Ongoing and Planned PrEP Trials as of December 2008

Location	Sponsor/ Funder	Population (mode of exposure)	Intervention arms	PrEP strategy(ies) being tested	Status / Expected completion
United States	CDC	400 gay men and other men who have sex with men (penile/rectal)	1	TDF	Fully enrolled – Ongoing / 2009
Thailand	CDC	2,400 injecting drug users (parenteral)	1	Tenofovir disoproxil fumarate (TDF)	Enrolling / 2010
Brazil, Ecuador, Peru, South Africa, Thailand, US (iPrEX Study)	NIH, BMGF	3,000 gay men and other men who have sex with men (penile/rectal)	1	TDF+FTC	Enrolling / 2010
Botswana	CDC	1,200 heterosexual men and women (penile and vaginal)	1	TDF+emtricitabine (FTC) (switched from TDF Q1 2007)	Enrolling / 2011
Kenya, Uganda (Partners PrEP Study)	BMGF	3,900 serodiscordant heterosexual couples (penile and vaginal)	2	TDF; TDF + FTC	Enrolling / 2012
Kenya, Malawi, South Africa, Tanzania, additional sites TBD (FEMPrEP)	FHI, USAID	3,900 high-risk women (vaginal)	1	TDF+FTC	Planning / 2012 Anticipated start Q1/2009
Southern Africa, sites to be determined (VOICE Study)	MTN, NIH	4,200 sexually active women (vaginal)	3	TDF; TDF+FTC; TDF gel	Planning / 2012 Anticipated start Q1/2009

BMGF – Bill & Melinda Gates Foundation; CDC - US Centers for Disease Control; FHI – Family Health International; MTN – Microbicide Trials Network; NIH – US National Institutes of Health; USAID – United States Agency for International Development

Completed PrEP Trials

Location	Sponsor / Funder	Population (mode of exposure)	Intervention arms	PrEP strategy being tested	Completion date	Key findings
Ghana[1]	FHI	936 women (vaginal)	1	TDF	2006	No statistically significant differences in rates of adverse events between women who received the study drug and those who received placebo during the trial; in addition no evidence in this sample of women of complications such as hepatitis flares after the study drug (which is also a hepatitis treatment) was stopped. There were two (2) infections among women taking the study drug compared to six (6) among women receiving placebo. This is not a statistically significant finding and should not be interpreted as evidence that PrEP works. However these safety data do provide a rationale for further study.

[1] Analysis included some data gathered in Nigeria and Cameroon prior to closure of trials at these sites.

PrEP Trials Completed, Halted or Cancelled to Date

Location	Sponsor / Funder	Population	Reason for closing
Cambodia	NIH/FHI	960 women (vaginal exposure)	Stopped before enrollment Controversy stemming from local and international activist groups' ethical concerns about standards of health care for volunteers during and after the trial
Cameroon	FHI	400 women (vaginal exposure)	Stopped after enrollment Controversy related to international debate around trial ethics and standard of care which originated with Cambodian trial
Malawi	FHI	400 men (penile exposure)	Stopped November 2005 before enrolling Concerns on the part of Malawi Ministry of Health that studies of tenofovir as PrEP could complicate use of the drug as a treatment for HIV-infected individuals
Nigeria	FHI	400 women (vaginal)	Stopped by trial sponsors due to concerns about local sites' capacity