MTN-013/IPM 026 Baseline/Follow-up Medical History Overview

Screening Visit

- Complete the Baseline Medical History Questions sheet. For any items marked “yes”, complete an entry on the Medical History Log.
- Complete the Menstrual History and Baseline Pregnancy/Contraceptive History sheets.
- Add any medical conditions newly-identified during the visit to the Medical History Log as needed. This includes signs/symptoms/diagnoses identified as a result of pelvic exam, physical exam, and/or laboratory evaluations.
- Complete Concomitant Medications Log CRF.

Enrollment Visit  

*All of the below to be completed prior to randomization/enrollment of ppt.*

- Review completed Baseline Medical History Questions sheet and update responses as needed. Add entries to the Medical History Log as needed.
- Add any medical conditions newly-identified during the visit to the Medical History Log as needed. This includes signs/symptoms/diagnoses identified as a result of pelvic exam, physical exam, and/or laboratory evaluations.
- Update previously-recorded entries on the Baseline Medical History as needed (i.e. add Outcome Dates as applicable).
- Review all entries of the Medical History Log(s). Transcribe each ongoing entry onto the Pre-existing Conditions CRF.
- Review/update Concomitant Medications Log CRF.

Follow-up Visits

- Review all pages of the Medical History Log(s) – review will be documented on the applicable visit checklist. Update “Outcome Date” of previously-recorded entries as needed. Add entries as needed for any newly-identified events (including signs/symptoms/diagnoses).
- Complete and/or update Adverse Experience Log (AE Log) CRFs as needed, ensuring data recorded on the Medical History Log matches data recorded on the corresponding AE Log CRF.
- Review/update Concomitant Medications Log CRF.