



Online Expert Poster Review and Discussion
 ARV Therapies and Therapeutic Strategies
Reporting From
 The 19th Conference on Retroviruses and Opportunistic Infections (CROI)
 JOINTLY SPONSORED BY THE POSTGRADUATE INSTITUTE FOR MEDICINE AND VIRALeD, LLC

The FEM-PrEP Trial: TDF/FTC (Truvada®) as Pre-exposure Prophylaxis for HIV Infection Among African Women

Lut Van Damme, M.D.
 On behalf of the FEM-PrEP Team

Abstract 32LB



Final Results: Participant Disposition

Screened (N=4163)



Randomize (N=2120)

Arusha, Tanzania N=63		Bondo, Kenya N=739		Bloemfontein, SA N=554		Pretoria, SA N=764	
FTC/TDF				Placebo			
N=1024 with follow-up (702 women-years)				N=1032 with follow-up (706 women-years)			
148	(13.9%)	Lost to FU		118	(11.2%)	Lost to FU	
59	(5.6%)	Discontinued		54	(5.1%)	Discontinued	
855	(80.5%)	Completed		886	(83.7%)	Completed	

Van Damme L et al. 19th CROI; Seattle, WA; March 5-8, 2012; Abst. 32LB.



Baseline Data

	TDF/FTC N=1062	Placebo N=1058
Age < 25 yr	%	%
Sex for gifts/money with non-primary partners	59	59
Condom use	13	12
Little or no perceived chance of HIV	51	52
Gonorrhea	69	71
Chlamydia	6	6
	15	13
Vaginal sex acts/week: mean (range)	3.7 (0-28)	3.7 (0-23)

Van Damme L et al. 19th CROI; Seattle, WA; March 5-8, 2012; Abst. 32LB.



Primary Effectiveness Analysis

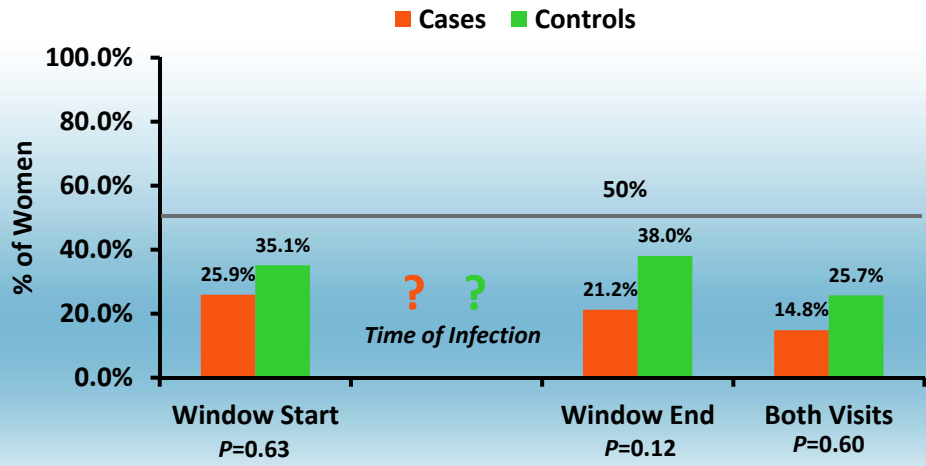
	TDF/FTC N=1024	Placebo N=1032
HIV Infections	33	35
Incidence Rate	4.7 per 100 P-Y	5.0 per 100 P-Y

Estimated Effectiveness: 6% Reduction in Risk
Hazard Ratio = 0.94 (0.59, 1.52): p-value = 0.81

Van Damme L et al. 19th CROI; Seattle, WA; March 5-8, 2012; Abst. 32LB.



Infected **Cases** and Matched **Controls** with ≥ 10 ng/ml Tenofovir in Plasma at Visits Defining Infection Windows



Van Damme L et al. 19th CROI; Seattle, WA; March 5-8, 2012; Abst. 321B.