

Supplemental Table 1. Schedule of Visits and Procedures for PC952 (Zimbabwe) and PC953 (South Africa)

PROCEDURES	VISIT Day/Week													
	V0	V1	V2	V3	V4	V5	V6	V7 ³	V8 ²	V9 ²	V10 ²	V11 ²	V12 ²	V13 ¹ /Early Termination
	Day ≤-45	Day 1	Wk 4	Wk 8	Wk 12	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36	Wk 40	Wk 44	Wk 48
Visit Type	SCR	ENR	FU	FU	CO	FU	FU	CH	FU	FU	FU	FU	FU	CLO
ADMINISTRATIVE														
Informed consent	X													
Assign participant ID number	X													
Assess eligibility	X	X												
Demographics	X													
Randomization		X												
COUNSELING														
HIV pre and post-test counseling and testing, risk reduction counseling	X	X	X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²
STI/HIV risk reduction counseling	X	X	X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²
Contraceptive counseling	X	X	X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²
Protocol adherence counseling		X	X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	
CLINICAL														
Administer HIV risk assessments (clinician-based and self-assessment)	X													
Medical history	X													
Record medication history/ concomitant medications	X	*	*	*	*	*	*	*	*	*	*	*	*	*
Vital signs	X♦§	X	X♦	X	X	X♦	X	X	X♦ ²	X ²	X ²	X ²	X ²	X♦ ²
Complete physical exam	X	*	*	*	*	*	*	X ¹	*	*	*	*	*	X
Targeted physical exam		X	*	*	*	*	*	*	*	*	*	*	*	
Pelvic exam	* ² X	*	*	*	*	*	*	*	*	*	*	*	*	*
Record adverse events/social harms		*	*	*	*	*	*	*	*	*	*	*	*	*
LABORATORY ASSESSMENTS														
Urine														
Urine pregnancy test	X	X	X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²
GeneXpert (urine) for chlamydia and gonorrhea (NAAT)	X	*	*	*	*	*	*	*	*	*	*	*	*	*
Urinalysis	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Blood														
Rapid HIV-1 blood tests	X	X	X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²
HIV confirmation blood test	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Syphilis serology	X	*	*	*	*	*	*	*	*	*	*	*	*	*
Hepatitis B antigen test	X													
Hepatitis C test	X ³													
Creatinine blood test	X	*	X	*	*	X	*	X ¹	X ²	*	*	*	*	X ²

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	V0	V1	V2	V3	V4	V5	V6	V7 ³	V8 ²	V9 ²	V10 ²	V11 ²	V12 ²	V13 ¹ /Early Termination
	Day ≤-45	Day 1	Wk 4	Wk 8	Wk 12	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36	Wk 40	Wk 44	Wk 48
Collect blood for DBS to assess adherence			X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²
Blood draw for Complete Blood Count	X ¹	*	*	*	*	*	*	X ¹						
Pelvic														
Rapid trichomonas (TV)	X ³													
Wet mount (TV, BV, candida)	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Study product														
DOD first dose of regimen		X			X									
Distribute product supply		X	X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²	
Collect used and unused product supplies			X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²	X ²
Behavioral														
CASI baseline questionnaire		X												
CASI monthly questionnaire			X	X	X	X	X	X ²	X ²	X ²	X ²	X ²	X ²	X ²
In-depth exit interview								X ¹						(X) ²

¹Zimbabwe only; ²South Africa only; ³Visit 7 is the Closing Visit in Zimbabwe

V = Visit; Wk = week; SCR = Screening; ENR = Enrolment; FU = follow up; CO = crossover; CH = Choice; CLO =

Closing Visit; *If indicated; (X) sub-set of participants

♦Weight only at specified visits (when creatinine/creatinine clearance assessed); \$Height only at Screening