64834

PEDS-C
Treatment Period Assessment Summary
Week 32 Visit

PDC 52
Rev 0
03/30/2005

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week	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 w32ptcnt

B. If **No**, date of the Withdrawal/Close-out Form: w32wddt ___ / ___ / ____ (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 w32phexm

B. If **Yes**, date of the form: w32phxdt ___ / ___ / ____ (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 w32ptprb

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

B. Was a Serious Adverse Event Form completed? ◯ Yes ◯ No w32sae

C. If **Yes**, date of the SAE form: w32saedt ___ / ___ / ____ (mm / dd / yyyy)

D. Was a Non-Serious Adverse Event Form completed? ◯ Yes ◯ No w32ae

E. If **Yes**, date of the AE form: w32aedt ___ / ___ / ____ (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 w32nwmed

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

B. Has the Concurrent Medications Form been completed? ◯ Yes ◯ No w32meds

C. If **Yes**, date of the form: w32mdsdt ___ / ___ / ____ (mm / dd / yyyy)

Signature: ______________________ **Certif. #:** staffid1 ___ - ___

PEDS-C
Treatment Period Assessment Summary
Week 32 Visit

63711

PDC 52
Rev 0
03/30/2005

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week	assessdt __ / __ / ____ (mm dd yyyy)	idn __ - __ - __	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 w32fem

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

B. Was a serum pregnancy test done? ○ Yes ○ No w32spgst

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

C. Date of the test: w32spgdt __ / __ / ____ (mm dd yyyy)

D. Serum pregnancy test result: ○ Positive ○ Negative w32spgrs

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

E. If **Positive**, Date of the Therapy Stop/Restart Form: w32ftrdt __ / __ / ____ (mm dd yyyy)

F. 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 w32fpgrep

6.A. Is the patient a sexually active male? ○ Yes ○ No w32xactm

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

B. Is his sexual partner pregnant? ○ Yes ○ No w32mpreg

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: w32mtrdt __ / __ / ____ (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 w32mprep

Signature: ____________________ **Certif. #:** staffid2 __ - __

PEDS-C
Treatment Period Assessment Summary
Week 32 Visit

34623

Please Use Black Pen To Fill Out Form.

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

CRA Use Only

Patient Study Drug Therapy

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ◯ Yes ◯ No w32mddry

B. If **Yes**, Diary start date: w32mdrdt __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

8.A. Have there been any changes in the patient's doses? ◯ Yes ◯ No w32tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w32tdadt __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

9.A. Has the patient's therapy been stopped for any reason? ◯ Yes ◯ No w32thrsp

B. If **Yes**, date of the Therapy Stop/Restart Form: w32thtdt __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

10.A. Has the patient missed any doses since the last visit? ◯ Yes ◯ No w32msdos

B. If **Yes**, date of the Therapy Missed Dose Form: w32msddt __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

List of Laboratory Tests Ordered at Week 32

	Done	Unable to obtain	
11.A. Hematology:	◯	◯	w32hmtst
B. Chemistry / Pregnancy:	◯	◯	w32chmst

Signature: ______________________________ **Certif. #:** staffid3 __ __ - __ __ __