

## Target Meeting's 3rd World Drug Discovery Online Conference 2013

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### **Title:**

Models and Their Utility in The Drug Development Process

### **Abstract:**

Drug development is a costly and time consuming process, which includes expensive human clinical trials. Unfortunately, it is a common fate that candidate molecules are found not to be as effective as expected at the late stage of development, resulting in significant delays and added costs in bringing new medicines to the patients. Use of mathematical and computer models as tools in the drug development process has gained an industry-wide attention recently, as these models enable study outcome predictions in-silico, hence decreasing the number of studies to be conducted as well as the number of subjects required to be studied. Various mathematical models are used in the process of drug development, including, but not limited to, pharmacokinetic/pharmacodynamics (PK/PD) models, physiologically based PK models, mechanistic PD models, and systems pharmacology models. The choice of the model to be used should be determined by the type of the research question that needs to be answered. While some models rely solely on the available data and hence may have limited utility, others incorporate knowledge from different sources together with the in-house data to provide a better understanding of the drug and the disease progression. Each type of modeling offers advantages and shortcomings in answering different questions during the process. It is argued that various types of models are suited best to answer specific questions in hand. Furthermore, differences in the modeling approaches and how they address different types of questions will be discussed. Examples of each type of the models and their utility will also be presented.