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Form: SAE Instructions

INSTRUCTIONS:

- **The forms contained in the SAE folder are designed to collect all information required for reporting of Serious Adverse Events (SAEs).**
- **The majority of the questions are related to what has happened up until the SAE occurred, which may or may not coincide with completion of a cycle or visit and the scheduled data collection.**
- **Where possible, data has been pre-populated in the SAE-specific forms based on data entry previously completed in the protocol-specific forms. All pre-populated data will be locked and unavailable for updates within the SAE-specific forms. If data in an SAE-specific form is incorrect, the source filed within the protocol-specific forms must be updated in order to make the change.**
- **Completion requirements:**
    - **If either the "Report Due By" or "Report type selected by user" field on the protocol-specific Adverse Events form is identified as "24 Hrs", or the "Report type selected by user" on the SAE-specific SAE forms is identified as "24 Hrs", the following forms (where required) must be completed within 24 hours, and all other forms must be completed within 10 days:**
        - SAE Report Initiation
        - SAE Information
        - SAE Description of Event
        - SAE Reporting Period Information
        - SAE Protocol Agent Intervention (if applicable)
        - SAE Protocol Radiation Intervention (if applicable)
        - SAE Participant Information
        - SAE Pre-Existing Conditions (if applicable)
        - SAE Concomitant Medications (if applicable)
        - SAE Prior Therapy (if applicable)
        - SAE Additional Information (if applicable)
        - SAE Attribution
        - SAE Submission
    - **If the "Report Due By" field on the Adverse Events form is identified as "10 Days" and the "Report type selected by user" on the SAE and Adverse Events CRFs are identified as "10 days", all forms in this SAE folder (which are required and applicable to the primary SAE being reported) must be completed within 10 days.**

>> **Next Step:** Complete the SAE Report Initiation Form in the appropriate SAE Cycle Folder.

Form: SAE Report Initiation

Report ID _____ *(populated via CF)*

Treating Physician

Select treating physician name * (CTEP ID) _____ *(dynamic search list)*

Treating physician email address _____ *(populated via CF)*

Treating physician first name _____ *(populated via CF)*

Treating physician last name _____ *(populated via CF)*

Treating physician middle name _____ *(populated via CF)*

Treating physician phone number _____ *(populated via CF)*

Treating physician fax number _____ *(populated via CF)*

Reporter

Select reporter name * (CTEP ID) _____ *(dynamic search list)*

Reporter email address _____ *(populated via CF)*

Reporter first name _____ *(populated via CF)*

Reporter last name _____ *(populated via CF)*

Reporter middle name _____ *(populated via CF)*

Reporter phone number _____ *(populated via CF)*

Reporter fax number _____ *(populated via CF)*

INSTRUCTIONS:

- **You must specify any additional email addresses that should be copied when the report is submitted. caAERS will send an email (to all identified recipients) to notify them that the report was successfully submitted.**
- **To enter in multiple email addresses, separate each with a semicolon (;). Example: username1@site.edu; username2@site.com.**

Additional email recipients _____

Comments _____

>> Next Step:

Date Time *(dd MMM yyyy / hh:mm:ss)* __ __ - __ __ __ - __ __ __ __ / __ __ : __ __ : __ __ *(populated via CF)*

Form: SAE Information

- Adverse events determined to be serious based on the caAERS validation rules, have been derived to this SAE form for expedited reporting.
- Additional adverse events associated with the derived SAE(s) require the user to select the "Add a new Log line" to add adverse events reported on the Adverse Events CRF

<< ***Previous Step:***

Forms Instructions *[?]*

***red asterisk before a field denotes a required response**

FORM_OID _____ *(defaulted)*

Report ID _____ *(populated via CF)*

Start date of this course/cycle (derived) *(dd MMM yyyy)* __ __ - __ __ __ - __ __ __ __ *(populated via CF)*

Report type selected by user (derived)

