



DATA SUMMARY REPORT

ENROLLMENT, RETENTION, PROCEDURE COMPLETION,
DATA MANAGEMENT QUALITY

MTN-011

MAY 2014

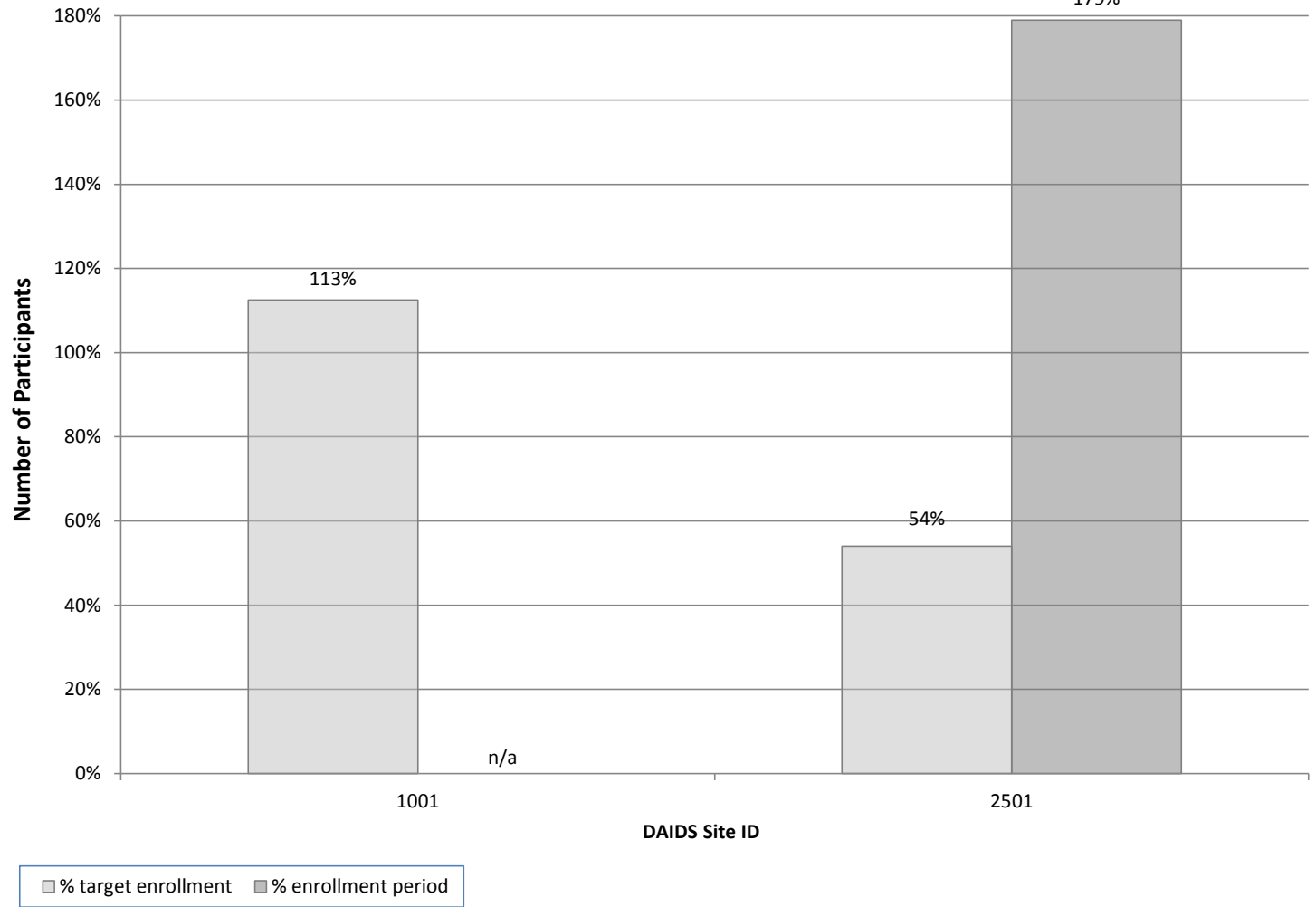
MTN-011 Enrollment

Evaluation Period: Study start through 16 June 2014

"Overall Site Target" is the total number of couples targeted for enrollment into the study. "Total Enrolled" is the cumulative number of couples enrolled to-date. The "% Target Enrollment" is calculated as the "Total Enrolled" divided by the "Overall Site Target". The "% Enrollment Period" is the elapsed portion of the enrollment period as specified in the SSP. A listing of 'closed' indicates accrual was closed at the site prior to completion of the target enrollment. *Data source: MTN 011 Accrual Summary on Atlas and MTN Executive Summary Report.*

