

PEDS-C
TREATMENT FAILURE / REASSIGNMENT
REPORT - WEEK 24

PDC 31
Rev 0
01/31/2005
Page 1 of 2

56615

Please Use Black Pen To Fill Out Form.

Week # week	Date of Assessment assessdt	Patient ID idn	Patient Letter Code letcode	corrfix 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"/>	
	mm dd yyyy			

Instructions:

Use this form for all patients with HCV-RNA test results at Week 24 to report responses to therapy and subsequent therapy reassignments.

1. Patient's therapy assignment at enrollment:

Peg2a + placebo (Mono therapy)

Peg2a + RV (Combo therapy) **tf24enrlassn**

If Combo therapy, then skip to item 4.

CRA Use
Only

Mono Therapy Patients Only

2. Date of the Week 24 HCV-RNA test:

tf24monhcvstdt

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
		mm		dd		yyyy	

3. Did the test show viral disappearance ?

Yes No **tf24monvirdis**

If **Yes**, the patient will remain in the Mono therapy group and follow the assessment schedule in Protocol Table 1.

If **No**, re-assign the patient to compassionate Mono/Combo therapy. Week 28 to Week 52 assessments will follow the schedule in Protocol Table 1A and the patient will be re-evaluated for viral disappearance at Week 52.

Skip to item 7.

Please continue to page 2.

Signature: _____

Certif. #:

staffid1

<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>
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PEDS-C TREATMENT FAILURE / REASSIGNMENT REPORT - WEEK 24

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Please Use Black Pen To Fill Out Form.

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

COMBO Therapy Patients Only

4. Date of the Week 24 HCV-RNA test: *tf24comhcvststd*

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

mm dd yyyy

5. Did the test show viral disappearance ? Yes No *tf24comvirdis*

If **Yes**, the patient will remain in the Combo therapy group and follow the *Week 28* to *Week 72* assessment schedule in Protocol Table 1. Skip to item 7.

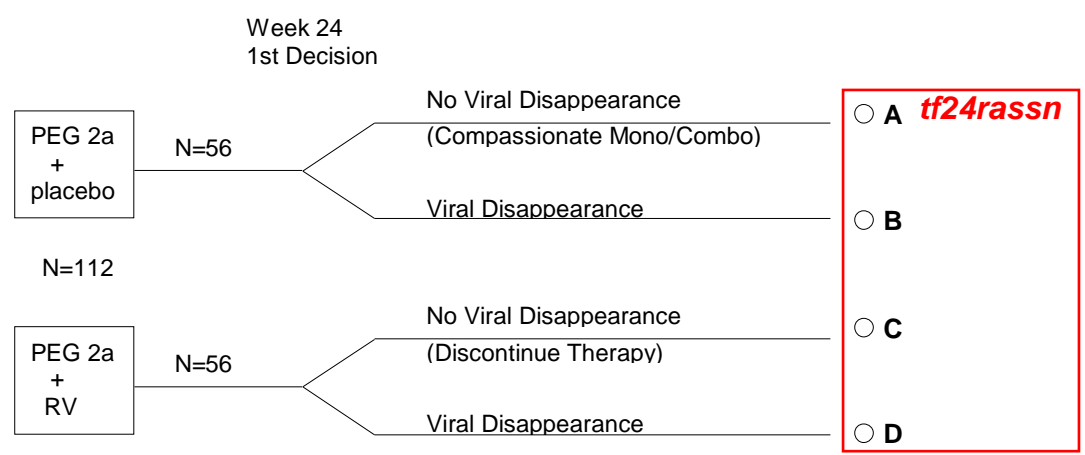
If **No**, discontinue study drug therapy and move the patient to untreated follow-up. *Week 28* to *Week 48* assessments will follow the schedule in Protocol Table 1 for *Weeks 52* to *72* (Untreated Follow-up weeks 4 - 24).

6. If **No**, Date of Therapy Stop/Restart Form reporting discontinuation of therapy: *tf24comthrstpdt*

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

mm dd yyyy

7. Flow diagram check on re-assignment
Please summarize the action taken by marking one flow diagram outcome (A, B, C, or D).



CRA Use Only

Signature: _____

Certif. #: *staffid2*

[][] - [][][]