* **Adverse event** (Adverse event ID)	* **Verbatim term** (derived)	* **Adverse event term** (CTCAE v4.0) (derived)	**MedDRA adverse event code** (CTCAE v4.0) (derived)	**Adverse event grade** (derived)	**Hospitalization** (derived)	**Present status** (required if primary AE is Yes)	**Adverse event ID** (derived)	**Report ID** (derived)	**AE identified as primary for the reporting period** (only one AE can be designated as the primary)	**Date first learned** (derived)	**Time zone** (derived)	**Start date**	**End date** (required if primary AE is Yes)	**Serious?** (derived)	**Comments**

NOTE: A response of "YES" to any of the questions below will require the user to complete the selected form in this SAE cycle folder.

Are there pre-existing conditions associated with any serious events occurring this reporting period? *

Are there concomitant medications associated with any serious events occurring this reporting period? *

Are there prior therapies associated with any serious events occurring this reporting period? *

Are there laboratory results associated with any serious events occurring this reporting period? *

>> **Next Step:**

Form Date *(dd MMM yyyy / hh:mm:ss)* __ __ - __ __ __ - __ __ __ __ / __ __ : __ __ : __ __ *(populated via CF)*

Form: SAE Attribution of Adverse Events

FORM_OID *pending*

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: For each adverse event, attribute the level of relatedness to each potential cause (factor). The adverse events and factors listed below were created based on the information provided in the previous SAE forms.

Adverse Event	Factor	Attribution
(derived)	(derived)	☐Unrelated ☐Unlikely ☐Possible ☐Probable ☐Definite

Comments

_____

_____

_____

Form: SAE Reporting Period Information

FORM_OID PID3787771_V1_0

Reporting Period ID _____ *(derived)*

Treatment Assignment Code _____ *(derived)*

(If other), treatment assignment description _____

Start date of first course *(dd MMM yyyy)* __ __-__ __ __-__ __ __ __ *(derived)*

Start date of course associated with expedited report *(dd MMM yyyy)* __ __-__ __ __-__ __ __ __ *(derived)*

Course number on which event occurred __ __ *(derived)*

Total number of courses to date __ __ *(derived)*

INSTRUCTIONS: Only select "Yes" to the following 4 questions if the protocol intervention was received. Select "No" if the intervention was not a part of the protocol plan or was not yet received by the subject.

Was an investigational agent administered on this protocol? *(check one)* ☐Yes ☐No

Was an investigational device administered on this protocol? *(check one)* ☐Yes ☐No

Was there a surgical intervention administered on this protocol? *(check one)* ☐Yes ☐No

Was there a radiation intervention administered on this protocol? *(check one)* ☐Yes ☐No

Comments

_____

_____

_____

Form: SAE Prior Therapy

FORM OID PID3787771_V1_0

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: Enter all prior therapies for the current study disease by adding a new log line for each therapy received. Include prior therapies for a disease other than the study disease if those therapies are relevant for this report.

- **If "Prior Therapy Administered Type" is Chemotherapy single agent systemic, Chemotherapy multiple agents systemic, Chemotherapy (NOS), Chemotherapy non-cytotoxic, Drug and/or immunotherapy, Hormonal therapy, Prior Therapy NOS, Anti-retroviral Therapy, Antisense, Oncolytic Virotherapy, Vaccine, or Therapy (NOS), please provide "Agent Name".**
- **If multiple agents are associated with a therapy, additional log-lines will need to be added.**
- **Multi-modality treatment should be listed separately. For example, mastectomy followed by tamoxifen should be entered in two separate log-lines. One row for surgery and one row for hormonal therapy.**

