PEDS-C
Treatment Period Assessment Summary
Week 40 Visit (3)

15925

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 patients in the original Mono or original Combo therapy groups with viral disappearance at Week 24.

CRA Use Only

1.A. Is the patient willing and able to continue in the study? ◯ Yes ◯ No a40ptcnt

B. If **No**, date of the Withdrawal/Close-out Form: a40wddt ___ ___ / ___ ___ / ___ ___ ___ ___ (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 a40phexm

B. If **Yes**, date of the form: a40phxdt ___ ___ / ___ ___ / ___ ___ ___ ___ (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 a40ptprb

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

B. Was a Serious Adverse Event Form completed? ◯ Yes ◯ No a40sae

C. If **Yes**, date of the SAE form: a40saedt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

D. Was a Non-Serious Adverse Event Form completed? ◯ Yes ◯ No a40ae

E. If **Yes**, date of the AE form: a40aedt ___ ___ / ___ ___ / ___ ___ ___ ___ (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 a40nwmed

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

B. Has the Concurrent Medications Form been completed? ◯ Yes ◯ No a40meds

C. If **Yes**, date of the form: a40mdsdt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

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

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 a40fem

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

B. Was a serum pregnancy test done? ◯ Yes ◯ No a40spgst

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

C. Date of the test: a40spgdt ___ / ___ / ____ (mm dd yyyy)

D. Serum pregnancy test result: ◯ Positive ◯ Negative a40spgrs

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: a40ftrdt ___ / ___ / ____ (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 a40pgrep

6.A. Is the patient a sexually active male? ◯ Yes ◯ No a40xactm

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

B. Is his sexual partner pregnant? ◯ Yes ◯ No a40mpreg

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: a40mtrdt ___ / ___ / ____ (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 a40mprep

Signature: ______________________ **Certif. #:** staffid2 ___ - ___

PEDS-C
Treatment Period Assessment Summary
Week 40 Visit (3)

11758

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**

CRA Use Only

Patient Study Drug Therapy

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No a40mddry

B. If **Yes**, Diary start date: a40mdrdt ___ / ___ / ____ (mm dd yyyy)

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No a40tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: a40tdadt ___ / ___ / ____ (mm dd yyyy)

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No a40thrsp

B. If **Yes**, date of the Therapy Stop/Restart Form: a40thtdt ___ / ___ / ____ (mm dd yyyy)

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No a40msdos

B. If **Yes**, date of the Therapy Missed Dose Form: a40msddt ___ / ___ / ____ (mm dd yyyy)

List of Laboratory Tests Ordered at Week 40

	Done	Unable to obtain	
11.A. Hematology:	○	○	a40hmtst
B. Chemistry / Pregnancy:	○	○	a40chmst
C. Serum bank:	○	○	a40serbk

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