








Absence of evidence is not evidence of absence

*Shirin Heidari*  
*Journal of the International AIDS Society*  
*Gender Summit, Brussels - Nov 2011*



## Women have:

-  Higher HIV transmission risk
-  Lower Viral Load early on
-  Faster disease progression given same Viral Load
-  Different profile of adverse events
-  Higher CD4 T cells
-  Lower CCR5 density on CD4 cells
-  Higher CD8 T cell activation

- *Hormones, HIV and ARVs??*

# Reporting?



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## **About** *Journal of the International AIDS Society*

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### **Analysis of differences by race and gender**

Submitting authors are strongly encouraged to include data disaggregated by sex (and, whenever possible, by race) and provide a comprehensive analysis of gender and racial differences.

The authors should include the number and percentage of men, women and, if appropriate, transgender who participated in the research study. Anatomical and physiological differences between men and women (height, weight, body fat-to-muscle ratios, cell counts, hormonal cycles, etc.), as well social and cultural variables (socio-economic, education, access to care, etc.), should be taken into consideration in the presentation of data and/or analysis of the results. If statistically significant differences are found - between men and women or between different racial or cultural groups - in the effects of the studied intervention, the implications, if any, for clinical and/or public health should be adequately discussed.

If the research study was specific to one sex/gender, the reasons for this should be clearly stated.

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# Reporting?



AIDS 2010

XVIII INTERNATIONAL AIDS CONFERENCE  
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## Gender Analysis in Abstracts

Inclusion of gender breakdown of data is strongly encouraged, and should be provided as well as a comprehensive gender analysis in the results section whenever possible. If applicable, your abstract should include the number and percentage of men, women and transgender who participated in your research or project, and disaggregation of results by gender. If your research or project was specific to one gender, please state.

Environmental Scan:

# Mapping HIV Research Priorities for Women and Children



July 2010



Consensus Statement

# ASKING THE RIGHT QUESTIONS: Advancing an HIV Research Agenda for Women and Children



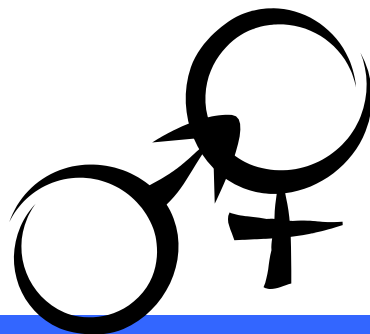
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March 2010



# CLINICAL: TREATMENT FOR WOMEN

- Disaggregate clinical cohorts and clinical trial **data by sex, ethnicity and race**
- How reproductive health and **hormonal changes** affect treatment outcome?
- Impact of **endogenous and exogenous hormonal changes** on ART and treatment outcomes for women?
- What **additional studies** are required to assess if **sex-based PK/PD differences** are clinically relevant?
- Ensure **greater representation of women** in ARV **PK/PD** studies.



# Making Clinical Trials Work for Women and Girls



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Decades after AIDS first became a global health threat, it has become clear that analysis of data by sex is a crucial consideration in trials exploring new ways to stop the spread of HIV and treat HIV-related disease.

Yet, until relatively recently, women were under-represented as participants in trials for all types of clinical interventions, including trials for HIV vaccines. Most HIV trials are not designed with women in mind. Women are considered "difficult" to study and enrol in trials given the complexities of their biology and their lives.

### Resources:

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- ▶ [Global Coalition on Women and AIDS](#)

### Feature stories:

- ▶ [Meeting ethical concerns over HIV trials \( 3 December 2007\)](#)
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