



MTN 012/IPM 010 (187)

IV-1 (350)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Interim Visit

Visit Date

dd MMM yy

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

- 1a. in-person visit to report new symptoms
- 1b. phone call with participant to report new symptoms
- 1c. follow-up of symptoms and/or AE(s)
- 1d. participant needs replacement product
- 1e. participant is returning used or unused applicators
- 1f. other, specify: _____

Complete/Update Adverse Experience Log if applicable.

Complete Replacement Product Dispensation.

Complete/Update Study Product Returns.

2. Besides this Interim Visit form, what other DataFax study forms were completed at this visit? *Mark all that apply.*

- 2a. none —> **End of form.**
- 2b. Genital Exam
- 2c. Adverse Experience Log (new)
- 2d. Laboratory Results
- 2e. STI Laboratory Results
- 2f. Study Product Returns
- 2g. Product Hold/Discontinuation Log (new)
- 2h. other, specify: _____

of pages

2c1. How many **new** AE Log pages have been completed for this visit?

Comments: _____

Interim Visit (IV-1)

Purpose: Complete this form when an interim visit occurs during study follow-up. See the Study-specific Procedures Manual for a definition and examples of interim visits that require an Interim Visit form to be completed.

General Information/Instructions: Any other forms completed for this visit must have the same Visit Code as this Interim Visit form.

Item-specific Instructions:

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
 - Record the one-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was Enrollment (Visit Code = 02.0), record “02” to the left of the decimal point in the visit code field.
 - Record the number that corresponds to the Interim Visit in the third box (the box to the right of the decimal point):
 - 0X.1 = First Interim Visit after the most recent scheduled regular visit.
 - 0X.2 = Second Interim Visit after the most recent scheduled regular visit.
- **Item 2:** Note that marking a box indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
- **Item 2a:** Mark the “none” box if the Interim Visit form is the only DataFax form completed for this visit.
- **Item 2c:** Mark this box if a new (previously unreported) AE is reported or observed at this visit. If the box to the left of “Adverse Experience Log (new)” is marked, record how many new AE Log pages were completed for this visit in item 2d1. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
- **Item 2g:** Mark this box if a new (previously unreported) product hold or discontinuation is reported at this visit.