MTN-003D
Data Management

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RTI International
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Overview

- Management of:
  - CRFs
  - Audio files
  - Debriefing reports
  - Transcripts
- Data tracking and other DM tips
**CRF Management**

CRF is completed

Queries responded to & updated CRF efaxed

Updated CRF reviewed

Confirmation of completion sent

[No remaining queries]

CRFs reviewed & any queries sent to the site

CRFs efaxed to MTN003D@rti.org

Quality of CRFs reviewed

[Queries remain]

[No remaining queries]
## CRF Queries

<table>
<thead>
<tr>
<th>Query #</th>
<th>MTN-003D PTID</th>
<th>VOICE PTID</th>
<th>Issue</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1001</td>
<td></td>
<td>Visit date not completed at top of form</td>
<td>Visit date filled in.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Q10 (date of termination) does not match Q9 (date IDI conducted). Please either correct or include a comment as to why these dates differ.</td>
<td>Error in recording of Q10, date now matches Q9, which is when the IDI was conducted and completed.</td>
</tr>
<tr>
<td>2</td>
<td>1001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Completion Responsibility Legend:
- Column completed by RTI
- Column completed by Site
# CRF Timeline

<table>
<thead>
<tr>
<th>Task</th>
<th>Timeline</th>
</tr>
</thead>
</table>
| Completed CRFs reviewed locally and efaxed to RTI                    | **Initial timeline:** Within two working days of completion  
**Timeline upon reaching high quality status:** Once per week        |
| CRFs reviewed by RTI and queries sent to site                        | Within **two working days** of initial receipt |
| Queries responded to and updated CRFs efaxed to RTI                  | Within **two working days** of receipt of queries |
Audio File Management

Interviewer(s) copies file to hard-drive & provides copy to site

File transferred to secure ftp site

File downloaded for back-up

File downloaded for transcription/translation

Once transcripts are finalized, audio file is destroyed
# Audio File Timeline

<table>
<thead>
<tr>
<th>Task</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audio file checked, saved to hard-drive, copied for the site</td>
<td><strong>Same day</strong> as IDI completion</td>
</tr>
<tr>
<td>Site staff upload audio file to ftp site</td>
<td><strong>Same day</strong> as IDI completion</td>
</tr>
<tr>
<td>Audio file destroyed</td>
<td>Upon confirmation from RTI that associated transcript is finalized</td>
</tr>
</tbody>
</table>
Debriefing Report Management

Interviewer(s) create debriefing report

DTHF/Interviewers review DR and send to RTI

Debriefing report reviewed

Queries sent to DTHF/Interviewers

DTHF/Interviewers respond to queries

Updated debriefing report reviewed

[No remaining queries]

Debriefing report finalized and emailed to study team

[Queries remain]
2. What were the most important themes or ideas discussed? (Describe in detail the most important ideas discussed within each of the main topic areas [motivations to join the trial, adherence, and anal sex] and any important issues that were raised)

a. Motivation to join trial (include risk perception and life events):

The participant stated that she was introduced to the trial by a friend and she joined the trial mainly because of the health care benefits. She was not especially concerned about her risk for HIV, but she was not always able to use condoms with her main partner because he dislikes them, so she did express some level of concern. She said this wasn’t the reason that she joined the trial, but she felt like the HIV tests were an added benefit.

b. Adherence (discussion around measures and adherence reporting):

In discussing factors that affected her own adherence, the participant stated that she did not have difficulty taking the study tablets. She said it became a habit for her, though she heard that it was an issue for some people who were stigmatized for taking ARVs. She did not experience issues of stigma, her partner and family were supportive, there were no issues with privacy or storing the tablets. The discussion around how the participant responded to the rating scale reflected her general opinion about the ease of using the product. She said that she usually rated herself as “very good” because she felt that she didn’t have any problems during the month. She did rate herself “good” one month towards the beginning of her participation because she was having trouble swallowing the tablets and would have to try to take them a couple of times.

c. Anal sex (include lubricant/gel use):

As previously mentioned, the participant was shy to discuss anal sex practices.

Comment [MAH1]: Can you specify if the participant said why she was not able to always use condoms and if this was an issue with any type of partner in particular? Also, how did this relate to her motivation to join the trial?

AB: Additional text has been added to explain these points.

Comment [MAH2]: Statement says the participant had no issues with privacy or “storing the tablets”? Does this refer to storing the tablets or a side effect, such as sores from the tablets?

