



# CDC U.S. EXTENDED PrEP SAFETY TRIAL

## QUICK FACTS ON TRIAL DESIGN

CDC's Phase II U.S. extended safety study of oral tenofovir for HIV prevention among gay and bisexual men was conducted by CDC in collaboration with the San Francisco Department of Public Health, the AIDS Research Consortium of Atlanta, and Fenway Community Health in Boston. The trial examined if a 300 mg tablet of tenofovir disoproxil fumarate taken daily was safe among HIV-negative men who have sex with men (MSM)<sup>1</sup>. It was conducted in San Francisco, Atlanta, and Boston.

This study was the first to examine clinical and behavioral safety of daily tenofovir for HIV prevention among MSM — an approach known as pre-exposure prophylaxis, or PrEP. A prior study conducted in Ghana, Nigeria, and Cameroon found that the drug was safe among heterosexual women at high risk. Several studies are underway to examine the efficacy of PrEP for HIV prevention. It will be necessary to wait for the results of those studies to determine whether PrEP can prevent HIV infection.

### Overall Trial Design

- ▶ The study enrolled 400 HIV-negative MSM who reported having had anal intercourse with a man in the prior 12 months. Participants were randomly assigned to one of four study arms. Neither researchers nor participants knew participants' group assignments.
- ▶ Participants in two arms of the study received either tenofovir or placebo (a tablet without active medication) immediately upon enrollment, while participants in the remaining two arms received either tenofovir or placebo after nine months of enrollment. This design allowed researchers to compare risk behaviors among those taking a daily pill and those not taking pills.

### Informed Consent and Prevention Services

- ▶ All trial participants were fully informed about risks and benefits of participation, and were required to pass a comprehension test prior to providing written informed consent. Participants were free to withdraw from the trial at any time and for any reason.
- ▶ All participants received regular HIV education, extensive risk-reduction counseling, condoms, and STD testing and treatment throughout the trial.

### Monitoring and Care for Study Participants

- ▶ The study was conducted in accordance with U.S. and international ethical and safety guidelines. The health of participants was closely monitored throughout the trial, including examination of both clinical and behavioral safety on an ongoing basis. An independent safety review committee met regularly during the trial to examine participant safety data and ensure no problems had emerged.
- ▶ Participants were tested regularly for HIV, and those who became infected during the trial were linked to appropriate counseling and HIV care and treatment.

### Community Involvement

- ▶ All three study sites established active community advisory boards that were consulted regularly about study procedures and educational materials for potential participants. Members of these boards provided ongoing advice during the trial.

### Additional Information

More detailed information about PrEP trials being conducted by CDC and others is available at the following websites:

- ▶ [www.cdc.gov/hiv/prep/resources/factsheets/index.htm](http://www.cdc.gov/hiv/prep/resources/factsheets/index.htm)
- ▶ [www.avac.org/prep](http://www.avac.org/prep)

<sup>1</sup> The term men who have sex with men is used in CDC surveillance systems. It indicates the behaviors that transmit HIV infection, rather than how individuals self-identify in terms of their sexuality.