



DATA SUMMARY REPORT

ENROLLMENT, RETENTION, PROCEDURE COMPLETION, DATA MANAGEMENT QUALITY

MTN 017

September 10, 2015

**MTN 017 - Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil
Fumarate Tablet and Rectally-Applied Tenofovir Reduced-Glycerin 1% Gel
Data as of September 9, 2015**

Accrual Summary by Site

Site	Activation Date	First Enrollment Date	Last Enrollment Date¹	Duration of Accrual² (weeks)	Total Screened	Total Enrolled	Enrollment Target	Screen/Enroll	Average Enrolled per Week	Percent Enrolled	Percent Accrual Duration³
1. Peru - Lima	15JAN2014	23JAN2014	10NOV2014	41.7	55	38	36	1.4	0.9	105.6%	Completed
2. Puerto Rico - San Juan	15NOV2013	13FEB2014	18JUL2014	22.3	13	7	7	1.9	0.3	100.0%	Completed
3. South Africa - Cape Town	28FEB2014	10APR2014	30OCT2014	29.1	40	18	18	2.2	0.6	100.0%	Completed
4. Thailand - Bangkok	27JUN2014	09JUL2014	22OCT2014	15.1	32	24	24	1.3	1.6	100.0%	Completed
5. Thailand - Chiang Mai	06JAN2014	04FEB2014	13NOV2014	40.4	55	30	30	1.8	0.7	100.0%	Completed
6. USA - Boston	06SEP2013	25SEP2013	29JAN2014	18.1	12	7	6	1.7	0.4	116.7%	Completed
7. USA - Pittsburgh	27SEP2013	24OCT2013	10NOV2014	54.7	45	33	30	1.4	0.6	110.0%	Completed
8. USA - San Francisco	24SEP2013	29OCT2013	18NOV2014	55.1	97	38	36	2.6	0.7	105.6%	Completed
All Sites	06SEP2013	25SEP2013	18NOV2014	60.0	349	195	187	1.8	3.3	104.3%	N/A

¹ Date of most recent enrollment as of September 9, 2015.

² Duration of accrual based on first enrollment date.

³ This is the percent of time that has elapsed from the first enrollment to the expected duration of accrual per protocol. For example, if the report is run on May 31, 2014, the site's first enrollment is on January 1, 2014 and the expected duration of accrual is 6 months, then the Percent Accrual Duration = 83.3%.

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Cumulative Percent Retention by Site

	Total Enrolled	# Completed Visits	# Expected Visits	Retention Rate
1. Peru - Lima	38	248	266	93.2%
2. Puerto Rico - San Juan	7	49	49	100%
3. South Africa - Cape Town	18	118	126	93.7%
4. Thailand - Bangkok	24	168	168	100%
5. Thailand - Chiang Mai	30	207	210	98.6%
6. USA - Boston	7	44	49	89.8%
7. USA - Pittsburgh	33	211	231	91.3%
8. USA - San Francisco	38	251	266	94.4%

