PEDS-C
Treatment Period Assessment Summary
Week 16 Visit

26753

Please Use Black Pen To Fill Out Form.

Week # week: 0 1 6

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode:

corrfix: Correction

Instructions

Use this form for all therapy groups at Week 16 Visit.

CRA Use Only

1.A. Is the patient willing and able to continue in the study? ○ Yes ○ No w16patcont

B. If **No**, date of the Withdrawal/Close-out Form: w16wddt 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 w16physexm

B. If **Yes**, date of the form: w16physexmdt 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 w16patprob

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

B. Was a Concurrent Medical Condition Form completed? ○ Yes ○ No w16medcon

C. If **Yes**, date of the form: w16medcondt mm / dd / yyyy

D. Was a Serious Adverse Event Form completed? ○ Yes ○ No w16sae

E. If **Yes**, date of the SAE form: w16saedt mm / dd / yyyy

F. Was an Adverse Event Form completed? ○ Yes ○ No w16ae

G. If **Yes**, date of the AE form: w16aedt 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 w16newmed

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

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No w16meds

C. If **Yes**, date of the form: w16medsdt mm / dd / yyyy

Signature: _____ **Certif. #:** staffid1 -

PEDS-C
Treatment Period Assessment Summary
Week 16 Visit

38407

Please Use Black Pen To Fill Out Form.

Week # week: 0 1 6

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 w16fem

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

B. Has a urine pregnancy test been done? ○ Yes ○ No w16urnptst

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

C. Date of the urine test: w16urnptstdt mm / dd / yyyy

D. Urine pregnancy test result: ○ Positive ○ Negative w16urnptstres

If **Negative**, skip to item 7.

E. If **Positive**, date of serum test: w16srmptstdt mm / dd / yyyy

F. Serum pregnancy test result: ○ Positive ○ Negative w16srmptstres

If either the urine or serum test was **Positive**, stop therapy and begin untreated follow-up at the next visit.

G. If either **Positive**, Date of the Therapy Stop/Restart Form: w16fthrstpdt mm / dd / yyyy

H. If either **Positive**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ○ Yes ○ No w16fpregrep

6.A. Is the patient a sexually active male? ○ Yes ○ No w16sexactm

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

B. Is his sexual partner pregnant? ○ Yes ○ No w16mppreg

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: w16mthrstpdt 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 w16mppregrep

Signature: _____ **Certif. #:** staffid2 -

PEDS-C
Treatment Period Assessment Summary
Week 16 Visit

52612

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week 0 1 6	assessdt mm / dd / yyyy	idn - -	letcode	corrfix ○ Correction

CRA Use Only

Patient Study Drug Therapy

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No w16meddry

B. If **Yes**, Diary start date: w16meddrydt mm / dd / yyyy

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No w16tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w16tdadt mm / dd / yyyy

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w16thrstp

B. If **Yes**, date of the Therapy Stop/Restart Form: w16thrstpdt mm / dd / yyyy

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w16misdos

B. If **Yes**, date of the Therapy Missed Dose Form: w16misdosdt mm / dd / yyyy

List of Laboratory Tests Ordered at Week 16

	Done	Unable to obtain	
11.A. Hematology:	○	○	w16hmtotst
B. Chemistry:	○	○	w16chemtst

Signature: _____ **Certif. #:** staffid3 -