

# PEDS-C Serious Adverse Event

PDC 35  
Rev 1  
04/06/2005  
Page 1 of 8



22949

Please Use Black Pen To Fill Out Form.

**correct**  
Correction

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

### Instructions

Use this form to report adverse events that were life threatening, resulting in inpatient hospitalization or disability, or required medical or surgical intervention to prevent death, inpatient hospitalization, or disability. If you are reporting one diagnosis, sequence # = 01. If you are reporting a cluster of symptoms in the same week, use a separate form for each symptom and give each form a separate consecutive sequence number, starting with 01.

### Event or symptom

CRA Use Only

1. Serious Adverse event: Diagnosis only (if known) OR serious signs / symptoms:

*saedx*

2. Date observed / onset:

/  /  *saedt*

mm      dd                  yyyy

3. Body system (Choose one):

<input type="radio"/> Respiratory	<input type="radio"/> Urinary	<input type="radio"/> Blood/Lymphatic	<input type="radio"/> Other
<input type="radio"/> Cardiovascular	<input type="radio"/> Neurologic	<input type="radio"/> Skin	
<input type="radio"/> Gastrointestinal	<input type="radio"/> Reproductive	<input type="radio"/> Musculoskeletal	
<input type="radio"/> Hepatobiliary/Pancreas	<input type="radio"/> Endocrine/Metabolic	<input type="radio"/> Psychiatric	<i>saebsys</i>

4. Maximum intensity:

*saeintns*  Mild  Moderate  Severe  NA

5. Maximum toxicity:

*saxtox*  Grade 1  Grade 2  Grade 3  Grade 4  NA

6. Outcome

<input type="radio"/> Resolved	<input type="radio"/> Condition still present and under TX
<input type="radio"/> Recovered with minor sequelae	<input type="radio"/> Condition continues to worsen
<input type="radio"/> Recovered with major sequelae	<input type="radio"/> Patient died

*saeoutcm*

7. Date of resolution or death:

/  /  *saeresdt*

mm      dd                  yyyy

Signature: \_\_\_\_\_

Certif. #: *staffid1*  -

# PEDS-C Serious Adverse Event

PDC 35  
Rev 1  
04/06/2005  
Page 2 of 8

24953

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Week #	Date of Assessment	Sequence #	Patient Letter Code	Patient ID
<i>week</i>	<i>assessdt</i>	<i>seqno</i>	<i>letcode</i>	<i>idn</i>
mm	dd / yy			- - - -

**Event or symptom (Continued)**

**CRA Use Only**

8. Action taken with Peg2a as a result of the SAE (Choose one):

<input type="radio"/> None  <input type="radio"/> Dose adjusted  <input type="radio"/> Temporarily interrupted  <input type="radio"/> Permanently discontinued	<input type="radio"/> Counteractive medication Specify <input type="text"/> <i>saepgsp1</i>  <input type="radio"/> Medical surgical intervention Specify <input type="text"/> <i>saepgsp2</i>  <input type="radio"/> Other Specify <input type="text"/> <i>saepgsp3</i>  <input type="radio"/> NA <i>saepgact</i>
--	--

9. Action taken with RV/placebo as a result of the SAE (Choose one):

<input type="radio"/> None  <input type="radio"/> Dose adjusted  <input type="radio"/> Temporarily interrupted  <input type="radio"/> Permanently discontinued	<input type="radio"/> Counteractive medication Specify <input type="text"/> <i>saervsp1</i>  <input type="radio"/> Medical surgical intervention Specify <input type="text"/> <i>saervsp2</i>  <input type="radio"/> Other Specify <input type="text"/> <i>saervsp3</i>  <input type="radio"/> NA <i>saervact</i>
--	--

10. Withdrawal: Did the subject withdraw from study as a result of this SAE?

Yes  No  Unknown *saewdrw*

11. Relationship to study drug(s):

Definitely unrelated     Probably related  
 Unlikely                       Definitely related  
 Possibly related                      *saestdrg*

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

*staffid2* -

# PEDS-C Serious Adverse Event

PDC 35  
Rev 1  
04/06/2005  
Page 3 of 8

7490

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Week #	Date of Assessment	Sequence #	Patient Letter Code	Patient ID
<b>week</b>	<b>assesdft</b> <small>mm / dd / yyyy</small>	<b>seqno</b>	<b>letcode</b>	<b>idn</b> - - - - -