Site	DAIDS Site ID #	Date of First Enrollment	Overall Site Target	Total Enrolled	% Target Enrollment	% Enrollment Period
Pittsburgh, USA	1001	25-Jan-13	16	18	113%	n/a
CASE/Cleveland, USA	2501	21-Dec-12	24	13	54%	179%

MTN-011 % Target and % Enrollment - Cumulative



MTN-011 Retention

Due to the complexity of the visit structures between male and female participants as well as differences between Group 1 and Group 2, please refer to the MTN-011 Enrollment and Retention Report on Atlas for a retention summary for this study.

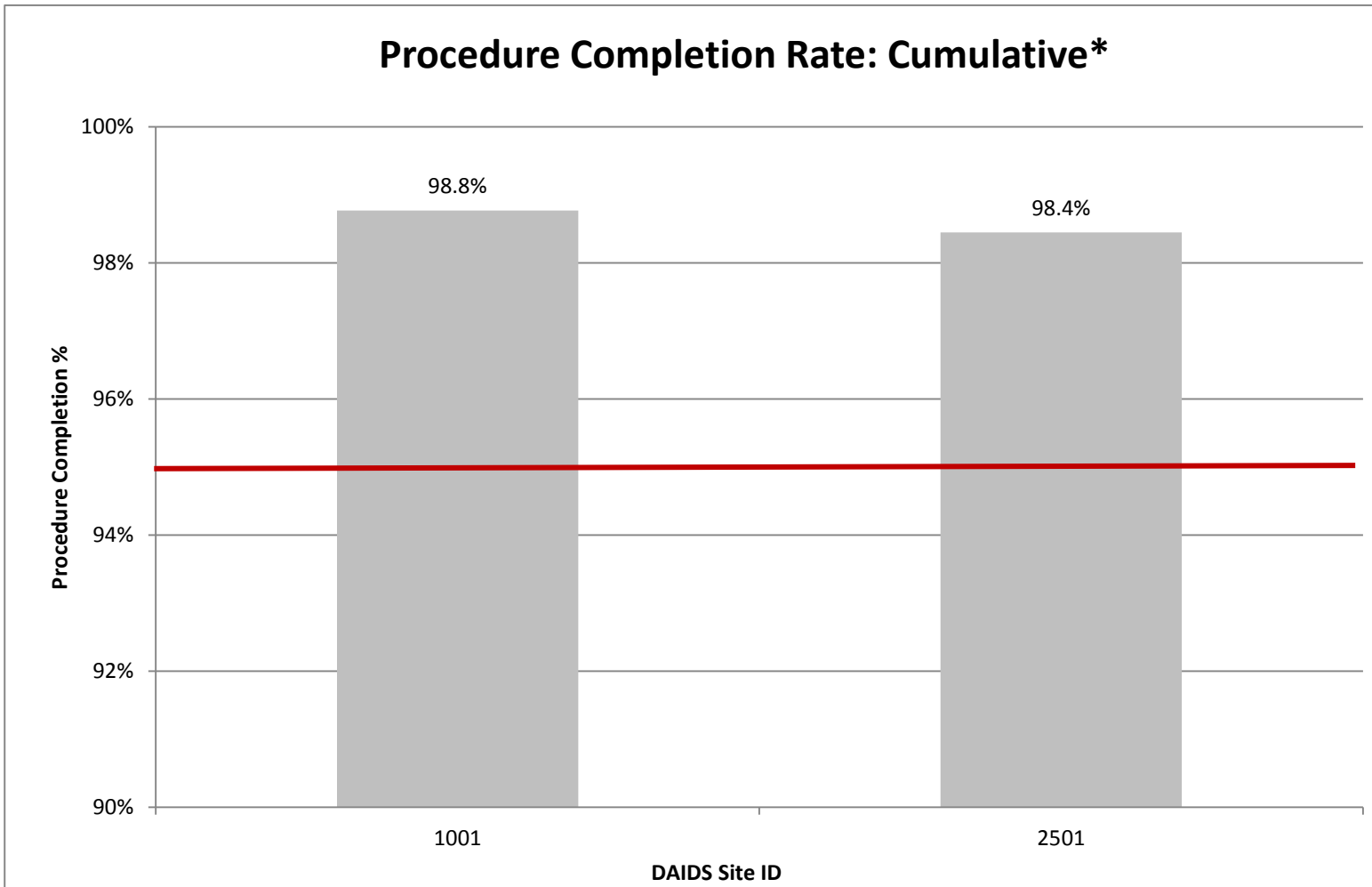
Procedure Completion: Pelvic Exams, Pregnancy testing, CVL collection, Vaginal and Cervical Tissue Biopsy, Cervical Cytobrush, Blood Draw, Rectal Sponge

