

**MICROBICIDE CANDIDATES IN ONGOING CLINICAL TRIALS
SUMMARY AS OF NOVEMBER 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	DFID (Funder), Indevus, MRC	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, CONRAD, FHI, Gilead, LIFElab, South African Dept of Science and Technology, USAID,	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)	DAIDS/NIAID, Indevus, MTN, ReProtect	Malawi, South Africa, United States, Zambia, Zimbabwe
2	Tenofovir gel	RI	Adherence and pharmacokinetics study of oral and vaginal preparations of tenofovir (MTN 001)	CONRAD, DAIDS/NIAID, Gilead, MTN	South Africa, Uganda, United States
1/2	VivaGel® (SPL7013 gel)	EFI	Assessment of local retention and duration of activity of SPL7013 following vaginal application of 3% SPL7013 Gel (VivaGel®) in healthy volunteers	NIAID, NIH, Starpharma,	Australia
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	S	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
	PRO 2000	EFI	Postcoital anti-viral activity of cervicovaginal secretions following intravaginal application of 0.5% PRO 2000/5 Gel (P)	AECOM, Indevus, NIH	United States
	Tenofovir gel‡	RI	Pharmacokinetic study of the vaginal microbicide agent 1% tenofovir gel (A04-095)	CONRAD, IPM/USAID	Dominican Republic, United States
	Tenofovir gel	RI	Maternal pharmacokinetics and placental perfusion of tenofovir/PMPA gel (MTN 002)	CONRAD, DAIDS/NIAID, MTN, NICHD	United States
	Tenofovir gel	RI	Effect of repeated applications of tenofovir gel on mucosal mediators of immunity and intrinsic antimicrobial activity of cervicovaginal secretions	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	CONRAD, NIAID, UCLA	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, CONRAD, Thailand Ministry of Health	Thailand
	UC-781 gel‡	RI	Male tolerance study (A06-104)	CONRAD	United States
UC-781 gel	RI	Safety and acceptability of UC-781 topical vaginal microbicide in heterosexual women and male partners (HC 101)	CDC, CONRAD, Emory University	United States	

Please turn over for further details about this table

	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, MTN, NICHD, Starpharma	Puerto Rico, United States
N/A	No Product	N/A	An observational cohort study of women following HIV-1 seroconversion in microbicide trials (MTN 015)	DAIDS/NIAID, MTN	Malawi, South Africa, Uganda, Zambia, Zimbabwe
	Placebo ring‡	Placebo	Safety and acceptability of a placebo vaginal ring microbicide delivery method for the prevention of HIV infection in women (IPM 011)	IPM	South Africa, Tanzania (ongoing sites); Kenya (follow-up)

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

*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 is currently in data analysis.

‡These trials have completed clinical studies, but data analysis is ongoing.

**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.