Appendix 1

SAE Report Number: ……

SERIOUS ADVERSE EVENTS REPORTING FORM (SAE) IN CLINICAL TRIAL

1. SUMMARY

Report type: ☐ Initial report ☐ Additional report

Classification by severity of the event:

☐ Subject died
☐ In-Patient hospitalisation or prolongation
☐ Congenital anomaly/birth defect
☐ Life Threatening
☐ Persistent or significant disability/ Incapacity
☐ Requiring appropriate medical intervention to prevent the above situations from happening or other medically important events following the investigator's judgement.

Study title ……

……

Study design ☐ Open label ☐ Single Blind ☐ Double blind

If blinded, blind broken? ☐ Yes ☐ No ☐ N/A

Sponsor ……

Name of Principal investigator ……

Study site ……

Date of SAE Awareness ……

Start date of SAE ……

Stop date of SAE (or state if ongoing) ……..... ☐ Ongoing

Name of SAE (SAE diagnose or main ……

symptoms of SAE) ……

Subject Initials ……

Subject ID ……

2. SAE INFORMATION

Provide information on signs, clinical symptoms, laboratory tests related to SAE, SAE management measures where available (including dose / regimen reduction / termination), developments after the implementation of such measures and other necessary information.

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Outcomes:

☐ Recovered ☐ Recovering ☐ Patient died ……..…

☐ Recovered with sequelae ☐ Continuing ☐ Unknown

3. SUBJECT DETAILS

Date of birth ……

Age ……

Sex ☐ Male ☐ Female For female: ☐ Pregnant (week: ……)

Weight (Kg) ……

Relevant medical history ……

4. INVESTIGTIONAL PRODUCT/ TREATMENT REGIMEN

No.	Investigational Product/ Treatment regimen[(a)]	Dosage form, content	Route	Dose	Date of drug using *(dd/mm/yyyy)*	
					Start date	Stop date
i						
ii						
iii						
iv						
v						
vi						

[(a)] Specify the investigational product / regimen used by the subject in the clinical trial. For blind studies and SAE did not lead to the blind broken / unidentifiability of the investigational product/regimen used by the study subject, indicating the regimen used in the study and Arm of the study subject in the clinical trial (described in section 2) (if available).

5. INTERVENTION WITH INVESTIGATIONAL PROTOCOL/REGIMEN AFTER SAE HAPPENED

No. [(b)]	Stopped/lowered dose of investigational product / treatment regimen on the subject?		If stopped/lowered dose of investigational product/regimen (or blind broken), did the event resolve after this?			If investigational product/regimen reintroduced did the event reappear?			
	Yes	No	Yes	No	N/A	Yes	No	No	Not reintroduced
i	☐	☐	☐	☐	☐	☐	☐	☐	☐
ii	☐	☐	☐	☐	☐	☐	☐	☐	☐
iii	☐	☐	☐	☐	☐	☐	☐	☐	☐
iv	☐	☐	☐	☐	☐	☐	☐	☐	☐
v	☐	☐	☐	☐	☐	☐	☐	☐	☐
vi	☐	☐	☐	☐	☐	☐	☐	☐	☐

[(b)] Order number (No.) corresponds to section 4

6. RELEVANT CONCOMITANT MEDICATIONS/PRODUCTS FOLLOWING THE INVESTIGATOR'S JUDGEMENT (exclude medications used in SAE treatment)

No.	Concomitant Medication/ product (name, brand name)	Dosage form, content	Route	Dose	Date of drug using *(dd/mm/yyyy)*	
					Start date	Stop date
1						
2						
3						
4						
5						
6						

7. EVALUATION OF PRINCIPAL INVESTIGATOR/INVESTIGATOR ON CAUSAL RELATIONSHIP BETWEEN SAE AND INVESTIGATIONAL PRODUCT/ REGIMEN)

No. [b]	Evaluation of causal relationship between SAE and investigational product/regimen			If causal relationship is **'related ',** was the event **'expected'** per Investigator's Brochure/ study protocol?[c]	
	Related	Unrelated	Not clear	known/expected	Unexpected
i	☐	☐	☐	☐	☐
ii	☐	☐	☐	☐	☐
iii	☐	☐	☐	☐	☐
iv	☐	☐	☐	☐	☐
v	☐	☐	☐	☐	☐
vi	☐	☐	☐	☐	☐

[b] Order number (No.) corresponds to section 4

[c] The evaluation of SAE is *"expected"* or *"unexpected"* must be based on investigational product/regimen related documents such as updated study protocol if investigational product has not been marketed authorized or summary of product characteristics if the investigational product has been approved marketed authorized.

8. COMMENTS OF REPRESENTATIVE OF THE STUDY SITE ETHICS/SCIENCE COMMITTEE (if any)

Proposal for the subject in clinical trial *(not applicable in case of the subject died):*

☐ Continue to participate the study ☐ Discontinue to participate the study ☐ Withdraw from the study

Proposal for the study:

☐ Continue the study ☐ Discontinue the study ☐ Stop the study

Other proposal (if any): ……

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9. REPORTOR INFORMATION (principal investigator or designate investigator)

Signature ……

Date *(dd/mm/yyyy)* ……

Full name ……

Title, department ……

Telephone number ……

Email address ……

REPRESENTATIVE OF INSTITUTE'S ETHICS/ SCIENCE COMMITTEE
(name, signature) [d]

HEAD OF INSTITUTE
(Name, signature and stamp)

[d] Only applicable if LEC comments in section 8.