Prior Therapy Administered Type	Prior Therapy Other Administered Specify	Start Date	Stop Date	Agent Name
☐No prior therapy [10052052] ☐Chemotherapy single agent systemic [10008456] ☐Chemotherapy multiple agents systemic [10008452] ☐Chemotherapy (NOS) [10050693] ☐Chemotherapy non-cytotoxic [90003014] ☐Drug and/or immunotherapy [90003006] ☐Hormonal Therapy [10065646] ☐Surgery [10042609] ☐Radiation Therapy [10037770] ☐Bone Marrow Transplant [10061730] ☐Prior Therapy NOS [90003010] ☐Gene Transfer [90003004] ☐Anti-retroviral Therapy [90003000] ☐Antisense [90003002] ☐Oncolytic Virotherapy [90003008] ☐Vaccine [10021430] ☐Therapy (NOS) [90003012] ☐Hematopoietic Stem Cell Transplantation [10063581] ☐Image Directed Local Therapy [90003016]		__-__-____	__-__-____	(LOV???)

(add log line)

Comments

_____

_____

_____

KA Comment: For some prior therapies, an agent name is required. Need Control Type=Dynamic Search List once CF and LOV look-up table are available for the Agent Name field.

Form: SAE Protocol Device

Form OID *(pending)*

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: The following fields must be answered…

Brand Name *(name of the device according to the manufacturer)*	**Common Name**	**Device Type**	**Manufacturer Name** *(name of company that manufactured the device)*	**Manufacturer City**	**Manufacturer State/Province**	**Model #**	**Lot #** *(optional)*	**Catalog #** *(optional)*	**Expiration Date**	**Serial #**	**Other #** *(optional)*
					(need list)				__-___-____		

…continued

Service Operator *(person who uses the device)*	**Other Device Operator** *(if an additional person uses device)*	**Implanted Date**	**Removed Date**	**Reprocessed for Additional Use**	**Reprocessor Name** *(name of organization)*	**Reprocessor Address** *(optional)*	**Device Available for Evaluation** *(do not send to FDA)*	**Returned Date** *(date device was returned)*
		__-___-____	__-___-____	☐Yes ☐No			☐Yes ☐No	__-___-____

Comments

_____

_____

_____

KA Comment: “Returned Date” – date device was returned to whom?

Form: SAE Laboratory Tests and Results

Form OID PID3783852_V1_0

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: Certain lab results may suggest an adverse event, enter the applicable lab information for the expedited report. For example, if a lab result indicates that white blood cell count is low, that is an adverse event and should be included.

Lab Category	Lab Test	Other Lab Test Name	Baseline Value	Baseline Unit of Measure	Baseline Date	Nadir (Worst) Value	Nadir (Worst) Unit of Measure	Nadir (Worst) Date	Recovery or Latest Value	Recovery or Latest Unit of Measure	Recovery or Latest Date
☐Any ☐Bone marrow biopsy ☐Chemistry ☐Coagulation ☐Hematologic ☐Microbiology ☐Respiratory	(LOV)			(LOV)	__-___-____		(LOV)	__-___-____		(LOV)	__-___-____

…continued

Infectious Agent Test Date	Infectious Agent	Site of Infection
__-___-____		

Comments

_____

_____

_____

KLA Comment: Need to add caAERS-specific LOVs for Lab Test, Baseline Units of Measure, Nadir/Worst Units of Measure, Recovery or Latest Units of Measure, and possibly Infectious Agent???

Form: SAE Concomitant Medications

Form OID PID3785723_V1_0

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: Concomitant medications are any prescription and over-the-counter drugs and supplements a study participant has taken along with the study intervention. Document any non-protocol medications that may have contributed to the adverse event(s) reported.

Concomitant Agent Name
(drop down list)

(add log line)

Comments

_____

_____

_____

Form: SAE Pre-Existing Conditions

Form OID PID3785723_V1_0

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: If applicable, enter any medical conditions that existed before the subject entered the study, such as allergies, race, pregnancy, smoking and alcohol use, and hepatic/renal dysfunction, that maybe have affected the adverse event.

Medical History Description
(LOV??)

(add log line)

Comments

_____

_____

_____

KLA Comment: Is there an LOV for this field, or are we collecting just the description???

