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The role of population PK and PK/PD in bioequivalence and biosimilarity assessment

The importance and relevance of population PK/PD within the drug development process over the last 30 years has been increasing in parallel with the constant improvements seen in the availability of personal computing power. Population PK/PD tools and importance initially arose from clinical and academic needs to better understand the links between dosing regimens, PK, PD, clinical attributes of patients and disease states, and the safety and efficacy of drugs, all the while collecting less observational data and at diverse points in time. From then, population PK/PD was introduced in the drug development process to analyze PK/PD data from pivotal Phase III studies. This movement to the regulated pharmaceutical industry resulted in much needed improvement and order on how models are selected, validated and presented. Population PK/PD importance then progressed from Phase III to all phases of drug development especially after Lewis Sheiner's Learn and Confirm idea. In contrast to its now essential role in the new drug development process, population PK/PD is often misunderstood and/or severely underutilized in generic and biosimilar submissions. This presentation will review the types of studies, specific PK/PD behavior and circumstances in which population PK/PD can help optimize bioequivalence and biosimilarity programs. Case examples will be shown for drugs with atypical characteristics or specific formulations where population PK/PD can actually optimize the drug development process by predicting or proving bioequivalence or biosimilarity using novel more robust methods while decreasing the number or complexity of the clinical studies themselves.

Biography

Murray Ducharme has a B-Pharm from the University of Montreal and a Post-graduate PharmD from Wayne State University in Detroit Michigan. He is President and CEO of Learn and Confirm Inc. He has presented in more than 300 seminars internationally including posters and published more than 150 abstracts, manuscripts and book chapters in clinical pharmacology. He has been involved in thousands of Phase I clinical trials as a PI or sub-PI, and has served as an Expert Consultant in the drug development field for dozens of pharmaceutical companies located in the USA, Europe, Africa, Middle-East, Asia and Canada. He has directed the work of 6 PhD, 5 Post-doctoral Fellows, and 11 MSc candidates. He is a Fellow of the American College of Clinical Pharmacy and of the American College of Clinical Pharmacology. He is the Past-Chair of the American Association of Pharmaceutical Scientists, Bioequivalence Focus Group, and he is a Core Member of Health Canada Scientific Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology.

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