



HPTN 076 DATA MANAGEMENT QUALITY REPORT

June 2017

Cumulative: 13-April-2015 through 30-June-2017

Site	Total Records	Total QCs	Total QCs Resolved (%)	QC Rate Per 100 Records	Mean Days To Fax In	Mean Days to Fax in AEs	Mean Days to Fax in Product Holds
US, New York: Bronx Prevention Center	2844	254	100.0%	8.9	2.8	6.5	8.0
US, Newark: New Jersey Medical School	3250	409	100.0%	12.6	5.8	20.9	9.2
South Africa, Cape Town: Emavundleni Centre	7496	659	100.0%	8.8	5.0	4.9	5.6
Zimbabwe, Harare: Spilhaus	9195	266	100.0%	2.9	3.9	6.1	12.3
TOTAL	22785	1588	100.0%	7.0	4.4	8.9	8.3

Previous Month: 01-June-2017 through 30-June-2017

Site	Total Records	Total QCs	Total QCs Resolved (%)	QC Rate Per 100 Records	Mean Days To Fax In	Mean Days to Fax in AEs	Mean Days to Fax in Product Holds
US, New York: Bronx Prevention Center	0	0	n/a	n/a	n/a	n/a	n/a
US, Newark: New Jersey Medical School	0	6	100.0%	n/a	n/a	n/a	n/a
South Africa, Cape Town: Emavundleni Centre	1	5	100.0%	500.0	105	n/a	n/a
Zimbabwe, Harare: Spilhaus	0	2	100.0%	n/a	n/a	n/a	n/a
TOTAL	1	13	100.0%	1300.0	105.0	N/A	N/A

DEFINITION OF TERMS

Total Records: Total number of CRF pages received by SCHARP DataFax. This includes refaxes.

Total QCs: Total number of quality control (QC) notes sent to the site during the specified time period. Does not include "missing page" reminders that appear on QC

Total QCs Resolved (%): The percentage of QCs sent to the site that have been resolved. Obtained by taking the number of QCs that have been resolved and dividing by the total number of QCs sent to the site ("Total QCs"). This percentage is expected to be close to 100% for the cumulative time frame but may not be for the previous month (due to the time needed by the site and SCHARP to resolve QCs).

QC Rate Per 100 Records: This is the rate of QCs applied based on a set rate of 100 records. Obtained by dividing "Total QCs" by "Total Records".

Mean Days to Fax In: Mean number of days it takes for records to be received at SCHARP. Calculated by taking the date the record was received at SCHARP and subtracting the date the visit was conducted (as recorded on the CRF).

Mean Days to Fax in AEs: Mean number of days it takes for AE Log records to be received at SCHARP. Calculated by taking the date the record was received at SCHARP and subtracting the date the AE was reported to the site.