
VIT
VICTORY

Serious Adverse Events (SAEs)

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Any untoward medical event that:

+ Results in death
+ Is life-threatening
+ Requires hospitalization or prolongation of hospitalization
+ Results in significant or permanent disability/incapacity
+ Leads to a congenital anomaly/birth defect
+ Other serious medically important event (e.g. may require medical or surgical intervention)

SAEs: Identification

Given the high acuity of diseases and morbidity related to burns, **adverse events** are **NOT** reported to CERU.

Only report Serious Adverse Events (SAEs) that are:

- **Unexpected** – NOT expected due to the progression of the underlying disease or co-morbid illnesses.

  Example: Seizure in the absence of seizure disorder

OR

- **Related to the Study Intervention** – caused by the vitamin C

SAE Reporting: Death

Not all deaths need to be reported

Do not report expected events that lead to death.

+ Example: Patient with severe burns develops sepsis and dies. It is not unexpected and thus does not need to be reported to CERU.

Do not report death as an SAE.

+ If a reportable SAE results in death, record death as the outcome and the underlying cause of death as the SAE. Death is an outcome, not an event.

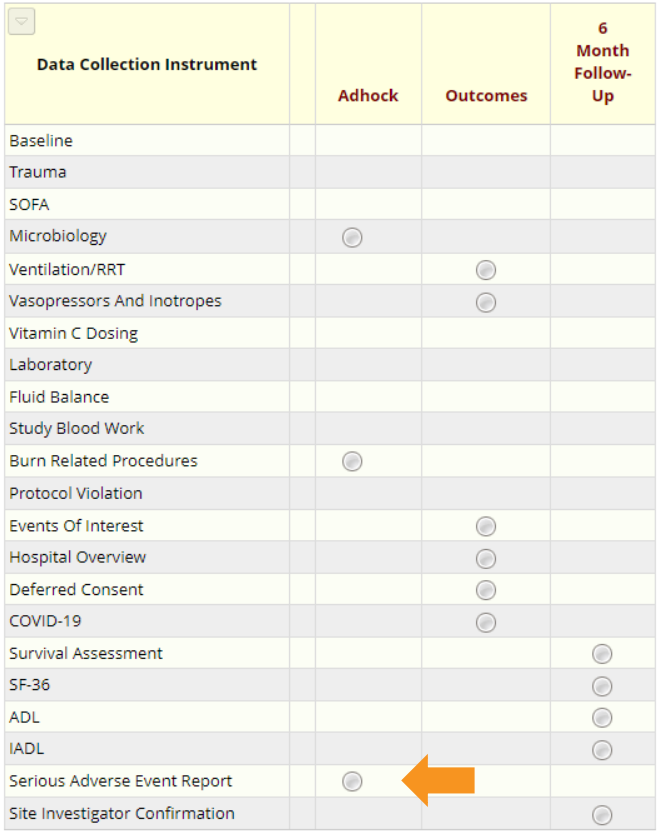
NOTE: please follow local ethics requirements for reporting death and adverse events to your local ethics.

SAE Reporting

+ **Report** all SAEs **within 24 hours** of become aware of the event
+ **Report** the SAE by entering the event data **into REDCap** (electronic data capture system)
+ **De-Identify** all supporting **documents** before uploading them to REDCap (remove or black out the patient's name, date of birth, or any other information that could identify the patient)

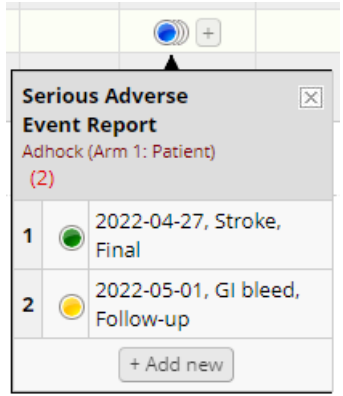
SAEs in REDCap

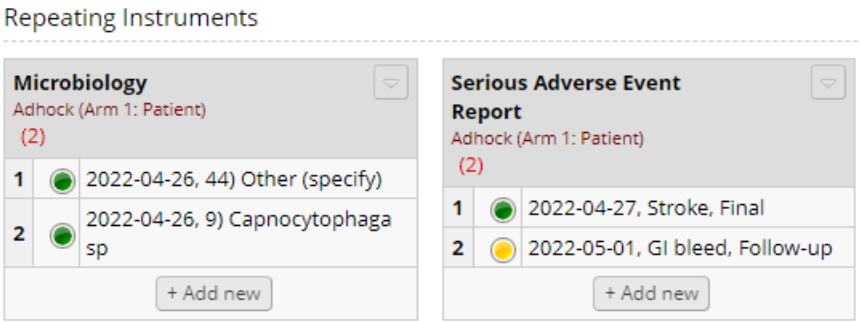
+ SAE forms are located on the grid in the **Adhock** event.
+ Click the grey dot on the grid to reveal SAE form.
+ The SAE form is now a **Repeating Instance**. You may report as many SAEs as needed by adding a **New Instance**.