Evaluation Period: Study start through 15 June 2014

Procedures included are required Pelvic Exams, pregnancy testing, CVL collection, vaginal and cervical tissue biopsy, cervical cytobrush, blood draw, rectal sponge. "# Procedures Expected" is based on the number of actual study visits completed (does not include visits that were missed). "# Procedures Completed" is the number of those expected procedures that were completed based on data received and entered at SCHARP. "Overall Procedure Completion Rate" is the number of completed study procedures divided by the number of expected procedures. *Data source: Procedures Completion Report on Atlas.*

Site	DAIDS Site ID #	# Procedures Expected	# Procedures Completed	Overall Procedure Completion Rate
Pittsburgh, USA	1001	650	642	98.8%
CASE/Cleveland, USA	2501	515	507	98.4%

Procedure Completion Rate: Cumulative*



— Indicates 95% completion rate

* Required & expected Pelvic Exams, pregnancy testing, CVL collection, vaginal and cervical tissue biopsy, cervical cytobrush, blood draw, rectal sponge data used to calculate procedure completion for each site.

MTN-011 Data Management Quality - May 2014

Evaluation Period: Month of May 2014

Total QCs: Total number of quality control (QC) notes sent to the site. This does not include "missing page" reminders that appear on QC Reports.

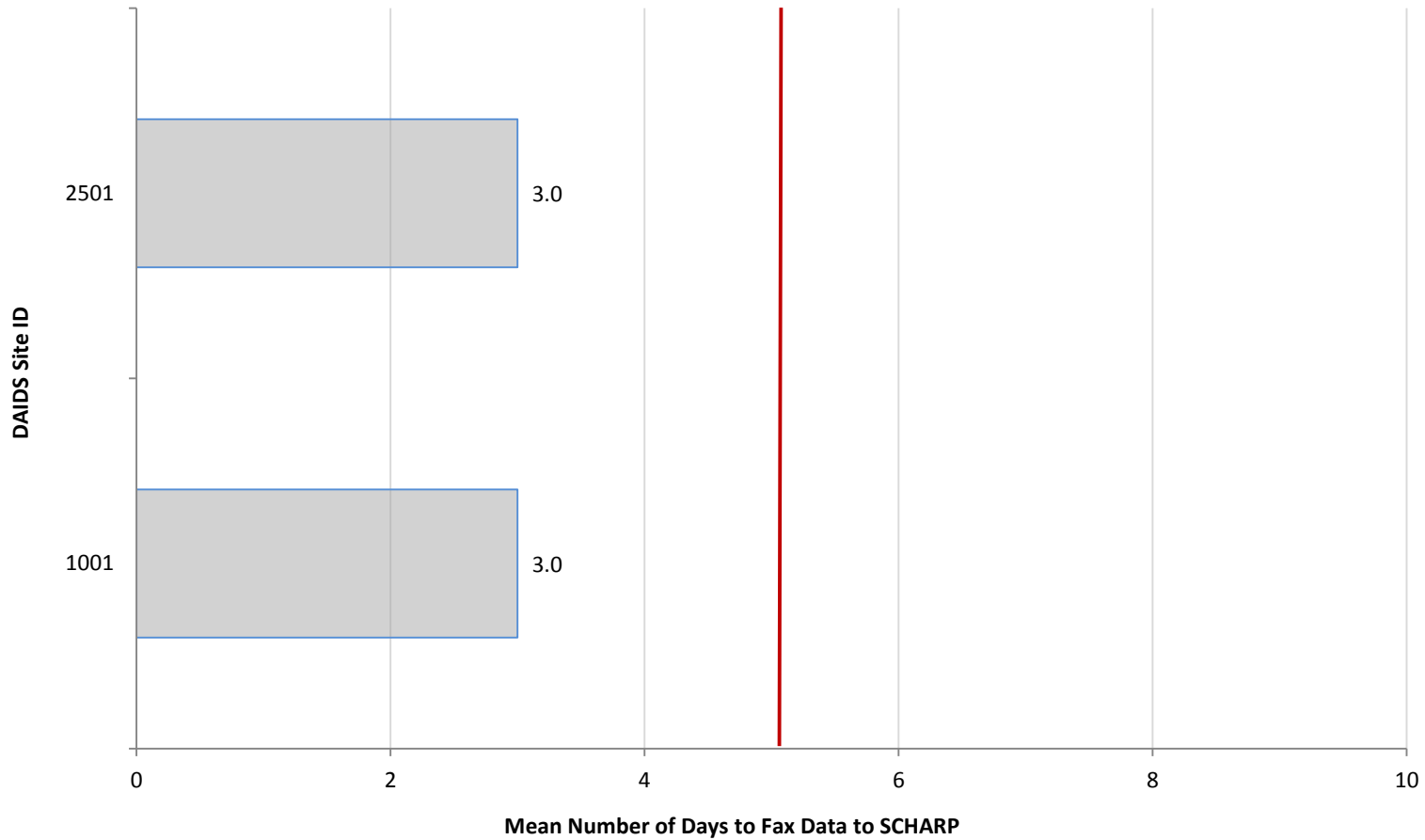
Total QCs Resolved (%): The percentage of QCs sent to the site that have been resolved. Obtained by taking the number of QCs that have been resolved and dividing by the total number of QCs sent to the site ("Total QCs"). This percentage is expected to be close to 100% for the cumulative time frame, but less than 100% for the monthly time frame due to time required at 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". If the number of pages received in the previous month < 100 pages, QC Rate will not be reported on the Monthly DMQ.

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. This calculation does not include laboratory results forms, log forms, or refaxed forms.

Site	DAIDS Site ID #	Total Records	Total QCs	QCs Resolved (%)	QC Rate/100 Records	Mean Days to Fax In	% Received Within 5 days
Pittsburgh, USA	1001	38	3	100%	n/a	3.0	100%
CASE/Cleveland, USA	2501	15	0	n/a	n/a	3.0	100%

