HALT-C Trial Q x Q

Sustained Virologic Responder Follow-up Ancillary Study:

Study Visit

Form # 710 Version A: 05/01/2008

Purpose of Form #710: The Study Visit form uses interview format to document any overnight hospitalizations, day surgery, visits to a healthcare provider, and/or changes in health **related to possible clinical outcomes** that the patient may have had since the W72 study visit.

When to complete Form #710: This form should be completed once for all patients who consented to the Sustained Virologic Responder Follow-up Ancillary Study.

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. The visit number, SVR, is pre-printed on the form and does not need to be data entered.

A4. Record the date the patient was seen at the HALT-C Clinical Center or interviewed by telephone using MM/DD/YYYY format.

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

SECTION B: INFORMED CONSENT

B1. Did the patient visit the HALT-C Clinical Center or was the patient interviewed by telephone?

- Circle 1 if the interview was conducted at a HALT-C Clinical Center visit.
- Circle 2 if the interview was conducted by telephone.

The purpose of this section is to assess whether the patient has had any possible clinical outcomes that have not been previously reported since the W72 study visit.

Probe the patient for information to determine if a Clinical Outcome (Form #763) should be completed. If appropriate, have the patient sign a medical record release form.

HALT-C SVR Ancillary Study: Clinical Outcomes

Death from any cause
Development of hepatocellular carcinoma
CTP score of 7 or higher
Variceal hemorrhage
Ascites
Spontaneous bacterial peritonitis
Hepatic encephalopathy
Liver transplant
Development of presumed hepatocellular carcinoma

B2. If the patient had *any liver related imaging such as an ultrasound / MRI / CT* that indicated possible HCC or ascites since the W72 study visit, circle 1 for YES. Also, complete Form #763: Clinical Outcome. HAVE THE PATIENT SIGN A MEDICAL RECORD RELEASE FORM.

Otherwise, circle 2 for NO.

B3. If the patient had a *liver biopsy* that indicated possible HCC since the W72 study visit, circle 1 for YES. Also, complete Form #763: Clinical Outcome. HAVE THE PATIENT SIGN A MEDICAL RECORD RELEASE FORM.

Otherwise, circle 2 for NO.

B4. If the patient had an *endoscopy* that indicated a possible variceal bleed since the W72 study visit, circle 1 for YES. Also, complete Form #763: Clinical Outcome. HAVE THE PATIENT SIGN A MEDICAL RECORD RELEASE FORM.

Otherwise, circle 2 for NO.

B5. If the patient has the patient had *a hospital admission* that indicated a possible clinical outcome since the W72 study visit, circle 1 for YES. Also, complete Form #763: Clinical Outcome. HAVE THE PATIENT SIGN A MEDICAL RECORD RELEASE FORM.

Otherwise, circle 2 for NO.

B6. If the patient has the patient had *any other changes in her/his health* that may be considered a possible clinical outcome since the W72 study visit, circle 1 for YES. Also, complete Form #763: Clinical Outcome. HAVE THE PATIENT SIGN A MEDICAL RECORD RELEASE FORM.

Otherwise, circle 2 for NO.

B7. If you are requesting source documentation for a possible clinical outcome, circle 1 for YES.

Otherwise, circle 2 for NO.

SECTION C: ANTIVIRAL MEDICATIONS FOR HEPATITIS C

C1. The purpose of this question is to assess whether the patient has taken any prescription antiviral medications for hepatitis C since the W72 study visit. Do not include any medications taken before W72.

If the patient has taken prescription antiviral medications for hepatitis C since the W72 study visit, circle 1 for YES. The form is complete.

Otherwise, circle 2 for NO and the form is complete.