

MTN 039

Data Management Quality (DMQ) Report Previous Month: June2021

SITE	Data Entered On Time Within 7 Days			AEs Entered On Time Within 3 Days			Query Rate			Query Response Within 7 Days		
	Pages Included in Time Metric	Pages Entered On Time	% Pages Entered On Time	AEs Entered	AEs Entered On Time	% AEs Entered On Time	Total Queries	Total Pages Entered	Queries per 100 pages	Queries Answered	Queries Answered On Time	% Queries Answered On Time
Birmingham	0	0	.	0	0	.	1	0	0.00	1	1	100%
Pittsburgh	0	0	.	0	0	.	9	2	450.00	9	9	100%
All Sites	0	0	.	0	0	.	10	2	500.00	10	10	100%
Query data excludes system queries, cancelled queries, and queries placed by PPD monitors												

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Data Management Quality (DMQ) Report Cumulative Through: June2021

SITE	Data Entered On Time Within 7 Days			AEs Entered On Time Within 3 Days			Query Rate			Query Response Within 7 Days		
	Pages Included in Time Metric	Pages Entered On Time	% Pages Entered On Time	AEs Entered	AEs Entered On Time	% AEs Entered On Time	Total Queries	Total Pages Entered	Queries per 100 pages	Queries Answered	Queries Answered On Time	% Queries Answered On Time
Birmingham	430	430	100%	13	13	100%	15	3215	0.47	15	15	100%
Pittsburgh	396	294	74%	4	4	100%	34	2847	1.19	34	28	82%
All Sites	826	724	88%	17	17	100%	49	6062	0.81	49	43	88%

Query data excludes system queries, cancelled queries, and queries placed by PPD monitors

DEFINITION OF TERMS

#Pages included in Time Metric: It is the total number of case report forms (CRFs) entered into the SCHARP Medidata Rave database with an initial data entry date (i.e. the first date when data is saved on the form) that falls within the reporting period. It excludes certain study specific CRFs as determined by the study CDM (Screening Visits, Ongoing Logs, as well as the following CRFs: Additional Study Procedures, Behavioral Assessment, Follow-up Visit Y/N, Follow-up Visit Summary, Study Termination, Participant Replacement Assessment, Discontinuation of Study Product, Participant Identifier, HIV Confirmatory Tests, HIV Test Results, Interim Visit Summary, Chemistry Panel, Hematology, STI Tests, Pregnancy Test Result, Pregnancy History, Pregnancy Outcome, and Pregnancy Report. All inactivated forms and missed visits (as evidenced by the presence of a Missed Visit CRF) will be excluded, since they do not have a visit date.

of Pages Entered on Time: It is defined as the # of Pages Included in Time Metric where the initial Data Entry Date is less than or equal to 7 calendar days from the Visit Date. For each study, the study CDM will identify the forms that should be used as the "Visit Date" for purposes of this calculation.

% Pages entered on Time: The percentage of CRFs entered into the SCHARP Medidata Rave database where the initial Data Entry Date is less than or equal to 7 calendar days of the visit date. It is obtained by dividing # Pages entered on time by # Pages included in Time Metric and multiplying by 100.

of AEs Entered: It is defined as the total number of AE log lines with the AE term (description) field populated in the SCHARP Medidata Rave database within the reporting period. For each AE log line, the earliest data entry date for the completed data fields is used to determine if an AE falls within the reporting period.

of AEs Entered on Time: It is defined as the # of AEs Entered within 3 days of the "Date AE Reported to Site" variable. It is calculated by comparing the AE log line data entry date (i.e. the earliest date that data was entered for its completed data fields) with the AE-"Date AE Reported to Site" variable.

% AEs on Time: It is the percentage of AEs Entered on Time into the SCHARP Medidata Rave database. It is obtained by dividing the # AEs Entered on Time by the # of AEs Entered and multiplying by 100.

Total # of Queries: It is defined as the total number of queries or Quality Control notes (QCs) that have been manually placed by the study staff, which includes the following query marking groups: Site from DM, Site from Safety, Site from Coder. The Total # of Queries is determined by utilizing the query open date that falls within the reporting period. The total number of Queries excludes system generated queries, canceled queries and queries placed by monitors (i.e., Site from CRA marking group).

Total # Pages Entered: It is defined as the total number of pages entered into the SCHARP Medidata Rave database where the initial data entry date (i.e., the first time the page is saved with data) falls within the reporting period. All CRFs with an initial data entry date within the reporting period are included (no visits/CRFs are excluded). For log forms, each completed log line (partial or full data) is counted as a separate page.

Queries per 100 Pages: It is defined as the query rate per 100 pages. It is obtained by dividing Total # of Queries by Total # of Pages Entered and multiplying by 100.

Total # Queries Answered: It is defined as the Total # of Queries with a site answer date present as of the date the DMQ report is generated.

Queries Answered on Time: It is defined as the Total # of Queries Answered with a site answer date that is 7 days or less from the query open date.

% Queries Answered on Time: It is the percentage of queries answered on time. It is obtained by dividing Total # Queries Answered on Time by Total # Queries Answered and multiplying by 100.

DEFINITION OF TERMS

Definition of Terms – MTN/HPTN Studies:

Queries not answered on Time: It displays all the queries that took more than 7 days to answer from query open date within the DMQ reporting period

Participant: It is the participant id

Folder: It is the Visit

Form: It is the Case Report Form (CRF) name

Field: It is the annotated variable name used on the CRF

Log#: It indicates the log line number

Query open date: It is the date on which the query was opened

Query Response date: It is the date on which the site responded to the query

Days to Respond: It is the difference between Query Response Date and Query Open date.

AEs not entered on Time: It displays all the AEs that took more than 3 days to enter in Medidata Rave from the "Date AE Reported to Site" within the DMQ Reporting period

Date Reported: It is the date on which AE was reported to site

Date Entered: It is the date on which the site entered the AE

Days to enter the AE: It is the difference between AE Date Entered and Date AE Reported to Site

Pages not entered on Time: It displays all the CRFs that took more than 7 calendar days to enter in Medidata Rave from the Visit Date within the DMQ reporting period

Date_CRF_entered: It is the date on which the CRF was first entered

Visit date: It is the date the study visit occurred.

Days to enter the CRF: It is the difference between Visit date and initial Data Entry Date.
