

HALT-C Trial  
**Sustained Virologic Responder Follow-up Ancillary Study:**  
**Clinical Outcome**

Form # 763    Version A: 05/01/2008

**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:   \_\_ \_\_ \_\_

**SECTION B: CLINICAL OUTCOME**

**Please report one clinical outcome per form.**

B1. Using the code box below, enter the number that corresponds to the clinical outcome being reported.

**Clinical Outcome Codes**

- |  |    |                           |
|--|----|---------------------------|
| Death from any cause .....                             | 1  | (ALSO COMPLETE SECTION E) |
| Development of hepatocellular carcinoma .....          | 2  | (ALSO COMPLETE SECTION F) |
| CTP score of 7 or higher .....                         | 3  |                           |
| Variceal hemorrhage .....                              | 4  |                           |
| Ascites .....  | 5  |                           |
| Spontaneous bacterial peritonitis .....                | 6  |                           |
| Hepatic encephalopathy .....                           | 7  |                           |
| Liver transplant .....                                 | 8  | (ALSO COMPLETE SECTION G) |
| Development of presumed hepatocellular carcinoma ..... | 10 | (ALSO COMPLETE SECTION F) |

_____ - _____ - ____
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**SECTION C: SOURCE DOCUMENTS**

C1. Using the Source Document Code Table, indicate the available source documents for this clinical outcome

	<b>Source Document Code</b> If code = 99 (other) specify in space in box. a.	<b>Date</b> (MM / DD / YYYY) b.
1.	_____ Sp. _____	___ / ___ / _____
2.	_____ Sp. _____	___ / ___ / _____
3.	_____ Sp. _____	___ / ___ / _____
4.	_____ Sp. _____	___ / ___ / _____
5.	_____ Sp. _____	___ / ___ / _____
6.	_____ Sp. _____	___ / ___ / _____

- | <b>Source Document Codes</b>                     |
|--|
| 1. Endoscopy report                              |
| 2. Liver ultrasound report                       |
| 3. Physical exam report                          |
| 4. Liver biopsy report                           |
| 5. Operative report                              |
| 6. AFP result                                    |
| 7. Hospital record (e.g. clinic note, ER report) |
| 8. Liver MRI report                              |
| 9. Liver CT report                               |
| 10. Peritoneal tap results                       |
| 11. Paracentesis report                          |
| 12. Thoracentesis lab report                     |
| 13. Autopsy report                               |
| 14. Death report                                 |
| 15. Pathology report                             |
| 16. Lab report                                   |
| 17. Trails test results                          |
| 18. Explant histology report                     |
| 19. CXR report                                   |
| 99. Other (specify in C1a)                       |

**SECTION D: DESCRIPTION**

D1. Describe the clinical outcome including the clinical events and procedures that lead to the diagnosis of the clinical outcome:

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**IF REPORTED OUTCOME IS DEATH, COMPLETE SECTION E.**

**IF REPORTED OUTCOME IS DEFINITE HCC OR PRESUMED HCC, COMPLETE SECTION F.**

**IF REPORTED OUTCOME IS LIVER TRANSPLANT, COMPLETE SECTION G.**

**FOR OTHER TYPES OF OUTCOMES, FORM IS COMPLETE.**

\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**SECTION E: COMPLETE ONLY IF REPORTED OUTCOME IS DEATH**

E1. Date of death: (MM/DD/YYYY)

\_\_\_\_ / \_\_\_\_ / \_\_\_\_\_

E2. Information regarding the circumstances surrounding the death was obtained from (circle all that apply):

Social Security Death Index	Yes ..... 1	No..... 2
Family member	Yes ..... 1	No..... 2
Medical personnel	Yes ..... 1	No..... 2
Hospital records	Yes ..... 1	No..... 2
Autopsy Report	Yes ..... 1	No..... 2
Death Certificate	Yes ..... 1	No..... 2
Other	Yes ..... 1	No..... 2

E3. Is a copy of the Death Certificate available?

Yes ..... 1  
No ..... 2

**(ATTACH AND SEND DEATH CERTIFICATE)**

E4. Cause of death:

- a. immediate \_\_\_\_\_
- b. due to \_\_\_\_\_
- c. due to \_\_\_\_\_
- d. due to \_\_\_\_\_

E5. Classification of cause of death by a HALT-C site Principal Investigator (circle all that apply):

Hepatitis C related	Yes ..... 1	No..... 2
Liver related death	Yes ..... 1	No..... 2
Other	Yes ..... 1	No..... 2
Unknown – Sudden Death	Yes ..... 1	No..... 2
Unknown – No Information	Yes ..... 1	No..... 2

\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**SECTION F: COMPLETE ONLY IF REPORTED OUTCOME IS DEFINITE OR PRESUMED HCC**

F1. 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)

F2. Was the diagnosis of HCC made on the basis of histology?  
Yes.....1 (END OF SECTION F)  
No.....2

F3. Was the diagnosis of HCC determined by the presence of a new hepatic lesion with AFP >1000 ng/mL?  
Yes.....1 (END OF SECTION F)  
No.....2

F4. 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

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_

**SECTION G: COMPLETE ONLY IF REPORTED OUTCOME IS LIVER TRANSPLANT**

G1. Date patient first received a liver transplant: (MM/DD/YYYY) \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_

G2. Was this patient diagnosed to have HCC prior to transplant?

- Yes..... 1
- No .....2
- Unknown .....-8

G3. Does the liver pathology report show HCC in the explant liver?

- Yes..... 1
- No .....2
- Report not available .....3