

HALT-C Trial

Clinical Outcome Review

Form # 65 Version C: 10/15/2003

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: _ _ _ _

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) _ _ _

<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
9. Meets 1999 criteria for UNOS transplant Status 2b
10. Development of presumed hepatocellular carcinoma

B3. Adverse Event Number (from question B1, on form # 60, Adverse Event):
If this is not an Adverse Event please enter -1 for not applicable.

Clinical Outcome Number: _____

B4. Source documents received:

	Source Document Code (If code = 99 (other) specify in box) a.	Date 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)

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: ___/___/_____

Clinical Outcome Number: ___ __ __

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 F: REVIEWER 1 RESPONSE

Complete the information below using the attached source documentation:

F1. Reviewer 1 initials: ___ ___ a. Date information received: ___ / ___ / ___

F2. 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 |
| 9. | Meets 1999 criteria for UNOS transplant Status 2b |
| 10. | Development of presumed hepatocellular carcinoma |

F3. Has the clinical outcome been met? Yes 1
No 2 **(F5)**

F4. Date patient met criteria for the outcome: ___ / ___ / ___ **(F6)**

F5. 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: _____

F6. Explain reason(s) the clinical outcome was, or was not, met:

Clinical Outcome Number: ___ ___

SECTION G: REVIEWER 2 RESPONSE

Complete the information below using the attached source documentation:

G1. Reviewer 2 initials: ___ ___ a. Date information received: ___ / ___ / ___

G2. 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 |
| 9. | Meets 1999 criteria for UNOS transplant Status 2b |
| 10. | Development of presumed hepatocellular carcinoma |

G3. Has the clinical outcome been met? Yes 1
No 2 (G5)

G4. Date patient met criteria for the outcome: ___ / ___ / ___ (G6)

G5. 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: _____

G6. Explain reason(s) the clinical outcome was, or was not, met:

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 |
| 9. | Meets 1999 criteria for UNOS transplant Status 2b |
| 10. | Development of presumed 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:

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: ___ ___ / ___ ___ / ___ ___