



MTN-025 (HOPE) Operational Guidance #6: PUEVs Not Completed by 30AUG2018 (Missed PUEVs)

The purpose of this Operational Guidance document is to outline procedures in the event a participant has not completed their PUEV by the final allowable date of 30AUG2018 but presents to the clinic prior to the study end date (10OCT2018). In these cases, sites should:

- Notify the MTN-025 Management Team and the MTN-025 PSRT
- Proceed with completion of procedures as outlined for an *Early Termination Visit* (this visit type essentially combines required PUEV and SEV procedures into a single visit). Reference the **PUEV/Term/Early Term visit checklist** for required procedures

CRF Completion Guidance

Please complete a Missed Visit CRF for the V8 – Month 12 (PUEV). Select ‘No’ for the item “Did the participant complete this visit?” on the Date of Visit CRF will populate the Missed Visit CRF within the V8 – Month 12 folder.

The screenshot shows the SCHARP web application interface. At the top, there is a navigation bar with the SCHARP logo and the text 'UAT'. Below the navigation bar, there is a breadcrumb trail: 'MTN025 > Test2 > 990562426 > V8 - Month 12 (1) > Date of Visit'. The main content area displays a form for 'Date of Visit' with the following details:

- Subject: 990562426
- Page: Date of Visit - V8 - Month 12 (1)
- Question: Did the participant complete this visit? (Answer: No)
- Visit Date: (Field is empty)

At the bottom of the form, there are links for 'Printable Version', 'View PDF', and 'Icon Key'. A footer note reads: 'CRF Version 1120 - Page Generated: 31 Aug 2018 13:53:27 Pacific Daylight Time'. There are 'Save' and 'Cancel' buttons at the bottom right.

Proceed with completing an Early Termination Visit as an Interim Visit:

- Complete the Date of Visit CRF with the applicable Visit Date.
- Complete the Interim Visit Procedures CRF and select ‘Yes’ for the applicable early termination procedures per the Early Termination Visit Checklist and SSP Section 14, Table 14-3. Please contact SCHARP if a CRF is not available or not populating so that this form can manually be added and please complete a paper CRF in the meantime.

Page: **Interim Visit Procedures - Interim Visit 8.01**

Interim Visit Number	8.01
Follow-up Visit Summary	Yes
ACASI Tracking	Yes
Pelvic Exam	Yes
Physical Exam	Yes
Vital Signs	Yes
STI Test Results	Yes

- Complete the Follow-up Visit Summary CRF by selecting ‘Yes’ for the item “Is this visit a PUEV, scheduled Study Exit Visit, or an early termination?” and select the visit type as ‘early termination’. This will dynamically add the Termination CRF to the Interim Visit folder.
- Complete the Termination CRF and for the “Reason for termination”, select ‘Other’ and specify the details within the ‘Specify’ text field indicating that the participant did not complete her PUEV within the allowable window.

Should a participant who has missed the PUEV by the allowable cutoff of 30AUG2018 **not** present to clinic by 10OCT2018:

- Complete a Missed Visit CRF for the V8 – Month 12 (PUEV) as per guidance above
- Follow documentation guidance as outlined in Operational Guidance #5 related to termination in absentia

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

DocuSigned by:
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Date