

# MTN-016 Training

## Women: Follow-up Visit Scheduling and Visit Coding

### SSP Sections 13.3.2

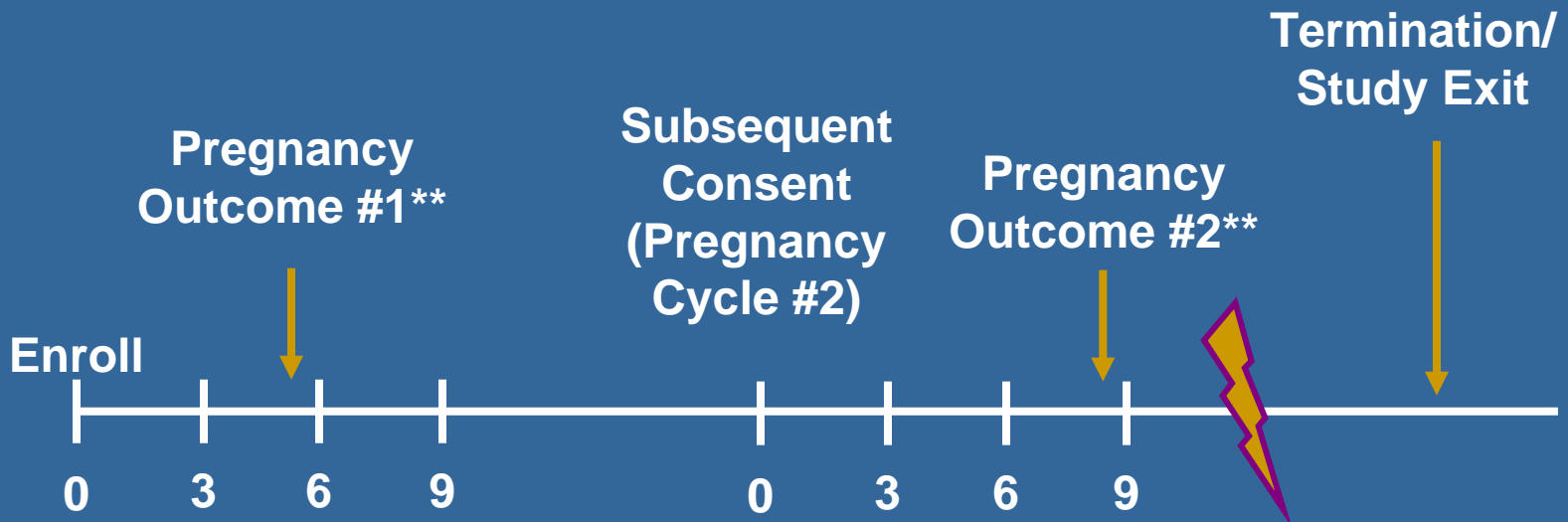


# MTN-016 Follow-up: Women

- Day 0 is defined as the date of enrollment
- Women who are pregnant at the time of Enrollment:
  - will be seen for follow-up visits on a quarterly schedule until the pregnancy outcome is known
- Women who are NOT pregnant at the time of Enrollment:
  - will complete the Screening/Enrollment Visit and Pregnancy Outcome Visit on the same day; no Quarterly follow-up visits or documentation required
- All Women: do not terminate from 016 until ppt terminates from parent protocol (VOICE) or 016 ends

# MTN-016 Required Follow-up Visits

Follow-up for women participants pregnant at Enrollment (in months)



The Pregnancy Outcome Visit is determined by when the pregnancy outcome occurs – it is not a formally-scheduled visit; no quarterly visits for that cycle completed once outcome is known

Termination only occurs once ppt is terminated from VOICE or 016 ends/closes

# Visit Windows: Women

- visit windows for follow-up visits are 45 days before or after the target date (i.e. +/- 45 days).
  - For example, if a woman participant enrolls into MTN-016 on 15 September, her first Quarterly Visit target date is 14 December
  - However, she can complete her Quarterly Visit #1 any time between 31 October and 28 January

