

**HIV/STI Prevention Research and Development:  
October 2009 Pipeline Update of Microbicide and PrEP Candidates\***

Number of microbicide and PrEP candidates in clinical trials: 11

- Total number of ARV-based HIV prevention candidates: 6

Number of clinical trials: 38

- Total number of ongoing clinical trials: 27
- Total number of planned/funded clinical trials: 11

Number of clinical candidates not currently in trials: 3

- Ethanol in Emollient Gel (U. Washington)
- Praneem Polyherbal Vaginal Tablet (ICMR)
- Terameprocol (U. Maryland)

Other ongoing studies:

- Assessment of markers of inflammation after vaginal product use (HEC vs. CS vs. N-9) (CONRAD) – Data Analysis
- Assessing reporting of adherence and sexual behavior in microbicide trials (ACASI) (Population Council) – Data Analysis

Other HIV prevention-related studies:

*Ongoing*

- Anorectal Microbicide Project (AMP): Observational study of rectal health and behaviors (UCLA)
- “In the Pipeline,” a Rectal Microbicide Registry, part of the Network for AIDS Research Los Angeles (NARLA)
- IPM 011: Safety and acceptability study of a placebo vaginal ring microbicide delivery method for prevention of HIV infection in women
- MTN-015: Observational cohort study of women following HIV-1 seroconversion in microbicide trials
- Product Acceptability Study II (PAS II): Market research study of vaginal film, vaginal tablet, and soft-gel capsule (IPM) – Study in data analysis in Burkina Faso and Zambia, and planned in Tanzania and Mozambique

*Planned*

- Adolescent women and microbicide trials: Assessing the challenges and opportunities to their participation (FHI/NIMH)
- IPM 007: Seroconverter protocol
- MTN-005: Expanded safety and acceptability study of a non-medicated intravaginal ring

**PIPELINE CHANGES SINCE 1 SEPTEMBER**

Changes

- MSPRO 030: Postcoital anti-viral activity of cervicovaginal secretions following intravaginal application of 0.5% PRO 2000/5 Gel (P) – Enrollment Completed, Data Analysis Ongoing (AECOM, Indevus, NIH)
- MTN 003 (VOICE): Safety and effectiveness of tenofovir 1% gel (PMPA) with two oral HIV prevention approaches - tenofovir and Truvada™, a tenofovir-FTC drug combination – Now Ongoing, Sites in Malawi, South Africa, Uganda, Zambia, Zimbabwe
- MTN 006: Safety, acceptability, and pharmacokinetic trial of topical, vaginally-formulated tenofovir 1% gel applied rectally compared with oral TDF (RMP-02/MTN-006) – Now Open to Accrual
- Safety and acceptability of CAP vaginal microbicide soft tablet – Study Withdrawn

**Current Microbicide and PrEP Candidates**

<b>Candidate</b>	<b>Current Status – Phase</b>
PRO 2000: Gel	Ongoing – Phase 3
Truvada®: Oral†	Ongoing – Phase 3
Viread®: Oral†	Ongoing – Phase 3
Tenofovir: Gel†	Ongoing – Phase 2B
Dapivirine: Gel†	Ongoing – Phase 1/2
VivaGel®: Gel†	Ongoing – Phase 1/2
Acidform: Gel	Ongoing – Phase 1
Dapivirine: Ring	Ongoing – Phase 1
UC-781: Gel†	Ongoing – Phase 1
BufferGel®: Gel‡	Planned – Phase 3
Invisible Condom®: Gel	Planned – Phase 2/3
MIV-150+gel: Gel/Ring	Planned – Phase 1

\* This Update is a brief overview and summary of the microbicide and PrEP pipeline, produced and disseminated at the beginning of every month. As changes occur frequently, please visit [www.microbicide.org](http://www.microbicide.org) for the most recent information or details, and/or contact Alliance Research Associate Stephanie Tillman ([stillman@microbicide.org](mailto:stillman@microbicide.org)) for further information.

†These candidates are in multiple clinical trials. For more information, please view the summary tables of all Ongoing and Planned/Funded trials at [www.microbicide.org/cs/microbicide\\_pipeline](http://www.microbicide.org/cs/microbicide_pipeline).

‡Primary endpoints for this Phase 3 trial are gonorrhea and Chlamydia. For all other late-stage trials listed, HIV is primary endpoint.