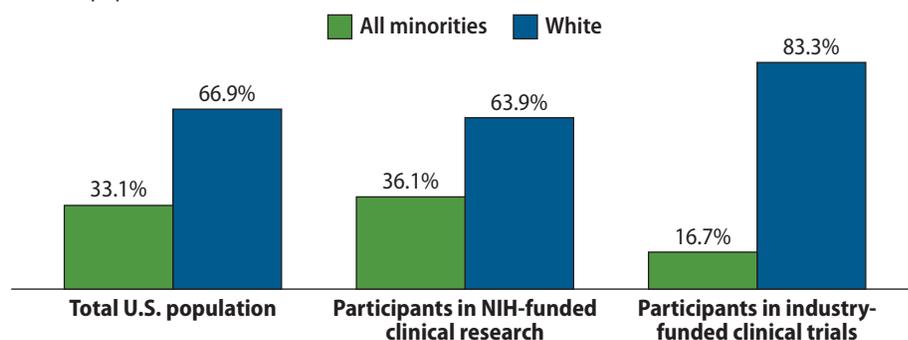
“The public and private sectors have definitely demonstrated a greater interest in diversifying the patient pool of clinical trials so researchers can evaluate data reflective of our multicultural society,” said Kim Ribeiro, patient recruitment specialist II at Parexel. “The growing appeal for pharmacogenomics demands greater participation of racial and ethnic minorities.”

Ken Getz, director of sponsored programs and assistant professor at the Tufts Center for the Study of Drug Development, said he has seen more drug makers set up task forces and hold seminars on how to improve racial and ethnic diversity in trials.

Getz’s research shows one reason life science companies may be paying more attention to attracting minority participants: They are making more drugs targeted for use by those populations. The number of medicines for diseases that disproportionately affect Hispanics jumped from 245 in 2001 to 581 in just eight years. In 1999, there were just 156 new drugs

### Study volunteer disparities in clinical research

Percent of population



Source: U.S. Census Bureau; NIH; Tufts CSDD <<https://csdd.tufts.edu>>

for diseases that disproportionately affected African Americans, but a decade later that total jumped to 709.

The pressure for more targeted medicines, he said, comes from policy makers, payers and regulators. “As we move toward more targeted medicine, it’s ever more important to understand these subgroups.”

But Getz’s research shows a gaping hole in the patient population. While one third of the U.S. population is minority, just 16.7% of volunteers participating in industry-funded trials are from minority populations.

“We have to be more inclusive and concerned about all sectors of our population to be a healthy nation,” said Dr. August White III, professor of medical education and orthopedic surgery at Harvard Medical School.

The FDA does require a new drug application to include information on safety and effectiveness by age, gender and race.

Dr. Robert Temple, FDA deputy director of clinical science, said the level of participation by blacks has risen to be about proportional to the population. A 2010 FDA study showed black participation was almost 10%. Because that total included foreign trials without as much black representation, the U.S. portion probably was close to the black proportion of the population, or 13%, said Temple. If a drug application doesn’t have enough information about safety and effectiveness in a particular demographic group, the FDA can send the drug maker back to get more data.

“We’re for including a broad spectrum of patients. We’ve been trying to do that for 30 years,” Temple said. “On the whole, it’s working pretty well.”

But having minority trial participants proportionate to the overall population isn’t good enough, said Dr. James Powell, a clinical pharmacologist whose company, Strategic Medical Associates,