

FDA Drug Trials Snapshots and Diversity When Testing New Drugs

John J. Whyte, M.D., M.P.H.

Did you know that some drugs affect men and women differently? For instance, women are often prescribed only half the dose that men take of the sleep medication, Ambien (zolpidem). Race and ethnicity also make a difference. One type of drug commonly used to treat high blood pressure, angiotensin-converting enzyme (ACE) inhibitors, has been shown to be less effective in African American patients than in white patients.

These are just two examples of why it's important to test drugs on the appropriate patient populations. This is especially true for drugs we call "novel drugs," new medicines that have never been used before in the U.S. marketplace. Over the past two years, FDA's Center for Drug Evaluation and Research (CDER) approved 67 novel drugs. So it's no surprise that in recent years, representation in clinical trials of certain subgroups, such as people of different ages, races, ethnic groups, and genders, has become of growing interest.

To help keep the public better informed, CDER piloted the *Drug Trials Snapshots* program two years ago to provide easily accessible information about patient representation in clinical trials. Snapshots show who participated in the studies used to approve a novel drug and organize information from the studies by sex, race, and age subgroups. Further, they provide a brief narrative on whether there were any reported differences in how the drug worked by subgroup and whether there were any reported differences in side effects among the different groups. Since January 2015, CDER has published a Drug Trials Snapshot within a month of each novel drug's official approval date.

Just this week, we released our *Drug Trials Snapshots Summary Report*, which provides a yearly average of the diversity of participants in the clinical trials for novel drugs approved in 2015 and 2016. It shows for example, that women were represented at a rate of 40 percent in 2015 and 48 percent in 2016 and African Americans were represented at a rate of 5 percent in 2015 and 7 percent in 2016. The report also lays out the extent to which safety and effectiveness data are based on demographic factors such as sex, age, and race. At its heart, this report is an effort to be transparent – to provide information to the public, and actually show the number and participation of men and women, of various races and age groups within the clinical trials. Being able to share more information and facts will help us to facilitate a thorough and robust discussion about clinical trial demographics. Now, anyone can go to the site and see the numbers for themselves in a quick snapshot.

Until the late 1980s, clinical trials were conducted predominantly on men. Much has changed since then. Our Drug Trials Snapshots program and Summary Report underscore FDA's commitment to enhancing transparency and better understanding of patient representation in clinical trials.