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Titel: HDC-SM-RD Causality assessment scales

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Titel	Reference Document Causality Assessment Scales
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Omschrijving	Dit document bevat referentiemateriaal dat kan worden toegepast bij het doen van een Causality Assessment bij SAE evaluatie op SUSAR criteria.

Reference Document Causality Assessment Scales

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WHO-UMC Causality Categories

Causality term	Assessment criteria*
Certain	♦ Event or laboratory test abnormality, with plausible time relationship to drug intake ♦ Cannot be explained by disease or other drugs ♦ Response to withdrawal plausible (pharmacologically, pathologically) ♦ Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) ♦ Rechallenge satisfactory, if necessary
Probable /Likely	♦ Event or laboratory test abnormality, with reasonable time relationship to drug intake ♦ Unlikely to be attributed to disease or other drugs ♦ Response to withdrawal clinically reasonable ♦ Rechallenge not required
Possible	♦ Event or laboratory test abnormality, with reasonable time relationship to drug intake ♦ Could also be explained by disease or other drugs ♦ Information on drug withdrawal may be lacking or unclear
Unlikely	♦ Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) ♦ Disease or other drugs provide plausible explanations
Conditional / Unclassified	♦ Event or laboratory test abnormality ♦ More data for proper assessment needed, or ♦ Additional data under examination
Unassessable / Unclassifiable	♦ Report suggesting an adverse reaction ♦ Cannot be judged because information is insufficient or contradictory ♦ Data cannot be supplemented or verified

* All points should be reasonably complied with

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2 NARANJO's ALGORITHM

Question	Yes	No	Don't know
Are there previous conclusion reports on this reaction?	+1	0	0
Did the adverse event appear after the suspect drug was administered?	+2	-1	0
Did the AR improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0
Did the AR reappear when drug was readministered?	+2	-1	0
Are there alternate causes [other than the drug] that could solely have caused the reaction?	-1	+2	0
Did the reaction reappear when a placebo was given?	-1	+1	0
Was the drug detected in the blood [or other fluids] in a concentration known to be toxic?	+1	0	0
Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
Was the adverse event confirmed by objective evidence?	+1	0	0

Source: A METHOD FOR ESTIMATING THE PROBABILITY OF ADVERSE DRUG REACTIONS - **NARANJO et al** (1981)

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2.1 SCORING FOR NARANJO's ALGORITHM

- > 9 = definite relationship
- 5-8 = probable relationship
- 1-4 = possible relationship
- 0 = doubtful relationship