



# **DATA SUMMARY REPORT**

**ENROLLMENT, RETENTION, PROCEDURE COMPLETION, DATA MANAGEMENT QUALITY**

***MTN 020***

**October 14, 2015**

**MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)  
Data as of October 13, 2015**

**Accrual Summary by Site**

Site	Activation Date	First Enrollment Date	Last Enrollment Date <sup>1</sup>	Duration of Accrual <sup>2</sup> (weeks)	Total Screened	Total Enrolled	Enrollment Target	Screen/Enroll	Average Enrolled per Week	Percent Enrolled
1. Malawi - Blantyre	22MAY2013	13JUN2013	11JUN2014	52.0	199	130	130	1.5	2.5	100.0%
2. Malawi - Lilongwe	24MAY2013	17JUN2013	11JUN2014	51.4	200	142	142	1.4	2.8	100.0%
3. SA - Cape Town	04SEP2012	19SEP2012	12JUN2014	90.3	217	166	166	1.3	1.8	100.0%
4. SA - CAPRISA eThekwini	13SEP2012	10OCT2012	11JUN2014	87.1	736	244	244	3.0	2.8	100.0%
5. SA - MRC/Botha's Hill	28AUG2012	10SEP2012	22MAY2014	88.6	436	180	180	2.4	2.0	100.0%
6. SA - MRC/Chatsworth	28AUG2012	11SEP2012	22MAY2014	88.4	411	150	150	2.7	1.7	100.0%
7. SA - MRC/Isipingo	28AUG2012	19SEP2012	24JUN2013	39.9	314	117	117	2.7	2.9	100.0%
8. SA - MRC/Tongaat	28AUG2012	17SEP2012	14JUN2013	38.7	351	103	103	3.4	2.7	100.0%
9. SA - MRC/Verulam	28AUG2012	13SEP2012	22MAY2014	88.1	346	150	150	2.3	1.7	100.0%
10. SA - MRC/Umkomaas	28AUG2012	14SEP2012	09JUN2014	90.6	259	103	103	2.5	1.1	100.0%
11. SA - WRHI	16OCT2012	30OCT2012	12JUN2014	84.4	401	213	213	1.9	2.5	100.0%
12. Uganda - Kampala	19JUL2012	21AUG2012	10MAR2014	81.0	408	253	253	1.6	3.1	100.0%
13. Zimbabwe - Seke South	22OCT2012	01NOV2012	29MAY2014	82.1	434	224	224	1.9	2.7	100.0%
14. Zimbabwe - Spilhaus	22OCT2012	30OCT2012	15MAY2014	80.4	403	230	230	1.8	2.9	100.0%
15. Zimbabwe - Zengeza	23OCT2012	13NOV2012	27MAY2014	80.1	401	224	224	1.8	2.8	100.0%
All Sites	19JUL2012	21AUG2012	12JUN2014	94.4	5516	2629	2629	2.1	27.8	100.0%

<sup>1</sup> Date of the most recently enrolled participant as of October 13, 2015.

<sup>2</sup> Duration of accrual based on first enrollment date.

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**Cumulative Percent Retention by Site**

	<b>Total Enrolled</b>	<b># Completed Visits</b>	<b># Expected Visits</b>	<b>Retention Rate</b>
1. Malawi - Blantyre	130	2238	2680	83.5%
2. Malawi - Lilongwe	142	2344	2949	79.5%
3. SA - Cape Town	166	3964	4886	81.1%
4. SA - CAPRISA eThekweni	244	5296	6367	83.2%
5. SA - MRC/Botha's Hill	180	4375	5144	85.1%
6. SA - MRC/Chatsworth	150	3702	4458	83%
7. SA - MRC/Isipingo	117	3232	3835	84.3%
8. SA - MRC/Tongaat	103	2755	3374	81.7%
9. SA - MRC/Verulam	150	3677	4419	83.2%
10. SA - MRC/Umkomaas	103	2632	3160	83.3%
11. SA - WRHI	213	4539	5624	80.7%
12. Uganda - Kampala	253	6148	7265	84.6%
13. Zimbabwe - Seke South	224	4782	6034	79.3%
14. Zimbabwe - Spilhaus	230	5123	6190	82.8%
15. Zimbabwe - Zengeza	224	4664	5846	79.8%

<sup>1</sup> This report includes data received and entered at SCHARP through this date.

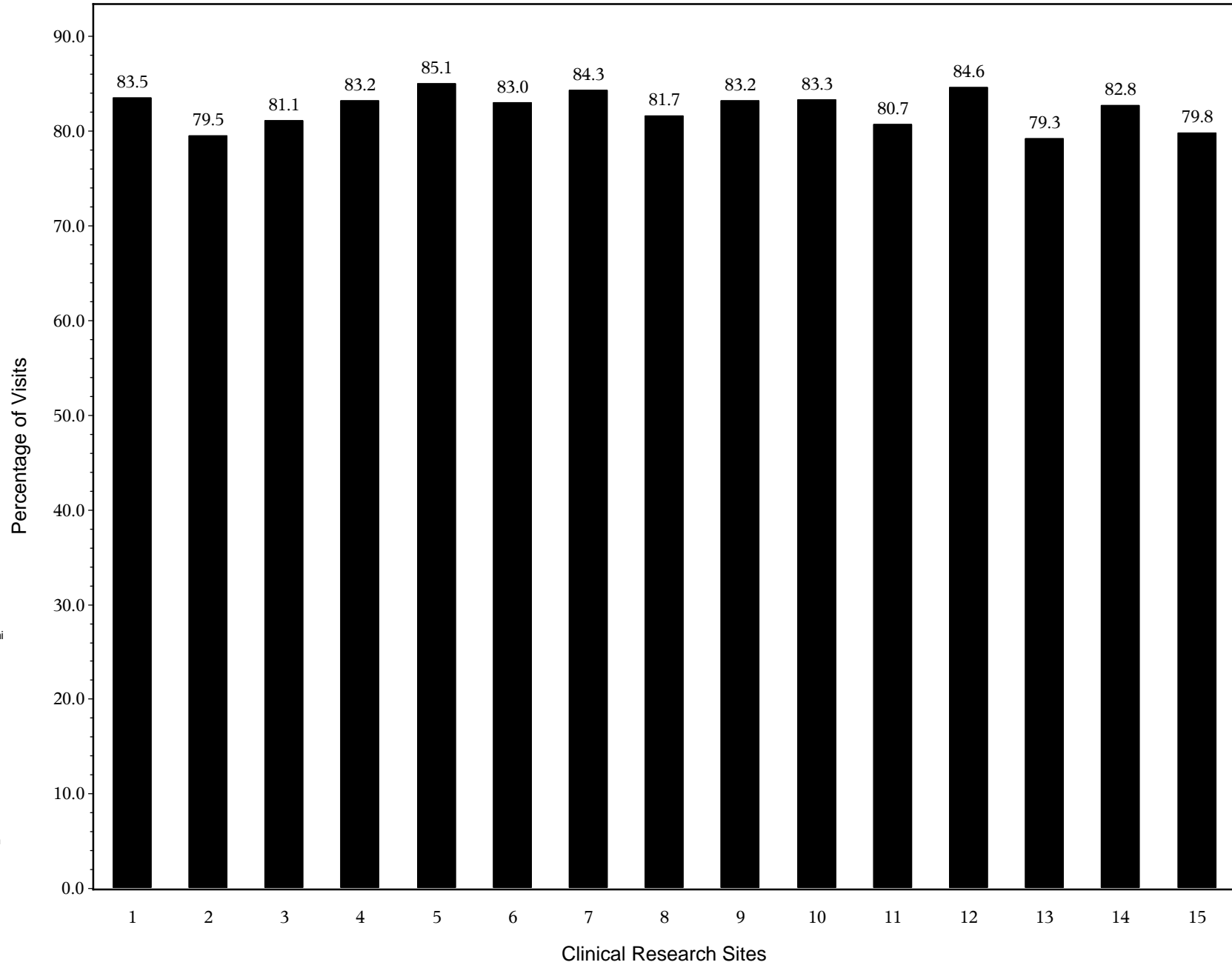
<sup>2</sup> The measures in this report summarize retention over all expected visits.

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 Study 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)  
Data as of October 13, 2015

Cumulative Percent Retention by Site



1. Malawi-Blantyre
2. Malawi-Lilongwe
3. SA-Cape Town
4. SA-CAPRISA eThekweni
5. SA-MRC/Botha's Hill
6. SA-MRC/Chatsworth
7. SA-MRC/Isipingo
8. SA-MRC/Tongaat
9. SA-MRC/Verulam
10. SA-MRC/Umkomaas
11. SA-WRHI
12. Uganda-Kampala
13. Zimbabwe-Seke South
14. Zimbabwe-Spilhaus
15. Zimbabwe-Zengeza

**MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)  
Data as of October 13, 2015**

**Visit Adherence: Completion of Procedures by Site<sup>1</sup> - Sites 1-5**

	<b>All Sites</b>	<b>1. Malawi - Blantyre</b>	<b>2. Malawi - Lilongwe</b>	<b>3. SA - Cape Town</b>	<b>4. SA - CAPRISA eThekweni</b>	<b>5. SA - MRC/Botha's Hill</b>
Participants Enrolled	2629	130	142	166	244	180
1. Behavioral Assessment Required and Expected	19133/19133 (100%)	704/704 (100%)	747/747 (100%)	1273/1273 (100%)	1689/1689 (100%)	1407/1407 (100%)
2. Adherence Assessment Required and Expected	56571/56571 (100%)	2116/2116 (100%)	2220/2220 (100%)	3773/3773 (100%)	5052/5052 (100%)	4105/4105 (100%)
3. Acceptability Assessment Required and Expected	19133/19133 (100%)	704/704 (100%)	747/747 (100%)	1273/1273 (100%)	1689/1689 (100%)	1407/1407 (100%)
4. Social Harms Assessment Required and Expected	19133/19133 (100%)	704/704 (100%)	747/747 (100%)	1273/1273 (100%)	1689/1689 (100%)	1407/1407 (100%)
5. Pelvic Exams Required and Expected	9163/9327 (98%)	352/352 (100%)	377/386 (98%)	620/628 (99%)	795/807 (99%)	668/676 (99%)
6. Pregnancy Tests Required and Expected	56406/56471 (>99%)	2206/2206 (100%)	2281/2284 (>99%)	3763/3770 (>99%)	4995/4995 (100%)	3943/3947 (>99%)
7. Trichomoniasis, Gonorrhoea and Chlamydia Tests Required and Expected	8378/8948 (94%)	325/329 (99%)	299/334 (90%)	562/599 (94%)	718/788 (91%)	624/650 (96%)
8. HIV-1 Tests Required and Expected	56405/56471 (>99%)	2206/2206 (100%)	2281/2284 (>99%)	3762/3770 (>99%)	4995/4995 (100%)	3943/3947 (>99%)
9. Hemograms Required and Expected	18257/18295 (>99%)	692/694 (>99%)	722/724 (>99%)	1220/1224 (>99%)	1591/1593 (>99%)	1294/1295 (>99%)
10. Differentials Required and Expected	18258/18295 (>99%)	692/694 (>99%)	722/724 (>99%)	1220/1224 (>99%)	1591/1593 (>99%)	1294/1295 (>99%)
11. Chemistries Required and Expected	18263/18295 (>99%)	693/694 (>99%)	722/724 (>99%)	1220/1224 (>99%)	1592/1593 (>99%)	1294/1295 (>99%)
12. Syphilis Serology Required and Expected	2446/2475 (99%)	127/127 (100%)	135/135 (100%)	144/145 (99%)	229/230 (>99%)	170/171 (99%)
13. Quarterly Plasma Storage Required and Expected	20418/20462 (>99%)	812/813 (>99%)	844/848 (>99%)	1349/1353 (>99%)	1796/1797 (>99%)	1443/1444 (>99%)
14. Plasma for Archive Required and Expected	2629/2629 (100%)	130/130 (100%)	142/142 (100%)	166/166 (100%)	244/244 (100%)	180/180 (100%)
15. Vaginal Fluid pH Required and Expected	9792/10098 (97%)	366/368 (99%)	392/410 (96%)	647/666 (97%)	858/882 (97%)	739/756 (98%)
16. Vaginal Smear for Gram Stain Required and Expected	9731/10002 (97%)	367/368 (>99%)	387/406 (95%)	650/662 (98%)	857/877 (98%)	737/752 (98%)
17. Vaginal Fluid Swab Required and Expected	54651/54740 (>99%)	2155/2156 (>99%)	2209/2226 (99%)	3704/3711 (>99%)	4826/4829 (>99%)	3887/3889 (>99%)
18. Pap Smear Required and Expected	2079/2092 (99%)	119/119 (100%)	120/120 (100%)	124/126 (98%)	198/198 (100%)	145/145 (100%)
19. Endocervical Swab Required and Expected	9723/10002 (97%)	366/368 (99%)	386/406 (95%)	650/662 (98%)	857/877 (98%)	737/752 (98%)
20. Used Vaginal Ring Specimen Storage Required and Expected	42085/43049 (98%)	2022/2047 (99%)	2076/2125 (98%)	2674/2791 (96%)	3836/3898 (98%)	2759/2798 (99%)
21. Follow-up ACASI Questionnaire Required and Expected	4820/5000 (96%)	250/255 (98%)	261/270 (97%)	289/302 (96%)	446/467 (96%)	324/341 (95%)

<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. Summary measures reflect the # completed/ # expected.

