






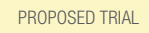
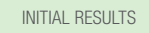


TRIAL RESULTS: A COMPREHENSIVE TIMELINE OF HIV PREVENTION EFFICACY AND FOLLOW-ON TRIALS* (January 2012)

2009	2010	2011	2012	2013	2014+
<p>HPTN 035 Fewer infections in women using PRO 2000 than women using the placebo gel but difference not statistically significant. No evidence of benefit in women using BufferGel.</p>	<p>CAPRISA 004 1% tenofovir gel before and after sex reduced risk of HIV by an average of 39% in women (95% CI 6 to 60; P=0.017).</p>	<p>FEM-PrEP No evidence of benefit daily oral TDF/FTC. Trial stopped early for futility.</p>	<p>CDC 4370 Phase II/III trial to evaluate the safety and efficacy of daily oral TDF for HIV prevention in HIV-negative injecting drug users (Thailand)</p>	<p>VOICE (MTN-003) Phase IIb trial to evaluate the safety and effectiveness of daily oral TDF/FTC to prevent HIV infection in women; <i>daily oral TDF and 1% tenofovir gel arms were dropped for futility after DSMB reviews in 2011.</i></p>	<p>FACTS 001 Phase III trial to evaluate the safety and effectiveness of 1% tenofovir gel before and after sex to prevent HIV and HSV-2 infection in women (South Africa)</p>
<p>PARTNERS IN PREVENTION No evidence of reduced rates of HIV transmission but reduced rates of genital ulcers and HIV viral load.</p>	<p>iPrEx Daily oral TDF/FTC reduced risk of HIV by an average of 44% in gay men, other men who have sex with men and transgender women (95% CI 15.4 to 62.6; P=0.005).</p>	<p>HPTN 052 Early results released based on data from DSMB review in HIV-serodiscordant couples showed that ART initiation at CD4 cell count 350–550 reduced risk of transmitting HIV to the uninfected sexual partner by 96% (CI 73% to 99%; P<0.001).</p>		<p>PARTNERS PrEP Phase III trial to evaluate the safety and efficacy of two different strategies to prevent HIV transmission in HIV-serodiscordant couples: daily oral TDF and daily oral TDF/FTC provided to HIV-negative partners. <i>Since initial results released in July 2011, TDF and TDF/FTC arms will continue and those receiving placebo will be randomized to TDF or TDF/FTC.</i></p>	<p>HPTN 052 Phase III trial to evaluate the effectiveness of two treatment strategies to prevent HIV transmission in HIV-serodiscordant couples: immediate ART (CD4 350-550) and ART as indicated by guidelines. <i>Since initial results released in May 2011, those receiving ART continue and those in the delayed arm offered ART.</i></p>
<p>ALVAC-AIDSVAX (RV144) ALVAC-HIV prime/AIDSVAX B/E boost vaccine reduced risk by an average of 31% (95% CI 1.1 to 52.1; P=0.04). No effect on viral load.</p>		<p>PARTNERS PrEP Early results released based on data from DSMB review showed that in HIV-serodiscordant couples daily oral TDF reduced risk of HIV in seronegative partners by an average of 62% (95% CI 34 to 78; P=0.0003); daily oral TDF/FTC reduced risk of HIV by an average of 73% (95% CI 49 to 85; P=0.0001).</p>		<p>iPrEx OLE (Open-Label Extension) Safety and adherence follow-on trial to evaluate daily oral TDF/FTC in HIV-negative iPrEx trial participants (Brazil, Ecuador, Peru, South Africa, Thailand and the US)</p>	<p>ANRS IPERGAY Pilot for a Phase III trial to evaluate the safety and efficacy of intermittent oral TDF/FTC, before and after sex, in MSM and transgender women (Canada, France)</p>
<p>MDP 301 No evidence of benefit in women using PRO 2000.</p>		<p>TDF2 (CDC 4940) Daily oral TDF/FTC reduced risk of HIV by an average of 63% in heterosexual men and women (95% CI 21 to 83; P=0.013).</p>		<p>HVTN 505 Phase IIb test-of-concept trial to evaluate the safety and efficacy of a DNA prime/Ad5-boost vaccine strategy to reduce risk of HIV infection and decrease viral load in participants who later become infected with HIV (US)</p>	<p>TasP (ANRS 12249) Phase III trial to assess the acceptability, feasibility, and efficacy of regular and widespread HIV testing with immediate ART initiation (South Africa) <i>Proposed start date Q1 2012</i></p>
		<p>VOICE (MTN 003) Oral TDF and 1% tenofovir gel arms stopped for futility based on data from DSMB review. Study now looking at effectiveness of daily oral TDF/FTC compared to placebo in women.</p>		<p>CAPRISA 008 Open-label implementation study to evaluate the effectiveness of distributing 1% tenofovir gel in communities where CAPRISA 004 took place (South Africa) <i>Proposed start date Q2 2012</i></p>	<p>The Ring Study (IPM 027) Phase III trial to evaluate the safety and efficacy of a long-acting dapivirine vaginal ring, replaced every four weeks (Kenya, Malawi, Rwanda, South Africa, TBD) <i>Proposed start date Q1 2012</i></p>
				<p>ALVAC-AIDSVAX (RV144) Late-Boost Strategies Phase II trial to evaluate safety, immunogenicity and tolerability of late-boost regimens of AIDSVAX B/E alone, ALVAC-HIV alone, or ALVAC-HIV/AIDSVAX B/E combination in HIV-negative participants from the RV144 trial (Thailand) <i>Proposed start date 2012</i></p>	<p>ASPIRE (MTN-020) Phase III trial to evaluate the safety and efficacy of a long-acting dapivirine vaginal ring, replaced every four weeks (Malawi, South Africa, Uganda, Zambia, Zimbabwe) <i>Proposed start date mid-2012</i></p>
				<p>TDF2 Open-Label Extension (CDC 494) Follow-on trial of daily oral TDF/FTC in heterosexual men and women (Botswana) <i>Proposed start date Q1 2012</i></p>	<p>CHOICE (MTN-018) Phase IIb open-label follow-on study to VOICE to collect additional data if daily oral TDF/FTC proves effective (South Africa, Uganda, Zimbabwe) <i>Proposed start date 2013</i></p>

 VACCINE	 TREATMENT AS PREVENTION
 MICROBICIDE	 HERPES SIMPLEX VIRUS 2 (HSV-2) TREATMENT/SUPPRESSION
 PRE-EXPOSURE PROPHYLAXIS (PrEP)	 VAGINAL RING
 TRIAL COMPLETED OR STOPPED	 PROPOSED TRIAL
 INITIAL RESULTS	

* The trial end-dates are estimates—due to the nature of clinical trials the actual dates may change. Trials listed here are subject to interim analyses. To view this timeline online with trial details please visit www.avac.org/timeline.