

**WHO Tool for Causality Assessment**  
**INSTITUTIONAL ETHICS COMMITTEE**  
**HM PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD**

**CAUSALITY ASSESSMENT**

**Clinical Trial Protocol No. :**

**Clinical Trial Title:**

**Reference:**

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

**WHO Causality Assessment Categories**

Causality term	Assessment Criteria*
Certain	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with plausible time relationship to drug intake</li> <li>• Cannot be explained by disease or other drugs</li> <li>• Response to withdrawal plausible (pharmacologically, pathologically)</li> <li>• Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon)</li> <li>• Rechallenge satisfactory, if necessary</li> </ul>
Probable/ Likely	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with reasonable time relationship to drug intake</li> <li>• Unlikely to be attributed to disease or other drugs</li> <li>• Response to withdrawal clinically reasonable</li> <li>• Rechallenge not required</li> </ul>
Possible	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with reasonable time relationship to drug intake</li> <li>• Could also be explained by disease or other drugs</li> <li>• Information on drug withdrawal may be lacking or unclear</li> </ul>
Unlikely	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)</li> <li>• Disease or other drugs provide plausible explanations</li> </ul>
Conditional/ Unclassified	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality</li> <li>• More data for proper assessment needed, or</li> <li>• Additional data under examination</li> </ul>
Unassessable/ Unclassifiable	<ul style="list-style-type: none"> <li>• Report suggesting an adverse reaction</li> <li>• Cannot be judged because information is insufficient or contradictory</li> <li>• Data cannot be supplemented or verified</li> </ul>

\*All points should be reasonably complied with