

MTN-016 Training

Infants: Follow-up Visit Scheduling and Visit Coding

SSP Sections 13.3.2



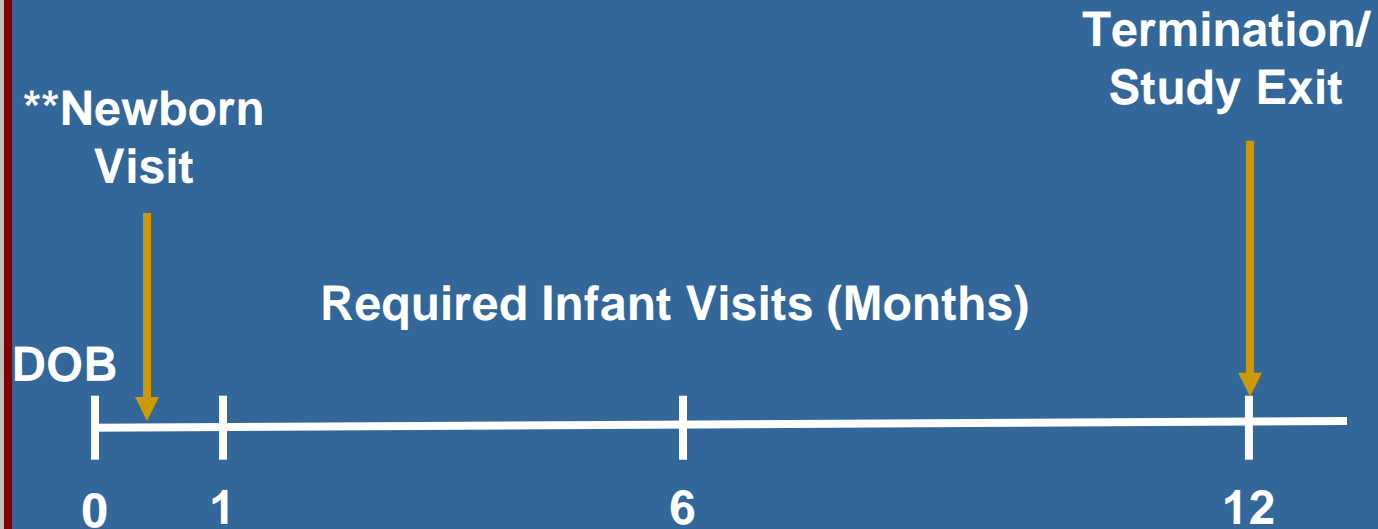
MTN-016 Follow-up: Infants

- 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

*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

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 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 Date of Birth and the schedule will automatically be generated

INFANT MTN 016 STUDY VISIT CALENDAR

Infant PTID:

111-1234-7-1

Staff Initials:

handwritten

Date of Birth

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)

**SAMPLE. DO NOT FAX
TO DATAFAX**

MTN 016 (168)



MV-1 (463)

Infant Missed Visit (MV-1)

Visit Code 0 1

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Participant ID

- - -

Site Number

Participant Number

Chk

Cohort

Infant Missed Visit

Form Completion Date

dd

MMM

yy

dd

MMM

yy

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 Interim Visit.

Please refer to infant CRF
packet