PANTAI HOSPITAL
Kuala Lumpur

PHKL REC SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Section A. Details of Principal Investigator	
Name	
Address	
Telephone	
Email	
Section B. Details of Study	
PHKL REC Reference No.	
Full Study Title	
Protocol Number	
NMRR ID	
Sponsor	
Date of PHKL REC Initial Approval	
Section C. Subject's Information	
Subject ID	
Diagnosis	
Gender	☐ Male ☐ Female
Date of Birth (dd-mm-yyyy)	
Age	
Section 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)

Severity	☐ Mild ☐ Moderate ☐ Severe
Relationship of Event to the Investigational Product	☐ Unrelated ☐ Possible ☐ Probable ☐ Definite
Action Taken to the Investigational Product	☐ Dose maintained ☐ Dose reduced ☐ Interrupted ☐ Discontinued permanently ☐ Others _____
Outcome of the SAE	☐ Resolving/ Ongoing ☐ Resolved without sequalae ☐ Resolved with sequalae (specify) _____ ☐ Unresolved
Expectedness of the SAE	☐ Expected ☐ Unexpected
SAE Narratives:	

Section E. Suspected Product Information

Suspected Product	Dose	Route of Administration	Treatment Start Date	Treatment Stop Date	Last Dose before SAE	Action Taken
						☐ Dose maintained ☐ Dose reduced ☐ Interrupted ☐ Discontinued permanently ☐ Others _____
						☐ Dose maintained ☐ Dose reduced ☐ Interrupted ☐ Discontinued permanently ☐ Others _____
						☐ Dose maintained ☐ Dose reduced ☐ Interrupted ☐ Discontinued permanently ☐ Others _____
						☐ Dose maintained ☐ Dose reduced ☐ Interrupted ☐ Discontinued permanently ☐ Others _____

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Section F. Treatment(s) Given

Medication Name	Dose	Route of Administration	Treatment Start Date	Treatment Stop Date	Ongoing
					☐
					☐
					☐
					☐

Section G. Relevant Laboratory Test(s)

Tests	Date	Result (unit)	Reference Range

Section H. Declaration

I declare that the information in this form is accurate to the best of my knowledge and belief, and I take full responsibility for it.

Principal Investigator:

_____
Name:
Date:

Section I. For Office Use Only

Date of Received	
Received By	
Signature	
SAE ID	
Remarks	

Section J. Review by SAE Subcommittee

Additional actions or information required? If Yes, please specify	☐ Yes ☐ No _____ _____
Recommendations by the SAE Subcommittee	

Reviewed by:

_____

Name:
Date: