

# Ongoing and Planned Clinical Trials of Topical Microbicide Candidates, January 2012



Study Name	Phase	Start Date	Sponsor/Funder ***	Locations ***	Population *	Intervention arms **	Status/Expected Completion
<b>Phase III (safety and effectiveness)</b>							
<b>ASPIRE (MTN 020)</b>	Phase III	Q2-Q3 2012	IPM, MTN, NIAID, NIMH	Malawi, South Africa, Uganda, Zambia, Zimbabwe	3,476 women	4-week vaginal dapivirine ring	Pending / Q4 2014 - Q1 2015
<b>IPM 027</b>	Phase III	Q1 2012	IPM	Kenya, Malawi, South Africa, Rwanda, TBD	1,650 women	4-week vaginal dapivirine ring	Planned / 2015
<b>FACTS 001</b>	Phase III	October 2011	South Africa DST, South Africa National DOH, USAID	South Africa (Cape Town, Soweto, Rustenburg, Soshanguve, GaRankuwa, Tembisa, Yeoville, Ladysmith, Pietermaritzburg)	2,200 women	1% tenofovir gel up to 12 hours before intercourse and within 12 hours following intercourse	Planned / Q1-Q2 2014
<b>Phase II (safety, adherence, acceptability, feasibility)</b>							
<b>MTN 017</b>	Phase II	Q2-3 2012	CONRAD, Gilead, MTN, NIAID, NIMH,	Peru, South Africa, Thailand, United States	216 men who have sex with men	Reformulated (reduced glycerin) rectal 1% tenofovir gel	In development / Q1-Q2 2014
<b>Phase I/II (safety, adherence, acceptability, feasibility)</b>							
<b>TFV-LNG IVR ring</b>	Phase I/II	Q2 2012	CONRAD	EVMS and TBD	TBD	TFV-LNG IVR ring	Planned / TBD
<b>IPM 015</b>	Phase I/II	April 2010	IPM	Kenya (Kisumu), Malawi (Lilongwe), South Africa (Brits, Edendale, Mbekweni, Ladysmith, Masiphumelele, Nyanga, Pinetown), Tanzania (Moshi)	280 women	4-week vaginal dapivirine ring	Data analysis / Q1 2012
<b>IPM 014A</b>	Phase I/II	November 2009	IPM	Kenya (Kisumu), Malawi (Blantyre), South Africa (Brits, Ladysmith, Mbekweni, Pinetown, Nyanga), Rwanda (Kigali)	280 women	Once-daily dapivirine vaginal gel	Data analysis / Q2 2012
<b>IPM 014B</b>	Phase I/II	September 2009	IPM	South Africa (Brits, Mbekweni and Masiphumelele)	100 women	Once-daily dapivirine vaginal gel	Data analysis / Q2 2012
<b>IPM 020</b>	Phase I/II	July 2009	IPM	United States (Bronx, NY; Los Angeles, CA; Chicago, IL; Baltimore, MD; Birmingham, AL)	128 women	Once-daily dapivirine vaginal gel	Data Analysis / Q2 2012
<b>Phase I (safety, adherence, acceptability, feasibility)</b>							
<b>Safety and Pharmacokinetic Assessment of a NNRTI Microbicide Gel Formulation in HIV Negative Women</b>	Phase I	Q3 2012	Population Council, USAID	United States (sites TBD)	30 women	MIV-150/Zinc acetate vaginal gel vs. carageenan-based placebo gel	Planned / Q1 2013
<b>MTN 014</b>	Phase I	Q2-Q3 2012	CONRAD, MTN, NIAID, NIMH	South Africa, United States	TBD	Reformulated (reduced glycerin) rectal and vaginal 1% tenofovir gel	In development / Q2-Q3 2013
<b>MTN 011</b>	Phase I	Q2-Q3 2012	CONRAD, MTN, NIAID, NIMH	United States	TBD	1% tenofovir gel	In development / Q2-Q3 2013
<b>PK PD TFV ring</b>	Phase I	Q2 2012	CONRAD	EVMS and TBD	TBD	1% tenofovir vaginal ring	Planned / Q4 2012

