

# Women, elderly, minorities poorly represented in lung cancer drug trial data submitted to US FDA

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Women, older people and minorities are enrolled less frequently in lung cancer drug trials and the numbers do not reflect the prevalence of lung cancer in these populations, according to research presented at the 14th World Conference on Lung Cancer in Amsterdam, hosted by the International Association for the Study of Lung Cancer (IASLC).

"Our results suggest that the trial population used for approval of drugs do not represent well the U.S. population who may receive the marketed agent," said principal investigator Dr. Shakun Malik, a medical officer at the U.S. [Food and Drug Administration](#) (FDA) in Silver Spring, Maryland.

Researchers reviewed trial data submitted for FDA drug approvals for the treatment of non-small cell lung cancer (NSCLC) over the last decade.

Of U.S. patients diagnosed with lung cancer according to the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) data released on April 15, 2011, and collected between years 1975-2008, 58% were men and 42% women. But in 10 national and international trials for agents approved to treat NSCLC between January 2000 and December 2010, 68% of enrollees were men and 32% were women.

In addition, 73% of U.S. [lung cancer patients](#) are older than 65 but only

36% of the drug trial population was older than 65, researchers found.

Meanwhile, African-Americans develop [lung cancer](#) at higher rates (72.7 per 100,000) than Caucasians (68 per 100,000), but only 2% of trial participants were black. [Caucasians](#) made up 78% of the trial population, Asians 15%, Hispanics 2% and "other" 2%.

"Disparity was especially pronounced in the age and ethnicity," Dr. Malik wrote. "This fact is concerning particularly for older patients who may experience greater toxicity when given the same dose and combination of drugs based on testing in a younger population."

Provided by International Association for the Study of Lung Cancer

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