HALT-C Trial Q x Q

Study Visit

Form # 10 Version B: 10/01/2001

Purpose of Form #10: The Study Visit form uses interview format to document any overnight hospitalizations, day surgery, visits to a healthcare provider, and/or changes in health the patient may have had since the last study visit. The form also records the patient's method of contraception and any doses of trial medication that the patient may have missed.

When to complete Form #10: This form should be completed for all patients at each study visit, beginning with the Week 2 (W02) study visit for Lead-In patients or the Month 9 (M09) visit for Express patients.

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.

A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

A3. Enter the three-digit code corresponding to this visit.

A4. Record the date of this visit using MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

SECTION B: HOSPITALIZATION, SURGERY, VISIT TO A HEALTHCARE PROVIDER, AND CHANGES IN HEALTH

The purpose of this section is to assess the need to obtain additional information from the patient regarding their health status since the last visit. This section should be administered using appropriate interview technique. The patient diary should be referred to as necessary.

If the patient answers YES to any question, complete the interview as written. Once the interview is concluded, you may probe the patient for additional information to determine if an Adverse Event Form #60, a Serious Adverse Event Form #61, or a Clinical Outcome Form #63 should be completed.

For each hospitalization, surgery, visit to a healthcare provider, and if appropriate, changes in health, have the patient sign a medical record release form.

B1. If the patient was hospitalized overnight for any reason since the last study visit, circle 1 for YES. Otherwise, circle 2 for NO.

B2. If the patient had surgery not requiring an overnight stay in the hospital for any reason since the last study visit, circle 1 for YES. Otherwise, circle 2 for NO.

B3. If the patient saw a healthcare provider since the last study visit for any reason not previously discussed, including any visit to an emergency room (unless the patient was admitted to the hospital from the emergency room), circle 1 for YES. Otherwise, circle 2 for NO.

B4. If the patient had a change in health (including new or changing symptoms) since the last study visit not previously discussed, circle 1 for YES. Otherwise, circle 2 for NO.

SECTION C: ADEQUATE CONTRACEPTION

For female patients, Section C should be completed at each study visit.

For male patients, Section C should be completed while the patient is taking interferon-ribavirin combination therapy and for 6 months thereafter as follows:
- Lead in phase: Complete at all visits, beginning with Week 2 (W02)
- Randomized phase: Complete at M09
- Week 20 responders: Complete at W30-W60

For all other visits for male patients, record "-1" for question C1 and then skip to section D.

C1. Use standard interview technique to review the method(s) of contraception the patient is using. A "-1" should be recorded in the next box after filling in all applicable codes.

- Enter the code(s) corresponding to each method of contraception that the patient or the patient's partner is using.

- Code of 5, "Barrier method plus contraceptive jelly":
  - The patient must be using a barrier method AND contraceptive jelly or foam.

- Code of 6, "Patient or patient's partner not of childbearing potential" includes:
  - Women who have had a hysterectomy, their fallopian tubes or ovaries removed, or are menopausal. A diagnosis of infertility should NOT be included.
  - Male partners of male patients.

- If the patient or patient's partner is using a type of contraception for which a code is not listed, enter a code of 99 for "other" and specify the type in the space provided.

- Enter a code of 99 for "other" if a female patient is in the control group, and specify "Pt. In control group" in the space provided.

SECTION D: MISSED DOSES OF TRIAL MEDICATION(S)

This section documents the doses of either HALT-C Peginterferon alfa-2a or Ribavirin the patient may have missed.

Use the patient diary to review any documented missed doses. Record missed doses on this form IF:
- Initiated by the patient
- Initiated by non-HALT-C personnel (such as the patient's primary care physician)
- Less than 2 consecutive doses of interferon
- Less than 4 consecutive doses of ribavirin

Form #28 and/or Form #29 should be used for recording missed doses or dose adjustments due to the protocol or the HALT-C PI's discretion.

D1. Since the last Form #10 was completed, did the patient take any Peginterferon alfa-2a for the HALT-C Trial? If yes, then record either a YES or NO.

- Circle 1 for YES if the patient was expected to take any Peginterferon alfa-2a since the last time a Form #10 was completed and missed one or more doses. Continue to Question D2.
- Circle 2 for No if the patient was expected to take any Peginterferon alfa-2a since the last time a Form #10 was completed and did not miss any doses. Skip to Question D4.
- Circle 3 for N/A if the patient was not expected to take any Peginterferon alfa-2a since the last time a Form #10 was completed. Skip to Question D4.
- Circle 3 for N/A if the patient is in the control group and has taken any Peginterferon from a non-HALT-C physician since the last time a Form #10 was completed. (Record the non-HALT-C Peginterferon on Medications Interview Form #12.) Skip to Question D4.

