PEDS-C
THERAPY STOP/RESTART FORM

47353

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 to report therapy stops and restarts. Report the date therapy was first started on the Baseline Assessment.

CRA Use Only

PEG 2A STOPPED

1. Has the patient's Peg2a therapy been stopped? — Yes ○ No ○

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

2. Date Peg2a therapy stopped: mm / dd / yyyy

3. Type of stop (choose one item): ○ Temporary ○ Permanent ○ Undetermined

4. Reason(s) for stop (Answer each item):

	Yes	No
A. Parent withdrew consent:	○	○
B. Patient withdrew consent:	○	○
C. Positive serum or urine pregnancy test (patient):	○	○
D. Male patient's sexual partner pregnant:	○	○
E. Evidence of severe retinopathy:	○	○
F. Patient hospitalized:	○	○
G. Concurrent medical condition:	○	○
H. Serious adverse event:	○	○
I. Major, unresponsive depression:	○	○
J. Absolute neutrophil count < 250 or febrile neutropenia	○	○
K. Platelet count < 25,000	○	○
L. Life threatening toxicity	○	○
M. Hemoglobin < 8.5 gm/dl	○	○
N. Indirect bilirubin > 5 mg/dl	○	○
O. Indirect bilirubin > 5 mg/dl for > 4 weeks	○	○
P. End of therapy per Protocol	○	○ *stppegprotend*
Q. Other	○	○

Specify: _____

Please continue to page 2.

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

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4195

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PEG 2A RE-START

	Yes	No
5. Has the patient's Peg2a therapy been restarted?	○	○

If **No**, skip to item 8.

6. Restart dose: ___ mcg

7. Date Peg2a therapy restart: ___ / ___ / ___ (mm / dd / yyyy)

RV/PLACEBO STOPPED

	Yes	No
8. Has the patient's RV/placebo therapy been stopped?	○	○

If **No**, skip to item 12.

9. Date RV/placebo therapy stopped: ___ / ___ / ___ (mm / dd / yyyy)

10. Type of stop (choose one item): ○ **Temporary** ○ **Permanent** ○ **Undetermined**

11. Reason(s) for stop (Answer each item):

	Yes	No
A. Parent withdrew consent:	○	○
B. Patient withdrew consent:	○	○
C. Positive serum or urine pregnancy test (patient):	○	○
D. Male patient's sexual partner pregnant:	○	○
E. Evidence of severe retinopathy:	○	○
F. Patient hospitalized:	○	○
G. Concurrent medical condition:	○	○
H. Serious adverse event:	○	○
I. Major, unresponsive depression:	○	○
J. Absolute neutrophil count < 250 or febrile neutropenia	○	○
K. Platelet count < 25,000	○	○
L. Life threatening toxicity	○	○
M. Hemoglobin < 8.5 gm/dl	○	○
N. Indirect bilirubin > 5 mg/dl	○	○
O. Indirect bilirubin > 5 mg/dl for > 4 weeks	○	○
P. End of therapy per Protocol	○	○ *stprvprotend*
Q. Other	○	○

Specify: _____

CRA Use Only

Please continue to page 3.

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

PEDS-C
THERAPY STOP/RESTART FORM

33425

Please Use Black Pen To Fill Out Form.

Week # | **Date of Assessment** (mm / dd / yyyy) | **Patient ID** | **Patient Letter Code** | ○ **Correction**

RV/PLACEBO RESTART

	Yes	No
12. Has the patient's RV/placebo therapy been restarted?	○	○

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

13. Restart dose of RV/placebo:

A. In AM: ____ **mg**

B. In PM: ____ **mg**

14. Date therapy restart: ____ / ____ / ____ (mm / dd / yyyy)

CRA Use Only

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