

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**.

Data Collection Instrument	Adhock	Outcomes	6 Month Follow-Up
Baseline			
Trauma			
SOFA			
Microbiology	<input type="radio"/>		
Ventilation/RRT		<input type="radio"/>	
Vasopressors And Inotropes		<input type="radio"/>	
Vitamin C Dosing			
Laboratory			
Fluid Balance			
Study Blood Work			
Burn Related Procedures	<input type="radio"/>		
Protocol Violation			
Events Of Interest		<input type="radio"/>	
Hospital Overview		<input type="radio"/>	
Deferred Consent		<input type="radio"/>	
COVID-19		<input type="radio"/>	
Survival Assessment			<input type="radio"/>
SF-36			<input type="radio"/>
ADL			<input type="radio"/>
IADL			<input type="radio"/>
Serious Adverse Event Report	<input type="radio"/>		
Site Investigator Confirmation			<input type="radio"/>

# 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**.



## Repeating Instruments

Microbiology	
Adhock (Arm 1: Patient) (2)	
1	2022-04-26, 44) Other (specify)
2	2022-04-26, 9) Capnocytophaga sp
<a href="#">+ Add new</a>	

Serious Adverse Event Report	
Adhock (Arm 1: Patient) (2)	
1	2022-04-27, Stroke, Final
2	2022-05-01, GI bleed, Follow-up
<a href="#">+ Add new</a>	

Serious Adverse Event Report	
Adhock (Arm 1: Patient) (2)	
1	2022-04-27, Stroke, Final
2	2022-05-01, GI bleed, Follow-up
<a href="#">+ Add new</a>	

# Opening or Adding SAEs in REDCap

Serious Adverse Event Report		
Adhock (Arm 1: Patient)		
(2)		
1		2022-04-27, Stroke, Final
2		2022-05-01, GI bleed, Follow-up
<a href="#">+ Add new</a>		

- + 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.

Outcome:	<input type="radio"/> SAE persisting at time of report <input type="radio"/> Complete recovery/return to baseline <input type="radio"/> Resolved (no sequelae) <input checked="" type="radio"/> Resolved with sequelae, specify <input type="radio"/> Death, specify date/time <input type="radio"/> Unknown/Lost to follow-up	reset
Is the event unexpected?	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
Relationship of Study Intervention to event:	<input type="radio"/> Not related <input type="radio"/> Unlikely related <input checked="" type="radio"/> Possibly related <input type="radio"/> Probably related	reset
Action Taken with Study Intervention:	<input type="radio"/> Study intervention completed at time of event onset <input type="radio"/> Study intervention ongoing <input checked="" type="radio"/> Study intervention interrupted (temporarily), specify date <input type="radio"/> Study intervention permanently stopped, specify date	reset

# 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.

<b>Name of Responsible Investigator:</b>	<input type="text"/>
<b>Institution:</b>	<input type="text"/>
<b>Report completed by:</b>	<input type="text"/>
<b>Date of Report:</b>	<input type="text"/>  Today Y-M-D YYYY-MM-DD
<b>Report type:</b>	<input type="radio"/> Initial <input type="radio"/> Follow-up <input type="radio"/> Final

reset

# 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: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____ <input type="checkbox"/> Final

### Patient Information

Patient RZ #:	Age:	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	Date patient started study intervention:
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### Event Information

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

# Questions