# MTN-016 Follow-up: Women

- List of Visits, Visit Codes, Target Visit Dates, and Target Visit Windows

Visit	Visit Code	Day target window opens	Target Date	Day target window closes
Enrollment	1.0	N/A	0	N/A
Quarterly #1	2.0	46	90	135
Quarterly #2	3.0	136	180	225
Quarterly #3	4.0	226	270	315

# Tools for Determining Participant's Follow-up Visit Schedule

- SCHARP developed an Excel file that you can use to create a participant study visit schedule/calendar
- Requires a small amount of information to be entered (PTID, Enrollment Date)
- The target dates and visit windows will be programmed into the tool such that a visit schedule is created for the participant
- The visit schedule can be printed and placed in the participant's MTN-016 study notebook

# Visit calendar tool: Women

## INSTRUCTIONS

Changing the "Enrollment Date" or "Subsequent Consent Date" will automatically calculate the target visit date and visit windows for all follow-up visits for a given Pregnancy Cycle. This calendar is used for women participants who are pregnant at the time of enrollment. Depending how far along in pregnancy a woman is at the time of enrollment will determine how many follow-up visits she will have. For those enrolled *after* their pregnancy outcome, all protocol required procedures will be completed on the same day.

To generate an MTN 016 woman participant calendar:

1. Once a participant enrolls, enter the woman PTID and Enrollment Date (cells in peach). The participant's visit calendar will be automatically calculated.
2. Print the calendar. Hand record your initials in "Staff Initials". Place calendar in the participant's MTN 016 study notebook.
3. As the participant completes study visits, hand-record the date of the visit in the "Actual Visit Date" column (optional).

Enter the PTID and Enrollment Date and the schedule will automatically be generated

## WOMAN MTN 016 STUDY VISIT CALENDAR

Woman PTID: 111-1234-7-0

Staff Initials:

*handwritten*

Pregnancy Cycle #1 Enrollment Date: 15-Aug-09  
(dd-Mmm-yy)

Visit	Pregnancy Number	Visit Code	Target Window Opens	Target Date	Target Window Closes	Actual Visit Date
Quarterly #1	1.0	2.0				
Quarterly #2	1.0	3.0				
Quarterly #3	1.0	4.0				
Pregnancy Outcome	1.0	Will vary				

**\*NOTE:** Please enter the MTN 016 enrollment date using the "American date format": month/day/year. For example, 6 August 2009 would be entered "8/6/09".

# Visit calendar tool: Women

## WOMAN MTN 016 STUDY VISIT CALENDAR

Woman PTID: 111-1234-7-0

Staff Initials:

Pregnancy Cycle #2 Subsequent Consent Date\*: 20-May-11

(dd-Mmm-yy)

Visit	Pregnancy Number	Visit Code	Target Window Opens	Target Date	Target Window Closes	Actual Visit Date
Quarterly #1	2.0	2.0	05-Jul-11	18-Aug-11	02-Oct-11	
Quarterly #2	2.0	3.0	03-Oct-11	16-Nov-11	31-Dec-11	
Quarterly #3	2.0	4.0	01-Jan-12	14-Feb-12	30-Mar-12	
Pregnancy Outcome	2.0	Will vary				

**\*NOTE:** Please enter the MTN 016 enrollment date using the "American date format": month/day/year.  
For example, 6 August 2009 would be entered "8/6/09").



# Visit calendar tool: Women

## WOMAN MTN 016 STUDY VISIT CALENDAR

Woman PTID: 111-1234-7-0

Staff Initials:

Pregnancy Cycle #3 Subsequent Consent Date\*: 15-Jan-13

(dd-Mmm-yy)

Visit	Pregnancy Number	Visit Code	Target Window Opens	Target Date	Target Window Closes	Actual Visit Date
Quarterly #1	3.0	2.0	02-Mar-13	15-Apr-13	30-May-13	
Quarterly #2	3.0	3.0	31-May-13	14-Jul-13	28-Aug-13	
Quarterly #3	3.0	4.0	29-Aug-13	12-Oct-13	26-Nov-13	
Pregnancy Outcome	3.0	Will vary				

**\*NOTE:** Please enter the MTN 016 enrollment date using the "American date format": month/day/year.  
For example, 6 August 2009 would be entered "8/6/09").

