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PROTOCOL REPORT UPDATES FORM (SAE/SUSARS Form 4.7)

IRB Protocol No.		Date Received (D/M/Y):	
Protocol Title:		Sponsor:	
Principal & Sub Investigators:		Type of SAE Site of SAE	☐ SAE ☐ SUSAR ☐ On-site ☐ Off site (International) ☐ Off site (National)

A: TITLE OF REPORT: _____Date of Event: _____

B. SUMMARY OF SIGNIFICANT DATA:

☐ With Full Document Attachment ☐ With Partial Data Attachment

Name of the study medicine/device	Report Date: dd/mm/yyyy IREB Submission Date: dd/mm/yyyy ☐ Initial ☐ Follow-up Onset date: dd/mm/yyyy	
Date of first use:		
Patient's Initial/Number:	Age:	☐ Male ☐ Female
Patient's Date of Birth: dd/mm/yyyy	Weight: kg	Height: cm
Relevant medical history and concurrent conditions:		

I. REACTION INFORMATION:

Check all appropriate to adverse reaction: ☐ Patient died ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistence or significant disability or incapacity	☐ Life threatening ☐ Congenital anomaly

II. SUSPECT DRUG/S INFORMATION:

Suspect drug/s (include generic name)		Did reaction abate after stopping drug? ☐ Yes ☐ No ☐ NA
Daily dose/s:	Route/s of administration:	Did reaction appear after reintroduction? ☐ Yes ☐ No ☐ NA
Indication/s for use:		
Therapy date/s: (from/to)	Therapy duration:	
Is this reaction ☐ Unexpected ☐ Expected		
Treatment given for Adverse Event:		
Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System) ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable		
Outcome of reaction/event at the time of last observation: ☐ Recovered ☐ Recovering with sequelae ☐ Death ☐ Recovering ☐ Not recovering ☐ Unknown ☐		

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature Over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature Over Printed Name Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited ☐ **Full Board** ☐

Reviewer's Comments:

Final Action:

( ) Request an amendment to the protocol or the consent form.
( ) Request further information
( ) Recommend further Action (indicate action)
( ) Take Note and No Further Action needed
( ) Others: _____

Acknowledged by:

_____	_____	_____
Name of Reviewer IRB Member-Secretary	**Signature**	**Date**