008-FORM-HREC INVESTIGATOR SERIOUS ADVERSE EVENT (SAE) REPORT

Date of report:					
FAX OR EMAIL TO:	The Royal Australian and New Zealand College of Ophthalmologists - HREC Fax: 02 9690 1321 Email: ranzco@ranzco.edu				
STUDY DETAILS					
HREC Ref. No:					
Investigator:		Site:			
PARTICIPANT DETAILS					
Participant's DOB:		Participant initials:		Sex F ❑ M ❑	
Investigational product:		Date of onset of reaction:		Weight _____kg	
EVENT DETAILS					
Route of administration:		Date commenced:	_ _ / _ _ / _ _	Date stopped:	_ _ / _ _ / _ _

Event resulted in:

- ❑ Death ___/___/___ Cause of death _____
- ❑ Threat to life
- ❑ Inpatient or prolongation of hospitalization Date of admission ___/___/___
- ❑ Severe or permanent disability
- ❑ Congenital abnormality
- ❑ Required medical or surgical intervention to prevent one of the above
- ❑ None of the above

Description of event:

Treatment of the event:

Was the event related to the study article?

Definitely ❑	Probably ❑	Possibly ❑	Not related ❑

Did the event stop after stopping the investigational product? Yes ❑ No ❑
(*If yes, describe*)

Concomitant medication

All drug therapy/vaccines prior to reaction	Dose and frequency	Date begun:	Date stopped:	Reason for use

Attach page if more space is required.

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Medical history:
Treatment of reaction:
Outcomes:

	Yes. Tick	No. Tick
Has the study sponsor or Data Safety Monitoring Board been notified?	❑	❑
Did the participant remain in the study	❑	❑
In light of this event, is a change required to the Participant Information and Informed Consent Form?	❑	❑
If yes, will already enrolled participants be re-consented? If not, please explain:	❑	❑
If yes, is the revised Participant Information and Informed Consent Form enclosed?	❑	❑
Will you be sending follow up information about this event?	❑	❑

Signature of person submitting report:		Date:	_ _/_ _/_ _
Name:		Fax:	
Telephone:		Email:	

Acknowledged by RANZCO HREC: _____ Meeting date: _____

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