

MTN-030: A Phase 1, Randomized, Double-Blind Pharmacokinetic and Safety Study of Dapivirine/Levonorgestrel Vaginal Rings
Data Management Quality (DMQ) Report
Previous Month: August 2017

	Data Entered on Time: Submitted within 7 days			AEs Entered on Time: Submitted within 3 days			Query Rate			Query Response: Queries Answered within 7 days		
Site	# Pages Included in Time Metric	# Pages Entered on Time	% Pages on Time	# AEs Entered	# AEs Entered on Time	% AEs on Time	Total # Queries	Total # Pages Entered	Queries per 100 pages	Total # Queries Answered	# Queries Answered on Time	% Queries Answered on Time
Birmingham CRS	164	164	100%	0	0	0%	10	191	5.24	9	9	100%
Pittsburgh CRS	82	80	98%	3	3	100%	12	136	8.82	12	12	100%

Query Data excludes system queries, canceled queries and queries placed by PPD monitors

Data Management Quality (DMQ) Report
Cumulative: Study Start through August 2017

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	# Pages Included in Time Metric	# Pages Entered on Time	% Pages on Time	# AEs Entered	# AEs Entered on Time	% AEs on Time	Total # Queries	Total # Pages Entered	Queries per 100 pages	Total # Queries Answered	# Queries Answered on Time	% Queries Answered on Time
Birmingham CRS	745	742	100%	22	22	100%	46	1325	3.47	45	26	58%
Pittsburgh CRS	755	752	100%	24	21	88%	41	1305	3.14	41	40	98%

Query Data excludes system queries, canceled 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 CRFs from the Screening Visit, Ongoing Logs, as well as the following CRFs: Pharmacy Dispensation, Hematology, Local Laboratory Results, Hormone Tests, HIV Tests, and STI Tests. All inactivated forms and missed visits (as evidenced by the presence of a Missed Visit CRF) are excluded, since they do not have an actual 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 date entered on the Randomization, Follow-up Visit Summary, Treatment Discontinuation, and Study Discontinuation CRFs.

% Pages entered on Time: The percentage of CRFs entered into 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 the # Pages Entered on Time by the # 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 number of Queries is determined by utilizing the query open date that falls within the reporting period. The Total # 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 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.
