

25759

Please Use Black Pen To Fill Out Form.

Week #
week

Date of Assessment
assesdt
mm / dd / yyyy

Patient ID
idn

Patient Letter Code
letcode

corrfix
Correction

Instructions

Use this form for all therapy groups at Week 3 Visit.

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

Yes No **w3patcont**

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

w3wddt
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 **w3physexm**

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

w3physexmdt
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 **w3patprob**

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

B. Was a Concurrent Medical Condition Form completed?

Yes No **w3medcon**

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

w3medcpndt
mm / dd / yyyy

D. Was a Serious Adverse Event Form completed?

Yes No **w3sae**

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

w3saedt
mm / dd / yyyy

F. Was an Adverse Event Form completed?

Yes No **w3ae**

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

w3aedt
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 **w3newmed**

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

B. Has the Concurrent Medications Form been completed?

Yes No **w3meds**

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

w3medsdt
mm / dd / yyyy

Signature: _____

Certif. #: _____

staffid1 - _____

Treatment Period Assessment Summary
Week 3 Visit

11466

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 *w3fem*

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

B. Was a serum pregnancy test done?

Yes No *w3srmpstst*

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

C. Date of the test:

w3srmpststdt
mm / dd / yyyy

D. Serum pregnancy test result:

Positive Negative *w3srmpstres*

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:

w3fthrstopdt
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 *w3fpregrep*

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

Yes No *w3sexactm*

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

B. Is his sexual partner pregnant?

Yes No *w3mppreg*

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:

w3mthrstopdt
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 *w3mppregrep*

Signature: _____

Certif. #: *staffid2* - _____

Treatment Period Assessment Summary
Week 3 Visit

2722

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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>	Correction <i>corrfix</i>
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Patient Study Drug Therapy

CRA Use Only

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

Yes No *w3meddry*

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

w3meddrydt
mm / dd / yyyy

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

Yes No *w3tda*

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

w3tdadt
mm / dd / yyyy

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

Yes No *w3thrstp*

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

w3thrstpdt
mm / dd / yyyy

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

Yes No *w3misdos*

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

w3misdosdt
mm / dd / yyyy

List of Laboratory Tests Ordered at Week 3

11.A. Hematology:

Done Unable to obtain *w3hmtotst*

B. Chemistry / Pregnancy:

w3chemtst

C. HCV-RNA (Research):

w3hcvrshstst

Signature: _____

Certif. #:

staffid3 - [] [] [] []