Division of Microbiology and Infectious Diseases

SAE Reporting Instructions

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) are reported to DMID-CROMS Pharmacovigilance (PVG) **within 24 hours** of site awareness (or as stipulated by the protocol) by submitting a completed SAE form v4.0 via email or fax.

General Instructions:

- Software Requirements: Adobe Acrobat Reader.
    - If Adobe Acrobat Reader is not available, please download and print the form.
    - Do not fill out the form using a web browser, the form will not function properly.
- Please make sure all entries are typed or clearly handwritten.
- Please complete all required fields marked with an asterisk (*) or highlighted in RED.
- ***Please note the form is locked once electronically signed, and no further changes can be made.***
- Calendar Date format DD-MMM-YYYY (e.g., June 1, 2022 = 01 JUN 2022).
    - If exact date is unknown, please provide best estimate.
- For long narratives, attach additional pages as needed. If attaching additional pages, please do the following:
    - Label each page with the protocol number and participant ID.
    - Indicate the section number for the narrative.
- For attaching source documentation, label each document with the protocol number and participant ID.
- If the case involves more than one (1) SAE, please submit each SAE on a separate SAE form.
- Please do not include any personally identifiable information (PII) on the SAE report form and redact all PII from any attached documents. Examples of PII include names, addresses, social security number (SSN), hospital, or medical record numbers.
- Some fields will only allow one value to be selected (e.g., severity). To change the selected value, check a different value.
- Non-serious events can be reported if they meet the other criteria for reporting as specified by sponsor or protocol.
- If the required fields are left blank, an error message will appear to indicate that the necessary information is needed. For example, you may see the following error message: "Before submitting the document, please complete the following required fields: product1Text_3SAE." In this context, "product1Text_3SAE" refers to the requirement of entering information for Section 3 SAE product 1.

Case Information

- ***DMID Protocol # (required):** please enter assigned DMID protocol number (e.g., 22-0011).
- ***DMID Participant ID (required):** please enter the assigned participant or subject ID.
- **Site Name:** please provide the name of the site.
- **Site SAE Awareness Date:** please provide the date the investigator was first made aware of the SAE (not the information being used to support the SAE).
    - Site awareness date should not change unless the site awareness date is being corrected.
- **Initial Report Date:** please check initial report if this report is the first time the SAE is reported to PVG and provide the date the initial report is filled out.
- **Follow up #/Date:** please check follow-up if this report is a follow-up to a previously submitted initial report.
    - Please enter “1” if this is the first follow-up report or “2” if it is the second follow-up report, etc.
    - Please provide the date the follow-up report is filled out.

Participant Information (Section 1)

- ***Sex (required):** please check one.
- **Gender:** please check one.
- ***Age (required):** please indicate age of patient at the time of event onset and check time unit (e.g., years) and include applicable units per age group.

- If participant is a neonate (birth to 28 days), please enter gestational age at birth, birth weight and APGAR scores.
- **Weight:** please enter most recent weight and check weight unit (e.g., kg). This is a free text field; unit can be entered as applicable.
- If the SAE occurred in an infant, please check if the participant information refers to the "mother" or "infant".
- ***Ethnicity (required):** please check one.
- **Race:** please check all that apply.

***SAE Category (Section 2) (required)**

- Please check ALL categories that apply to the SAE. Reference 21 CFR 312.32(a) for definitions.
- Please indicate **Admission Date** and **Discharge Date** for hospitalization if applicable.
- **Other Reporting Requirement:** please check and indicate any additional protocol requirement(s) that apply for the event (e.g., if the event is also an adverse event of special interest (AESI), medically attended adverse event (MAAE), new onset chronic medical condition (NOCMC), unanticipated problem (UP), potential immune-mediated medical condition (PIMMC) or any other requirement as specified by the sponsor or protocol).

SAE Information (Section 3)

- ***SAE Term (required):** please use the term or parameter in the toxicity table used for the protocol or provide a single medical diagnosis that best describes the event (e.g., "anemia" for symptoms of low Hgb, SOB, lethargy).
    - Common or standard medical abbreviations may be used when describing the SAE term.
    - Adverse events can be complex and often result in more than one abnormal sign, symptom, or laboratory parameter. Whenever possible, report the resulting overall diagnosis as the SAE term. For example, report "pancreatitis" instead of "abdominal pain" or "Grade 4 amylase" or "Grade 3 nausea," or "Myocardial Infarction" instead of "Chest Pain."
    - Terms such as "hospitalization" and names of procedures or medical/surgical interventions are not acceptable. Instead, the reason for the hospitalization, procedure or medical/surgical intervention should be reported as the SAE term. For example, if a participant was hospitalized for cholecystectomy due to cholecystitis, the event term should be "cholecystitis" and not "cholecystectomy."
    - In case of death, cardiac arrest, or any organ failure, the main cause or diagnosis leading to the death or organ failure should be used as the SAE term.
    - Hospitalizations to facilitate elective or planned procedures are not SAEs. However, an event that requires hospitalization for a medical or surgical intervention to prevent permanent impairment or damage may be considered an SAE.
- ***Onset Date (required):** Please provide the actual or best estimate of the date the event met criteria for reporting.
- ***Severity (required):** Please select one based on toxicity table or the protocol definition of severity.
- ***Relationship to Study Product or Intervention (required):** Please provide the Investigator's assessment of causality or relationship between each study product and the SAE.
    - Up to 4 study products or interventions can be listed. Please indicate the name of the study product.
    - If the study products are "Not Related" to the event, please select an alternative cause in the **Alternate Etiology** column and indicate the suspected cause of the SAE.

