



MTN-011 (135)

PDL-1 (495)

Note: Number pages sequentially (01, 02, 03) for each participant.

Page

Participant ID

- - -
 Protocol PTID Chk Cohort

Form Completion Date

dd MMM yy

Protocol Deviation Log

1. Site awareness date:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>				
2. Deviation date:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>				
3. Has or will this deviation be reported to local IRB/EC?	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; padding: 0 10px;"><i>yes</i></td> <td style="text-align: center; padding: 0 10px;"><i>no</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	<i>yes</i>	<i>no</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>yes</i>	<i>no</i>				
<input type="checkbox"/>	<input type="checkbox"/>				
4. Has or will this deviation be reported to DAIDS as a critical event?	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; padding: 0 10px;"><i>yes</i></td> <td style="text-align: center; padding: 0 10px;"><i>no</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	<i>yes</i>	<i>no</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>yes</i>	<i>no</i>				
<input type="checkbox"/>	<input type="checkbox"/>				
5. Type of deviation:	<input type="text"/> <input type="text"/> <i>deviation code (See back of form for code listing.)</i>				
6. Description of deviation:	<hr/> <hr/> <hr/>				
7. Plans and/or action taken to address the deviation:	<hr/> <hr/> <hr/>				
8. Plans and/or action taken to prevent future occurrences of the deviation:	<hr/> <hr/> <hr/>				
9. Deviation reported by:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>staff code</i>				

Protocol Deviation Log (PDL-1)

Purpose: This form documents and reports protocol deviations identified for study participants.

General Information/ Instructions: Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.

Item-specific Instructions:

Page: Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.

Item 2: Record the date the event occurred (start date).

Item 5: Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.

Code	Description
01	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
02	Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
03	Study product management deviation: Site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
04	Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form. Pharmacy staff must follow up with the MTN Pharmacist separately.
05	Study product use/non-use deviation: Participant did not use the study product (including product refusals) or used it incorrectly (i.e., not in accordance with protocol requirements).
06	Study product sharing: Participant has shared study product with another person or study participant.
07	Study product not returned: Study product was not returned by the participant per protocol requirements.
08	Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.
09	Improper AE/EAE follow-up: Use when an AE or EAE is not followed-upper protocol. For example, a clinical finding/lab result that is not re-assessed as outlined in the protocol.
10	Unreported AE: Site staff become aware of an AE, but not report it per protocol requirements.
11	Unreported EAE: Site staff become aware of an EAE, but not report it per protocol and DAIDS EAE Manual requirements.

Code	Description
12	Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.
13	Physical assessment deviation: Include missed or incomplete physical/pelvic/rectal exam assessments.
14	Lab assessment deviation: Include missed, or incomplete lab specimen collection.
15	Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
16	Staff performing duties that they are not qualified to perform: Use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
17	Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
18	Counseling deviation: Protocol-required counseling was not done and/or not documented correctly.
19	Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.
20	Use of excluded concomitant medications, devices or non-study products
21	Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
22	Visit completed outside of window: Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, use if Visit 3.0 procedures are done in the Visit 4.0 window.

Item 6: Briefly describe the specific details of the deviation.

Item 9: Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.