PEDS-C
Treatment Period Assessment Summary
Week 30 Visit

56141

PDC 51
Rev 0
03/30/2005

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week 0 3 0	assessdt mm / dd / yyyy	idn - -	letcode	corrfix ◯ Correction

Instructions

Use this form for patients in the Mono/Combo therapy group who had no viral disappearance at Week 24.

CRA Use Only

1.A. Is the patient willing and able to continue in the study? ◯ Yes ◯ No w30ptcnt

B. If **No**, date of the Withdrawal/Close-out Form: w30wddt mm / dd / yyyy

Vital Signs and Symptom Directed Physical

2.A. Has a Vital Signs and Symptom Directed Physical Exam form been completed? ◯ Yes ◯ No w30phexm

B. If **Yes**, date of the form: w30phxdt mm / dd / yyyy

Concurrent Medications and Conditions

3.A. *Ask the parent (or patient) the following question:* Has your child (have you) had any other problems since your last visit? ◯ Yes ◯ No w30ptprb

If **No**, skip to item 4.

B. Was a Serious Adverse Event Form completed? ◯ Yes ◯ No w30sae

C. If **Yes**, date of the SAE form: w30saedt mm / dd / yyyy

D. Was a Non-Serious Adverse Event Form completed? ◯ Yes ◯ No w30ae

E. If **Yes**, date of the AE form: w30aedt mm / dd / yyyy

4.A. *Ask the parent (or patient) the following question:* Has your child (have you) taken any new medicines, other than those given to you within this study, since the last visit? ◯ Yes ◯ No w30nwmed

If **No**, skip to item 5.

B. Has the Concurrent Medications Form been completed? ◯ Yes ◯ No w30meds

C. If **Yes**, date of the form: w30mdsdt mm / dd / yyyy

Signature: _____ **Certif. #:** staffid1 -

PEDS-C
Treatment Period Assessment Summary
Week 30 Visit

62571

PDC 51
Rev 0
03/07/2006

Please Use Black Pen To Fill Out Form.

Week # week: 030

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode

corrfix: ◯ Correction

Concurrent Medications and Conditions (Continued)

CRA Use Only

5.A. Is the patient a female at least 10 years of age? ◯ Yes ◯ No w30fem

If **No**, skip to item 6.

B. What was the first day of her last menstrual period? w30mnsdt: mm / dd / yyyy NA ◯ w30mnsna

C. Does she show secondary amenorrhea of 1 week or more? ◯ Yes ◯ No ◯ NA w30amnor

If **No** or **NA**, skip to item 7.

D. Was a serum pregnancy test done? ◯ Yes ◯ No w30spgst

If **No**, skip to item 7.

E. Date of the test: w30spgdt: mm / dd / yyyy

F. Serum pregnancy test result: ◯ Positive ◯ Negative w30spgrs

If **Negative**, skip to item 7.
If **Positive**, stop therapy and begin untreated follow-up at the next visit.

G. If **Positive**, Date of the Therapy Stop/Restart Form: w30ftrdt: mm / dd / yyyy

H. If **Positive**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ◯ Yes ◯ No w30pgrep

6.A. Is the patient a sexually active male? ◯ Yes ◯ No w30xactm

If **No**, skip to item 7.

B. Is his sexual partner pregnant? ◯ Yes ◯ No w30mpreg

If **No**, skip to item 7.
If **Yes**, stop therapy and begin untreated follow-up at the next visit.

C. If **Yes**, Date of the Therapy Stop/Restart Form: w30mtrdt: mm / dd / yyyy

D. If **Yes**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ◯ Yes ◯ No w30mprep

Signature: _____ **Certif. #:** staffid2 -

44475

PEDS-C
Treatment Period Assessment Summary
Week 30 Visit

Please Use Black Pen To Fill Out Form.

Week # week: 0 3 0

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode:

corrfix: ◯ Correction

Patient Study Drug Therapy

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ◯ Yes ◯ No w30mddry

B. If **Yes**, Diary start date: w30mdrdt: mm / dd / yyyy

8.A. Have there been any changes in the patient's doses? ◯ Yes ◯ No w30tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w30tdadt: mm / dd / yyyy

9.A. Has the patient's therapy been stopped for any reason? ◯ Yes ◯ No w30thrsp

B. If **Yes**, date of the Therapy Stop/Restart Form: w30thtdt: mm / dd / yyyy

10.A. Has the patient missed any doses since the last visit? ◯ Yes ◯ No w30msdos

B. If **Yes**, date of the Therapy Missed Dose Form: w30msddt: mm / dd / yyyy

CRA Use Only

List of Laboratory Tests Ordered at Week 30

	Done	Unable to obtain	
11.A. Hematology:	◯	◯	w30hmtst
B. Chemistry:	◯	◯	w30chmst

Signature: _____ **Certif. #:** staffid3 -