

MTN 028 - Phase 1 Pharmacokinetic Trial of Two Intravaginal Rings (IVRs) Containing Different Dose Strengths of Vicriviroc (MK-4176) and MK-2048
Report - March 2, 2017
Visit Cutoff Date: March 2, 2017
. Screen-out Summary by Site

	San Francisco	All Sites
Participants Screened	49	49
Participants Enrolled ¹	19 (39%)	19 (39%)
Participants not Enrolled	30 (61%)	30 (61%)
Participant did not complete all screening procedures	2 (4%)	2 (4%)
Participant is eligible but declined enrollment	0 (0%)	0 (0%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)
Participant not eligible ²	28 (57%)	28 (57%)
participant < 18 or > 45 years old	0 (0%)	0 (0%)
plans for relocation/travel	1 (4%)	1 (4%)
participant is pregnant or planning to become pregnant within the next 3 months	0 (0%)	0 (0%)
participant is breastfeeding	0 (0%)	0 (0%)
participant unwilling to refrain from receptive sexual activity	0 (0%)	0 (0%)
participant has enrolled in another research study in the last 60 days	0 (0%)	0 (0%)
diagnosed with PID,RTI, or STI, which has not resolved	0 (0%)	0 (0%)
PEP or PrEP exposure in the last 6 months	0 (0%)	0 (0%)
participant is HIV-positive	0 (0%)	0 (0%)
participant declines effective method of contraception	0 (0%)	0 (0%)
participant has a grade 1 or higher pelvic exam finding	1 (4%)	1 (4%)
participant does not meet laboratory eligibility criteria	7 (25%)	7 (25%)
participant does not meet other clinical eligibility criteria	9 (32%)	9 (32%)
Other reason, including investigator decision	13 (46%)	13 (46%)

¹ Number of participants enrolled could differ from the accrual report since the data is taken from the ECI-1 CRF and not the ENR-1 CRF.

² Participants may be ineligible for more than one reason.

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. Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	San Francisco	Concerns re: sobriety and changing sexual risk
2		poor venous access
3		time constraints
4		concerns with comprehension + comfort with clinical study procedures
5		cancelled screen 2 appt without explanation and hung up on clinician when called to inquire about cancellation.
6		cannot meet study schedule
7		Had spotting at enrollment
8		difficult venous access
9		enrollment closed
10		Enrollment completed; No available spots
11		menstrual bleeding on day of enrollment + unable to enroll within screening window
12		Did not tolerate pelvic exams
13		poor communication