

Please complete in English

Date of Report (dd/mm/yyyy)

Initial Report

Follow-up **N°:**

SITE INFORMATION

Trial N°: _____

EUDRACT n°: _____

Investigator Name : _____

Site Address : _____

Phone n°: _____

Fax n°: _____

Country : _____

SUBJECT INFORMATION

Initials Inclusion number : _____

Sex: M F

Date of Birth (dd/mm/yyyy)

Weight : _____ kg

Height : _____ cm

SERIOUS ADVERSE EVENT DIAGNOSIS

AE Diagnosis : _____

Date **AE** started :

Date **AE** ended :

SAE CATEGORY

Date **SAE** started :

Date **SAE** ended :

Death – Date of Death :

Life-threatening

New/prolonged hospitalization : from to

Persistent or significant disability/incapacity

Congenital anomaly/birth defect

Important medical event

SAE FORM	Initials <input style="width: 100%;" type="text"/>	<i>For GELARC use only</i>
	Inclusion number : <input style="width: 90%;" type="text"/>	<input style="width: 15%;" type="text"/> SAE N° <input style="width: 15%;" type="text"/> d <input style="width: 15%;" type="text"/> d <input style="width: 15%;" type="text"/> m <input style="width: 15%;" type="text"/> m <input style="width: 15%;" type="text"/> y <input style="width: 15%;" type="text"/> y

OUTCOME

- | | | |
|--|--|---|
| <input type="checkbox"/> Recovered without sequelae | <input type="checkbox"/> Recovered with sequelae | <input type="checkbox"/> Improved |
| <input type="checkbox"/> Not yet recovered | <input type="checkbox"/> Worsened | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Died Cause of Death : <input style="width: 200%;" type="text"/> | | Autopsy performed: yes <input type="checkbox"/> no <input type="checkbox"/> |

STUDY DRUGS INFORMATION

Study Drug	Route	Daily Dose	Start Date	Last Date before SAE
① _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
② _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
③ _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
④ _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
⑤ _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
⑥ _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
⑦ _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
⑧ _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
⑨ _____	_____	_____	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

ACTION TAKEN REGARDING TRIAL MEDICATION

- Unchanged
- Dose regimen adaptation
- Temporary stop Date stopped : Date restarted :
- Permanent stop Date stopped :

RELATIONSHIP TO TRIAL MEDICATION (CAUSALITY)

(For each drug number please complete the causality)

Study Drug Number <i>(as described above)</i>		1	2	3	4	5	6	7	8	9
Relationship	Unrelated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Remote	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Probable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Possible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

