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TITLE

INTER-INDIVIDUAL VARIABILITY AND DRUG DEVELOPMENT: BA/BE AS RESEARCH TOOL

Harish Padh

PERD Centre and Project Director,
NIPER-Ahmedabad, India.

Pharmacokinetics based BE study is a good tool primarily used as regulatory testing for establishing equivalence of a formulation for ANDA application. Examining the underlying science behind BE testing, one can see that it is an excellent tool to study population genetics, particularly, inter-individual variations and inter-population variations. The pharmacokinetics based phenotypic variations can be correlated with genotype and such correlations can be used for predicting efficacy and toxicity.

The presentation will include data from BE study of several drugs, inter-individual variability observed in many cases, genotyping of the volunteers for several drug metabolizing enzymes (DMEs), correlation between genotype and phenotype (C_{max} and AUC). The presentation will illustrate use of BE data to understand ADME 'population' as well as 'individual' and will demonstrate link between BA/BE and the newly emerged science of Pharmacogenetics.