HALT-C Trial Q X Q

Clinical Outcome Review

Form # 65 Version C: 10/15/2003

Purpose of Form #65: This form is used to document the evaluation of reported primary clinical outcomes, secondary clinical outcomes requiring permanent cessation of Trial medication, or presumed hepatocellular carcinoma. Reported events are evaluated by a three member Outcome Review Board, consisting of a rotating group of HALT-C Trial Investigators.

When to complete Form #65: This form is completed each time one of the above events is reported to the Data Coordinating Center (DCC). A DCC staff person completes Sections A-E and I. Outcome Review Board members complete Sections F, G, and H.

Procedure for completing Sections F, G, and H of Form #65: Each reviewer will receive a packet of information about an event. This packet will include:

- A cover letter detailing the type of outcome and attached documents.
- A single page of Form 65 to complete and return to the DCC.
- A copy of the relevant Clinical Outcome definition and criteria from the MOO Appendix I-2.
- A blinded copy of the Description from Form 63 (Clinical Outcome) written by a staff member at the reporting clinical center.
- Blinded copies of source documents provided by the reporting clinical center.

REVIEWER RESPONSES.

Section F is Reviewer 1; Section G is Reviewer 2; Section H is Reviewer 3 (Tiebreaker)

H1. A third reviewer is required if Reviewers 1 and 2 do not have identical answers to Questions F3 and G3. When this occurs, DCC staff will answer question H1 “Yes” and request a tiebreaker review.

F1/G1/H2. The DCC staff will fill in your initials on this question.

F1/G1/H2(a). Enter the date you received the packet of information using the MM/DD/YYYY format.

F2/G2/H3. The DCC staff will complete this question. Refer to the code box to determine which clinical outcome is being assessed for this particular review.

F3/G3/H4. The DCC staff will include a copy of the relevant Clinical Outcome definition and criteria from the MOO Appendix 1-2. Review the source documentation regarding the event and compare to the Clinical Outcome definition and criteria. Determine if the event met the HALT-C criteria.

- **If you decide the event <u>met</u> the clinical outcome criteria,** circle “Yes” or "1", answer F4/G4/H5, and skip question F5/G5/H6.

  F4/G4/H5. The DCC staff will include a copy of the relevant Clinical Outcome definition and criteria from the MOO Appendix 1-2. Review the source documentation regarding the event and determine when the event first fulfilled Clinical Outcome criteria.

- **If you decide the event <u>did not meet</u> the clinical outcome criteria,** circle “No” or "2", skip question F4/G4H/5, and answer question F5/G5/H6.

  F5/G5/H6. Circle “Yes” or “No” for all reasons that the clinical outcome was not met. For “other," please specify the reason in the space provided. 100 characters (including spaces and punctuation) are provided.

F6/G6. Explain your reasoning why the event met or did not meet the clinical outcome criteria. 750 spaces are provided.

Return your form to DCC by fax or by Federal Express within two weeks of receipt. Please keep a copy of your form in case the DCC does not receive your reply.

DCC Contact Information

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