Safety Notification Management PV_SOP_01

1. Scope
    - Pharmacovigilance Department
    - Regulatory Department
    - Documentation Department
2. Adverse Event (AE)

Any adverse event which can be connected with period of taking the drug.

3. Serious Adverse Event

Any adverse event of medical nature irrespective of a dose of medicine which can result:

- Patient's death
- Danger to life
- Necessity of hospitalization or its extension
- Permanent or significant damage to health

4. Suspected Unexpected Serious Adverse Reaction (SUSAR)

An adverse event that occurs in a participant in a clinical trial that, in the opinion of the sponsor or investigator, is related to the medicine. Information about this drug effect is not mentioned in Investigator Brochure. Drug effect bad affects on patient health conditio and should reported imidietly to Regulatory Authoritory and bioethical commission.