



SJD Institutional Review Board

Title: Consolidated SAE Report

Code: SJDIRB Form 14.2

Version: 00

SJDIRB Reference Code				Protocol Code				SJREB Code					
Study Protocol Title													
Principal Investigator								Expertise					
Date of Initial Submission				Date of Resubmission				Date of Submission					
Primary Reviewer								Expertise					
ICF Reviewer								Expertise		Protocol Version			
										No.			
R	Reaction Initial/Follow-up	Date Repo rted	Offsite/ Onsite	Onset/ Stop of SUSAR Outcome	Date Drug Started/ Stopped	A	S	Co m o r b	Causali ty Assess ment of Investi	Causali ty Assess ment	Action	Reviewer's Causality Assessment/ Comments/ Reasons	
SUMMARY													
Total Number of New Events					Total Number of Definite					Total Number of Probable			
Total Number of Deaths					Total Number of Doubtful					Total Number of Possible			
Items Which Need Follow-up													
For SJDIRB Use													



PHREB
ACCREDITED
LEVEL III





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SAE Reviewer Comments		Discussion	
SAE Reviewer		SJDIRB Final Action	
<ul style="list-style-type: none">○ Request additional information○ Suspend enrollment of new research participants○ Suspend all trial-related procedures○ Recommend termination of study○ Take note and continue monitoring○ For Clarificatory Interview○ Conduct study site Visit○ Others; _____		<ul style="list-style-type: none">○ Request additional information○ Suspend enrollment of new research participants○ Suspend all trial-related procedures○ Recommend termination of study○ Take note and continue monitoring○ For Clarificatory Interview○ Conduct study site Visit○ Others; _____	
Name & Signature of SAE Reviewer	Date	Name & Signature of Board/Panel Secretary	Date
Name & Signature of SAE Reviewer	Date	Name & Signature of Chair/Panel Lead	Date