

HALT-C Trial
Central Death Review

Form # 964 Version A: 01/09/2009

SECTION A: GENERAL INFORMATION

- A1. Affix ID Label Here → _ _ _ - _ _ _ - _ _
- A2. Patient initials: _ _ _ _
- A3. Date of review: MM / DD / YYYY _ _ _ / _ _ _ / _ _ _ _
- A4. Number of reviewers: _____
- A5. Clinical Outcome Number: _ _ _ _

SECTION B: CENTRAL REVIEW DETERMINATION

- B1. What was the primary cause of death? (CIRCLE ONE)
- Disease of the heart..... 1
 - Malignant neoplasm (not HCC)..... 2
 - Cerebrovascular disease 3
 - Chronic lower respiratory disease 4
 - Accidental (unintentional injuries) 5
 - Alzheimer's disease..... 6
 - Diabetes mellitus 7
 - Influenza & pneumonia 8
 - Renal disease..... 9
 - Septicemia..... 10
 - Intentional self-harm (suicide)..... 11
 - Chronic liver disease and cirrhosis..... 12
 - Hepatocellular carcinoma (HCC) 13
 - Other known cause..... 14
- SPECIFY: _____
- Unable to determine (insufficient data)..... 15

Clinical Outcome Number: _ _ _

Causality Codes		
<i>Causality score</i>	<i>Likelihood</i>	<i>Description</i>
Definite or highly likely	≥ 75%	The evidence for causality is “beyond a reasonable doubt” or “clear and convincing”.
Probable	50 to 74%	The causality is supported by “the preponderance of the evidence” but the evidence cannot be considered definite or highly likely.
Possible	25 to 49%	The causality is not supported by “the preponderance of the evidence”; however, one cannot exclude the possibility.
Unlikely	< 25%	The evidence for causality is “highly unlikely” based upon the available information.

B2. Was hepatitis C related liver disease a contributing cause of death? (CIRCLE ONE)

Yes 1 (GO TO QUESTION B2a)

No (likelihood < 25%)..... 2 (SKIP TO QUESTION B3)

B2a. Using the code box above, what is the likelihood that hepatitis C related liver disease was a contributing cause of death? (CIRCLE ONE)

Definitely or highly likely (likelihood ≥ 75%) 1

Probably (likelihood 50 - 74%)..... 2

Possibly (likelihood 25 - 49%) 3

B3. Was interferon therapy a contributing cause of death? (CIRCLE ONE)

Yes 1 (GO TO QUESTION B3a)

No (likelihood < 25%)..... 2 (END OF FORM)

B3a. Using the code box above, what is the likelihood that interferon therapy was a contributing cause of death? (CIRCLE ONE)

Definitely or highly likely (likelihood ≥ 75%) 1

Probably (likelihood 50 - 74%)..... 2

Possibly (likelihood 25 - 49%) 3