

## **SAE FORM COMPLETION INSTRUCTIONS**

To avoid query-generation by Studienzentrum / Clinical trials Unit SAE management Center has to complete the SAE form as detailed as possible. It is important for clarifying processes to contact your site, therefore don't forget to add your contact details.

### **SAE form page 1**

#### **Header**

- Centre No.: 3 digits to be entered
- Screening No.: 3 digits representing your patients in ascending order to be entered
- Subject information: Year of birth: Enter in the format requested YYYY

#### **Investigator information**

- Enter your name
- Site address
- Site telephone number
- E-mail address (if available)
- Sign (and stamp, if available) the SAE form in the space provided

#### **Type of report**

Check **initial**, referring to a new SAE case yes or no or **Follow-up**, referring to additional information yes or no to a previously reported SAE case.

Note: A Follow-up may also be documented on the initial report by adding the follow-up information, in that case note date of follow-up and sign and date all changes separately.

Include date of initial report and date of noticed SAE in the format requested dd/mm/YYYY

Check Number of SAE regarding each patient, please number consecutively if more than one SAE occurs.

#### **Patient data**

Include age and gender as required.

#### **Description of Symptoms / problems in detail**

##### **Description of SAE (Circumstances, symptoms, cause of event)**

Please write a narrative describing the circumstances, symptoms and cause of the event. Try to find a **primary diagnosis**. Enter the medical term used to describe the SAE. If no diagnosis made, enter the signs and symptoms of the event. (should be the same as the AE entry on the CRF).

## **SAE form page 2**

### **Header**

- Centre No.: 3 digits to be entered
- Screening No.: 3 digits representing your patients in ascending order to be entered
- Subject information: Year of birth: Enter in the format requested YYYY

### **Occurrence and progression**

**Add Duration** from .....to, enter the date in the format DD/MM/YYYY. Enter the date that the event met a seriousness criterion (e.g. date of admission to hospital in case of hospitalization). Please note that this date may be different from the date of the onset of symptoms.

### **Seriousness**

If an event is serious, please check all of the following criteria that apply: check the appropriate box

- Results in Death
- Life-threatening: Any event in which the subject was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe.
- Hospitalization prolongation: Any event which caused an existing in-patient hospitalization to be prolonged.
- Results in persistent or significant disabling/incapacitating: Any event which caused substantial disruption of a person's ability to conduct normal life functions

### **Intensity**

Check the appropriate box (mild, moderate, severe)

- Mild: temporary event which is tolerated well by the subject
- Moderate: event which results in discomfort for the subject and impairs his/her normal activity
- Severe: event which results in substantial impairment of normal activities of subject

### **Causality to trial intervention**

A physician who is a member of the investigational staff must make the assessment regarding the relationship of the SAE to the trial intervention. One option noted on the SAE report form must be ticked.

Please note: definite, possible, probable and not assessable will met the criteria causality related to trail intervention.

### **Interventions / Countermeasures**

Check the appropriate box

- None
- Drug treatment
- Other

If applicable, please complete this section with all information regarding intervention, please specify as possible

### **Outcome of SAE**

Check the appropriate box

- Ongoing
- Recovered completely
- Recovered with sequelae
- Death
- Unknown (try to avoid this box as possible)

### **Subject's death**

If applicable, please complete this section with all information regarding the subject's death: date of death and cause of death

### **Investigator information**

- Enter your name
- The date the SAE form was completed
- Sign the SAE form