MICROBICIDE AND PrEP CANDIDATES IN ONGOING CLINICAL TRIALS
SUMMARY AS OF OCTOBER 2009

ALLIANCE FOR MICROBICIDE DEVELOPMENT

Phase	*Candidate Name*	*MoA*	*Title of Study*	*Sponsor**	*Sites by Country*
3	PRO 2000/5: Gel	EFI	Efficacy and safety of 0.5% PRO 2000/5 gel for the prevention of vaginally acquired HIV infection (MDP 301)	DFID (Funder), Indevus, MRC	South Africa, Tanzania, Uganda, Zambia
	Truvada®: Oral	RI	Chemoprophylaxis for HIV prevention in men (iPrEx)	BMGF, NIH	Brazil, Ecuador, Peru, South Africa, Thailand, United States
	Truvada®: Oral	RI	Safety and efficacy of daily and oral antiretroviral use for the prevention of HIV infection in heterosexually active young adults (TDF2)	CDC	Botswana
	Truvada®: Oral, Viread®: Oral	RI	Parallel comparison of Tenofovir and Emtricitabine/Tenofovir PrEP to prevent HIV-1 acquisition within HIV-1 discordant couples (Partners PrEP)	BMGF, University of Washington	Kenya, Uganda
	Truvada®: Oral	RI	Study to assess the role of Truvada® in preventing HIV acquisition in women (FEM-PrEP)	BMGF, FHI, USAID	Kenya, Malawi, Tanzania, Zambia
2/3	Viread®: Oral	RI	Safety and efficacy of daily tenofovir to prevent HIV infection (BTS)	CDC	Thailand
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, USAID	South Africa
	Tenofovir gel	RI	Safety and effectiveness of tenofovir 1% gel (PMPA) with two oral HIV prevention approaches - tenofovir and Truvada™, a tenofovir-FTC drug combination (MTN-003 – VOICE)§	CONRAD, DAIDS/NIAID, Gilead, MTN, NICHD, NIMH	Malawi, South Africa, Uganda, Zambia, Zimbabwe
2	Tenofovir: Gel, Viread®: Oral	RI	Adherence and pharmacokinetics study of oral and vaginal preparations of tenofovir (MTN-001)	CONRAD, DAIDS/NIAID, Gilead, MTN	South Africa, Uganda, United States
	Viread®: Oral	RI	Extended safety trial	CDC	United States
1/2	Dapivirine: Gel	RI	Safety and acceptability of dapivirine gel, conducted using daily monitored adherence in healthy HIV-negative women (IPM 014A)	IPM	Kenya, Malawi, Rwanda, South Africa, Tanzania
	Dapivirine: Gel	RI	Safety and acceptability of dapivirine gel, conducted using daily monitored adherence in healthy HIV-negative women (IPM014B)	IPM	Kenya, Malawi, Rwanda, South Africa, Tanzania
	Dapivirine: Gel	RI	Dapivirine gel expanded safety study (IPM 020)	IPM	United States
	VivaGel®: Gel (SPL7013)‡	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	Acidform: Gel	VDE	Safety of Acidform lubricant (Amphora) in women at low risk for HIV-1 infection (AF 020)	AECOM, NIAID/DAIDS	United States
	Dapivirine: Ring	RI	Safety and pharmacokinetic trial to assess delivery of dapivirine from the matrix vaginal ring (IPM 024)	IPM	Belgium
	Device	N/A	Acceptability and performance of a device for vaginal drug delivery	FHI	South Africa
	HEC/CS/N-9†: Gels	N/A	Assessment of markers of inflammation after vaginal product use	CONRAD/USAID	USA

	PRO 2000: Gel[‡]	EFI	Postcoital anti-viral activity of cervicovaginal secretions following intravaginal application of 0.5% PRO 2000/5 Gel (P) (MSPRO 030)	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	Safety, acceptability, and pharmacokinetic trial of topical, vaginally-formulated tenofovir 1% gel applied rectally compared with oral TDF (RMP-02/MTN-006)	CONRAD, Gilead, MTN, NIAID/DAIDS	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 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
	VivaGel®: Gel (SPL7013)[**]	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	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); Kenya (site closure)

For modifications, please contact Stephanie Tillman, email stillman@microbicide.org.

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.*
[§]*This study includes an observational cohort study (MTN 003B), entitled Bone Mineral Density Substudy, which will explore the effects of oral study products on bone mineral density.*
[‡] *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.*