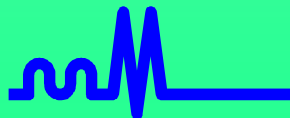


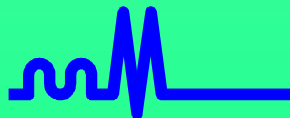
Definitions

- Pharmacovigilance
- Adverse event
- Adverse reaction
 - Unexpected adverse reaction
 - Serious adverse reaction
- Side effect
- Signal
- Causality



Definitions

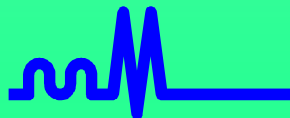
- Organisations involved:
 - WHO - World Health Organization
 - CIOMS - Council of International Organizations of Medical Sciences
 - ICH - International Conference on Harmonisation



Pharmacovigilance

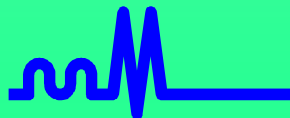
WHO, 2002

- The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem



Adverse event

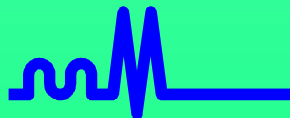
- Medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related



Adverse reaction

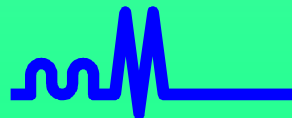
WHO, (1972)

- 'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function'.



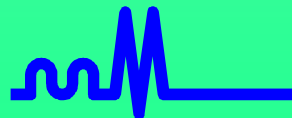
Unexpected adverse reaction

- Not consistent with applicable product information or characteristics of drug.



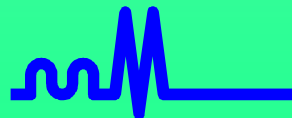
Side effect

- Unintended effect occurring at normal dose related to the pharmacological properties



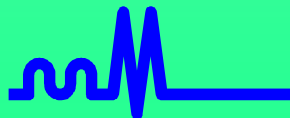
Signal

- Possible causal relationship adverse event and drug
- Previously unknown or incompletely documented
- More than one report is needed.
Depending on:
 - Quality of the information
 - Seriousness of the event



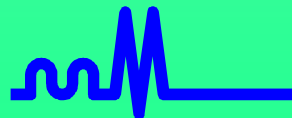
Serious adverse event or reaction

- Any untoward medical occurrence that at any dose;
 - Results in death
 - Life threatening
 - Requires inpatient hospitalization or prolongation of existing hospitalization
 - Results in persistent or significant disability or incapacity



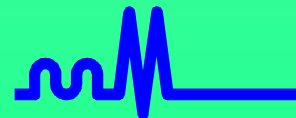
Frequency of adverse drug reactions (CIOMS)

- Very common
 - Common (frequent)
 - Uncommon (infrequent)
 - Rare
 - Very rare
- $\geq 1/10$
 - $\geq 1/100$ and $< 1/10$
 - $\geq 1/1000$ and $< 1/100$
 - $\geq 1/10000$ and $< 1/1000$
 - $< 1/10000$



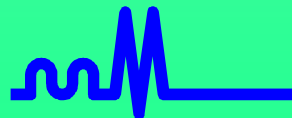
Certain

- 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 (*An objective and specific medical disorder or a recognised pharmacological phenomenon*)
 - Rechallenge (if necessary)



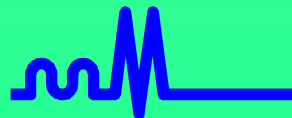
Probable

- 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 necessary



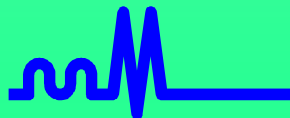
Possible

- 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 lacking or unclear



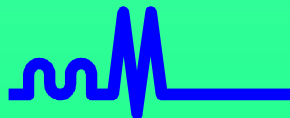
Unlikely

- Event or laboratory test abnormality, with a time to drug that makes a relationship improbable (but not impossible)
- Diseases 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

- A report suggesting an adverse reaction
- Cannot be judged because of insufficient or contradictory information
- Report cannot be supplemented or verified

