HALT-C Trial

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

Form # 765 Version A: 05/01/2008

SECTION A: GENERA	AL INFORMATION
A1. Affix ID Label Here	→
A2. Patient initials:	 _
A3. Date form complete	d: MM / DD / YYYY / /
A4. Initials of person co	mpleting form:
A5. Clinical Outcome No.	umber:
SECTION B: SOURC	E DOCUMENTS
B1. Date clinical outco	ome information received by DCC: (MM/DD/YYYY)//
B2. Type of outcome:	(Enter code from the Clinical Outcome Codes table below)
	Clinical Outcomes
	1. Death
	Development of hepatocellular carcinoma
	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

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Clinical Outcome Number:

B2. Source documents received:

	Source Document Code (If code = 99 (other)	Date MM/DD/YYYY	
	specify in box) a.	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
- 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)

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Clinical Outcome Number:	
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SECTION C: FIRST REVIEWER SHIPMENT AND RECEIPT

C1. Reviewer 1 initials:	a. Date information shipped:	//
	b. Date response received: _	//
SECTION D: SECOND REVIEWER SHIPI	MENT AND RECEIPT	
D1. Reviewer 2 initials:	a. Date information shipped:	/
	b. Date response received: _	///
SECTION E: THIRD REVIEWER SHIPME	ENT AND RECEIPT	
E1. Is a third reviewer needed for this outco	ome?	Yes 1
		No 2 (F1)
E2. Reviewer 3 initials:		
E3. Date information shipped:/	_/	
E4. Date response received:/	_/	

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SECTION F: REVIEWER 1 RESPONSE

Complete the information below	using the attached source documenta	tion:	
F1. Reviewer 1 initials:	a. Date information receiv	ed: /	_/
F2. Type of outcome:	Clinical Outcomes 1. Death 2. Development of hepatocellular carcino 3. CTP score of 7 or higher at two consect 4. Variceal hemorrhage 5. Ascites 6. Spontaneous bacterial peritonitis 7. Hepatic encephalopathy 8. Liver transplant 10. Development of presumed hepatocellular	cutive study visits	
F3. Has the clinical outcome bee	n met?	Yes 1	-
		No 2	? (F5)
F4. Date patient met criteria for t	he outcome: / / /	(F6)	
F5. Reason(s) why reviewer did	not agree: (circle all that apply) ion does not meet outcome criteria	<u>Yes</u> 1	<u>No</u> 2
b. Inadequate or incorrect s		1	2
c. Other:		1	2
F6. Explain reason(s) the clinica	I outcome was, or was not, met:		

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Clinical Outcome Number:	
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SECTION G: REVIEWER 2 RESPONSE

Complete the information below	using the attached source documentat	ion:	
G1. Reviewer 2 initials:	a. Date information receive	ed: /	/
G2. Type of outcome:	Clinical Outcomes 1. Death 2. Development of hepatocellular carcinom 3. CTP score of 7 or higher at two consecu 4. Variceal hemorrhage 5. Ascites 6. Spontaneous bacterial peritonitis 7. Hepatic encephalopathy 8. Liver transplant 10. Development of presumed hepatocellular	tive study visits	3
G3. Has the clinical outcome bee	en met?	Yes	1
		No	2 (G5)
G4. Date patient met criteria for	the outcome: / / /	(G6)	
G5. Reason(s) why reviewer did		<u>Yes</u>	<u>No</u>
a. Although present, condition does not meet outcome criteriab. Inadequate or incorrect source documentation		1 1	2
c. Other:		1	2
Specify:			
G6. Explain reason(s) the clinical	al outcome was, or was not, met:		

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SECTION H: THIRD REVIEWER RESPONSE

H1. Is a third reviewer needed for this outcome?		Yes	Yes 1	
		No	. 2 (Section I)	
Complete the information bel	ow using the attached source documentat	ion:		
H2. Reviewer 3 initials:	a. Date information receive	ed: /	/	
H3. Type of outcome:				
	1. Death 2. Development of hepatocellular carcinom 3. CTP score of 7 or higher at two consect 4. Variceal hemorrhage 5. Ascites 6. Spontaneous bacterial peritonitis 7. Hepatic encephalopathy 8. Liver transplant 10. Development of presumed hepatocellul	itive study visits		
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, co	ndition does not meet outcome criteria	1	2	
·	ect source documentation	1	2	
c. Other:		1	2	
• •	nical outcome was, or was not, met:			

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Clinical Outcome Number:

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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:	/	/		

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