



HPTN
HIV Prevention
Trials Network



Monitoring Data Quality

**HPTN Regional Meeting
19 October 2017**

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Presentation Topics

- Electronic Data Capture
- HPTN Data Management Quality Metrics
- Common Data Queries

Types of Data Submitted to SCHARP

Case Report Form (CRF or eCRF) data

SCHARP DEM-1, Page 1 of 2

HPTN 076 (214) DEM-1 (001)

Participant ID: Site Number Participant Number Chk

Form Completion Date: dd MM yy

Demographics

1. What is the participant's date of birth? dd MM yy OR If unknown, record age: years

SCHARP UAT iMedidata Messages My Profile Help Home Logout
User: Lynda Emel Associate Director/Staff Scientist (Data Manager)

HPTN083 UCLA Care Center 701381659 V2.0 - Day 0/Enrollment Enrollment

Subject: 701381659
Page: Enrollment - V2.0 - Day 0/Enrollment

Is the participant enrolling in the study? No

If participant did not enroll, skip to "Record Participant's Sex Pro Score" and complete remaining items.

Which version of the Sex Pro Tool was used? North America

Record participant's Sex Pro score 15

Complete the following item only if participant does not enroll. If more than one reason, add additional log lines.

#	Reason participant was not enrolled in the study:
1	Has a history of seizure disorder

Printable Version View PDF Icon Key
CRF Version 519 - Page Generated: 10 Oct 2017 11:04:44 Pacific Daylight Time

Save Cancel

Why Electronic Data Capture (EDC)?

DATA ACCURACY

- Real-time data & consistency checks
- Legible entries
- Automatic calculations
- Better data management quality performance

ORGANIZATION

- User-friendly navigation
- Search and filter options
- Unified database
- Reports
- Greater visibility

EFFICIENT DATA MANAGEMENT

- Data entry at sites
- SDMC data entry process
- Real-time data access
- Help Options onscreen
- Less time managing queries

DATA SECURITY

- Data protected
- Data backed-up
- User and role-specific permissions

REGULATORY COMPLIANCE

- Validated system
- Data integrity
- 21 CFR Part 11 (Electronic Records, Electronic Signatures)
- Electronic source data verification (monitors)
- CDISC/SDTM output
- Submission-ready data

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HPTN Data Quality Metrics

- Timely submission of study data
- Timely submission of Adverse Experience data
- Quality of data submitted (number of queries)
- Data Query resolution

HPTN Data Quality Metrics

Timely submission of study data

- DataFax: within 5 calendar days of study visit
- EDC: 90% of pages within 7 calendar days of study visit
 - Excludes ongoing log forms (e.g., Concomitant Medications) and study-specific visits or forms as determined by the study CDM

HPTN Data Quality Metrics

Timely submission of Adverse Experience data

- DataFax: 3 calendar days from site awareness
- EDC: 90% of AE submitted ≤ 3 days of date reported to site
 - Compares earliest data entry date to “date reported to site” item for each AE Log entry

HPTN Data Quality Metrics

Quality of data submitted (number of queries)

- DataFax: no standard
- EDC: < 10 per 100 pages
 - Total number of Data Queries that have been manually placed by SCHARP staff. Automatic system queries and queries that have been canceled or placed by monitors are excluded.

HPTN Data Quality Metrics

Timely Data Query resolution

- DataFax: 28 days or 7 days
- EDC: 80% answered ≤ 7 calendar days after query opened
 - When site answers/responds to a query, the query is closed if sufficiently answered, canceled if not a valid query, or re-queried if not resolved based on the site response. Re-queries are counted as new queries in Rave.

Common Data Queries

- Entering text in response to query but not correcting/entering the data item itself
- Missing data items
- Discrepancies between forms
 - AE Log indicates medication but no medication entered into Concomitant Medication Log
 - Gradable abnormal lab values not entered as an AE
 - Fatal AE diagnosis not matching cause of death on Termination form
- Not entering UN or UNK for unknown day or month for Con Meds or Pre-existing Conditions

EXAMPLE DATA MANAGEMENT QUALITY REPORT

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

ACKNOWLEDGEMENTS



SCHARP Data Management Team
HPTN Performance Evaluation Committee



The HIV Prevention Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068619, UM1AI068613, UM1AI1068617), with co-funding from the National Institute of Mental Health, and the National Institute on Drug Abuse, all components of the U.S. National Institutes of Health.

Questions?