

PEDS-C

Treatment Period Assessment Summary Week 36 Visit

PDC 54
Rev 0
04/06/2005
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60416

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 / yyyy	mm / dd / yyyy	mm - dd - yyyy	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 **w36ptcnt**

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

w36wdt 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 **w36phexm**

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

w36phxdt 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 **w36ptprb**

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

B. Was a Serious Adverse Event Form completed?

Yes No **w36sae**

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

w36saedt mm / dd / yyyy

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

Yes No **w36ae**

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

w36aedt 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 **w36nwmed**

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

B. Has the Concurrent Medications Form been completed?

Yes No **w36meds**

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

w36mdsdt mm / dd / yyyy

Signature: _____

Certif. #:

staffid1 - mm - dd - yyyy

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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	

Concurrent Medications and Conditions (Continued)

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

Yes No *w36fem*

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

B. Was a serum pregnancy test done?

Yes No *w36spgst*

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

C. Date of the test:

w36spgdt mm / dd / yyyy

D. Serum pregnancy test result:

Positive Negative *w36spgrs*

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:

w36ftrdt 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 *w36fpgrep*

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

Yes No *w36xactm*

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

B. Is his sexual partner pregnant?

Yes No *w36mpreg*

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:

w36mtrdt 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 *w36mpreg*

Signature: _____

Certif. #: *staffid2* - mm / dd / yyyy

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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

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

Yes No *w36mdry*

B. If Yes, Diary start date:

w36mdrdt mm / dd / yyyy

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

Yes No *w36tda*

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

w36tdadt mm / dd / yyyy

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

Yes No *w36thrsp*

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

w36thtdt mm / dd / yyyy

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

Yes No *w36msdos*

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

w36msddt mm / dd / yyyy

List of Laboratory Tests Ordered at Week 36

11.A. Hematology:

Done	Unable to obtain
<input type="radio"/>	<input type="radio"/> <i>w36hmtst</i>

B. Chemistry / Pregnancy:

w36chmst

C. Thyroid function:

w36thyst

Signature: _____

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