

PEDS-C

Treatment Period Assessment Summary
Week 30 Visit

PDC 51
Rev 0
03/30/2005
Page 1 of 3

56141

Please Use Black Pen To Fill Out Form.

Week # week	Date of Assessment assessdt	Patient ID idn	Patient Letter Code letcode	corrfix Correction
mm dd yy	mm / dd / yyyy	id - -		

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 **w30ptcnt**

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

w30wdt 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 **w30phexm**

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

w30phxdt 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 **w30ptprb**

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

B. Was a Serious Adverse Event Form completed?

Yes No **w30sae**

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

w30saedt mm / dd / yyyy

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

Yes No **w30ae**

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

w30aedt 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 **w30nwmed**

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

B. Has the Concurrent Medications Form been completed?

Yes No **w30meds**

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

w30mdsdt mm / dd / yyyy

Signature: _____

Certif. #:

staffid1 - mm - dd - yyyy

PEDS-C

Treatment Period Assessment Summary
Week 30 Visit

PDC 51
Rev 0
03/07/2006
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62571

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	- - -		

Concurrent Medications and Conditions (Continued)

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

Yes No *w30fem*

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

B. What was the first day of her last menstrual period?

w30mnsdt mm / dd / yyyy

NA
 w30mnsna

C. Does she show secondary amenorrhea of 1 week or more?

Yes No NA *w30amnorr*

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

D. Was a serum pregnancy test done?

Yes No *w30spgst*

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

E. Date of the test:

w30spgdt mm / dd / yyyy

F. Serum pregnancy test result:

Positive Negative *w30spgrs*

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

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

w30ftrdt mm / dd / yyyy

H. 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 *w30pgrep*

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

Yes No *w30xactm*

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

B. Is his sexual partner pregnant?

Yes No *w30mpreg*

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:

w30mtrdt 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 *w30mpreg*

CRA Use Only

Signature: _____

Certif. #: _____

staffid2 - - -

PEDS-C

Treatment Period Assessment Summary
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44475

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			

Patient Study Drug Therapy

CRA Use Only

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

Yes No *w30mddry*

B. If Yes, Diary start date:

w30mdrdt / /

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

Yes No *w30tda*

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

w30tdadt / /

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

Yes No *w30thrsp*

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

w30thtdt / /

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

Yes No *w30msdos*

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

w30msdtdt / /

List of Laboratory Tests Ordered at Week 30

11.A. Hematology:

Done Unable to obtain
 w30hmtst

B. Chemistry:

 w30chmst

Signature: _____

Certif. #:

staffid3 -