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**Visit Adherence: Completion of Procedures by Site<sup>1</sup> - Sites 6-10**

	<b>All Sites</b>	<b>6. SA - MRC/Chatsworth</b>	<b>7. SA - MRC/Isipingo</b>	<b>8. SA - MRC/Tongaat</b>	<b>9. SA - MRC/Verulam</b>	<b>10. SA - MRC/Umkomaas</b>
Participants Enrolled	2629	150	117	103	150	103
1. Behavioral Assessment Required and Expected	19133/19133 (100%)	1197/1197 (100%)	1049/1049 (100%)	898/898 (100%)	1190/1190 (100%)	851/851 (100%)
2. Adherence Assessment Required and Expected	56571/56571 (100%)	3501/3501 (100%)	3081/3081 (100%)	2610/2610 (100%)	3471/3471 (100%)	2463/2463 (100%)
3. Acceptability Assessment Required and Expected	19133/19133 (100%)	1197/1197 (100%)	1049/1049 (100%)	898/898 (100%)	1190/1190 (100%)	851/851 (100%)
4. Social Harms Assessment Required and Expected	19133/19133 (100%)	1197/1197 (100%)	1049/1049 (100%)	898/898 (100%)	1190/1190 (100%)	851/851 (100%)
5. Pelvic Exams Required and Expected	9163/9327 (98%)	559/569 (98%)	470/474 (99%)	392/403 (97%)	546/551 (99%)	406/415 (98%)
6. Pregnancy Tests Required and Expected	56406/56471 (>99%)	3390/3399 (>99%)	2887/2894 (>99%)	2492/2493 (>99%)	3328/3345 (99%)	2441/2450 (>99%)
7. Trichomoniasis, Gonorrhea and Chlamydia Tests Required and Expected	8378/8948 (94%)	501/554 (90%)	472/494 (96%)	384/427 (90%)	519/553 (94%)	360/401 (90%)
8. HIV-1 Tests Required and Expected	56405/56471 (>99%)	3388/3399 (>99%)	2887/2894 (>99%)	2492/2493 (>99%)	3330/3345 (>99%)	2441/2450 (>99%)
9. Hemograms Required and Expected	18257/18295 (>99%)	1113/1114 (>99%)	948/952 (>99%)	822/824 (>99%)	1098/1099 (>99%)	811/813 (>99%)
10. Differentials Required and Expected	18258/18295 (>99%)	1113/1114 (>99%)	948/952 (>99%)	822/824 (>99%)	1098/1099 (>99%)	811/813 (>99%)
11. Chemistries Required and Expected	18263/18295 (>99%)	1113/1114 (>99%)	948/952 (>99%)	824/824 (100%)	1098/1099 (>99%)	811/813 (>99%)
12. Syphilis Serology Required and Expected	2446/2475 (99%)	140/140 (100%)	109/109 (100%)	98/99 (99%)	140/143 (98%)	97/98 (99%)
13. Quarterly Plasma Storage Required and Expected	20418/20462 (>99%)	1229/1230 (>99%)	1037/1042 (>99%)	900/901 (>99%)	1216/1218 (>99%)	891/893 (>99%)
14. Plasma for Archive Required and Expected	2629/2629 (100%)	150/150 (100%)	117/117 (100%)	103/103 (100%)	150/150 (100%)	103/103 (100%)
15. Vaginal Fluid pH Required and Expected	9792/10098 (97%)	612/635 (96%)	539/549 (98%)	452/477 (95%)	620/633 (98%)	428/450 (95%)
16. Vaginal Smear for Gram Stain Required and Expected	9731/10002 (97%)	609/630 (97%)	540/548 (99%)	449/470 (96%)	614/626 (98%)	422/441 (96%)
17. Vaginal Fluid Swab Required and Expected	54651/54740 (>99%)	3280/3294 (>99%)	2775/2780 (>99%)	2327/2327 (100%)	3183/3186 (>99%)	2374/2382 (>99%)
18. Pap Smear Required and Expected	2079/2092 (99%)	112/115 (97%)	86/86 (100%)	67/69 (97%)	113/113 (100%)	77/77 (100%)
19. Endocervical Swab Required and Expected	9723/10002 (97%)	609/630 (97%)	540/548 (99%)	449/470 (96%)	614/626 (98%)	422/441 (96%)
20. Used Vaginal Ring Specimen Storage Required and Expected	42085/43049 (98%)	2276/2330 (98%)	1923/2001 (96%)	1598/1693 (94%)	2219/2260 (98%)	1557/1583 (98%)
21. Follow-up ACASI Questionnaire Required and Expected	4820/5000 (96%)	269/285 (94%)	202/217 (93%)	181/191 (95%)	271/290 (93%)	184/194 (95%)

