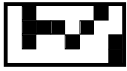


Untreated Follow-Up Assessment Summary



29769

Follow-Up Week 16 Telephone

Please Use Black Pen To Fill Out Form.

Week #

[][][]

Date of Assessment

[][] / [][] / [][][][]
mm dd yyyy

Patient ID

[][] - [][][][] - [][]

Patient Letter Code

[][][][]

Correction

Instructions

Use this form for all therapy groups .

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

Yes No

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

[][] / [][] / [][][][]
mm dd yyyy

CRA Use Only

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

If No, skip to item 3.

B. Was a Concurrent Medical Condition Form completed?

Yes No

C. If Yes, date of the form:

[][] / [][] / [][][][]
mm dd yyyy

D. Was a Serious Adverse Event Form completed?

Yes No

E. If Yes, date of the SAE form:

[][] / [][] / [][][][]
mm dd yyyy

F. Was an Adverse Event Form completed?

Yes No

G. If Yes, date of the AE form:

[][] / [][] / [][][][]
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

If No, skip to item 4.

B. Has the Concurrent Medications Form been completed?

Yes No

C. If Yes, date of the form:

[][] / [][] / [][][][]
mm dd yyyy

Signature: _____

Certif. #: _____

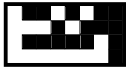
[][] - [][][][]

PEDS-C

Untreated Follow-Up Assessment Summary

Follow-Up Week 16 Telephone

PDC 65
Rev 1
08/21/2006
Page 2 of 2



6013

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code																																
<table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table>					<table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table> / <table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table> / <table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table> <div style="display: flex; justify-content: space-around; font-size: small;"> mmddyyyy </div>									<table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table> - <table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table> - <table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table>											<table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table>					<table border="1" style="width: 100%; height: 25px;"> <tr><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td><td style="width: 25px;"> </td></tr> </table>					<input type="radio"/> Correction

Concurrent Medications and Conditions (Continued)

CRA Use Only

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

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

B. Was a urine pregnancy test done? Yes No

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

C. Date of the test:

 /

 /

mm dd yyyy

D. Urine pregnancy test result: Positive Negative

If **Negative**, skip to item 5.

E. Was a serum pregnancy test done? Yes No

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

F. Date of the test:

 /

 /

mm dd yyyy

G. Serum pregnancy test result: Positive Negative

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

5. Is the patient a sexually active female at least 10 years old or a sexually active male? Yes No

If **No**, skip to Signature and Certif. #.

6. Indicate all types of contraception used (Answer each item):

- A. Oral contraceptive
- B. Intrauterine contraceptive device
- C. Depot contraceptives (implants, injectables)
- D. Physical barrier (condom, diaphragm)
- E. Abstinence
- F. None
- G. Other

Specify

Signature: _____

Certif. #:

 -