

Division of Microbiology and Infectious Diseases

SAE Reporting Guidelines

For questions on SAE reporting or SAE form completion, contact DMID-CROMS Pharmacovigilance:

Email: PVG@dmidcroms.com SAE Hotline: 1-800-537-9979 (US) or 1-301-897-1709 (Outside US)

SAE Fax Line: 1-800-275-7619 (US) or 1-301-897-1710 (Outside US)

Serious Adverse Events (SAEs) must be reported to DMID-CROMS Pharmacovigilance (PVG) **within 24 hours** of site awareness (or as stipulated by the protocol) by submitting a completed SAE form via email or fax.

Subject Information (Section 1)

- Before providing source documentation to PVG, label documents with the appropriate protocol number and subject ID number on each page.
- Review the documentation to ensure no other personally identifiable information is forwarded. There should be no names, addresses, identifying numbers (social security, hospital, medical record) on submitted documents.

SAE Category (Section 2)

- Check ALL applicable categories that apply to the event.
- If “Other Protocol Requirement” is chosen, please specify the requirement for reporting the event.

SAE Information (Section 3)

SAE Term

- A specific diagnosis or syndrome should be provided rather than symptoms when possible (for example “gastroenteritis” instead of “nausea, vomiting and diarrhea”). Use accurate medical terminology when providing the SAE term, which can be updated when more information or a final diagnosis becomes available.
- Terms such as “hospitalization” or a procedure name are not acceptable. For example, if a subject was hospitalized for cholecystectomy due to cholecystitis, the event term should be “cholecystitis” and not “cholecystectomy.”
- In case of death, the SAE term should be the cause of death. Do not use the term “death” and avoid using “cardiac arrest” or “respiratory failure” if possible. Instead provide the diagnosis leading to cardiac arrest or respiratory failure.
- Elective procedures requiring hospitalization will not be considered SAEs if they were planned prior to signing consent; however, other events may occur during this hospitalization that may be considered SAEs and will need to be reported according to the protocol.
- If a subject experiences more than one SAE during the same time period (e.g. a hospitalization), each SAE should be reported individually on a separate SAE form.

Onset Date

- Onset date is the date the Investigator considers the event to meet one of the seriousness criteria in Section 2.

Severity

- Please select severity based on the definitions or toxicity tables provided in the protocol.

Relationship to Study Product

- Provide the Investigator’s assessment of the relationship between the study product and this SAE. This is a mandatory field.
- If “Not Related” is indicated, please suggest an alternative cause for this SAE by selecting from the provided list.

SAE Outcome (Section 4)

- Only ONE outcome can be selected per SAE.
- For “Recovered/Resolved” or “Recovered/Resolved with sequelae” document the date of resolution. Note that SAEs will be followed until **resolution** (until the subject’s health has returned to his/her baseline status or all variables have returned to normal).
- For “Recovered/Resolved with sequelae,” indicate the sequelae (for example, if the event is “stroke” the sequelae may be “numbness in left arm”).
- If “Fatal” is chosen:
 - Include the date of death.

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- Provide a copy of the autopsy report and/or death certificate if available.
- Only ONE event per subject will have an outcome of “Fatal.” For SAEs that did not cause the death and were not resolved prior to the death, the outcome should be entered as “Not Recovered/Not Resolved.”
- Some events do not resolve, such as chronic conditions, cancer, congenital anomalies and disabilities. These events will be followed until **stabilization** (until the Investigator does not expect any further improvement or worsening). Once the event is determined to be stable, it may be marked resolved, with the stabilization date and sequelae (if applicable) clearly marked on the SAE form.

Study Product Information (Section 5)

- Under “Study Product Name” enter the study product(s) that the subject received. If the study product is blinded, indicate this by checking the box.
- Under “Action Taken With Study Product” indicate the action taken with the study product as a result of this SAE. Mark “Not applicable” if dosing was complete prior to SAE onset or if the SAE resulted in death.

Laboratory Results and Diagnostic Tests (Sections 6 and 7)

- Include pre-SAE laboratory values under “Baseline Result” and indicate the date.
- Include normal reference ranges for all reported laboratory values.
- Copies of all relevant labs and diagnostic tests should be submitted with the SAE report.

Concomitant Medications (Section 8)

- Concomitant medications refer to medications the subject was receiving at the time of SAE onset. Any other relevant or treatment medications should be included in Section 9.
- Indicate if any of the concomitant medications are suspected to have caused the SAE.

Event Summary (Section 9)

- Please provide a detailed chronological description of the clinical progression of the reported SAE. Attach relevant source documentation (discharge summary, medical history, autopsy report, death certificate etc.)

Reporter Information and Signatures (Section 10)

- It is mandatory that the Principal Investigator (PI) or sub-Investigator on FDA form 1572 sign the SAE form.
- Do not delay submission of an SAE if the PI is not immediately available to sign the report. The PI signature should be forwarded as soon as possible.

Submitting SAE Forms to PVG:

- If submitting an SAE form via email, include the following information in the subject line: DMID protocol number, Subject ID, “Serious Adverse Event” or “SAE” and Initial/Follow-up #.
- If submitting an SAE form via fax, complete the DMID SAE fax cover sheet.
- PVG will provide a receipt confirmation via email for all submissions. Please retain all confirmations and copies of all information sent to PVG.
- When submitting a follow-up SAE form:
 - Save a copy of the original SAE form before making any changes to it.
 - On the copy, enter the Follow-up # and Date. All changes should be neat and legible.
 - On handwritten reports, initial and date all changes. Provide PI signature on each follow-up.
 - Submit all 4 pages of the SAE form even if changes were made to one or two of the pages.
 - DO NOT resend source documents that had been previously submitted (unless changes have been made on them).
 - For subsequent changes, update the last SAE form sent to PVG.