

MTN-020

Data Communiqué #2

Documentation of Missed Menses Events

Screening Menstrual History CRF

When completing item 2 (“usual menstrual cycle”):

- If the participant has missed menses for the past 5 or fewer months, mark “regular” or “irregular” based on her most recently-experienced menses. In item 8, comment on the duration and reason (if known) for the missed menses.
- If the participant has indeed missed menses for the past 6 or more months, mark “amenorrheic for past 6 months”, in the “specify” line record the reason for the amenorrhea, and provide more details as needed in item 8. Complete items 3-7 based on most recently-experience menses.

Determining Start Dates

When determining start dates for missed menses/oligoamenorrhea/amenorrhea, use the first month of missed menses as the start.

Example:

A participant's last menstrual period was in March, 2012. The start date for her missed menses event is April, 2012 (the first time she was expected to have menses but did not).

If this participant were screened in September, 2012, she would have missed menses for the past 5 months (April, May, June, July, and August).

Terminology

Use the table below to determine which term to use to describe the missed menses event (based on duration)

Missed menses duration	Term to use
1-3 months	missed menses
4-5 months	oligoamenorrhea
6 or more months	amenorrhea

Pre-existing Conditions (PRE) CRF

Record all instances of missed menses/oligoamenorrhea/amenorrhea identified at screening on the PRE CRF, regardless of cause

Events determined to be due to contraceptive use or post-partum are not gradable (per the FGGT). Mark “not gradable” for severity grade on the PRE entry.

If cause is not known/unexplained, grade per row of FGGT. ***Careful considerations should be given before enrolling a participant who has unexplained missed menses.***

SMH and PRE CRF documentation – example 1

Participant comes in to screen in early October. Her last menstrual period was in April, 2012. She had had regular periods up until April, with around 20-24 days between menses, each period lasting between 2-5 days.

When determining duration, do not include October 2012, since the full month has not passed. You cannot say the participant did not have menses in October until after October 31.

Let's look at how the SMH and PRE entry would look....

SMH and PRE CRF documentation – example 1

Ex: Participant comes in to screen in October. Her last menstrual period was in April, 2012. She had had regular periods up until April, with around 20-24 days between regular periods up until April, with around 20-24 days between menses, each period lasting between 2-5 days.

Note item 2 – do not mark “amenorrheic for past 6 months” since it has only been 5 months since no menses

Screening Menstrual History	
1. Age of first menses (menarche)	<input type="text" value=""/> <input type="text" value=""/> years
2. Usual menstrual cycle	regular <input checked="" type="checkbox"/> irregular <input type="checkbox"/> amenorrheic for past 6 months <input type="checkbox"/> → Specify: _____
3. Usual number of days between menses (1 st day to 1 st day)	minimum <input type="text" value="20"/> # of days TO <input type="text" value="24"/> # of days maximum
4. Usual number of bleeding days (record range)	minimum <input type="text" value="02"/> # of days TO <input type="text" value="05"/> # of days maximum
5. First day of last menstrual period	<input type="text" value=""/> <input type="text" value="AAR"/> <input type="text" value="12"/> dd MMM yy <i>UMK</i>
6. Last day of last menstrual period	<input type="text" value=""/> <input type="text" value="AAR"/> <input type="text" value="12"/> OR <input type="checkbox"/> ongoing dd MMM yy <i>MC 05-OCT-12</i>
7. Usual type of menstrual flow (at heaviest day of menses)	light <input type="checkbox"/> moderate <input checked="" type="checkbox"/> heavy <input type="checkbox"/>
8. Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern.	<i>Ppt had 1st Depo injection end of April, 2012. Reports no menses or bleeding since this injection. 2nd injection rec'd in July, 2012. Reports mild cramping and slight headache for 1st day or two of menses. No other re-current menstrual symptoms.</i>

SMH and PRE CRF documentation – example 1

Ex. Participant comes in to screen in October. Her last menstrual period was in April, 2012. She had had regular periods up until April, with around 20-24 days between menses, each period lasting between 2-5 days.

On Pre entry, use “oligoamenorrhea” based on duration of 5 months. “Onset Date” is month/year of first missed menses. “Ongoing at Enrollment” = “yes”, and mark “not gradable” since the FGGT row does not apply.

Pre-existing Conditions		
1. Condition	Onset Date	Staff Initials/Date
oligoamenorrhea	MMM yy MAY 12	ME 05.09.12
Comments	Ongoing at Enrollment?	Severity Grade
Result of Depo injections in April - July 2012.	yes no <input checked="" type="checkbox"/> <input type="checkbox"/>	grade not gradable <input type="checkbox"/> <input checked="" type="checkbox"/>

SMH and PRE CRF documentation - example 2

Ex. Participant comes in to screen in October. Her last menstrual period was in October 2011, at which time she started Depo. SMH items 2-7 would look like.....

1. Age of first menses (menarche)	<input type="text"/> years
2. Usual menstrual cycle	<input type="checkbox"/> regular <input type="checkbox"/> irregular <input checked="" type="checkbox"/> amenorrheic for past 6 months Specify: <u>Depo</u>
3. Usual number of days between menses (1 st day to 1 st day)	minimum <input type="text" value="21"/> # of days TO maximum <input type="text" value="26"/> # of days
4. Usual number of bleeding days (record range)	minimum <input type="text" value="02"/> # of days TO maximum <input type="text" value="06"/> # of days
5. First day of last menstrual period	<input type="text"/> <input type="text" value="OCT"/> <input type="text" value="11"/> dd MMM yy
6. Last day of last menstrual period	<input type="text"/> <input type="text" value="OCT"/> <input type="text" value="11"/> OR <input type="checkbox"/> ongoing dd MMM yy
7. Usual type of menstrual flow (at heaviest day of menses)	<input type="checkbox"/> light <input checked="" type="checkbox"/> moderate <input type="checkbox"/> heavy

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SMH and PRE CRF documentation - example 2

Ex. Participant comes in to screen in October. Her last menstrual period was in October 2011, at which time she started Depo. The PRE entry would look like.....

Pre-existing Conditions		
1. Condition	Onset Date	Staff Initials/Date
amenorrhea	MMM Nov	yy 11
Comments	Ongoing at Enrollment?	Severity Grade
Due to Depo use	yes <input checked="" type="checkbox"/> no <input type="checkbox"/>	grade <input type="checkbox"/> not gradable <input checked="" type="checkbox"/>

During Follow-up

New instances of missed menses (of any duration) that are due to contraceptive use, pregnancy, or post-partum are not adverse events. Do not record on AE Log or GAE Log. Do document in participant's file.

New instances of unexplained missed menses are reportable – report on AE Log CRF and grade per FGGT. Consult with PSRT if clinical management guidance is wanted.

Do not update terminology used on PRE entries. The PRE terminology should reflect the duration of the missed menses as first assessed at screening.



Questions???

- Please contact Jen Berthiaume and Missy Cianciola with any questions you have about this slide presentation or the Data Communiqué

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We are more than happy to hear from you!