Monitoring Data Quality

HPTN Regional Meeting
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Seattle, Washington, USA
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

[Diagram of Case Report Form]

Participant ID
Site Number
Participant Number
Clin

Form Completion Date

1. What is the participant’s date of birth?

[Fields for date of birth]

[Additional fields and sections for data submission]
# 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
## Why Electronic Data Capture (EDC)?

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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

**Previous Month: August 2017**

<table>
<thead>
<tr>
<th>Site</th>
<th>Data Entered on Time: Submitted within 7 days</th>
<th>AEs Entered on Time: Submitted within 3 days</th>
<th>Query Rate</th>
<th>Query Response: Queries Answered within 7 days</th>
</tr>
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<tbody>
<tr>
<td></td>
<td># Pages Included in Time Metric</td>
<td># Pages Entered on Time</td>
<td>% Pages on Time</td>
<td>Total # Queries</td>
</tr>
<tr>
<td>Birmingham CRS</td>
<td>164</td>
<td>164</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>Pittsburgh CRS</td>
<td>82</td>
<td>80</td>
<td>98%</td>
<td>3</td>
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*Query Data excludes system queries, canceled queries and queries placed by PPD monitors*
ACKNOWLEDGEMENTS

SCHARP Data Management Team
HPTN Performance Evaluation Committee

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Questions?