



MTN 008 (180)

FV-1 (121)

Visit Code

1

Participant ID

- - -
Site Number Participant Number Chk Who

Follow-up Visit

Visit Date

dd MMM yy

1. Which follow-up study visit/phone call is being completed?

- Day 1 phone call
- Day 3 phone call
- Day 6 visit
- Day 14 phone call
- Delivery visit (*Pregnancy Cohort only*)
- Post-delivery Assessment (*Pregnancy Cohort only*)

2. Were any **new** adverse experiences reported for this PTID during this follow-up visit/phone call?.....

yes no
 → *If no, go to item 3.*

2a. How many **new** AE Log pages were completed for this PTID for this visit?

of pages

ITEMS 3 AND 4 FOR MATERNAL PARTICIPANTS ONLY

3. Did the mother complete the CASI Follow-up Acceptability and Adherence Questionnaire at this visit?

yes no not required *If no or not required, go to item 4.*
 →

3a. Date the CASI Follow-up Acceptability and Adherence Questionnaire was completed:

dd MMM yy

4. Did the mother complete the CASI Gel Use Experiences Questionnaire?

yes no not required *If no or not required, end of form.*
 →

4a. Date the CASI Gel Use Experiences Questionnaire was completed:

dd MMM yy

Comments: _____

Follow-up Visit (FV-1)

Purpose: This form is used to document completion of all required follow-up visits and phone calls for maternal and infant study participants.

General Information/Instructions: This form is completed for each maternal and infant study participant, at the Day 1 Phone Call, the Day 3 Phone Call, the Day 6 Visit, the Day 14 Phone Call, the Delivery Visit (Pregnancy Cohort only), and the Post-delivery Assessment (Pregnancy Cohort only).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 3 and 4:** For maternal participants only. Completion of the CASI Follow-up Behavioral and Acceptability Questionnaire and the CASI Gel Use Experiences Questionnaire are required for all maternal participants at the Day 6 Visit. If the required questionnaire was not done, specify the reason on the Comments line.
- **Item 4a:** This is the date the participant completed the questionnaire, not the date the responses were entered into the computer.