

HALT-C Trial Q x Q

Early Termination from Trial

Form # 25 Version A: 6/15/2000 (Rev. 12/04/2000)

Purpose of Form #25: This form records the fact that a patient is no longer being followed in the HALT-C Trial. After Form #25 is data entered, the HALT-C Data Management System (DMS) will no longer expect any forms to be entered for this patient.

When to complete Form #25: Complete Form #25 when a patient is no longer being followed in the HALT-C trial for any reason other than completing the Trial.

Every attempt should be made to keep the patient in the trial, especially randomized patients. Form #25 should be completed only when there is no hope that the patient will continue in the trial.

If a patient wishes to rejoin the randomized phase of the trial after a Form #25 has been data entered in the DMS, contact the DCC for instructions.

Where to add Form #25: Form #25 is an addable form in the Data Management System. Add this form to the study visit closest in time to termination of follow-up. To add a form to a visit, click on the "Additional Forms" button at the bottom of the screen. Choose "#25: Early Termination of Trial" from the pull down menu, and then click the "OK" button. To see where this form has been added, click on the "More" link in the upper right hand corner of the screen.

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to the most recent study visit.
- A4. Record the date this form is completed using MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

SECTION B: EARLY TERMINATION FROM TRIAL INFORMATION

- B1. Record the date the patient was last seen at a HALT-C clinical center in MM/DD/YYYY format.
- B2. Circle one number indicating the primary reason for ending follow-up of the patient in the Trial.
- Circle 1 for "Patient lost to follow-up" if repeated efforts to contact the patient by telephone and mail have failed.
 - Circle 2 for "Patient moved to another location" if the patient is moving and unwilling to complete all future study visits at any HALT-C clinical center.
 - Circle 3 for "Patient enrolled in another treatment trial" if the patient has not been randomized and is participating in any other treatment based clinical trial.
 - Circle 4 for "Patient non-compliance -- visits" if repeated efforts to schedule visits with the patient have failed or if the patient repeatedly does not show up for visits.
 - Circle 5 for "Patient withdrew consent" if the patient has withdrawn his/her consent to participate in the trial and does not want to be contacted further.
 - Circle 9 for "Other" for any other reason. Give a detailed explanation in Question B3.
- B3. Record a detailed explanation of the reason for ending this patient's follow-up in the HALT-C trial. It is not sufficient to write "Pt no longer in trial."

250 characters, including punctuation and spaces, are provided. If the patient enrolled in another treatment trial, specify the treatment being tested if known. Explanation examples:

- "Pt unable to tolerate numerous side effects. Does not wish to be followed or to be contacted."
- "Unable to contact pt despite repeated efforts. No answer to registered letter sent 05/2003."