

MTN-003D

Data Management

Miriam Hartmann, MPH

Women's Global Health Imperative

RTI International

San Francisco, CA, USA

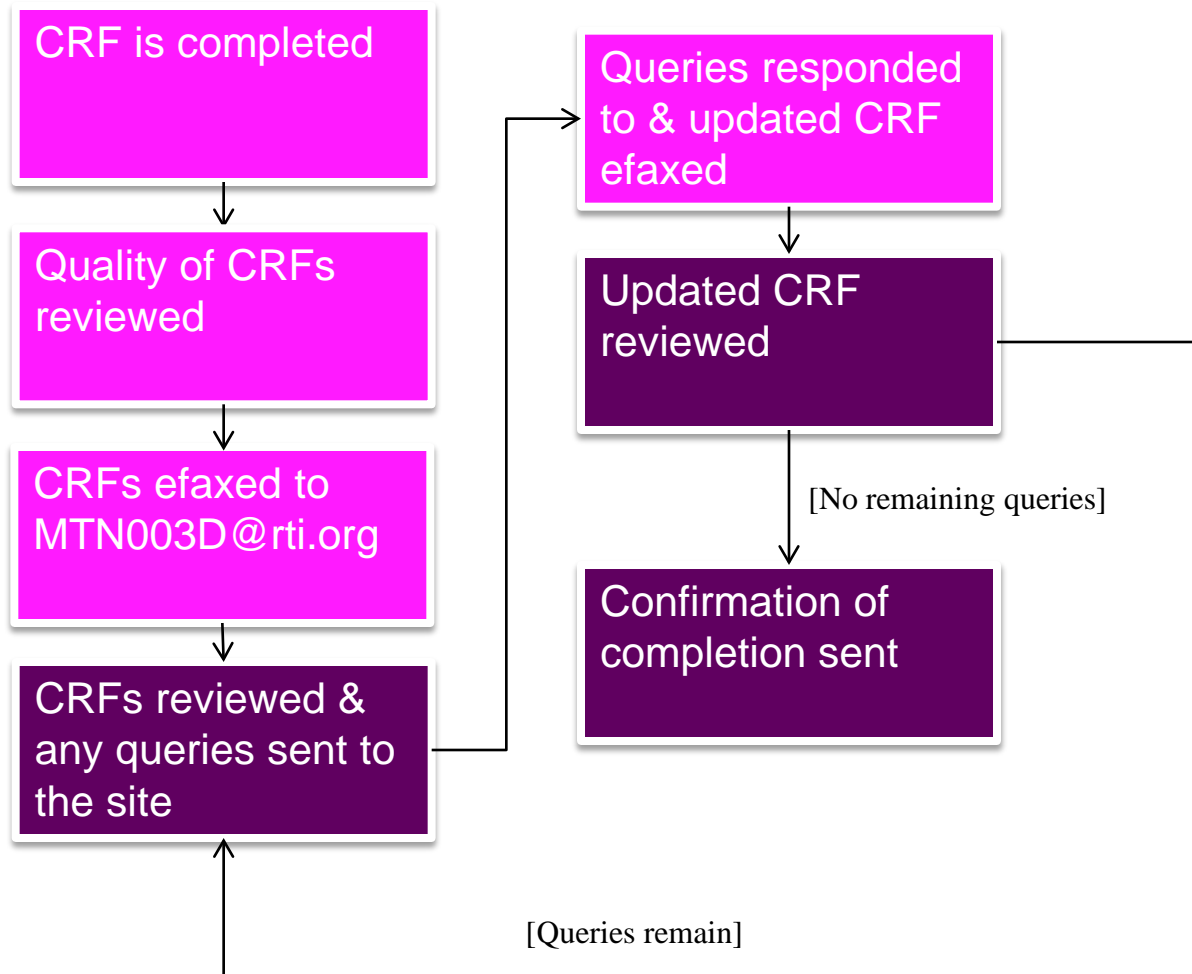




Overview

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

CRF Management



CRF Queries

MTN-003D CRF Queries.xlsx - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View Acrobat

