

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

- Visit Adherence: Completion of Procedures¹ by Site

	Birmingham, AL	Pittsburgh, PA	All Sites
Participants Enrolled	24	24	48
1. Physical Exams Required and Expected	283	287	570
Completed	283 (100.0%)	287 (100.0%)	570 (100.0%)
2. Pelvic Exams Required and Expected	283	287	570
Completed	283 (100.0%)	287 (100.0%)	570 (100.0%)
3. Pregnancy Tests Required and Expected	48	48	96
Completed	48 (100.0%)	48 (100.0%)	96 (100.0%)
4. Dipstick Urinalysis Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)
5. Hemograms Required and Expected	71	72	143
Completed	71 (100.0%)	72 (100.0%)	143 (100.0%)
6. HIV-1 Tests Required and Expected	23	24	47
Completed	23 (100.0%)	24 (100.0%)	47 (100.0%)
7. Serum Chemistries (AST/ALT/Creatinine) Required and Expected	71	72	143
Completed	71 (100.0%)	72 (100.0%)	143 (100.0%)
8. Plasma for PK Required and Expected	283	287	570
Completed	283 (100.0%)	287 (100.0%)	570 (100.0%)
9. Plasma for Archive Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)
10. Vaginal Fluid pH Required and Expected	164	167	331
Completed	163 (99.4%)	167 (100.0%)	330 (99.7%)
Not Completed	1 (0.6%)	0 (0.0%)	1 (0.3%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit Case Report Form (CRF), the procedures for that visit will not be included as expected.

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11. Vaginal fluid for PK Required and Expected	283	287	570
Completed	283 (100.0%)	287 (100.0%)	570 (100.0%)
12. Cervical cytobrush Required and Expected	48	48	96
Completed	48 (100.0%)	48 (100.0%)	96 (100.0%)
13. Cervical biopsy for PK Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)
14. Cervical biopsy for PD Required and Expected	0	24	24
Completed	0 (-%)	24 (100.0%)	24 (100.0%)
15. Quantitative vaginal culture Required and Expected	95	96	191
Completed	95 (100.0%)	96 (100.0%)	191 (100.0%)
16. Vaginal Smear for Gram Stain Required and Expected	95	96	191
Completed	95 (100.0%)	96 (100.0%)	191 (100.0%)
17. Vaginal Swab for biomarkers Required and Expected	95	96	191
Completed	95 (100.0%)	96 (100.0%)	191 (100.0%)
18. Rectal fluid for PK Required and Expected	20	40	60
Completed	20 (100.0%)	40 (100.0%)	60 (100.0%)
19. Used Vaginal Ring Specimen Storage Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)
20. Baseline CASI Questionnaire Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)

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21. Follow-up CASI Questionnaire Required and Expected	119	120	239
Completed	119 (100.0%)	120 (100.0%)	239 (100.0%)
22. In-depth Interview Required and Expected	23	24	47
Completed	23 (100.0%)	24 (100.0%)	47 (100.0%)

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