

PEDS-C

Treatment Period Assessment Summary
Week 76 Visit (3B)

PDC 85
Rev 0
10/27/2005
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30106

Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> 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"/>	
	mm dd yyyy			

Instructions

Use this form for patients in the Mono / Combo therapy group who had no viral disappearance at Week 24 and viral disappearance at Week 52.

1.A. Is the patient willing and able to continue in the study?

Yes No *b76ptcnt*

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

b76wddt / /

CRA Use Only

Vital Signs

2.A. Temperature: *b76tmp* . C B. Site: Oral Tympanic Axillary Unable to obtain *b76tmpst*

3. Blood Pressure: A. Systolic *b76sysbp* mmHg B. Diastolic *b76diabp* mmHg Unable to obtain *b76bpna*

4. Pulse: *b76puls* bpm Unable to obtain *b76pulna*

Anthropometry

	A. First measurement	B. Second measurement	C. Unable to measure
5. Height:	<i>b76ht1</i> <input type="text"/> . <input type="text"/> cm	<i>b76ht2</i> <input type="text"/> . <input type="text"/> cm	<input type="radio"/> <i>b76htna</i>
6. Weight:	<i>b76wt1</i> <input type="text"/> . <input type="text"/> kg	<i>b76wt2</i> <input type="text"/> . <input type="text"/> kg	<input type="radio"/> <i>b76wtna</i>
7. Mid-arm circumference (right):	<i>b76arm1</i> <input type="text"/> . <input type="text"/> cm	<i>b76arm2</i> <input type="text"/> . <input type="text"/> cm	<input type="radio"/> <i>b76armna</i>
8. Biceps skinfold: (right):	<i>b76bskn1</i> <input type="text"/> . <input type="text"/> mm	<i>b76bskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>b76bsknna</i>
9. Triceps skinfold: (right):	<i>b76tskn1</i> <input type="text"/> . <input type="text"/> mm	<i>b76tskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>b76tsknna</i>
10. Subscapular skinfold: (right):	<i>b76sskn1</i> <input type="text"/> . <input type="text"/> mm	<i>b76sskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>b76ssknna</i>
11. Iliac skinfold: (right):	<i>b76iskn1</i> <input type="text"/> . <input type="text"/> mm	<i>b76iskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>b76isknna</i>

Signature: _____

Certif. #: *staffid1* -

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<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"/>
	<small>mm / dd / yyyy</small>			

Anthropometry (Continued)

CRA Use Only

12.A. Has a DXA scan been performed?

Yes No *b76dxa*

B. If Yes, date of scan:

b76dxadt / /

13.A. Has a Bio-electrical Impedance Analysis been performed?

Yes No *b76bia*

B. If Yes, date of BIA:

b76biadt / /

14.A. Has the parent / patient been given the 3-day food diary?

Yes No *b76fdry*

B. If Yes, date of first diary day:

b76fdrdt / /

15.A. Has the Physical Activity Assessment been completed?

Yes No *b76pact*

B. If Yes, date completed:

b76pacdt / /

Physical Exam

16. Indicate if each body area is within normal limits. If No, specify or comment.

1. Yes No NA 2. Specify / Comment

A. Head, eyes, ears: *b76head*

B. Nose, mouth, throat: *b76nose*

C. Neck: *b76neck*

D. Chest (including breasts, axillae): *b76chst*

E. Genitalia, groin, buttocks: *b76gntl*

F. Abdomen: *b76abdm*

G. Each extremity: *b76extm*

H. Back, including spine: *b76back*

I. Skin: *b76skin*

Signature: _____

Certif. #: _____

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<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"/>
	mm / dd / yyyy			

Physical Exam (Continued)

17. Indicate if each organ system is within normal limits. If **No**, specify or comment.

1. Yes No NA 2. Specify

- A. Neurologic: *b76neur*
- B. Psychologic: *b76psyc*
- C. Genitourinary: *b76gnto*
- D. Hematologic / Lymphatic: *b76hmto*
- E. Allergies / Immunologic: *b76allr*
- F. Musculoskeletal: *b76musc*
- G. Other: *b76othog*

CRA Use Only

18.A. Was the patient referred to another health professional? Yes No *b76refr*

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

B. Reason for referral: _____

C. Date of referral: / / *b76refdt*

D. Name of health professional: _____

19. Is the patient a sexually active female at least 10 years old or a sexually active male? Yes No *b76sexat*

If **No**, skip to item 21.

20. Indicate all types of contraception used (Answer each item):

- | | Yes | No | |
|---|-----------------------|-----------------------|-----------------|
| A. Oral contraceptive | <input type="radio"/> | <input type="radio"/> | <i>b76cnora</i> |
| B. Intrauterine contraceptive device | <input type="radio"/> | <input type="radio"/> | <i>b76cniud</i> |
| C. Depot contraceptives (implants, injectables) | <input type="radio"/> | <input type="radio"/> | <i>b76cndep</i> |
| D. Physical barrier (condom, diaphragm) | <input type="radio"/> | <input type="radio"/> | <i>b76cnphy</i> |
| E. Abstinence | <input type="radio"/> | <input type="radio"/> | <i>b76cnabs</i> |
| F. None | <input type="radio"/> | <input type="radio"/> | <i>b76cnnon</i> |
| G. Other | <input type="radio"/> | <input type="radio"/> | <i>b76cnoth</i> |

Specify *b76cnosp*

Signature: _____

Certif. #: *staffid3*

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Week # <i>week</i>	Date of Assessment <i>assesdtt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> 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"/>
	<small>mm / dd / yyyy</small>			

Concurrent Medications and Conditions

CRA Use Only

21.A. Ask the parent (or patient) the following question:

Has your child (have you) had any other problems since your last visit?