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

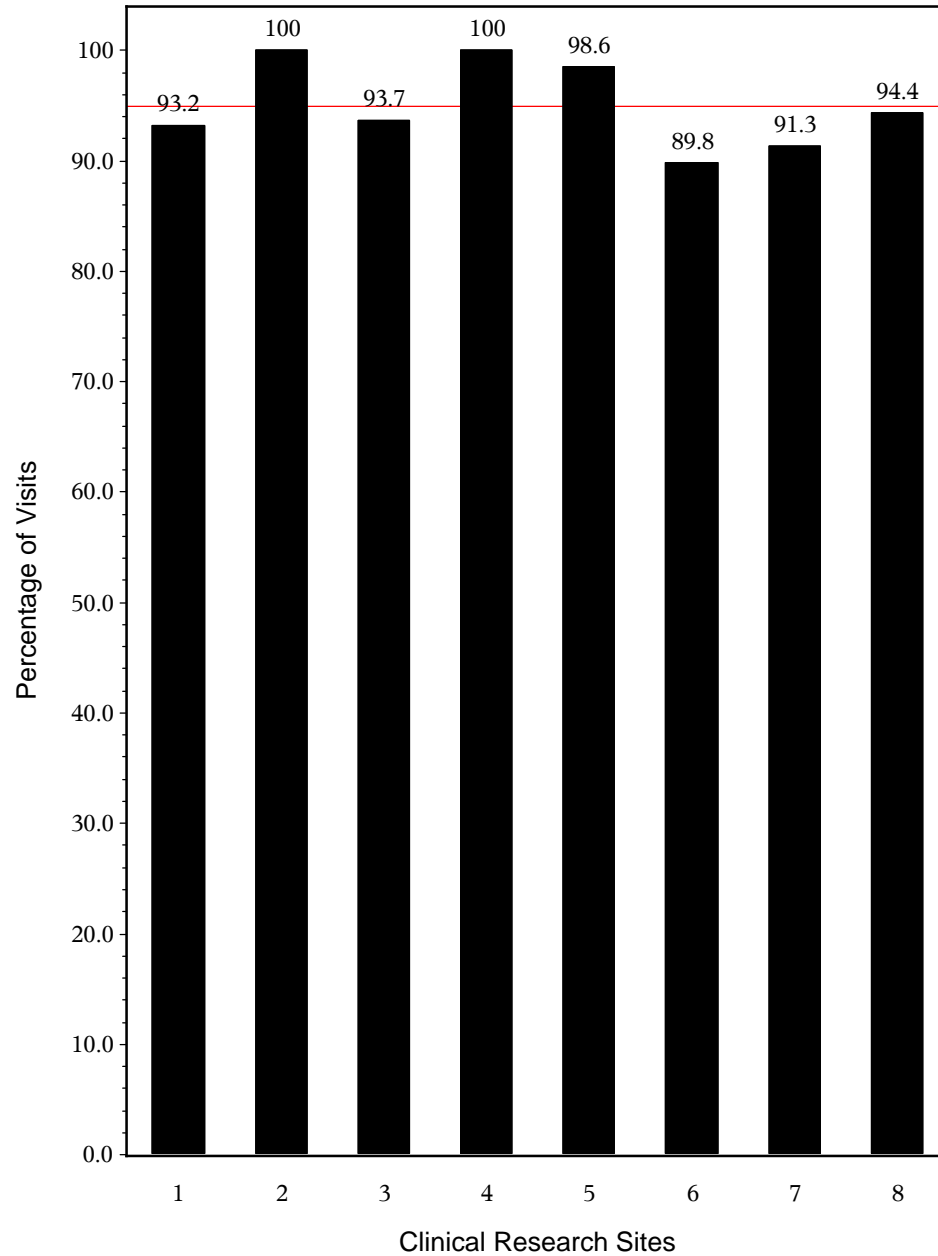
² The measures in this report summarize retention over all expected visits.

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

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

MTN 017 - Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil Fumarate Tablet and Rectally-Applied Tenofovir Reduced-Glycerin 1% Gel
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Cumulative Percent Retention by Site



1. Peru - Lima
2. Puerto Rico - San Juan
3. South Africa - Cape Town
4. Thailand - Bangkok
5. Thailand - Chiang Mai
6. USA - Boston
7. USA - Pittsburgh
8. USA - San Francisco

**MTN 017 - Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil Fumarate Tablet and Rectally-Applied Tenofovir Reduced-Glycerin 1% Gel
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Visit Adherence: Completion of Procedures During Follow-up¹ Visits by Site

