

**Date:** January 30, 2013  
**To:** MTN 020 Protocol Team  
**From:** SCHARP  
**RE:** **MTN 020 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 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)**  
**Data as of September 21, 2015**

**Visit Adherence: Completion of Procedures by Site<sup>1</sup> - First 8 Sites**

	All Sites	Malawi - Blantyre	Malawi - Lilongwe	SA - Cape Town	SA - CAPRISA eThekwinini	SA - MRC/ Botha's Hill	SA - MRC/ Chatsworth	SA - MRC/ Isipingo	SA - MRC/ Tongaat
Participants Enrolled	2629	130	142	166	244	180	150	117	103
1. Behavioral Assessment Required and Expected	19133	704	747	1273	1689	1407	1197	1049	898
Completed	19133 (100%)	704 (100%)	747 (100%)	1273 (100%)	1689 (100%)	1407 (100%)	1197 (100%)	1049 (100%)	898 (100%)
2. Adherence Assessment Required and Expected	56571	2116	2220	3773	5052	4105	3501	3081	2610
Completed	56571 (100%)	2116 (100%)	2220 (100%)	3773 (100%)	5052 (100%)	4105 (100%)	3501 (100%)	3081 (100%)	2610 (100%)
3. Acceptability Assessment Required and Expected	19133	704	747	1273	1689	1407	1197	1049	898
Completed	19133 (100%)	704 (100%)	747 (100%)	1273 (100%)	1689 (100%)	1407 (100%)	1197 (100%)	1049 (100%)	898 (100%)
4. Social Harms Assessment Required and Expected	19133	704	747	1273	1689	1407	1197	1049	898
Completed	19133 (100%)	704 (100%)	747 (100%)	1273 (100%)	1689 (100%)	1407 (100%)	1197 (100%)	1049 (100%)	898 (100%)
5. Pelvic Exams Required and Expected	9327	352	386	628	807	676	569	474	403
Completed	9163 (98%)	352 (100%)	377 (98%)	620 (99%)	795 (99%)	668 (99%)	559 (98%)	470 (99%)	392 (97%)
Not Completed	164 (2%)	0 (0%)	9 (2%)	8 (1%)	12 (1%)	8 (1%)	10 (2%)	4 (1%)	11 (3%)
6. Pregnancy Tests Required and Expected	56471	2206	2284	3770	4995	3947	3399	2894	2493
Completed	56406 (>99%)	2206 (100%)	2281 (>99%)	3763 (>99%)	4995 (100%)	3943 (>99%)	3390 (>99%)	2887 (>99%)	2492 (>99%)
Not Completed	65 (<1%)	0 (0%)	3 (<1%)	7 (<1%)	0 (0%)	4 (<1%)	9 (<1%)	7 (<1%)	1 (<1%)
7. Trichomoniasis, Gonorrhea and Chlamydia Tests Required and Expected	8948	329	334	599	788	650	554	494	427
Completed	8378 (94%)	325 (99%)	299 (90%)	562 (94%)	718 (91%)	624 (96%)	501 (90%)	472 (96%)	384 (90%)
Not Completed	570 (6%)	4 (1%)	35 (10%)	37 (6%)	70 (9%)	26 (4%)	53 (10%)	22 (4%)	43 (10%)
8. HIV-1 Tests Required and Expected	56471	2206	2284	3770	4995	3947	3399	2894	2493
Completed	56405 (>99%)	2206 (100%)	2281 (>99%)	3762 (>99%)	4995 (100%)	3943 (>99%)	3388 (>99%)	2887 (>99%)	2492 (>99%)
Not Completed	66 (<1%)	0 (0%)	3 (<1%)	8 (<1%)	0 (0%)	4 (<1%)	11 (<1%)	7 (<1%)	1 (<1%)
9. Hemograms Required and Expected	18295	694	724	1224	1593	1295	1114	952	824
Completed	18257 (>99%)	692 (>99%)	722 (>99%)	1220 (>99%)	1591 (>99%)	1294 (>99%)	1113 (>99%)	948 (>99%)	822 (>99%)
Not Completed	38 (<1%)	2 (<1%)	2 (<1%)	4 (<1%)	2 (<1%)	1 (<1%)	1 (<1%)	4 (<1%)	2 (<1%)
10. Differentials Required and Expected	18295	694	724	1224	1593	1295	1114	952	824
Completed	18258 (>99%)	692 (>99%)	722 (>99%)	1220 (>99%)	1591 (>99%)	1294 (>99%)	1113 (>99%)	948 (>99%)	822 (>99%)
Not Completed	37 (<1%)	2 (<1%)	2 (<1%)	4 (<1%)	2 (<1%)	1 (<1%)	1 (<1%)	4 (<1%)	2 (<1%)