<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. Summary measures reflect the # completed/ # expected.

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**Visit Adherence: Completion of Procedures by Site<sup>1</sup> - Sites 11-15**

	<b>All Sites</b>	<b>11. SA - WRHI</b>	<b>12. Uganda - Kampala</b>	<b>13. Zimbabwe - Seke South</b>	<b>14. Zimbabwe - Spilhaus</b>	<b>15. Zimbabwe - Zengeza</b>
Participants Enrolled	2629	213	253	224	230	224
1. Behavioral Assessment Required and Expected	19133/19133 (100%)	1460/1460 (100%)	1987/1987 (100%)	1541/1541 (100%)	1646/1646 (100%)	1494/1494 (100%)
2. Adherence Assessment Required and Expected	56571/56571 (100%)	4344/4344 (100%)	5855/5855 (100%)	4584/4584 (100%)	4918/4918 (100%)	4478/4478 (100%)
3. Acceptability Assessment Required and Expected	19133/19133 (100%)	1460/1460 (100%)	1987/1987 (100%)	1541/1541 (100%)	1646/1646 (100%)	1494/1494 (100%)
4. Social Harms Assessment Required and Expected	19133/19133 (100%)	1460/1460 (100%)	1987/1987 (100%)	1541/1541 (100%)	1646/1646 (100%)	1494/1494 (100%)
5. Pelvic Exams Required and Expected	9163/9327 (98%)	663/709 (94%)	964/980 (98%)	791/800 (99%)	823/827 (>99%)	737/750 (98%)
6. Pregnancy Tests Required and Expected	56406/56471 (>99%)	4413/4418 (>99%)	5978/5978 (100%)	4729/4730 (>99%)	4988/4988 (100%)	4572/4574 (>99%)
7. Trichomoniasis, Gonorrhea and Chlamydia Tests Required and Expected	8378/8948 (94%)	612/694 (88%)	896/935 (96%)	691/718 (96%)	740/766 (97%)	675/706 (96%)
8. HIV-1 Tests Required and Expected	56405/56471 (>99%)	4412/4418 (>99%)	5978/5978 (100%)	4730/4730 (100%)	4988/4988 (100%)	4572/4574 (>99%)
9. Hemograms Required and Expected	18257/18295 (>99%)	1404/1419 (99%)	1954/1954 (100%)	1523/1523 (100%)	1601/1602 (>99%)	1464/1465 (>99%)
10. Differentials Required and Expected	18258/18295 (>99%)	1405/1419 (99%)	1954/1954 (100%)	1523/1523 (100%)	1601/1602 (>99%)	1464/1465 (>99%)
11. Chemistries Required and Expected	18263/18295 (>99%)	1408/1419 (99%)	1954/1954 (100%)	1523/1523 (100%)	1600/1602 (>99%)	1463/1465 (>99%)
12. Syphilis Serology Required and Expected	2446/2475 (99%)	194/209 (93%)	231/235 (98%)	213/213 (100%)	213/214 (>99%)	206/207 (>99%)
13. Quarterly Plasma Storage Required and Expected	20418/20462 (>99%)	1585/1603 (99%)	2162/2163 (>99%)	1713/1713 (100%)	1793/1794 (>99%)	1648/1650 (>99%)
14. Plasma for Archive Required and Expected	2629/2629 (100%)	213/213 (100%)	253/253 (100%)	224/224 (100%)	230/230 (100%)	224/224 (100%)
15. Vaginal Fluid pH Required and Expected	9792/10098 (97%)	704/765 (92%)	999/1034 (97%)	805/819 (98%)	862/867 (99%)	769/787 (98%)
16. Vaginal Smear for Gram Stain Required and Expected	9731/10002 (97%)	699/751 (93%)	993/1029 (97%)	795/809 (98%)	854/857 (>99%)	758/776 (98%)
17. Vaginal Fluid Swab Required and Expected	54651/54740 (>99%)	4184/4202 (>99%)	5766/5771 (>99%)	4645/4646 (>99%)	4907/4907 (100%)	4429/4434 (>99%)
18. Pap Smear Required and Expected	2079/2092 (99%)	169/173 (98%)	203/205 (99%)	185/185 (100%)	187/187 (100%)	174/174 (100%)
19. Endocervical Swab Required and Expected	9723/10002 (97%)	697/751 (93%)	991/1029 (96%)	794/809 (98%)	853/857 (>99%)	758/776 (98%)
20. Used Vaginal Ring Specimen Storage Required and Expected	42085/43049 (98%)	3220/3340 (96%)	4678/4787 (98%)	3756/3827 (98%)	3944/3980 (99%)	3547/3589 (99%)
21. Follow-up ACASI Questionnaire Required and Expected	4820/5000 (96%)	394/415 (95%)	473/481 (98%)	425/431 (99%)	434/441 (98%)	417/420 (99%)

