



MTN-011 (135)

PDC-1 (260)

Visit Code

1

Participant ID

- - - 0

Protocol PTID Chk Cohort

Group 2—Participant-reported Dosing

Form Completion Date

dd MMM yy

HOME DOSING (Any dosing given during clinic visit captured on the Visit Summary form.)								
Study Gel Not Inserted	Dose #	Dosing Date			Dosing Time (24-hour clock)		Was this dosing time provided from the source document?	
		dd	MMM	yy	hr	min	yes	no
<input type="checkbox"/>	Dose # 2	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Dose # 3	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Dose # 4	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Dose # 5	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Dose # 6	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Dose # 7	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

Group 2—Participant-reported Dosing (PDC-1)

Purpose: This form is used to document home dosing dates and times for Group 2 participants.

General Information/Instructions: This form is completed for female participants in Group 2 only. Clinic staff will transcribe all relevant information from the participant's Home Dosing Log.

Item-specific Instructions:

- Dose # 2–7:**
- Transcribe the date and time of each daily dosing recorded on the participant's Home Dosing Log form. The date must be transcribed using the SCHARP DataFax standard, dd MMM yy. The time must be transcribed using the 24-hour clock.
 - If the participant marked the "I did not insert study gel today" box on her log, mark the "Study Gel Not Inserted" box, and leave all other items for that specific day blank.
 - For each day that dosing information is recorded, mark "yes" if the time of dosing is provided on the source documentation (i.e., the Home Dosing Log form). If the source documentation is blank or not available, but the participant is able to report an estimated dosing date and time, record the estimated date and time, and mark the "no" box.

- Dose #7:**
- The "Study Gel Not Inserted" box should be marked for the first and second home dosing periods.

- Comments:**
- Any relevant information from the participant's log(s) may be transcribed here (e.g., partial doses). You may leave this space blank if there are no additional relevant comments.