<sup>1</sup> This report includes all protocol-required procedures from screening, enrollment and follow-up visits as appropriate. Follow-up visit procedures are expected 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. Source: SCHARP (Iraj) - /trials/mtn/p020/reporting/progress/code/t\_visit\_adhere\_site.sas, SAS Version 9.4 (22SEP2015,9:48)

**MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)  
Data as of September 21, 2015**

**Visit Adherence: Completion of Procedures by Site<sup>1</sup> - First 8 Sites (Continued)**

	All Sites	Malawi - Blantyre	Malawi - Lilongwe	SA - Cape Town	SA - CAPRISA eThekweni	SA - MRC/ Botha's Hill	SA - MRC/ Chatsworth	SA - MRC/ Isipingo	SA - MRC/ Tongaat
11. Chemistries Required and Expected	18295	694	724	1224	1593	1295	1114	952	824
Completed	18263 (>99%)	693 (>99%)	722 (>99%)	1220 (>99%)	1592 (>99%)	1294 (>99%)	1113 (>99%)	948 (>99%)	824 (100%)
Not Completed	32 (<1%)	1 (<1%)	2 (<1%)	4 (<1%)	1 (<1%)	1 (<1%)	1 (<1%)	4 (<1%)	0 (0%)
12. Syphilis Serology Required and Expected	2475	127	135	145	230	171	140	109	99
Completed	2446 (99%)	127 (100%)	135 (100%)	144 (99%)	229 (>99%)	170 (99%)	140 (100%)	109 (100%)	98 (99%)
Not Completed	29 (1%)	0 (0%)	0 (0%)	1 (1%)	1 (<1%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)
13. Quarterly Plasma Storage Required and Expected	20462	813	848	1353	1797	1444	1230	1042	901
Completed	20418 (>99%)	812 (>99%)	844 (>99%)	1349 (>99%)	1796 (>99%)	1443 (>99%)	1229 (>99%)	1037 (>99%)	900 (>99%)
Not Completed	44 (<1%)	1 (<1%)	4 (<1%)	4 (<1%)	1 (<1%)	1 (<1%)	1 (<1%)	5 (<1%)	1 (<1%)
14. Plasma for Archive Required and Expected	2629	130	142	166	244	180	150	117	103
Completed	2629 (100%)	130 (100%)	142 (100%)	166 (100%)	244 (100%)	180 (100%)	150 (100%)	117 (100%)	103 (100%)
15. Vaginal Fluid pH Required and Expected	10098	368	410	666	882	756	635	549	477
Completed	9792 (97%)	366 (99%)	392 (96%)	647 (97%)	858 (97%)	739 (98%)	612 (96%)	539 (98%)	452 (95%)
Not Completed	306 (3%)	2 (1%)	18 (4%)	19 (3%)	24 (3%)	17 (2%)	23 (4%)	10 (2%)	25 (5%)
16. Vaginal Smear for Gram Stain Required and Expected	10002	368	406	662	877	752	630	548	470
Completed	9731 (97%)	367 (>99%)	387 (95%)	650 (98%)	857 (98%)	737 (98%)	609 (97%)	540 (99%)	449 (96%)
Not Completed	271 (3%)	1 (<1%)	19 (5%)	12 (2%)	20 (2%)	15 (2%)	21 (3%)	8 (1%)	21 (4%)
17. Vaginal Fluid Swab Required and Expected	54740	2156	2226	3711	4829	3889	3294	2780	2327
Completed	54651 (>99%)	2155 (>99%)	2209 (99%)	3704 (>99%)	4826 (>99%)	3887 (>99%)	3280 (>99%)	2775 (>99%)	2327 (100%)
Not Completed	89 (<1%)	1 (<1%)	17 (1%)	7 (<1%)	3 (<1%)	2 (<1%)	14 (<1%)	5 (<1%)	0 (0%)
18. Pap Smear Required and Expected	2092	119	120	126	198	145	115	86	69
Completed	2079 (99%)	119 (100%)	120 (100%)	124 (98%)	198 (100%)	145 (100%)	112 (97%)	86 (100%)	67 (97%)
Not Completed	13 (1%)	0 (0%)	0 (0%)	2 (2%)	0 (0%)	0 (0%)	3 (3%)	0 (0%)	2 (3%)
19. Endocervical Swab Required and Expected	10002	368	406	662	877	752	630	548	470
Completed	9723 (97%)	366 (99%)	386 (95%)	650 (98%)	857 (98%)	737 (98%)	609 (97%)	540 (99%)	449 (96%)
Not Completed	279 (3%)	2 (1%)	20 (5%)	12 (2%)	20 (2%)	15 (2%)	21 (3%)	8 (1%)	21 (4%)
20. Used Vaginal Ring Specimen Storage Required and Expected	43049	2047	2125	2791	3898	2798	2330	2001	1693
Completed	42085 (98%)	2022 (99%)	2076 (98%)	2674 (96%)	3836 (98%)	2759 (99%)	2276 (98%)	1923 (96%)	1598 (94%)
Not Completed	964 (2%)	25 (1%)	49 (2%)	117 (4%)	62 (2%)	39 (1%)	54 (2%)	78 (4%)	95 (6%)
21. Follow-up ACASI Questionnaire Required and Expected	5000	255	270	302	467	341	285	217	191
Completed	4820 (96%)	250 (98%)	261 (97%)	289 (96%)	446 (96%)	324 (95%)	269 (94%)	202 (93%)	181 (95%)
Not Completed	180 (4%)	5 (2%)	9 (3%)	13 (4%)	21 (4%)	17 (5%)	16 (6%)	15 (7%)	10 (5%)