<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. Summary measures reflect the # completed/ # expected.

**MTN-020 A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)**

**DATA MANAGEMENT QUALITY REPORT  
Cumulative: Study Start through September 2015**

Site	Total Records	Total QCs	QC Rate Per 100 Records (Goal < 5)	% QCs Resolved	%CRF Records Faxed within 7 days (Goal ≥ 95%)	Mean Days to Fax in AE
1. Blantyre/Malawi	23041	622	2.7	100%	92%	25.2
2. Lilongwe/Malawi	25819	951	3.7	100%	82%	13.2
3. Emavundleni/Cape Town	40639	1537	3.8	100%	97%	8.1
4. CAPRISA eThekweni	57607	2344	4.1	100%	96%	11.1
5. MRC - Botha's Hill	43160	1851	4.3	100%	94%	24.8
6. MRC - Chatsworth	36686	1511	4.1	100%	90%	14.1
7. MRC - Isipingo	31579	1099	3.5	100%	97%	17.6
8. MRC - Tongaat	27638	1144	4.1	100%	98%	10.3
9. MRC - Verulam	35855	803	2.2	100%	99%	2.7
10. MRC - Umkomaas	25531	913	3.6	100%	98%	11.6
11. WRHI/Johannesburg	48156	2543	5.3	100%	89%	18.6
12. MU-JHU/Kampala, Uganda	61023	1573	2.6	100%	98%	10.5
13. Seke South/Zimbabwe	49118	532	1.1	100%	97%	5.7
14. Spilhaus/Zimbabwe	51612	578	1.1	100%	97%	4.4
15. Zengeza/Zimbabwe	46093	627	1.4	100%	98%	8.6
<b>TOTAL</b>	<b>603557</b>	<b>18628</b>	<b>3.1</b>	<b>100%</b>	<b>95%</b>	<b>12.0</b>

**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.

**MTN-020 A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)**

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

Site	Total Records	Total QCs	QC Rate Per 100 Records (Goal < 5)	%CRF Records Faxed within 7 days (Goal ≥ 95%)	Mean Days to Fax in AE
1. Blantyre/Malawi	0	0			
2. Lilongwe/Malawi	0	0			
3. Emavundleni/Cape Town	0	0			
4. CAPRISA eThekweni	0	0			
5. MRC - Botha's Hill	0	0			
6. MRC - Chatsworth	0	0			
7. MRC - Isipingo	3	0	0.0		
8. MRC - Tongaat	0	0			
9. MRC - Verulam	0	0			
10. MRC - Umkomaas	0	0			
11. WRHI/Johannesburg	0	0			
12. MU-JHU/Kampala, Uganda	2	1	50.0		
13. Seke South/Zimbabwe	0	0			
14. Spilhaus/Zimbabwe	0	0			
15. Zengeza/Zimbabwe	0	0			
<b>TOTAL</b>	<b>5</b>	<b>1</b>	<b>20.0</b>		

**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.