

PHKL REC SERIOUS ADVERSE EVENT (SAE) REPORT FORM
A. Details of Principal Investigator	
Name	
Address	
Telephone	
Email	
Fax	
B. Details of Study	
PHKL REC Reference No.	
Full Study Title	
Protocol Number (if applicable)	
Date of PHKL REC Initial Approval	
Sponsor (if applicable)	
C. Subject's Information	
Subject ID	
Diagnosis	
Gender	☐ Male☐ Female
Date of Birth (dd-mm-yyyy)	
Age	
D. Serious Adverse Event Information	
Serious Adverse Event Term	
Type of Reports	☐ Initial ☐ Follow-Up ☐ Final
Place of SAE Occurrence	☐ On-Site ☐ Off-Site
Date of Awareness (dd-mm-yyyy)	
Onset Date (dd-mm-yyyy)	
Resolution Date (dd-mm-yyyy)	☐ On-going
Investigational Product	
Criteria for Seriousness	Resulting in death i. Autopsy done Yes No ii. Date of death iii. Cause of death Life-threatening Hospitalisation or prolongation of hospitalisation i. Date of admission ii. Date of discharge Persistent or significant disability incapacity Congenital anomaly/ birth defect Important medical event (protocol specify)

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Severity Mild Moderate Severe Severe Severe Moderate Severe									
Relationship of Event to the Investigational Product	Severity								
Relationship of Event to the Investigational Product Possible Probable Definite Action Taken to the Investigational Dose maintained Dose reduced Interrupted Discontinued permanently Outcome of the SAE Resolved without sequalae Resolved with sequalae (specify) Unresolved Unexpected SAE Narratives: Expected Product Information				_					
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F. Treatment(s) Given								
Medication Name	Dose	Route of	Treatment Start	Treatment Stop	Ongoing			
		Administration	Date	Date				
G. Relevant Laborate	ory Test(s)						
Tests	Tests		Result (unit)	Reference Range				
					-			
H. Declaration								
I declare that the info	rmation ir	n this form is accur	rate to the best of m	y knowledge and be	lief, and I take full			
responsibility for it.								
Principal Investigator:								
Name:								
Date:								
I. For Office Use Onl	у							
Date of Received								
Received By								
Signature								
SAE ID								
J. Review by SAE Subcommittee								
Additional actions or in			<u> </u>					
required?		□ No						
If Yes, please specify								
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Recommendations by Subcommittee	the SAE							
Subcommittee								
Reviewed by:								
<u></u>								
Name: Date:								

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