HALT-C Trial Q x Q

Trial ID Assignment

Form # 1 Version B: 02/05/2001

Purpose of Form #1: The Trial ID Assignment form is used to enter a new or re-screened patient into the Trial Data Management System, and to assign an ID number to that patient. Form #1 includes some demographic and prior treatment questions, providing a way to capture this information for all patients who are eligible for screening for the HALT-C Trial – whether or not they enter the Trial.

When to complete Form #1:
The Trial ID Assignment form should be completed and data entered for all patients at your center who meet all of the three following criteria:

1. Evidence of Hepatitis C.

2. Adequate treatment with interferon.

3. Non-response to this particular course of interferon.

Rescreened patients:
Patients may be rescreened in accordance with the guidelines specified in the HALT-C protocol (Section G) and the Manual of Operations (Section D-1).

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the patient number legibly.
- **The patient ID number is the six-digit number that was assigned to this patient on the screening log.**
- The first two digits of the ID label represent the clinical site. The next three digits are assigned in sequential order on the screening log. The last number is a check digit used internally by the Trial Data Management System to prevent transpositional errors during data entry of study forms.

A2. Enter the patient's initials.
- Enter the patient's first initial in the first space provided, middle initial in the second space provided, and last initial in the third space provided.
- If the patient does not have a middle name, enter the first initial in the first space provided, leave the second space blank, and enter the last initial in the third space provided.
- If the patient has a hyphenated last name or 2 last names, enter the initial of the first last name in the last space.
- **Note: The patient initials used on Form #1 will be used for the duration of the HALT-C Trial.**
- **Important Note on Rescreened Patients: If the patient is being rescreened, the patient's initials may change at this point. If the patient's initials have changed since the previous screening visit, use the new initials.**

A3. Record the date that Form #1 was completed.
- When entering this date, use the MM/DD/YYYY format.
- Enter the 2-digit number for the month in the first 2 spaces provided (i.e., January = "01", February = "02", etc.), the 2-digit number for the day of the month in the second 2 spaces provided, and the 4-digit number for the year in the final 4 spaces provided.

A4. Enter the initials of the person completing Form #1.
- Enter the first initial in the first space provided, middle initial in the second space provided, and last initial in the third space provided.
- If the person does not have a middle name, enter the first initial in the first space provided, leave the second space blank, and enter the last initial in the third space provided.
- If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the last space.

SECTION B: PATIENT ID INFORMATION

B0. Indicate if a Form # 1 has been completed previously for this patient (i.e. the patient has been previously screened and found ineligible).
- If the patient has been screened previously, answer "Yes" and go on to question B0a.
- If the patient has not been screened previously, answer "No", and go on to question B1.

B0a. Record the patient's previous ID number, exactly as recorded on the Form #1 from the previous screening. Now the new patient ID will be linked to the old patient ID in the Data Management System.

B0b. Record the patient's previous initials, exactly as recorded on the Form # 1 from the previous screening.

B1. Record the patient's date of birth using the MM/DD/YYYY format.

B2. Record the patient's gender. Circle 1 for Male or circle 2 for female.

B3, 3a. Circle the answer that best describes the patient's racial background and the source of information. If possible, the patient should report his/her own race.
- If the patient is of Hispanic or Latino ethnicity, circle 1 for YES on Question B4. Continue to probe to determine patient race for Question B3.
- If the answer is "other", explain briefly on the "please specify" line. This answer should not be "Hispanic".

B4, 4a. Circle the answer that best describes the patient's ethnicity and the source of information. If possible, the patient should report whether he/she is Latino or Hispanic.

B5. Indicate if the patient will continue with screening for the HALT-C trial. In order to complete the screening process, there must be source documentation for: 1) Evidence of Hepatitis C; 2) An adequate course of treatment with interferon; and 3) The non-response to that treatment. The definitions for these are provided below (Section C).
- If the patient will continue with screening, answer "Yes" and go on to Section C.
- If "No", Form #1 is complete. Form # 5, Trial Ineligibility, must also be completed.

SECTION C: MOST RECENT ADEQUATE COURSE OF TREATMENT WITH INTERFERON

Note on Section C: All questions refer to the most recent adequate course of interferon treatment. The patient may have had other, more recent courses of interferon treatment that were inadequate; or in which the patient responded to treatment; or in which there was neither documentation for the course of treatment nor documentation of non-response. Record answers in Section C that refer to the most recent adequate documented course of interferon to which there is a documented non-response.

The definitions provided for adequate course of interferon and non-response to treatment must be used. If there is no documentation, the patient is not eligible for screening.

LEAD-IN PATIENTS

An adequate course of interferon for Lead-in patients is defined as:

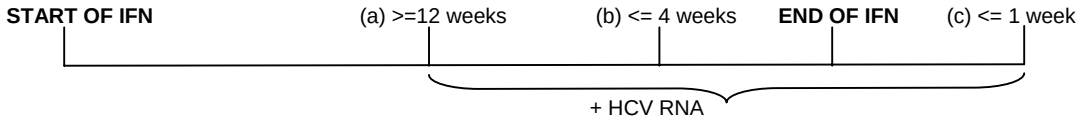
At least 12 weeks of treatment with either:

- Interferon at dosage of 3 MU tiw (three times a week) or 9 mcg tiw.
- Peg Intron A: 0.5 mcg (per kilogram of patient's weight) once a week
- Peginterferon alfa-2a: 90 mcg once a week

Non-Response for Lead-in patients is defined in the boxes below.