**Possible Causes of the SAE Other Than Study Drug(s)**

**CRA Use Only**

	Yes	No	Unknown	
12. Disease under study:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saestddis</b>
13. Withdrawal of study drug(s):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saestddrgwd</b>
14. Concurrent disorder(s):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saecondisord</b>
Specify: <span style="float: right; border: 1px solid red; color: red;"><b>saecondisordsp</b></span>				
15. Concurrent medication(s):	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown	<b>saeconmed</b>
Specify: <span style="float: right; border: 1px solid red; color: red;"><b>saeconmedsp</b></span>				
16. Activity related to study participation (e.g. procedures):	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown	<b>saestdpar</b>
Specify: <span style="float: right; border: 1px solid red; color: red;"><b>saestdparsp</b></span>				
17. Other:	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown	<b>saeothrcas</b>
Specify: <span style="float: right; border: 1px solid red; color: red;"><b>saeothrcassp</b></span>				

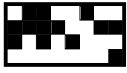
**Seriousness**

	Yes	No	Unknown	
18. Death:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saeserdt</b>
19. Life threatening:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saeserlif</b>
20. Hospitalization required or prolonged: (send Discharge Summary)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saeserhosp</b>
21. Disabling or incapacitating:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saeserdisab</b>
22. Congenital anomaly:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saesercongnt</b>
23. Other:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<b>saeserother</b>
Specify: _____				
24. If fatal, was an autopsy done / to be performed?: (send autopsy report when available)	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown	<b>saeautopsy</b>

Signature: \_\_\_\_\_

Certif. #: **staffid3** - - - - -

PEDS-C  
Serious Adverse Event



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

Relevant Medical Conditions

CRA Use Only

Specify any relevant past or current medical disorders, allergies, surgeries, etc., that can help explain the SAE.

25.A. Medical condition:

*saecon1*

B. Date of onset:

*saecon1dt*

C. Condition present at time of the SAE?

Yes  No *saecon1pres*

D. If No, date of last occurrence::

*saecon1lastdt*

26.A. Medical condition:

*saecon2*

B. Date of onset:

*saecon2dt*

C. Condition present at time of the SAE?

Yes  No *saecon2pres*

D. If No, date of last occurrence::

*saecon2lastdt*

27.A. Medical condition:

*saecon3*

B. Date of onset:

*saecon3dt*

C. Condition present at time of the SAE?

Yes  No *saecon3pres*

D. If No, date of last occurrence::

*saecon3lastdt*

28.A. Medical condition:

*saecon4*

B. Date of onset:

*saecon4dt*

C. Condition present at time of the SAE?

Yes  No *saecon4pres*

D. If No, date of last occurrence::

*saecon4lastdt*

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

*staffid4*

# PEDS-C Serious Adverse Event

PDC 35  
Rev 1  
04/06/2005  
Page 5 of 8



45782

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<i>week</i> <input type="text"/>	<i>assessdt</i> <input type="text"/> / <input type="text"/> / <input type="text"/>	<i>seqno</i> <input type="text"/>	<i>letcode</i> <input type="text"/>	<i>idn</i> <input type="text"/> - <input type="text"/> - <input type="text"/>
	<small>mm      dd                  yyyy</small>			

**Other Relevant Risk Factors**

CRA Use Only

Specify any family history or any social history, e.g. smoking, alcohol, diet, drug abuse, occupational hazard, relevant to the SAE.

29. Risk factor:	<input type="text"/>	<i>searsk1</i>
30. Risk factor:	<input type="text"/>	<i>searsk2</i>
31. Risk factor:	<input type="text"/>	<i>searsk3</i>
32. Risk factor:	<input type="text"/>	<i>searsk4</i>
33. Risk factor:	<input type="text"/>	<i>searsk5</i>

**Details of Study Drug(s)**

34. Peg 2a:	<b>Yes</b>	<b>No</b>	
A. Was the Peg2a dose adjusted based on this SAE?	<input type="radio"/>	<input type="radio"/>	<i>saepedadj</i>
B. Was the Peg2a dose ever adjusted?	<input type="radio"/>	<input type="radio"/>	<i>saepedajevr</i>
C. Was Peg2a Tx ever interrupted?	<input type="radio"/>	<input type="radio"/>	<i>saepegint</i>
D. Was Peg2a Tx ever discontinued?	<input type="radio"/>	<input type="radio"/>	<i>saepeddis</i>
35. RV or placebo:			
A. Was the RV/placebo dose adjusted based on this SAE?	<input type="radio"/>	<input type="radio"/>	<i>saervadj</i>
B. Was the RV/placebo dose ever adjusted?	<input type="radio"/>	<input type="radio"/>	<i>saervadjevr</i>
C. Was RV/placebo Tx ever interrupted?	<input type="radio"/>	<input type="radio"/>	<i>saervint</i>
D. Was RV/placebo Tx ever discontinued?	<input type="radio"/>	<input type="radio"/>	<i>saervdis</i>

