

**MTN 029 - Phase 1 Pharmacokinetic Study of the Dapivirine Vaginal Ring in Lactating Women
Data as of June 6, 2022**

Visit Adherence: Completion of Procedures¹ by Site

	Pittsburgh	Birmingham	All Sites
Participants Enrolled	8	8	16
1. Physical Exams Required and Expected	16	16	32
Completed	16 (100.0%)	16 (100.0%)	32 (100.0%)
2. Pelvic Exams Required and Expected	48	48	96
Completed	48 (100.0%)	48 (100.0%)	96 (100.0%)
3. Breast Exams Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)
4. Urine hCG Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)
5. HIV-1 Tests Required and Expected	10	9	19
Completed	10 (100.0%)	9 (100.0%)	19 (100.0%)
6. Serum Chemistries (AST/ALT) Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
7. Trichomonas Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
8. Cervical NAAT for Gonorrhea Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
9. Cervical NAAT for Chlamydia Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
10. Sexual Practices Assessment Required and Expected	40	40	80
Completed	40 (100.0%)	40 (100.0%)	80 (100.0%)

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 Practices Assessment Required and Expected	40	40	80
Completed	40 (100.0%)	40 (100.0%)	80 (100.0%)
12. Plasma for Archive Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
13. Enrollment PK Blood Draws Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
14. Follow-up PK Blood Levels Required and Expected	32	32	64
Completed	32 (100.0%)	32 (100.0%)	64 (100.0%)
15. Enrollment CVF Collection for PK Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
16. Follow-up CVF for PK Required and Expected	32	32	64
Completed	32 (100.0%)	32 (100.0%)	64 (100.0%)
17. Enrollment Breast Milk Collection for PD Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
18. Breast Milk for Anti-Viral Activity Required and Expected	32	32	64
Completed	32 (100.0%)	32 (100.0%)	64 (100.0%)
19. Enrollment Breast Milk Collection for PK and Lipids Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
20. Follow-up Breast Milk for PK and Lipids Required and Expected	32	32	64
Completed	32 (100.0%)	32 (100.0%)	64 (100.0%)

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21. Vaginal Biomarkers Required and Expected	40	40	80
Completed	40 (100.0%)	40 (100.0%)	80 (100.0%)
22. Quantitative Vaginal Culture Required and Expected	24	24	48
Completed	24 (100.0%)	24 (100.0%)	48 (100.0%)
23. Vaginal Smear for Gram Stain Required and Expected	40	40	80
Completed	40 (100.0%)	40 (100.0%)	80 (100.0%)
24. At-Home Breast Milk Sample Collection Required and Expected	24	24	48
Completed	24 (100.0%)	23 (95.8%)	47 (97.9%)
Not Completed	0 (0.0%)	1 (4.2%)	1 (2.1%)
25. Participant-reported Ring Use Data Collection Required and Expected	16	16	32
Completed	16 (100.0%)	16 (100.0%)	32 (100.0%)
26. Used Vaginal Ring Specimen Storage Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)
27. Pregnancy and Lactation History Required and Expected	8	8	16
Completed	8 (100.0%)	8 (100.0%)	16 (100.0%)

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