

PEDS-C

Treatment Period Assessment Summary Week 60 (3B)

PDC 81
Rev 0
10/20/2005
Page 1 of 3

47891

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 yy	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 *b60ptcnt*

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

b60wddt / /

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 *b60phexm*

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

b60phxdt / /

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 *b60ptprb*

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

B. Was a Serious Adverse Event Form completed?

Yes No *b60sae*

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

b60saedt / /

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

Yes No *b60ae*

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

b60aedt / /

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 *b60nwmed*

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

B. Has the Concurrent Medications Form been completed?

Yes No *b60meds*

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

b60mcdsdt / /

Signature: _____

Certif. #: _____

staffid1 -

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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

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

Yes No *b60fem*

If No, skip to item 6.

B. Has a serum pregnancy test been done?

Yes No *b60spgst*

C. If Yes, date of the serum test:

b60spgdt [][] / [][] / [][][][]
mm dd yyyy

D. If Yes, serum pregnancy test result:

Positive Negative *b60spgrs*

If the serum test was **Negative**, skip to item 7.
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:

b60frdt [][] / [][] / [][][][]
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 *b60pgrep*

Skip to item 7.

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

Yes No *b60xactm*

If No, skip to item 7.

B. If Yes, is his sexual partner pregnant?

Yes No *b60mpreg*

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:

b60mtrdt [][] / [][] / [][][][]
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 *b60mpreg*

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
<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>			

Patient Study Drug Therapy

CRA Use Only

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

Yes No *b60mdry*

B. If Yes, Diary start date:

b60mdrdt /

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

Yes No *b60tda*

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

b60tdadt /

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

Yes No *b60thrsp*

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

b60thtdt /

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

Yes No *b60msdos*

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

b60msddt /

List of Laboratory Tests Ordered at Week 60

11.A. Hematology:

Done Unable to obtain

b60hmtst

B. Chemistry / Pregnancy:

b60chmst

Signature: _____

Certif. #:

staffid3 -