SAE Outcome Information (Section 4)

- ***SAE Outcome (required):** Please check only one outcome. Additional fields may appear based on the outcome selected.
    - **Recovering/resolving:** Please provide a follow-up report when outcome resolves.

- **Not recovered/not resolved:** Please provide a follow-up report when outcome resolves.
- **Recovered/Resolved:** Please indicate the date of resolution.
- **Recovered/Resolved with sequelae:** Please indicate the date of resolution and state the sequelae or chronic complication caused by the SAE (e.g., numbness or tingling, paralysis, disfigurement, organ injury).
- **Fatal (death):** Please indicate the date of death and check if ***Autopsy (required when Fatal is selected)** or ***Death Certificate (required when Fatal is selected)** is available. Please provide a copy of the autopsy report or death certificate if available.

Study Product Information (Section 5)

- ***Study Product Name (required):** Please indicate the name of each study product if more than one was administered.
- ***Blinded (required):** Please check the box if the study product was blinded.
- ***Dosage, Route of Administration, and Frequency (required):** Please indicate the dose administered (e.g., 150 mg, 1 x 10^11 vp), the route (e.g., intramuscular, subcutaneous) and schedule of administration (e.g., daily, twice daily) at the time of the SAE or prior to the SAE.
- ***Date Started (required):** Please provide the actual date the study product was first given to or taken by the participant.
- **Date Last Taken Prior to SAE Onset:** Please indicate the actual date the study product was last given to or taken by the participant prior to SAE onset.
- ***Action Taken With Study Product (required):** Please indicate the action taken with the study product at the time of the SAE or as a result of the SAE.
  - **Not applicable:** Please use only if none of the other choices apply or the SAE resulted in death prior to any action taken with the study product.
- **Event Abated After Study Product Use Stopped or Dose Reduced?:** If the study product was interrupted (stopped) or reduced, please indicate if the SAE improved.
  - Please check "Does not apply" if the study product was not interrupted (stopped) or reduced.
  - Please indicate the date the event abated if the answer is "Yes".
  - Please include any relevant comments here or in Section 9.
  - Please provide supporting lab or diagnostic tests in Section 6, Section 7 or Section 9, if available.
- **Event Reappeared After Reintroduction of Study Product?:** If the study product was reintroduced, please indicate if the event reappeared.
  - Please check "does not apply" if the study product was not reintroduced.
  - Please indicate the date the event reappeared if the answer is "Yes".
  - Please include any relevant comments here or in Section 9.
  - Please provide supporting lab or diagnostic tests in Section 6, Section 7 or Section 9, if available.

Laboratory Results and Diagnostic Tests (Sections 6 and 7)

- Please list or attach copies of all relevant laboratory or diagnostic test results used to assess or diagnose the event. Include any relevant tests used to rule out a diagnosis if appropriate.
  - Please include any relevant baseline data from prior to the administration of the study product or the adverse event.
  - When attaching results, please redact any PII and label each page with the protocol number and participant ID.
- **No relevant laboratory/diagnostic tests:** Please check if no relevant laboratory or diagnostic test was used to evaluate the event.
- **Pending:** Please check if laboratory or diagnostic tests are pending at the time of reporting.

  - Please indicate the name of the pending tests or results.
  - Please submit copies of the pending tests or results in a follow-up report when available.
- **Test:** Please indicate the name of the test.
- **Test Date:** Please indicate the date of the test.
- **Result:** Please indicate the test result.
- **Baseline Date/Result:** Please enter the date and results of tests performed before event onset.
- **Site Normal Range:** Please provide the normal reference range for your site laboratory including the units.

Concomitant Medications (Section 8)

- **Medication:** Please list or attach copies of all concomitant medications (including non-prescription medications or supplements) taken or received by the participant at the time of SAE onset.
  - Generic or trade names can be used.
  - Please do not include medications used to treat the SAE at the time of the event or any treatment the participant received after the event. Any relevant treatment for the event should be included in Section 9.
  - When attaching a medication list, please redact PII and label each page with the protocol number and participant ID.
- **Start/Stop Date or Ongoing:** Please indicate the date the participant started and stopped taking the concomitant medication. If the subject continues to take the concomitant medication, please select "Ongoing."
- **Total Daily Dose:** Please indicate the total daily dose taken or received by the participant prior to the event.
- **Frequency/Route:** Please indicate the frequency and route of concomitant medication administration.
- **Indication:** Please state the reason the participant took the concomitant medication.
- **Suspect:** Please select "Yes" if the concomitant medication is suspected to have caused or contributed to the SAE.