Clipboard Font Alignment Number Styles

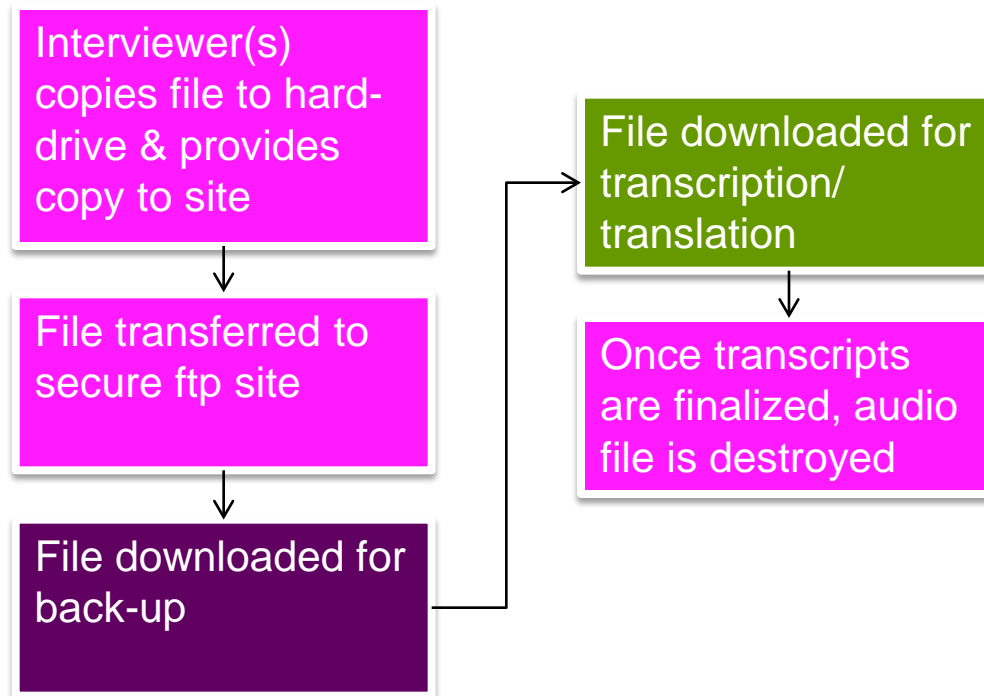
E18

	A	B	C	D	E	F	G	H	I
1	Participant Status Form Queries								
2	Query #	MTN-003D PTID	VOICE PTID	Issue	Action Taken	Site Staff Initials	Action Date	Date Issue Resolved	RTI Staff Initials
3	1	1001		Visit date not completed at top of form	Visit date filled in.	AB	31-Oct-12	5-Jan-12	MH
4	2	1001		Q10 (date of termination) does not match Q9 (date IDI conducted). Please either correct or include a comment as to why these dates differ.	Error in recording of Q10, date now matches Q9, which is when the IDI was conducted and completed.	AB	31-Oct-12	5-Jan-12	MH
5									
6									
7									
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10									
11									
12									
13									
14	Completion Responsibility Legend:								
15	Column completed by RTI								
16	Column completed by Site								

CRF Timeline

Task	Timeline
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 <i>two working days</i> of initial receipt
Queries responded to and updated CRFs efaxed to RTI	Within <i>two working days</i> of receipt of queries