	1. Peru Lima	2. Puerto Rico San Juan	3. South Africa Cape Town	4. Thailand Bangkok	5. Thailand Chiang Mai	6. USA Boston	7. USA Pittsburgh	8. USA San Francisco	All Sites
Participants Enrolled	38	7	18	24	30	7	33	38	195
1. Abbreviated Physical Exam Required and Expected	112/112 (100%)	21/21 (100%)	50/50 (100%)	71/71 (100%)	89/89 (100%)	19/19 (100%)	95/95 (100%)	112/112 (100%)	569/569 (100%)
2. Anorectal Exam Required and Expected	360/360 (100%)	70/70 (100%)	154/157 (98%)	236/236 (100%)	295/295 (100%)	61/61 (100%)	305/306 (>99%)	354/358 (98%)	1835/1843 (>99%)
3. Rectal Sponge for Adherence PK Required and Expected	284/284 (100%)	55/56 (98%)	117/121 (96%)	188/188 (100%)	235/235 (100%)	47/47 (100%)	239/240 (>99%)	278/282 (98%)	1443/1453 (99%)
4. Rectal Sponge for PD Required and Expected	322/322 (100%)	62/63 (98%)	135/139 (97%)	212/212 (100%)	265/265 (100%)	54/54 (100%)	272/273 (>99%)	316/320 (98%)	1638/1648 (99%)
5. Rectal Sponge for Mucosal Immunology Required and Expected (subset only)	0/0 (0%)	0/0 (0%)	0/0 (0%)	72/72 (100%)	0/0 (0%)	0/0 (0%)	74/74 (100%)	0/0 (0%)	146/146 (100%)
6. Rectal Biopsy for PK Required and Expected (subset only)	0/0 (0%)	0/0 (0%)	0/0 (0%)	54/54 (100%)	0/0 (0%)	0/0 (0%)	55/55 (100%)	0/0 (0%)	109/109 (100%)
7. Rectal Biopsy for PD Required and Expected (subset only)	0/0 (0%)	0/0 (0%)	0/0 (0%)	72/72 (100%)	0/0 (0%)	0/0 (0%)	74/74 (100%)	0/0 (0%)	146/146 (100%)
8. Rectal Biopsy for mucosal T-cell Phenotyping Required and Expected (subset only)	0/0 (0%)	0/0 (0%)	0/0 (0%)	72/72 (100%)	0/0 (0%)	0/0 (0%)	74/74 (100%)	0/0 (0%)	146/146 (100%)
9. Rectal Biopsy for Mucosal Gene Expression Required and Expected (subset only)	0/0 (0%)	0/0 (0%)	0/0 (0%)	72/72 (100%)	0/0 (0%)	0/0 (0%)	74/74 (100%)	0/0 (0%)	146/146 (100%)
10. Rectal Biopsy for Histology Required and Expected (subset only)	0/0 (0%)	0/0 (0%)	0/0 (0%)	72/72 (100%)	0/0 (0%)	0/0 (0%)	74/74 (100%)	0/0 (0%)	146/146 (100%)
11. Rectal Biopsy for Proteomics Required and Expected (subset only)	0/0 (0%)	0/0 (0%)	0/0 (0%)	72/72 (100%)	0/0 (0%)	0/0 (0%)	73/74 (98%)	0/0 (0%)	145/146 (99%)
12. Anal Swab for HPV Required and Expected	38/38 (100%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	30/30 (100%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	195/195 (100%)
13. Rectal NAAT for GC/CT Required and Expected	179/180 (99%)	34/35 (97%)	77/81 (95%)	118/118 (100%)	147/148 (99%)	31/31 (100%)	154/156 (98%)	179/179 (100%)	919/928 (99%)
14. Dipstick UA Required and Expected	38/38 (100%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	30/30 (100%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	195/195 (100%)
15. Urine NAAT for GC/CT Required and Expected	74/74 (100%)	14/14 (100%)	32/32 (100%)	47/47 (100%)	59/59 (100%)	12/12 (100%)	62/62 (100%)	74/74 (100%)	374/374 (100%)

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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Visit Adherence: Completion of Procedures During Follow-up¹ Visits by Site

