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The role of modeling and simulations to better understand, optimize and predict Bioequivalence

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Modeling and simulations have arguably revolutionized the field of clinical pharmacology, enabling clinicians, academicians and regulators to better understand the efficacy and toxicity of drugs by linking their relationship with exposure metrics. Virtually all new drug submissions nowadays incorporate a modeling and simulation component. In contrast, modeling and simulations are often misunderstood and severely underutilized in the bioequivalence field. This presentation will review the types of studies, specific pharmacokinetic behavior and circumstances in which modeling and simulations can help optimize bioequivalence programmes. Case examples will be shown for drugs with atypical characteristics or specific formulations where modeling and simulations can actually optimize the drug development process by predicting or proving bioequivalence using novel methods in a more robust scientific manner while decreasing the number or complexity of the clinical studies.

Biography

Murray P. Ducharme has a pharmacy degree from the University of Montreal, and a post-graduate Pharm.D. from Wayne State University. He has been with Cetero Research since 2007 where he is globally responsible for scientific and regulatory affairs. His research interests have focused on the role of modeling and simulations to better understand the clinical pharmacology of drugs and optimizing the drug development process. Dr. Ducharme has been principal or sub-investigator on thousands of trials, has authored more than 150 articles, abstracts, book chapters and manuals, and has presented internationally more than 200 posters and seminars.