

HALT-C Trial QxQ
Sustained Virologic Responder Follow-up Ancillary Study:
Ultrasound, MRI, CT

Form #722 Q x Q Version A: 05/01/2008

Purpose of Form #722: This form is used to record the results of liver ultrasound, MRI, or CT scans. The preference is an ultrasound test, however, an MRI or CT test may be used in place of an ultrasound. A printed copy of the ultrasound, MRI, or CT report should be filed in the patient's record.

When to complete Form #722: This form should be completed once for all patients who consented to the Sustained Virologic Responder Follow-up Ancillary Study.

If liver imaging was not done at the HALT-C clinical site at the time of the study visit, the information may be collected from the patient's medical record. Use the most recent imaging study when recording data from the medical record onto Form #722. An imaging study done within the last 6 months is preferred.

If no liver imaging was done, record a brief explanation on the incomplete Form #722. The data entry person should set the Form #722 to missing in the DMS and type the explanation in the "Enter Missing Form Reason" box.

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 form was completed using MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

SECTION B: TEST RESULTS

- B1. Record the date that the ultrasound, MRI, or CT was performed using MM/DD/YYYY format.
- B2. Record the type of liver imaging test performed.
 - Circle "1" if an Ultrasound was performed.
 - Circle "2" if an MRI was performed.
 - Circle "3" if a CT was performed.
- B3. Was the liver imaging test performed at HALT-C Clinical Center or at another location?
 - Circle 1 if the liver imaging test was performed at a HALT-C Clinical Center visit.
 - Circle 2 if the liver imaging test was performed at another location.
- B4. Was there evidence of ascites?

Ascites is considered absent if there is no clear-cut evidence of abnormal peritoneal fluid. If there is no evidence of ascites, circle "2" and skip to question B5. If there is evidence of ascites, circle "1" and continue to question B4a.

- B4a. Record the characterization of ascites that is most appropriate.
- Circle "1" for Minimal: Isolated thin sliver of fluid around the liver, or small pelvic pocket, or small amount of fluid in lesser sac.
 - Circle "2" for Mild: Multiple small collections as a thin sliver around the liver, pelvic pockets, small abdominal pockets.
 - Circle "3" for Moderate: Fluid collection in multiple areas of the abdomen and around the intestines.
 - Circle "4" for Marked (large): Bowel loops separated by fluid and large pools around liver, pelvis and peritoneal gutters.

If the ascites was Mild, Moderate, or Marked, also complete Form #763: Clinical Outcome.

- B5. Was there evidence of a liver mass suggestive of HCC?

If there was evidence of one or more liver masses suggestive of hepatocellular carcinoma (HCC), circle "1". Form #722 is complete. Also complete Form #763: Clinical Outcome. Consult the Principal Investigator regarding possible additional follow-up.

If the scan or test showed no evidence of any liver mass, circle "2". Form #722 is complete.

If there was evidence of one or more liver masses that were ambiguous for hepatocellular carcinoma (HCC), circle "3" and continue to question B5a.

- B5a. Record the description of the ambiguous findings in the "specify" space.