

## HALT-C Trial Q X Q

**HCC Diagnosis**

Form # 66 Version A: 11/01/2003

**Purpose of Form #66:** The HCC Diagnosis Form records the diagnosis of HCC and the characteristics of the tumor.

**When to complete Form #66:** This form should be completed when a randomized patient meets the criteria of definite or presumed HCC. Form #66 can be added to the Clinical Outcome Form Summary by clicking on the "Additional Forms" button on the bar at the bottom 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. Record the date of this visit (the date the physical exam was done) using the MM/DD/YYYY format.
- A4. Enter the initials of the person completing the form.

**SECTION B: DIAGNOSIS**

- B1. Record the date the patient first met the criteria for definite/presumed HCC (in patient where the diagnosis of HCC is based on 2 imaging tests, please enter the date of the second confirming test) using MM/DD/YYYY format.
- B2. Indicate if the diagnosis of HCC was made on the basis of histology.
  - If the HCC was diagnosed by histology, skip to question C1.
  - If the HCC was not diagnosed by histology, go to question B3.
- B3. Indicate if the diagnosis of HCC was determined by the presence of a new hepatic lesion with AFP >1000 ng/mL.
  - If the HCC was diagnosed by the new lesion and AFP >1000 ng/mL, skip to question C1.
  - If the HCC was not diagnosed by the new lesion and AFP >1000 ng/mL, go to question B4.
- B4. Indicate the method of diagnosis. Choose only one of the methods from the code list. If the method is not listed, enter 99 and then specify the method in the space provided.

**SECTION C: TUMOR CHARACTERISTICS**

- C1. Indicate the number of tumor nodules in the liver.
  - Circle the appropriate number (1-6).
  - If Diffuse (6) is the correct answer, then skip to question C3.
  
- C2. Indicate the tumor size (maximum diameter of largest tumor nodule) in centimeters. Three decimal places are allowed.
  
- C3. Indicate the tumor location.
  - If unilobar, circle "1."
  - If bilobar, circle "2."
  
- C4. Indicate if there is vascular invasion.
  - If yes, circle "1."
  - If no, circle "2."
  - If unable to determine, circle "3."
  
- C5. Indicate whether there is extrahepatic spread.
  - If yes, circle "1."
  - If no, circle "2."
  - If unable to determine, circle "3."
  
- C6. Indicate the tumor staging based on TNM Classification. Use the classification table provided.
  - Record the T-factor at C6a.
  - Record the N-factor at C6b.
  - Record the M-factor at C6c.

AMERICAN LIVER TUMOR STUDY GROUP MODIFIED TUMOR-NODE-METASTASIS (TNM) CLASSIFICATION			
<u>CLASSIFICATION</u>	<u>DEFINITION</u>		
TX, NX, MX	Not assessed		
T0, N0, M0	Not found		
T1	1 nodule <=1.9 cm		
T2	One nodule 2.0-5.0 cm; two or three nodules, all <3.0 cm		
T3	One nodule >5.0 cm; two or three nodules, at least one >3.0 cm		
T4a	Four or more nodules, any size		
T4b	T2, T3, or T4a plus gross intrahepatic portal or hepatic vein involvement as indicated by CT, MRI, or ultrasound		
N1	Regional (portal hepatitis) nodes, involved		
M1	Metastatic disease, including extrahepatic portal or hepatic vein involvement		
Stage I	T1	Stage IVA1	T4a
Stage II	T2	Stage IVA2	T4b
Stage III	T3	Stage IVB	Any N1, any M1