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Patient no.: |__|__|__|__|__|

Unexpected serious adverse events (unexpected SAEs)

Unexpected/extra-ordinary SAEs must be reported within 24 hrs.

Date of onset/occurrence _____/_____/_____ dd/mm/yy

Date of detection by investigator _____/_____/_____ dd/mm/yy

Brief description of event

_____

_____

_____

Clinical/laboratory tests

Date	Assessment/test	Finding

Assessment of "seriousness" of event (tick one or more box)

- ☐ Is immediately life-threatening or results in death
- ☐ Requires hospitalisation or prolongation of hospitalisation
- ☐ Results in persistent or significant disability
- ☐ Is 'important': May require intervention to prevent one of the above outcomes

Assessment of "causality": Antithrombotic treatment, or trial-related procedure

	Dose	Date given	"Reasonable possibility of causality"?
Antithrombotic treatment:	_____ mg	_____/_____/_____ dd/mm/yy	☐ Yes ☐ No
Procedure:	_____		☐ Yes ☐ No

Comments (e.g. temporal relationship, etc.): _____

_____

Assessment of "causality": Other treatments

Name	Dose	Date start	Date stop	Indication for use	Reasonable possibility of causality? (yes/no)
		/ /	/ /		
		/ /	/ /		
		/ /	/ /		
		/ /	/ /		

Other relevant history (previous events/diseases, allergies, drug reactions)

_____

_____

Action taken by investigator

- ☐ None
- ☐ Describe specific action taken:

_____

Outcome

- ☐ Recovered/resolved Date: _____
- ☐ Not recovered/resolved
- ☐ Death Date: _____

Date	Investigator's name (capital letters)	Signature