Safety Pharmacology

Safety pharmacology studies predict whether a medicine is likely to be found unsafe when administered to human populations within the therapeutic range. Safety pharmacology studies aim to prevent the use of unsafe medicines.

Normally, results from previous safety pharmacology studies and effects related to the therapeutic effects of the medicine are considered. Safety pharmacology uses the basic principles of pharmacology in a regulatory-driven process to generate data to inform benefit-risk assessments. Safety pharmacology includes a regulatory requirement to predict the risk of rare lethal events. The vigilant post-marketing surveillance (PMS) efforts of regulatory authorities are necessary to detect the existence of a rare adverse event occurrence after approval for human use.