Mean Days to Fax: May 2014



— Indicates target of 5 days for data submission

MTN-011 Data Management Quality - Cumulative

Evaluation Period: Cumulative through May 2014

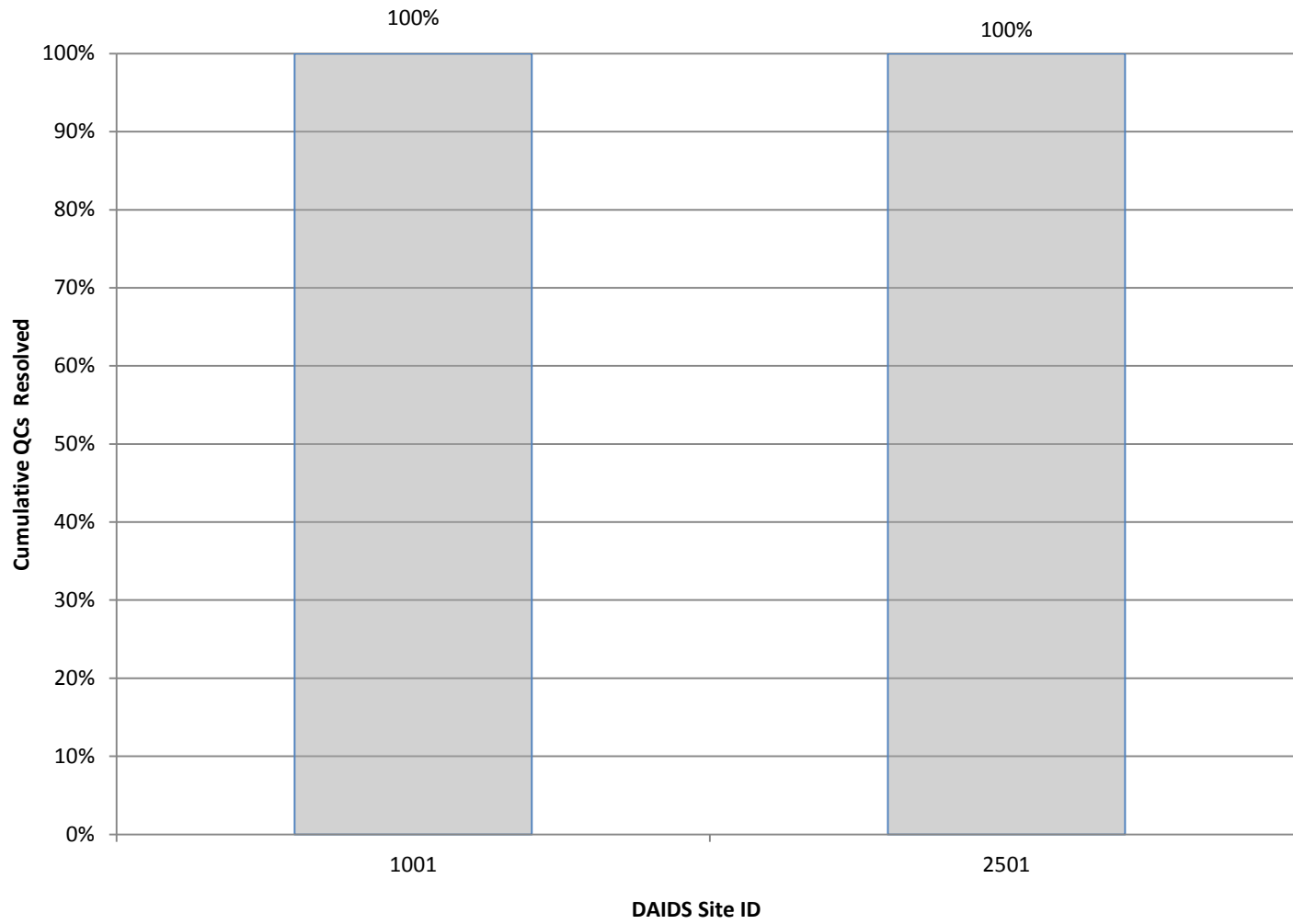
Total QCs: Total number of quality control (QC) notes sent to the site. This does not include "missing page" reminders that appear on QC Reports.

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 less than 100% for the monthly time frame due to time required at SCHARP to resolve QCs.

