



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

MTN 012/IPM 010 (187)

PRE-1 (012)

Participant ID

- -

Site Number Participant Number Chk

Pre-existing Conditions

No pre-existing conditions reported or observed. Staff Initials / Date → **End of form. Fax to SCHARP DataFax.**

1.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/Surgery		
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	Comments	Severity Grade		Is condition ongoing?		Staff Initials / Date
		<input type="checkbox"/>	<input type="checkbox"/> <i>not gradable</i>	yes	no	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

2.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/Surgery		
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	Comments	Severity Grade		Is condition ongoing?		Staff Initials / Date
		<input type="checkbox"/>	<input type="checkbox"/> <i>not gradable</i>	yes	no	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

3.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/Surgery		
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	Comments	Severity Grade		Is condition ongoing?		Staff Initials / Date
		<input type="checkbox"/>	<input type="checkbox"/> <i>not gradable</i>	yes	no	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

4.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/Surgery		
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	Comments	Severity Grade		Is condition ongoing?		Staff Initials / Date
		<input type="checkbox"/>	<input type="checkbox"/> <i>not gradable</i>	yes	no	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

5.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/Surgery		
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	Comments	Severity Grade		Is condition ongoing?		Staff Initials / Date
		<input type="checkbox"/>	<input type="checkbox"/> <i>not gradable</i>	yes	no	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

6.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/Surgery		
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	Comments	Severity Grade		Is condition ongoing?		Staff Initials / Date
		<input type="checkbox"/>	<input type="checkbox"/> <i>not gradable</i>	yes	no	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Pre-existing Conditions (PRE-1)

Purpose: This form is used to document the participant's pre-existing medical conditions.

General Information/Instructions: Only medical conditions experienced up to study product initiation should be recorded unless otherwise specified in the protocol or Study Specific Procedures (SSPs). Include current medical conditions and any ongoing conditions such as mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).

Item-specific Instructions:

- **Page:** 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.
- **Description:** 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."
- **Date of Diagnosis/Surgery:** If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.
- **Comments:** This field is optional. Use it to record any additional relevant information about the condition.
- **Severity Grade:** For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *Male Genital Toxicity Table*. If a condition is not gradable, mark the "not gradable" box.
- **Is condition ongoing?:** Mark "yes" if condition is ongoing at enrollment.
- **Pre-existing Conditions Revisions and Updates:** If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s).