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.

Version 1.0

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AMERICAN SOCIETY OF CLINICAL ONCOLOGY

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SUBMITTING A SERIOUS ADVERSE EVENT TO A TRIAL SPONSOR

SERIOUSNESS

Is the AE serious?*

NO → STOP — Do NOT submit SAE report to sponsor

YES → GO — Submit SAE report to 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

EXPECTED EVENT FOR THE DRUG

*Is the AE expected**?*

YES → GO — Attribute to drug if no alternative explanation

***An expected AE is an event that is listed in the investigator brochure.*

NO → *Is there evidence to suggest the drug caused the event? Consider the following.*

UNCOMMON IN THE PATIENT POPULATION AND ASSOCIATED WITH DRUG EXPOSURE

Is the AE uncommon in the population under study and known to be strongly associated with drug exposure in general (e.g., angioedema, hepatic injury, agranulocytosis, Stevens-Johnson Syndrome)?

YES → GO — Attribute to drug if no alternative explanation

NO

UNCOMMON IN THE PATIENT POPULATION AND UNCOMMON WITH DRUG EXPOSURE

In general, is the AE uncommon with both drug exposure and in the patient population under study (e.g., tendon rupture)?

YES → GO — Attribute to drug if no alternative explanation

NO

UNANTICIPATED IN THE STUDY POPULATION

Is the AE unanticipated in the population under study independent of drug exposure based on any of the following: underlying disease, demographics (age, comorbidities), or

YES → GO — Attribute to drug if no alternative explanation

NO → STOP — Do NOT attribute to drug unless there is evidence to suggest causality

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