HIV/AIDS Clinical Trials & Women

Written by David Mariner with help from Mark Baker, Catherine McCartin, and Claire Rappoport

What We Know

- Women make up one quarter of the population estimated to be living with HIV OR AIDS in the United States, or approximately 200,000 to 225,000 women.¹

- Women comprise a growing share of new AIDS cases each year. The proportion of AIDS cases among women has more than tripled since 1986 from 7% to 23%²

- Women of color are disproportionately impacted. Although African American women represent only 13% of the US female population, they account for almost two-thirds of new AIDS cases reported among women in 1999. Similarly, Latinas accounted for 18% of new cases among women in 1999, but only 11% of the US Population³

Women & Clinical Trials

- Before 1993, women were often excluded from clinical trials. Researchers often cited concerns about pregnancy not wanting to cause harm to a fetus. In 1993, however, the Food and Drug Administration said women could no longer be kept out of trials.

- Women are still underrepresented in HIV/AIDS clinical trials. One analysis of 49 antiretroviral therapy trials conducted between 1990 and 2000 showed an average of 12.25% of women in trials.⁴

- Eligibility criteria may make it more difficult for women to enter into clinical trials. The Women’s Independent Health Study is currently the largest database of women with HIV in the United States, with over 2,600 HIV positive and HIV negative women. Over 80% of the WIHS trial participants, however, would be ineligible to participate in a typical AACTG trial due to illness, concomitant medications, and psychiatric conditions.⁵

Gender Differences

- Because there has not been as much research, there is a lot we don’t know about women and HIV. Some areas that are of particular interest to women include: hormone levels, lipodystrophy, gynecological care, and bone loss. For more information, an excellent brochure ‘Treatment Issues for Women’ is available from the AIDS Community Research Initiative (www.acria.org)
The Role of the Some Facts about Pregnancy and Clinical Trials

- In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can’t join a trial of an untested drug because it is not known if the drug might harm the baby.

- Some women think they must have an abortion if they become pregnant while in a study; this is not true.

- Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join.

---

For more information on AIDS Research and Communities of Color

**Woman Alive**  
1566 Burnside Ave, Los Angeles, CA 90019. (323) 965-1564  
www.women-alive.org

Woman Alive is a national treatment-focused, non-profit organization by and for women living with HIV/AIDS.

**WORLD**  
414 13th Street, 2nd floor, Oakland CA 94612. (510) 986-0340  
www.womenhiv.org

WORLD is a diverse community of women living with HIV/AIDS and their supporters

**Babes Network**  
1001 Broadway, Suite 100, Seattle, WA 98122. (206) 720-5566 ext. 12  
www.babesnetwork.org

Babes Network is a sisterhood of women facing HIV together. Babes Network produces a monthly newsletter available online or by mail.

---


