

| Ongoing and Planned Clinical Trials of Topical Microbicide Candidates (June 2010) | | | | | |
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| <i>Study Name/ Phase</i> | <i>Location</i> | <i>Sponsor/ Funder</i> | <i>Population</i> | <i>Candidate(s)</i> | <i>Status</i> |
| 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 |
| CAPRISA 004 Phase IIb, safety and effectiveness | South Africa | CAPRISA, CONRAD, FHI, Gilead, LIFElab, USAID | 900 heterosexual women | Tenofovir gel | Completed |
| VOICE (MTN 003) Phase IIb, safety and effectiveness | Malawi, South Africa, Uganda, Zimbabwe | CONRAD, Gilead, MTN, NIAID, NICHD, NIMH | 5,000 heterosexual women | Tenofovir gel; oral TDF; oral TDF/FTC | Ongoing |
| MTN 001 Phase II, adherence and P/K | South Africa, Uganda, United States | CONRAD, Gilead, MTN, NIAID | 144 women | Tenofovir gel; oral TDF | Ongoing |
| 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 |
| IPM 014B Phase I/II, safety | South Africa | IPM | 320 women | Dapivirine vaginal gel | Ongoing |
| IPM 020 Phase I/II, safety | United States | IPM | 180 women | Dapivirine vaginal gel | Ongoing |
| IPM 015 Phase I/II, safety | South Africa (ongoing), Kenya, Malawi, Rwanda, Tanzania, Zambia (planned) | IPM | 280 women | Dapivirine vaginal ring | Ongoing |
| IPM 024 Phase I, P/K | Belgium | IPM | 16 women | Dapivirine vaginal ring | Data analysis |
| A04 095 Phase I | Dominican Republic, United States | CONRAD, IPM, USAID | 49 women | Tenofovir gel | 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 |
| MTN 004 Phase I, safety and acceptability | United States | MTN, NICHD | 61 women | SPL7013 gel | Data analysis |
| RMP 002/ MTN 006 Phase I, rectal safety and acceptability | United States | CONRAD, Gilead, MTN, NIAID | 18 men and women | Tenofovir gel; oral TDF | Data analysis |
| AF 020 Phase I | United States | AECOM, NIAID | 36 women | Amphora™ / ACIDFORM™ gel | Ongoing |
| IPM 013 Phase I, P/K | Belgium | IPM | 48 women | Dapivirine vaginal ring | Ongoing |
| Pilot Study Phase I | United States | CONRAD | 15 women | UC-781 gel | Ongoing |
| IPM 010 Phase I, male tolerance | TBD | IPM | TBD | Dapivirine gel | Planned |

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| 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 | 230 women | Placebo vaginal ring | Data analysis |
| 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 N/A, seroconverter protocol | Kenya, Malawi, Rwanda, South Africa, Tanzania, Zambia | 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 |
| 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 | | | | | |