HALT-C Trial Q x Q

Sustained Virologic Responder Follow-up Ancillary Study:

Physical Exam

Form #711 Version A: 05/01/2008

Purpose of Form #711: The Physical Exam form records general and physical examination results.

When to complete Form #711: This form should be completed once for all patients who consented to the Sustained Virologic Responder Follow-up Ancillary Study.

If the physical exam is not completed at the time of the study visit, information from the patient's medical record may be used to the complete the form. When using medical records to fill out Form #711, record the data from the most recent physical exam. A physical exam done within the last 6 months is preferred.

If no physical examination was done, record a brief explanation on the incomplete Form #711. The data entry person should set the Form #711 to missing in the DMS and type the explanation in the "Enter Missing Form Reason" box.

If only a partial physical examination was completed, record a brief explanation on the incomplete Form #711. The data entry person should enter all recorded data and type an explanation in form level and field level comments as necessary.

It is not sufficient to write "Not Done." Explanation examples:
- "Physician unavailable."
- "Pt late for appt., no MD available."

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 of the physical exam using MM/DD/YYYY format.

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

SECTION B: GENERAL EXAMINATION

B1. Was the physical exam performed at HALT-C Clinical Center or at another location?

- Circle 1 if the physical exam was performed at a HALT-C Clinical Center visit.
- Circle 2 if the physical exam was performed at another location.

B2. Record the patient's weight. If possible, patient's weight should be measures with clothes on and heavy outerwear and shoes off.

- Record the weight in units (kg or lb) that were used on the measuring instrument. Round kilograms to 0.1 kg. Round pounds to the nearest lb.
- It is not necessary to record both kilograms and pounds.

B3. Ascites.

- Circle 1 for YES if ascites is detected. Continue to Question B3a.
- Circle 2 for NO if there is no ascites detected. Skip to Question B4.

B3a. Ascites severity. Characterize the ascites using the following definitions. Also, complete Form #763: Clinical Outcome.

- Mild: barely detectable. Circle 1 and continue to Question B4.
- Moderate: easily detectable. Circle 2 and continue to Question B4.
- Severe: large (tense) abdomen. Circle 3 and continue to Question B4.

B4. Encephalopathy

- Circle 1 for YES if encephalopathy is detected. Continue to Question B4a.
- Circle 2 for NO if there is no encephalopathy detected. The form is complete.

B4a. Encephalopathy grade. Circle the corresponding encephalopathy grade using the following definitions then the form is complete. Also, complete Form #763: Clinical Outcome.

- Grade 1: mild confusion; sleep disorder; forgetfulness; altered mood (euphoria, depression) or behavior; slurred speech; may have asterixis
- Grade 2: lethargy; moderate confusion; drowsiness; inappropriate behavior; asterixis
- Grade 3: stupor (can speak and obey simple commands); somnolent, but arousable; inarticulate speech; marked confusion
- Grade 4: coma