HALT-C Trial Q x Q

Alternative Study Visit

Form #924 Version B: 10/10/2006

Purpose of Form #924: To collect data on any liver biopsies, endoscopies, clinical outcomes, and/or serious adverse events that have occurred during a time when a patient missed two or more randomized phase study visits. The form also collects data on the patient's use of interferon since the last completed study visit.

When to complete Form #924: If a patient has missed two consecutive randomized visits, this form must be completed along with Form # 24 (Missed Visit). Only questions B1 and B1a may be completed with information collected from a third party (such as the patient's spouse or outside physician). All other information must be collected during an in-person or telephone conversation with the patient. This form is the only form to be completed at Month 66 for all those patients eligible. See end of QxQ for special instructions for M66 visit.

Where to add Form #924: Add this form to the second of the two consecutive randomized visits. For example, if the patient did not come for his Month 9 visit, and now has missed his M12 visit, add a Form # 924 in the M12 visit. To add a form to a visit, click on the "Additional Forms" button at the bottom of the screen. Choose "#924: Alternative Study Visit" 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 code corresponding to this visit.

A4. Record the contact date in MM/DD/YYYY format. If you are unable to reach the patient, for whatever reason, record the date of the most recent day you tried to contact the patient.

A5. Enter the initials of the person completing the form.

A6. Date of last version of consent form signed in MM/DD/YYYY format.
- Each site needs to check with their IRB regarding collection of data from a patient who has not signed the most recent consent form.

SECTION B: POTENTIAL SERIOUS ADVERSE EVENTS, CLINICAL OUTCOMES, ULTRASOUND/ MRI/CT AND LIVER BIOPSIES AND ENDOSCOPIES

General Instructions for Section B: When a patient has missed two consecutive randomized phase visits, the coordinator should try to complete this form with the patient. The purpose of this section is to assess whether the patient has had any serious adverse events or clinical outcomes, any liver-related imaging (such as Ultrasound, MRI, and CT), and any liver biopsies or endoscopies since the last completed study visit or the last time a Form #924 was completed.

NOTE: If necessary, ask the patient to sign a medical record release form. You may need to mail the medical record release form to the patient for signature and return.

B1. This question determines whether the coordinator was able to speak with the patient to collect information for this form.

- If the answer is YES, circle "1", and skip to question B2.
- If unable to speak with the patient, or unable to obtain any information for this form, the answer is NO, circle "2", and continue to question B1a.

B1a. Describe in one or two brief sentences why you were unable to obtain information. After completing this question, skip to the end of the form and sign your name indicating that you can verify the data you have collected on this form.

- Examples: "Patient refused to talk", "Left 3 phone messages, but patient never responded", "Patient's spouse said that patient was too ill to speak with me".

B2. Record if the patient reports that he/she was hospitalized overnight for any reason since the last completed Form #924 or in-person study visit.

- If the answer is YES, circle "1". Complete an Adverse Event Form #60. Also, complete a Serious Adverse Event Form #61 or a Clinical Outcome Form #63.
- If the answer is NO, circle "2".

B3. Record if the patient reports that he/she has had any liver-related imaging procedures such as an Ultrasound, MRI, or CT scan since the last completed Form #924 or in-person study visit.

- If the answer is YES, circle "1". Complete an Ultrasound/MRI/CT Form #22. If applicable, also complete a Serious Adverse Event Form (# 61) or a Clinical Outcome Form (#63).
- If the answer is NO, circle "2".

B4. Record if the patient reports that he/she has had a liver biopsy since the last completed Form #924 or in-person study visit.

- If the answer is YES, circle "1". Complete a Clinical Center Biopsy Form #52. Obtain information so liver biopsy slides can be requested for review.
- If the answer is NO, circle "2".

B5. Record if the patient reports that he/she has had an endoscopy since the last completed Form #924 or in-person study visit.

- If the answer is YES, circle "1". Complete an Endoscopy Form #23. Obtain information so endoscopy photos can be requested for review.
- If the answer is NO, circle "2".

