

MTN-020 Data Communiqué #6- February 22, 2013

This is official study documentation for MTN- 020. Please circulate it among relevant staff for their review, print it, and place it in your MTN-020 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-020 SSP manual.

UPDATES - None

CLARIFICATIONS

1. Concomitant Medications Log – Frequency and Route

Note that if “once” is marked for a medication’s frequency, both a Date Started and a Date Stopped must be present, and these should be the same date.

When recording intra-uterine contraceptive devices or contraceptive implants, record the date of insertion as the Date Started, and leave the Date Stopped blank (record a Date Stopped once the device or implant is removed). Mark “other, specify” for frequency and on the line provided, specify “continuous” as the frequency. When recording contraceptive implants, mark “other, specify” for route and on the line provided, specify “sub-dermal”.

2. Grading of menorrhagia, metrorrhagia, and menometrorrhagia at Baseline

Note that any menorrhagia, metrorrhagia, or menometrorrhagia events ongoing at the time of randomization are marked as ‘not gradable’ on the Pre-existing Conditions (PRE) CRF. This is because the FGGT grades 1-4 for these events (see rows below) are relative to each participant’s baseline (day of randomization) status. In the “Comments” field of the ongoing PRE entry, include text similar to what is in the FGGT row to describe the severity/frequency. For example, for an ongoing event of menorrhagia, mark “not gradable” and in the PRE Comments, record “no interference with ppt’s usual activities” (similar to text used in the FGGT to describe Grade 1). Adding such text to the Comments field will help ensure that increases in the severity or frequency of these events compared to the participant’s baseline status are easily identified (and reported as AEs on an AE Log CRF). Refer to SSP Section 10.6.1 as needed.

Any resolved (not ongoing) menorrhagia, metrorrhagia, or menometrorrhagia events documented on the PRE CRF should be assigned a grade from 1-4 per the FGGT.

PARAMETER	GRADE 0 NORMAL	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
ABNORMAL UTERINE BLEEDING UNRELATED TO PREGNANCY					
Menorrhagia ² (prolonged and/or heavy menstrual bleeding)	Participant report of normal bleeding relative to her baseline	Increase from usual with no or minimal interference with usual social & functional activities (including sexual functioning)	Increase from usual with moderate interference with usual social & functional activities (including sexual)	Incapacitating or severe interference with usual social & functional activities (including sexual functioning), transfusion indicated	Life threatening hemorrhage with or without shock
Metrorrhagia ² (intermenstrual or frequent bleeding)	None or any expected nonmenstrual bleeding	Increase from usual with no or minimal interference with usual social & functional activities (including sexual functioning)	Increase from usual with moderate interference with usual social & functional activities (including sexual)	Incapacitating or severe interference with usual social & functional activities (including sexual functioning), transfusion indicated	Life threatening hemorrhage with or without shock

REMINDERS - None