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) 
- Pranecom 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 

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Current Status – Phase</th>
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<tbody>
<tr>
<td>PRO 2000: Gel</td>
<td>Ongoing – Phase 3</td>
</tr>
<tr>
<td>Truvada™: Oral</td>
<td>Ongoing – Phase 3</td>
</tr>
<tr>
<td>Viread®: Oral</td>
<td>Ongoing – Phase 3</td>
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<tr>
<td>Tenofovir: Gel</td>
<td>Ongoing – Phase 2B</td>
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<tr>
<td>Dapivirine: Gel</td>
<td>Ongoing – Phase 1/2</td>
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<tr>
<td>VivaGel™: Gel</td>
<td>Ongoing – Phase 1/2</td>
</tr>
<tr>
<td>AcidForm: Gel</td>
<td>Ongoing – Phase 1</td>
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<tr>
<td>Dapivirine: Ring</td>
<td>Ongoing – Phase 1</td>
</tr>
<tr>
<td>UC-781: Gel</td>
<td>Ongoing – Phase 1</td>
</tr>
<tr>
<td>BufferGel™: Gel</td>
<td>Planned – Phase 3</td>
</tr>
<tr>
<td>Invisible Condom™: Gel</td>
<td>Planned – Phase 2/3</td>
</tr>
<tr>
<td>MIV-150+gel: Gel/Ring</td>
<td>Planned – Phase 1</td>
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*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 for the most recent information or details, and/or contact Alliance Research Associate Stephanie Tillman (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. 

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

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