

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.