



SJD Institutional Review Board

Title: Onsite SAE Form

Code: SJDIRB Form 14.1

Version: 07

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

SJDIRB Reference Code		Date of Submission		DD Month YYYY	
Protocol Code		SJREB Code			
Protocol Title					
Principal Investigator					
Sponsor/CRO					
Approval Date		DD Month YYYY		Start Date	
				DD Month YYYY	
Date of last continuing review approval		DD Month YYYY		Latest version of approved protocol	
				Latest version of approved ICF	
				DD Month YYYY	
Name of Primary Investigator			Signature		Date
Indicators		SAE Report # 1		SAE Report # 2	
Suspected Drug					
Patient No.					
Report Date					
Date of SAE					
Date of First Use					
Duration of Therapy					
Age					
Sex					
City/Municipality					
Nature of SAE		Patient died, Involved or prolonged inpatient hospitalization, involved persistence or significant disability or incapacity, life threatening		Patient died, Involved or prolonged inpatient hospitalization, involved persistence or significant disability or incapacity, life threatening	
Summary description of the SAE					
Comorbidities					
Reaction abated after stopping drug		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
Reaction appeared after reintroduction		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
Treatment of SAE					
Status					
FOR SJDIRB USE ONLY		Reviewer's Assessment		Reviewer's Assessment	
Causality Assessment		<input type="radio"/> Definite <input type="radio"/> Probable <input type="radio"/> Possible <input type="radio"/> Doubtful		<input type="radio"/> Definite <input type="radio"/> Probable <input type="radio"/> Possible <input type="radio"/> Doubtful	
Reason/Comment					
Adequacy of Treatment of SAE					
Recommended Action					
Summary of Recommendation					
Naranjo adverse drug reaction probability scale					
Scoring Interpretation		SAE #1		SAE #2	



SJD Institutional Review Board

Title: Onsite SAE Form

Code: SJDIRB Form 14.1

Version: 07

	>9 = Definite 1 to 4 = Possible	5 to 8 = Probable 0 = Doubtful	Yes	No	Don't Know	Yes	No	Don't Know
1. Are there previous conclusive reports on this reaction?			1	0	0	1	0	0
2. Did the adverse event appear after the suspected drug was administered?			2	1	0	2	1	0
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?			1	0	0	1	0	0
4. Did the adverse event reappear when the drug was re-administered?			2	1	0	2	1	0
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?			1	2	0	1	2	0
6. Did the reaction reappear when a placebo was given?			1	1	0	1	1	0
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?			1	0	0	1	0	0
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased			1	0	0	1	0	0
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?			1	0	0	1	0	0
10. Was the adverse event confirmed by any objective evidence?			1	0	0	1	0	0
TOTAL								
Decision Points								
<input type="checkbox"/> Request additional information <input type="checkbox"/> Suspend enrollment of new research participants <input type="checkbox"/> Suspend all trial-related procedures <input type="checkbox"/> Recommend termination of study <input type="checkbox"/> Take note and continue monitoring <input type="checkbox"/> For Clarificatory Interview <input type="checkbox"/> Conduct study site Visit <input type="checkbox"/> Others; _____								
Primary Reviewer			Signature			Date		
SJDIRB Final Action								
Final Decision			Recommendation/Comments					
<input type="checkbox"/> Request additional information <input type="checkbox"/> Suspend enrollment of new research \ participants <input type="checkbox"/> Suspend all trial-related procedures <input type="checkbox"/> Recommend termination of study <input type="checkbox"/> Take note and continue monitoring <input type="checkbox"/> For Clarificatory Interview <input type="checkbox"/> Conduct study site Visit <input type="checkbox"/> Others; _____			(e.g. Proceed with the recommendation of the reviewer or full board meeting last _____)					
SJDIRB Officer			Name			Signature		Date
Board/Panel Secretary								
Chair/Panel Lead								