

MTN-020 Data Communiqué #2 - September 24, 2012

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.

DOCUMENTATION OF MISSED MENSES EVENTS DURING SCREENING

SCREENING MENSTRUAL HISTORY (SMH) CRF, ITEM 2

Item 2 should be marked "amenorrhic for past 6 months" only in those cases where the participant has been amenorrhic for the past 6 or more months. If amenorrhic for past 5 months or fewer, mark "regular" or "irregular" for item 2 based on the most recently-experience menses. In item 8, describe how long the participant has missed menses (i.e. for past 5 months, 4 months, etc.). See more information on determining start date of amenorrhea below.

PRE-EXISTING CONDITIONS (PRE) CRF

All instances of missed menses identified at the Screening Visit should be recorded on the PRE CRF. This is because missed menses/amenorrhea, regardless of cause or duration, is considered an irregular bleeding pattern, and as such, requires documentation as a pre-existing condition.

If the amenorrhea is "expected", that is, due to hormonal contraceptive use or post-partum, the PRE entry should be marked as "not gradable". This is per the FGGT row which does not apply to cases where missed menses is due to hormonal contraception or post-partum. The cause for the missed menses should be noted in the "Comments" section of the PRE entry.

If the amenorrhea is unexplained, it should be graded per the FGGT row for "unexplained infrequent bleeding", i.e. 1-3 months in duration is Grade 1, durations of 4 months or longer is Grade 2. In "Comments" of PRE entry, note the duration. *Note that a participant with unexplained missed menses (for any duration) may indicate further review prior to enrollment into the study.*

Terminology

For missed menses events of 1-3 months in duration, use the term "missed menses".
For missed menses events of 4-5 months in duration, use the term "oligoamenorrhea".
For missed menses events of 6 months or longer, use "amenorrhea".

Determining Start Date

When determining duration (start date of missed menses/oligoamenorrhea/amenorrhea), use the first month of missed menses as the start. For example, if a participant's last menstrual period was in March, 2012, the start date for her missed menses is April 2012 (her next time that she would have expected menses if it had not been missed). Once the duration is established, use the guidance above to describe the missed menses event.

DURING FOLLOW-UP

Note that new instances of missed menses (of any duration) due to hormonal contraception use, pregnancy, or post-partum are not adverse events. These events should be documented in the participant's file but not reported on an AE Log or GAE Log CRF. This is per the FGGT row, which excludes cases of missed menses due to hormonal contraception use, pregnancy, and post-partum.