



**HPTN**  
HIV Prevention  
Trials Network



# Monitoring Data Quality

**HPTN Regional Meeting  
27 March 2018**

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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:  -  -       Form Completion Date:     
Site Number      Participant Number      Chk      dd      MM      yy

**Demographics**

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

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 **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

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CRF Version 519 - Page Generated: 10 Oct 2017 11:04:44 Pacific Daylight Time

# 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 manual queries)
- Timely Data Query resolution

# HPTN Data Quality Metrics

## Timely submission of study data

- DataFax: within 5 calendar days of study visit
- Rave: 90% of pages entered within 7 calendar days of study visit
  - Excludes 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  $\leq$  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 manual queries per 100 pages
  - Data Queries that have been manually added 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  $\leq 7$  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.

# EXAMPLE DATA MANAGEMENT QUALITY REPORT

HPTN-083

## Data Management Quality (DMQ) Report Previous Month: February 2018

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 On Time	AEs Entered	AEs Entered On Time	% AEs On Time	Total Queries	Total Pages Entered	Queries per 100 Pages	Queries Answered	Queries Answered On Time	Percent On Time
Site A	181	180	99%	20	12	60%	1	335	0.30	1	1	100%
Site B	160	160	100%	30	27	90%	8	298	2.68	5	4	80%
Site C	233	233	100%	24	13	54%	2	539	0.37	2	2	100%
Site D	252	224	89%	37	6	16%	5	481	1.04	5	4	80%
Site E	181	177	98%	15	10	67%	9	483	1.86	9	9	100%
Site F	206	206	100%	29	23	79%	9	384	2.34	9	9	100%
Site G	225	216	96%	14	5	36%	20	378	5.29	15	7	47%
Site H	83	83	100%	8	7	88%	3	198	1.52	3	2	67%

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

# Common Data Queries

- Entering text in response to query but not correcting/entering the data item itself

Did the participant exit/terminate the study at this visit?

? Data is required. Please complete.  
Opened To Site from System (29 Aug 2017)

Data Entry Error ▼

Yes  No



# Common Data Queries, cont'd

- 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
- Not entering UN or UNK for unknown day or month for Con Meds or Pre-existing Conditions

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SCHARP Data Management Team  
HPTN Performance Evaluation Committee



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Questions?