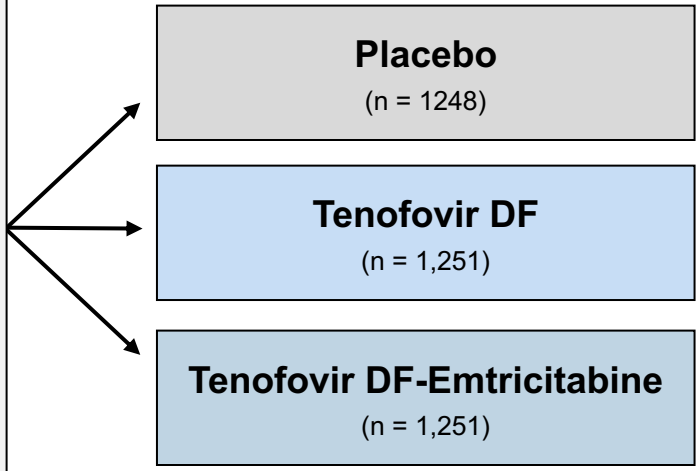
Preexposure Prophylaxis in HIV Serodiscordant Couples

Partners PrEP Trial

Oral HIV PrEP for Heterosexual Couples in Kenya and Uganda Partners PrEP: Study Design

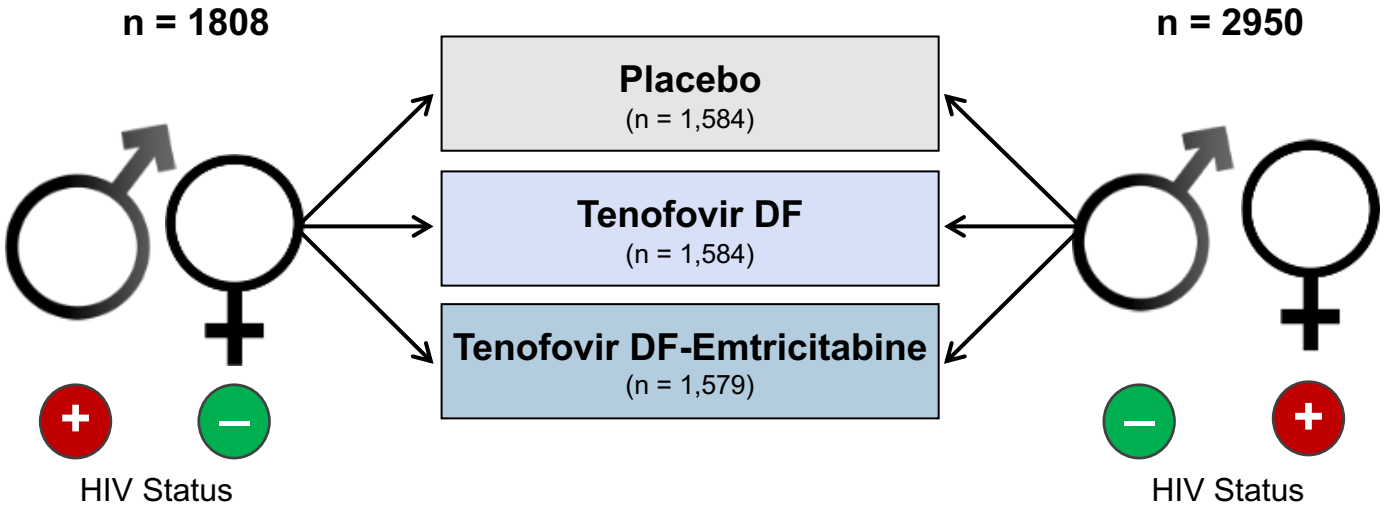
- **Background**: Randomized, placebo-controlled trial that examined efficacy and safety of tenofovir DF and tenofovir DF-emtricitabine as HIV PrEP in heterosexual HIV-1 serodiscordant couples from Kenya and Uganda
- **Inclusion Criteria** (4,758 enrolled)
  - 18 years of age or older
  - HIV-1-serodiscordant couples
  - HIV-seropositive partner: not receiving ART and did not meet Kenyan or Ugandan guidelines for initiation of ART
  - HIV-seronegative partners: normal renal function; not infected with HBV; not breastfeeding
- **Treatment Arms**
  - Placebo: 1 pill daily
  - Tenofovir DF: 1 pill daily
  - Tenofovir DF-emtricitabine: 1 pill daily



Source: Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Oral HIV PrEP for Heterosexual Couples in Kenya and Uganda
Partners PrEP: Study Design

