

## From pre-clinical experiments to clinical trials: a model-based approach

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Use model-based approach to prospectively link all preclinical information to clinical development by applying a PK/PD orientation and by using animal PK/PD (efficacy & toxicity) to target human PK/PD as a guidance for progressing drug candidate to humans, for selecting starting dose and dose-escalation scheme in humans.

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*Roberto Gomeni obtained a degree in Mathematics from the University of Milano (Italy), a PhD in Pharmacokinetics and HDR from the University of Montpellier I (France). Roberto was the former head of Pharmacometrics at GlaxoSmithKline R&D, King of Prussia, PA (USA). He is responsible for strategic and leveraged utilisation of model-based approach for improving efficiency in drug development projects (from lead optimisation to marketing). His current research interests are focused on the identification and on the implementation of strategies to enhance drug development process, drive decision making and risk management using drug and disease progression models, clinical trial simulation, Bayesian modelling and knowledge-based computer-assisted drug development processes. Roberto is the author of more than 150 original research papers published in international scientific journals on individual and population PK/PD analysis and mathematical modelling in drug discovery, pre-clinical and clinical pharmacology.*