

HALT-C Trial QxQ

Ultrasound, MRI, CT

Form # 22 Q x Q Version B: 09/10/2001

Purpose of Form #22: 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 #22: This form should be completed for all patients at the following study visits:

- **Screening phase:** Screening visit 1 or 2 (S01 or S02).
- **Lead-in phase:** Week 20 (W20).
- **Responder phase:** Week 48 (W48) and Week 72 (W72). If a patient is to be randomized after the Week 30 (W30), Week 36 (W36), Week 42 (W42), or Week 60 (W60) study visit, an ultrasound is required.
- **Randomization phase:** Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48).

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 the appropriate patient visit.
- A4. Record the patient visit date 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.
 - In the ADEPT Data Management System (DMS), a Data Entry Validation Error window might pop up to inform the data entry person that the date entered is outside the visit window.
 - Check that the date entered was recorded and typed correctly. If yes, a brief explanation is needed. Click on the Set **Override button**. In the window, type an explanation that explains why the liver-imaging test was done outside of the visit window, and initial the override.
- 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. 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 B4. If there is evidence of ascites, circle "1" and continue to question B3a.

- B3a. 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.
- B4. Evidence of Liver mass: If the scan or test showed no evidence of any liver mass, circle “2” and skip to question B5. If there was evidence of one or more liver masses, circle “1” and continue to question B4a.
- B4a. Record the size of the liver mass. Record the best estimate of the maximum diameter of liver mass, expressed in centimeters.
- B4b. Record the characteristics of the liver mass.
- Circle “11” if the liver mass is well-defined. A discrete defect with relatively sharp margins indicating a clear-cut abnormality is considered ‘well-defined’.
 - Circle “12” if the liver mass is ill-defined. A mass with poorly defined margins or equivocal abnormality (i.e. geographic) is considered ‘ill-defined’.
- B4c. Record if there are prior film(s) or report(s) available.
- Circle “1” if a prior film or report is available and continue to Question B4d.
 - Circle “2” if a prior film or report is not available and skip to Question B4e.
- B4d. Record the size and stability of the lesion in the present scan compared to the prior film/report.
- Circle “1” if, compared to the prior film, the present lesion is seen and stable.
 - Circle “2” if, compared to the prior film, the present lesion is seen and increased in size.
 - Circle “3” if, compared to the prior film, the present lesion is seen and decreased in size.
 - Circle “99” if, compared to the prior film, none of the above reasons is sufficient. In the “specify” space, record a brief statement on the size and stability of the liver mass.
- B4e. Record whether the liver mass requires additional follow-up after this visit:
- Circle “1” for YES if further follow-up is necessary and skip to Question B4g.
 - Circle “2” for NO if no further follow-up is necessary and continue to Question B4f.
- B4f. Record the reason that follow-up is not necessary in the “specify” space.
- B4g. This question should be answered after the additional follow-up test is complete. Record whether the follow-up test indicated that the liver mass was suggestive of HCC.
- Circle “1” for YES if the liver mass is suggestive of HCC. (This may require completion of a Clinical Outcome Form #63). Continue to Question B4h.
 - Circle “2” for NO if the follow-up test does not suggest a liver mass with potential to be HCC. Continue to Question B4h.
 - Circle “3” for AMBIGUOUS if the follow-up test results are ambiguous for HCC. In the “specify” space, record a brief statement explaining the ambiguous results.
- B4h. Record the type of follow-up 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.

- B4i. Record the date that the follow-up test was performed using MM/DD/YYYY format.
- B5. Record if there was evidence of splenomegaly (enlarged spleen > 13 cm).
- Circle "1" for YES if there was splenomegaly. Continue to Question B5a.
 - Circle "2" for NO if the spleen was \leq 13 cm. Skip to Question B6.
 - Circle "3" if no spleen data were available. Skip to Question B6.
- B5a. Record the greatest length of the spleen in any dimension, measured in centimeters for patients with splenomegaly (enlarged spleen > 13 cm).
- B6. Other findings (e.g. portal vein thrombosis, gall stones, pancreatic lesions)
- Circle "1" for YES if there were other findings. Continue to Question B6a.
 - Circle "2" for NO if there were no other findings. The form is complete
- B6a. In the "specify" space, record a brief statement explaining the other findings. In particular, record whether the scan or test revealed evidence of portal vein thrombosis, gallstones, or pancreatic lesions.