

**Title: Statistics in Pharmacology and Pre-Clinical Studies**

**Author(s): Tze Leung Lai, Mei-Chiung Shih and Guangrui Zhu**

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**Abstract:**

Herein we give an overview of the basic principles, models and statistical methods in pharmacokinetics and pharmacodynamics. An active area of research in the field is pharmacometrics, and we review some recent trends in this area. Particular attention will be directed to population pharmacokinetics and its interactions with several branches of modern statistics, including nonlinear mixed effects models, hierarchical and empirical Bayes methods, and generalized linear mixed effects models. We also discuss the role of pharmacokinetic and pharmacodynamic studies in drug development. Specifically they are used to determine the dosage regimen of the drug (i.e. how much and how often it should be taken). These studies are initially performed *in vitro* and then on animals to come up with rough guesses of a region of dosage regimens in which clinical studies on human subjects are to be performed. This *in vitro* and animal studies are called "pre-clinical" and precede the clinical studies that are classified as Phase I studies (on healthy volunteers) and Phase II and III clinical trials (on patients). Other statistical applications in pharmacology and pre-clinical studies are also discussed, including drug discovery, bioequivalence and bioavailability, assay development and validation.