B6. Record if the patient reports that he/she has any changes in her/his health that may be considered a clinical outcome since the last completed Form #924 or in-person study visit. Use the code box below that summarizes HALT-C Clinical Outcomes. Probe appropriately to determine if the patient has experienced any new clinical outcomes.

- If the answer is YES, circle "1". Complete a Clinical Outcome Form #63. Obtain information so required source documentation can be requested for review. Continue to question B7.
- If the answer is NO, circle "2", and skip to Section C.

Probe for information on these HALT-C Clinical Outcomes

Development of definite or presumed hepatocellular carcinoma
Variceal hemorrhage
Ascites
Bacterial peritonitis
Hepatic encephalopathy
Liver transplant

B7. Record if you are requesting source documentation to determine whether a reported event meets the criteria of a HALT-C Clinical Outcome. By answering YES to this question, it will let the DCC know that source documentation is on the way for a possible HALT-C Clinical Outcome. See Section I of the MOO for a list of possible source documents.

- If you have requested source documentation, circle "1" for YES. Skip to Section C.
- If the answer is NO, circle "2" and continue to question B7a.

B7a. Describe in one or two brief sentences why you are not requesting source documentation on a reported event that could be a HALT-C Clinical Outcome. For example, "Patient refused to sign medical record release form", or "Patient does not know and can't obtain the name of the hospital in Bulgaria where the endoscopy was performed."

SECTION C: TRIAL MEDICATION(S)

General instructions for section C: The purpose of this section is to assess whether the patient has taken any interferon since the last completed study visit or the last time a Form #924 was completed. Collect information if the patient is taking Pegasys® provided by the HALT-C trial or is taking any type of interferon prescribed outside of the HALT-C trial. See special instructions for Month 66 at end of QxQ.

NOTE: Complete a Dose Adjustment Form #28 if Pegasys® provided by the HALT-C Trial has been stopped for any reason since the last completed study visit or the last time a Form #924 was completed.

C1. Record whether the patient reports currently taking any type of interferon. "Current" is defined as having injected interferon within the last 10 days. If the patient stopped taking interferon 11 days ago, then the answer is NO.

- If the answer is YES, circle "1".
- If the answer is NO, circle "2". Skip to the end of the form and sign your name indicating that you can verify the data you have collected on this form.

C2. Record the dose of the current interferon the patient reports taking

- If the current dose is 90 mcg, circle “1”.
- If the current dose is 180 mcg, circle “2”.
- If the current dose is something other than 90 mcg or 180 mcg, circle “99”.
  - Specify the current dose in mcg in the three-digit space provided.
  - If the dose is not known, circle “99”, and write “unknown". Data enter "-8" in the DMS.

NOTE: It is important to know if a HALT-C physician prescribed the interferon for a patient in the treatment group of HALT-C. It is also possible that a patient who is in the control group is receiving peginterferon alfa 2-a from another physician outside of the trial.

C3. Record the type of interferon preparation the patient reports taking.

- If the patient is randomized to the treatment group and reports currently taking Pegasys® prescribed by the HALT-C physician, circle “1”. Skip to the end of the form and sign your name indicating that you can verify the data you have collected on this form.

- If the patient reports taking any type of interferon, including Pegasys®, prescribed by a physician outside of the HALT-C Trial, circle “2”.

- If neither of the above answers is applicable, circle “99”
  - Give a brief explanation. Example, “patient is in control group but was prescribed interferon by HALT-C physician”.

C4. Record the date when the patient first started taking interferon outside of the HALT-C trial using MM/DD/YYYY format. If day is unknown, enter 15 for DD.

Signature of Interviewer: The signature of the interviewer is mandatory. This signature validates that the interviewer has collected this data and this form can be used as a source document.

Form # 924 at Month 66: Section C: If the patient is currently on interferon at Month 66, the answer to C3 would be “2” because the Pegasys® is no longer being prescribed for the treatment group of the main trial. C4, the start date of interferon should match start date of interferon on form # 610 at Month 60, if applicable. Obviously one should disregard the reminder regarding completing the dose adjustment form.