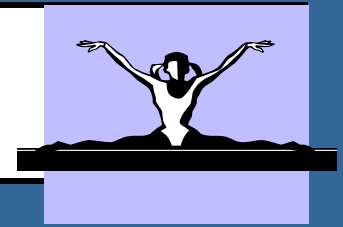
# Things to Consider When Scheduling Follow-up Visits

- Target Days and Visit Windows
- Holidays
- The participant's schedule (ex. any plans to be away from the clinic area)
- Other considerations?

# Follow-up and Retention

- Target days and visit windows do not change – they stay the same even if visits are not conducted on the target day
- A participant is considered “retained” and will be listed as “completed on-time” in the MTN-016 Retention Report if the visit is completed within the visit window (even if not completed on the target day)

# Split Visits



- Per protocol, required study visits may take place over multiple days (“split” visits)
- All days must be within the visit window
- All CRFs completed for the visit are assigned the same whole-number visit code
  - A QC will not be generated for CRFs with different dates but the same visit code as long as all visit dates are within the same visit window

# Missed Visits



- A follow-up visit is *missed* when a participant does not complete *any* part of the visit during the visit window
- Missed Visits are documented using the MTN-016 Missed Visit form (Woman or Infant as appropriate)
- Once the visit window has closed, complete and fax a Missed Visit form. Do not complete or fax any other CRFs for that visit
- The Missed Visit form will let DataFax know not to expect any other forms for that participant for that particular visit

# Woman Missed Visit CRF

MTN 016 Data Collection

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

**SAMPLE. DO NOT FAX  
TO DATAFAX**

MTN 016 (164)



MV-1 (463)

Woman Missed Visit (MV-1)

Pregnancy #    
     Visit Code    
   Page 1 of 1

Participant ID

-     -  -   **Woman Missed Visit**  
 Site Number     Participant Number     Chk     Cohort

Form Completion Date

dd     MMM     yy

1. Target Visit Date:

2. Reason visit was missed. *Mark only one.*

- 2a. unable to contact participant
- 2b. unable to schedule appointment within visit window
- 2c. participant refused visit
- 2d. participant incarcerated
- 2e. participant admitted to a health care facility
- 2f. participant withdrew from the study —————> **Complete a Termination form.**
- 2g. participant deceased —————> **Complete a Termination form.**
- 2h. other, specify:  
 \_\_\_\_\_
- 2i. participant relocated

Record the target visit date and the main reason the visit was missed

# Woman Missed Visit CRF

- Note that the Woman Missed Visit CRF is NOT required when a woman has a pregnancy outcome before completing all of her quarterly follow-up visits
- Ex.: A pregnant woman is enrolled in 016, and 40 days after enrolling, she delivers her baby
- The woman will not complete any of her quarterly follow-up visits, but no Missed Visit CRFs are required, only the Pregnancy Outcome form
- SCHARP has programmed the DataFax database to not expect any more CRFs for a woman for that pregnancy cycle once the Pregnancy Outcome form for that pregnancy is received

# Interim Visits – Three Types

- **Type 1:** a participant presents to the site after already completing the required study visit evaluations
  - *Example:* Infant ppt completes the Month 6 visit, but returns 2 weeks later for follow-up on previously identified abnormal findings
- **Type 2:** a participant presents to the site after already completing the required study visit evaluations, but requires a procedure to be repeated
  - *Example:* Woman ppt returns 5 weeks after enrollment to repeat the ultrasound examination
- **Type 3:** a participant calls the clinic to report a social harm



# Woman Interim Visit CRF

MTN 016 Data Collection  
 Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

**SAMPLE: DO NOT FAX TO DATAFAX**

MTN 016 (164) IV-1 (350)