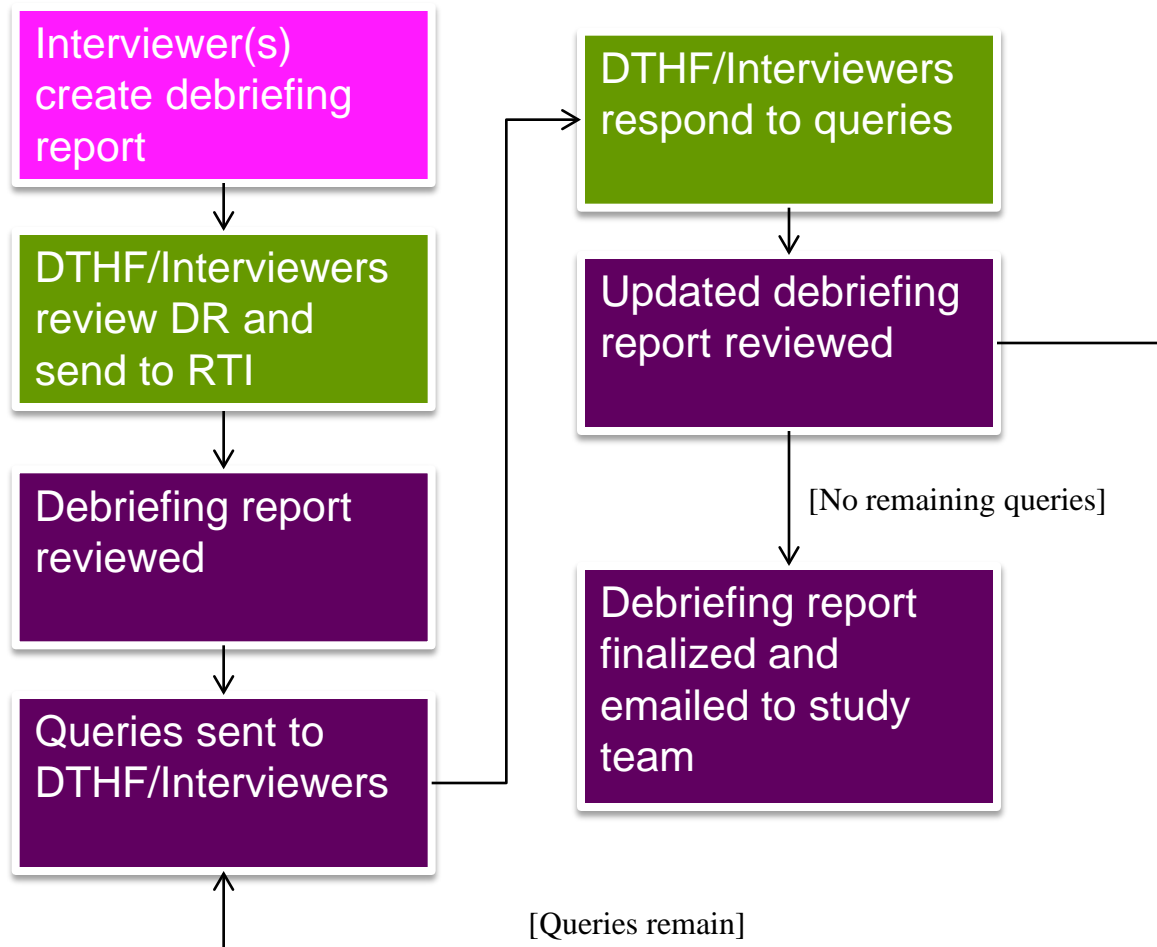
Audio File Management



Audio File Timeline

Task	Timeline
Audio file checked, saved to hard-drive, copied for the site	Same day as IDI completion
Site staff upload audio file to ftp site	Same day as IDI completion
Audio file destroyed	Upon confirmation from RTI that associated transcript is finalized

Debriefing Report Management



Debriefing Report Queries

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

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.

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

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.

