

ASCO Adverse Events Reporting Decision Aid[®]

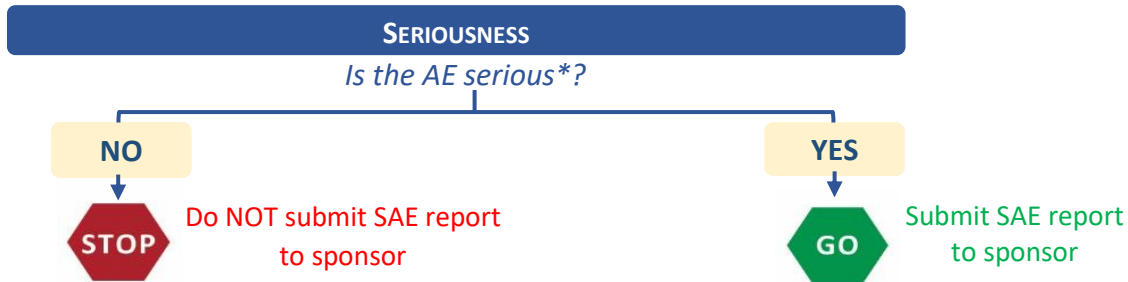
The ASCO Adverse Events Reporting Decision Aid is intended to assist physician investigators and research staff in determining whether an adverse event (AE) should be: (i) reported to the sponsor as a serious AE (SAE) and (ii) attributed to the investigational drug.

The Decision Aid is intended to be a general guide for deciding whether an adverse event is caused by an investigational drug. These decisions ultimately require clinical judgement to determine if there is a reasonable possibility that the drug caused the event.

The Decision Aid accompanies an ASCO Toolkit that includes other educational resources related to AE reporting. The Toolkit is available via [ASCO.org](https://www.asco.org).

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SUBMITTING A SERIOUS ADVERSE EVENT TO A TRIAL SPONSOR



* An SAE is one resulting in death, a life-threatening situation, in-patient hospitalization or prolongation of hospitalization, persistent or significant incapacity or substantial disruption in ability to conduct normal life functions, congenital anomaly or birth defect, or an important medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the previously listed outcomes.

ATTRIBUTING AN ADVERSE EVENT TO AN INVESTIGATIONAL DRUG IN AN SAE REPORT

