HALT-C Trial Q x Q

Pregnancy Report

Form # 68 Version A: 06/15/2000

Purpose of Form #68: The Pregnancy Report form is used to report the pregnancy of a patient or a patient's partner(s) during the HALT-C Trial.

When to complete Form #68: Sites must report all pregnancies in patients and patients' partners that occur from the time the patient signs the Main Trial Screening consent form through Month 54 (M54) for patients who enter the Randomized Phase and Week 72 (W72) for patients who enter the Responder Phase. Pregnancy events may be reported at a study visit or between study visits.

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. Record the date this form was completed using MM/DD/YYYY format.

A4. Enter the initials of the person completing the form.

SECTION B: PREGNANCY REPORT

B1. Pregnancy:
- Circle "1" for a patient in HALT-C who is pregnant.
- Circle "2" for a partner of a patient in HALT-C who is pregnant.

B2. Last Menstrual Period Date:
- Record LMP of pregnant person using MM/DD/YYYY format.
- If exact date is not known, record month and year, indicating the day as unknown.

SECTION C: PEGINTERFERON ALFA-2A

C1. Peginterferon alfa-2a:

- Circle "1" for YES if the patient has taken Peginterferon alfa-2a during this pregnancy.
- Circle "2" for NO if the patient has **NOT** taken Peginterferon alfa-2a during this pregnancy.
- This report is only for recording peginterferon specifically dispensed for the HALT-C Trial. The purpose is to record whether there is any abnormality from HALT-C study drug(s). Any interferon given to the patient not dispensed through the HALT-C Trial will not be reported on this form.

C2. Peginterferon alfa-2a dose:

- Record the dose of Peginterferon alfa-2a the patient was taking at the onset of pregnancy in MU or mcg.

SECTION D: RIBAVIRIN

D1. Ribavirin:

- Circle “1” for YES if the patient has taken Ribavirin during this pregnancy.
- Circle “2” for NO if the patient has **NOT** taken Ribavirin during this pregnancy.
- This report is only for recording ribavirin specifically dispensed for the HALT-C Trial. The purpose is to record whether there is any abnormality from HALT-C study drug(s). Any ribavirin given to the patient not dispensed through the HALT-C Trial will not be reported on this form.

D2. Ribavirin dose:

- Record the dose of Ribavirin the patient was taking at the onset of pregnancy in mg.

SECTION E: SUMMARY INFORMATION ABOUT PREGNANCY

E1. Pregnancy summary:

- In the space provided, please give a brief summary of the pregnancy. It is important to state whether the pregnancy is normal or abnormal, whether the birth is normal or abnormal and whether the baby is normal or abnormal. If the pregnancy terminates through a miscarriage or abortion, state any abnormalities known and/or reason for termination. If there is no available information regarding the pregnancy, birth or outcome, state that the information is not known or attainable.