

Date: November 11, 2013
To: MTN 017 Protocol Team
From: SCHARP
RE: MTN 017 Visit Adherence, Completion of Procedures by Site Report

Purpose

To summarize, overall and by site, completion of required and expected follow-up visit procedures.

Definition of Required and Expected Procedures

Refer to the protocol and/or the Study-Specific Procedures Manual for required procedures at each follow-up visit.

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.

Definition of Completed Procedures

Completion of a procedure is defined by specific data elements on the CRF. For example, for laboratory assays, the assay is counted as completed if a result is present on the appropriate CRF. For other procedures, a completion date, completion time, and/or response of “yes” or “stored” on the appropriate CRF may be the indication that the procedure was completed.

**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**

Visit Adherence: Completion of Procedures During Follow-up¹ Visits by 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
1. Abbreviated Physical Exam Required and Expected	112	21	50	71	89	19	95	112	569
Completed	112 (100.0%)	21 (100.0%)	50 (100.0%)	71 (100.0%)	89 (100.0%)	19 (100.0%)	95 (100.0%)	112 (100.0%)	569 (100.0%)
2. Anorectal Exam Required and Expected	360	70	157	236	295	61	306	358	1843
Completed	360 (100.0%)	70 (100.0%)	154 (98.1%)	236 (100.0%)	295 (100.0%)	61 (100.0%)	305 (>99%)	354 (98.9%)	1835 (>99%)
Not Completed	0 (0.0%)	0 (0.0%)	3 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (1.1%)	8 (0.4%)
3. Rectal Sponge for Adherence PK Required and Expected	284	56	121	188	235	47	240	282	1453
Completed	284 (100.0%)	55 (98.2%)	117 (96.7%)	188 (100.0%)	235 (100.0%)	47 (100.0%)	239 (>99%)	278 (98.6%)	1443 (99.3%)
Not Completed	0 (0.0%)	1 (1.8%)	4 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	4 (1.4%)	10 (0.7%)
4. Rectal Sponge for PD Required and Expected	322	63	139	212	265	54	273	320	1648
Completed	322 (100.0%)	62 (98.4%)	135 (97.1%)	212 (100.0%)	265 (100.0%)	54 (100.0%)	272 (>99%)	316 (98.8%)	1638 (99.4%)
Not Completed	0 (0.0%)	1 (1.6%)	4 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	4 (1.3%)	10 (0.6%)
5. Rectal Sponge for Mucosal Immunology Required and Expected (subset only)	0	0	0	72	0	0	74	0	146
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	74 (100.0%)	0 (0.0%)	146 (100.0%)
6. Rectal Biopsy for PK Required and Expected (subset only)	0	0	0	54	0	0	55	0	109
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	54 (100.0%)	0 (0.0%)	0 (0.0%)	55 (100.0%)	0 (0.0%)	109 (100.0%)
7. Rectal Biopsy for PD Required and Expected (subset only)	0	0	0	72	0	0	74	0	146
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	74 (100.0%)	0 (0.0%)	146 (100.0%)
8. Rectal Biopsy for mucosal T-cell Phenotyping Required and Expected (subset only)	0	0	0	72	0	0	74	0	146
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	74 (100.0%)	0 (0.0%)	146 (100.0%)

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Visit Adherence: Completion of Procedures During Follow-up¹ Visits by 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
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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
9. Rectal Biopsy for Mucosal Gene Expression Required and Expected (subset only)	0	0	0	72	0	0	74	0	146
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	74 (100.0%)	0 (0.0%)	146 (100.0%)
10. Rectal Biopsy for Histology Required and Expected (subset only)	0	0	0	72	0	0	74	0	146
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	74 (100.0%)	0 (0.0%)	146 (100.0%)
11. Rectal Biopsy for Proteomics Required and Expected (subset only)	0	0	0	72	0	0	74	0	146
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	73 (98.6%)	0 (0.0%)	145 (99.3%)
Not Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.7%)
12. Anal Swab for HPV Required and Expected	38	7	18	24	30	7	33	38	195
Completed	38 (100.0%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	30 (100.0%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	195 (100.0%)
13. Rectal NAAT for GC/CT Required and Expected	180	35	81	118	148	31	156	179	928
Completed	179 (99.4%)	34 (97.1%)	77 (95.1%)	118 (100.0%)	147 (99.3%)	31 (100.0%)	154 (98.7%)	179 (100.0%)	919 (99.0%)
Partially Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)
Not Completed	1 (0.6%)	1 (2.9%)	4 (4.9%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	8 (0.9%)
14. Dipstick UA Required and Expected	38	7	18	24	30	7	33	38	195
Completed	38 (100.0%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	30 (100.0%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	195 (100.0%)
15. Urine NAAT for GC/CT Required and Expected	74	14	32	47	59	12	62	74	374
Completed	74 (100.0%)	14 (100.0%)	32 (100.0%)	47 (100.0%)	59 (100.0%)	12 (100.0%)	62 (100.0%)	74 (100.0%)	374 (100.0%)
16. CBC Required and Expected	74	14	32	47	59	12	62	74	374
Completed	74 (100.0%)	14 (100.0%)	32 (100.0%)	47 (100.0%)	59 (100.0%)	12 (100.0%)	62 (100.0%)	74 (100.0%)	374 (100.0%)

