# MTN-016 Training

Infants: Follow-up Visit Scheduling and Visit Coding

SSP Sections 13.3.2





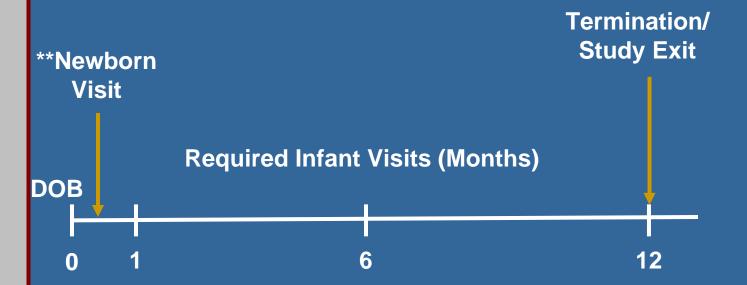
## MTN-016 Follow-up: Infants

- Day 0 is defined as the infant's date of birth (not the date the infant is enrolled)
- There are 3 scheduled follow-up visits for infants
  - Month 1
  - Month 6
  - Month 12 (includes Study Exit)
- Whenever possible, conduct the follow-up visit on the target day
- If not possible, conduct within the Visit Window



### MTN-016 Infant Required Visits

Required visits for infant participants (in months)





### Visit windows: Infants

- visit windows for infants are as follows:
  - Newborn Visit can be completed within 10 days after the infant's birth
  - Month 1 Visit has a 2 week window before and after the target date (i.e. +/- 2 weeks)
  - Month 6 and Month 12 Visits have a 30 day window before and after the target date (i.e. +/-30 days)

For each Infant visit not completed within the window, an Infant Missed Visit CRF is required

SCHARP

<sup>\*</sup>If the Newborn visit is missed, complete an Infant Missed Visit CRF as well as the Infant Enrollment CRF and Infant Con Meds Log (infants can enroll up to 1 year (12 months) of age

### Visit codes and windows: Infants

Visit	Visit Code	Day target window opens	Target Date	Day target window closes
Newborn	1.0	0	0	10
Month 1	2.0	16	30	44
Month 6	3.0	152	182	212
Month 12	4.0	334	364	394



# 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, Birth 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: Infants

Enter the PTID and Date of Birth and the schedule will automatically be generated

#### INSTRUCTIONS

Changing the "Date of Birth" will automatically calculate the target visit date and visit windows for all follow-up visits.

#### To generate an MTN 016 infant participant calendar:

- 1. Once a participant is born and enrolls, enter the infant PTID and Date of Birth (cells in green). The partipant'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).

#### **INFANT MTN 016 STUDY VISIT CALENDAR**

Infant PTID: 111-1234-7-1 Staff Initials:

handwritten

14-Feb-10

(dd-Mmm-yy)

Visit	Visit Code	Target Window Opens	Target Date	Target Window Closes	Actual Visit Date
Newborn/Initial	1.0				
Month 1	2.0				
Month 6	3.0				
Month 12	4.0				

\*NOTE: Please enter the MTN 016 date of birth 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 infant 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
  - Ex: Ppt completes all required Month 6 visit
     evaluations on the target day except for the developmental screening exam; the infant returns 5 days later and completes the exam
  - All CRFs, including the Developmental Screening Exam form, are assigned the Month 6 visit code (03.0)
  - 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



### Infant Missed Visit CRF

MTN 016 Data Collection Statistical Center for HIV/AIDS Research & Prevention (SCHARP)	Infant Missed	/isit (MV-1)
SAMPLE: DO NOT FAX  O DATAFAX	Visit 0	1
MTN 016 (168) MV-1 (463)		Page 1 of 1
Participant ID	Form Completion Dat	e
Infant Missed Visit		
Site Number Participant Number Chk Cohort	dd MMM	уу
1. Target Visit Date:		
2. Comments:		

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

# Interim Visit - Infant Example

- An infant participant's Month 6 target visit date is 02-NOV-09. All required evaluations for the visit are completed on 01-NOV-09.
  - However, during the physical exam, the pediatrician notes a finding which requires clinical follow-up in a few weeks. The follow-up physical exam takes place on 02-DEC-09.
- Although the infant is still within the visit window, all the required visit evaluations have been completed; thus, the 02-DEC-09 follow-up exam is an <u>Interim Visit</u>.



### Infant Interim Visit CRF

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Participa	ant ID			Infant Interim Visit		Visit Date		_
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Site Nurr	nber	Participant Number	Chk Cohort			dd	MMM	<i>y</i> ,
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ı. vvii								
	1a.	follow-up on	previous abno	rmal findings				
	1b.	follow-up on	HIV-exposed	or HIV-infected infant				
Г	1c.	photographic	c documentatio	on of suspected or confirmed	d anomalies			
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Record the reason for the interim visit, which DataFax forms are being faxed for the visit

Note: the Infant Visit form must also be completed for Interim Visits









# Please refer to infant CRF packet