Event Summary Information (Section 9)

- ***Event Summary (required):** Please describe in chronological order the clinical progression of the reported SAE.
  - Participant's relevant past medical history, family history, social history and allergies can also be provided here. For newborn and pregnant participants include relevant maternal, obstetric and prenatal history if applicable.
  - Please attach relevant source documentation (discharge summary, medical history, reactogenicity records, autopsy report, or death certificate) as needed to support assessment of the SAE.
  - When attaching documents, please redact PII and label each page with the protocol number and participant ID.

Reporter Information and Signatures (Section 10)

- **NOTE:** ***The form is locked once electronically signed, and no further changes can be made.***
  - Please save a version of the form without a signature if future changes will be made (e.g., follow-up report).
- **Investigator Name:** Please provide the first and last name of the Principal Investigator or designee.
  - The investigator must be listed on the signed FDA form 1572 or the site delegation of authority log.
- **Investigator Signature/Date:** Please provide the named investigator's signature and the date signed.
  - Please do not delay submission of an SAE if the Principal Investigator is not available to sign the report.
  - SAE form can be submitted without an investigator signature, please forward investigator signature when available.
- ***Reporter Name (required):** Please provide the first and last name of the person submitting the report.

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

- ***Reporter's Email Address (required):** Please provide the email address for the reporter.
- **Reporter's phone number:** Please provide the phone number for the reporter.
- ***Reporter Signature (required)/Date:** Please provide the named reporter's signature and the date signed.
    - The reporter signature is required to submit the SAE form.
    - The date field is not mandatory for submission.
    - Signatures can be applied electronically via Adobe or by hand by printing the SAE form.
    - When signing electronically, Adobe will prompt you to save the signed form.
    - Please save the signed form under a different file name (e.g., SAE Form signed).

Submission Methods for SAE Forms to PVG: Please choose one of the following submission methods.

- **SUBMIT Button:** After signing, click the submit button on the bottom right of the last page of the SAE form.
    - A pop-up notification will appear if there is any missing required information. The pop-up will describe the section number, field or section name that the required information is missing from.
    - Please provide the missing information and click the submit button again.
    - After clicking the submit button, an email message addressed to PVG with the SAE form attached will appear.
        - ***Note: First-time users may receive a pop-up notification asking the user to choose an email application. Choose your preferred email application and click 'Remember my choice'.***
        - ***The email message addressed to PVG may take several seconds (e.g., up to 20 secs) to appear.***
    - Please verify the PVG email address is correct: PVG@dmidcroms.com
    - Please edit the subject heading to include: DMID Protocol Number, Participant ID, and Initial SAE or SAE Follow-up # (e.g., Protocol #22-0011, Participant ID CV0504067, Initial SAE or SAE Follow-up #1).
- **EMAIL Submission:** SAE form may be submitted via an email attachment.
    - Please attach the saved or scanned SAE form to the email.
    - Please edit the subject heading to include: DMID Protocol Number, Participant ID, and Initial SAE or SAE Follow-up # (e.g., Protocol #22-0011, Participant ID CV0504067, Initial SAE or SAE Follow-up #1).
    - Please enter PVG's email address: PVG@dmidcroms.com
- **FAX Submission:** SAE form may be submitted via fax if electronic or email submission is not possible.
    - Please complete and include the DMID SAE fax cover sheet found here: SAEfaxcover.doc (dmidcroms.com)
    - Please fax to PVG SAE Fax Line: 1-800-275-7619 (USA) or 1-301-897-1710 (International).
- **Confirmation of Receipt:** PVG will provide a receipt confirmation via email for all submissions.
- Please save a copy of the reported SAE form and retain all copies of all information sent to/received from PVG.

Follow-up SAE Report:

- **Electronic Submissions:** Please use a saved copy of the initial SAE form or most recent follow-up SAE form.
    - Please modify the SAE form by checking **Follow-up, and entering the Follow-up # and Date.**
    - Do not change the site awareness date unless it is a correction from the initial site awareness date.
- **Handwritten Submissions**: Please use a saved copy of the initial SAE form or the most recent follow-up SAE form.
    - Please use a single line to cross-out existing information, and initial and date all changes.
- **Signature Requirement:** Please have reporter, PI or designee sign and date each follow-up report.
- Submit all pages of the SAE form even if changes were made to only one or two pages.
- Please send only NEW redacted source documents and DO NOT send previously submitted source documents unless new information is available.