PEDS-C
Treatment Period Assessment Summary
Week 28 Visit

56648

PDC 30
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 w28patcont

B. If **No**, date of the Withdrawal/Close-out Form: w28wddt ___ / ___ / ____ (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 w28physexm

B. If **Yes**, date of the form: w28physexmdt ___ / ___ / ____ (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 w28patprob

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

B. Was a Serious Adverse Event Form completed? ○ Yes ○ No w28sae

C. If **Yes**, date of the SAE form: w28saedt ___ / ___ / ____ (mm dd yyyy)

D. Was a Non-Serious Adverse Event Form completed? ○ Yes ○ No w28ae

E. If **Yes**, date of the AE form: w28aedt ___ / ___ / ____ (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 w28newmed

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

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No w28meds

C. If **Yes**, date of the form: w28medsdt ___ / ___ / ____ (mm dd yyyy)

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

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19049

PDC 30
Rev 0
03/30/2005

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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 w28fem

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

B. Has a urine pregnancy test been done? ◯ Yes ◯ No w28upgst

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

C. Date of the urine test: w28upgdt (mm / dd / yyyy)

D. Urine pregnancy test result: ◯ Positive ◯ Negative w28upgrs

If **Negative**, skip to item 7.

E. If **Positive**, date of serum test: w28spgdt (mm / dd / yyyy)

F. Serum pregnancy test result: ◯ Positive ◯ Negative w28spgrs

If either the urine or serum test was **Positive**, stop therapy and begin untreated follow-up at the next visit.

G. If either **Positive**, Date of the Therapy Stop/Restart Form: w28ftrdt (mm / dd / yyyy)

H. If either **Positive**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ◯ Yes ◯ No w28fpgrep

6.A. Is the patient a sexually active male? ◯ Yes ◯ No w28xactm

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

B. Is his sexual partner pregnant? ◯ Yes ◯ No w28mpreg

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: w28mtrdt (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 w28mprep

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

PEDS-C
Treatment Period Assessment Summary
Week 28 Visit

11397

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 w28mddry

B. If **Yes**, Diary start date: w28mdrdt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

8.A. Have there been any changes in the patient's doses? ◯ Yes ◯ No w28tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w28tdadt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

9.A. Has the patient's therapy been stopped for any reason? ◯ Yes ◯ No w28thrsp

B. If **Yes**, date of the Therapy Stop/Restart Form: w28thtdt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

10.A. Has the patient missed any doses since the last visit? ◯ Yes ◯ No w28msdos

B. If **Yes**, date of the Therapy Missed Dose Form: w28msddt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

List of Laboratory Tests Ordered at Week 28

	Done	Unable to obtain	
11.A. Hematology:	◯	◯	w28hmtst
B. Chemistry:	◯	◯	w28chmst
C. Serum bank:	◯	◯	w28serbk

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