PEDS-C
Baseline Assessment

12128

Please Use Black Pen To Fill Out Form.

Week # 0 0 0

Date of Assessment mm / dd / yyyy

Patient ID - -

Patient Letter Code

○ **Correction**

Instructions

Use this form at the Baseline Visit for patients in all therapy groups who have been screened and randomized.

CRA Use Only

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

If **Yes**, skip to item 2.

B. If **No**, Date of Withdrawal / Close-out mm / dd / yyyy

Skip to Signature and Staff ID # at the bottom of THIS page.
Do NOT complete the remaining pages of this form.

Vital Signs and Symptom Directed Physical

2.A. Has a Vital Signs and Symptom Directed Physical Exam Form been completed? **Yes** ○ **No** ○

B. If **Yes**, date of form: mm / dd / yyyy

Anthropometry

	A. First measurement	B. Second measurement	C. Unable to measure
3. Height:	. cm	. cm	○
4. Weight:	. kg	. kg	○
5. Mid-arm circumference (right):	. cm	. cm	○
6. Biceps skinfold: (right):	. mm	. mm	○
7. Triceps skinfold: (right):	. mm	. mm	○
8. Subscapular skinfold: (right):	. mm	. mm	○
9. Iliac skinfold: (right):	. mm	. mm	○

Signature: _____ **Certif. #:** -

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Patient Letter Code ___

○ **Correction**

CRA Use Only

Anthropometry (Continued)

10.A. Has a DXA scan been performed? ○ **Yes** ○ **No**

B. If **Yes**, date of scan: mm / dd / yyyy

11.A. Has a Bio-electrical Impedance Analysis been performed? ○ **Yes** ○ **No**

B. If **Yes**, date of BIA: mm / dd / yyyy

12.A. Has the parent / patient been given the 3-day food diary and been instructed? ○ **Yes** ○ **No**

B. If **Yes**, date of first diary day: mm / dd / yyyy

13.A. Has the Physical Activity Assessment been completed? ○ **Yes** ○ **No**

B. If **Yes**, date completed: mm / dd / yyyy

Concurrent Medication and Conditions

14.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 15.

B. Was a Concurrent Medical Conditions form completed? ○ **Yes** ○ **No**

1. If **Yes**, date of the form: mm / dd / yyyy

C. Was a Serious Adverse Event form completed? ○ **Yes** ○ **No**

1. If **Yes**, date of SAE form: mm / dd / yyyy

D. Was an Adverse Event form completed? ○ **Yes** ○ **No**

1. If **Yes**, date of AE form: mm / dd / yyyy

Signature: _____ **Certif. #:** ___ - ___

PEDS-C
Baseline Assessment

52454

Please Use Black Pen To Fill Out Form.

Week # 0 0 0

Date of Assessment ___ / ___ / ____ (mm / dd / yyyy)

Patient ID ___ - ___ - ___

Patient Letter Code ___

○ **Correction**

CRA Use Only

Concurrent Medication and Conditions

15.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**

B. Was a Concurrent Medications form completed? (Complete for all concurrent medications, including pre-dose medications) ○ **Yes** ○ **No**

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

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

If **No**, skip to item 17.

B. Has a urine pregnancy test been done? ○ **Yes** ○ **No**

1. If **Yes**, urine pregnancy test result: ○ **Positive** ○ **Negative**

2. If **Yes**, date of the test: ___ / ___ / ____ (mm / dd / yyyy)

If the urine test was **Negative**, skip to item 18.

3. Serum pregnancy test result: ○ **Positive** ○ **Negative**

4. Date of the serum test: ___ / ___ / ____ (mm / dd / yyyy)

If the urine or serum test was **Positive**, DO NOT BEGIN DRUG THERAPY and withdraw the patient from the study (no further visits).

5. Date of Withdrawal / Close-out form: ___ / ___ / ____ (mm / dd / yyyy)

Skip to item 21.

17.A. Is the patient a sexually active male? ○ **Yes** ○ **No**

If **No**, skip to item 18.

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

If **No**, skip to item 18. If **Yes**, DO NOT BEGIN DRUG THERAPY and withdraw the patient from the study

C. Date of Withdrawal / Close-out form: ___ / ___ / ____ (mm / dd / yyyy)

Signature: _____ **Certif. #:** ___ - ___

PEDS-C
Baseline Assessment

11903

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Week # 0 0 0

Date of Assessment ___ / ___ / ____ (mm / dd / yyyy)

Patient ID ___ - ___ - ___

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○ **Correction**

CRA Use Only

Depression Screen

18.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on the CES-D? ○ **Yes** ○ **No**

If **No**, skip to item 19.

B. Was the patient referred for depression management according to Protocol requirements? ○ **Yes** ○ **No**

If **Yes**, DO NOT BEGIN DRUG THERAPY. Begin a Depression Management Tracking Form.

Patient Study Drug Therapy

19.A. Was the first injection of Peg2a given to the patient today? ○ **Yes** ○ **No**

If **No**, skip to item 20.

B. Time of the injection (12 hour clock): ___ (hh) : ___ (mm) C. ○ **AM** ○ **PM**

D. Dose: ___ **mcg** E. ___ . ___ **ml**

20.A. Was the first dose of RV / placebo given today? ○ **Yes** ○ **No**

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

B. Time given (12 hour clock): ___ (hh) : ___ (mm) C. ○ **AM** ○ **PM**

D. Dose: ___ **mg** E. Number of tablets: ___

21.A. Was the parent or patient given instructions on how to administer medications? ○ **Yes** ○ **No**

B. Was the parent or patient given the Patient's Medication Diary? ○ **Yes** ○ **No**

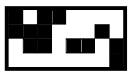
C. If **Yes**, Diary start date: ___ (mm) / ___ (dd) / ____ (yyyy)

Laboratory Tests Ordered at Baseline

	Done	Not done	Unable to obtain
22.A. Hematology	○	○	○
B. Chemistry	○	○	○
C. HCV-RNA (Clinical)	○	○	○
D. HCV-RNA (Research)	○	○	○
E. Serum bank	○	○	○

Signature: _____ **Certif. #:** ___ - ____

PEDS-C
Baseline Assessment



57965

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Week # 0 0 0

Date of Assessment mm / dd / yyyy

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○ **Correction**

Quality of Life Tests Administered at Baseline

CRA Use Only

Test Name	1. Completed		2. Form date			3. Completed by	
	Yes	No	mm	dd	yyyy	Patient	Parent
23.A. CHQ (Patient)	○	○	/	/		○	○
B. CHQ (Parent)	○	○	/	/		○	○
C. BRIEF (Parent)	○	○	/	/		○	○
D. CBCL (Parent)	○	○	/	/		○	○
E. ABCL (Parent)	○	○	/	/		○	○
F. LEC (Parent)	○	○	/	/		○	○
G. SF-36 (Parent)	○	○	/	/		○	○

Signature: _____ **Certif. #:** ___ - ___