	1. Peru Lima	2. Puerto Rico San Juan	3. South Africa Cape Town	4. Thailand Bangkok	5. Thailand Chiang Mai	6. USA Boston	7. USA Pittsburgh	8. USA San Francisco	All Sites
16. CBC Required and Expected	74/74 (100%)	14/14 (100%)	32/32 (100%)	47/47 (100%)	59/59 (100%)	12/12 (100%)	62/62 (100%)	74/74 (100%)	374/374 (100%)
17. AST/ALT Required and Expected	73/74 (98%)	14/14 (100%)	32/32 (100%)	47/47 (100%)	59/59 (100%)	12/12 (100%)	62/62 (100%)	74/74 (100%)	373/374 (>99%)
18. Creatinine Required and Expected	142/142 (100%)	28/28 (100%)	63/63 (100%)	94/94 (100%)	118/118 (100%)	24/24 (100%)	123/123 (100%)	141/141 (100%)	733/733 (100%)
19. Plasma for Archive Required and Expected	38/38 (100%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	30/30 (100%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	195/195 (100%)
20. Plasma for Storage Required and Expected	211/211 (100%)	42/42 (100%)	88/91 (96%)	141/141 (100%)	177/177 (100%)	35/35 (100%)	180/181 (99%)	208/211 (98%)	1082/1089 (99%)
21. PBMC for PK Required and Expected	104/104 (100%)	21/21 (100%)	44/45 (97%)	70/70 (100%)	88/88 (100%)	17/17 (100%)	90/90 (100%)	102/103 (99%)	536/538 (>99%)
22. Syphilis RPR Required and Expected	38/38 (100%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	30/30 (100%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	195/195 (100%)
23. HIV 1 Serology Required and Expected	287/287 (100%)	56/56 (100%)	127/127 (100%)	189/189 (100%)	237/237 (100%)	49/49 (100%)	247/247 (100%)	287/287 (100%)	1479/1479 (100%)
24. HSV 1/2 Antibody Required and Expected	38/38 (100%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	29/30 (96%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	194/195 (99%)
25. Hepatitis B Surface Antigen and Antibody Required and Expeted	38/38 (100%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	30/30 (100%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	195/195 (100%)
26. Hepatitis C Antibody Required and Expected	38/38 (100%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	30/30 (100%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	195/195 (100%)
27. Coagulation Blood Test Required and Expected	0/0 (0%)	0/0 (0%)	0/0 (0%)	18/18 (100%)	0/0 (0%)	0/0 (0%)	19/19 (100%)	0/0 (0%)	37/37 (100%)
28. Data Convergence Interview Required and Expected	211/211 (100%)	42/42 (100%)	91/91 (100%)	141/141 (100%)	177/177 (100%)	35/35 (100%)	181/181 (100%)	211/211 (100%)	1089/1089 (100%)
29. Baseline Behavioral Questionnaire (CASI) Required and Expected	37/38 (97%)	7/7 (100%)	18/18 (100%)	24/24 (100%)	30/30 (100%)	7/7 (100%)	33/33 (100%)	38/38 (100%)	194/195 (99%)
30. Follow Up Behavioral Questionnaire (CASI) Required and Expected	104/104 (100%)	20/21 (95%)	45/49 (91%)	70/72 (97%)	88/88 (100%)	18/18 (100%)	90/90 (100%)	102/106 (96%)	537/548 (98%)

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.

**MTN-017 Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil
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**DATA MANAGEMENT QUALITY REPORT
Cumulative: Study Start through August 2015**

Site	Total Records	Total QCs	QC Rate Per 100 Records (Goal <5)	% QCs Resolved	%CRF Pages Received Within 7 days (Goal ≥ 95%)	Mean Days to Fax in AE
1. Peru - Lima	3518	212	6.0	100%	99%	4.4
2. Puerto Rico - San Juan	813	177	21.8	100%	93%	10.5
3. South Africa - Cape Town	2094	164	7.8	100%	95%	6.8
4. Thailand - Bangkok	2768	52	1.9	100%	100%	1.2
5. Thailand - Chiang Mai	3227	89	2.8	100%	95%	5.0
6. USA - Boston	645	101	15.7	100%	97%	2.5
7. USA - Pittsburgh	3114	133	4.3	100%	98%	7.2
8. USA - San Francisco	4594	350	7.6	100%	99%	4.8
TOTAL	20773	1278	6.2	100%	98%	5.0

DEFINITION OF TERMS

Total Records: Total number of CRF records submitted to SCHARP DataFax (via fax or EDC) in the reporting time period. For CRFs submitted multiple times (via refaxes and EDC), the most recent CRF record submitted (using the record creation date) is included.