AB: Should be “storing the tablets.” Text has been modified.
# Debriefing Report Timeline

<table>
<thead>
<tr>
<th>Task</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Debriefing Report completed</td>
<td>Same day as interview completion</td>
</tr>
<tr>
<td>DR reviewed by DTHF/Interviewers/Note-takers and emailed to RTI</td>
<td>Within one week of IDI completion</td>
</tr>
<tr>
<td>RTI reviews DR and sends queries to DTHF/Interviewers/Note-takers</td>
<td>Within one week of initial receipt</td>
</tr>
<tr>
<td>DTHF/Interviewers/Note-takers respond to RTI queries</td>
<td>Within one week of query receipt</td>
</tr>
</tbody>
</table>
Transcript Management

1. DTHF/site develop local language transcript
   - Local language transcript reviewed
   - English language transcript reviewed
   - English transcript updated and emailed to RTI
   - Transcript reviewed
   - Queries sent to DTHF/site
   - DTHF/site respond to queries
     - Updated transcript reviewed
     - Transcript finalized and emailed to study team

2. [No remaining queries]

3. [Queries remain]
Transcription Tips

- Audio file transcribed in language of IDI
- Should be done verbatim to reflect everything actually said by the interviewer and respondent
- Extended pauses, nonverbal process, etc. (e.g. “Mmm”) should also be captured
Translation Tips

- Should reflect the local language, terms, and expressions of the respondent, with explanation in brackets
  - CORRECT: He went to his small house [to see his girlfriend]
  - INCORRECT: He went to see his girlfriend
  - Other examples:
    - He was not in good books with her [they were not getting along]
    - He went with him to see her… [Partner went with his brother to see his girlfriend]
    - Everyone was saying she looked sick [suspected HIV]
    - I inserted a mixture of coke and jik [bleach]
Transcript Queries

154. R: I don't know, even before I had children, I have never menstruated.
155. I: But you fell pregnant?
156. R: Yes. I just see at the clinic when they said to me that [you are so how many months pregnant?]
157. I: You have never menstruated in your entire life?
158. R: Never! Even after I had given birth, I have to bleed a lot, I bleed a lot while on/after I was at the hospital, but when I left/leave there it stopped. [ends]
159. I: So even if you can use a family planning method, still you won’t menstruate?
160. R: Mhm. I am like [I get an injection myself with a needle] for contraception, but I have never menstruated.
161. I: How do you feel?
162. R: At first it bothered me, because when I was still growing up like when my friends chatted about it, it bothered me but now I no longer care. I am used to it.
163. I: Before we started the interview I heard you saying that your partner is not here.
164. R: Like he left for a week, he left, to go home, he left on Monday.
165. I: When he is not available, can you use the gel?
166. R: Yes, I can. I use it.
167. I: Don’t you tell yourself that he is not available, so I won’t have sex therefore let me take a break with the gel?
168. R: No, I use it always.
169. I: What inspires you so much, for you to apply these gels?
170. R: Eish!
171. I: Are you really enthusiastic?
172. R: Yes. I am enthusiastic.
# Transcript Timeline

<table>
<thead>
<tr>
<th>Task</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial English language transcript developed and emailed to RTI</td>
<td>Within <em>one month</em> of the IDI completion</td>
</tr>
<tr>
<td>(inclusive of site-level review)</td>
<td></td>
</tr>
<tr>
<td>RTI reviews transcript and sends queries to DTHF/Interviewers</td>
<td>Within <em>two weeks</em> of initial transcript receipt</td>
</tr>
<tr>
<td>DTHF/Interviewers respond to RTI queries</td>
<td>Within <em>two weeks</em> of query receipt</td>
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</tbody>
</table>
DATA TRACKING AND OTHER DM TIPS
Data Tracking

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>MRC Data Tracking Log</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>MTN-003D PTID</td>
<td>IDI Date</td>
<td>Date PSF Received</td>
<td>PSF Status</td>
<td>Date DEM Received</td>
<td>DEM Status</td>
<td>Date Audio File Received</td>
<td>Date DR Received</td>
<td>Date DR Status</td>
<td>Date Transcript Received</td>
<td>Transcript Status Date</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1001</td>
<td>31-Oct-12</td>
<td>2-Nov-12</td>
<td>Finalized</td>
<td>2-Nov-12</td>
<td>Finalized</td>
<td>1-Jan-12</td>
<td>6-Nov-12</td>
<td>Finalized</td>
<td>16-Nov-12</td>
<td>Finalized</td>
<td>18-Dec-12</td>
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</table>

Status Options:
- Received
- RTI Queried
- Site Responded to Queries
- Finalized
File Naming Conventions

- **Initial format:**
  - IDI_1001_Audio File_31OCT12

- **Query format:**
  - IDI_1001_Debriefing Report_31OCT12_MH_AB

- **Final format:**
  - IDI_1001_Debriefing Report_31OCT12_FINAL
Transcript Formatting Tips

- Header Includes: Participant ID, Clinical Site, Interview Date, Interviewer Name, Audio-tape Length, Transcriber Name
- After header, label next section “Interview Text,” insert a hard return and begin transcribing the content of the audio file verbatim.
- Use “I:” before Interviewer remarks and “R:” before respondent remarks.
- Auto-number the transcript by paragraph so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number.
- Replace all references to individual names or other identifying data with pseudonyms.
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets].
- Long pauses can be represented by use of an ellipsis “…”. 
- Insert a footer with page X of X on right-hand side.
- Spell check the transcript for any spelling and grammar errors.
- Be consistent with all formatting!