

PEDS-C

Treatment Period Assessment Summary
Week 52 Visit

PDC 58
Rev 0
05/06/2005
Page 1 of 5



23167

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 Mono/Combo therapy group who had no viral disappearance at Week 24.

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

Yes No **w52ptcnt**

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

/ / **w52wddt**
mm dd yyyy

CRA Use Only

Vital Signs and Physical Measurements

2. Weight:

. **w52wt**

kg

3. Height:

. **w52ht**

cm

4.A. Temperature:

. **w52tmp**

C

4.B. Site:

Oral Tympanic Axillary Unable to obtain **w52tmpst**

5. Blood Pressure:

A. Systolic

w52sysbp

mmHg

B. Diastolic

w52diabp

mmHg

Unable to obtain **w52bpna**

6. Pulse:

w52puls

bpm

Unable to obtain

w52pulna

Physical Exam

7. Indicate if each body area is within normal limits. If No, specify or comment.

1. Yes No NA 2. Specify / Comment

A. Head, eyes, ears:

w52head

B. Nose, mouth, throat:

w52nose

C. Neck:

w52neck

D. Chest (including breasts, axillae):

w52chst

E. Genitalia, groin, buttocks:

w52gntl

F. Abdomen:

w52abdm

G. Each extremity:

w52extm

H. Back, including spine:

w52back

I. Skin:

w52skin

Signature: _____

Certif. #: _____

staffid1 -

PEDS-C

Treatment Period Assessment Summary Week 52 Visit

PDC 58
Rev 0
05/06/2005
Page 2 of 5

988

Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assesdft</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/>	
<small>mm</small>	<small>dd</small>	<small>yyyy</small>		

Physical Exam (Continued)

CRA Use
Only

8. Indicate if each organ system is within normal limits. If **No**, specify or comment.

1. Yes No NA 2. Specify

A. Neurologic:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>w52neur</i>
B. Psychologic:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>w52psyc</i>
C. Genitourinary:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>w52gnto</i>
D. Hematologic / Lymphatic:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>w52hmto</i>
E. Allergies / Immunologic:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>w52allr</i>
F. Musculoskeletal:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>w52musc</i>
G. Other:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>w52othog</i>

9. Is the patient a sexually active female at least 10 years old or a sexually active male? Yes No *w52sexat*

If **No**, skip to item 11.

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

A. Oral contraceptive	<input type="radio"/> Yes	<input type="radio"/> No	<i>w52cnora</i>
B. Intrauterine contraceptive device	<input type="radio"/>	<input type="radio"/>	<i>w52cniud</i>
C. Depot contraceptives (implants, injectables)	<input type="radio"/>	<input type="radio"/>	<i>w52cndep</i>
D. Physical barrier (condom, diaphragm)	<input type="radio"/>	<input type="radio"/>	<i>w52cnphy</i>
E. Abstinence	<input type="radio"/>	<input type="radio"/>	<i>w52cnabs</i>
F. None	<input type="radio"/>	<input type="radio"/>	<i>w52cnnon</i>
G. Other	<input type="radio"/>	<input type="radio"/>	<i>w52cnoth</i>

Specify

<input type="text"/>	<i>w52cnosp</i>
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Signature: _____

Certif. #: _____

<i>staffid2</i>	-	<input type="text"/>	<input type="text"/>
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PEDS-C

Treatment Period Assessment Summary
Week 52 Visit

PDC 58
Rev 0
05/06/2005
Page 3 of 5

10002

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Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
mm / dd / yyyy	mm / dd / yyyy	mm - dd - yyyy	mm / dd / yyyy	

Concurrent Medication and Conditions

CRA Use Only

11.A. Ask the parent (or patient) the following question:
"Has your child (have you) had any other problems since your last visit?"

Yes No *w52ptprb*

If No, skip to item 12.

B. Was a Serious Adverse Event form completed?

Yes No *w52sae*

C. If Yes, date of SAE form:

w52saedt mm / dd / yyyy

D. Was an Non-Serious Adverse Event form completed?

Yes No *w52ae*

E. If Yes, date of AE form:

w52aedt mm / dd / yyyy

12.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 *w52nwmed*

B. Was a Concurrent Medications form completed?
(Complete for all concurrent medications, including pre-dose medications)

Yes No *w52meds*

C. If Yes, date of the form:

w52mdsdt mm / dd / yyyy

13.A. Is the patient a female at least 10 years of age?

If No, skip to item 14.

Yes No *w52fem*

B. Has a serum pregnancy test been done?

Yes No *w52spgst*

C. If Yes, date of the serum test:

w52spgdt mm / dd / yyyy

D. If Yes, serum pregnancy test result:

Positive Negative *w52spgrs*

If the serum test was **Negative**, skip to item 15.
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:

w52frdt 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 *w52fpgrep*

Skip to item 15.

Signature: _____

Certif. #: _____

staffid3 mm - dd

PEDS-C Treatment Period Assessment Summary Week 52 Visit

PDC 58
Rev 0
05/06/2005
Page 5 of 5

18707

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Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>correct</i> Correction
[][]	[][] / [][] / [][][][] <small>mm dd yyyy</small>	[][] - [][][][] - [][]	[][][]	

Patient Study Drug Therapy (Continued)

18.A. Has the patient's therapy been stopped for any reason?

Yes No *w52thrsp*

B. If **Yes**, date of the Therapy Stop/Restart Form:

w52thtdt [][] / [][] / [][][][]
mm dd yyyy

19.A. Has the patient missed any doses since the last visit?

Yes No *w52msdos*

B. If **Yes**, date of the Therapy Missed Dose Form:

w52msddt [][] / [][] / [][][][]
mm dd yyyy

CRA Use
Only

Depression Screen

20.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on the CES-D?

Yes No *w52cdi19*

If **No**, skip to item 21.

B. If **Yes**, was the patient referred for depression management according to Protocol requirements?

Yes No *w52refdp*

If **No**, skip to item 21.

If **Yes**, continue drug therapy and begin a Depression Management Tracking Form.

List of Laboratory Tests Ordered at Week 52

21.A. Hematology:

Done	Unable to obtain
<input type="radio"/>	<input type="radio"/> <i>w52hmtst</i>

B. PT / PTT:

<input type="radio"/>	<input type="radio"/> <i>w52ptst</i>
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C. Chemistry / Pregnancy:

<input type="radio"/>	<input type="radio"/> <i>w52chmst</i>
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D. HCV-RNA (Clinical):

<input type="radio"/>	<input type="radio"/> <i>w52vlcst</i>
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E. Thyroid function:

<input type="radio"/>	<input type="radio"/> <i>w52thyst</i>
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F. Serum bank:

<input type="radio"/>	<input type="radio"/> <i>w52serbk</i>
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G. Urinalysis:

<input type="radio"/>	<input type="radio"/> <i>w52urnst</i>
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Signature: _____

Certif. #: _____

staffid5 - [][]