

HALT-C Trial
Additional HCC Outcome Form
Form # 69 Version A: 10/05/2006

SECTION A: GENERAL INFORMATION

A1. Affix ID label here →

____ - ____ - ____

A2. Patient Initials: __ __ __

A3. Date form completed / updated: 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: DIAGNOSIS

B1. Date when last imaging showed no tumor nodule:

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

B1a. Type of imaging:

- Ultrasound1
- MRI.....2
- CT3
- Angiogram4

B2. Date when imaging first showed a suspicious nodule:

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

B2a. Type of imaging:

- Ultrasound1
- MRI.....2
- CT3
- Angiogram4

____ - ____ - ____

- 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 or thrombus:
- Yes.....1
 - No.....2
 - Unable to determine.....3

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

_ _ _ - _ _ _ - _

SECTION C: HCC TREATMENT

C1. Has the patient received any treatment for HCC? Yes1
No.....2 (D1)

C2. What treatment modalities were used? Circle YES or NO for all answers, for each treatment used provide date when that treatment was first administered

C2a. Surgical resection

Yes.....1 Date: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
No2

C2b. Liver transplantation

Yes.....1 Date: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
No2

C2c. Local ablation – radiofrequency

Yes.....1 Date: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
No2

C2d. Local ablation – injection of alcohol

Yes.....1 Date: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
No2

C2e. Intra-arterial chemotherapy +/- embolization

Yes.....1 Date: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
No2

____ - ____ - ____

C2f. Systemic chemotherapy

Yes.....1 Date: ____/____/____ (MM/DD/YYYY)

No2

C2g. Radiation therapy

Yes.....1 Date: ____/____/____ (MM/DD/YYYY)

No2

C2h. Other

Yes.....1 Specify: _____

Date: ____/____/____ (MM/DD/YYYY)

No2

SECTION D. SUPPORTING DOCUMENTS TO BE SUBMITTED TO NERI

	<u>Source Document</u>	<u>Available</u>
	a.	b.
1.	Radiology report of last imaging showing no tumor nodule.	Yes.....1 No.....2
2.	Radiology report of first imaging showing suspicious nodule.	Yes.....1 No.....2
3.	Radiology report when patient first met criteria for definite/presumed HCC.	Yes.....1 No.....2
4.	Explant liver path report for patients who have undergone liver transplant.	Yes.....1 No.....2 N/A..... -1