4,758 Heterosexual, HIV-1-Serodiscordant Couples

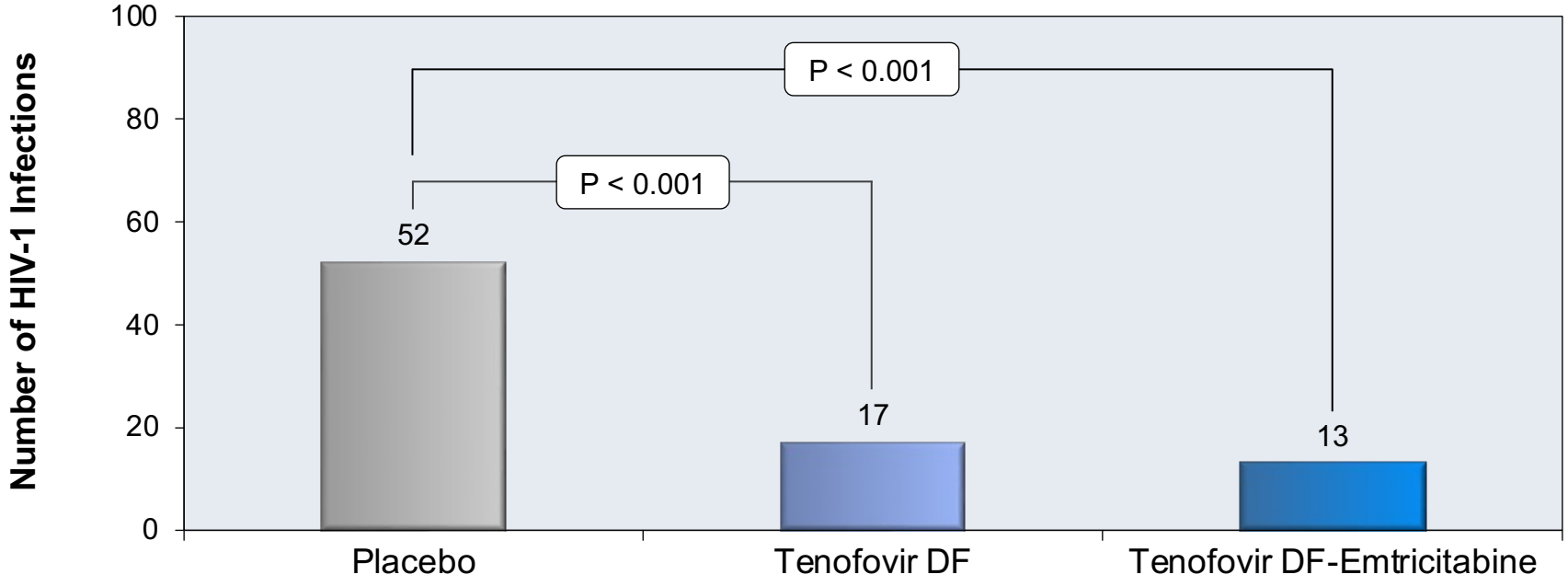


11 total couples found to be ineligible and not included in the intention-to-treat analysis.

Source: Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Oral HIV PrEP for Heterosexual Couples in Kenya and Uganda
Partners PrEP: Results

