

Clinical Trial Causality Assessment Report

Evaluation Date: _____ Evaluated by: _____ Date of Adverse Event: _____

Suspect Investigational Product: _____ Dosing Regimen: __ Is medication new?
Yes No

Adverse Event: _____

Probability Event Related to Medication (from the Naranjo Probability Scale below):

Definite (≥ 9) Probable (5-8) Possible (1-4) Doubtful (0)

Consequence of Adverse Event (check all that apply):

- No change - therapy continued Therapy changed to another agent Therapy discontinued
 Increased monitoring Symptomatic medical treatment Corrective surgical procedure
 Disability Permanent Damage Delayed discharge
 Hospitalization Other (specify): _____

Reviewer: _____ Date: _____

Naranjo Probability Scale Adapted for Clinical Trial Serious Adverse Events

The following scale is used to assess the likelihood a particular adverse reaction is related to a medication. Answer each of the 10 questions, calculate the total score, and determine if an adverse drug reaction is Definitely, Probably, Possibly, or unlikely related to the investigational product in question. (*Interpretation of the probability classification can be found in Table 2 on the next page*)

Table 1: Adapted Naranjo Probability

Question	Yes	No	Do Not Know	Score
Are there previous CONCLUSIVE reports on this reaction? <i>Answer yes if 2 or more well-described case reports can be found in the literature.</i>	+ 1	0	0	
Did the adverse reaction appear after the suspected investigational product was administered? <i>Answer yes if reaction occurs in close temporal relation (e.g., within 1-2 days) after investigational product administration.</i>	+ 2	- 1	0	
Did the adverse event improve when the investigational product was discontinued or a specific antagonist given? <i>Answer yes if event lessens or disappears after the suspect investigational product stops or a pharmacologic antagonist given.</i>	+ 1	0	0	
Did the adverse event reappear when the investigational product was re-administered? <i>Answer yes if the event disappears after investigational product discontinuation but reappears when the investigational product was restarted.</i>	+ 2	- 1	0	
Are there alternative causes (other than the suspect investigational product) that could have caused the event? <i>Answer yes if the event can be explained by causes or medications other than the suspect investigational product.</i>	- 1	+ 2	0	
Did the event reappear when a placebo was given? <i>Answer yes if the event reappears after administration of a placebo.</i>	- 1	+ 1	0	
Was the investigational product detected in blood or other fluids in concentrations known to be toxic? <i>Answer yes if investigational product concentration is in the toxic or supratherapeutic range.</i>	+ 1	0	0	
Was the event more severe when dose was increased or less severe when dose was decreased? <i>Answer yes if the intensity of the event is stronger with higher dose or weaker with lower dose.</i>	+ 1	0	0	
Did the patient have a similar event to the same or similar investigational products in any previous exposure? <i>Answer yes if patient has a similar documented event when exposed to the suspect investigational product or related medication in the past.</i>	+ 1	0	0	
Was the adverse event confirmed by any objective evidence? <i>Answer yes if the event can be confirmed by abnormal laboratory values, imaging, or physical examination</i>	+ 1	0	0	
	Total Score			

Table 2. Interpretation of Probability Categories

Category	Score Range	Interpretation
Definite	≥ 9	Reaction 1) followed a reasonable temporal sequence after an investigational product or in which a toxic investigational product level had been established in body fluids or tissues; 2) followed a recognized response to the suspected investigational product; and 3) was confirmed by withdrawal but not by exposure to the investigational product
Probably	5 – 8	Reaction 1) followed a reasonable temporal sequence after an investigational product; 2) followed a recognized response to the suspected investigational product; 3) was confirmed by withdrawal but not by exposure to the investigational product; 4) could not be reasonably explained by the known characteristics of the patient's clinical state
Possible	1 – 4	Reaction 1) followed a temporal sequence after an investigational product; 2) possibly followed a recognized pattern to the suspected investigational product; 3) could be explained by characteristics of the patient's disease
Doubtful	0	Reaction was likely related to factors other than an investigational product

Assessor's Comments (if any):

.....
.....
.....
.....
.....
.....
.....