

SUPPLEMENTARY TABLE S1. HIV VACCINE TRIALS NETWORK 505 REDESIGN OPTIONS IN 2010, FOLLOWING THE iPrEx STUDY RESULTS SHOWING PARTIAL EFFICACY OF TDF-FTC AS ORAL PREEXPOSURE PROPHYLAXIS²

	Option 0: <i>Continue current design with primary endpoint setpoint viral load, monitor PrEP use</i>	Expanded Option 0: <i>Add HIV acquisition as coprimary endpoint, monitor PrEP use</i>	Option A: <i>Add PrEP and Vaccine + PrEP arms</i>
Scientific questions addressed	Vaccine effect on setpoint viral load	Vaccine effect on HIV acquisition and setpoint viral load	Vaccine, PrEP, and Vaccine + PrEP effects on HIV acquisition and setpoint viral load
Total sample size (# of HIV infections in 24 month follow-up)	<i>n</i> = 1,350 (50–60 infections)	<i>n</i> = 3200 (132 infections)	<i>n</i> = 3900 (132 infections)
PrEP assumptions	Uptake = 20% Efficacy = 44%	Uptake = 20% Efficacy = 44%	Uptake = 55% Efficacy = 44%
Power for VE over 24 month follow-up	46% to detect VE = 40%	80% to detect VE = 40%	80% to detect VE = 40%
Increase in accrual period, relative to current design	None	17 months	20 months
Increase in total trial duration, relative to current design	1–2 months	12 months	15 months

PrEP, preexposure prophylaxis; VE, vaccine efficacy.