PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

12413

Please Use Black Pen To Fill Out Form.

Week # 0 2 4

Date of Assessment ___ / ___ / ___ (mm / dd / yyyy)

Patient ID ___ - ___ - ___

Patient Letter Code ___

○ **Correction**

Instructions

Use this form for all therapy groups at the Week 24 visit.

CRA Use Only

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

If **Yes**, skip to item 2.

B. If **No**, Date of Withdrawal / Close-out ___ / ___ / ___ (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** ○

B. If **Yes**, date of form: ___ / ___ / ___ (mm / dd / yyyy)

Anthropometry

	A. First measurement	B. Second measurement	C. Unable to measure
3. Height:	___.___ cm	___.___ cm	○
4. Weight:	___.___ kg	___.___ kg	○
5. Mid-arm circumference (right):	___.___ cm	___.___ cm	○
6. Biceps skinfold: (right):	___.___ mm	___.___ mm	○
7. Triceps skinfold: (right):	___.___ mm	___.___ mm	○
8. Subscapular skinfold: (right):	___.___ mm	___.___ mm	○
9. Iliac skinfold: (right):	___.___ mm	___.___ mm	○

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

PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

11707

Please Use Black Pen To Fill Out Form.

Week # 0 2 4

Date of Assessment ___ / ___ / ____ (mm / dd / yyyy)

Patient ID ___ - ___ - ___

Patient Letter Code ___

○ **Correction**

CRA Use Only

Anthropometry (Continued)

10.A. Has a DXA scan been performed? ○ **Yes** ○ **No**

B. If **Yes**, date of scan: ___ / ___ / ____ (mm / dd / yyyy)

11.A. Has a Bio-electrical Impedance Analysis been performed? ○ **Yes** ○ **No**

B. If **Yes**, date of BIA: ___ / ___ / ____ (mm / dd / yyyy)

12.A. Has the parent / patient been given the 3-day food diary? ○ **Yes** ○ **No**

B. If **Yes**, date of first diary day: ___ / ___ / ____ (mm / dd / yyyy)

13.A. Has the Physical Activity Assessment been completed? ○ **Yes** ○ **No**

B. If **Yes**, date completed: ___ / ___ / ____ (mm / dd / yyyy)

Concurrent Medication and Conditions

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

If **No**, skip to item 15.

B. Was a Concurrent Medical Conditions form completed? ○ **Yes** ○ **No**

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

C. Was a Serious Adverse Event form completed? ○ **Yes** ○ **No**

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

D. Was an Adverse Event form completed? ○ **Yes** ○ **No**

1. If **Yes**, date of AE form: ___ / ___ / ____ (mm / dd / yyyy)

Signature: _____ **Certif. #:** ___ - ____

PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

58900

PDC 29
Rev 1
08/05/2005

Please Use Black Pen To Fill Out Form.

Week # 0 2 4

Date of Assessment ___ / ___ / ___ (mm / dd / yyyy)

Patient ID ___ - ___ - ___

Patient Letter Code ___

○ Correction

Concurrent Medication and Conditions

CRA Use Only

15.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

If **No**, skip to item 16.

B. Was a Concurrent Medications form completed? ○ Yes ○ No

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

16.A. Is the patient a female at least 10 years of age? ○ Yes ○ No

If **No**, skip to item 17.

B. Has a serum pregnancy test been done? ○ Yes ○ No *w24srmptst*

If **No**, skip to item 18.

C. Date of serum test: ___ / ___ / ___ (mm / dd / yyyy)

D. Serum pregnancy test result: ○ Positive ○ Negative

If **Positive**, stop therapy and begin untreated follow-up at the next visit.
If **Negative**, skip to item 18.

E. If **Positive**, Date of the Therapy Stop/Restart Form: ___ / ___ / ___ (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

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

If **No**, skip to item 18.

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

If **No**, skip to item 18.
If **Yes**, stop therapy and begin untreated follow-up at the next visit.

C. If **Yes**, Date of the Therapy Stop/Restart Form: ___ / ___ / ___ (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

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

PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

35053

Please Use Black Pen To Fill Out Form.

Week # 0 2 4

Date of Assessment ___ mm / ___ dd / ____ yyyy

Patient ID ___ - ___ - ___

Patient Letter Code ___

○ **Correction**

CRA Use Only

Concurrent Medication and Conditions (Continued)

18.A. Has the patient had an ophthalmologic exam? ○ **Yes** ○ **No**

If **No**, skip to item 19.

B. If **Yes**, date of the Ophthalmology Summary:: ___ mm / ___ dd / ____ yyyy

C. Did the patient have new or worsening ocular disorders? ○ **Yes** ○ **No**

If **No**, skip to item 19.

D. If **Yes**, was the patient referred to an ophthalmologist? ○ **Yes** ○ **No**

E. If **Yes**, date of the referral: ___ mm / ___ dd / ____ yyyy

Patient Study Drug Therapy

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

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

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

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

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

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

22.A. Has the patient missed any doses since the last visit? ○ **Yes** ○ **No**

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

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

PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

58002

Please Use Black Pen To Fill Out Form.

Week # 0 2 4

Date of Assessment mm / dd / yyyy

Patient ID - -

Patient Letter Code

○ **Correction**

CRA Use Only

Depression Screen

23.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on ther CESD? ○ **Yes** ○ **No**

If **No**, skip to item 24.

B. If **Yes**, was the patient referred for depression management according to Protocol requirements? ○ **Yes** ○ **No**

If **No**, skip to item 24.
If **Yes**, continue drug therapy and begin a Depression Management Tracking Form.

List of Laboratory Tests Ordered at Week 24

	Done	Unable to obtain		Done	Unable to obtain
24.A. Hematology:	○	○	E. HCV-RNA (Research):	○	○
B. PT / PTT:	○	○	F. Thyroid function:	○	○
C. Chemistry / Pregnancy:	○	○	G. Serum bank:	○	○
D. HCV-RNA (Clinical):	○	○	H. Urinalysis:	○	○

Quality of Life Tests Administered at Week 24

Test Name	1. Completed Yes	1. Completed No	2. Form date mm / dd / yyyy	3. Completed by Patient	3. Completed by Parent
25.A. CHQ (Patient)	○	○	/ /	○	○
B. CHQ (Parent)	○	○	/ /	○	○
C. BRIEF (Parent)	○	○	/ /	○	○
D. CBCL (Parent)	○	○	/ /	○	○
E. ABCL (Parent)	○	○	/ /	○	○
F. LEC (Patient)	○	○	/ /	○	○
G. SF-36 (Parent)	○	○	/ /	○	○

Remember to obtain HCV-RNA test results and to use the Treatment Failure / Reassignment Report Week 24 to evaluate responses to therapy.

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