



MTN-024/IPM 031 Operational Guidance #2: Documentation of Participant Menopausal Symptoms and/or History

This operational guidance to MTN-024/IPM 031 sites is intended to provide further guidance on how to document post-menopausal medical history at baseline and to clarify 'age of menopause' as noted on the Screening Menstrual History Form.

Documenting Post-Menopausal Symptoms at Baseline

When obtaining a focused baseline medical history at the Screening Visit, it is not necessary to document the participant's lifetime medical history. Rather, use the following guidance to probe for the most accurate information available from the participant:

- First, focus on conditions (including chronic conditions), changes and/or symptoms that have occurred since the age/onset of the menopause
- Secondly, focus on conditions (including chronic conditions), changes and/or symptoms that have occurred within the 12 months prior to the Screening Visit,
- Lastly, focus on conditions (including chronic conditions), changes and/or symptoms that directly affects eligibility (for example, severe pelvic relaxation or shortening and tightening of the vaginal canal that could make ring use difficult)

Site clinicians should use their best clinical judgment when assessing whether these conditions, changes and/or symptoms should be documented as pre-existing conditions. If any reported conditions, changes and/or symptoms first occurred within the initial few years of transition but have not occurred since, unless it is deemed relevant, it is recommended to document these only in source documents and on the Screening Menstrual History form. Documentation as a Pre-existing condition is not necessary. In the event previously experienced conditions, changes and/or symptoms occur during follow up, these conditions may then be documented on the Pre-existing Conditions CRF. If the Pre-existing Conditions CRF is updated after enrollment, site staff should document in a chart note why the update has been made.

Screening Menstrual History Form: Age of Menopause

'Age of menopause' is defined as the date in which a woman's menses permanently ceases. A woman is considered menopausal once she has gone one year without having a menses. The 'age of menopause' should be documented as the age in which the participant had her last menstrual period (LMP). .

All Operational Guidance documents must be printed and filed with regulatory documentation.