**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
  + 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)]

**SAE Report Form**

Once you are given a user name and password to the DMID-CROMS Web Library website, go to the following link: <http://www.dmidcroms.com> to access theSAE Report Forms, Guidelines and the Fax transmittal form.

**DMID Reporting Timelines**

* Any AE that meets a protocol-defined serious criterion must be submitted within 24 hours of site awareness on an SAE form.
* 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 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](mailto: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 to DMID-CROMS PVG within the specified timelines.
* Note: If utilizing a Central Unit or if protocol instructions differ, then follow the protocol instructions.

**Questions**

Contact the DMID-CROMS Pharmacovigilance Group:

* Via email: [pvg@dmidcroms.com](mailto: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.

Box 1, Investigators report SAEs and record non-serious adverse events.
Arrow from Box 1 to Box 2
Box 2, DMID. Sponsor reports serious, unexpected and suspected adverse reactions (reasonable possiblity the study product caused the event)
Arrow from Box 2 to Box 3
Box 3, FDA.
Arrow from Box 2 to Box 4
Box 4, All investigators. Report unanticipated problems involving risks to subjects. Provide information on significant new findings.
Arrow from Box 4 to Box 5
Box 5, IRB/IEC. SAEs must be reported to the local IRB/IEC, as required by IRB/IEC policy.
Arrow from Box 4 to Box 6
Box 6, Patient/Subject.
