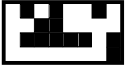


PEDS-C

Treatment Period Assessment Summary Week 24 Visit

PDC 29
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08/05/2005
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12413

Please Use Black Pen To Fill Out Form.

Week # [][] [][]	Date of Assessment [][] / [][] / [][][][] mm dd yyyy	Patient ID [][] - [][][][] - [][]	Patient Letter Code [][][]	Correction ○
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Instructions

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

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

CRA Use Only

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	○

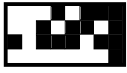
Signature: _____

Certif. #: [][] - [][][][]

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11707

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	<input type="checkbox"/>
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Correction
	mm dd yyyy			

Anthropometry (Continued)

CRA Use Only

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. #: -

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Treatment Period Assessment Summary

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58900

Please Use Black Pen To Fill Out Form.

Week #

Date of Assessment

mm
dd
yyyy

Patient ID

Patient Letter Code

Correction

Concurrent Medication and Conditions

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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 **w24srmpst**

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. #: _____

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35053

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	Correction
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
	mm dd yyyy			

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

CRA Use
Only

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. #: _____

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58002

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	<input type="radio"/>
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Correction
	mm dd yyyy			

Depression Screen

CRA Use Only

23.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on their 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:	<input type="radio"/>	<input type="radio"/>	E. HCV-RNA (Research):	<input type="radio"/>	<input type="radio"/>
B. PT / PTT:	<input type="radio"/>	<input type="radio"/>	F. Thyroid function:	<input type="radio"/>	<input type="radio"/>
C. Chemistry / Pregnancy:	<input type="radio"/>	<input type="radio"/>	G. Serum bank:	<input type="radio"/>	<input type="radio"/>
D. HCV-RNA (Clinical):	<input type="radio"/>	<input type="radio"/>	H. Urinalysis:	<input type="radio"/>	<input type="radio"/>

Quality of Life Tests Administered at Week 24

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

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

Signature: _____

Certif. #: _____

<input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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