

PEDS-C

Treatment Period Assessment Summary
Week 12 Visit

PDC 25
Rev 0
01/21/2005
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26389

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)

CRA Use Only

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

Yes No *w12fem*

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

B. Was a serum pregnancy test done?

Yes No *w12srmpst*

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

C. Date of the test:

w12srmpststdt
mm / dd / yyyy

D. Serum pregnancy test result:

Positive Negative *w12srmpstres*

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:

w12fthrstopdt
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 *w12fpregrep*

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

Yes No *w12sexactm*

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

B. Is his sexual partner pregnant?

Yes No *w12mppreg*

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:

w12mthrstopdt
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 *w12mppreg*

Signature: _____

Certif. #: _____

staffid2 - - - - -

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Week # <i>week</i>	Date of Assessment <i>assesdtdt</i> mm / dd / yyyy	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
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Patient Study Drug Therapy

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

Yes No *w12meddry*

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

w12meddrydt
mm / dd / yyyy

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

Yes No *w12tda*

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

w12tdadt
mm / dd / yyyy

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

Yes No *w12thrstp*

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

w12thrstopdt
mm / dd / yyyy

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

Yes No *w12misdos*

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

w12misdosdt
mm / dd / yyyy

CRA Use Only

Depression Screen

11.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on the CES-D?

Yes No *w12cdigt19*

If **No**, skip to item 12.

B. If **Yes**, was the patient referred for depression management according to Protocol requirements?

Yes No *w12refdep*

If **No**, skip to item 12.

If **Yes**, continue drug therapy and begin a Depression Management Tracking Form.

List of Laboratory Tests Ordered at Week 12

12.A. Hematology:

Done Unable to obtain *w12hmtotst*

B. Chemistry / Pregnancy:

w12chemtst

C. HCV-RNA (Clinical):

w12hcvclntst

D. HCV-RNA (Research):

w12hcvrshstst

E. Serum bank:

w12sermtst

F. Urinalysis:

w12urintst

Signature: _____

Certif. #: [] - []