

**Naranjo Adverse Drug Reaction Probability Scale**  
**INSTITUTIONAL ETHICS COMMITTEE**  
**HM PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD**

**CAUSALITY ASSESSMENT [to assess the adverse drug reaction]**

**Clinical Trial Protocol No.:**

**Protocol Title:**

**Reference:**

- Centre Number:
- Patient ID:
- SAE:
- Date:

Sr. No.	Please answer the following questionnaire and give the pertinent score	Yes	No	Do Not Know	Score
1	Are there previous <i>conclusive</i> reports on this reaction?	1	0	0	
2	Did the adverse event occur after the suspected drug was administered?	2	-1	0	
3	Did the adverse reaction improve when the drug was discontinued or a <i>specific</i> antagonist was administered?	1	0	0	
4	Did the adverse reaction reappear when the drug was readministered?	2	-1	0	
5	Are there alternative causes (other than the drug) that could have on their own caused the reaction?	-1	2	0	
6	Did the reaction reappear when a placebo was given?	-1	1	0	
7	Was the blood detected in the blood (or other fluids) in concentrations known to be toxic?	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	
9	Did the patient have a similar reaction to the same or similar drugs in <i>any</i> previous exposure?	1	0	0	
10	Was the adverse event confirmed by any objective evidence?	1	0	0	
<b>Total</b>					

The Naranjo criteria classify the probability that an adverse event is related to drug therapy based on a list of weighted questions, which examine factors such as the temporal association of drug administration and event occurrence, alternative causes for the event, drug levels, dose – response relationships and previous patient experience with the medication.

The ADR is assigned to a probability category from the total score as follows:

<i>definite</i>	if the overall score is 9 or greater
<i>probable</i>	for a score of 5-8
<i>possible</i>	for 1-4
<i>doubtful</i>	if the score is 0

The Naranjo criteria do not take into account drug-drug interactions. Drugs are evaluated individually for causality, and points deducted if another factor may have resulted in the adverse event, thereby weakening the causal association.