

PEDS-C

Untreated Follow-Up Assessment Summary  
Follow-Up Week 12

PDC 64  
Rev 0  
03/10/2005  
Page 1 of 2

24163

Please Use Black Pen To Fill Out Form.

Week #  
*week*

Date of Assessment  
*assessdt*  
mm / dd / yyyy

Patient ID  
*idn*

Patient Letter Code  
*letcode*

*corrfix*  
Correction

Instructions

Use this form for all therapy groups .

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

Yes  No *u12ptcnt*

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

*u12wdt*  
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 *u12phexm*

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

*u12phxd*  
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 *u12ptprb*

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

B. Was a Concurrent Medical Condition Form completed?

Yes  No *u12mdcon*

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

*u12mcdc*  
mm / dd / yyyy

D. Was a Serious Adverse Event Form completed?

Yes  No *u12sae*

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

*u12saedt*  
mm / dd / yyyy

F. Was an Adverse Event Form completed?

Yes  No *u12ae*

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

*u12aed*  
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 *u12nwmed*

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

B. Has the Concurrent Medications Form been completed?

Yes  No *u12meds*

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

*u12mcdsdt*  
mm / dd / yyyy

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

Certif. #: \_\_\_\_\_

*staffid1* - \_\_\_\_\_

PEDS-C

Untreated Follow-Up Assessment Summary  
Follow-Up Week 12

PDC 64  
Rev 0  
03/10/2005  
Page 2 of 2

45120

Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assesdtdt</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 *u12fem*

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

B. Was a serum pregnancy test done?

Yes  No *u12spgst*

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

C. Date of the test:

*u12spgdt*  
mm / dd / yyyy

D. Serum pregnancy test result:

Positive  Negative *u12spgrs*

E. 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 *u12fprep*

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

Yes  No *u12xactm*

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

B. Is his sexual partner pregnant?

Yes  No *u12mpreg*

C. 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 *u12mpreg*

List of Laboratory Tests Ordered at Follow-Up Week 4

	Done	Unable to obtain
7.A. Hematology:	<input type="radio"/>	<input type="radio"/> <i>u12hmtst</i>
B. Chemistry / Pregnancy:	<input type="radio"/>	<input type="radio"/> <i>u12chmst</i>
C. HCV-RNA (Clinical):	<input type="radio"/>	<input type="radio"/> <i>u12vlcst</i>
D. HCV-RNA (Research):	<input type="radio"/>	<input type="radio"/> <i>u12vlrst</i>
E. Serum bank:	<input type="radio"/>	<input type="radio"/> <i>u12serbk</i>

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

Certif. #: *staffid2* - [ ] [ ] [ ] [ ]