Total QCs: Total number of Quality Control records (QCs) created in the reporting time period that have appeared on QC Reports (sent to sites or accessed via iDataFax.) This does not include "missing page", "overdue visit", or "fax noise" QCs.

QC Rate Per 100 Records: This is the rate of QCs per 100 records. Obtained by dividing Total QCs by Total Records, and multiplying by 100.

% QCs Resolved: The percentage of Total QCs that have been resolved. Obtained by dividing the number of resolved QCs by Total QCs. % QCs Resolved is expected to be close to 100% for the cumulative reporting time period, but may be significantly less than 100% for the monthly reporting time period due to the scheduling/access of the QC Reports.

% CRF Records Faxed within 7 Days: The percentage of CRF records faxed to SCHARP within 7 days of the visit date. For CRFs faxed in multiple times, only the initial CRF record faxed in contributes to this metric. CRF records submitted via EDC do not contribute to this metric.

Mean Days to Fax in AE: Mean number of days for the site to complete the AE CRF and fax to SCHARP. Days to Fax in AE is the difference between the AE Reported to Site Date and the DataFax fax date stamp, in number of days. AE CRF records with a fax date within the reporting time period are included. For CRFs faxed in multiple times, only the initial CRF record faxed in contributes to this metric. CRF records submitted via EDC do not contribute to this metric.

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**DATA MANAGEMENT QUALITY REPORT
Previous Month: August 2015**

Site	Total Records	Total QCs	QC Rate Per 100 Records (Goal < 5)	%CRF Pages Received Within 7 days (Goal ≥ 95%)	Mean Days to Fax in AE
1. Peru - Lima	0	0	.	.	.
2. Puerto Rico - San Juan	0	0	.	.	.
3. South Africa - Cape Town	0	0	.	.	.
4. Thailand - Bangkok	0	0	.	.	.
5. Thailand - Chiang Mai	0	0	.	.	.
6. USA - Boston	0	0	.	.	.
7. USA - Pittsburgh	1	1	100	.	.
8. USA - San Francisco	0	1	.	.	.
TOTAL	1	2	200	.	.

DEFINITION OF TERMS

Total Records: Total number of CRF records submitted to SCHARP DataFax (via fax or EDC) in the reporting time period. For CRFs submitted multiple times (via refaxes and EDC), the most recent CRF record submitted (using the record creation date) is included.

Total QCs: Total number of Quality Control records (QCs) created in the reporting time period that have appeared on QC Reports (sent to sites or accessed via iDataFax.) This does not include "missing page", "overdue visit", or "fax noise" QCs.

QC Rate Per 100 Records: This is the rate of QCs per 100 records. Obtained by dividing Total QCs by Total Records, and multiplying by 100.

% CRF Records Faxed within 7 Days: The percentage of CRF records faxed to SCHARP within 7 days of the visit date. For CRFs faxed in multiple times, only the initial CRF record faxed in contributes to this metric. CRF records submitted via EDC do not contribute to this metric.

Mean Days to Fax in AE: Mean number of days for the site to complete the AE CRF and fax to SCHARP. Days to Fax in AE is the difference between the AE Reported to Site Date and the DataFax fax date stamp, in number of days. AE CRF records with a fax date within the reporting time period are included. For CRFs faxed in multiple times, only the initial CRF record faxed in contributes to this metric. CRF records submitted via EDC do not contribute to this metric.