Viewing SAEs in REDCap

+ Once you have entered an SAE a summary of the forms entered can be viewed by **clicking on the dot** in the grid to display the summary or at the **bottom of the grid**.





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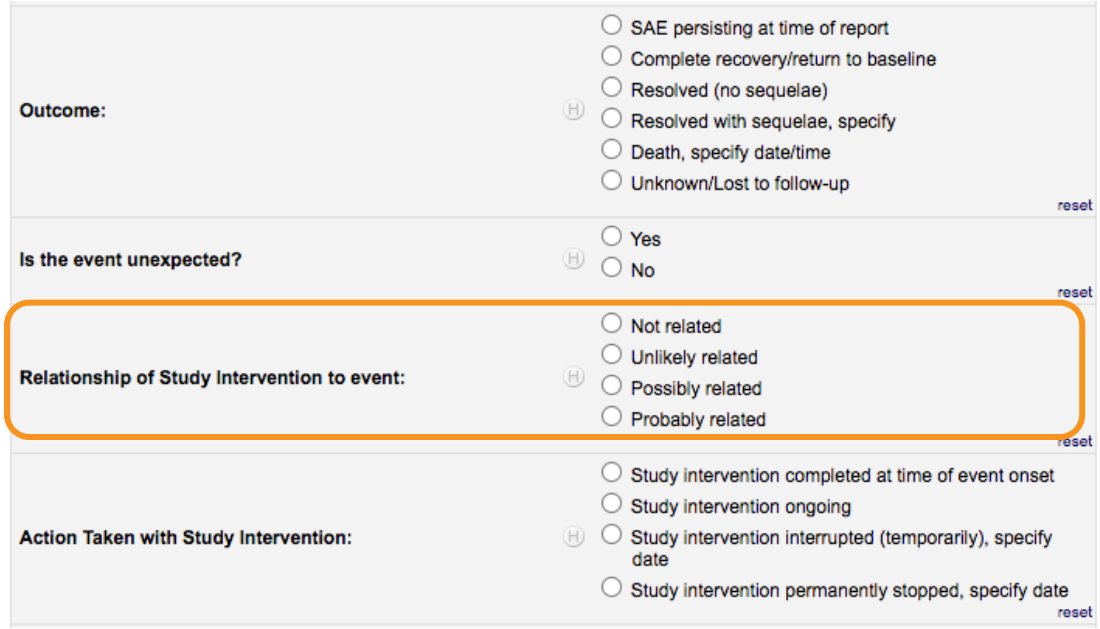
Opening or Adding SAEs in REDCap

- The summary displays the Event Onset Date, Name of Event, and the Report Type so you can see at a glance which SAE is which.
- Click on an existing SAE to open it or click on **+ Add new** to report a new SAE.

- Remember to update the data in existing SAEs until the information in the report is final and change the Report Type to Final.

SAE Reporting in REDCap

+ Complete the data in REDCap.
+ **IMPORTANT:** The **Site Investigator** or delegated sub-I **must** determine the event **relationship** to study **intervention.**



SAE Relationship to Intervention

Refer to the definitions below when determining relatedness:

Not related: A serious adverse event that is clearly due to extraneous causes (disease, environment, etc.) and does not meet the criteria for drug relationship listed under “Possibly” or “Probably”.

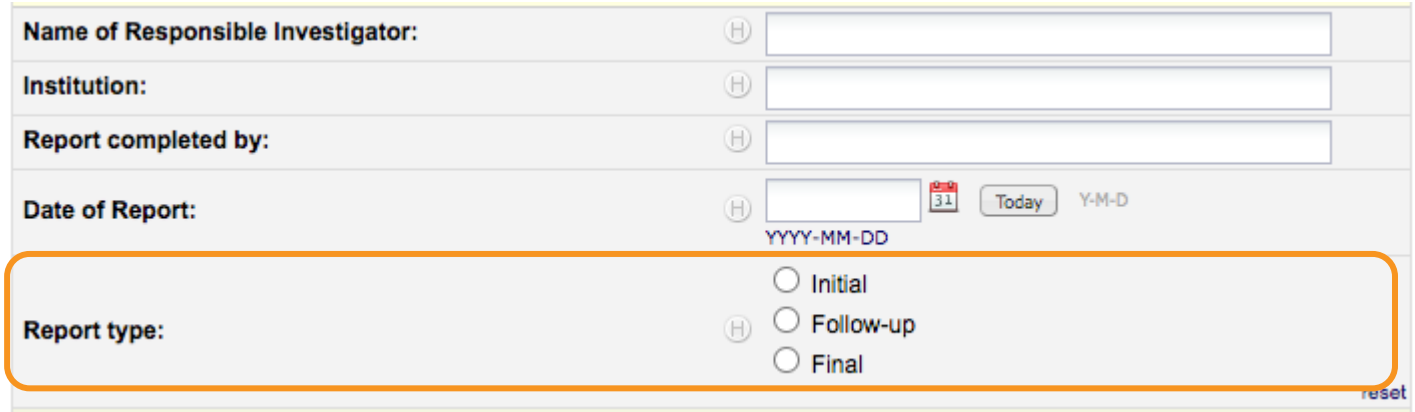
Unlikely related: A serious adverse event that is more likely due to other causes than the study supplement.

