

Form A200: Adverse Event Form

INSTRUCTIONS: Complete this form each time an adverse event occurs. When an event that was ongoing at the time of initial data entry resolves, then please record all resolution information on another A200 form. Do not update the initial A200 form with resolution information. The Study Coordinator should refer to the CTCAE v.3 booklet, the form QxQ's and Section C.2.6 of the protocol for event definitions and classifications. The Study PI or Clinical Center PI must review and initial this form.

Section A: KEY IDENTIFYING INFORMATION

- A1. Study Identification Number _____ - _____ - _____ - _____ - _____
- A2. Event number (assigned sequentially by DMS) _____
- a. Form type: INITIAL.....1 (A3) RESOLUTION.....2
1. Did anything change since the initial form was completed? YES.....1 (B3) NO.....2 (B11)
- A3. Onset date _____ / _____ / _____
M M D D Y Y Y Y
- A4. Date form initiated _____ / _____ / _____
M M D D Y Y Y Y
- A5. Name of person completing form _____
PRINT FULL NAME INITIALS
- A6. Did this Adverse Event occur during the Musculoskeletal Ancillary Study measurements or within 24 hours after measurements were completed? YES 1 NO.....2
- A7. Was this event/episode first identified or reported while completing an A116 ADRQ form? YES 1 NO.....2 (B1)
- a. Date of A116 where AE first identified or reported _____ / _____ / _____
M M D D Y Y Y Y

Section B: DESCRIPTION OF ADVERSE EVENT

- B1. Is this AE related to a previously reported AE? YES.....1 NO.....2 (B2)
- a. If YES, specify AE event # _____
- B2. Event code (CTCAEMedDRAcode) _____
- a. Specify (Event Name per CTCAE Code List) _____

B3. Serious Adverse Event

YES.....1

NO.....2 **(B4)**

Reason(s) for definition of SERIOUS (Answer each question)			
		YES	NO
a.	Subject death	1	2
b.	Life-threatening	1	2
c.	Required hospitalization or prolonged hospitalization	1	2
d.	Results in persistent/significant incapacity or disruption of normal life functioning	1	2
e.	Results in a congenital anomaly in the offspring of a participant	1	2
f.	Important medical event	1	2

B4. Severity of event (refer to CTCAE v3.0)

GRADE 1.....1

GRADE 2.....2

GRADE 3.....3

GRADE 4.....4

GRADE 5.....5

B5. Expectedness

UNEXPECTED.....1

EXPECTED.....2

B6. Relationship to Drug (Causality)

NOT RELATED.....1 **(B7)**

POSSIBLY RELATED.....2

PROBABLY RELATED.....3

a. Date last dose of study drug taken

__	__	/	__	__	/	__	__	__	__
M	M		D	D		Y	Y	Y	Y

b. Time __ __ : __ __

1. Units

AM.....1

PM.....2

24 HR3

c. Study drug action taken

NO CHANGE TO STUDY DRUG.....1

STUDY DRUG DOSAGE ADJUSTED2

STUDY DRUG DOSAGE TEMPORARILY STOPPED3

STUDY DRUG PERMANENTLY DISCONTINUED4

B7. Assessment of Event

a. Were any labs, tests or studies done to diagnose/evaluate this event? YES 1 NO.....2 **(B8)**

b. Number of labs, tests or studies done _____ (1 – 10)

1a. Test Name	1b. Test Date (mm/dd/yyyy)	1c. Result
i.	i.	i.
ii.	ii.	ii.
iii.	iii.	iii.
iv.	iv.	iv.
v.	v.	v.

B8. Does the subject have any pre-existing medical conditions relevant to this event (other than Marfan Syndrome)? YES 1 NO.....2 **(B9)**

a. If yes, specify _____

B9. Treatment/Intervention status

a. Action Taken YES 1 NO.....2 **(B10)**

1. Medical Therapy (non-drug) YES 1 NO.....2 **(B9a2)**

i. If yes, specify _____

2. Number of Medications administered to treat this AE _____ (0 – 10) **If 0, skip to B9a3**

Treatment Medication Codes
(see Code list D)

i. _ _ . _ _

ii. _ _ . _ _

iii. _ _ . _ _

iv. _ _ . _ _

Specify Medication Name for 99 codes (other)

3. Number of Surgeries or Procedures performed to treat this AE _____ (0- 5) **If 0, skip to B10**

Specify Name of Procedure

Date of Procedure

i. _____

_ M _ M / _ D _ D / _ Y _ Y _ Y _ Y

ii. _____

_ M _ M / _ D _ D / _ Y _ Y _ Y _ Y

B10. Number of medications subject was taking at the time of the event (exclude study drug) ____ (0-10)

If 0, skip to B11

Medication Code (see Code list D)	Specify Medication Name for 99 codes (other)	Start Date (mm/yyyy) (If estimated, check box.)	Stop Date (mm/yyyy) (If estimated, check box.)
a1. ____ . ____	a2.	a3. <input type="checkbox"/>	a4. <input type="checkbox"/>
b1. ____ . ____	b2.	b3. <input type="checkbox"/>	b4. <input type="checkbox"/>
c1. ____ . ____	c2.	c3. <input type="checkbox"/>	c4. <input type="checkbox"/>
d1. ____ . ____	d2.	d3. <input type="checkbox"/>	d4. <input type="checkbox"/>
e1. ____ . ____	e2.	e3. <input type="checkbox"/>	e4. <input type="checkbox"/>

B11. Outcome Status

- a. Outcome (select ONE) CONTINUING -5 (B14)
 RESOLVED 1 (B11b)
 RESOLVED WITH SEQUELAE 2

1. Specify: _____

b. Resolution date ____ / ____ / ____
 M M D D Y Y Y Y

B12. Did the patient die? YES 1 NO 2 (B13)

a. How is this AE related to the cause of death?

PRIMARY 1
 CONTRIBUTING 2
 NOT RELATED 3
 UNKNOWN 4

b. Date of Death

____ / ____ / ____
 M M D D Y Y Y Y

B13. Did event code from question B2 change? YES 1 NO 2 (B14)

a. Updated event code (CTCAE
MedDRA code)

b. Specify (Event Name per CTCAE Code List)

B14. Adverse Event Narrative

[illegible]

B15. Date faxed to PHN DCC _____/_____/_____

$$\frac{\text{M}}{\text{M}} / \frac{\text{D}}{\text{D}} / \frac{\text{Y}}{\text{Y}} \frac{\text{Y}}{\text{Y}} \frac{\text{Y}}{\text{Y}}$$

- ***Please review this form with the Study PI/Clinical Center PI prior to data entry and submission to the Data Coordinating Center (DCC) for the initial event and the resolution.***
- ***The Study PI/Clinical Center PI must signify their review by initialing this form.***

Initial of PI:

Date:

SUBMISSION INSTRUCTIONS: Please follow reporting timeframes below based on seriousness of event.

Seriousness	Reporting Timeframe
Serious	Within 24 hours of first knowledge of event
Important Medical Event (including pregnancy)	Within 24 hours of first knowledge of event
Not serious	Within 7 calendar days of first knowledge of event

Fax all forms to: AE Medical Monitor
PHN Data Coordinating Center
Fax number: 617-673-9540

DATA ENTRY INSTRUCTIONS:
This form must be entered into ADEPT as well as faxed to the DCC according to the reporting timeframe above.

Section Z: TIME TO COMPLETE FORM

Z1. How long did it take to complete this form? _____ minutes

END OF FORM