

HALT-C Trial
HCC Diagnosis

Form #66 Version A: 11/01/2003

SECTION A: GENERAL INFORMATION

- A1. Affix ID label here →
- A2. Patient Initials: __ __ __
- A3. Date form completed: MM/DD/YYYY ____/____/____
- A4. Initials of person completing form: __ __ __

THIS FORM SHOULD ONLY BE COMPLETED FOR PATIENTS IN THE RANDOMIZED PHASE.

SECTION B: DIAGNOSIS (to be completed when a randomized patient first meets the criteria of definite or presumed HCC)

B1. Date patient first met criteria for definite/presumed diagnosis of HCC (in patient where the diagnosis of HCC is based on 2 imaging tests, please enter date of the second confirming test)

____/____/____ (MM/DD/YYYY)

B2. Was the diagnosis of HCC made on the basis of histology?

Yes.....1 (C1)

No.....2

B3. Was the diagnosis of HCC determined by the presence of a new hepatic lesion with AFP >1000 ng/mL?

Yes.....1 (C1)

No.....2

B4. Method of Diagnosis (choose one of the methods from the code list below): ____

- METHODS OF DIAGNOSIS**
1. New hepatic lesion on ultrasound, and characteristics of HCC on additional imaging
 2. AFP above normal, and 2 imaging studies with characteristics of HCC
 3. Progressively enlarging hepatic lesion and resulting in death of patient
 4. New hepatic lesion with doubling in size or tripling if initial size <1 cm
 5. New hepatic lesion with AFP increased to >200 ng/mL and more than tripling of mean baseline value
 99. Other SPECIFY: _____

SECTION C: TUMOR CHARACTERISTICS (based on radiological findings at the time patient first meets criteria for definite or presumed diagnosis of HCC)

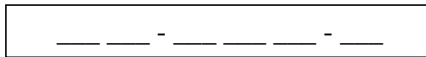
- C1. Number of tumor nodules in the liver:
- 1 1
 - 2 2
 - 3 3
 - 4 4
 - > 4 5
 - Diffuse 6 **(C3)**

C2. Tumor size (maximum diameter of largest tumor nodule): _____ cm

- C3. Tumor location:
- Unilobar 1
 - Bilobar 2

- C4. Vascular invasion:
- Yes 1
 - No 2
 - Unable to determine 3

- C5. Extrahepatic spread:
- Yes 1
 - No 2
 - Unable to determine 3



C6. Tumor staging based on TNM Classification:

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

C6a. T-factor: ____

C6b. N-factor: ____

C6c. M-factor: ____