<b>CONRAD Assess Contraceptive markers on vaginal immunity and the PK and PD of Tenofovir Gel on these methods and the menstrual cycle</b>	Phase I	January 2012	CONRAD	United States (Eastern Virginia Medical School; University of Pittsburgh School of Medicine); Dominican Republic (PROFAMILIA)	72 women	Depo-provera; 1% tenofovir vaginal gel	Ongoing / 2012-2013
<b>MTN 013 / IPM 026</b>	Phase I	November 2011	IPM, MTN, NIAID, NIMH	United States	48 women	Vaginal dapivirine ring (25 mg), vaginal maraviroc ring (100 mg), vaginal dapivirine-maraviroc ring (25 mg dapivirine + 100 mg maraviroc) for 28 days	Enrolling / Q1-Q2 2013
<b>MTN 005</b>	Phase I	June 2011	MTN, NIAID, NIMH, Population Council	India, United States	252 women and men	Placebo vaginal ring	Enrolling / Q1-Q2 2013
<b>MTN 008</b>	Phase I	April 2011	CONRAD, MTN, NIAID, NICHD	United States	90 pregnant women and 15 breastfeeding women	1% tenofovir gel for 7 days	Enrolling / Q2-Q3 2013
<b>MTN 012 / IPM 010</b>	Phase I	April 2011	IPM, MTN, NIAID, NIMH	United States	48 men	Once-daily dapivirine vaginal gel for 7 days	Results pending
<b>MTN 007</b>	Phase I	November 2010	CONRAD, MTN, NIAID, NIMH	United States	65 women and men	Reformulated (reduced glycerin) rectal 1% tenofovir gel	Results pending
<b>Project Gel</b>	Phase I	October 2010	NICHD, NIMH, CONRAD	Puerto Rico, United States	240 MSM	1% tenofovir and placebo rectal gel	Ongoing / December 2012
<b>AF 020</b>	Phase I	February 2009	AECOM, NIAID	United States	36 women	Amphora/ACIDFORM vaginal gel	Ongoing / TBD
<b>TFV/FTC and TFV only fast dissolve tablets Phase</b>	Phase I	TBD	CONRAD	EVMS and TBD	TBD	TFV/FTC and TFV only fast dissolve tablets	TBD
<b>Other</b>							
<b>Effects of TFV on Caprisa samples</b>	Pre-clinical	Q4 2013	CONRAD	EVMS and TBD	TBD	Tenofovir	Planned / 2014
<b>EMBRACE (MTN 016)</b>	Pregnancy exposure registry	October 2010	MTN, NIAID, NICHD	Malawi, South Africa, Uganda, Zambia, Zimbabwe	500 women and 300 infants	N/A	Enrolling / May 2013
<b>MTN 009</b>	Cross-sectional resistance study	September 2010	MTN, NIAID	United States	1074 women	N/A	Results pending
<b>MTN 003C</b>	MTN 003 (VOICE) Community Sub-study	July 2010	MTN, NIAID, NIMH	South Africa	275 participants (includes women in VOICE, their male partners, CAB members and community stakeholders)	N/A	Enrolling / late-2012 to early-2013
<b>A Simulated Microbicide Clinical Trial to Explore Willingness to Participate and Methods for Improving Reporting of Adherence Among a Sex-Workers</b>	Feasibility	February 2010	NIH, Population Council, USAID	India (Nellore, Andhra Pradesh)	267 female sex workers	HEC placebo topical vaginal gel	Data collection completed; analysis ongoing / December 2011

<b>MTN 003B</b>	MTN 003 (VOICE) bone mineral density sub-study	November 2009	Gilead, MTN, NIAID	Uganda, Zimbabwe	518 women	Oral TDF; oral TDF/FTC	Fully enrolled / late-2012 to early-2013
<b>MTN 015</b>	Seroconverter protocol	August 2008	MTN, NIAID	Malawi, South Africa, Uganda, Zambia, Zimbabwe	500 HIV-positive women	N/A	Enrolling / May 2011
<b>SILCS diaphragm plus TFV</b>	Phase I/II/III	TBD	CONRAD	TBD	TBD	SILCS diaphragm and Tenofovir	TBD

Eastern Virginia Medical School (EVMS); Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); International Partnership for Microbicides (IPM); Microbicide Trials Network (MTN); Not applicable (N/A); South Africa Department of Science Technology (DST), South Africa National Department of Health (DOH), Tenofovir (TFV); Tenofovir disoproxil fumarate (TDF); To be determined (TBD); United States Agency for International Development (USAID); United States National Institute of Allergy and Infectious Diseases (NIAID); United States National Institutes of Health (NIH); United States National Institute of Mental Health (NIMH)

*\*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.*