DMID SAE REPORTING FACT SHEET

Definition

Serious Adverse Event (SAE) or Serious Suspected Adverse Reaction: An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- Life-threatening adverse event[1]
- Inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- Congenital anomaly/birth defect
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above. (Examples: allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.) [21 CFR 312.32(a)]
- Requires intervention to prevent permanent impairment or damage

Other Types of Adverse Events:

- Adverse Events of Special Interest (AESI) – an adverse event (serious or non-serious) that is of scientific and medical concern specific to the study product or research program (e.g., myocarditis for mRNA vaccines). Therefore, ongoing monitoring and rapid communication by the Investigator to the sponsor may be appropriate and such an event may require further investigation in order to characterize and understand it.
- Medically Attended Adverse Events (MAAEs) – defined as AEs with medically attended visits including hospital, emergency room, urgent care clinic, or other visits to or from medical personnel for any reason. Adverse events (e.g., abnormal vitals) identified at a routine study visit will not be considered MAAEs.
- New Onset Chronic Medical Conditions (NOCMCs) – defined as any new International Classification of Diseases diagnosis (per current International Statistical Classification of Diseases and Related Health Problems) that is applied to the participant during the course of the trial, after receipt of the study product, that is expected to continue for at least 3 months and requires continued health care intervention.
- Potentially Immune-Mediated Medical Conditions (PIMMCs) – defined as a subset of adverse events that include autoimmune diseases and other inflammatory or neurological disorders of interest that might have an autoimmune etiology.
- Sponsor requested adverse events – defined as an adverse event that would not otherwise be reported to DMID-CROMS PVG, but requested to be submitted to DMID-CROMS PVG by the sponsor.

SAE Report Form

Once you are given a username and password to the DMID-CROMS Web Library website, go to the following link: http://www.dmidcroms.com to access the SAE Report Form, instructions and the fax transmittal form. The SAE Report Form can be used to submit other types of adverse events as well as serious adverse events.

DMID Reporting Timelines

- Any AE that meets a protocol-defined seriousness or reporting criterion must be submitted on an SAE form according to protocol timelines.
- Additional contacts and local regulatory authorities should be notified as specified in the protocol.

How to report SAEs to the DMID-CROMS Pharmacovigilance Group (PVG)

Complete the SAE Report form following the provided instructions and the fax transmittal form, and submit to the DMID-CROMS PVG:

- Via the Safety fax line: **1-800-275-7619 (US)** or **1-301-897-1710 (outside US)**
- Via email: pvg@dmidcroms.com
- Via phone: The Safety Hotline (available 24 hours a day, 7 days a week) at **1-800-537-9979 (US)** or **1-301-897-1709 (outside US)**
    - If DMID-CROMS PVG is notified of an SAE via phone, an SAE Report must still be faxed or emailed to DMID-CROMS PVG within the specified timelines.

Note: If protocol instructions differ, then follow the protocol instructions.

[1] Refers to the seriousness criterion of Life-Threatening, and not the severity grade.

Questions

Contact the DMID-CROMS Pharmacovigilance Group:

- Via email: pvg@dmidcroms.com
- Via the Safety Hotline (available 24 hours a day, 7 days a week): **1-800-537-9979 (US)** or **1-301-897-1709 (outside US)**

Figure: Overview of Safety Reporting for DMID held INDs.