

PEDS-C

Treatment Period Assessment Summary  
Week 48 Visit

PDC 57  
Rev 0  
05/04/2005  
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55165

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.

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

Yes  No *w48ptcnt*

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

*w48wddt*  /  /

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 *w48phexm*

B. If **Yes**, date of the form:

*w48phxdt*  /  /

mm dd yyyy

Anthropometry

A. First measurement      B. Second measurement      C. Unable to measure

3. Height:	<i>w48ht1</i> <input type="text"/> . <input type="text"/> cm	<i>w48ht2</i> <input type="text"/> . <input type="text"/> cm	<input type="radio"/> <i>w48htna</i>
4. Weight:	<i>w48wt1</i> <input type="text"/> . <input type="text"/> kg	<i>w48wt2</i> <input type="text"/> . <input type="text"/> kg	<input type="radio"/> <i>w48wtna</i>
5. Mid-arm circumference (right):	<i>w48arm1</i> <input type="text"/> . <input type="text"/> cm	<i>w48arm2</i> <input type="text"/> . <input type="text"/> cm	<input type="radio"/> <i>w48armna</i>
6. Biceps skinfold: (right):	<i>w48bskn1</i> <input type="text"/> . <input type="text"/> mm	<i>w48bskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>w48bsknna</i>
7. Triceps skinfold: (right):	<i>w48tskn1</i> <input type="text"/> . <input type="text"/> mm	<i>w48tskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>w48tsknna</i>
8. Subscapular skinfold: (right):	<i>w48sskn1</i> <input type="text"/> . <input type="text"/> mm	<i>w48sskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>w48ssknna</i>
9. Iliac skinfold: (right):	<i>w48iskn1</i> <input type="text"/> . <input type="text"/> mm	<i>w48iskn2</i> <input type="text"/> . <input type="text"/> mm	<input type="radio"/> <i>w48isknna</i>

Signature: \_\_\_\_\_

Certif. #: *staffid1*  -

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Please Use Black Pen To Fill Out Form.

Week #  
*week*

Date of Assessment  
*assessdt*  
mm / dd / yyyy

Patient ID  
*idn*

Patient Letter Code  
*letcode*

*corrfix*  
Correction

Anthropometry (Continued)

CRA Use Only

10.A. Has a DXA scan been performed?

Yes  No *w48dxa*

B. If Yes, date of scan:

*w48dxadt*  
mm / dd / yyyy

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

Yes  No *w48bia*

B. If Yes, date of BIA:

*w24biadt*  
mm / dd / yyyy

12.A. Has the parent / patient been given the 3-day food diary and been instructed?

Yes  No *w48fdry*

B. If Yes, date of first diary day:

*w48fdrdt*  
mm / dd / yyyy

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

Yes  No *w48pact*

B. If Yes, date completed:

*w48pacdt*  
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 *w48ptprb*

If No, skip to item 15.

B. Was a Serious Adverse Event form completed?

Yes  No *w48sae*

C. If Yes, date of SAE form:

*w48saedt*  
mm / dd / yyyy

D. Was an Non-Serious Adverse Event form completed?

Yes  No *w48ae*

E. If Yes, date of AE form:

*w48aedt*  
mm / dd / yyyy

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 *w48nwmed*

B. Was a Concurrent Medications form completed?  
(Complete for all concurrent medications, including pre-dose medications)

Yes  No *w48meds*

C. If Yes, date of the form:

*w48mdsdt*  
mm / dd / yyyy

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

*staffid2*

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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
[ ][ ][ ]	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] <small>mm dd yyyy</small>	[ ][ ] - [ ][ ][ ][ ] - [ ][ ]	[ ][ ][ ]	

Concurrent Medication and Conditions (Continued)

CRA Use Only

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

Yes  No *w48fem*

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

B. Has a serum pregnancy test been done?

Yes  No *w48spgst*

C. If **Yes**, date of the serum test:

*w48spgdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
mm dd yyyy

D. If **Yes**, serum pregnancy test result:

Positive  Negative *w48spgrs*

If the serum test was **Negative**, skip to item 18.

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:

*w48ftrdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
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 *w48fpgrep*

Skip to item 18.

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

Yes  No *w48xactm*

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

B. If **Yes**, is his sexual partner pregnant?

Yes  No *w48mpreg*

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:

*w48mtrdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
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 *w48mprep*

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

*staffid3* [ ][ ] - [ ][ ][ ]

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Week #  **week**

Date of Assessment  **assesdtdt** /  /    
 mm dd yyyy

Patient ID  **idn** -  -

Patient Letter Code  **letcode**

**corrfix** Correction

Ophthalmology Exam

CRA Use Only

18.A. Has the patient had an ophthalmology exam?

Yes  No **w48opexm**

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

B. Date of Follow-Up Ophthalmology Summary:

**w48opxdtdt** /  /    
 mm dd yyyy

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

Yes  No **w48opsym**

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

D. Was the patient referred to another ophthalmologist?

Yes  No **w48opref**

E. If **Yes**, date of referral:

**w48oprtdt** /  /    
 mm dd yyyy

F. If **Yes**, name of the ophthalmologist: \_\_\_\_\_

Patient Study Drug Therapy

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

Yes  No **w48mddry**

B. If **Yes**, Diary start date:

**w48mdrtdt** /  /    
 mm dd yyyy

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

Yes  No **w48tda**

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

**w48tdadt** /  /    
 mm dd yyyy

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

Yes  No **w48thrsp**

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

**w48thtdt** /  /    
 mm dd yyyy

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

Yes  No **w48msdos**

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

**w48msdtdt** /  /    
 mm dd yyyy

List of Laboratory Tests Ordered at Week 48

23.A. Hematology:

Done  Unable to obtain  **w48hmtst**

B. Chemistry / Pregnancy:

**w48chmst**

Signature: \_\_\_\_\_

Certif. #:

**staffid4** -

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Quality of Life Tests Administered at Week 48

Test Name	1. Completed		2. Form date			3. Completed by		CRA Use Only
	Yes	No	mm	dd	yyyy	Patient	Parent	
24.A. CHQ (Patient)	<b>w48cht</b> <input type="radio"/>	<input type="radio"/>	<b>w48chtdt</b>	/	/	<b>w48chtby</b>		
B. CHQ (Parent)	<b>w48chr</b> <input type="radio"/>	<input type="radio"/>	<b>w48chrdt</b>	/	/	<b>w48chrby</b>		
C. BRIEF (Parent)	<b>w48brf</b> <input type="radio"/>	<input type="radio"/>	<b>w48brfdt</b>	/	/	<b>w48brfby</b>		
D. CBCL (Parent)	<b>w48cbc</b> <input type="radio"/>	<input type="radio"/>	<b>w48cbcdt</b>	/	/	<b>w48cbcbby</b>		
E. ABCL (Parent)	<b>w48abc</b> <input type="radio"/>	<input type="radio"/>	<b>w48abcdt</b>	/	/	<b>w48abcbby</b>		
F. LEC (Parent)	<b>w48lec</b> <input type="radio"/>	<input type="radio"/>	<b>w48lecdt</b>	/	/	<b>w48lecbby</b>		
G. SF-36 (Parent)	<b>w48s36</b> <input type="radio"/>	<input type="radio"/>	<b>w48s36dt</b>	/	/	<b>w48s36by</b>		

Signature: \_\_\_\_\_

Certif. #: **staffid5** -