SAE FORM (SJDEFIIRB FORM 3.5)

Section 1.To be filled up by the Principal Investigator. *Documents relevant to the SAE should be submitted together with this form*

IRB Reference Code				
Protocol No.				
Submission Date				
Study Protocol Title				
Principal investigator				
Sponsor				
PATIENT INFORMATION				
Investigational Product	Report Date ☐ Initial ☐ Follow-up	Onset Date		Date of First Use
Patient Initials/No.		Age		☐ Male ☐ Female
Date of Birth		Weight		Height
Relevant Medical History				

REACTION INFORMATION	
_____ (Use CIOMS definition) Relevant test results:	Check all appropriate ☐ Patient died ☐ Involved or prolonged hospitalization ☐ Involved persistence or significant disability or incapacity ☐ Life-threatening

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SUSPECT DRUG/S INFORMATION

Suspect Drug/s (include generic and brand name)				Did reaction abate after stopping drug? ☐ YES ☐ NO ☐ N/A Did reaction appear after reintroduction? ☐ YES ☐ NO ☐ N/A
Dose		Route		
Indication				
Start Date		End Date		
Treatment given for adverse event				Is this reaction ☐ Expected ☐ Unexpected

Causality assessment by investigator (WHO-UMC Causality Assessment System)
- ☐ Certain
- ☐ Probable
- ☐ Possible
- ☐ Unlikely
- ☐ Unclassifiable

Outcome of reaction/event at the time of last observation
- ☐ Recovered
- ☐ Recovering
- ☐ Recovering with sequelae
- ☐ Not recovering
- ☐ Death
- ☐ Unknown

CONCOMITANT DRUG/S

MANUFACTURER'S INFORMATION

Name and Address	

Section 2. FOR IRB USE ONLY

RECOMMENDATIONS		
Changes to the protocol recommended ☐No ☐Yes Comments:		
Changes to the ICF recommended ☐No ☐ Yes Comments:		
SAE REVIEWER	Signature	Date

IRB FINAL ACTION

☐ Uphold original approval with no further action
☐ Request information

_____
_____
_____
_____
_____

☐ Recommend further action

_____
_____
_____
_____

MEMBER-SECRETARY	Signature	Date
CHAIR	Signature	Date