

Case number:

# SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Sponsor: Médecins Sans Frontières	Protocol/Program n°:	Site n° (for studies) or country:
Initial report: <input type="checkbox"/>	Follow-up report: <input type="checkbox"/>	Date of report: ____ / ____ / ____ (dd/Mmm/yyyy)

## Patient information

Patient n°:	Initials:	Date of birth: ____ / ____ / ____ (dd/Mmm/yyyy)	Gender: F <input type="checkbox"/> M <input type="checkbox"/>	Height: ..... cm	Weight: ..... kg
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Serious adverse event(s) information		SAE 1	SAE 2	SAE 3
Adverse event term		.....	.....	.....
Event onset date (dd/Mmm/yyyy)		____ / ____ / ____	____ / ____ / ____	____ / ____ / ____
Date event became serious (dd/Mmm/yyyy)		____ / ____ / ____	____ / ____ / ____	____ / ____ / ____
Event end date (dd/Mmm/yyyy)		____ / ____ / ____	____ / ____ / ____	____ / ____ / ____
Duration if <1 day (hrs/min)		____ / ____	____ / ____	____ / ____
Seriousness criteria	Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		In case of death: Death date: ____ / ____ / ____ Autopsy: Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Life-threatening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Hospitalization required / prolonged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Hospitalization dates: Admission: ____ / ____ / ____ Discharge: ____ / ____ / ____		
	Persistent or significant disability / incapacity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Congenital anomaly / birth defect	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Otherwise medically important	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Non-serious reportable information		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severity		Grade 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>	Grade 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>	Grade 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>
Event outcome	Fatal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not resolved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Resolved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Resolved with sequelae	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Resolving	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Suspected drug(s)	Drug 1	Drug 2	Drug 3	Drug 4	Drug 5	Drug 6	Drug 7
Suspected drug name (INN)	.....	.....	.....	.....	.....	.....	.....
Daily dose & route							
Batch number							
Treatment start date (dd/Mmm/yyyy)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
Treatment stop date (dd/Mmm/yyyy)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
Action taken in response to the event							
Dose maintained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dose reduced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
New daily dose							
On (dd/Mmm/yyyy)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
Drug permanently withdrawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
On (dd/Mmm/yyyy)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
Drug interrupted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
From (dd/Mmm/yyyy)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
To (dd/Mmm/yyyy)	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
Not applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Event diminished after drug stopped/dose reduced?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>
Event reappeared after drug/dose reintroduction?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>	Yes <input type="checkbox"/> / No <input type="checkbox"/> / N/A <input type="checkbox"/>

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Causality assessment	SAE 1							SAE 2							SAE 3						
Related to Drug No.	1	2	3	4	5	6	7	1	2	3	4	5	6	7	1	2	3	4	5	6	7
	<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"/>	<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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other drugs, specify:																					
Not related to Drug No.	1	2	3	4	5	6	7	1	2	3	4	5	6	7	1	2	3	4	5	6	7
	<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"/>	<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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other drugs, specify:																					
Other causal factors (incl. med.history, procedure, etc.)																					

## Event description

Provide a clear description of the sequence of events, diagnosis, relevant investigation results (ECG, CT scan, etc.), corrective treatments, evolution.

## Relevant laboratory tests

Test	Date (dd/Mmm/yyyy)	Result (unit)	Reference range
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		

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### Concomitant medications

Drug name (INN)	Daily dose and route	Indication	Treatment start date (dd/Mmm/yyyy)	Treatment stop date (dd/Mmm/yyyy)	Continued
			___/___/___	___/___/___	<input type="checkbox"/> Yes <input type="checkbox"/> No
			___/___/___	___/___/___	<input type="checkbox"/> Yes <input type="checkbox"/> No
			___/___/___	___/___/___	<input type="checkbox"/> Yes <input type="checkbox"/> No
			___/___/___	___/___/___	<input type="checkbox"/> Yes <input type="checkbox"/> No
			___/___/___	___/___/___	<input type="checkbox"/> Yes <input type="checkbox"/> No

### Relevant medical history

Indicate relevant medical history, including prior diagnoses, past laboratory investigations, X-ray, ECG prior to treatment, previous procedures, and relevant past drugs.

### Reporter

Name of reporter:	Role in trial/program:	Date of event's awareness: <i>ALL SAEs to be reported within 24 hrs of awareness</i> ___/___/___	Address:  Email: Phone:	Date and signature:  ___/___/___
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Further information on this SAE expected?

Yes ☐ No ☐

*If yes please send a follow-up report once  
new information is available*

Any annex to this document? (e.g. discharge  
summary, autopsy report, lab results)

Yes ☐ No ☐

*If yes, list the annexes:*