

HALT-C Trial

HCC Working Group Review Form

Form #969 Version A: 10/05/2006 (Revised 10/03/2007)

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 WHO WERE RANDOMIZED AND MEET CRITERIA FOR PRESUMED OR DEFINITE HCC.

SECTION B: RADIOLOGY

B1. Date when last imaging showed no tumor nodule

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

- B1a. Type of imaging:
 - Ultrasound..... 1
 - MRI..... 2
 - CT 3
 - Angiogram..... 4

B2. Date when imaging first showed a suspicious nodule:

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

- B2a. Type of imaging:
 - Ultrasound..... 1
 - MRI..... 2
 - CT 3
 - Angiogram..... 4

- B2b. Number of tumor nodules in the liver:
- 1 1
 - 2 2
 - 3 3
 - 4 4
 - > 4 5
 - Diffuse 6 (B2d)

B2c. Nodule size (maximum diameter of largest nodule): ____ ____ . ____ cm

- B2d. Nodule location:
- Right Lobe 1
 - Left Lobe 2
 - Bilobar 3

- B2e. Portal vein invasion:
- Yes 1
 - No 2
 - Unable to determine 3

- B2f. Extrahepatic spread:
- Yes 1
 - No 2
 - Unable to determine 3

_____ - _____ - _____

B3. Date when patient first met criteria for presumed or definite HCC:

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

- B3a. Type of imaging/histology:
- Ultrasound..... 1 (B3b)
 - MRI..... 2 (B3b)
 - CT 3 (B3b)
 - Angiogram..... 4 (B3b)
 - Biopsy 5 (B3b)
 - Explant 6 (B3b)
 - Other 99

B3a1. Specify: _____

- B3b. Number of tumor nodules in the liver:
- 1 1
 - 2 2
 - 3 3
 - 4 4
 - > 4 5
 - Diffuse 6 (B3d)

B3c. Nodule size (maximum diameter of largest nodule): ____ . ____ cm

- B3d. Nodule location:
- Right Lobe 1
 - Left Lobe 2
 - Bilobar 3

- B3e. Portal vein invasion:
- Yes..... 1
 - No 2
 - Unable to determine..... 3

B3f. Extrahepatic spread: Yes..... 1
No 2
Unable to determine..... 3

SECTION C: HCC TREATMENT

C1. Has the patient received any treatment for HCC? Yes 1
No..... 2 (D1)

C2. Date when HCC treatment was first administered ____ / ____ / ____ (MM/DD/YYYY)

SECTION D: EXPLANT LIVER PATHOLOGY

D1. Did the patient undergo liver transplant? Yes 1
No..... 2 (E1)

D1a. Ishak fibrosis score: ____

D1b. Number of tumor nodules in the liver: 1 1
2 2
3 3
4 4
> 4 5
Diffuse..... 6 (E1)

D1c. Nodule size (maximum diameter of largest nodule): ____ . ____ cm

SECTION E. TUMOR STAGING

E1. When did tumor nodule meet criteria?

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

E2. Tumor staging based on TNM Classification:

AMERICAN LIVER TUMOR STUDY GROUP MODIFIED TUMOR-NODE-METASTASIS (TNM) CLASSIFICATION			
CLASSIFICATION	DEFINITION		
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

E2a. T-factor: ____

E2b. N-factor: ____

E2c. M-factor: ____