Safety reporting – Investigator responsibilities

Adverse Event (AE)

- any untoward medical occurrence in a clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment

Serious Adverse Event (SAE)

- any untoward medical occurrence that at any dose:
  - results in death,
  - is life-threatening,
  - requires inpatient hospitalisation or prolongation of existing hospitalisation,
  - results in persistent or significant disability/incapacity
  - is a congenital anomaly/birth defect
  - Medically significant event

Time frames for reporting

- AE: as soon as possible → in CRF
- SAE: within 24 hours → to the sponsor