

Adverse event [AE]

Any untoward (not favourable) medical occurrence in a patient, or clinical trial participant receiving a medicine, and which does **not** necessarily have a causal relationship with this treatment.

Adverse events can therefore be: any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease **temporally associated with the use of a medicine**, whether or not considered related to the medicine.