

**MTN 026 - Dapivirine Gel Rectal Safety and PK Study**  
**Data as of May 3, 2018**

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

	<b>Birmingham, AI</b>	<b>Pittsburgh, PA</b>	<b>Bangkok, Thailand</b>	<b>All Sites</b>
Participants Enrolled	7	7	9	23
1. Physical Exam Required and Expected	14	14	18	46
Completed	14 (100.0%)	14 (100.0%)	18 (100.0%)	46 (100.0%)
2. Vital Signs Required and Expected	14	14	18	46
Completed	14 (100.0%)	14 (100.0%)	18 (100.0%)	46 (100.0%)
3. Sexual Lubricant Form Required and Expected	26	21	32	79
Completed	26 (100.0%)	21 (100.0%)	32 (100.0%)	79 (100.0%)
4. Pregnancy Test Required and Expected	14	4	0	18
Completed	14 (100.0%)	4 (100.0%)	-(-%)	18 (100.0%)
5. Chemistries Required and Expected	13	12	14	39
Completed	13 (100.0%)	12 (100.0%)	14 (100.0%)	39 (100.0%)
6. Pelvic Exam Required and Expected	17	5	0	22
Completed	17 (100.0%)	5 (100.0%)	-(-%)	22 (100.0%)
7. Rectal Exam Required and Expected	44	41	53	138
Completed	44 (100.0%)	41 (100.0%)	53 (100.0%)	138 (100.0%)
8. Plasma Archive Required and Expected	19	17	21	57
Completed	19 (100.0%)	17 (100.0%)	21 (100.0%)	57 (100.0%)
9. Plasma for PK Required and Expected	61	52	72	185
Completed	60 (98.4%)	52 (100.0%)	72 (100.0%)	184 (99.5%)
Partially Completed	1 (1.6%)	-(-%)	-(-%)	1 (0.5%)

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10. HIV Tests Required and Expected	26	24	30	80
Completed	26 (100.0%)	24 (100.0%)	30 (100.0%)	80 (100.0%)
11. CVL for PD Required and Expected	9	1	0	10
Completed	9 (100.0%)	1 (100.0%)	-(-%)	10 (100.0%)
12. Cervicovaginal Fluid for PK Required and Expected	9	1	0	10
Completed	9 (100.0%)	1 (100.0%)	-(-%)	10 (100.0%)
13. Cervical Tissue for PK Required and Expected	9	1	0	10
Completed	9 (100.0%)	1 (100.0%)	-(-%)	10 (100.0%)
14. Rectal Fluid for PK Required and Expected	37	30	44	111
Completed	36 (97.3%)	30 (100.0%)	44 (100.0%)	110 (99.1%)
Not Completed	1 (2.7%)	-(-%)	-(-%)	1 (0.9%)
15. Rectal Tissue for PK Required and Expected	25	20	30	75
Completed	24 (96.0%)	20 (100.0%)	30 (100.0%)	74 (98.7%)
Not Completed	1 (4.0%)	-(-%)	-(-%)	1 (1.3%)
16. Rectal Fluid for Mucosal Safety Required and Expected	20	16	25	61
Completed	19 (95.0%)	16 (100.0%)	25 (100.0%)	60 (98.4%)
Not Completed	1 (5.0%)	-(-%)	-(-%)	1 (1.6%)
17. Rectal Tissue for Mucosal Safety Required and Expected	20	16	25	61
Completed	19 (95.0%)	16 (100.0%)	25 (100.0%)	60 (98.4%)
Not Completed	1 (5.0%)	-(-%)	-(-%)	1 (1.6%)
18. Rectal Tissue for PD Required and Expected	32	27	39	98
Completed	31 (96.9%)	27 (100.0%)	39 (100.0%)	97 (99.0%)
Not Completed	1 (3.1%)	-(-%)	-(-%)	1 (1.0%)

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19. Rectal Enema Effluent for PK/PD Required and Expected	25	23	30	78
Completed	25 (100.0%)	22 (95.7%)	30 (100.0%)	77 (98.7%)
Not Completed	-(-%)	1 (4.3%)	-(-%)	1 (1.3%)
20. Behavioural Assessment Required and Expected	19	16	23	58
Completed	19 (100.0%)	16 (100.0%)	23 (100.0%)	58 (100.0%)
21. In-depth Interview Required and Expected	12	9	14	35
Completed	11 (91.7%)	9 (100.0%)	11 (78.6%)	31 (88.6%)
Not Completed	1 (8.3%)	-(-%)	3 (21.4%)	4 (11.4%)

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