MTN-020
Data Communiqué #6

February 25, 2013

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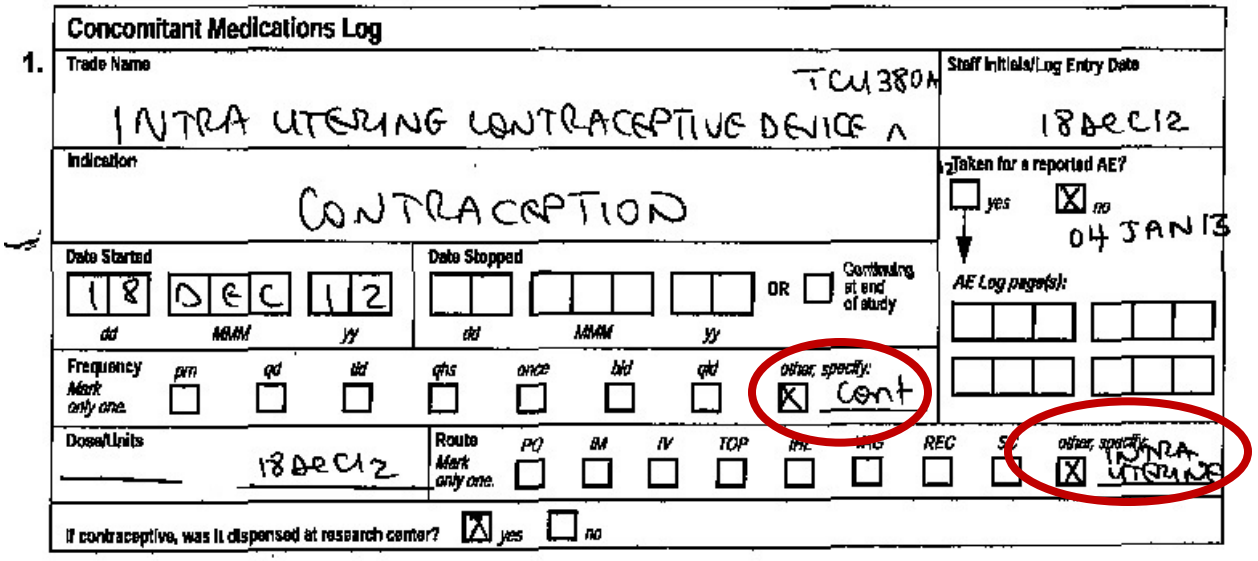
Concomitant Medications Log – Frequency and Route

- If “once” is marked for a medication’s frequency, both a Date Started and a Date Stopped must be present, and be the same date.
- When recording IUCDs or contraceptive implants, record date of insertion as ‘Date Started’, and leave ‘Date Stopped’ blank (record a Date Stopped once device or implant is removed). Mark “other, specify:” and record “cont” for frequency.
- When recording contraceptive implants, mark “other, specify: and record “sub-dermal” for route.



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Grading of menorrhagia, metrorrhagia, and menometrorrhagia at Baseline

- Any menorrhagia, metrorrhagia, or menometrorrhagia events ongoing at the time of randomization should be marked as 'not' gradable' on the Pre-existing Conditions (PRE) CRF.

  - This is because the FGGT (see next slide) grade 0 (same as non-gradable) is defined as the participant's baseline status of these event. Grades 1-4 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.

    - Ex: 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.

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Grading of menorrhagia, metrorrhagia, and menometrorrhagia at Baseline

- Any past, 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

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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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