

**MTN 038 - PK and Safety Study of a 90-Day Intravaginal Ring Containing Tenofovir  
Data as of December 5, 2022**

**Visit Adherence: Completion of Procedures During Enrollment and Follow-up<sup>1</sup> by Site**

	<b>Birmingham, AL</b>	<b>Pittsburgh, PA</b>	<b>San Francisco, CA</b>	<b>All Sites</b>
Participants Enrolled	13	21	15	49
1. Physical Exam Required and Expected	26	42	30	98
Completed	26 (100.0%)	42 (100.0%)	30 (100.0%)	98 (100.0%)
2. Vital Signs Required and Expected	26	42	30	98
Completed	26 (100.0%)	42 (100.0%)	29 (96.7%)	97 (99.0%)
Not Completed	0 (0.0%)	0 (0.0%)	1 (3.3%)	1 (1.0%)
3. Pelvic Exam Required and Expected	117	184	135	436
Completed	117 (100.0%)	184 (100.0%)	135 (100.0%)	436 (100.0%)
4. Pregnancy Test Required and Expected	65	102	75	242
Completed	65 (100.0%)	102 (100.0%)	75 (100.0%)	242 (100.0%)
5. HIV Tests Required and Expected	39	62	45	146
Completed	39 (100.0%)	62 (100.0%)	45 (100.0%)	146 (100.0%)
6. Plasma Archive Required and Expected	13	21	15	49
Completed	13 (100.0%)	21 (100.0%)	15 (100.0%)	49 (100.0%)
7. Chemistries Required and Expected	26	41	30	97
Completed	26 (100.0%)	41 (100.0%)	30 (100.0%)	97 (100.0%)
8. CBC with Differential and Platelets Required and Expected	26	41	30	97
Completed	26 (100.0%)	41 (100.0%)	30 (100.0%)	97 (100.0%)
9. Creatinine Required and Expected	26	41	30	97
Completed	26 (100.0%)	41 (100.0%)	30 (100.0%)	97 (100.0%)

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10. Plasma for PK Required and Expected	91	141	104	336
Completed	91 (100.0%)	140 (99.3%)	103 (99.0%)	334 (99.4%)
Not Completed	0 (0.0%)	1 (0.7%)	1 (1.0%)	2 (0.6%)
11. Vaginal Swabs for Microbiota Required and Expected	52	81	60	193
Completed	52 (100.0%)	79 (97.5%)	60 (100.0%)	191 (99.0%)
Not Completed	0 (0.0%)	2 (2.5%)	0 (0.0%)	2 (1.0%)
12. Vaginal Gram Stain Required and Expected	52	81	60	193
Completed	52 (100.0%)	79 (97.5%)	60 (100.0%)	191 (99.0%)
Not Completed	0 (0.0%)	2 (2.5%)	0 (0.0%)	2 (1.0%)
13. Cervicovaginal Fluid for anti-HSV-2 activity Required and Expected	39	61	45	145
Completed	39 (100.0%)	60 (98.4%)	45 (100.0%)	144 (99.3%)
Not Completed	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (0.7%)
14. Cervicovaginal Fluid for PK Required and Expected	104	162	119	385
Completed	104 (100.0%)	161 (99.4%)	118 (99.2%)	383 (99.5%)
Not Completed	0 (0.0%)	1 (0.6%)	1 (0.8%)	2 (0.5%)
15. Cervicovaginal Fluid for Biomarkers Required and Expected	104	163	120	387
Completed	104 (100.0%)	161 (98.8%)	120 (100.0%)	385 (99.5%)
Not Completed	0 (0.0%)	2 (1.2%)	0 (0.0%)	2 (0.5%)
16. Cervicovaginal Lavage for PD PK or Biomarkers Required and Expected	39	61	45	145
Completed	39 (100.0%)	60 (98.4%)	45 (100.0%)	144 (99.3%)
Not Completed	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (0.7%)
17. Cervical Biopsy for PK Required and Expected	26	39	30	95
Completed	26 (100.0%)	38 (97.4%)	30 (100.0%)	94 (98.9%)
Not Completed	0 (0.0%)	1 (2.6%)	0 (0.0%)	1 (1.1%)
18. Cervical Biopsy for PD Required and Expected	13	19	15	47
Completed	13 (100.0%)	18 (94.7%)	15 (100.0%)	46 (97.9%)

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Not Completed	0 (0.0%)	1 (5.3%)	0 (0.0%)	1 (2.1%)

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19. Rectal Fluid for PK Required and Expected	65	101	75	241
Completed	65 (100.0%)	100 (99.0%)	74 (98.7%)	239 (99.2%)
Not Completed	0 (0.0%)	1 (1.0%)	1 (1.3%)	2 (0.8%)
20. Behavioral Assessment Required and Expected	52	81	60	193
Completed	52 (100.0%)	81 (100.0%)	60 (100.0%)	193 (100.0%)
21. In-depth Interview Required and Expected	9	9	9	27
Completed	7 (77.8%)	9 (100.0%)	9 (100.0%)	25 (92.6%)
Not Completed	2 (22.2%)	0 (0.0%)	0 (0.0%)	2 (7.4%)

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