Participant ID: [ ][ ]-[ ][ ][ ][ ]-[ ][ ]-[0] **Woman Interim Visit**

Site Number Participant Number Chk Cohort

Pregnancy# [ ][ ] Visit Code [ ][ ] [1] Page 1 of 1

Visit Date [ ][ ] [ ][ ][ ][ ] [ ][ ]  
 dd MMM yy

1. What is the reason for this interim visit? *Mark all that apply.*

1a. report pregnancy outcome

1b. ultrasound exam

1c. other, specify: \_\_\_\_\_

2. Besides this Interim Visit form, what other DataFax forms were completed at this visit? *Mark "none" or all that apply.*

2a. none → **If none, go to item 3.**

2b. Pregnancy Outcome

2c. Ultrasound Results

2d. Woman Termination

2e. Woman End of Study Inventory

2f. Social Harms Assessment

2g. other, specify: \_\_\_\_\_

3. Is the participant completing a parent protocol (MTN only) visit at this MTN 016 visit?.....  yes  no → **If no, go to item 4.**

3a. Visit code of parent protocol visit completed today. .... Visit Code [ ][ ] [ ][ ]

4. Has the woman been tested for HIV since her last MTN 016 study visit? .....  yes  no → **If no, end of form.**

4a. Woman's HIV status: .....  negative  positive  indeterminate

4b. Date and source of most recent HIV test: ..... [ ][ ] [ ][ ][ ][ ] [ ][ ]  parent protocol  self-report  
 dd MMM yy

[ ][ ][ ][ ] x 08-JUL-09

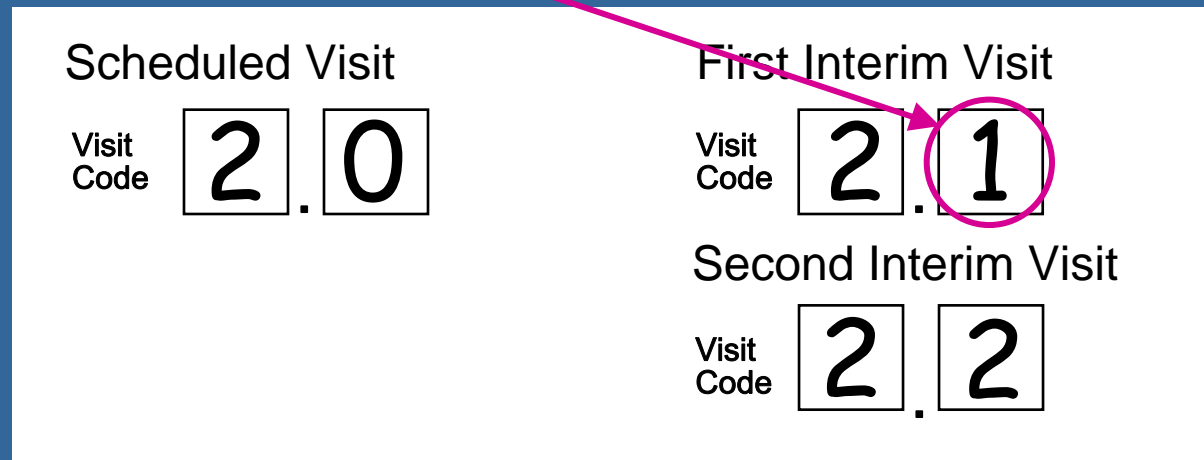
13-44 N:\hivnet\forms\MTN\_016\forms\forms\_woman\m016\_wom\_std\_interim\_visit\_29may08\_fm Version 1.0

01 Language Staff Initials / Date 29 July 2009

Record the reason for the interim visit, which DataFax forms are being faxed for the visit, and items 3 and 4

# Interim Visit Codes

- Use visit code of the most recent required visit (or most recently-completed interim visit) and add “1” to the digit in the box to the right of the decimal



Please refer to Woman CRF Packet