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Company-Organized Symposium

Consistency of the pharmacodynamic index required for the decisions in drug discovery and drug development moving from the preclinical to the clinical studies

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Relationship between pharmacokinetics (PK) of candidate substances and pharmacodynamic changes caused by candidate substances, i.e., PK/PD is requested to maintain consistency among different R&D stages from in vitro to in vivo or from nonclinical to clinical. It is essential to anticipate clinical efficacy and to verify its outcome in clinical trials. However, there are few data available for modeling and simulation when selecting molecular targets in the early stages of drug discovery and screening candidate substances from various compounds, and it is extremely challenging to quantitatively consider the extrapolation to the clinical. Furthermore, efficacy assessments often take into account species differences in targets and limited suitability with the clinical manifestations of animal models, which often require individualized assessment depending on the target molecule or disease state.

In this topic, we will discuss the improvement of the success rate of drug discovery and development from the viewpoint of efficacy through the introduction of some cases for our type 2 diabetes drugs from the discovery to the post-launch stage.