Possibly related: Suggests that the association of this SAE with the study supplements is unknown and the event is not reasonably supported by other conditions.

Probably related: Suggests that a reasonable temporal sequences of this SAE with study supplement administration exists and the association of the event with the study supplement seems likely.

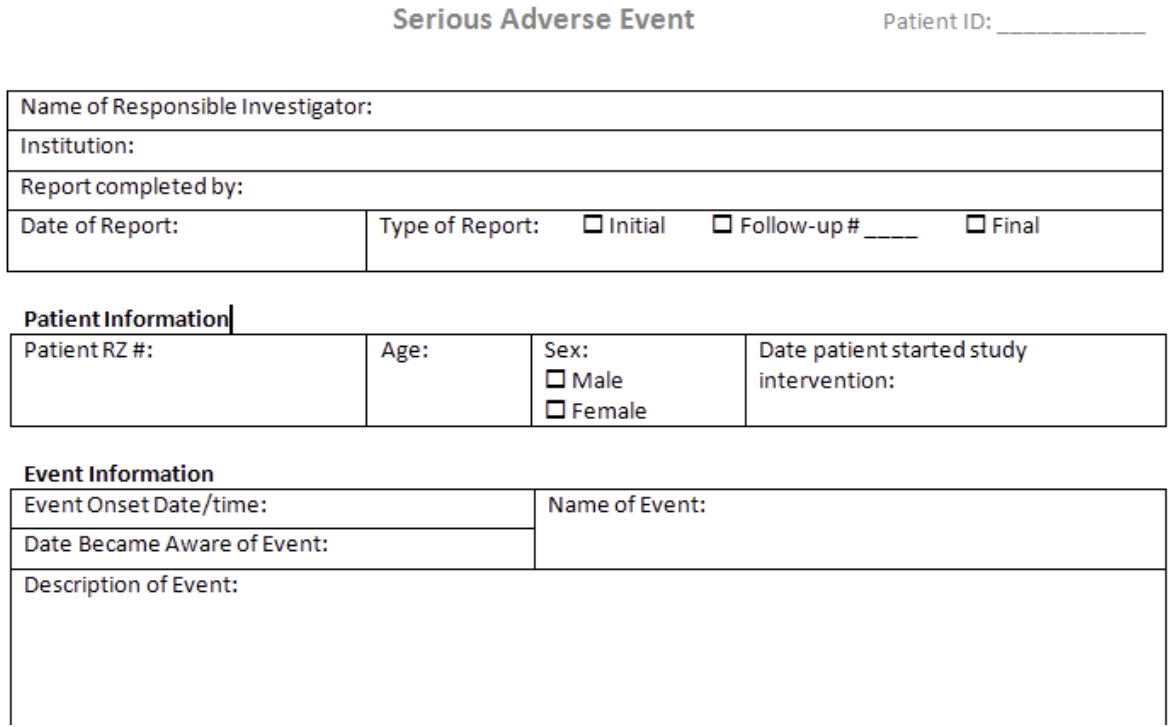
SAE Updates

- Return to the same form to update data as it becomes available, do NOT complete a new form.
- Indicate the report status as updates are provided.



SAE Worksheets

- Worksheets are provided to assist with data collection if you wish to use them.
- **SAEs must be entered in REDCap.**



Serious Adverse Event Patient ID: _____

Name of Responsible Investigator:	
Institution:	
Report completed by:	
Date of Report:	Type of Report: ☐ Initial ☐ Follow-up # ____ ☐ Final

Patient Information

Patient RZ #:	Age:	Sex: ☐ Male ☐ Female	Date patient started study intervention:

Event Information

Event Onset Date/time:	Name of Event:
Date Became Aware of Event:	
Description of Event:	

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Questions

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