

MTN 001 – Phase II Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir
Data as of: August 10, 2010
– Visit Adherence: Number of Days Between Target and Actual Visit Date

	Total	South Africa Durban Bothas Hill	South Africa Durban Umkomaas	Uganda Kampala	United States Birmingham	United States Bronx	United States Cleveland	United States Pittsburgh
Week 3 Visit								
N	155	13	36	27	13	12	27	27
Mean (STD)	-0.1 (2.5)	0.8 (2.2)	-0.6 (2.8)	0.5 (1.5)	-0.4 (1.2)	-1.3 (3.2)	0.1 (3.6)	-0.3 (1.8)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-9.0, 10.0	0.0, 8.0	-9.0, 7.0	0.0, 6.0	-3.0, 1.0	-8.0, 2.0	-7.0, 10.0	-6.0, 5.0
25th, 75th %tile	0.0, 0.0	0.0, 0.0	-0.5, 0.0	0.0, 0.0	-1.0, 0.0	-3.5, 1.0	-1.0, 1.0	-1.0, 0.0
Week 6 Visit								
N	146	13	36	23	13	12	21	28
Mean (STD)	-0.8 (2.4)	-1.1 (2.7)	-0.4 (2.0)	-0.6 (1.9)	0.0 (1.5)	-0.5 (1.2)	-2.3 (3.4)	-0.6 (2.5)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-9.0, 3.0	-7.0, 3.0	-8.0, 3.0	-7.0, 1.0	-3.0, 2.0	-4.0, 0.0	-9.0, 1.0	-9.0, 3.0
25th, 75th %tile	-1.0, 0.0	-2.0, 0.0	-1.0, 0.0	0.0, 0.0	-1.0, 1.0	-0.5, 0.0	-6.0, 0.0	-2.0, 1.0
Week 7 Visit								
N	149	13	36	24	13	12	24	27
Mean (STD)	1.1 (2.7)	1.0 (1.8)	1.3 (3.0)	0.7 (2.2)	0.5 (1.1)	-0.1 (1.7)	2.8 (3.6)	0.6 (2.6)
Median	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
Min, Max	-3.0, 10.0	0.0, 6.0	-2.0, 10.0	0.0, 10.0	-1.0, 2.0	-3.0, 2.0	-1.0, 10.0	-3.0, 7.0
25th, 75th %tile	0.0, 1.0	0.0, 1.0	0.0, 2.0	0.0, 0.0	0.0, 2.0	-1.0, 1.0	0.0, 6.0	-1.0, 1.0
Week 10 Visit								
N	148	13	35	24	13	12	24	27
Mean (STD)	0.2 (2.0)	0.1 (1.0)	0.3 (2.0)	0.0 (0.3)	0.2 (1.4)	-1.0 (2.6)	0.6 (2.7)	0.4 (2.6)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-7.0, 10.0	-2.0, 2.0	-3.0, 7.0	-1.0, 1.0	-3.0, 3.0	-7.0, 3.0	-3.0, 10.0	-3.0, 8.0
25th, 75th %tile	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	-2.0, 0.0	-0.5, 1.0	-1.0, 1.0
Week 13 Visit								
N	146	13	34	24	13	12	23	27
Mean (STD)	-1.2 (2.8)	-1.0 (3.2)	-1.1 (2.6)	-1.8 (3.9)	0.1 (1.0)	-1.6 (2.8)	-1.4 (3.2)	-1.1 (2.1)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-1.0
Min, Max	-10.0, 3.0	-9.0, 3.0	-10.0, 3.0	-10.0, 3.0	-1.0, 2.0	-7.0, 1.0	-8.0, 2.0	-6.0, 3.0
25th, 75th %tile	-2.0, 0.0	0.0, 0.0	-3.0, 0.0	-3.5, 0.0	-1.0, 1.0	-2.5, 0.0	-3.0, 1.0	-2.0, 0.0