Yes No *b76ptprb*

If No, skip to item 22.

B. Was a Serious Adverse Event Form completed?

Yes No *b76sae*

C. If Yes, date of the SAE form:

b76saedt / /
mm / dd / yyyy

D. Was a Non-Serious Adverse Event Form completed?

Yes No *b76ae*

E. If Yes, date of the AE form:

b76aedt / /
mm / dd / yyyy

22.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 *b76nwmed*

If No, skip to item 23.

B. Has the Concurrent Medications Form been completed?

Yes No *b76meds*

C. If Yes, date of the form:

b76mdsdt / /
mm / dd / yyyy

23.A. Is the patient a female at least 10 years of age?

Yes No *b76fem*

If No, skip to item 24

B. Has a serum pregnancy test been done?

Yes No *b76spgst*

C. If Yes, date of the serum test:

b76spgdt / /
mm / dd / yyyy

D. If Yes, serum pregnancy test result:

Positive Negative *b76spgrs*

If the serum test was **Negative**, skip to item 25.
If the serum test was **Positive**, stop therapy and begin untreated follow-up at the next visit.

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

b76ftrdt / /
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 *b76fpgrep*

Skip to item 25.

Signature: _____

Certif. #: _____

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<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"/>
	mm dd yyyy			

Concurrent Medications and Conditions (Continued)

CRA Use Only

24.A. Is the patient a sexually active male?

Yes No *b76xactm*

If No, skip to item 25.

B. If Yes, is his sexual partner pregnant?

Yes No *b76mpreg*

If No, skip to item 25. If Yes, stop therapy and begin untreated follow-up at the next visit.

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

b76mtrdt
 / /

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 *b76mprep*

25.A. Has the patient had an ophthalmologic exam?

If No, skip to item 26.

Yes No *b76opexm*

B. If Yes, date of the Ophthalmology Summary:

b76opxdt
 / /

C. Did the patient have new or worsening ocular disorders?

If No, skip to item 26.

Yes No *b76opsym*

D. If Yes, was the patient referred to an ophthalmologist?

Yes No *b76opref*

E. If Yes, date of the referral:

b76oprdt
 / /

Patient Study Drug Therapy

26.A. Has the Patient Medication Diary been reviewed with the parent (patient)?

Yes No *b76mddry*

B. If Yes, Diary start date:

b76mrdrt
 / /

27.A. Have there been any changes in the patient's doses?

Yes No *b76tda*

B. If Yes, date of the Therapy Dose Adjustment Report:

b76tdadt
 / /

28.A. Has the patient's therapy been stopped for any reason?

Yes No *b76thrsp*

B. If Yes, date of the Therapy Stop/Restart Form:

b76thtdt
 / /

29.A. Has the patient missed any doses since the last visit?

Yes No *b76msdos*

B. If Yes, date of the Therapy Missed Dose Form:

b76msdtdt
 / /

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Certif. #: _____

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Week # <i>week</i>	Date of Assessment <i>assesdtdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
	mm / dd / yyyy	- - - -		

Depression Screen

30.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on the CES-D?

Yes No *b76cdi19*

If **No**, skip to item 31.

B. If **Yes**, was the patient referred for depression management according to Protocol requirements?

Yes No *b76refdp*

If **No**, skip to item 31.
If **Yes**, continue drug therapy and begin a Depression Management Tracking Form.

CRA Use Only

List of Laboratory Tests Ordered at Week 76

	Done	Unable to obtain
31.A. Hematology:	<input type="radio"/>	<input type="radio"/> <i>b76hmtst</i>
B. Chemistry / Pregnancy:	<input type="radio"/>	<input type="radio"/> <i>b76chmst</i>
C. HCV-RNA (Clinical):	<input type="radio"/>	<input type="radio"/> <i>b76vlcst</i>
D. Thyroid function:	<input type="radio"/>	<input type="radio"/> <i>b76thyst</i>
E. Serum bank:	<input type="radio"/>	<input type="radio"/> <i>b76serbk</i>
F. Urinalysis:	<input type="radio"/>	<input type="radio"/> <i>b76urnst</i>

Quality of Life Tests Administered at Week 76

Test Name	1. Completed		2. Form date			3. Completed by	
	Yes	No	mm	dd	yyyy	Patient	Parent
32.A. CHQ (Patient)	<input type="radio"/> <i>b76cht</i>	<input type="radio"/>	<i>b76chtdt</i>	/	/	<i>b76chtby</i>	<input type="radio"/>
B. CHQ (Parent)	<input type="radio"/> <i>b76chr</i>	<input type="radio"/>	<i>b76chrdt</i>	/	/	<i>b76chrby</i>	<input type="radio"/>
C. BRIEF (Parent)	<input type="radio"/> <i>b76brf</i>	<input type="radio"/>	<i>b76brfdt</i>	/	/	<i>b76brfby</i>	<input type="radio"/>
D. CBCL (Parent)	<input type="radio"/> <i>b76cbc</i>	<input type="radio"/>	<i>b76cbcdt</i>	/	/	<i>b76cbcby</i>	<input type="radio"/>
E. ABCL (Parent)	<input type="radio"/> <i>b76abc</i>	<input type="radio"/>	<i>b76abcdt</i>	/	/	<i>b76abcby</i>	<input type="radio"/>
F. LEC (Parent)	<input type="radio"/> <i>b76lec</i>	<input type="radio"/>	<i>b76lecdt</i>	/	/	<i>b76lecby</i>	<input type="radio"/>
G. SF-36 (Parent)	<input type="radio"/> <i>b76s36</i>	<input type="radio"/>	<i>b76s36dt</i>	/	/	<i>b76s36by</i>	<input type="radio"/>

Signature: _____

Certif. #: *staffid6* - _____