Form: SAE Protocol Radiation Intervention

Form OID PID3785729_V1_0

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: Record information related to the protocol radiation received only until the occurrence of the SAE.

Type of Radiation Administration	**Total Dose** *(to date)*	**Units of measure**	**Date of last treatment**	**Scheduled number of fractions** *(planned number of radiation sessions)*	**Number of elapsed days** *(number of days that therapy has not been performed due to adverse event)*	**Adjustment**
☐Extensive radiation ☐Limited radiation ☐External beam IMRT ☐Radiation NOS		(LOV)	__-___-____			(LOV)

(add log line)

Comments

_____

_____

_____

Form: SAE Protocol Agent Intervention

Form OID *(pending)*

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: Record information related to the protocol agent received only until the occurrence of the SAE.

Agent Name	Lot # *(if known)*	Total Dose Administered this Course *(to date)*	Units of Measure	Date Last Administered	Delay	Duration Delay	Delay Unit of Measure	Dose Modifications	Dose Modifications Comments
(drop down list)			(LOV)	__-___-____	☐Yes ☐No		(LOV)	☐Drug withdrawn ☐Dose reduced ☐Dose increased ☐Dose not changed ☐Not applicable	

(add log line)

Comments

_____

_____

_____

KA Comment: Does "Formulation" need to be added? Reminder that Agent Name is the User Data String and NSC # is the Coded Value.

Form: SAE Participant Information

Form OID PID3786951_V1_0

Reporting Period ID _____ *(derived)*

Study participant identifier _____ *(derived)*

Baseline performance status (ECOG) __ *(derived if collected)*

Height *(after the SAE)* __ __ __ __ __ . __ __ *(cm)*

Weight *(after the SAE)* __ __ __ __ __ . __ __ *(kg)*

Disease name *(LOV) (drop down) (possibly default)*

(If Solid tumor, NOS or Hematopoietic malignancy, NOS), other disease name _____

Primary disease site *(LOV) (drop down) (possibly default)*

(If other), other primary disease site _____

Date of initial diagnosis *(if known) (dd MMM yyyy)* __ __-__ __ __-__ __ __ __

Site of Metastatic Disease	Other Site of Metastatic Disease
(LOV)*(drop down)*	

(add log line)

Comments

_____

_____

_____

Form: SAE

FORM OID PID3786011_V1_0

Reporting Period ID _____ *(derived)*

caAERS Report ID _____ *(derived)*

Start date of this cycle *(dd MMM yyyy)* __ __-__ __ __-__ __ __ __ *(derived)*

Report type selected by user ☒24-hour notification
☐10-day report *(derived from Adverse Events CRF)*

INSTRUCTIONS: The table listed below has been populated from those adverse events determined by caAERS to be serious adverse events which need further reporting. If you feel there are additional adverse events that should be associated with the case, these should be added to this table. Add a log line and select any adverse events from the drop-down (must have been reported on the Adverse Events CRF) to add to the case.

SERIOUS ADVERSE EVENT(S)

Adverse Event Term (CTCAE v4.0)	**MedDRA Adverse Event Code (CTCAE v4.0)**	**Adverse Event ID**	**Reporting Period ID**	**Serious?**	**SAE Identified as Primary for the Reporting Period?** *(only one AE can be designated as the primary)*	**Start Date** *(required for primary SAE)*	**End Date**
(derived)	*(derived)*	*(derived)*	*(derived)*	☐Yes ☐No *(derived)*	☐Yes ☐No	_ _-_ _ _-_ _ _ _	_ _-_ _ _-_ _ _ _

(add log line)

Are there prior therapies associated with any serious events occurring this reporting period? *(check one)*
☐Yes ☐No *(If yes), complete the SAE Prior Therapy form.*

Are there concomitant medications associated with any serious events occurring this reporting period? *(check one)* ☐Yes ☐No *(If yes), complete the SAE Concomitant Medications form.*

