MTN-025 (HOPE) Operational Guidance #5:
Final Allowable PUEV and SEV Dates

The purpose of this Operational Guidance document is to outline the final allowable product use end visit (PUEV) and study exit visit (SEV) dates for the MTN-025/HOPE study.

Study sites should schedule PUEVs and SEVs based on the target dates and visit windows generated by the MTN-025/HOPE Study Participant Visit Calendar tool and Study Exit Visit Calculator tool, respectively. Note that participants who enrolled after 15SEP2017 have a truncated follow-up visit schedule, and modified visit calendar tools were provided to sites to use for these late enrollees based on the participant enrollment date.

The visit calendar tools note that the allowable visit windows for PUEVs and SEVs remain open "until study completion." For all MTN-025/HOPE participants, the final allowable visit windows will close as follows:

- **Final allowable date for all PUEVs: 30AUG2018**
- **Final allowable date for all SEVs: 10OCT2018**

No PUEVs or SEVs should be conducted after these dates.

In the event that a participant does not come for her PUEV by the cutoff date, please contact the MTN-025 Management Team for guidance.

Should a participant fail to present for her SEV by the cutoff date (10OCT2018), sites should move forward with terminating the participant in absentia. For these participants:

- Notify the MTN-025 management team that a SEV visit was unable to be completed.
- Record the reason(s) for not completing applicable visit in the participant study records.
- Complete the study exit worksheet and participant permission to contact logs to the best of your ability (i.e. based on available study source documentation and/or phone conversations with the participant, if applicable).
- Please contact SCHARP so that the Missed Visit CRF can be added and applicable forms can be inactivated within the participant's V9 – Study Exit/Termination folder. In addition, please note the following CRF completion guidance:
    - Complete an interim visit.
    - Complete the Date of Visit, indicating 10 Oct 2018 as the "Visit Date" to populate the Follow-up Visit Summary CRF.
    - Complete the Follow-up Visit Summary CRF. For "Reason for interim visit", ensure 'Other' is checked and specify this participant is being terminated in absentia. Indicate this is an 'early termination' for "Visit type" in order to populate the Termination CRF. ("Scheduled termination" should only be selected if the Study Exit Visit is completed.
    - Complete the Termination CRF, selecting the applicable reason for termination (e.g. "unable to contact participant", "participant relocated, no follow-up planned", or "Other" if applicable).
- If the participant has study product she was unable to return, please report these as protocol deviations for 'study product not returned'.

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

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Date