



HPTN 077 DATA MANAGEMENT QUALITY REPORT

June 2018

Cumulative: 23-Feb-2015 through 31-May-2018

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 Hold
US, Chapel Hill: UNC AIDS CTU	8872	293	100.0%	3.3	3.8	4.3	111.3
US, Los Angeles: UCLA Care Center	4093	270	100.0%	6.6	6.2	7.4	799.00
US, San Francisco: Department of Public Health	6422	373	100.0%	5.8	2.2	4.3	80.5
US, Washington DC: George Washington University CTU	5851	199	100.0%	3.4	4.0	6.8	0.4
South Africa, Soweto: Soweto CTU	4469	410	100.0%	9.2	4.7	29.6	125.5
South Africa, Durban: CAPRISA Vulindlela CRS	5834	819	100.0%	14	13.6	34.6	7.4
Malawi, Lilongwe: UNC Global Prevention and Treatment	4530	415	100.0%	9.2	4.5	35.6	287.2
Brazil, Rio de Janeiro: IPEC-Fiocruz	9561	1029	100.0%	10.8	6.3	11.1	8.00
TOTAL	49632	3808	100.0%	7.7	5.5	15.5	130.4

Previous Month: 01-May-2018 through 31-May-2018

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 Hold
US, Chapel Hill: UNC AIDS CTU	36	0	n/a	0.0	3.8	3.5	n/a
US, Los Angeles: UCLA Care Center	0	0	n/a	n/a	n/a	n/a	n/a
US, San Francisco: Department of Public Health	57	0	n/a	0.0	2.5	n/a	n/a
US, Washington DC: George Washington University CTU	13	0	n/a	0.0	2.0	9.0	n/a
South Africa, Soweto: Soweto CTU	27	3	100.0%	11.1	6.7	n/a	n/a
South Africa, Durban: CAPRISA Vulindlela CRS	69	0	n/a	0.0	82.8	n/a	n/a
Malawi, Lilongwe: UNC Global Prevention and Treatment	45	0	n/a	0.0	16.9	6.0	n/a
Brazil, Rio de Janeiro: IPEC-Fiocruz	30	1	100.0%	3.3	30.8	n/a	n/a
TOTAL	277	4	100.0%	1.4	25.0	5.4	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 Reports.

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.