

Overview of Pharmacokinetics/Pharmacodynamics of monoclonal antibody

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Monoclonal antibody(Mab) are exhibited several pharmacokinetic profiles. The endogenous IgG shows a longer half life, however variety half life of Mab was reported. Following hypothesis are able to consider that the variability of amount of target antigen in a body or interaction with FcRn receptor are related with Vmax on the clearance.

To consider PK/PD profile of Mab, mode of action is generally clear, however effects of outcomes are much more complex. Because many of Mab can apply for a wide range of therapeutic area whose clinical end point are specifically prescribed and it was discrepancy from the mode of action. Therefore, to find the surrogate biomarker as a coupler between the mode of action and clinical end points are one of the key success factor to establish the Mab PK/PD approach, especially early clinical stage.

This session will introduce the overview of Mabs development from a published data and also explain the complexities of PK/PD relationship.