

**MICROBICIDE AND PrEP CANDIDATES IN PLANNED AND/OR FUNDED CLINICAL TRIALS  
SUMMARY AS OF OCTOBER 2009**

| <i>Phase</i> | <i>Candidate Name</i>                           | <i>MoA</i> | <i>Title of Study</i>   | <i>Sponsor*</i>                            | <i>Sites by Country</i>                               |
|--------------|---|------------|---|--|---|
| <b>3</b>     | BufferGel <sup>®</sup> : Barrier Method and Gel | VDE        | Trial of the diaphragm with a candidate microbicide to prevent sexually transmitted infections (MIARADIA) <sup>†</sup>                                      | CDC, CONRAD, NIAID/NIH, UNC, UNC-MD, USAID | Madagascar  |
|              | Dapivirine: Gel and Ring                        | RI         | Dapivirine efficacy study (IPM 009)   | IPM  | Various   |
|              | Tenofovir: Gel                                  | RI         | Daily or pericoital tenofovir gel for the prevention of vaginally acquired HIV (MDP 302)  | MRC/UVRI                                   | Mozambique, South Africa, Tanzania, Uganda, Zambia    |
| <b>2/3</b>   | Invisible Condom <sup>®</sup> : Gel             | EFI        | Effectiveness of Invisible Condom <sup>®</sup> in high-risk women <sup>‡</sup>  |  |   |
| <b>1/2</b>   | Dapivirine: Ring                                | RI         | Safety of an intravaginal matrix ring with dapivirine for the prevention of HIV infection in healthy HIV-negative women (IPM 015)                           | IPM  | Kenya, Malawi, Rwanda, South Africa, Tanzania, Zambia |
|              | Dapivirine: Ring                                | RI         | Dapivirine vaginal ring expanded safety study (IPM 021) – <i>Status TBD</i>   | IPM  | Denmark, Germany, Netherlands, United Kingdom         |
| <b>1</b>     | Dapivirine: Gel                                 | RI         | Dapivirine gel male tolerance study (IPM 010)   | IPM  | TBD   |
|              | Dapivirine: Ring                                | RI         | PK and safety study in healthy HIV-negative women to assess delivery of dapivirine from matrix vaginal rings (IPM 013)                                      | IPM  | Belgium   |
|              | MIV-150 + gel: Gel                              | C          | <i>This study protocol is under review.</i>   | Population Council                         | TBD   |
|              | MIV-150: Ring                                   | RI         | <i>This study protocol is under review.</i>   | Population Council                         | TBD   |
|              | Tenofovir: Gel                                  | RI         | Rectal safety and acceptability study of 1% tenofovir gel (MTN-007)   | CONRAD, MTN/NIAID/DAIDS                    | United States   |
| <b>N/A</b>   | No product                                      | N/A        | Seroconverter protocol (IPM 007)  | IPM  |   |
|              | Placebo: Ring                                   | Placebo    | Expanded safety and acceptability study of a non-medicated intravaginal ring (MTN-005)  | DAIDS/NIAID, MTN                           | India, United States                                  |
|              | No product                                      | N/A        | EMBRACE (Evaluation of Maternal and Baby Outcome Registry After Chemoprophylactic Exposure) (MTN-016)   | DAIDS/NIAID/NICHD/NIH                      | Malawi, South Africa, Uganda, Zambia, Zimbabwe        |
|              | Placebo: Gel and Ring                           | Placebo    | Simulated microbicide clinical trial to explore methods for improving adherence and reporting of adherence among women                                      | Population Council                         | Zambia  |
|              | Placebo: Gel                                    | Placebo    | Simulated microbicide clinical trial to explore willingness to participate (WTP) and methods for improving reporting of adherence among a sex-worker cohort | Population Council                         | India   |

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*Definition of acronyms used in this table: Mechanism of Action (MoA), Entry/Fusion Inhibitor (EFI), Replication Inhibitor (RI), and Vaginal Defense Enhancer (VDE), Combination (C)*

*\*The Alliance uses the term “sponsor” as defined by the International Conference on Harmonisation (Guideline for Good Clinical Practice, 1996) as follows: “An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.” For definitions of acronyms, please visit the Alliance website.*

*†Because of recent political events in Madagascar, the plans for MIARADIA are being revised.*

*‡Currently un-funded.*