



International Conference & Exhibition Bioequivalence and Bioavailability 2010

doi:10.4172/0975-0851.1000012

TITLE

BIOEQUIVALENCE STRATEGIES FOR ONCOLOGY PRODUCTS

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The mortality due to cancer is huge and the treatment is very costly. Generic drugs are necessary now to reduce the cost of treatment and make medicines available to the needy at affordable costs. Developing generic versions of oncology products involves huge costs and risks. Many challenges are to be faced and strategies to be adopted to conduct bioequivalence of oncology products. Conducting BE studies for these products are not as simple and straight forward as other products. Strategies are to be adopted from protocol development, recruitment of patients to conduct of clinical study and regulatory requirements. These molecules are various types and act through various mechanisms and have their unique adverse effects. There are many ethical issues concerning using normal subjects and patients for these studies. Various designs options are to be adopted based n the formulation whether it is injection, infusion, oral or entrapped liposomal and nanoparticle formulations. The above issues will be discussed in the presentation.