NCTU Ref Number	

Serious Adverse Event Reporting Form
Clinical Trials of Investigational Medicinal Products (CTIMPs)

For queries regarding this report please telephone 0115 8231575
Submit to Nottingham Clinical Trials Unit (NCTU) by one of the following methods:

☐ Email (nctu-sae@nottingham.ac.uk) ☐ Fax (0115 7484091)

DATE MUST BE ENTERED DD/MMM/YYYY **Time must be entered HH:MM**

Section 1: Study Information			
Study Title:	ASAP	**Site Address/Number:**	ENTER ADDRESS
Chief Investigator:	Wei Shen Lim	**Principal Investigator:**	ENTER PI DETAILS
R&I Ref Number:	110RM013	**EudraCT Number:**	2013-001051-12

Section 2: Participant Information							
Initials:	INITIALS	**Participant Number:**	PARTICIPANT NUMBER	**Date of Birth:**	DATE OF BIRTH	**Gender:**	☐ Male ☐ Female

Section 3: Event Information							
Date of Report:	DD/MMM/YYYY	**Date of Event Onset:**	DD/MMM/YYYY	**Date Site became aware:**	DD/MMM/YYYY	**Time Site Became Aware:**	HH:MM
Event:	DETAIL EVENT						
Description of Event: *Specify diagnosis or cause of death if known; otherwise provide signs and symptoms, relevant tests/results. Do **NOT** use abbreviations*	ADD DESCRIPTION OF EVENT						

Seriousness		**Event Outcome**			
Death	☐	Fatal *(Give cause of death if known in event description)*	☐	Date of death	DD/MMM/YYYY
Life threatening	☐	Recovered/Resolved	☐	Date recovered	DD/MMM/YYYY
Hospitalisation or prolongation of hospital stay	☐	Recovered/Resolved with sequelae *(Give detail in event description)*	☐	Date recovered	DD/MMM/YYYY
Persistent or significant disability or incapacity	☐	On-going *(Give detail in event description)*	☐		
Congenital abnormality or birth defect	☐	On-going (*No further action required*)	☐		
Otherwise considered serious	☒	Unknown at time of report	☐		

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^To be completed by a medically qualified doctor only				
^Severity of Event:		**^Relationship to IMP**		**^Causality:** *(Detail all possible and suspected causes, including relevant medical history)*
Mild	☐	Definitely	☐	DETAIL CAUSE OF EVENT
Moderate	☐	Probably	☐	
Severe	☐	Possibly	☐	
		Not related	☐	
^Section Completed by: *(If different from PI)*	NAME *Name (PRINT)*		SIGNATURE *Signature*	DATE *Date*

Section 4: Study Medication Information					
Participant has been Administered Study Medication	☐ No *(Give reason i.e. screening)* ……..... ☐ Yes *(Provide details below)*				
Name of Medication	**Indication(s) for Use**	**Dose (units)**	**Route of Administration**	**Date of First Administration**	**Date of Last Administration**
Avastin	Wet AMD	1.25mg/ 0.625mg	Intravitreal	DD/MMM/YYYY	DD/MMM/YYYY
MEDICATION	INDICATION	DOSE	ROUTE	DD/MMM/YYYY	DD/MMM/YYYY
MEDICATION	INDICATION	DOSE	ROUTE	DD/MMM/YYYY	DD/MMM/YYYY

Section 5: Action Taken as Result of Event:		
None	☐	*Details including new dose (units), date(s) of administration, duration:*
Dose Reduction	☐	DETAIL ADDITIONAL INFORMATION
IMP Treatment delayed	☐	
IMP Treatment delayed and dose reduced	☐	
IMP treatment permanently discontinued		
Other *(i.e. treated with **concomitant medication(s)**)*	☐	
Unknown at time of report	☐	*Tick if **concomitant medication** is listed on a separate sheet and indicate number of pages* ☐ **Pages:**

Section 6: Participant Status			
Blind Broken:	☐ Not Applicable	☐ Yes	☐ No
☐ Continuing in the trial			
☐ Completed the trial	**Date of Completion:**	DD/MMM/YYYY	
☐ Withdrawn from the trial	**Date of Withdrawal:**	DD/MMM/YYYY	

Section 7: Additional Information
DETAIL ADDITIONAL INFORMATION

Section 8: Completion Details			
Report Completed by:	NAME *Name (PRINT)*	SIGNATURE *Signature*	DD/MMM/YYYY *Date*
PI Review: *(If not reporter)*	NAME	SIGNATURE	DD/MMM/YYYY

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	Name (PRINT)	*Signature*	*Date*

Medical Monitor Assessment					
Causality Assessment:	☐ Not Related (SAE) ☐ Related (SAR)	**Expectedness Assessment:** *(if related)*	☐ Expected (SAR) ☐ Unexpected **(SUSAR)**	**SAE Follow up Required:**	☐ Yes ☐ No
Reference Safety Information Used for Expectedness Assessment:					

MedDRA Code:

Event term	SOC	SOC code	LLT	LLT code

Comments:			
Assessment Completed by:	*Name (PRINT)*	*Signature*	*Date*