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17. AST/ALT Required and Expected	74	14	32	47	59	12	62	74	374
Completed	73 (98.6%)	14 (100.0%)	32 (100.0%)	47 (100.0%)	59 (100.0%)	12 (100.0%)	62 (100.0%)	74 (100.0%)	373 (>99%)
Not Completed	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
18. Creatinine Required and Expected	142	28	63	94	118	24	123	141	733
Completed	142 (100.0%)	28 (100.0%)	63 (100.0%)	94 (100.0%)	118 (100.0%)	24 (100.0%)	123 (100.0%)	141 (100.0%)	733 (100.0%)
19. Plasma for Archive Required and Expected	38	7	18	24	30	7	33	38	195
Completed	38 (100.0%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	30 (100.0%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	195 (100.0%)
20. Plasma for Storage Required and Expected	211	42	91	141	177	35	181	211	1089
Completed	211 (100.0%)	42 (100.0%)	88 (96.7%)	141 (100.0%)	177 (100.0%)	35 (100.0%)	180 (99.4%)	208 (98.6%)	1082 (99.4%)
Not Completed	0 (0.0%)	0 (0.0%)	3 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (1.4%)	7 (0.6%)
21. PBMC for PK Required and Expected	104	21	45	70	88	17	90	103	538
Completed	104 (100.0%)	21 (100.0%)	44 (97.8%)	70 (100.0%)	88 (100.0%)	17 (100.0%)	90 (100.0%)	102 (99.0%)	536 (>99%)
Not Completed	0 (0.0%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	2 (0.4%)
22. Syphilis RPR Required and Expected	38	7	18	24	30	7	33	38	195
Completed	38 (100.0%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	30 (100.0%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	195 (100.0%)
23. HIV 1 Serology Required and Expected	287	56	127	189	237	49	247	287	1479
Completed	287 (100.0%)	56 (100.0%)	127 (100.0%)	189 (100.0%)	237 (100.0%)	49 (100.0%)	247 (100.0%)	287 (100.0%)	1479 (100.0%)
24. HSV 1/2 Antibody Required and Expected	38	7	18	24	30	7	33	38	195
Completed	38 (100.0%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	29 (96.7%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	194 (99.5%)
Not Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)

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25. Hepatitis B Surface Antigen and Antibody Required and Expeted	38	7	18	24	30	7	33	38	195
Completed	38 (100.0%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	30 (100.0%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	195 (100.0%)
26. Hepatitis C Antibody Required and Expected	38	7	18	24	30	7	33	38	195
Completed	38 (100.0%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	30 (100.0%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	195 (100.0%)
27. Coagulation Blood Test Required and Expected	0	0	0	18	0	0	19	0	37
Completed	0 (0.0%)	0 (0.0%)	0 (0.0%)	18 (100.0%)	0 (0.0%)	0 (0.0%)	19 (100.0%)	0 (0.0%)	37 (100.0%)
28. Data Convergence Interview Required and Expected	211	42	91	141	177	35	181	211	1089
Completed	211 (100.0%)	42 (100.0%)	91 (100.0%)	141 (100.0%)	177 (100.0%)	35 (100.0%)	181 (100.0%)	211 (100.0%)	1089 (100.0%)
29. Baseline Behavioral Questionnaire (CASI) Required and Expected	38	7	18	24	30	7	33	38	195
Completed	37 (97.4%)	7 (100.0%)	18 (100.0%)	24 (100.0%)	30 (100.0%)	7 (100.0%)	33 (100.0%)	38 (100.0%)	194 (99.5%)
Not Completed	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
30. Follow Up Behavioral Questionnaire (CASI) Required and Expected	104	21	49	72	88	18	90	106	548
Completed	104 (100.0%)	20 (95.2%)	45 (91.8%)	70 (97.2%)	88 (100.0%)	18 (100.0%)	90 (100.0%)	102 (96.2%)	537 (98.0%)
Not Completed	0 (0.0%)	1 (4.8%)	4 (8.2%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.8%)	11 (2.0%)

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