

HALT-C Trial

**Sustained Virologic Responder Follow-up Ancillary Study:  
Clinical Outcome Review**

Form # 765    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: \_\_\_\_ \_\_\_\_

A5. Clinical Outcome Number: \_\_\_\_\_

**SECTION B: SOURCE DOCUMENTS**

B1. Date clinical outcome information received by DCC: (MM/DD/YYYY)    \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_

B2. Type of outcome: (Enter code from the Clinical Outcome Codes table below)    \_\_\_\_

**Clinical Outcomes**

1. Death
2. Development of hepatocellular carcinoma
3. CTP score of 7 or higher at two consecutive study visits
4. Variceal hemorrhage
5. Ascites
6. Spontaneous bacterial peritonitis
7. Hepatic encephalopathy
8. Liver transplant
10. Development of **presumed** hepatocellular carcinoma

Clinical Outcome Number: \_\_\_\_

B2. Source documents received:

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

- Source Document Codes**
1. Endoscopy report
  2. Liver ultrasound report
  3. Physical exam report
  4. Liver biopsy report
  5. Operative report
  6. AFP report
  7. Hospital record (e.g. clinic note, ER record, discharge summary)
  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. Trail test results
  18. Explant histology report
  19. CXR report
  99. Other (Explain in B1a)

Clinical Outcome Number: \_\_\_\_

**SECTION C: FIRST REVIEWER SHIPMENT AND RECEIPT**

C1. Reviewer 1 initials: \_\_\_\_ a. Date information shipped: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

b. Date response received: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**SECTION D: SECOND REVIEWER SHIPMENT AND RECEIPT**

D1. Reviewer 2 initials: \_\_\_\_ a. Date information shipped: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

b. Date response received: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**SECTION E: THIRD REVIEWER SHIPMENT AND RECEIPT**

E1. Is a third reviewer needed for this outcome? Yes ..... 1

No ..... 2 (F1)

E2. Reviewer 3 initials: \_\_\_\_

E3. Date information shipped: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

E4. Date response received: \_\_\_\_ / \_\_\_\_ / \_\_\_\_





Clinical Outcome Number: \_\_\_\_

**SECTION H: THIRD REVIEWER RESPONSE**

H1. Is a third reviewer needed for this outcome? Yes ..... 1  
No ..... 2 (Section I)

Complete the information below using the attached source documentation:

H2. Reviewer 3 initials: \_\_\_\_ a. Date information received: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

H3. Type of outcome: \_\_\_\_

- | <u>Clinical Outcomes</u> |  |
|--------------------------|--|
| 1.                       | Death  |
| 2.                       | Development of hepatocellular carcinoma                  |
| 3.                       | CTP score of 7 or higher at two consecutive study visits |
| 4.                       | Variceal hemorrhage                                      |
| 5.                       | Ascites  |
| 6.                       | Spontaneous bacterial peritonitis                        |
| 7.                       | Hepatic encephalopathy                                   |
| 8.                       | Liver transplant   |
| 10.                      | Development of <b>presumed</b> hepatocellular carcinoma  |

H4. Has the clinical outcome been met? Yes ..... 1  
No ..... 2 (H6)

H5. Date patient met criteria for the outcome: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (H7)

H6. Reason(s) why reviewer did not agree: (circle all that apply)	<u>Yes</u>	<u>No</u>
a. Although present, condition does not meet outcome criteria	1	2
b. Inadequate or incorrect source documentation	1	2
c. Other:	1	2

Specify: \_\_\_\_\_

H7. Explain reason(s) the clinical outcome was, or was not, met:

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Clinical Outcome Number: \_\_\_\_

**SECTION I: RESULT**

I1. Initials of the person completing this section: \_\_\_\_

I2. Was the clinical outcome met? Yes ..... 1

No ..... 2 (END OF FORM)

I3. Date patient met criteria for the outcome: \_\_\_\_ / \_\_\_\_ / \_\_\_\_