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Editorial

Pharmacometrics: a quantitative tool of pharmacological research

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Pharmacometrics is an interdisciplinary science with tremendous potential to influence decision making through the construction of mathematical and statistical models combined with graphical methods that define, challenge, and resolve queries surrounding the biological processes of a drug. In 2004, FDA published the white paper *the Challenge and Opportunity on the Critical Path to New Products*, which advocates the model-based drug development (MBDD). Since then, pharmacometric analysis has become an increasingly important component of New Drug Application (NDA) and Biological License Application (BLA) submitted to FDA for drug approval, labeling and trial design decisions[1, 2]. The academic clinical researchers are likewise confronted with the need to use data from various sources (experimental biology, preclinical models of disease, *etc*) in order to organize translational clinical studies in a therapeutic area. The administrators are faced with bringing together a variety of data (preclinical and clinical data, literatures, and other regulatory submissions of similar therapies) in order to make regulatory decisions. A great deal has been published in the literatures on quantitative research, especially in the field of clinical pharmacology. Therefore, wherever in industry, academia, or regulatory agencies, pharmacometrics is at the center of the translational medicine paradigm[3, 4]. It is difficult to imagine a more efficient, powerful, and informative drug development and evaluation process without comprehensive pharmacometric studies.

China is growing to be not only one of the biggest pharmaceutical markets in the world, but potentially one of most productive countries in R&D of new drugs as well. since 1979, *the Professional Committee of Mathematical Pharmacology* (PCMP) led by *the Chinese Society of Pharmacology* has been devoting to promote research, education and training of Chinese scientists in academia, industry and regulatory agencies with regard to the use of PK/PD modeling to help drug development and to optimize drug application in clinical therapies[5, 6]. The papers organized by PCMP in this Special Issue of *Acta Pharmacologica Sinica* are focused on phase I trial design[7], phase I PK study[8, 9], physiologically based PK modelling (PBPK)[10], PK/PD linking[11-14], population approach[15–17], dose finding[18], and stochastic simulation[19]. We hope that these papers serve as an introduction for the readers in academia, regulatory authorities and pharmaceutical industry to understand the role of pharmacometrics in drug development and approval processes, which will improve the success rate in drug development, and the beneficiaries will ultimately be the patients in need.

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