

MTN-012/IPM 010 Baseline and Follow-up Medical History Overview

| Visit | Forms/Documentation to Complete |
|------------|---|
| Screening | <p>Complete MTN-012/IPM 010 Baseline Medical History form (non-DataFax) and document all medical events in chart notes or Baseline Medical History Chart Note Sheets.</p> <p>Complete Concomitant Medications Log form.</p> <p>Complete Behavioral Eligibility form (non-DataFax).</p> <p>Complete Enrollment Eligibility form (non-DataFax).</p> |
| Enrollment | <p>Review completed MTN-012/IPM 010 Baseline Medical History form (non-DataFax) and update as needed. Document any updates in a labeled chart note.</p> <p>Record all ongoing acute medical events identified during the baseline medical history onto the Pre-existing Conditions form. Also record all ongoing laboratory events and signs/diagnoses identified at the Screening or Enrollment visits.</p> <p>Update Concomitant Medications Log form.</p> <p>Update Behavioral Eligibility form (non-DataFax).</p> <p>Update Enrollment Eligibility form (non-DataFax).</p> <p>Once enrolled, transcribe all ongoing events on the Pre-existing Conditions form onto the Follow-up Medical History Log (non-DataFax).</p> |
| Follow-up | <p>At each follow-up (post-enrollment) visit, review all pages of the Follow-up Medical History Log form (non-DataFax) and update ongoing events as applicable. Add any new events identified (e.g. signs, symptoms, diagnoses, laboratory events).</p> <p>Complete and update Adverse Experience Log forms as applicable.</p> <p>Update Concomitant Medications Log form.</p> |