CAUSALITY ASSESSMENT

Estimating the probability of a relationship between exposure to Anti-TB drugs and the occurrence of an adverse reaction.

ASSESSMENT CRITERIA*

1 TIME RELATIONSHIP
(BETWEEN DRUG ADMINISTRATION AND EVENT)

2 PHARMACOLOGICAL CHARACTERISTICS
(KINETICS, DYNAMICS, PREVIOUS KNOWLEDGE OF SIDE EFFECTS)

3 MEDICAL PLAUSIBILITY
(CHARACTERISTIC SIGNS/SYMPTOMS, LAB. TESTS, PATHOLOGICAL FINDINGS)

4 DECHALLENGE
(WITHDRAWING DRUG & RECORDING OUTCOME)

5 RECHALLENGE
(READMINISTRATION DRUG & RECORDING OUTCOME)

*World Health Organization-Uppsala Monitoring Centre Scale

CERTAIN
Clearly related to study agent (confirmed by 'Dechallenge' and 'Rechallenge')
- Time relationship
- Definite pharmacological characteristic
- Medical plausibility
- Positive De-challenge
- Positive Re-challenge

PROBABLE
Likely related to study agent (confirmed by 'De-challenge')
- Time relationship
- Definite pharmacological characteristic
- Medical plausibility
- Positive De-challenge

POSSIBLE
May be related to study agent
- Time relationship
- Medical plausibility
- De-challenge information lacking/unclear

UNLIKELY
Doubtfully related to study agent
- Time relationship – may not be conclusive
- Concomitant diseases/other drugs – provide possible reason

Serious Adverse Event (SAE) is any untoward medical occurrence that at any dose:

Results in **death**	Is **life threatening**	Requires **hospitalization/ prolongation** of existing hospitalization	Results in **persistent** or **significant disability/ incapacity**	Is a **congenital anomaly/ birth defect**	Is a **suspected transmission** of any **infectious** agent via a **medical product**	Is **medically important**

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