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Integrating genetic variability affecting bioavailability of drugs in clinical research and development: Indian and global perspectives

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Bioavailability is a pharmacokinetic term that describes the rate and extent to which the active drug ingredient is absorbed from a drug product and becomes available at the site of drug action. The bioavailability of a drug substance formulated into a pharmaceutical product is fundamental to the goals of dosage form design and essential for the clinical efficacy of the medication. Bioavailability determination are performed by drug manufacturers to ensure that a given drug product will get the therapeutic agent to its site of action in an adequate concentration. Bioavailability is of clinical and regulatory interest. Genetic makeup of a patient importantly influence inherent pharmacokinetic, ultimately giving rise to inter patient variation in drug absorption, distribution, biotransformation, and elimination. It has been estimated that genetics can account for 20 to 95% of variability in drug disposition and effects. There are numerous drug metabolizing enzymes, drug transport proteins, and drug targets, all of which may have genetic variants with potential functional effects on the pharmacokinetic of a specific drug. Recent advances in molecular techniques and data analysis from the Human Genome Project have identified numerous regions of genetic variability with over 60,000 of these residing in the coding region of human genes, both single-nucleotide polymorphisms (SNPs) and microsatellite regions. Pharmacogenetics, or the more genome-wide approach of pharmacogenomics taking polygenic effects into consideration, therefore, aims to identify the inherited basis for inter-individual differences in drug response. Clinical genetics research will provide an opportunity to incorporate pharmacogenetic into drug development, allowing individualization of drug dosing. Regulatory interest of bioavailability includes agencies approving the sale of products in their nation, as well as reimbursement agencies. New drug application from manufacturer seeking regulatory approval must furnish exhaustive information about a drug pharmacokinetics. Typically such evidence entails studies wherein the drug has been administered orally. While such trials may broadly be viewed as bioavailability studies many are ostensibly designed to assess the drug's safety and efficacy. The FDA has provided recommendations related to many of these factor in the context of drug development, the most recent being evaluation of study design with respect to concomitant medication. One of the important sources of variability in drug exposure is genetic variability in drug metabolizing enzyme. Drug companies increasingly bank DNA samples to investigate genetic variability. Overall it highlights several aspects of bioavailability as related to clinical research and regulatory recommendations in early drug development to include genetic variability in pharmacokinetic studies.

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