

Ongoing and Planned Clinical Trials of Topical Microbicide Candidates (September 2010)					
Study Name/ Phase	Location	Sponsor/ Funder	Population	Candidate(s)	Status/ Expected Completion
IPM 009 Phase III, effectiveness	Multiple countries, Africa	IPM	TBD, women	Dapivirine vaginal ring	Planned
MDP 302 Phase III	Mozambique, South Africa, Tanzania, Uganda, Zambia	MRC/UVRI	6,320 heterosexual women	Tenofovir gel	Planned
VOICE (MTN 003) Phase IIb, safety and effectiveness	Malawi, South Africa, Uganda, Zimbabwe	CONRAD, DAIDS/NIAID, Gilead, MTN, NICHD, NIMH	5,000 heterosexual women	Tenofovir gel; oral TDF; oral TDF/FTC	Ongoing/ Q3 2012
MTN 001 Phase II, adherence and P/K	South Africa, Uganda, United States	CONRAD, DAIDS/NIAID, Gilead, MTN	144 women	Tenofovir gel; oral TDF	Ongoing/ Q4 2010
MTN 010 Phase II, expanded safety	TBD	NIAID, MTN	150 women	UC-781 gel	Planned
IPM 014A Phase I/II, safety	Kenya, Malawi, Rwanda, South Africa	IPM	320 women	Dapivirine vaginal gel	Ongoing/ 2011
IPM 014B Phase I/II, safety	South Africa	IPM	320 women	Dapivirine vaginal gel	Data analysis/ 2010-2011
IPM 020 Phase I/II, safety	United States	IPM	180 women	Dapivirine vaginal gel	Ongoing/ 2011
IPM 015 Phase I/II, safety	South Africa, Kenya, Malawi, Rwanda, Tanzania	IPM	280 women	Dapivirine vaginal ring	Ongoing/ 2011
IPM 024 Phase I, P/K	Belgium	IPM	16 women	Dapivirine vaginal ring	Data analysis
MTN 002 Phase I, P/K and placental transfer	United States	CONRAD, MTN, NIAID, NICHD	16 pregnant women	Tenofovir gel	Data analysis
TFV 010 Phase I	United States	NIAID	30 women	Tenofovir gel	Data analysis/ Q2 2010
AF 020 Phase I	United States	AECOM, NIAID	36 women	Amphora™ / ACIDFORM™ gel	Ongoing/ Q4 2010
IPM 013 Phase I, P/K	Belgium	IPM	48 women	Dapivirine vaginal ring	Ongoing/ 2010-2011
Pilot Study Phase I	United States	CONRAD	15 women	UC-781 gel	Ongoing
IPM 010/ MTN 012 Phase I, male tolerance	United States	IPM/ MTN	TBD	Dapivirine gel	Planned
MIV-150/Zinc Salt Gel Study Phase I	TBD	Population Council	TBD	MIV-150/zinc acetate gel	Planned
MTN 007 Phase I, rectal safety and acceptability	United States	CONRAD, MTN, NIAID	60 men and women	Tenofovir gel	Planned
MTN 008 Phase I, expanded safety	United States	MTN, NIAID	230 mothers and their infants	Tenofovir gel	Planned
Vaginal Applicator Study Phase I	Dominican Republic	CONRAD, PATH	25 women	Tenofovir gel	Planned

PK/PD, Mucosal Safety Study Phase I	Dominican Republic, United States	CONRAD	50 women	UC-781 gel	Planned
Zinc Salt Gel Study Phase I	TBD	Population Council	TBD	Zinc acetate gel	Planned
IPM 011 N/A, safety and acceptability	South Africa, Tanzania	IPM	220 women	Placebo vaginal ring	Data analysis/ Q3 2010
MTN 003B N/A, bone mineral density substudy	Malawi, South Africa, Uganda, Zambia, Zimbabwe	MTN, NIAID	300 women (enrolled in oral arm of MTN 003)	Oral TDF/FTC; oral TDF	Ongoing
MTN 015 N/A, seroconverter protocol	Malawi, South Africa, Uganda, Zambia, Zimbabwe	MTN, NIAID	HIV-positive women	N/A	Ongoing
EMBRACE (MTN 016) N/A, pregnancy exposure registry	Malawi, South Africa, Uganda, Zambia, Zimbabwe	MTN, NIAID, NICHD	Pregnant women and their infants	N/A	Ongoing
Adherence in Sex-workers N/A, simulated trial	India	Population Council	TBD, female sex workers	Placebo gel	Ongoing
IPM 007 and IPM 008 N/A, seroconverter protocol	Kenya, Malawi, Rwanda, South Africa	IPM	N/A, HIV-positive women	N/A	Planned
MTN 009 N/A, cross-sectional substudy	Various	MTN, NIAID	350 HIV-positive women	N/A	Planned
MTN 003C N/A, product adherence substudy	Malawi, South Africa, Uganda, Zambia, Zimbabwe	MTN, NIAID	1,375 trial participants, male partners, CAB members, key stakeholders	N/A	Planned
MTN 005 N/A, expanded safety and acceptability	India, United States	IPM, MTN, NIAID	252 women	Placebo vaginal ring	Planned
Adherence Study N/A, simulated trial	Zambia	Population Council	TBD	Placebo gel and vaginal ring	Planned
<p>BMGF: Bill and Melinda Gates Foundation; CAB: community advisory board; CAPRISA: Centre for the AIDS Programme of Research in South Africa; FHI: Family Health International; IPM: International Partnership for Microbicides; MRC/UVRI: Uganda Research Unit on AIDS; MTN: Microbicide Trials Network; N/A: not applicable; NIAID: US National Institute of Allergy and Infectious Diseases; NICHD: Eunice Kennedy Shriver National Institute of Child Health and Human Development; NIMH: US National Institute of Mental Health; RMP: Rectal Microbicide Program; TBD: to be determined; TDF: tenofovir disoproxil fumarate; USAID: United States Agency for International Development</p>					