



MTN-011 (135)

VS-1 (121)

Visit Code

Participant ID

- - - 0

Protocol PTID Chk Cohort

Visit Summary

Visit Date

dd MMM yy

1. What was the participant's last day of previous menses?	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<i>amenorrheic for past 6 months</i>
2. hCG for pregnancy:	<i>not required</i> <input type="checkbox"/> <i>negative</i> <input type="checkbox"/> <i>positive</i> <input type="checkbox"/>	<i>If positive, complete Pregnancy Report form and Product Hold/Discontinuation Log.</i>
3. Has participant's method of contraception/family planning changed since her last visit?	<i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/>	<i>If yes, complete Family Planning form.</i>
4. How many new AE Log pages were completed for the female participant at this visit?	<i># of pages</i> <input type="text"/> <input type="text"/>	
5. How many new Product Hold/Discontinuation Log pages were completed for this visit?	<i># of pages</i> <input type="text"/> <input type="text"/>	
6. Did the female participant complete the CASI Behavioral Questionnaire (BEH)?	<i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/> <i>not required</i> <input type="checkbox"/>	
7. Time during visit of study product insertion:	<i>24-hour clock</i> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>not required</i> <input type="checkbox"/>
8. Did the couple complete coitus?	<i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/> <i>not required</i> <input type="checkbox"/>	<i>If no or not required, go to instructions above item 9.</i>
8a. Time of completion of coitus:	<i>24-hour clock</i> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
Complete item 9 for Group 1 participants only, and only at Visit Code 09.0. For all other visits, leave item 9 blank.		
9. Time of post-coital study product insertion:	<i>24-hour clock</i> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>not inserted</i> <input type="checkbox"/>

Visit Summary (VS-1)	
Purpose:	This form is used to document completion of all Follow-up Visits (required and interim) completed by female participants once enrolled.
Item-specific Instructions:	
Item 1:	If the participant is unable to recall the complete date, obtain participant's best estimate. At a minimum, the month and year are required. Only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period.
Item 4:	Record in item 4 how many new AE Log pages were completed for the female participant at this visit. 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 5:	Record how many new Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds/discontinuations were reported, record "02." Note that the Visit Code recorded in item 1 of the Product Hold/Discontinuation Log pages should be the same as the Visit Code recorded on this form.
Items 8 and 8a:	Completion of coitus is defined as when the male partner ejaculates into the female partner's vagina.
Item 9:	When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12).