D2. Indicate the number of doses of Peginterferon alfa-2a not taken since the last study visit. Include only those doses of Peginterferon alfa-2a the patient has missed entirely (regardless of the reason) and did not take at a later time to stay on the medication schedule.

- If the patient took a reduced dose of Peginterferon alfa-2a, record the dose reduction on the Peginterferon alfa-2a Dose Adjustments Form #28.

D3a. Enter the date(s) the patient did not take the dose(s) using MM/DD/YYYY format.

D3b. Using the code box, indicate the reason the dose(s) was not taken.

- If using “Other” code 99, explain on the line provided. Forty characters (including punctuation and spaces) are provided.

D4. Since the last Form #10 was completed, did the patient take any ribavirin for the HALT-C Trial? If yes, then record either a YES or NO.

- Circle 1 for YES if the patient was expected to take any ribavirin since the last time a Form #10 was completed and missed one or more doses. Continue to Question D5.
- Circle 2 for No if the patient was expected to take any ribavirin since the last time a Form #10 was completed and did not miss any doses. The form is complete.
- Circle 3 for N/A if the patient was not expected to take any ribavirin since the last time a Form #10 was completed. The form is complete.
- Circle 3 for N/A if the patient is in the control group and has taken any ribavirin from a non-HALT-C physician since the last time a Form #10 was completed. (Record the non-HALT-C ribavirin on Medications Interview Form #12.) The form is complete.

D5. Indicate the number of doses of ribavirin not taken since the last study visit. Include only those doses of ribavirin the patient has missed entirely (regardless of the reason) and did not take at a later time to stay on the medication schedule.

- If the patient took a reduced dose of ribavirin, record the dose reduction on the Ribavirin Dose Adjustments Form #29.

D6. Using the code box, indicate the reason the dose(s) was not taken.

- If using "Other" code 99, explain on the line provided. Forty characters (including punctuation and spaces) are provided.

How do I answer the contraception question for control patients?

99"other" pt in control

__ __ - __ __ __ - __

SECTION C: ADEQUATE CONTRACEPTION

When to complete Section C

For women: complete at all study visits.

For men: complete while patient is taking interferon-ribavirin combination therapy and for 6 months thereafter.

- Lead in Phase: complete at all visits, W02 – W24.
- Randomized phase: complete at M09.
- Week 20 responders: complete at W30, W36, W42, W48, W60.

Male pts: Skip after Month 9

C1. What method(s) of contraception will the patient and/or the patient's partner(s) be using? 99 ☐ ☐ ☐

If other, then specify Pt in control group

Contraception Codes

1. Oral contraceptives
2. Nor-plant implant
3. IUD
4. Depo-provera injections
5. Barrier method (diaphragm, condom or cervical cap) plus contraceptive jelly
6. Patient or patient's partner(s) not of childbearing potential

99. Other

Any pt who has N/A has Form # 28 stating dose = 0.

Since the last Form #10 was completed, did the pt take any Peg for the HALT-C Trial? If YES, then answer with either a YES or NO any doses missed not recorded on Form # 28.

SECTION D: MISSED DOSES OF TRIAL MEDICATION(S)

THIS SECTION IS TO RECORD ANY MISSED DOSES OF STUDY DRUG SINCE THE LAST VISIT WHICH WERE INITIATED BY THE PATIENT AND/OR NON-HALT-C PERSONNEL.

FORMS # 28 AND/OR # 29 SHOULD BE USED FOR RECORDING HELD DOSES OR DOSE ADJUSTMENTS DUE TO THE PROTOCOL OR PI'S DISCRETION. (SEE QXQ FOR CLARIFICATION).

D1. If the patient was on Peginterferon alfa-2a were there any doses not taken since the last study visit, not recorded on form # 28? (Not taken later to stay on medication schedule)

Yes..... 1

No..... 2 (D4)

N/A..... 3 (D4)

Pt in control group but is taking peg not associated with HALT-C: N/A ◯

Pt in control group: N/A ◯

Pt in tx group, but has refused to take peg: N/A ◯

HALT-C Trial Form # 10 Version B: 10/01/2001 Page 2 of 3

Pt in tx group, remains taking peg since last visit, except one time when the dentist told him to stop for one week: YES ☐

Pt in tx group, remains taking peg since last visit, has missed no doses: NO △

Pt in tx group, was taken off peg since last visit by HALT-C PI & remains off peg: N/A ◯