MTN 015 (143) AIN-1 (079)

Participant ID

Site Number – Participant Number – Chk

ART Initiation Information—Revised

Form Completion Date

dd MMM yy

1. What is the primary reason for initiating ART?

- ☐ CD4 meets treatment guidelines for local ART program in absence of WHO Stage 2–4 condition
- ☐ AIDS-defining condition (WHO Stage 3 or 4)
- ☐ WHO Stage 2 condition
- ☐ pregnancy
- ☐ ART initiated as part of a research study without either a CD4 or clinical criteria being met. Indicate name/number of the study: _____
- ☐ other reason, specify: _____
- ☐ unknown (clinician cannot determine reason for ART initiation from available resources including participant report and records)

Not done/ Not collected ☐ Specimen Collection Date dd MMM yy

2. Last known viral load prior to initiation of ART:

2a. HIV RNA PCR (plasma): ☐ > ☐ = ☐ < viral copies/mL ☐☐☐☐☐☐☐☐ OR ☐ target not detected

2a1. HIV RNA PCR kit lower limit of detection: ☐ 20 ☐ 40 OR ☐☐☐ viral copies/mL

2b. Source of result: ☐ 015 clinic ☐ other research clinic ☐ other clinic

Not done/ Not collected ☐ Specimen Collection Date dd MMM yy

3. Last known CD4+ result prior to initiation of ART:

3a. Absolute CD4+ ☐☐☐☐ cells/mm^3

3b. CD4+ % ☐ not available OR ☐☐.☐ %

3c. Source of result: ☐ 015 clinic ☐ other research clinic ☐ other clinic

Comments:

☐ ☐ ☐ ☒ 15-FEB-13

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01 Language

Staff Initials / Date

ART Initiation Information—Revised (AIN-1)	
Purpose:	This form is used to document the primary reason the participant initiated ART. This form is also used to document (when available) the participant's last HIV RNA PCR and CD4+ results prior to ART initiation.
General Information/ Instructions:	This form is completed only once for each ART participant, and is completed at the same visit that the ART Enrollment CRF is completed for the participant (the visit at which the participant enrolls in the ART track). Specimen Collection Date: Record the date that the specimen was collected (NOT the date results were reported or recorded on the form). A complete date is required. Not done/Not collected: For every test, mark either the "Not done/Not collected" box or enter a test result. If a result is not available, mark the "Not done/Not collected" box.
Item-specific Instructions:	
Item 1:	Record the primary reason the participant began using ART. Mark only one response, the response that best describes the reason for ART initiation.
Item 2:	If available, record the collection date of the last known HIV viral load collected prior to the participant's first use of ART. Record the actual result in item 2a. If not available, mark the "Not done/Not collected" box and go to item 3.
Item 2a:	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation. If result is "target not detected", mark the "target not detected" box and do not enter any numbers in the "viral copies/mL" boxes. If the result is "<20 Below Range" or "<40 Detected", leave the "Target not detected" box blank, and mark the "<" box and the number "00000020" or "00000040" in the "viral copies/ mL" boxes. Note that the ">" symbol is "greater than" and the "<" symbol is "less than."
Item 2b:	If the result was obtained from the MTN 015 clinic lab, as part of MTN015 study procedures, mark "015 clinic." If the result was obtained from another research site/clinic, mark "other research clinic." If obtained from a non-research clinic, mark "other clinic."
Item 3:	If available, record the collection date of the last known absolute CD4+ result collected prior to the participant's first use of ART. Record the actual result in items 3a and 3a1. If not available, mark the "Not done/Not collected" box and end the form.
Item 3b:	If available, record the CD4+ percentage that was reported for the specimen in item 3. If the CD4+ percentage is not available, mark the "not available" box.