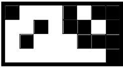

11591

PEDS-C
Treatment Period Assessment Summary
Week 5 Visit

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week	assessdt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)	idn ___ ___ - ___ ___ ___ - ___	letcode	corrfix ◯ Correction

Instructions
Use this form for all therapy groups at Week 5 Visit.

CRA Use Only

1.A. Is the patient willing and able to continue in the study? ◯ Yes ◯ No w5patcont

B. If **No**, date of the Withdrawal/Close-out Form: w5wddt ___ / ___ / ___ (mm / dd / yyyy)

Vital Signs and Symptom Directed Physical

2.A. Has a Vital Signs and Symptom Directed Physical Exam form been completed? ◯ Yes ◯ No w5physexm

B. If **Yes**, date of the form: w5physexmdt ___ / ___ / ___ (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 w5patprob

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

B. Was a Concurrent Medical Condition Form completed? ◯ Yes ◯ No w5medcon

C. If **Yes**, date of the form: w5medcondt ___ / ___ / ___ (mm / dd / yyyy)

D. Was a Serious Adverse Event Form completed? ◯ Yes ◯ No w5sae

E. If **Yes**, date of the SAE form: w5saedt ___ / ___ / ___ (mm / dd / yyyy)

F. Was an Adverse Event Form completed? ◯ Yes ◯ No w5ae

G. If **Yes**, date of the AE form: w5aedt ___ / ___ / ___ (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 w5newmed

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

B. Has the Concurrent Medications Form been completed? ◯ Yes ◯ No w5meds

C. If **Yes**, date of the form: w5medsdt ___ / ___ / ___ (mm / dd / yyyy)

Signature: ______________________ **Certif. #:** staffid1 ___ ___ - ___ ___ ___

30635

PEDS-C
Treatment Period Assessment Summary
Week 5 Visit

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

Concurrent Medications and Conditions (Continued)

CRA Use Only

5.A. Is the patient a female at least 10 years of age? ◯ Yes ◯ No w5fem

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

B. What was the first day of her last menstrual period? w5mensdt __ __ / __ __ / __ __ __ __ (mm / dd / yyyy) NA ◯ w5mensdtna

C. Does she show secondary amenorrhea of 1 week or more? ◯ Yes ◯ No ◯ NA w5amenor

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

D. Was a serum pregnancy test done? ◯ Yes ◯ No w5srmptst

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

E. Date of the test: w5srmptstdt __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

F. Serum pregnancy test result: ◯ Positive ◯ Negative w5srmptstres

If **Negative**, skip to item 7.
If **Positive**, stop therapy and begin untreated follow-up at the next visit.

G. If **Positive**, Date of the Therapy Stop/Restart Form: w5fthrstpdt __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

H. 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 w5fpregrep

6.A. Is the patient a sexually active male? ◯ Yes ◯ No w5sexactm

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

B. Is his sexual partner pregnant? ◯ Yes ◯ No w5mppreg

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: w5mthrstpdt __ __ / __ __ / __ __ __ __ (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 w5mppregrep

Signature: ____________________ **Certif. #:** staffid2 __ __ - __ __ __

PEDS-C
Treatment Period Assessment Summary
Week 5 Visit

42064

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week	assessdt ___ / ___ / ____ (mm dd yyyy)	idn ___ - ___ - ___	letcode	corrfix Correction

Patient Study Drug Therapy

CRA Use Only

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No w5meddry

B. If **Yes**, Diary start date: w5meddrydt ___ / ___ / ____ (mm dd yyyy)

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No w5tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w5tdadt ___ / ___ / ____ (mm dd yyyy)

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w5thrstp

B. If **Yes**, date of the Therapy Stop/Restart Form: w5thrstpdt ___ / ___ / ____ (mm dd yyyy)

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w5misdos

B. If **Yes**, date of the Therapy Missed Dose Form: w5misdosdt ___ / ___ / ____ (mm dd yyyy)

List of Laboratory Tests Ordered at Week 5

	Done	Unable to obtain	
11.A. Hematology:	○	○	w5hmtotst
B. Chemistry:	○	○	w5chemtst
C. HCV-RNA (Research):	○	○	w5hcvrshtst

Signature: ____________________ **Certif. #:** staffid3 ___ - ___