

PEDS-C

Treatment Period Summary  
Telephone Assessment Week 56 (3B)

PDC 80  
Rev 0  
10/14/2005  
Page 1 of 3



43882

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

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 *b56ptcnt*

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

*b56wdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
mm dd yyyy

CRA Use Only

Concurrent Medications and Conditions

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

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

Yes  No *b56ptprb*

If **No**, skip to item 3.

B. Was a Serious Adverse Event Form completed?

Yes  No *b56sae*

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

*b56saedt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
mm dd yyyy

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

Yes  No *b56ae*

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

*b56aedt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
mm dd yyyy

3.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 *b56nwmed*

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

B. Has the Concurrent Medications Form been completed?

Yes  No *b56meds*

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

*b56mdsdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
mm dd yyyy

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

Certif. #:

*staffid1* [ ][ ] - [ ][ ][ ][ ]

PEDS-C

Treatment Period Summary  
Telephone Assessment Week 56 (3B)

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45467

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

Concurrent Medication and Conditions (Continued)

CRA Use Only

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

Yes  No *b56fem*

If No, skip to item 5.

B. Has a serum pregnancy test been done?

Yes  No *b56spgst*

C. If Yes, date of the serum test:

*b56spgdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
mm dd yyyy

D. If Yes, serum pregnancy test result:

Positive  Negative *b56spgrs*

If the serum test was **Negative**, skip to item 6.  
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:

*b56ftrdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
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 *b56pgrep*

Skip to item 6.

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

Yes  No *b56xactm*

If No, skip to item 6.

B. If Yes, is his sexual partner pregnant?

Yes  No *b56mpreg*

If No, skip to item 6. If Yes, stop therapy and begin untreated follow-up at the next visit.

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

*b56mtrdt* [ ][ ] / [ ][ ] / [ ][ ][ ][ ]  
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 *b56mpreg*

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

Certif. #:

*staffid2* [ ][ ] - [ ][ ][ ]

# PEDS-C

## Treatment Period Summary

### Telephone Assessment Week 56 (3B)

PDC 80  
Rev 0  
10/14/2005  
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8151

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			

#### Patient Study Drug Therapy

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

Yes  No *b56mddry*

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

*b56mdrdt* /

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

Yes  No *b56tda*

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

*b56tdadt* /

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

Yes  No *b56thrsp*

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

*b56thtdt* /

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

Yes  No *b56msdos*

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

*b56msdtdt* /

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#### List of Laboratory Tests Ordered at Week 56

10.A. Hematology:

Done      Unable to obtain  
       *b56hmtst*

B. Chemistry / Pregnancy:

      *b56chmst*

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

Certif. #:

*staffid3* -