doi:10.4172/0975-0851.1000011

TITLE

CHALLENGES IN THE DESIGN OF COMPARATIVE BIOAVAILABILITY STUDIES – AN INDUSTRY PERSPECTIVE

Dr. Siddarth Chachad

Department of Clinical and Bioequivalence Research, Cipla Ltd, Mumbai, India.

In anticipation of the patent expiry of the innovator pharmaceutical product, pharma companies develop generic equivalents with formulation and pharmaceutical properties as close as possible to the original Innovator product. In case of such regulatory submissions, comparative bioavailability studies are required so as to demonstrate bioequivalence between the generic and innovator products. The maximum concentration in plasma and area under the curve are primary parameters of such bioequivalence studies. Although conventional bioequivalence studies can be designed for most drugs, in the era of complexly characterized Liposomal and biotechnology drugs, the study designs of comparative bioavailability studies become further more complex. Challenges in designing such studies include analysis of drugs having low systemic bioavailability, nature of some drugs such as cytotoxic drugs which require studies in patients and not healthy volunteers; and pharmacokinetics of certain drugs which is non-linear. Issues whether to analyze parent drug or metabolite, whether to use single unit or multiple units, crossover or parallel truncated design, sample size rationale, high intraindividual variability and lack of clarity in the regulatory guidance present further challenge in designing comparative bioavailability studies.