

**MTN 027 - Safety and PK in IVRs Containing VCV (MK-4176) and/or MK-2048**  
**Report - March 2, 2017**  
**Visit Cutoff Date: March 2, 2017**  
**- Screen-out Summary by Site**

	Birmingham, AL	Pittsburgh, PA	All Sites
Participants Screened	32	38	70
Participants Enrolled <sup>1</sup>	24 (75%)	24 (63%)	48 (69%)
Participants not Enrolled	8 (25%)	14 (37%)	22 (31%)
Participant did not complete all screening procedures	0 (0%)	1 (3%)	1 (1%)
Participant is eligible but declined enrollment	1 (3%)	2 (5%)	3 (4%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)
Participant not eligible <sup>2</sup>	7 (22%)	11 (29%)	18 (26%)
Participant < 18 or > 45 years old	0 (0%)	0 (0%)	0 (0%)
Participant plans to relocate/travel	0 (0%)	0 (0%)	0 (0%)
Participant is pregnant or planning to become pregnant within the next 3 months	0 (0%)	0 (0%)	0 (0%)
Participant is breastfeeding	0 (0%)	0 (0%)	0 (0%)
Participant unwilling to refrain from receptive sexual activity	0 (0%)	0 (0%)	0 (0%)
Participant has enrolled in another research study in the last 60 days	0 (0%)	0 (0%)	0 (0%)
Participant diagnosed with PID, RTI, or STI, which has not resolved	0 (0%)	1 (9%)	1 (6%)
Participant has been exposed to PEP or PrEP in the last 6 months	0 (0%)	0 (0%)	0 (0%)
Participant is HIV-positive	0 (0%)	0 (0%)	0 (0%)
Participant declines effective method of contraception	0 (0%)	0 (0%)	0 (0%)
Participant has a grade 1 or higher pelvic exam finding	1 (14%)	1 (9%)	2 (11%)
Participant does not meet laboratory eligibility criteria	2 (29%)	1 (9%)	3 (17%)
Participant does not meet other clinical eligibility criteria	2 (29%)	3 (27%)	5 (28%)
Other reason, including investigator decision	2 (29%)	7 (64%)	9 (50%)

<sup>1</sup> 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.

<sup>2</sup> Participants may be ineligible for more than one reason.

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**- Listing of Other Reasons for Ineligibility by Site**

<b>Obs</b>	<b>Site</b>	<b>Reason</b>
1	Birmingham, AL	New job - unable to take off
2		Inadequate venous access
3	Pittsburgh, PA	not good venous access
4		uncontrolled hypertension
5		Inconsistent and unreported medical problems
6		unreliable history; uncontrolled nausea and vomiting
7		Enrollment Completed for Site
8		Difficulty with blood draws.
9		Untreated Bipolar Disease and no medical care for 3 years