

CDASH V 1.1 - Adverse Events

Record ID

Adverse Events

Were any adverse events experienced?

- ☐ No
☐ Yes
(Indicate if the subject experienced any adverse events.)

AE Identifier

(Record unique identifier for each adverse event for this subject. Number sequence for all following forms should not duplicate existing numbers for the subject.)

What is the adverse event term?

(Record only one diagnosis, sign or symptom per form (e.g., nausea and vomiting should not be recorded in the same entry, but as two separate entries). See eCRF completion instruction for more information.)

Does the subject have (specific adverse event)?

- ☐ No
☐ Yes
(Please indicate if (specific adverse event) has occurred /is occurring by checking Yes or No.)

What is the date the adverse event started?

(Record the start date of the adverse event using the MM-DD-YYYY format.)

At what time did the adverse event start?

(If appropriate, record the time the AE started using the HH:MM (24-hour clock) format.)

Is the adverse event still ongoing?

- ☐ No
☐ Yes
(Select one.)

What date did the adverse event end?

(Record the end date of the adverse event using the MM-DD-YYYY format.)

At what time did the adverse event end?

(If appropriate, record the time the AE ended using the HH:MM (24-hour clock) format.)

What was the severity of the adverse event?	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe (The reporting physician/healthcare professional will assess the severity of the event using the sponsor-defined categories. This assessment is subjective and the reporting physician/healthcare professional should use medical judgment to compare the reported Adverse Event to similar type events observed in clinical practice. Severity is not equivalent to seriousness.)
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What is the toxicity grade of the adverse event?	<input type="radio"/> Grade 1 <input type="radio"/> Grade 2 <input type="radio"/> Grade 3 <input type="radio"/> Grade 4 <input type="radio"/> Grade 5 (Severity CTCAE GradeThe reporting physician/healthcare professional will assess the severity of the adverse event using the toxicity grades.)
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Is the adverse event serious?	<input type="radio"/> No <input type="radio"/> Yes (Assess if an adverse event should be classified as serious based on the serious criteria defined in the protocol.)
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Is the adverse event associated with a congenital anomaly or birth defect?	<input type="radio"/> No <input type="radio"/> Yes (Record whether the serious adverse event was associated with congenital anomaly or birth defect.)
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Did the adverse event result in Persistent or significant disability or incapacity?	<input type="radio"/> No <input type="radio"/> Yes (Record whether the serious adverse event resulted in a persistent or significant disability or incapacity.)
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Did the adverse event result in death?	<input type="radio"/> No <input type="radio"/> Yes (Record whether the serious adverse event resulted in death.)
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Did the adverse event result in initial or prolonged hospitalization for the subject?	<input type="radio"/> No <input type="radio"/> Yes (Record whether the serious adverse event resulted in an initial or prolonged hospitalization.)
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Is the adverse event Life Threatening?	<input type="radio"/> No <input type="radio"/> Yes (Record whether the serious adverse event is life threatening.)
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Is the adverse event a medically important event not covered by other ?serious? criteria?

- ☐ No
☐ Yes
(Record whether the serious adverse event is an important medical event, which may be defined in the protocol or in the Investigator Brochure.)

Is this event related to study treatment?

- ☐ Definitely
☐ Probably
☐ Possibly
☐ Not Related
(Indicate if the cause of the adverse event is related to the study treatment and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, and/or other interventions).)

What action was taken with study treatment?

- ☐ Dose Increased
☐ Dose Not Changed
☐ Dose Reduced
☐ Drug Interrupted
☐ Drug Withdrawn
☐ Not Applicable
☐ Unknown
(Record changes made to the study treatment resulting from the adverse event.)

What other action was taken in response to this adverse event?

(Record all action(s) taken resulting from the adverse event.)

What was the outcome of this adverse event?

- ☐ Fatal
☐ Not recovered / Not resolved
☐ Recovered / Resolved
☐ Recovered / Resolved with sequelae
☐ Recovering / Resolving
☐ Unknown
(Record the appropriate outcome of the event in relation to the subject's status.)

Did the adverse event cause the subject to be discontinued from the study?

- ☐ No
☐ Yes
(Record if the AE caused the subject to discontinue from the study.)

CDISC wishes to acknowledge all the companies that have generously donated their resources in staff, time and other forms support to develop the CDASH standard. For more information on CDASH implementation please refer to the CD