ONGOING AND PLANNED PRE-EXPOSURE PROPHYLAXIS (PREP) TRIALS

April 2012

Trial	Phase	Start Date	Sponsor [1]	Location [1]	Population [2]	Intervention arm(s) [3]	Status/Results Expected
Open-label							
TDF2 Follow-Up OLE	Open-label	Q3 2012	CDC	Botswana	TDF 2 participants	Daily oral TDF/FTC	Protocol in preparation / Q1 – Q2 2013
iPrEx OLE	Open-label	Q2 2011	NIH	Brazil, Ecuador, Peru, South Africa, Thailand, US	iPrEx, ATN 082 and CDC Phase II extended safety study of TDF among HIV negative men (Project T) participants offered opportunity to enroll in open label extension	HIV-negative participants offered daily TDF/FTC (if eligible) and may remain in follow-up not receiving TDF/FTC if they choose; HIV-positive participants offered continued monitoring and risk-reduction services	Enrolling / 2014
Phase III, II/III, IIb (safety and effectiveness)							
ANRS IPERGAY	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 TDF/FTC taken at the time of sexual intercourse	Ongoing / Q3 2016
VOICE (MTN 003)	Phase IIb	September 2009	CONRAD, Gilead, MTN, NIAID, NICHD, NIMH	South Africa, Uganda, Zimbabwe	5,029 women	Daily oral TDF/FTC	Fully enrolled / Q1 2013 *Oral TDF and tenofovir gel arms dropped for futility based on data from DSMB reviews. Oral TDF/FTC and oral placebo arms continuing.*
Partners PrEP	Phase III	May 2008	BMGF	Kenya, Uganda	4,700 serodiscordant heterosexual couples	Daily oral TDF; daily oral TDF/FTC	Fully enrolled / Q1 2013 *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 and participants offered the chance to be randomized to active arms for balance of the study. Additional data expected 2013.*
Bangkok Tenofovir Study (CDC4370)	Phase II/III	June 2005	CDC	Thailand	2,400 injecting drug users	Daily oral TDF	Fully enrolled / Q4 2012
Phase I, II, I/II (safety, adherence, acceptability, feasibility)							
NEXT-PrEP (HPTN 069/ ACTG 5305)	Phase II	Q2 2012	ACTG, HPTN, NIAID	US	400 MSM	Four arm study of daily oral PrEP: MVC 300mg; MVC 300mg + FTC 200 mg; MVC 300mg + TDF 300mg; TDF 300mg + FTC 200mg. A total of three pills per day will be taken.	In development
ADAPT (HPTN 067)	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
TMC278LA (SSAT 040)	Phase I	January 2011	St. Stephens AIDS Trust	UK	66 men and women	Single dose of TMC278LA injected intramuscularly in different doses	Enrolling / 2012

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

1. Countries, sponsors and funders are listed alphabetically. 2. The studies listed in this table are HIV prevention trials and thus trial participants are HIV-negative, unless otherwise noted. 3. 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.