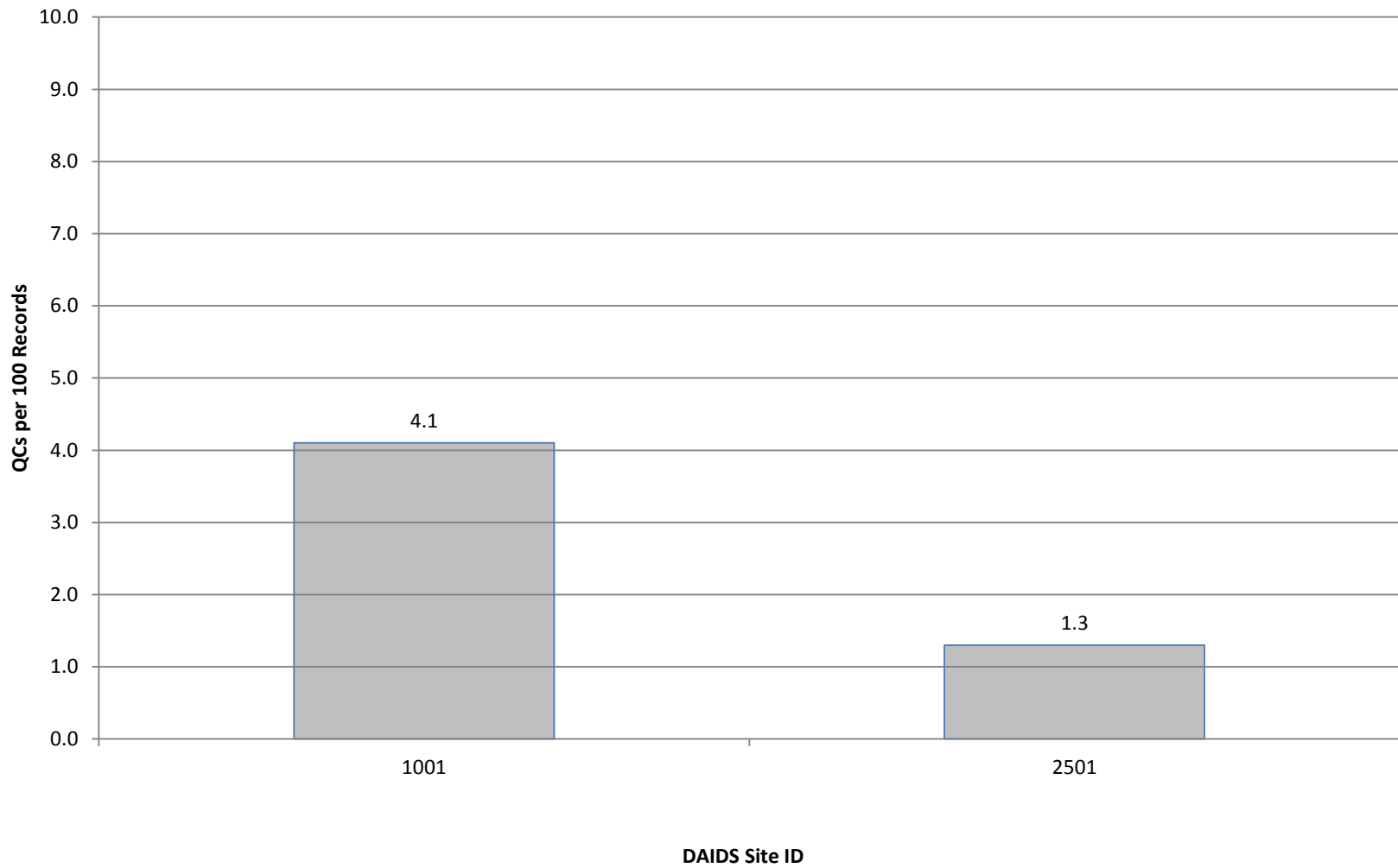
QC Rate Per 100 Records: This is the rate of QCs applied based on a set rate of 100 records. Obtained by dividing "Total QCs" by "Total Records".

