

Adverse Event Form Coding Instructions

Overview

Pages 1-2 are reviewed and entered at site. Then pages 1-3 are faxed to CC for blinded clinician review. Following clinician review, the CC enters page 3 and faxes a copy of pages 1-3 back to site. Sites should file both the original and the coded copy.

The master copy of the data from pages 1-2 will reside at the sites. The master copy of the data form page 3 will reside at the CC.

All data (including text descriptions) will be entered and available for use in reporting.

Adverse Events are specifically defined as a) a “yes” answer to Q#15 on the Symptoms Questionnaire, b) a “yes” answer to Q#17 on the Symptoms Questionnaire that upon examination, a clinician feels could be recoded into one of the categories in Q#15 or c) an instance of physician-confirmed angina. An event is therefore not counted as an AE until one of the previous instances occur. Once one of these instances has been determined to occur, this form should be completed and sent to the CC. Ideally, the form should be faxed to the CC once all pertinent information has been entered on the form.

Administration Instructions

This form is completed by site personnel.

Place ID labels on pages one through three.

Enter the date of the event on page one. Be sure to use a four digit year.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions</u>
1	1	Check the appropriate time frame in which the AE occurred. AE’s may only occur after randomization; AE’s may not occur during screening.
	2	Check the appropriate source of the AE, i.e. how the AE was originally identified.
	3	Briefly describe the circumstances surrounding the AE. Be sure to indicate whether it is ongoing or resolved.
2	4-5	An unblinded site study clinician should complete these questions. Further notes are optional.
3	1-3	A CC clinician should complete these questions.