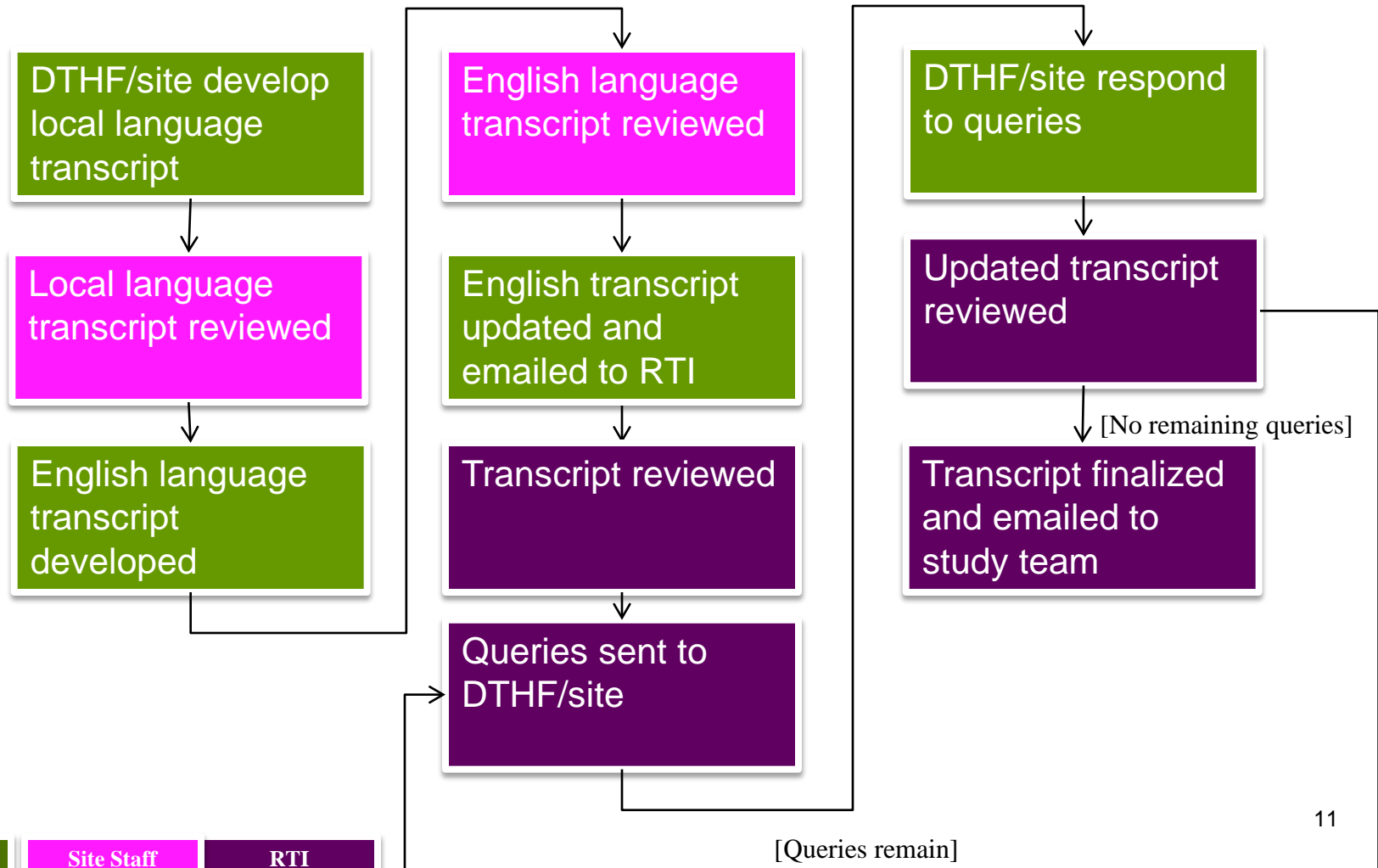
c. Anal sex (*include lubricant/gel use*):

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

Debriefing Report Timeline

Task	Timeline
Initial Debriefing Report completed	Same day as interview completion
DR reviewed by DTHF/Interviewers/Note-takers and emailed to RTI	Within one week of IDI completion
RTI reviews DR and sends queries to DTHF/Interviewers/Note-takers	Within one week of initial receipt
DTHF/Interviewers/Note-takers respond to RTI queries	Within one week of query receipt

Transcript Management





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 ~~en~~ I was ~~am~~ 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.*

Comment [MAH1]: This sounds weird for a quote. Can you double check?

SS: corrected

Comment [MAH2]: Can you double check this. "I have to bleed a lot" sounds strange and I think the tense is wrong in the rest of the sentence.

SS: corrected

Comment [MAH3]: Does this mean she uses injectable contraceptives?

SS: corrected

Transcript Timeline

Task	Timeline
Initial English language transcript developed and emailed to RTI (inclusive of site-level review)	Within one month of the IDI completion
RTI reviews transcript and sends queries to DTHF/Interviewers	Within two weeks of initial transcript receipt
DTHF/Interviewers respond to RTI queries	Within two weeks of query receipt



DATA TRACKING AND OTHER DM TIPS

Data Tracking

MTN-003D Data Tracking Log.xlsx - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View Acrobat Design

Clipboard: Cut, Copy, Paste, Format Painter

Font: Calibri, 11, Bold, Italic, Underline, Text Color, Background Color

Alignment: Wrap Text, Merge & Center

Number: General, Currency, Percentage, Decimals

Styles: Normal, Bad, Good, Neutral, Calculation, Check

A3 1001

MRC Data Tracking Log													
	Date PSF		Date DEM		Date Audio File		Date DR		DR Status	Date Transcript		Trascript Status	
MTN-003D PTID	IDI Date	Received	PSF Status	Received	DEM Status	Received	Received	DR Status	Date	Received	Transcript Stat	Date	
1001	31-Oct-12	2-Nov-12	Finalized	2-Nov-12	Finalized	1-Jan-12	6-Nov-12	Finalized	16-Nov-12	20-Nov-12	Finalized	18-Dec-12	
4													
5													
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10													
11													
12													
13													
14													
15	Status Options:												
16	Received												
17	RTI Queried												
18	Site Responded to Queries												
19	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!