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Week 14 Visit								
N	149	13	37	24	13	12	23	27
Mean (STD)	0.9 (2.5)	-0.5 (1.7)	1.3 (2.7)	0.0 (0.3)	1.1 (2.6)	1.8 (2.4)	1.6 (3.0)	0.6 (2.9)
Median	0.0	0.0	1.0	0.0	0.0	1.5	0.0	0.0
Min, Max	-3.0, 10.0	-3.0, 2.0	-3.0, 8.0	-1.0, 1.0	-1.0, 9.0	-3.0, 7.0	-3.0, 8.0	-3.0, 10.0
25th, 75th %tile	0.0, 1.0	-2.0, 0.0	0.0, 3.0	0.0, 0.0	0.0, 1.0	1.0, 3.0	0.0, 2.0	-1.0, 1.0
Week 17 Visit								
N	150	13	37	25	13	12	24	26
Mean (STD)	0.2 (2.8)	-0.2 (1.1)	0.1 (3.5)	-0.2 (2.6)	1.4 (2.6)	-0.6 (2.9)	1.4 (3.5)	0.0 (1.6)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-7.0, 9.0	-3.0, 2.0	-7.0, 8.0	-7.0, 9.0	-2.0, 7.0	-7.0, 3.0	-5.0, 9.0	-3.0, 4.0
25th, 75th %tile	-1.0, 1.0	0.0, 0.0	-2.0, 1.0	0.0, 0.0	0.0, 2.0	-2.0, 1.5	0.0, 3.0	-1.0, 1.0
Week 20 Visit								
N	147	13	35	25	12	12	24	26
Mean (STD)	-0.8 (2.4)	-0.7 (2.8)	-0.5 (2.1)	-0.2 (1.1)	0.5 (1.2)	-1.4 (2.3)	-2.8 (3.5)	-0.3 (1.8)
Median	0.0	0.0	0.0	0.0	0.0	0.0	-2.5	0.0
Min, Max	-10.0, 3.0	-10.0, 1.0	-6.0, 3.0	-4.0, 1.0	-2.0, 2.0	-7.0, 0.0	-8.0, 2.0	-3.0, 3.0
25th, 75th %tile	-1.0, 0.0	0.0, 0.0	-1.0, 0.0	0.0, 0.0	0.0, 1.5	-2.5, 0.0	-6.0, 0.5	-2.0, 1.0
Week 21 Visit								
N	147	13	36	24	13	12	23	26
Mean (STD)	0.2 (2.2)	0.6 (1.6)	0.6 (3.7)	0.0 (0.3)	0.6 (1.3)	-1.0 (1.7)	-0.2 (1.3)	0.3 (1.4)
Median	0.0	0.0	0.0	0.0	1.0	-0.5	0.0	0.0
Min, Max	-3.0, 19.0	-3.0, 3.0	-3.0, 19.0	-1.0, 1.0	-3.0, 2.0	-3.0, 2.0	-3.0, 2.0	-3.0, 4.0
25th, 75th %tile	0.0, 1.0	0.0, 2.0	-1.0, 1.0	0.0, 0.0	1.0, 1.0	-3.0, 0.0	-1.0, 1.0	0.0, 1.0

MTN 001 – Phase II Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir
Data as of: August 10, 2010
– Visit Adherence: Duration of Washout Period

	Total	South Africa Durban Bothas Hill	South Africa Durban Umkomaas	Uganda Kampala	United States Birmingham	United States Bronx	United States Cleveland	United States Pittsburgh
Duration of First Washout Period								
N	149	13	36	24	13	12	24	27
Mean (STD)	8.7 (3.3)	9.1 (2.9)	8.7 (4.1)	7.9 (2.0)	7.5 (0.9)	7.4 (1.3)	11.6 (4.3)	8.4 (2.6)
Median	7.0	8.0	7.0	7.0	7.0	7.5	13.0	8.0
Min, Max	4.0, 25.0	6.0, 14.0	5.0, 25.0	7.0, 14.0	6.0, 9.0	4.0, 9.0	6.0, 22.0	4.0, 15.0
25th, 75th %tile	7.0, 9.0	7.0, 12.0	7.0, 8.0	7.0, 8.0	7.0, 8.0	7.0, 8.0	7.0, 14.0	7.0, 9.0
Duration of Second Washout Period								
N	149	13	37	24	13	12	23	27
Mean (STD)	9.0 (3.7)	7.5 (3.7)	9.3 (4.0)	8.8 (3.9)	8.0 (2.1)	10.4 (2.6)	10.0 (4.7)	8.7 (3.2)
Median	7.0	7.0	7.0	7.0	7.0	10.0	8.0	8.0
Min, Max	4.0, 21.0	4.0, 16.0	4.0, 18.0	5.0, 17.0	6.0, 14.0	7.0, 15.0	5.0, 21.0	5.0, 20.0
25th, 75th %tile	7.0, 10.0	4.0, 9.0	7.0, 12.0	7.0, 10.5	7.0, 9.0	8.5, 12.5	7.0, 13.0	7.0, 9.0
Duration of Third Washout Period								
N	147	13	36	24	13	12	23	26
Mean (STD)	8.0 (3.2)	8.3 (3.6)	8.1 (4.7)	7.2 (1.1)	7.1 (1.2)	7.4 (2.2)	9.7 (3.6)	7.6 (1.9)
Median	7.0	7.0	7.0	7.0	7.0	7.0	8.0	7.0
Min, Max	3.0, 32.0	4.0, 19.0	3.0, 32.0	6.0, 11.0	4.0, 8.0	4.0, 11.0	6.0, 16.0	4.0, 14.0
25th, 75th %tile	7.0, 8.0	7.0, 9.0	7.0, 8.0	7.0, 7.0	7.0, 8.0	7.0, 8.5	7.0, 13.0	7.0, 8.0

