



Women Are Missing From HIV Trials

Researchers with the Food and Drug Administration looked at women's participation in Phase III antiretroviral therapy trials submitted to the agency since 2010.

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Women living with HIV are underrepresented in late-stage clinical trials of new treatments, and the disparity is particularly stark for Black women. Women account for 19% of people newly diagnosed with HIV and nearly one quarter of people living with HIV in the United States. About 60% of newly diagnosed women are Black, while white and Latina women each account for around 20%.

Researchers with the Food and Drug Administration looked at women's participation in Phase III antiretroviral therapy trials submitted to the agency since 2010. The analysis included 18 studies conducted in various countries that together enrolled more than 13,000 previously untreated participants, including about 5,300 in the United States. Overall, 15% were women; 45% of the women were white and 36% were Black, compared with 69% and 18%, respectively, among men. But in U.S. trials, only 11% were women, of whom 34% were white and 62% were Black. The researchers calculated that, overall, women were not adequately represented in clinical trials relative to their share of the HIV population. But when this was broken down by race, there was a disparity for Black women but not for white women.

Representative trial participation is important because therapies may work differently or have different side effects in men versus women. Previous studies have found that women may not join trials for a variety of reasons, including lack of awareness, family responsibilities and barriers to access. "Additional research into innovative approaches to recruit and retain females in clinical trials should continue," the study authors concluded.

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