Efficacy and safety of drugs are very important parameters that are evaluated at every stage of drug development and post-marketing. Non-clinical and clinical drug safety evaluation involves assessment of the safety profile of therapeutic agents through the conduct of studies and trials (in vitro, animals and, humans, is an essential step in the progress of new and existing therapeutic agents. In past decade, modernization of safety evaluation methods and incorporation of novel approaches have revealed more insights of toxicity caused by the drugs. Toxicokinetics, toxicodynamics and toxicogenomics (TK/TD/TG) are the methods that have been recognised as potential tools in human health risk assessment. Application of these techniques include: more precise scenario of drug kinetics and metabolism; improved assessment strategy with greater efficiency, use fewer animals and provide better data for risk assessment purposes; rescue at-risk programs in preclinical/early clinical development; proactively screen/evaluate leads at early stages using predictive tools for toxicity and mechanism of action; develop pre-clinical biomarkers of drug response and toxicity; adoption of toxicity management approaches to improve the therapeutic outcomes. Studies based on above these techniques revealed many insights of drug toxicity at molecular as well as genetic level that helps researchers and physicians to reduce the undesired effects of drugs. It is also becoming apparent that TK/TD/TG approaches are very important to develop experiments designed to understand the molecular basis of drug toxicities.

The objective of this thematic issue is to report recent studies based on application of toxicokinetics, toxicodynamics and toxicogenomics approaches to drug safety and efficacy. This thematic issue would be more focused on studies of following categories:

1. Pre-clinical/Clinical studies that are focused on investigation of mechanism of drug toxicity (including kinetics of toxicants) and adverse drug reactions using TK/TD/TG will be of high interest.
2. Application of toxicogenomics in preclinical drug safety evaluation and biomarkers identification
3. Role of TK/TD/TG in pharmacogenomics and personalized medicine.

The scope of this issue is not limited to above sub-domains and we would be interested in other aspects as well.

Key words: toxicokinetics, toxicodynamics, toxicogenomics, biomarkers, pharmacogenomics, drug toxicity, predictive toxicology, gene expression, drug safety, drug efficacy, adverse drug reactions, molecular toxicology, toxicology database, toxicity evaluation.