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**Data as of September 21, 2015**

**Visit Adherence: Completion of Procedures by Site<sup>1</sup> - Last 7 Sites**

	All Sites	SA - MRC/ Verulam	SA - MRC/ Umkomaas	SA - WRHI	Uganda - Kampala	Zimbabwe - Seke South	Zimbabwe - Spilhaus	Zimbabwe - Zengeza
Participants Enrolled	2629	150	103	213	253	224	230	224
1. Behavioral Assessment Required and Expected	19133	1190	851	1460	1987	1541	1646	1494
Completed	19133 (100%)	1190 (100%)	851 (100%)	1460 (100%)	1987 (100%)	1541 (100%)	1646 (100%)	1494 (100%)
2. Adherence Assessment Required and Expected	56571	3471	2463	4344	5855	4584	4918	4478
Completed	56571 (100%)	3471 (100%)	2463 (100%)	4344 (100%)	5855 (100%)	4584 (100%)	4918 (100%)	4478 (100%)
3. Acceptability Assessment Required and Expected	19133	1190	851	1460	1987	1541	1646	1494
Completed	19133 (100%)	1190 (100%)	851 (100%)	1460 (100%)	1987 (100%)	1541 (100%)	1646 (100%)	1494 (100%)
4. Social Harms Assessment Required and Expected	19133	1190	851	1460	1987	1541	1646	1494
Completed	19133 (100%)	1190 (100%)	851 (100%)	1460 (100%)	1987 (100%)	1541 (100%)	1646 (100%)	1494 (100%)
5. Pelvic Exams Required and Expected	9327	551	415	709	980	800	827	750
Completed	9163 (98%)	546 (99%)	406 (98%)	663 (94%)	964 (98%)	791 (99%)	823 (>99%)	737 (98%)
Not Completed	164 (2%)	5 (1%)	9 (2%)	46 (6%)	16 (2%)	9 (1%)	4 (<1%)	13 (2%)
6. Pregnancy Tests Required and Expected	56471	3345	2450	4418	5978	4730	4988	4574
Completed	56406 (>99%)	3328 (99%)	2441 (>99%)	4413 (>99%)	5978 (100%)	4729 (>99%)	4988 (100%)	4572 (>99%)
Not Completed	65 (<1%)	17 (1%)	9 (<1%)	5 (<1%)	0 (0%)	1 (<1%)	0 (0%)	2 (<1%)
7. Trichomoniasis, Gonorrhea and Chlamydia Tests Required and Expected	8948	553	401	694	935	718	766	706
Completed	8378 (94%)	519 (94%)	360 (90%)	612 (88%)	896 (96%)	691 (96%)	740 (97%)	675 (96%)
Not Completed	570 (6%)	34 (6%)	41 (10%)	82 (12%)	39 (4%)	27 (4%)	26 (3%)	31 (4%)
8. HIV-1 Tests Required and Expected	56471	3345	2450	4418	5978	4730	4988	4574
Completed	56405 (>99%)	3330 (>99%)	2441 (>99%)	4412 (>99%)	5978 (100%)	4730 (100%)	4988 (100%)	4572 (>99%)
Not Completed	66 (<1%)	15 (<1%)	9 (<1%)	6 (<1%)	0 (0%)	0 (0%)	0 (0%)	2 (<1%)
9. Hemograms Required and Expected	18295	1099	813	1419	1954	1523	1602	1465
Completed	18257 (>99%)	1098 (>99%)	811 (>99%)	1404 (99%)	1954 (100%)	1523 (100%)	1601 (>99%)	1464 (>99%)
Not Completed	38 (<1%)	1 (<1%)	2 (<1%)	15 (1%)	0 (0%)	0 (0%)	1 (<1%)	1 (<1%)
10. Differentials Required and Expected	18295	1099	813	1419	1954	1523	1602	1465
Completed	18258 (>99%)	1098 (>99%)	811 (>99%)	1405 (99%)	1954 (100%)	1523 (100%)	1601 (>99%)	1464 (>99%)
Not Completed	37 (<1%)	1 (<1%)	2 (<1%)	14 (1%)	0 (0%)	0 (0%)	1 (<1%)	1 (<1%)

