

PEDS-C

Treatment Period Assessment Summary  
Week 32 Visit (3)

PDC 71  
Rev 0  
05/03/2005  
Page 1 of 3

39202

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
mm / dd / yyyy	mm / dd / yyyy	mm - dd - yyyy	mm / dd / yyyy	

Instructions

Use this form for patients in the original Mono or original Combo therapy groups with viral disappearance at Week 24.

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

Yes  No *a32ptcnt*

CRA Use Only

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

*a32wdt* 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 *a32phexm*

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

*a32phxd* 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 *a32ptprb*

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

B. Was a Serious Adverse Event Form completed?

Yes  No *a32sae*

C. If **Yes**, date of the SAE form:

*a32saedt* mm / dd / yyyy

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

Yes  No *a32ae*

E. If **Yes**, date of the AE form:

*a32aedt* 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 *a32nwmed*

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

B. Has the Concurrent Medications Form been completed?

Yes  No *a32meds*

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

*a32mstdt* mm / dd / yyyy

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

Certif. #:

*staffid1* - mm / dd / yyyy

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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
	mm / dd / yyyy	- - - - -		

Concurrent Medications and Conditions (Continued)

CRA Use Only

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

Yes  No *a32fem*

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

B. Was a serum pregnancy test done?

Yes  No *a32spgst*

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

C. Date of the test:

*a32spgdt* mm / dd / yyyy

D. Serum pregnancy test result:

Positive  Negative *a32spgrs*

If **Negative**, skip to item 7.  
If **Positive**, stop therapy and begin untreated follow-up at the next visit.

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

*a32ftrdt* 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 *a32pgrep*

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

Yes  No *a32xactm*

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

B. Is his sexual partner pregnant?

Yes  No *a32mpreg*

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:

*a32mtrdt* 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 *a32mprep*

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
mm	dd / yyyy	- - - -		

Patient Study Drug Therapy

CRA Use Only

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

Yes  No *a32mddry*

B. If Yes, Diary start date:

*a32mdrdt* mm / dd yyyy

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

Yes  No *a32tda*

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

*a32tdadt* mm / dd yyyy

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

Yes  No *a32thrsp*

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

*a32thtdt* mm / dd / yyyy

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

Yes  No *a32msdos*

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

*a32msdtdt* mm / dd / yyyy

List of Laboratory Tests Ordered at Week 32

11.A. Hematology:

Done	Unable to obtain
<input type="radio"/>	<input type="radio"/> <i>a32hmtst</i>

B. Chemistry / Pregnancy:

*a32chmst*

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

Certif. #: *staffid3* - [ ] [ ] [ ] [ ]