

SHIELD STUDY

Serious Adverse Event Report

Study Central Office
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**Please fax this form to :
Professor S J Proctor
44 191 222 5524**

Chief Investigator: Professor S J Proctor

Event reported by: _____ **Date:** _____

Patient initials : _____

Patient trial number: _____

DOB : _____

Study Drug Details :	
Name:	
.....	
Dose :	Route :

SAE DETAILS

Diagnosis (es)	Intensity	Date of Onset	Date Ended	Relationship to Study drug (s)

↑
1=mild
2=moderate
3+severe

↑
A=none D=probable
B=unlikely E=definite
C=possible

Details of SAE(s) and comments

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Concomitant drug administration

Brand name/generic name	Indication	Dosage	Start date	End date	Ongoing (y/n)

Treatment for Serious Adverse Event

1	2	3
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Study medication action taken

	NO	YES		NO	YES
Dose reduced	<input type="checkbox"/>	<input type="checkbox"/>	Did the SAE abate after dose Reduction/interruption	<input type="checkbox"/>	<input type="checkbox"/>
Medicine interrupted	<input type="checkbox"/>	<input type="checkbox"/>	Did the SAE appear after Reintroduction	<input type="checkbox"/>	<input type="checkbox"/>
Medicine discontinued	<input type="checkbox"/>	<input type="checkbox"/>			

Outcome

<input type="checkbox"/>	Recovered	
<input type="checkbox"/>	Recovered with persistent damage →	specify :
<input type="checkbox"/>	Not yet recovered	
<input type="checkbox"/>	Not known	
<input type="checkbox"/>	Patient died	Cause of death:
	Confirmed by post mortem	<input type="checkbox"/>

Name of investigator: Date :

Signature of investigator:

Please continue on a separate form if necessary
Fax to Central Trial Office : 44 191 222 5524