Site	DAIDS	Total			QC Rate/100	Mean Days to	% Received Within
	Site ID #	Records	Total QCs	QCs Resolved (%)	Records	Fax In	5 days
Pittsburgh, USA	1001	1401	58	100%	4.1	3.5	96%
CASE/Cleveland, USA	2501	1019	13	100%	1.3	1.8	96%

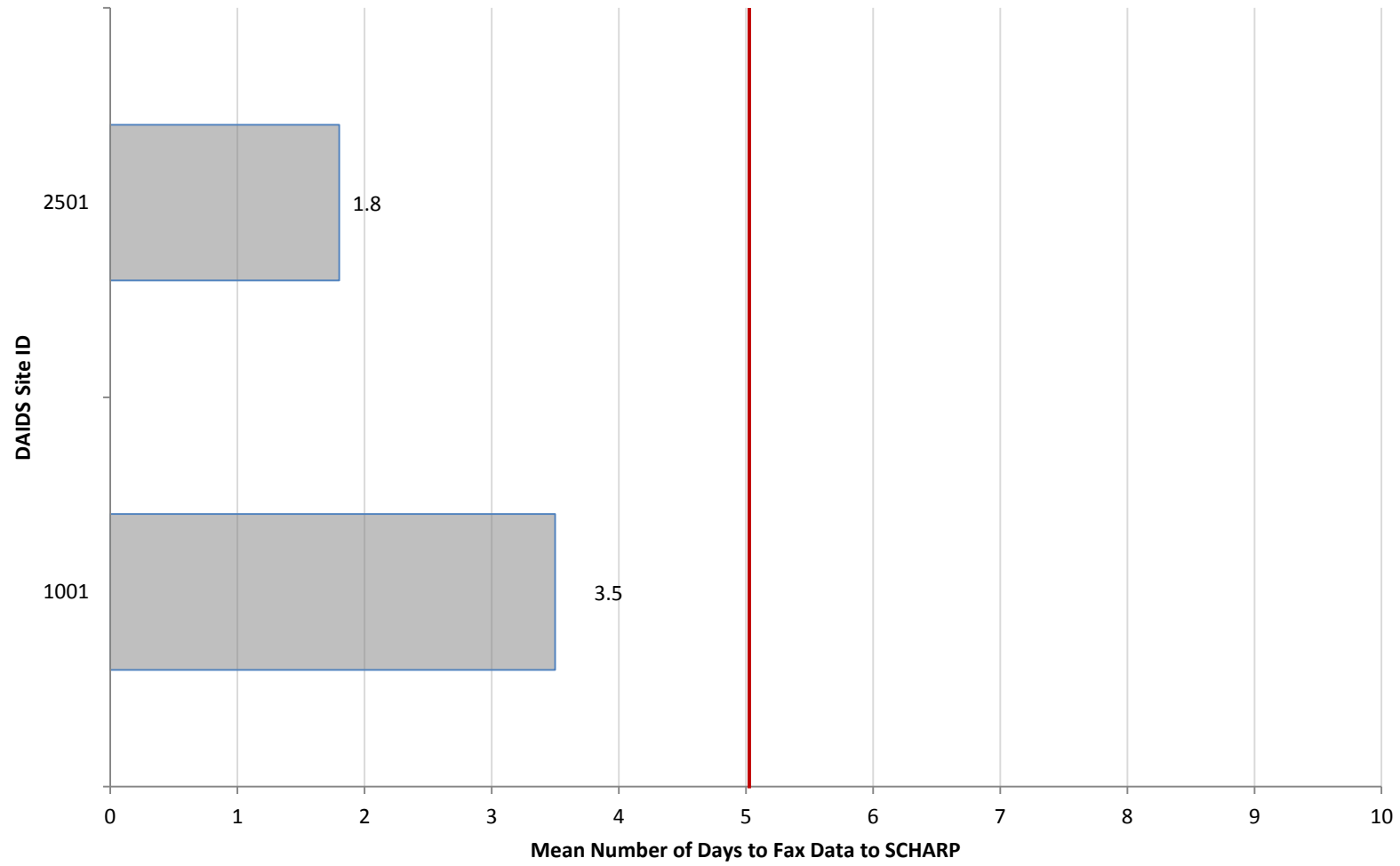
% QCs Resolved: Cumulative



QC Rate per 100 Records: Cumulative



Mean Days to Fax: Cumulative



— Indicates target of 5 days or less for data

Ideally, completed forms will be faxed to SCHARP within 1–2 days of completing the visit, though up to 5 days is allowed.