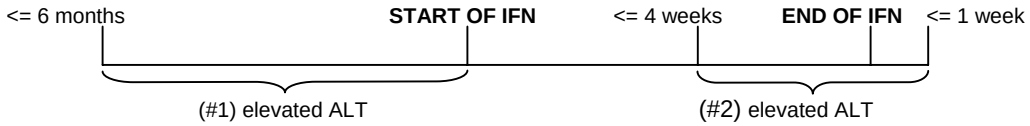
EITHER: A documented positive HCV RNA test EITHER:

a) on or after treatment week 12 on adequate course interferon therapy while still being treated; OR
b) within 4 weeks before discontinuing the most recent adequate course of interferon. This positive test must have occurred at treatment week 12 or later; OR
c) within 1 week after discontinuing the most recent adequate course of interferon. This positive test must have occurred at treatment week 12 or later.



OR: If virologic measurements were not performed or are unavailable from the most recent adequate treatment, two elevated serum ALT must be documented:

(1) within 6 months prior to the beginning of interferon treatment; AND
(2) within 4 weeks before OR within 1 week after discontinuing the course of interferon.



EXPRESS PATIENTS

An adequate course of interferon for Express patients is defined as intent to treat with:

- peginterferon alfa-2a 180 mcg/wk or peginterferon alfa-2b 1.5 mcg/kg/wk; AND
- 800 mg daily of ribavirin (minimum).
  - Dose adjustment is dependent on patient's tolerance to the drug(s) and is at the discretion of the treating physician.

Non-Response for Express patients is defined as a positive HCV-RNA obtained at least 20 weeks after the start of the adequate course of treatment with pegylated interferon with ribavirin and before Screening for HALT-C. This test may be obtained either on or off treatment.

C1. Record the start date of the patient's most recent adequate course of treatment with any type of interferon using the MM/DD/YYYY format.

C2. Refer to the list of codes on the form, and enter the code for the interferon preparation used during this course of treatment.
- If the patient took an interferon preparation other than one on the list, use code 99, "other" and specify the type of preparation on the line provided. Twenty-five characters, including punctuation and spaces, are provided.

C3. Enter the initial dose of interferon for this course of treatment, choosing either MU or mcg units based on the interferon preparation the patient took.

C4. Enter the number of doses per week the patient took during this course of treatment with interferon.

C5. Enter the **total** number of weeks the patient took interferon during this most recent adequate course of treatment. This total number of weeks should be the sum of the initial dose of interferon plus all adjusted doses of interferon, including weeks where the dose was zero.

C6. Was the dose of interferon adjusted during this most recent treatment?
- If the interferon dosage was not adjusted, answer "NO" and skip to question C7.
- If "Yes", complete items a – c for each interferon dose adjustment. Complete as many lines as necessary:

a. Record the adjusted dose of interferon, choosing either MU or mcg units based on the interferon preparation the patient took. If the patient temporarily skipped a few doses, record the dose as zero.

b. Record the number of times per week that interferon was taken during this period.

c. Record the number of weeks at this adjusted dose of interferon.

Reminder: The sum of all the weeks of adjusted interferon should be less than or equal to the total number of weeks that the patient took this most recent adequate course of interferon as recorded in C5.

C7. Record if Ribavirin was given with this most recent adequate course of interferon.
- If "Yes", complete questions C8 through C10.
- If "No", go to question C11.

C8. Enter the initial daily dosage of ribavirin, in mg, for this most recent adequate course of treatment with interferon.
- For example, if the patient takes 600 mg of ribavirin twice a day, enter 1200 mg.

C9. Enter the **total** number of weeks the patient took ribavirin during this most recent adequate course of interferon treatment. This total number of weeks should be the sum of the initial dose of ribavirin plus all adjusted doses of ribavirin given during this course of interferon treatment.

C10. Was the dose of ribavirin adjusted during this most recent treatment?

- If the ribavirin dosage was not adjusted, answer "NO" and skip to question C8.

For each ribavirin dose adjustment, complete items a – b. Complete as many lines as necessary:

a. Record the adjusted total daily dose of ribavirin for this most recent adequate course of treatment with interferon.
   - For example, if the patient takes 600 mg of ribavirin twice a day, enter 1200 mg.

b. Record the number of weeks at this adjusted dose of ribavirin.

Reminder: The sum of all the weeks of adjusted ribavirin should be less than or equal to the total number of weeks that the patient took ribavirin during this most recent adequate course of interferon, as recorded in C9.

C11. Record the code that represents the criteria used to determine the non-response to interferon treatment. (Refer to page 1 of this document: When to complete Form #1.)

- Enter "1" if the patient had a positive test for HCV RNA at any one of the following timepoints:
  - For Lead-in patients:
    1. On or after treatment week 12 on adequate interferon therapy while still being treated or
    2. Within 4 weeks prior to or 1 week after discontinuing the most recent adequate course of interferon. This positive test must have occurred at treatment week 12 or later.
  - For Express patients:
    1. positive HCV-RNA obtained at least 20 weeks after the start of the adequate course of treatment with pegylated interferon with ribavirin and before Screening for HALT-C.
    2. This test may be obtained either on or off treatment.

- Enter "2" if the Lead-in patient has had two elevated serum ALT's at both of the following times:
  - For Lead-in patients only:
    1. Within 6 months prior to the beginning of treatment
       and
    2. At anytime during 4 weeks prior to, or 1 week after stopping this course of interferon therapy. In other words, there must be 2 elevated serum ALT's.

- Enter "3" if the Lead-in patient had **both** a positive test for HCV RNA and elevated ALT as defined above.