

**MTN 017 - Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil
Fumarate Tablet and Rectally-Applied Tenofovir Reduced-Glycerin 1% Gel**
Report Generation Date: September 10, 2015
Visit Cutoff Date: September 3, 2015¹
Retention by Visit and Site

	Peru Lima	Puerto Rico San Juan	South Africa Cape Town	Thailand Bangkok	Thailand Chiang Mai	USA Boston	USA Pittsburgh	USA San Francisco	All Sites
Participants Enrolled	38	7	18	24	30	7	33	38	195
Mid Period 1									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	36 (95%)	7 (100%)	18 (100%)	24 (100%)	30 (100%)	7 (100%)	32 (97%)	38 (100%)	192 (98%)
Not Completed	2 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)	3 (2%)
Missed	2 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)	1 (1%)
Not Expected	0	0	0	0	0	0	0	0	0
End Period 1									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	34 (89%)	7 (100%)	16 (89%)	24 (100%)	30 (100%)	7 (100%)	31 (94%)	35 (92%)	184 (94%)
Not Completed	4 (11%)	0 (0%)	2 (11%)	0 (0%)	0 (0%)	0 (0%)	2 (6%)	3 (8%)	11 (6%)
Missed	4 (11%)	0 (0%)	2 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (8%)	9 (5%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (6%)	0 (0%)	2 (1%)
Not Expected	0	0	0	0	0	0	0	0	0
Initiate Period 2									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	37 (97%)	7 (100%)	16 (89%)	24 (100%)	30 (100%)	6 (86%)	30 (91%)	38 (100%)	188 (96%)
Not Completed	1 (3%)	0 (0%)	2 (11%)	0 (0%)	0 (0%)	1 (14%)	3 (9%)	0 (0%)	7 (4%)
Missed	0 (0%)	0 (0%)	2 (11%)	0 (0%)	0 (0%)	1 (14%)	0 (0%)	0 (0%)	3 (2%)
Terminated Early	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (9%)	0 (0%)	4 (2%)
Not Expected	0	0	0	0	0	0	0	0	0
Mid Period 2									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	36 (95%)	7 (100%)	18 (100%)	24 (100%)	30 (100%)	6 (86%)	30 (91%)	35 (92%)	186 (95%)
Not Completed	2 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (14%)	3 (9%)	3 (8%)	9 (5%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (8%)	3 (2%)
Terminated Early	2 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (14%)	3 (9%)	0 (0%)	6 (3%)

¹ This report includes data received and entered at SCHARP through this date.

² A visit is considered expected only once the participant's visit window has closed.

³ A visit is considered completed once the Visit Summary form is received and entered at SCHARP.

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	Peru Lima	Puerto Rico San Juan	South Africa Cape Town	Thailand Bangkok	Thailand Chiang Mai	USA Boston	USA Pittsburgh	USA San Francisco	All Sites
Not Expected	0	0	0	0	0	0	0	0	0

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	Peru Lima	Puerto Rico San Juan	South Africa Cape Town	Thailand Bangkok	Thailand Chiang Mai	USA Boston	USA Pittsburgh	USA San Francisco	All Sites
End Period 2									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	34 (89%)	7 (100%)	17 (94%)	24 (100%)	29 (97%)	6 (86%)	30 (91%)	34 (89%)	181 (93%)
Not Completed	4 (11%)	0 (0%)	1 (6%)	0 (0%)	1 (3%)	1 (14%)	3 (9%)	4 (11%)	14 (7%)
Missed	2 (5%)	0 (0%)	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (11%)	7 (4%)
Terminated Early	2 (5%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	1 (14%)	3 (9%)	0 (0%)	7 (4%)
Not Expected	0	0	0	0	0	0	0	0	0
Initiate Period 3									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	36 (95%)	7 (100%)	17 (94%)	24 (100%)	29 (97%)	6 (86%)	29 (88%)	35 (92%)	183 (94%)
Not Completed	2 (5%)	0 (0%)	1 (6%)	0 (0%)	1 (3%)	1 (14%)	4 (12%)	3 (8%)	12 (6%)
Missed	0 (0%)	0 (0%)	1 (6%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	2 (5%)	4 (2%)
Terminated Early	2 (5%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	1 (14%)	3 (9%)	1 (3%)	8 (4%)
Not Expected	0	0	0	0	0	0	0	0	0
Mid Period 3									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	35 (92%)	7 (100%)	16 (89%)	24 (100%)	29 (97%)	6 (86%)	29 (88%)	36 (95%)	182 (93%)
Not Completed	3 (8%)	0 (0%)	2 (11%)	0 (0%)	1 (3%)	1 (14%)	4 (12%)	2 (5%)	13 (7%)
Missed	1 (3%)	0 (0%)	2 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	4 (2%)
Terminated Early	2 (5%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	1 (14%)	4 (12%)	1 (3%)	9 (5%)
Not Expected	0	0	0	0	0	0	0	0	0
End Period 3									
Expected ¹	38	7	18	24	30	7	33	38	195
Completed ²	36 (95%)	7 (100%)	16 (89%)	24 (100%)	29 (97%)	5 (71%)	29 (88%)	37 (97%)	183 (94%)
Not Completed	2 (5%)	0 (0%)	2 (11%)	0 (0%)	1 (3%)	2 (29%)	4 (12%)	1 (3%)	12 (6%)
Missed	0 (0%)	0 (0%)	2 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)
Terminated Early	2 (5%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	2 (29%)	4 (12%)	1 (3%)	10 (5%)
Not Expected	0	0	0	0	0	0	0	0	0

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