NCTU Ref Number	

Serious Adverse Event Follow Up 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

Follow up Report Number:	NUMBER	**Follow up Report Date:**	DD/MMM/YYYY	**SAE Reference Number:**	SAE REF NUMBER

Section 2: Participant Information					
Initials:	INITIALS	**Participant Number:**	PARTICIPANT NUMBER	**Gender:**	☐ Male ☐ Female

Section 3: Event Follow Up Information	
No Changes to Event detailed in Initial SAE Report ☐	**Changes to Event detailed in Initial SAE Report** ☐
Description of Changes to the Event and Action Taken Since Previous Report: *Include dates. Do **NOT** use abbreviations*	DETAIL ANY CHANGES TO THE EVENT AND ACTION TAKEN

Event Outcome			
Fatal *(Give cause of death if known in event description)*	☐	Date of death	DD/MMM/YYYY
Recovered/Resolved	☐	Date recovered	DD/MMM/YYYY
Recovered/Resolved with sequelae *(Give detail in event description)*	☐	Date recovered	DD/MMM/YYYY
On-going *(Give detail in event description)*	☐		
Unknown at time of report	☐		

Section 4: Concomitant Medication Information					
Participant has received Concomitant Medication	☐ No ☐ 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
MEDICATION	INDICATION	DOSE	ROUTE	DD/MMM/YYYY	DD/MMM/YYYY

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Continuation sheet attached *(Tick if additional **concomitant medication** is listed on a separate sheet and indicate number of pages)* ☐			
Section 5: 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☐ Withdrawn from the trial	**Date of Withdrawal:**	DD/MMM/YYYY	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 6: Additional Information
DETAIL ADDITIONAL INFORMATION

Section 7: Completion Details			
Report Completed by:	NAME *Name (PRINT)*	SIGNATURE *Signature*	DD/MMM/YYYY *Date*
PI Review: *(If not reporter)*	NAME *Name (PRINT)*	SIGNATURE *Signature*	DD/MMM/YYYY *Date*

Medical Monitor Assessment			
Initial MedDRA Code:		**MedDRA Code changed to: (if required):**	
Comments:			
Assessment Completed by:	*Name (PRINT)*	*Signature*	*Date*