Signature: \_\_\_\_\_

Certif. #: *staffid5* -

# PEDS-C Serious Adverse Event

PDC 35  
Rev 1  
04/06/2005  
Page 6 of 8



22439

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Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Sequence # <i>seqno</i>	Patient Letter Code <i>letcode</i>	Patient ID <i>idn</i>
<input type="text"/>	<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>		

## Relevant Concurrent Medications

CRA Use Only

Include any concurrent medications that may have contributed to the occurrence of the SAE.

36. A. Drug (Trade name preferred):

B. Dose:

C. Dose unit:

D. Frequency:

E. Route of administration:

PO  PR  SC  IM  IV  Other

F. Date started:

Date Unknown

G. Started Pre-Study?:

Yes  No

H. Date stopped:

Unknown

I. Conditions treated / indication:

37. A. Drug (Trade name preferred):

B. Dose:

C. Dose unit:

D. Frequency:

E. Route of administration:

PO  PR  SC  IM  IV  Other

F. Date started:

Date Unknown

G. Started Pre-Study?:

Yes  No

H. Date stopped:

Unknown

I. Conditions treated / indication:

Signature: \_\_\_\_\_

Certif. #:

PEDS-C  
Serious Adverse Event



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corrfix  
Correction

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

Relevant Concurrent Medications (Continued)

CRA Use Only

Include any concurrent medications that may have contributed to the occurrence of the SAE.

38. A. Drug (Trade name preferred): *saedrg3*

B. Dose: *saedrg3dos* C. Dose unit: *saedrg3unt*

D. Frequency: *saedrg3frq*

E. Route of administration:  PO  PR  SC  IM  IV  Other *saedrg3rt*

F. Date started: *saedrg3stdt* / / *saedrg3stdt*  
mm / dd / yyyy Date Unknown  *saedrg3stdtuk*

G. Started Pre-Study?:  Yes  No *saedrg3prestd*

H. Date stopped: *seadrg3endt* / / *saedrg3endtuk*  
mm / dd / yyyy Unknown  *saedrg3endtuk*

I. Conditions treated / indication: *saedrg3ind*

39. A. Drug (Trade name preferred): *saedrg4*

B. Dose: *saedrg4dos* C. Dose unit: *saedrg4unt*

D. Frequency: *saedrg4frq*

E. Route of administration:  PO  PR  SC  IM  IV  Other *saedrg4rt*

F. Date started: *saedrg4stdt* / / *saedrg4stdtuk*  
mm / dd / yyyy Date Unknown  *saedrg4stdtuk*

G. Started Pre-Study?:  Yes  No *saedrg4prestd*

H. Date stopped: *seadrg4endt* / / *saedrg4endtuk*  
mm / dd / yyyy Unknown  *saedrg4endtuk*

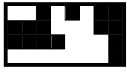
I. Conditions treated / indication: *saedrg4ind*

Signature: \_\_\_\_\_

Certif. #: *staffid7* -

PEDS-C  
Serious Adverse Event

PDC 35  
Rev 1  
04/06/2005  
Page 8 of 8



58353

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Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Sequence # <i>seqno</i>	Patient Letter Code <i>letcode</i>	Patient ID <i>idn</i>
<input type="text"/>	<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			

**Narrative / Comments**

Provide a narrative description of the adverse event (including treatment of the event).

**CRA Use Only**

**Details of Relevant Assessments**

Provide details of other assessments, e.g. laboratory data with normal ranges, or supplemental examinations

**Additional or Follow-up Information**

Use this space to provide any additional details on the serious adverse event not already captured on the previous pages.

**Reporting Investigator**

To the best of my knowledge, all information entered on these Serious Adverse Event pages for this patient is correct.

Name:

*seainvstnam*

Signature: \_\_\_\_\_

Certif. #:

*saeinvstid*  -

Signature: \_\_\_\_\_

Certif. #:

*staffid8*  -