



Note: Number pages sequentially (001, 002, 003) for each participant.

MTN 015 (143)

HA-1 (410)

Participant ID

- -
 Site Number Participant Number Chk

HIV/AIDS-associated Events Log

No events occurred throughout study. Staff Initials/Date _____
 End of form. Fax to SCHARP DataFax.

1. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed <input type="checkbox"/> probable <input type="checkbox"/> unknown <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study	
1a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

2. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed <input type="checkbox"/> probable <input type="checkbox"/> unknown <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study	
2a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

3. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed <input type="checkbox"/> probable <input type="checkbox"/> unknown <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study	
3a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

4. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed <input type="checkbox"/> probable <input type="checkbox"/> unknown <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study	
4a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

HIV/AIDS-associated Events Log (HA-1)

Purpose: This form is used to document HIV/AIDS-associated events experienced by the participant while on-study.

General Information/Instructions: Record only events that appear on the MTN 015 HIV/AIDS-associated Event Code List. Fax this form to SCHARP DataFax each time it is modified or updated.

Item-specific Instructions:

- **Page:** Number the pages sequentially starting with page 001.
- **HIV/AIDS Event Code:** Record the event code as listed on the MTN 015 HIV/AIDS-associated Event Code List. Whenever possible, obtain medical records so that you have as much information as possible about the event.
- **Visit Code:** Record the visit code at which the event was first reported or observed.
- **Clinical Diagnosis:** Refer to the *WHO Case Definitions of HIV for Surveillance and Revised Clinical Staging and Immunological Classification of HIV-related Disease in Adults and Children*. Mark “confirmed” if the listed criteria for definitive diagnosis have been met. Mark “probable” if the listed clinical diagnosis criteria have been met. If the definitive and clinical diagnosis are the same, and the criteria have been met, mark “confirmed.” Mark “unknown” if neither the clinical nor definitive diagnosis criteria have been met. Do not wait for a clinical or definitive diagnosis to be made before faxing the form to SCHARP DataFax. Mark “unknown” and update the item once a clinical or definitive diagnosis is available.
- **Date Started:** At minimum, month and year are required.
- **Date Stopped:** If a date stopped is recorded, at minimum, month and year are required. At the participant’s Termination visit, the “Date Stopped” must be recorded for each event or illness OR the “Ongoing at end of study” box must be marked.
- **Staff Initials/Log Entry Date:** Enter the staff initials and date of the staff member who records the date started.
- **Is this an AIDS-defining illness?:** Use the MTN 015 HIV/AIDS-associated Event Code List to help determine whether the event is an AIDS-defining illness. Contact the MTN 015 Protocol Chair with any questions about whether the event is an AIDS-defining illness.