

HALT-C Trial Q x Q

Clinical Conditions at End of Study

Form # 16 Version A: 12/17/2004

Purpose of Form #16: The Clinical Conditions at End of Study form records diagnoses of clinical conditions. Form #16 may be used as a source document, and, therefore, requires the signature of the HALT-C Investigator who completes the form.

When to complete Form #16: Form #16 should be completed **once for all Randomized patients**. Please complete at one of the following time points, as appropriate.

- During the Month 48 (M48) study visit.
- During the Month 54 (M54) study visit, if the patient has already completed the M48 visit.
- During the last randomized phase study visit, if the patient has died.
- During the last randomized phase study visit, if the patient has permanently discontinued participation in the HALT-C study and Form #25 "Early Termination from Trial" has been completed.

Where to add Form #16: This form is expected during the M48 study visit. This form is also an addable form in the DMS and can be added to any Randomized Phase visit. Form #16 should only be completed and data entered once for each randomized patient. To add a form to a visit, click on the "Additional Forms" button at the bottom of the screen. Choose "#16: Clinical Conditions at End of Study" from the pull down menu, and then click the "OK" button. To see where this form has been added, please 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 this visit.
- A4. Record the date the physical exam was done using MM/DD/YYYY format.
- A5. Enter the initials of the Investigator completing the form.

Note: The HALT-C Investigator who collects and records the data in **Section B** must sign the form in the space provided on page 7.

SECTION B: CLINICAL CONDITIONS

Section B is set up in table form to record information on 23 clinical conditions. Each Row addresses a clinical condition, and each Column contains specifics about that condition. The instructions below explain how to fill out the table Column by Column.

“B#” Column:

The first column on the left provides the row number associated with each of the 23 clinical conditions.

“Clinical Conditions” Column:

The second column provides a name or brief description of each of the 23 clinical conditions.

Note: The HALT-C Investigator should complete Columns (a – d) for each Row.
DK indicates that the investigator does not have enough information to answer the question.

Column (a): “Has the patient even been diagnosed with the condition?”

Record whether the patient has ever been diagnosed with the clinical condition. The definition of each clinical condition is the HALT-C Investigator’s clinical judgment.

- If the answer is YES → circle “1” → continue to Column (b).
- If the answer is NO → circle “2” → skip to Column (a) in the next Row.
- If the answer is DK → circle “-8” → skip to Column (a) in the next Row.

Column (b): “Was the diagnosis present at enrollment in HALT-C?”

Record whether the diagnosis was present when the patient enrolled in HALT-C.

- If the answer is YES → circle “1” → skip to Column (d).
- If the answer is NO → circle “2” → continue to Column (c).
- If the answer is DK → circle “-8” → continue to Column (c).

Column (c): “Was it diagnosed after enrolling in HALT-C?”

Record whether the patient was diagnosed with the clinical condition after enrolling in HALT-C.

- If the answer is YES → circle “1” → continue to Column (d).
- If the answer is NO → circle “2” → continue to Column (d).
- If the answer is DK → circle “-8” → continue to Column (d).

Column (d): “Has it become better or worse since enrollment?”

Record whether the clinical condition is better, worse, or unchanged since enrollment.

- If the answer is BETTER → circle “1” → continue to Column (a) in the next Row.
- If the answer is WORSE → circle “2” → continue to Column (a) in the next Row.
- If the answer is NO CHANGE → circle “3” → continue to Column (a) in the next Row.
- If the answer is DK → circle “-8” → continue to Column (a) in the next Row.

Note: After Row 23 has been completed, the HALT-C Investigator who collects and records the data in **Section B** must sign the form in the space provided on page 7.