PEDS-C
Treatment Period Summary
Telephone Assessment Week 44 (3)

26065

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 a44ptcnt

B. If **No**, date of the Withdrawal/Close-out Form: a44wddt ___ / ___ / ____ (mm dd yyyy)

Concurrent Medications and Conditions

2.A. *Ask the parent (or patient) the following question:*
Has your child (have you) had any other problems since your last visit? ○ Yes ○ No a44ptprb

If **No**, skip to item 3.

B. Was a Serious Adverse Event Form completed? ○ Yes ○ No a44sae

C. If **Yes**, date of the SAE form: a44saedt ___ / ___ / ____ (mm dd yyyy)

D. Was a Non-Serious Adverse Event Form completed? ○ Yes ○ No a44ae

E. If **Yes**, date of the AE form: a44aedt ___ / ___ / ____ (mm dd yyyy)

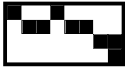
3.A. *Ask the parent (or patient) the following question:*
Has your child (have you) taken any new medicines, other than those given to you within this study, since the last visit? ○ Yes ○ No a44nwmed

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

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No a44meds

C. If **Yes**, date of the form: a44mdsdt ___ / ___ / ____ (mm dd yyyy)

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


27651

PEDS-C
Treatment Period Summary
Telephone Assessment Week 44 (3)

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

Concurrent Medication and Conditions (Continued)

4.A. Is the patient a female at least 10 years of age? ○ Yes ○ No a44fem

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

B. Has a serum pregnancy test been done? ○ Yes ○ No a44spgst

C. If **Yes**, date of the serum test: a44spgdt ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

D. If **Yes**, serum pregnancy test result: ○ Positive ○ Negative a44spgrs

If the serum test was **Negative**, skip to item 6.
If the serum test was **Positive**, stop therapy and begin untreated follow-up at the next visit.

E. If **Positive**, Date of the Therapy Stop/Restart Form: a44ftrdt ___ ___ / ___ ___ / ___ ___ ___ ___ (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 a44pgrep

Skip to item 6.

5.A. Is the patient a sexually active male? ○ Yes ○ No a44xactm

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

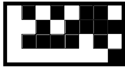
B. If **Yes,** is his sexual partner pregnant? ○ Yes ○ No a44mpreg

If **No**, skip to item 6. If **Yes**, stop therapy and begin untreated follow-up at the next visit.

C. If **Yes**, Date of the Therapy Stop/Restart Form: a44mtrdt ___ ___ / ___ ___ / ___ ___ ___ ___ (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 a44mprep

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


12154

PEDS-C
Treatment Period Summary
Telephone Assessment Week 44 (3)

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

6.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No a44mddry

B. If **Yes**, Diary start date: a44mdrdt __ __ / __ __ / __ __ __ __ (mm dd)

7.A. Have there been any changes in the patient's doses? ○ Yes ○ No a44tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: a44tdadt __ __ / __ __ / __ __ __ __ (mm dd)

8.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No a44thrsp

B. If **Yes**, date of the Therapy Stop/Restart Form: a44thtdt __ __ / __ __ / __ __ __ __ (mm dd)

9.A. Has the patient missed any doses since the last visit? ○ Yes ○ No a44msdos

B. If **Yes**, date of the Therapy Missed Dose Form: a44msddt __ __ / __ __ / __ __ __ __ (mm dd)

List of Laboratory Tests Ordered at Week 44

	Done	Unable to obtain	
10.A. Hematology:	○	○	a44hmtst
B. Chemistry / Pregnancy:	○	○	a44chmst

Signature: ______________________ **Certif. #:** staffid3 __ __ - __ __ __