

**MICROBICIDE CANDIDATES IN ONGOING CLINICAL TRIALS
SUMMARY AS OF MAY 2008**



<i>Phase</i>	<i>Candidate Name</i>	<i>MoA</i>	<i>Title of Study</i>	<i>Sponsor*</i>	<i>Sites by Country</i>
3	PRO 2000/5 gel	EFI	Efficacy and safety of 0.5% PRO 2000/5 gel for the prevention of vaginally acquired HIV infection	Indevus, MRC, DFID (Funder)	South Africa, Tanzania, Uganda, Zambia
2B	Tenofovir gel	RI	Safety and effectiveness of the vaginal microbicide 1% Tenofovir gel to prevent HIV infection in women in South Africa (CAPRISA 004)	CAPRISA, USAID, LIFElab, Gilead, FHI, CONRAD	South Africa
2/2B	PRO 2000/5 gel (P) and BufferGel®	EFI, VDE	Safety and effectiveness study of the vaginal microbicides BufferGel® and 0.5% PRO 2000/5 Gel (P) for the prevention of HIV infection in women (HPTN 035)	NIAID, Indevus, ReProtect	Malawi, South Africa, United States, Zambia, Zimbabwe
1	Dapivirine (TMC120) gel	RI	Safety and pharmacokinetics of two intravaginal dapivirine gel formulations in healthy, HIV-negative women (IPM 012)	IPM	Belgium
	Ethanol in Emollient Gel		Safety and acceptance of 62% ethanol in emollient gel as a topical male microbicide	NIAID	Kenya
	HEC/CS/N-9 [†]	N/A	Assessment of markers of inflammation after vaginal product use	CONRAD/USAID	USA
	Tenofovir/PMPA gel	RI	1% tenofovir gel PK study (A04-095)	CONRAD, IPM/USAID	Dominican Republic, United States
	Tenofovir gel	RI	Interventional study of mucosal and antimicrobial responses to repeated vaginal applications of tenofovir gel in HIV-uninfected women	NIAID	United States
	UC-781 gel	RI	Safety and persistence of 0.1% UC-781 vaginal gel in HIV-1 seronegative women	NIAID, CONRAD	United States
	UC-781 gel	RI	Safety and acceptability study of the UC-781 vaginal microbicide gel formulation applied rectally in HIV-1 seronegative adults	UCLA, NIAID, CONRAD	United States
	UC-781 gel	RI	Safety and acceptability of 0.1% and 0.25% UC-781 topical vaginal microbicide in women and acceptability in their male partners	CDC, Thailand Ministry of Health, CONRAD	Thailand
	UC-781	RI	Male tolerance study (A06-104)	CONRAD	United States
	UC-781	RI	Safety and acceptability of UC-781 topical vaginal microbicide in heterosexual women and male partners (HC 101)	CONRAD, CDC, Emory University	United States
	VivaGel™ (SPL7013 gel)‡	EFI	Safety and acceptability of 3% w/w SPL7013 Gel (VivaGel™) applied vaginally in sexually active young women (MTN-004)**	DAIDS/NIAID, NICHD, Starpharma	Puerto Rico, United States
	VivaGel™ (SPL7013 gel)	EFI	Expanded safety and tolerability of 3% w/w SPL7013 Gel (VivaGel™) in healthy young women	NIH/NIAID/DMID, Starpharma	Kenya, United States
N/A	Placebo ring‡	Placebo	Safety and acceptability of a placebo vaginal ring microbicide delivery	IPM	Kenya, South

method for the prevention of HIV infection in women (IPM 011)

Africa, Tanzania

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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)

*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.”

† HEC, CS, and N-9 are not in development as microbicides. Rather, this trial’s objective is to characterize inflammation and genital epithelial changes in healthy, sexually abstinent women before, during, and after 13½ days of twice-daily applications of one of three products: a hydroxyethylcellulose (HEC)-based “universal” placebo, 6% cellulose sulfate, or 4% nonoxynol-9 (Conceptrol®) gel; to determine the degree of correlation between different methods of clinical assessment; and to determine the degree of correlation between the results of this clinical study and the results of the preclinical assessment of the same compounds.

‡ This trial has been paused pending a protocol amendment.

** ATN 062, “Tell Juliana,” is an observational study taking place in parallel to MTN 004. Please visit the MRDD for further information on this ancillary study.

‡ This device is intended for use with a microbicide.