

HPTN 073 DATA MANAGEMENT QUALITY REPORT
October 2015

Cumulative: 01-Aug-2013 through 30-Sep-2015

Site	Total	Total QCs	Total QCs	QC Rate Per	Mean Days	Mean Days	Mean Days to Fax in
	Records		Resolved (%)	100 Records	To Fax In	to Fax in AEs	Product Holds
US, Washington DC: George Washington University	4456	110	100.0%	2.5	2.7	5.7	6.4
US, Los Angeles: UCLA Vine Street CRS	5053	535	99.0%	10.6	3.7	11.6	13.1
US, Chapel Hill: UNC AIDS	4060	161	99.0%	4.0	4.1	7.7	6.9
US, Raleigh: Wake County Health and Human Services CRS	174	10	100.0%	5.7	3.3	n/a	5.8
TOTAL	13743	816	99.0%	5.9	3.5	9.0	8.6

Previous Month: 01-Sep-2015 through 30-Sep-2015

Site	Total	Total QCs	Total QCs	QC Rate Per	Mean Days	Mean Days	Mean Days to Fax in
	Records		Resolved (%)	100 Records	To Fax In	to Fax in AEs	Product Holds
US, Washington DC: George Washington University	65	6	100.0%	9.2	6.8	3.0	2.5
US, Los Angeles: UCLA Vine Street CRS	140	16	75.0%	11.4	5.5	20.6	1.7
US, Chapel Hill: UNC AIDS	27	3	33.0%	11.1	5.0	n/a	2.5
US, Raleigh: Wake County Health and Human Services CRS	0	0	n/a	n/a	n/a	n/a	n/a
TOTAL	232	25	76.0%	10.8	5.7	16.7	2.0

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.

Mean Days to Fax In Product Hold: Mean number of days it takes for Product Hold records to be received at SCHARP. Calculated by taking the date the record was received at SCHARP and subtracting the date the product hold was initiated.