FDA: Men should be included in breast cancer clinical trials

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Men should be included in clinical trials of new breast cancer treatments, the U.S. Food and Drug Administration says.

"Less than 1 percent of all breast cancer cases occur in men, but men are more likely to be diagnosed at an older age and have a more advanced stage of disease. As breast cancer in men is rare, they have typically not been included in clinical trials for breast cancer treatment," according to an FDA news release. "This has led to a lack of data, so their treatment is generally based upon studies and data collected in women. While some FDA-approved treatments are gender-neutral in their indication, many therapies are only approved for women and further data may be necessary to support labeling indications for men."

The draft guidance that men be included in breast cancer clinical trials was issued by the FDA on Aug. 26.

"When finalized, the recommendations in the draft guidance will provide clarity for industry regarding how additional data to support efficacy and safety for male patients with breast cancer can be generated through a variety of trial designs using different data sources, including studies using real-world data," Richard Pazdur, M.D., director of the FDA Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA Center for Drug Evaluation and Research, said in the news release. "We hope that the recommendations in the draft guidance issued today will, when finalized, encourage drug development for the treatment of male breast cancer and ultimately, provide additional FDA-approved treatment options for patients."

More information: More Information