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1.certain 2.probable/likely 3.possible 4.unlikely 5.conditional/unclassified 6.unassessible/unclassifiable 4

certain probable/likely possible unlikely conditional/unclassified unassessible/unclassifiable

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CERTAIN A clinical event including laboratory test abnormality occurring in a plausible time relationship to drug administration and which cannot be explained by concurrent disease or chemicals. The response to withdrawal of the drug dechallenge should be clinically plausible. The event must be definitive pharmacologically or phenomenological using a satisfactory rechallenge procedure if necessary. PROBABLE/LIKELY A clinical event including laboratory test abnormality with a reasonable time sequence to administration of the drug unlikely to concurrent disease or other drugs or chemicals and which follows a clinically reasonable response in withdrawal dechallenge

Rechallenge information is not required to fulfil this definition. POSSIBLE A clinical event including laboratory test abnormality with a reasonable time sequence to administration of the drug but which could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear. UNLIKELY A clinical event including laboratory test abnormality with a temporal relationship to drug administration which makes a causal relationship improbable and in which other drugs chemicals or underlying disease provide plausible explanations. CONDITIONAL/UNCLASSIFIED A clinical event including laboratory test abnormality reported as an adverse reaction about which more data is essential for a proper assessment or the additional data are under examination. UNASSESSIBLE/UNCLASSIFIABLE A report suggesting an adverse reaction which cannot be judged because information is insufficient or contradictory and which cannot be supplemented or verified."#F8F8F8" 100Test