Number of HIV-1 Infections

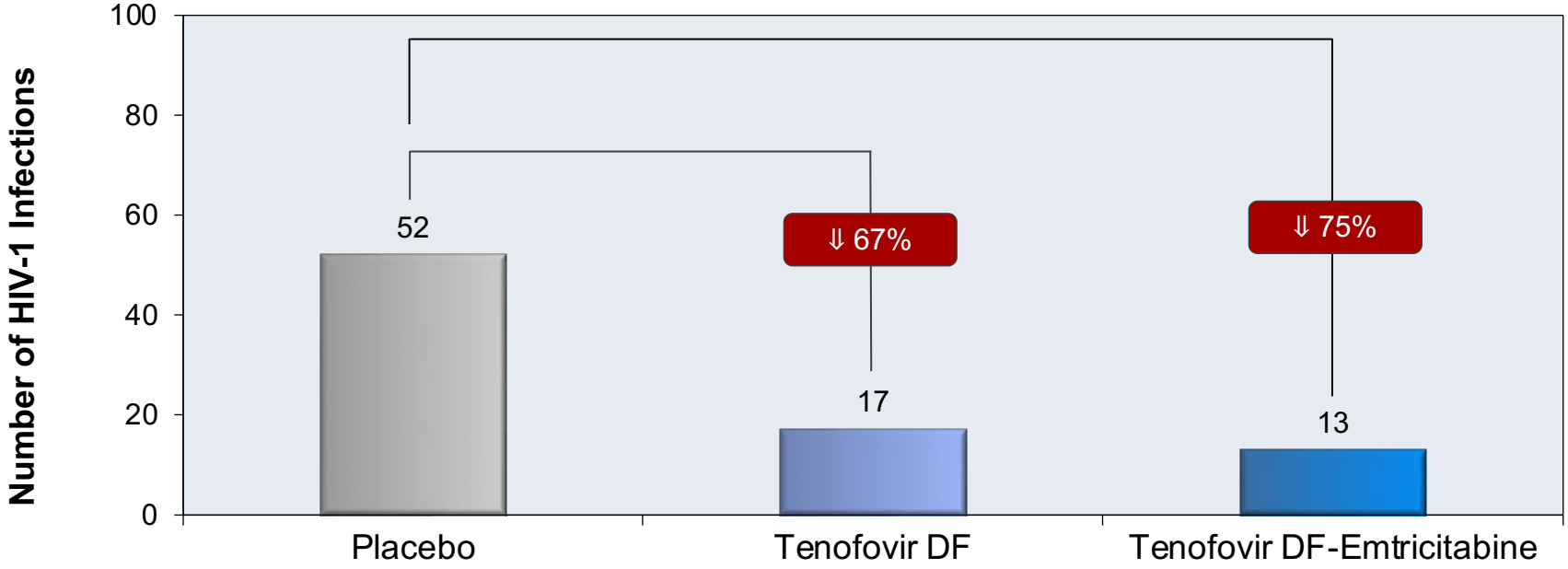


Study stopped July 2011 by DSMB because of PrEP efficacy

Source: Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Oral HIV PrEP for Heterosexual Couples in Kenya and Uganda
Partners PrEP: Results

Risk Reduction Compared with Placebo

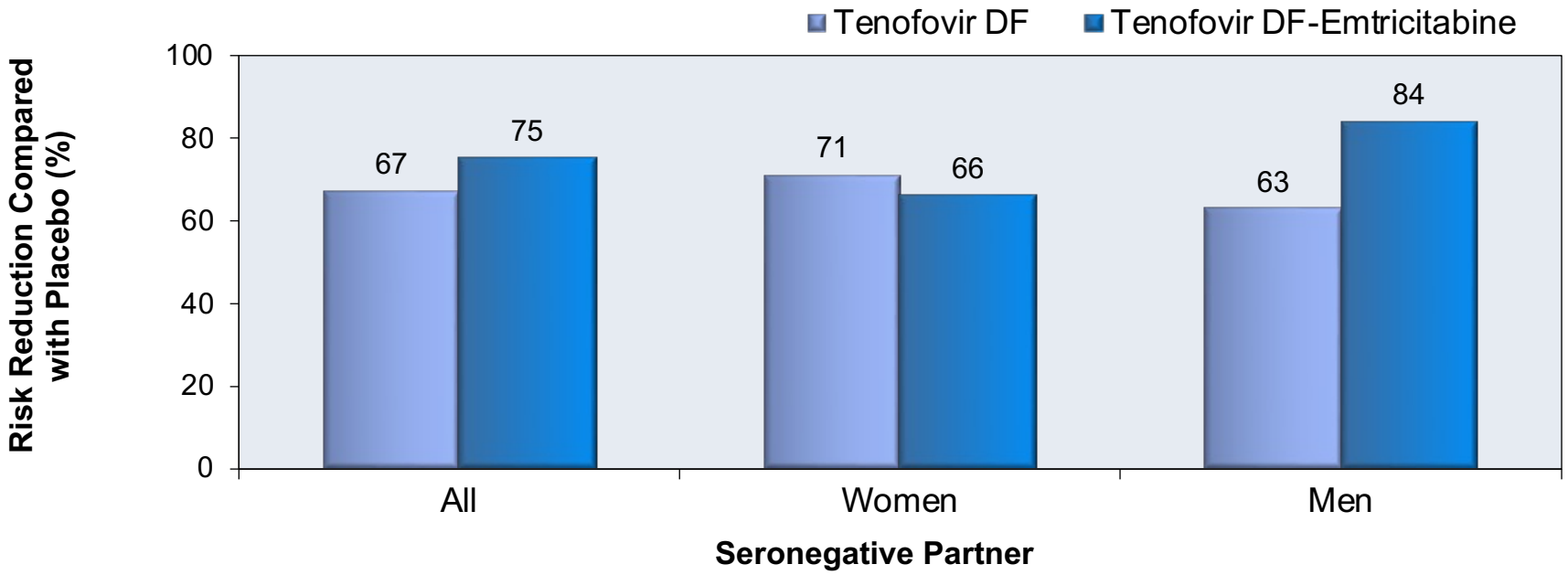


Study stopped July 2011 by DSMB because of PrEP efficacy

Source: Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Oral HIV PrEP for Heterosexual Couples in Kenya and Uganda
Partners PrEP: Results

HIV Risk Reduction Based on Gender of Seronegative Partner



Study stopped July 2011 by DSMB because of PrEP efficacy

Source: Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Oral HIV PrEP for Heterosexual Couples in Kenya and Uganda
Partners PrEP: Conclusions

Conclusions: “Oral tenofovir DF and tenofovir DF- emtricitabine both protect against HIV-1 infection in heterosexual men and women.”

Source: Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Acknowledgments

The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

AETC AIDS Education & Training Center Program

National HIV Curriculum

IDEA INFECTIOUS DISEASES EDUCATION & ASSESSMENT