

## Serious Adverse Events Reporting Form

R&D Department, Box 226, Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ

- Please complete and sign the following form and then fax within **one working day** of awareness to **CAROLE TURNER on 01223 414396**
- The original should be filed in the Trial Master file. Please ensure that the event is recorded in patient notes and case report form where applicable.

*Simvastatin in aneurysmal subarachnoid haemorrhage (STASH) – a multicentre randomised controlled clinical phase III study.*

Chief Investigator's name **Mr PJ Kirkpatrick**

Subject No  Subject Initials  Date of Birth //

### 1. Summary

Report type Please tick  
Initial report

Follow up report

Criteria for definition of SAE

Patient died

Life threatening

Prolongation of hospitalization (not SAH related)

Persistent or significant disability

Congenital anomaly or birth defect.

Date of SAE awareness.....

Start date of SAE.....

Stop date of SAE or state if ongoing.....

Event term (SAE Diagnosis).....

.....

### 2. Subject Details

Sex:            Male             Female

Subject No  Subject Initials  Date of Birth //

### 3. Narrative

*Please provide an account of the event, similar in format to that of a discharge summary. Mention any relevant lab data or diagnostic tests.*

### 4. Evaluation of Event

Outcome

- Recovered
- Recovered with sequelae
- Continuing
- Patient died
- Unknown

Severity

- Mild
- Moderate
- Severe

Action taken with study drug

- None
- Discontinued

Other action:

- None
- Treated with medication
- Other (specify).....

.....

Withdrawn due to SAE? *Yes/No*

- Yes
- No

**Subject No** □□□ **Subject Initials** □□□ **Date of Birth** □□/□□□/□□

**5. Death Details (if patient died)**

Date of death.....

Cause of death.....

Cause of death obtained from

- Working diagnosis
- Death certificate

**6. Relevant Medical/Surgical History**

No. of medical/surgical history pages attached:.....

If no pages attached, describe relevant medical history

**7. Principal Investigator Details (site specific, and if different from Chief Investigator)**

Name of PI .....

Signature of reporter.....

Date of signing

Full name

Designation

Contact telephone

Email address

Subject No  Subject Initials  Date of Birth //

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**This section is to be completed by a medically qualified investigator**

**8. Expectedness**

*Evaluation of relationship TO THE STUDY DRUG Please refer to the current SmPC*

Expected (reaction to study drug)   
 Unexpected (reaction to study drug)

**9. Causality**

*Evaluation of relationship TO THE STUDY DRUG*

Unrelated   
 \* Unlikely to be related   
 \* Possibly related   
 \* Probably related

**\*IF CAUSALITY IS CLASSED AS UNLIKELY, POSSIBLY OR PROBABLY RELATED PLEASE ALSO COMPLETE THE CONCOMITANT MEDICATIONS SHEET**

If the causal relationship is not clear, please indicate how you came to your decision.

Signature of Medically Qualified Investigator (e.g. PI) .....

Date of signing.....

Full name.....

Designation.....

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**This section is to be completed in Cambridge**

Agree with PI opinion? Yes  No

If no, please specify.....

Follow up required? Yes  No

Date of signing.....

Full name.....

Signature of Independent Medical Advisor or Chief Investigator

.....

Subject No  Subject Initials  Date of Birth //

CONCOMITANT MEDICATIONS Page ..... of .....

Drug Name (Generic name preferred; if combination product, use brand name)	Dose	Frequency	Route	Indication	Start Date	End Date (leave blank if continuing)
<i>Example:</i> <b>PARACETAMOL</b>	<b>1gm</b>	<b>TDS</b>	<b>PO</b>	<b>PAIN RELIEF</b>	<b>01/JAN/10</b>	<b>02/JAN/10</b>
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