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Role of Drug Metabolism and Pharmacokinetic Studies in Drug Discovery and Development

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The drug development process is scientifically complex, time consuming and expansive. Recent data indicate that the discovery and development of a new drug costs around 1.0 billion dollars and takes 12-15 years for the drug to reach the marketplace. In addition, 90% of all drugs in clinical development fail to make to the market. Efforts are being made to reduce attrition of drug candidates during the various stages of drug discovery and development, and to bring safer drugs to the market. The major reasons for the attrition and serious side effects are sub-optimal drug metabolism and pharmacokinetic (DMPK) profile, poor clinical efficacy and the formation of reactive metabolites. Given the inherent inefficiency of the development, it is essential to optimize/minimize such factors early in drug discovery process. This has led to greater integration of DMPK functions into early stages of drug discovery process and in addition to potency and selectivity; drug candidates are selected on the basis of DMPK properties, e.g. low clearance, good oral bioavailability, optimum half-life, and an acceptable metabolism profile in preclinical species and humans. This presentation will summarize the in vivo/in vitro techniques used for rapid determination of the DMPK profiles including absorption, metabolic stability, metabolite structures, cytochrome P450 inhibition/induction, and pharmacokinetics and role of these studies in the selection of the drug candidates for further development. Knowledge of metabolic profiles of these candidates in an early stage of drug discovery is essential to select compounds with favorable pharmacokinetic credentials and to aid medicinal chemists for rational drug design.