PEDS-C
Treatment Period Assessment Summary
Week 34 Visit

38947

Please Use Black Pen To Fill Out Form.

Week # week: 0 3 4

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code 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 w34ptcnt

B. If **No**, date of the Withdrawal/Close-out Form: w34wddt 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 w34phexm

B. If **Yes**, date of the form: w34phxdt 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 w34ptprb

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

B. Was a Serious Adverse Event Form completed? ○ Yes ○ No w34sae

C. If **Yes**, date of the SAE form: w34saedt mm / dd / yyyy

D. Was a Non-Serious Adverse Event Form completed? ○ Yes ○ No w34ae

E. If **Yes**, date of the AE form: w34aedt 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 w34nwmed

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

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No w34meds

C. If **Yes**, date of the form: w34mdsdt mm / dd / yyyy

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

PEDS-C
Treatment Period Assessment Summary
Week 34 Visit

17315

Please Use Black Pen To Fill Out Form.

Week # week: 0 3 4

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 w34fem

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

B. What was the first day of her last menstrual period? w34mnsdt: mm / dd / yyyy NA ○ w34mnsna

C. Does she show secondary amenorrhea of 1 week or more? ○ Yes ○ No ○ NA w34amnor

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

D. Was a serum pregnancy test done? ○ Yes ○ No w34spgst

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

E. Date of the test: w34spgdt: mm / dd / yyyy

F. Serum pregnancy test result: ○ Positive ○ Negative w34spgrs

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: w34ftrdt: 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 w34pgrep

6.A. Is the patient a sexually active male? ○ Yes ○ No w34xactm

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

B. Is his sexual partner pregnant? ○ Yes ○ No w34mpreg

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: w34mtrdt: 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 w34mprep

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

PEDS-C
Treatment Period Assessment Summary
Week 34 Visit

57114

PDC 53
Rev 0
04/04/2005

Please Use Black Pen To Fill Out Form.

Week # week: 0 3 4

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode:

corrfix: ○ Correction

Patient Study Drug Therapy

CRA Use Only

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No w34mddry

B. If **Yes**, Diary start date: w34mdrdt mm / dd / yyyy

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No w34tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w34tdadt mm / dd / yyyy

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w34thrsp

B. If **Yes**, date of the Therapy Stop/Restart Form: w34thtdt mm / dd / yyyy

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w34msdos

B. If **Yes**, date of the Therapy Missed Dose Form: w34msddt mm / dd / yyyy

List of Laboratory Tests Ordered at Week 34

	Done	Unable to obtain	
11.A. Hematology:	○	○	w34hmtst
B. Chemistry:	○	○	w34chmst

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