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Data as of: August 10, 2010
– Visit Adherence: Completion of Procedures

	Total	South Africa Durban Bothas Hill	South Africa Durban Umkomaas	Uganda Kampala	United States Birmingham	United States Bronx	United States Cleveland	United States Pittsburgh
Participant-visits at Which Study Product Adherence and Behavior Assessment Are Required and Expected	866	75	210	148	74	72	140	147
Completed	864 (100%)	75 (100%)	210 (100%)	147 (99%)	74 (100%)	72 (100%)	139 (99%)	147 (100%)
Participant-visits at Which the Last Three Doses of Study Product Are Required and Expected	848	75	208	140	74	72	134	145
Completed	836 (99%)	70 (93%)	203 (98%)	138 (99%)	74 (100%)	72 (100%)	134 (100%)	145 (100%)
Partially completed	7 (1%)	3 (4%)	4 (2%)	--	--	--	--	--
Participant-visits at Which Acceptability Assessment Are Required and Expected	288	26	70	47	25	24	44	52
Completed	287 (100%)	26 (100%)	69 (99%)	47 (100%)	25 (100%)	24 (100%)	44 (100%)	52 (100%)
Participant-visits at Which Final Acceptability Assessment Are Required and Expected	147	13	35	25	12	12	24	26
Completed	144 (98%)	12 (92%)	35 (100%)	25 (100%)	12 (100%)	12 (100%)	24 (100%)	24 (92%)
Participant-visits (Weeks 3, 10, 17) at Which PK Blood Draw Is Required and Expected	439	38	106	76	37	36	72	74
Completed	437 (100%)	38 (100%)	105 (99%)	76 (100%)	36 (97%)	36 (100%)	72 (100%)	74 (100%)
Participant-visits (Weeks 6, 13, 20) at Which Non-intensive PK Blood Draws Are Required and Expected	213	37	104	72	0	0	0	0
Completed	212 (100%)	37 (100%)	104 (100%)	71 (99%)	--	--	--	--
Partially completed	1 (<1%)	--	--	1 (1%)	--	--	--	--
Participant-visits (Weeks 6, 13, 20) at Which Non-intensive PK CVL Are Required and Expected	213	37	104	72	0	0	0	0
Completed	212 (100%)	37 (100%)	104 (100%)	71 (99%)	--	--	--	--
Participant-visits (Weeks 6, 13, 20) at Which Intensive PK Blood Draws Are Required and Expected	214	0	0	0	37	36	68	73
Completed	212 (99%)	--	--	--	36 (97%)	36 (100%)	68 (100%)	72 (99%)
Partially completed	2 (1%)	--	--	--	1 (3%)	--	--	1 (1%)

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Participant-visits (Weeks 6, 13, 20) at Which Intensive PK Genital Specimens Are Required and Expected	214	0	0	0	37	36	68	73
Completed	212 (99%)	--	--	--	36 (97%)	36 (100%)	68 (100%)	72 (99%)
Partially completed	1 (<1%)	--	--	--	--	--	--	1 (1%)
Participant-visits (Weeks 6, 13, 20) at Which Intensive PK Rectal Specimens Are Required and Expected	36	0	0	0	0	36	0	0
Completed	36 (100%)	--	--	--	--	36 (100%)	--	--
Participant-visits at Which Pregnancy Tests Are Required and Expected	1329	122	307	225	111	111	201	252
Completed	1329 (100%)	122 (100%)	307 (100%)	225 (100%)	111 (100%)	111 (100%)	201 (100%)	252 (100%)
Participant-visits at Which Follow-up Pelvic Exams Are Required and Expected	1188	104	286	196	103	96	188	215
Completed	1177 (99%)	103 (99%)	285 (100%)	187 (95%)	103 (100%)	96 (100%)	188 (100%)	215 (100%)
Participant-visits at Which HIV Tests Are Required and Expected	298	26	73	48	26	24	47	54
Completed	297 (100%)	26 (100%)	73 (100%)	48 (100%)	26 (100%)	24 (100%)	47 (100%)	53 (98%)
Participant-visits at Which Hemogram Tests Are Required and Expected	298	26	73	48	26	24	47	54
Completed	298 (100%)	26 (100%)	73 (100%)	48 (100%)	26 (100%)	24 (100%)	47 (100%)	54 (100%)
Participant-visits at Which Chemistries Tests Are Required and Expected	1188	104	286	196	103	96	188	215
Completed	1188 (100%)	104 (100%)	286 (100%)	196 (100%)	103 (100%)	96 (100%)	188 (100%)	215 (100%)
Participant-visits at Which Product Sharing Assessments Are Required and Expected	434	38	105	72	38	36	68	77
Completed	433 (100%)	38 (100%)	104 (99%)	72 (100%)	38 (100%)	36 (100%)	68 (100%)	77 (100%)