MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

Case number:

SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Sponsor: Médecins Sans Frontières	**Protocol/Program n°:**	**Site n° (for studies) or country:**
Initial report: ☐	**Follow-up report:** ☐	**Date of report:** ____ / _____ / _____ (dd/Mmm/yyyy)

Patient information					
Patient n°:	**Initials:**	**Date of birth:** ____ / _____ / _____ (*dd/Mmm/yyyy*)	**Gender:** F ☐ M ☐	**Height:** ..... cm	**Weight:** ..... kg

Serious adverse event(s) information		**SAE 1**	**SAE 2**	**SAE 3**
Adverse event term		.....	.....	.....
Event onset date (*dd/Mmm/yyyy*)		____ / _____ / _____	____ / _____ / _____	____ / _____ / _____
Date event became <u>serious</u> (*dd/Mmm/yyyy*)		____ / _____ / _____	____ / _____ / _____	____ / _____ / _____
Event end date (*dd/Mmm/yyyy*)		____ / _____ / _____	____ / _____ / _____	____ / _____ / _____
Duration if <1 day (*hrs/min*)		____ / _____	____ / _____	____ / _____
Seriousness criteria	**Death**	☐	☐	☐
		In case of death:	**Death date:** ____ / _____ / _____	**Autopsy: Yes** ☐ **No** ☐
	Life-threatening	☐	☐	☐
	Hospitalization required / prolonged	☐	☐	☐
		Hospitalization dates:	**Admission:** ____ / _____ / _____	**Discharge:** ____ / _____ / _____
	Persistent or significant disability / incapacity	☐	☐	☐
	Congenital anomaly / birth defect	☐	☐	☐
	Otherwise medically important	☐	☐	☐
<u>Non-serious</u> reportable information		☐	☐	☐
Severity		**Grade 1** ☐ **2** ☐ **3** ☐ **4** ☐	**Grade 1** ☐ **2** ☐ **3** ☐ **4** ☐	**Grade 1** ☐ **2** ☐ **3** ☐ **4** ☐
Event outcome	**Fatal**	☐	☐	☐
	Not resolved	☐	☐	☐
	Resolved	☐	☐	☐
	Resolved with sequelae	☐	☐	☐
	Resolving	☐	☐	☐
	Unknown	☐	☐	☐

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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	☐	☐	☐	☐	☐	☐	☐
Dose reduced	☐	☐	☐	☐	☐	☐	☐
New daily dose							
On (*dd/Mmm/yyyy*)	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____
Drug permanently withdrawn	☐	☐	☐	☐	☐	☐	☐
On (*dd/Mmm/yyyy*)	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____
Drug interrupted	☐	☐	☐	☐	☐	☐	☐
From (*dd/Mmm/yyyy*)	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____
To (*dd/Mmm/yyyy*)	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____	___/ ____/ _____
Not applicable	☐	☐	☐	☐	☐	☐	☐
Event diminished after drug stopped/dose reduced?	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐
Event reappeared after drug/dose reintroduction?	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐	**Yes** ☐ / **No** ☐ / **N/A** ☐

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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**
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other drugs, specify:	.....							.....							.....						
<u>Not</u> 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**
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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
			___ / ____ / _____	___ / ____ / _____	☐ Yes ☐ No
			___ / ____ / _____	___ / ____ / _____	☐ Yes ☐ No
			___ / ____ / _____	___ / ____ / _____	☐ Yes ☐ No
			___ / ____ / _____	___ / ____ / _____	☐ Yes ☐ No
			___ / ____ / _____	___ / ____ / _____	☐ Yes ☐ 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: ***ALL SAEs to be reported within 24 hrs of awareness*** ___ / ____ / _____	Address: Email: Phone:	Date and signature: ___ / ____ / _____

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:*