

ACRIN FORM COMPLETION INSTRUCTIONS

ADVERSE EVENT

6678 AE Form Completion Instructions

An adverse event (AE) form is to be completed for each reportable AE that occurs during the study. This form should be submitted via the ACRIN data center at www.acrin.org. All available dates should be reported as MM-DD-YYYY. Code all questions unless otherwise specified; do not leave mandatory questions blank. Instructions are provided below for all questions that are not self-explanatory. If further clarification is required for any question on the form, please contact the ACRIN AE Coordinator.

If revisions are required, a paper case report form (CRF) must be submitted. Refer to the general form completion instructions for additional details. Please use Good Clinical Practice (GCP) in making data corrections; a single line should be drawn through the incorrect data with your initials and the date. Please note that when revising the AE form, the investigator must also initial and date any revisions.

AE Description: Two 60-character fields are provided to allow for adequate adverse event description. Please include the investigator's determination of what the AE is related to.

AE Short Name CTCAE v 3.0/MedDRA: This field requires an online look-up into the National Cancer Institute's (NCI) Common Toxicology Criteria for Adverse Events (CTCAE) data table. Please note that each AE term is mapped to a MedDRA (Medical Dictionary for Regulatory Activities) term and MedDRA code number.

1. Select the blue 'Adverse Event' button next to the "AE Short Name CTCAE v 3.0/MedDRA (online look-up)" field.
2. You will then be taken to another page with three fields:
 - a. Category: you can select the drop down list which will include all terms in the selected category;
OR
 - b. Code Description: you can filter further by entering partial term and or the entire term;
OR
 - c. MedDRA Term: you can filter further by entering partial term and or the entire term.
3. Select the blue 'Retrieve' button to obtain a list of code descriptions.
4. Review the code description and MedDRA term and select the appropriate code number of the reported AE.
5. Once selected, MedDRA code number will be populated in the AE Short Name CTCAE v 3.0/MedDRA field. The MedDRA term will be displayed in red to the right of the AE Short Name CTCAE v 3.0/MedDRA field on the web entry screen when you are returned to the form.

In the event that a paper AE form is completed and sent to ACRIN Data Management for entry, please document the appropriate AE short name from the CTCAE v 3.0.

Grade: Select the investigator-determined grade based on the CTCAE version 3.0. If the AE worsens (e.g. Grade 2 (moderate) to Grade 3 (severe), a new AE form must be completed.

Grade 1 = Mild

Grade 2 = Moderate

Grade 3 = Severe

Grade 4 = Life threatening or disabling

Grade 5 = Fatal

Attribution: Select the investigator-determined relationship of the AE to the study.

Expectedness: Expected AEs are listed in section 12.5 of the protocol, informed consent or the investigator's brochure. Unexpected AEs refers to an adverse event that has not been previously observed.

ACRIN FORM COMPLETION INSTRUCTIONS

ADVERSE EVENT

Expedited Report Submitted: Refer to section 12.7 of the protocol for information on what events require expedited reporting.

Action Taken: Select all actions taken; if 'None' is selected, no other boxes may be marked. If "Other" is selected, please provide details in the comments section.

Outcome: Select the patient's outcome. If 'Ongoing' is selected, the AE 'Resolution Date' should be blank and the 'Ongoing?' box must be marked.

Start Date & Resolution Date: These dates are mandatory unless the stop date is ongoing. In the event that the start date and/or resolution date are unknown and/or partial dates, sites are required to document the reason for the date omission(s) and any details (e.g. partial dates or estimated dates) in the comments section. Please note that sites will be queried if dates are inconsistent or if adequate details are not provided in the comments section.

Comments: The comment field is provided for sites to document relevant clinical or study notations, etc. The comments section is not intended for "actionable" information you need to relate to data management (DM) and is not intended for data analysis. Comments should be limited to 120 characters.

Additional AEs to report: Only one adverse event is captured per form. If there are multiple events to report, select 'Yes' and an additional AE form will be populated to the patient calendar.

Was the AE assessed, reviewed, and signed by the investigator?: This question eliminates the need for entering the investigator's name into the database. However if a paper form is completed (e.g. for revision purposes, a down web system or if the AE form is used as a source document), the investigator's signature on the paper form is required.

Investigator's initials: Enter the initials [e.g. John Smith: JS] of the investigator responsible for assessing, reviewing and signing off on the AE.

IMPORTANT: Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed web confirmation or participant's chart) must have the investigator's signature.