

MTN 005 – Expanded Safety and Adherence Study of a Non-medicated Intravaginal Ring

Date as of: May 5, 2013

Visit Adherence: Number of Days Between Target and Actual Visit Date

	All Sites	India National AIDS Research Institute	United States Bronx Lebanon Hospital	United States University of Alabama
Participants Enrolled	195	93	51	51
Week 4 Visit				
N	188	89	50	49
Mean (SD)	-2.1 (4.0)	-3.3 (4.1)	-2.3 (3.5)	0.4 (3.0)
Median	-2.0	-5.0	-2.5	0.0
25th, 75th %tile	-6.0, 0.0	-7.0, -1.0	-6.0, 0.0	0.0, 2.0
Min, Max	-7.0, 7.0	-7.0, 7.0	-7.0, 6.0	-7.0, 7.0
Week 8 Visit				
N	187	89	50	48
Mean (SD)	-1.7 (4.4)	-2.1 (4.8)	-2.8 (3.8)	0.1 (3.9)
Median	-2.0	-3.0	-4.0	0.0
25th, 75th %tile	-6.0, 1.0	-6.0, 1.0	-6.0, 0.0	-2.5, 2.0
Min, Max	-7.0, 7.0	-7.0, 7.0	-7.0, 7.0	-7.0, 7.0
Week 12 Visit				
N	187	90	49	48
Mean (SD)	-2.1 (4.3)	-2.2 (4.4)	-3.6 (3.7)	-0.4 (4.3)
Median	-3.0	-3.0	-4.0	0.0
25th, 75th %tile	-6.0, 1.0	-6.0, 1.0	-7.0, -1.0	-4.5, 1.5
Min, Max	-7.0, 7.0	-7.0, 7.0	-7.0, 7.0	-7.0, 7.0
Week 16 Visit				
N	187	89	49	49
Mean (SD)	-2.1 (4.4)	-2.1 (4.6)	-3.0 (4.6)	-1.2 (3.6)
Median	-3.0	-3.0	-5.0	0.0
25th, 75th %tile	-6.0, 1.0	-7.0, 1.0	-6.0, 0.0	-4.0, 1.0
Min, Max	-7.0, 14.0	-7.0, 7.0	-7.0, 14.0	-7.0, 6.0

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Visit Adherence: Number of Days Between Sequential Visits

	All Sites	India National AIDS Research Institute	United States Bronx Lebanon Hospital	United States University of Alabama
Participants Enrolled	195	93	51	51
Week 4 Visit				
N	188	89	50	49
Mean (SD)	25.9 (4.0)	24.7 (4.1)	25.7 (3.5)	28.4 (3.0)
Median	26.0	23.0	25.5	28.0
25th, 75th %tile	22.0, 28.0	21.0, 27.0	22.0, 28.0	28.0, 30.0
Min, Max	21.0, 35.0	21.0, 35.0	21.0, 34.0	21.0, 35.0
Week 8 Visit				
N	187	89	50	48
Mean (SD)	28.4 (5.3)	29.5 (6.3)	27.4 (4.0)	27.6 (4.2)
Median	28.0	28.0	28.0	28.0
25th, 75th %tile	26.0, 32.0	26.0, 34.0	26.0, 29.0	26.0, 28.5
Min, Max	14.0, 42.0	14.0, 42.0	21.0, 35.0	16.0, 35.0
Week 12 Visit				
N	187	90	49	48
Mean (SD)	28.1 (6.6)	28.6 (7.0)	27.3 (5.0)	28.1 (7.2)
Median	28.0	28.0	28.0	28.0
25th, 75th %tile	25.0, 30.0	25.0, 30.0	24.0, 29.0	24.0, 30.5
Min, Max	14.0, 62.0	14.0, 56.0	15.0, 40.0	15.0, 62.0
Week 16 Visit				
N	187	89	49	49
Mean (SD)	28.3 (6.4)	28.1 (6.1)	29.0 (7.3)	28.0 (5.9)
Median	28.0	28.0	28.0	28.0
25th, 75th %tile	24.0, 31.0	24.0, 31.0	25.0, 32.0	26.0, 29.5
Min, Max	14.0, 56.0	14.0, 41.0	14.0, 56.0	16.0, 54.0

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Visit Adherence: Completion of Procedures by Site

	All Sites	India National AIDS Research Institute	United States Bronx Lebanon Hospital	United States University of Alabama
Participants Enrolled	195	93	51	51
Participant-visits at Which Follow-up Pelvic Exams Are Required and Expected	944	450	249	245
Completed	927 (98.2%)	439 (97.6%)	245 (98.4%)	243 (99.2%)
Participant-visits at Which Pregnancy Tests Are Required and Expected	187	89	49	49
Completed	187 (100.0%)	89 (100.0%)	49 (100.0%)	49 (100.0%)
Participant-visits at Which Colposcopic Examination Are Required and Expected	569	272	149	148
Completed	558 (98.1%)	265 (97.4%)	147 (98.7%)	146 (98.6%)
Participant-visits at Which Ring Adherence Assessments Are Required and Expected	374	178	98	98
Completed	374 (100.0%)	178 (100.0%)	98 (100.0%)	98 (100.0%)
Participant-visits at Which ACASI Questionnaires Are Required and Expected	749	357	198	194
Completed	727 (97.1%)	354 (99.2%)	183 (92.4%)	190 (97.9%)
Participant-visits at Which Plasma Storage Are Required and Expected	195	93	51	51
Completed	195 (100.0%)	93 (100.0%)	51 (100.0%)	51 (100.0%)
Participant-visits at Which Storage of Gram Stain Are Required and Expected	944	450	249	245
Completed	927 (98.2%)	439 (97.6%)	245 (98.4%)	243 (99.2%)
Participant-visits at Which Storage of Vaginal Swabs (PCR) Are Required and Expected	450	450	0	0
Completed	439 (97.6%)	439 (97.6%)	--	--
Participant-visits at Which Storage of Vaginal Swabs (Culture) Are Required and Expected	494	0	249	245
Completed	488 (98.8%)	--	245 (98.4%)	243 (99.2%)
Participant-visits at Which Storage of Cervical Swabs Are Required and Expected	200	0	100	100
Completed	198 (99.0%)	--	99 (99.0%)	99 (99.0%)
Participant-visits at Which HIV Tests Are Required and Expected	187	89	49	49
Completed	187 (100.0%)	89 (100.0%)	49 (100.0%)	49 (100.0%)