Monitoring Data Quality

HPTN Regional Meeting
27 March 2018

Leslie Cottle
Sr Clinical Data Manager HPTN SDMC
Fred Hutch
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

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

   - Day
   - Month
   - Year
   - OR
   - If unknown, record age: ___ YRS

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:
    - Has a history of seizure disorder

Printable Version View PDF Icon Key
### Why Electronic Data Capture (EDC)?

<table>
<thead>
<tr>
<th>DATA ACCURACY</th>
<th>ORGANIZATION</th>
<th>EFFICIENT DATA MANAGEMENT</th>
<th>DATA SECURITY</th>
<th>REGULATORY COMPLIANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Real-time data &amp; consistency checks</td>
<td>• User-friendly navigation</td>
<td>• Data entry at sites</td>
<td>• Data protected</td>
<td>• Validated system</td>
</tr>
<tr>
<td>• Legible entries</td>
<td>• Search and filter options</td>
<td>• SDMC data entry process</td>
<td>• Data backed-up</td>
<td>• Data integrity</td>
</tr>
<tr>
<td>• Automatic calculations</td>
<td>• Unified database</td>
<td>• Real-time data access</td>
<td>• User and role-specific permissions</td>
<td>• 21 CFR Part 11 (Electronic Records, Electronic Signatures)</td>
</tr>
<tr>
<td>• Better data management quality performance</td>
<td>• Reports</td>
<td>• Help Options onscreen</td>
<td></td>
<td>• Electronic source data verification (monitors)</td>
</tr>
<tr>
<td></td>
<td>• Greater visibility</td>
<td>• Less time managing queries</td>
<td></td>
<td>• CDISC/SDTM output</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Submission-ready data</td>
</tr>
</tbody>
</table>
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)?

**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)?

<table>
<thead>
<tr>
<th>DATA ACCURACY</th>
<th>ORGANIZATION</th>
<th>EFFICIENT DATA MANAGEMENT</th>
<th>DATA SECURITY</th>
<th>REGULATORY COMPLIANCE</th>
</tr>
</thead>
</table>
| • Real-time data & consistency checks  
• Legible entries  
• **Automatic calculations**  
• Better data management quality performance | • User-friendly navigation  
• Search and filter options  
• Unified database  
• Reports  
• Greater visibility | • Data entry at sites  
• SDMC data entry process  
• Real-time data access  
• Help Options onscreen  
• Less time managing queries | • Data protected  
• Data backed-up  
• User and role-specific permissions | • 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)?

<table>
<thead>
<tr>
<th>DATA ACCURACY</th>
<th>ORGANIZATION</th>
<th>EFFICIENT DATA MANAGEMENT</th>
<th>DATA SECURITY</th>
<th>REGULATORY COMPLIANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Real-time data &amp; consistency checks</td>
<td>• User-friendly navigation</td>
<td>• Data entry at sites</td>
<td>• Data protected</td>
<td>• Validated system</td>
</tr>
<tr>
<td>• Legible entries</td>
<td>• Search and filter options</td>
<td>• SDMC data entry process</td>
<td>• Data backed-up</td>
<td>• Data integrity</td>
</tr>
<tr>
<td>• Automatic calculations</td>
<td>• Unified database</td>
<td>• Real-time data access</td>
<td>• User and role-specific permissions</td>
<td>• 21 CFR Part 11 (Electronic Records,</td>
</tr>
<tr>
<td>• Better data management quality performance</td>
<td>• Reports</td>
<td>• Help Options onscreen</td>
<td></td>
<td>Electronic Signatures)</td>
</tr>
<tr>
<td></td>
<td>• Greater visibility</td>
<td></td>
<td></td>
<td>• Electronic source data verification</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(monitors)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• CDISC/SDTM output</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Submission-ready data</td>
</tr>
</tbody>
</table>
## Why Electronic Data Capture (EDC)?

<table>
<thead>
<tr>
<th>DATA ACCURACY</th>
<th>ORGANIZATION</th>
<th>EFFICIENT DATA MANAGEMENT</th>
<th>DATA SECURITY</th>
<th>REGULATORY COMPLIANCE</th>
</tr>
</thead>
</table>
| - Real-time data & consistency checks  
- Legible entries  
- Automatic calculations  
- Better data management quality performance | - User-friendly navigation  
- Search and filter options  
- Unified database  
- Reports  
- Greater visibility | - Data entry at sites  
- SDMC data entry process  
- Real-time data access  
- Help Options onscreen  
- Less time managing queries | - Data protected  
- Data backed-up  
- User and role-specific permissions | - Validated system  
- Data integrity  
- 21 CFR Part 11 (Electronic Records, Electronic Signatures)  
- Electronic source data verification (monitors)  
- CDISC/SDTM output  
- Submission-ready data |
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 ≤ 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 ≤ 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

<table>
<thead>
<tr>
<th>SITE</th>
<th>Data Entered On Time Within 7 Days</th>
<th>AEs Entered On Time Within 3 Days</th>
<th>Query Rate</th>
<th>Query Response Within 7 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pages Included in Time Metric</td>
<td>Pages Entered On Time</td>
<td>% Pages On Time</td>
<td>AEs Entered</td>
</tr>
<tr>
<td>Site A</td>
<td>181</td>
<td>180</td>
<td>99%</td>
<td>20</td>
</tr>
<tr>
<td>Site B</td>
<td>160</td>
<td>160</td>
<td>100%</td>
<td>30</td>
</tr>
<tr>
<td>Site C</td>
<td>233</td>
<td>233</td>
<td>100%</td>
<td>24</td>
</tr>
<tr>
<td>Site D</td>
<td>252</td>
<td>224</td>
<td>89%</td>
<td>37</td>
</tr>
<tr>
<td>Site E</td>
<td>181</td>
<td>177</td>
<td>98%</td>
<td>15</td>
</tr>
<tr>
<td>Site F</td>
<td>206</td>
<td>206</td>
<td>100%</td>
<td>29</td>
</tr>
<tr>
<td>Site G</td>
<td>225</td>
<td>216</td>
<td>96%</td>
<td>14</td>
</tr>
<tr>
<td>Site H</td>
<td>83</td>
<td>83</td>
<td>100%</td>
<td>8</td>
</tr>
</tbody>
</table>

*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
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
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?