MATRIX-002 Screening and Enrollment Log

If you are creating a new entry, complete the first three columns and initial and date in the fourth column. When enrollment or screen fail status is determined, complete the remaining columns and initial and date in the last column. Include all codes for screen failure/discontinuation that apply.

Screening Date	Screening Attempt*	PTID^	Staff Initials/Date	Enrollment Date (or N/A if not enrolled)	Screen Failure Date (or N/A if enrolled)	Screening Failure Codes (or N/A if enrolled)	Staff Initials/Date

***Per protocol, only one re-screening attempt is permitted**

^Assign new PTID with each screen attempt

I-1	Not 18 -45 y/o at Screening	I-6	HIV +	E-1c	Intends to relocate from study site	E-6b	Hysterectomy	E-7a	Grade 2 or higher AST
I-2	Not assigned female sex at birth	I-7	Not in monogamous relationship/partner with HIV or STI	E-1d	Intends to travel during study period and would interfere	E-6c	Pelvic surgical procedure w/in 30 days of enrollment	E-7b	Grade 2 or higher ALT
I-3	Did not provide consent	I-8	Positive pregnancy test at Screening or Enrollment	E-2	HIV +	E-6d	Use of diaphragm, NuvaRing, or spermicide in two weeks prior to screening	E-7c	Grade 2 or higher creatinine
I-4	Inadequate locator info	I-9	Abnormal Pap	E-3	STI at screening or past 12 months	E-6e	Antibiotic or antifungal (oral or intravaginal) within 7 days of enrollment	E-7d	Grade 2 or higher hemoglobin
I-5a	Unable/not willing to abstain from sex	I-10	Not protected from pregnancy/not on an effective contraception	E-4	UTI, PID or RTI at enrollment	E-6f	Prior use of PEP or PrEP in past 4 weeks; any use of long-acting systemic PrEP ever	E-8	Other condition per IoR
I-5b	Unable/not willing to abstain from vaginal products								
I-5c	Unable/not willing to abstain from intravaginal practices	E-1a	Intends to become pregnant	E-5	Grade 2 or higher pelvic exam finding at enrollment	E-6g	Use of non-therapeutic drugs in past 12 months as defined in the protocol	N-1	Other – Declines enrollment
I-5d	Unable/not willing to refrain from participation in other studies								
I-5e	Unable/not willing to respond to phone/SMS contacts	E-1b	Intends to breastfeed	E-6a	Known study product adverse reaction	E-6h	Significant uncontrolled active or chronic issue at screening or enrollment as determined by IoR/Designee	N-2	Other – Not enrolled visit within 45-day window
I-5f	Unable/not willing to attend clinic follow-up visits								