Modeling and simulation to support clinical development design and decision making: A few examples
Roland Fisch, Novartis Pharma AG, Basel
Abstract

In clinical development, the role of Modeling and Simulation is to build and use quantitative relationships among relevant pieces of information, e.g. biomarkers, drug concentrations, physico-chemical parameters, genotypes, patient demographics, dosage regimens, drop-out and compliance patterns, clinical endpoints. Specifically in early clinical development, M&S can be used in the planning and decision making within the development project. E.g., modeling (including, but not restricted to PKPD modeling) can support the choice of dose regimens, therapeutic drug monitoring schemes, or phase III trial design. A few specific examples from Novartis drug development will be presented.