

# Ongoing and Planned Pre-Exposure Prophylaxis (PrEP) Trials, January 2012



Trial	Phase	Start Date	Sponsor/ Funder ***	Location ***	Population *	Intervention arm(s) **	Status/Results Expected
<b>Open-label</b>							
<b>TDF2 Follow-Up Open Label Extension</b>	Open label	Q1 2012	CDC	Botswana	TDF 2 participants	Daily oral TDF/FTC	Protocol in preparation / Q1 – Q2 2013
<b>iPrEx OLE</b>	Open label extension	Q2 2011	NIH	Brazil, Ecuador, Peru, South Africa, Thailand, United States	iPrEx and ATN 082 participants offered opportunity to enroll in open label extension	HIV-negative participants offered daily TDF/FTC; HIV-positive participants offered continued monitoring and risk-reduction services	Enrolling / 2013
<b>Phase III, IIb (safety and effectiveness)</b>							
<b>ANRS IPERGAY</b>	Phase III	January 2012	ANRS	Canada, France (initial phase); other European countries (extension phase)	300 MSM (initial phase); 1,900 MSM (total enrollment)	On demand intermittent PrEP with Truvada taken at the time of sexual intercourse	Ongoing / Q3 2016
<b>VOICE (MTN 003)</b>	Phase IIb	September 2009	CONRAD, Gilead, MTN, NIAID, NIMH, NICHD,	South Africa, Uganda, Zimbabwe	5,029 women	Daily oral TDF/FTC	Fully enrolled / Q4 2012-Q1 2013 <i>Oral TDF and tenofovir gel arms dropped for futility based on data from DSMB reviews. Oral TDF/FTC and oral placebo arms continuing.</i>
<b>FEM-PrEP</b>	Phase III	May 2009	Early support from BMGF, FHI, USAID	Kenya, South Africa, Tanzania	3,900 women per protocol	Daily oral TDF/FTC or placebo	Data analysis / 2012 <i>Stopped for futility in April 2011, with 28 HIV infections in each arm.</i>
<b>Partners PrEP</b>	Phase III	May 2008	BMGF	Kenya, Uganda	4,700 serodiscordant heterosexual couples	Daily oral TDF; daily oral TDF/FTC	Fully enrolled / Q1 2013 <i>DSMB review in July 2011 showed daily TDF reduced risk of HIV by an average of 62%; daily TDF/FTC reduced risk of HIV by an average of 73%. As a result, placebo arms discontinued but the trial is ongoing. Additional data expected 2013.</i>
<b>Bangkok Tenofovir Study (CDC4370)</b>	Phase II/III	June 2005	CDC	Thailand	2,400 injecting drug users	Daily oral TDF	Fully enrolled / Q2 2012
<b>Phase I, II, I/II (safety, adherence, acceptability, feasibility)</b>							
<b>HPTN 069</b>	Phase II	February-March 2012	ACTG, HPTN, NIH	US	400 MSM	MVC 300mg orally once daily; MVC 300mg +FTC 200 mg orally once daily; MVC 300mg + TDF 300mg orally once daily; TDF 300mg + FTC 200mg orally once daily	In development
<b>TMC278LA (SSAT 040)</b>	Phase I	January 2011	St. Stephens AIDS Trust	UK	66 men and women	Single dose of TMC278LA injected intramuscularly in different doses	Enrolling / 2012
<b>ADAPT (HPTN 067)</b>	Phase II	September 2011	DAIDS, Gilead, HPTN, NIMH	South Africa, Thailand	180 women in Cape Town, 180 men in Bangkok	Intermittent dosing of TDF/FTC	Enrolling

AIDS Clinical Trials Group (ACTG); Adolescent Trial Network (ATN); Bill and Melinda Gates Foundation (BMGF); United States Centers for Disease Control and Prevention (CDC); Division of Acquired Immunodeficiency Syndrome (DAIDS); Family Health International (FHI); Emtricitabine (FTC); HIV Prevention Trials Network (HPTN); International AIDS Vaccine Initiative (IAVI); Microbicide Trials Network (MTN); Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); United States National Institute on Drug Abuse (NIDA); United States National Institutes of Health (NIH); National Institute of Mental Health (NIMH); Quarters 1 – 4 (Q1, Q2, Q3, Q4); To be determined (TBD); Tenofovir disoproxil fumarate (TDF); United States Agency for International Development (USAID)

\*The studies listed in this table are HIV prevention trials and thus are looking at whether the experimental intervention reduces the risk of HIV infection—trial participants are HIV-negative, unless otherwise noted. \*\*In addition to the assigned intervention, all trial participants receive a standard HIV prevention package, possibly including but not limited to: risk reduction counseling, condom provision and behavioral interventions.

\*\*\* Countries, sponsors and funders are listed alphabetically.