Are there pre-existing conditions associated with any serious adverse events occurring this reporting period? *(check one)* ☐Yes ☐No *(If yes), complete the SAE Pre-Existing Conditions form.*

Are there laboratory results associated with any serious events occurring this reporting period? *(check one)* ☐Yes ☐No *(If yes), complete the SAE Laboratory Tests and Results form.*

~~Is there additional information (consults, autopsies, discharge summary, pathology, etc.) to support the serious events occurring this reporting period? *(check one)* ☐Yes ☐No~~

Comments

_____

_____

_____

KA Comment: Dictionary "Recommended Report" is incorrect. Serious adverse events table will be pre-populated with data from the Adverse Events CRF, but the site will be able to add additional adverse events reported on the Adverse Events CRF to the SAE case.

Form: SAE Submission

Form OID *(pending)*

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: Enter the CTEP I-AM Account ID of the treating physician, reporter, and submitter and save the form. If the IDs supplied are found in the CTSU Roster/RSS, the corresponding fields (i.e. Email, First name, Middle name, Last name, Institution name, Phone, and Fax) will be populated.

TREATING PHYSICIAN

CTEP ID _____

Email *(derived)*
First name *(derived)*
Middle name *(derived)*
Last name *(derived)*
Institution name *(derived)*
Phone *(derived)*

REPORTER

CTEP ID _____

Email *(derived)*
First name *(derived)*
Middle name *(derived)*
Last name *(derived)*
Phone *(derived)*
Fax *(derived)*

SUBMITTER

CTEP ID _____

Email *(derived)*
First name *(derived)*
Middle name *(derived)*
Last name *(derived)*
Phone *(derived)*
Fax *(derived)*

INSTRUCTIONS: You must specify any additional email addresses to be copied when the report is submitted. To enter in multiple email addresses, separate each with a semicolon (;). Example: username1@site.edu; username2@site.com. An email is sent by caAERS to all the recipients identified to report a successful submission of the report.

Email recipients _____

Comments

_____

_____

_____

Form: SAE Additional Information

Form OID *(pending)*

Reporting Period ID _____ *(derived)*

INSTRUCTIONS: Add detailed information about all the adverse events for the course/cycle. Do not just describe the primary adverse event, but all of the adverse events. Include the presentation of each event, the treatment of the event, clinical findings, and the timing of the event in relation to study interventions. Be as complete as possible.

Description and treatment of event(s)

_____

_____

_____

Present status *(check one)*

- ☐ Intervention for AE continues
- ☐ Recovering/resolving
- ☐ Recovering/resolving with Sequelae
- ☐ Recovering/resolving without Sequelae
- ☐ Not recovered/Not resolved
- ☐ Fatal/Died

Date of recovery or death *(dd MMM yyyy)* __ __-__ __ __-__ __ __ __

(If fatal/died), was an autopsy performed? *(check one)* ☐ Yes ☐ No

Removed from protocol treatment *(check one)* ☐ Yes ☐ No

(If yes), date removed from protocol treatment *(dd MMM yyyy)* __ __-__ __ __-__ __ __ __

Has the subject been re-treated? *(check one)* ☐ Yes ☐ No

INSTRUCTIONS: Enter information regarding other circumstances that might have been related to the event or other situations that contributed to the event(s) being reported (e.g. the flu, Central Line Placement, IV hydration, etc.).

Other contributing causes _____

SUPPORTING DOCUMENTATION

INSTRUCTIONS: If you have supporting documentation to provide for this SAE, these documents should be faxed or emailed to AdEERS. (Provide instructions on how to do this.)

Comments

_____

_____

_____

Form: SAE Protocol Surgery Intervention

FORM OID PID3788031_V1_0

Reporting Period ID _____ *(derived)*

Site of Surgery	Date of Surgery
(LOV)(defaulted)	_ _-_ _ _-_ _ _ _

(add log line)

Comments

_____

_____

_____