S7-4

Modeling & Simulation (M&S): A Tool to Enable Efficient Clinical Drug

○Gao Christine[1] ([1]Pharsight Corporation)

Computer models of the likely range of responses to new drugs are being simulated to enable efficient trial design and clinical development decision-making in many pharmaceutical companies today. These models are developed from available pre-clinical and clinical data, and public data on analogues, competitors, and the disease process. Emerging clinical data is incorporated into the model to provide an up-to-date and a concise summary of relevant therapeutic knowledge. The models are used as part of the clinical trial planning process; the model is simulated to anticipate the likely range of outcomes in the patient population. This information is used to design trials efficiently, to understand the implications of different scientific assumptions, to evaluate alternate development strategies, and to quantify how well the drug candidate meets commercial objectives.The first goal of this lecture is to illustrate a software program that can be used to simulate clinical trials, namely Pharsight's Trial Simulator™ software. The second goal is to present an application of modeling and simulation to efficient clinical drug development using the Trial Simulator software. A key challenge in drug development is to identify what dose or dose range, if any, provides a marketable risk/benefit profile in a certain patient population. With this ultimate goal in mind, modeling and simulation provides an opportunity to anticipate the learning that will come from a trial, and to tune design variables and analysis plans to maximize the information that is gained while minimizing the number of patients and measurements. The scope of applications is expanding earlier in development to candidate selection, and later in development to regulatory interactions. Modeling and simulation is a valuable tool enabling efficient clinical drug development.