



MATRIX-[XXX]: [*Insert Study Title*]

[*Insert IND# or "A Non-IND Study", as applicable*]

Study design:

Study population: Approximately [XX] [*Insert brief description of target study population*], with approximately [XX] participants each at [XX] sites from [*DELETE if not applicable: the United States,*] Kenya, South Africa and/or Zimbabwe

Study product(s):

Study regimen:

Primary Objective:

- **Primary Endpoint(s):**

○

Secondary Objective:

- **Secondary Endpoint(s):**

○

Secondary Objective:

- **Secondary Endpoint(s):**

○

Exploratory Objective:

- **Exploratory Endpoint(s):**

○

Exploratory Objective:

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Exploratory Endpoint(s):

○

Key inclusion criteria:

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Key exclusion criteria:

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Background and Study Rationale:

[Provide brief background/rationale for conducting the study, e.g., Why develop this type of HIV prevention product in general? Why this specific study product in particular? Why conduct this study at this point in R&D? Why this study design?]

Visits and Study Procedures:

[List study visits and briefly describe procedures conducted, screen-to-enrollment window and if/when randomization occurs]

Visit Schedule / Study Product Regimen Figure:

[Insert Figure illustrating study visit sequence/timeline]

Schedule of Study Visits and Evaluations:

[Insert Table illustrating schedule of study visit procedures; see example below]

STUDY PROCEDURES	SCREEN	ENROLL						
	V1	V2	V3	V4	V5	V6	V7	V8
Day								
Length of Visit								
Medical History & Medication review								
Randomization								
Acceptability Questionnaire								
In-depth interview								
HIV pre- and post-test counseling								
HIV/STI risk reduction counseling								
HIV Rapid Test								

HIV Confirmatory Test								
Review Applicable Test Results								
Protocol Counseling								
AE assessment								
Urine Pregnancy Test								
Pelvic Exam with speculum								
Vaginal pH								
Gram Stain								
Genital swab for quantitative PCR								
GC/CT/Trich								
Wet mount								
Brief Physical Exam								
Provide study product								
Compensation								
Collect/update/review contact/locator information								

x = Required; ^ = If indicated and/or per local standard of care