



MTN-011 (135)

PRE-1 (012)

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

Page

Participant ID

-  -  0  
 Protocol PTID Chk Cohort

**Pre-existing Conditions**

No pre-existing conditions reported or observed.

Staff Initials/Date \_\_\_\_\_

End of form.  
Fax to SCHARP  
DataFax.

|              |   |                     |
|--------------|---|---------------------|
| 1. Condition | Onset Date<br><i>MMM yy</i><br><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
|--------------|---|---------------------|

|          |  |  |
|----------|--|--|
| Comments | Ongoing at Enrollment?<br><i>yes no</i><br><input type="checkbox"/> <input type="checkbox"/> | Severity Grade<br><i>grade not gradable</i><br><input type="checkbox"/> <input type="checkbox"/> |
|----------|--|--|

|              |   |                     |
|--------------|---|---------------------|
| 2. Condition | Onset Date<br><i>MMM yy</i><br><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
|--------------|---|---------------------|

|          |  |  |
|----------|--|--|
| Comments | Ongoing at Enrollment?<br><i>yes no</i><br><input type="checkbox"/> <input type="checkbox"/> | Severity Grade<br><i>grade not gradable</i><br><input type="checkbox"/> <input type="checkbox"/> |
|----------|--|--|

|              |   |                     |
|--------------|---|---------------------|
| 3. Condition | Onset Date<br><i>MMM yy</i><br><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
|--------------|---|---------------------|

|          |  |  |
|----------|--|--|
| Comments | Ongoing at Enrollment?<br><i>yes no</i><br><input type="checkbox"/> <input type="checkbox"/> | Severity Grade<br><i>grade not gradable</i><br><input type="checkbox"/> <input type="checkbox"/> |
|----------|--|--|

|              |   |                     |
|--------------|---|---------------------|
| 4. Condition | Onset Date<br><i>MMM yy</i><br><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
|--------------|---|---------------------|

|          |  |  |
|----------|--|--|
| Comments | Ongoing at Enrollment?<br><i>yes no</i><br><input type="checkbox"/> <input type="checkbox"/> | Severity Grade<br><i>grade not gradable</i><br><input type="checkbox"/> <input type="checkbox"/> |
|----------|--|--|

| <b>Pre-existing Conditions (PRE-1)</b>    |  |
|---|--|
| <b>Purpose:</b>                           | The Pre-existing Conditions form serves as the “starting point” or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).  |
| <b>General Information/ Instructions:</b> | <ul style="list-style-type: none"> <li>At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions occurring prior to Enrollment.</li> <li>At the Enrollment Visit, review and update as needed.</li> <li>Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment</li> </ul> |
| <b>Item-specific Instructions:</b>        |  |
| <b>Page:</b>                              | Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.   |
| <b>Condition:</b>                         | Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, “decreased hematocrit” or “increased ALT.”  |
| <b>Onset Date:</b>                        | If the participant is unable to recall the date, obtain participant’s best estimate. At a minimum, the year is required.   |
| <b>Comments:</b>                          | This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms.   |
| <b>Severity Grade:</b>                    | For each condition, grade the severity according to the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> and the <i>DAIDS Female Genital Grading Table for Use in Microbicide Studies</i> (as appropriate). If a condition is not gradable, mark the “not gradable” box. Review and update as needed for conditions ongoing at the Enrollment Visit.   |
| <b>Ongoing at Enrollment?</b>             | Mark the “yes” box for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form.  |