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	All Sites	SA - MRC/ Verulam	SA - MRC/ Umkomaas	SA - WRHI	Uganda - Kampala	Zimbabwe - Seke South	Zimbabwe - Spilhaus	Zimbabwe - Zengeza
11. Chemistries Required and Expected	18295	1099	813	1419	1954	1523	1602	1465
Completed	18263 (>99%)	1098 (>99%)	811 (>99%)	1408 (99%)	1954 (100%)	1523 (100%)	1600 (>99%)	1463 (>99%)
Not Completed	32 (<1%)	1 (<1%)	2 (<1%)	11 (1%)	0 (0%)	0 (0%)	2 (<1%)	2 (<1%)
12. Syphilis Serology Required and Expected	2475	143	98	209	235	213	214	207
Completed	2446 (99%)	140 (98%)	97 (99%)	194 (93%)	231 (98%)	213 (100%)	213 (>99%)	206 (>99%)
Not Completed	29 (1%)	3 (2%)	1 (1%)	15 (7%)	4 (2%)	0 (0%)	1 (<1%)	1 (<1%)
13. Quarterly Plasma Storage Required and Expected	20462	1218	893	1603	2163	1713	1794	1650
Completed	20418 (>99%)	1216 (>99%)	891 (>99%)	1585 (99%)	2162 (>99%)	1713 (100%)	1793 (>99%)	1648 (>99%)
Not Completed	44 (<1%)	2 (<1%)	2 (<1%)	18 (1%)	1 (<1%)	0 (0%)	1 (<1%)	2 (<1%)
14. Plasma for Archive Required and Expected	2629	150	103	213	253	224	230	224
Completed	2629 (100%)	150 (100%)	103 (100%)	213 (100%)	253 (100%)	224 (100%)	230 (100%)	224 (100%)
15. Vaginal Fluid pH Required and Expected	10098	633	450	765	1034	819	867	787
Completed	9792 (97%)	620 (98%)	428 (95%)	704 (92%)	999 (97%)	805 (98%)	862 (99%)	769 (98%)
Not Completed	306 (3%)	13 (2%)	22 (5%)	61 (8%)	35 (3%)	14 (2%)	5 (1%)	18 (2%)
16. Vaginal Smear for Gram Stain Required and Expected	10002	626	441	751	1029	809	857	776
Completed	9731 (97%)	614 (98%)	422 (96%)	699 (93%)	993 (97%)	795 (98%)	854 (>99%)	758 (98%)
Not Completed	271 (3%)	12 (2%)	19 (4%)	52 (7%)	36 (3%)	14 (2%)	3 (<1%)	18 (2%)
17. Vaginal Fluid Swab Required and Expected	54740	3186	2382	4202	5771	4646	4907	4434
Completed	54651 (>99%)	3183 (>99%)	2374 (>99%)	4184 (>99%)	5766 (>99%)	4645 (>99%)	4907 (100%)	4429 (>99%)
Not Completed	89 (<1%)	3 (<1%)	8 (<1%)	18 (<1%)	5 (<1%)	1 (<1%)	0 (0%)	5 (<1%)
18. Pap Smear Required and Expected	2092	113	77	173	205	185	187	174
Completed	2079 (99%)	113 (100%)	77 (100%)	169 (98%)	203 (99%)	185 (100%)	187 (100%)	174 (100%)
Not Completed	13 (1%)	0 (0%)	0 (0%)	4 (2%)	2 (1%)	0 (0%)	0 (0%)	0 (0%)
19. Endocervical Swab Required and Expected	10002	626	441	751	1029	809	857	776
Completed	9723 (97%)	614 (98%)	422 (96%)	697 (93%)	991 (96%)	794 (98%)	853 (>99%)	758 (98%)
Not Completed	279 (3%)	12 (2%)	19 (4%)	54 (7%)	38 (4%)	15 (2%)	4 (<1%)	18 (2%)
20. Used Vaginal Ring Specimen Storage Required and Expected	43049	2260	1583	3340	4787	3827	3980	3589
Completed	42085 (98%)	2219 (98%)	1557 (98%)	3220 (96%)	4678 (98%)	3756 (98%)	3944 (99%)	3547 (99%)
Not Completed	964 (2%)	41 (2%)	26 (2%)	120 (4%)	109 (2%)	71 (2%)	36 (1%)	42 (1%)
21. Follow-up ACASI Questionnaire Required and Expected	5000	290	194	415	481	431	441	420
Completed	4820 (96%)	271 (93%)	184 (95%)	394 (95%)	473 (98%)	425 (99%)	434 (98%)	417 (99%)
Not Completed	180 (4%)	19 (7%)	10 (5%)	21 (5%)	8 (2%)	6 (1%)	7 (2%)	3 (1%)

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