# Trial design
## The Power of Power

Pharmetheus
Pharmacometrics Consulting Services

# Trial design

Pharmetheus has extensive knowledge and experience to support drug developers with trial design. Pharmacometric models of dose, concentration, effect, or safety data are used to optimize study designs. Simulating outcomes after modifying study design parameters, such as sampling times, doses, or number of individuals assigned to different regimens, allows us to evaluate operating characteristics of multiple design options.

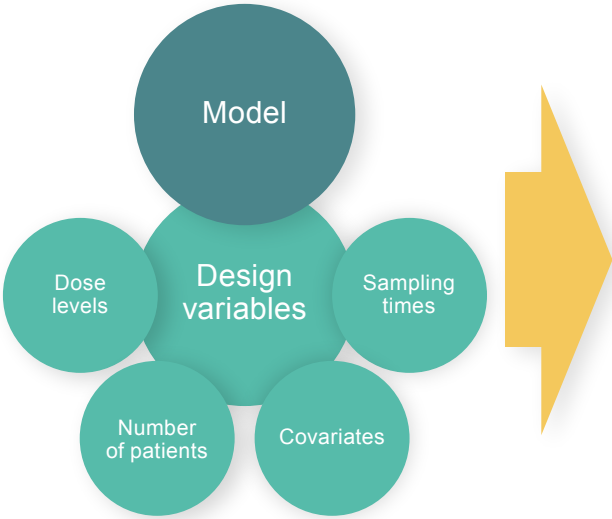
Simulation is often a very helpful tool to evaluate trial design and operating characteristics, to make informed decisions. Predictive Probability of Success (PPoS) is one such simulation-based outcome that is helpful in understanding the likelihood of success by quantifying the probability of a successful trial based on interim data.

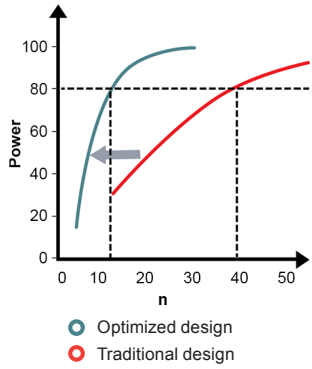
Simulations can also be useful in assessing the performance of different analysis options that could be used to model the data at the end of the trial.

Adaptations can also be implemented based on interim analyses such as dropping doses that are futile or increasing sample size in those in a 'promising zone'.

Implementing efficient and optimal design techniques is helpful in obtaining the most information with the least amount of patients exposed, which is particularly helpful in pediatrics and rare diseases where information is scarce. More generally, better utilization of information from fewer subjects, is in line with ethical standards with regards to the patients and healthy subjects participating in clinical studies. Simulations can also be useful in assessing the performance of different analysis options that could be used to model the data at the end of the trial.

Our team has the expertise to explore designs, interpret the results and take full advantage of the possibilities of alternative trial designs. We have the capability and expertise to deliver a wide range of design support from the traditional to more cutting edge methods.






Pharmetheus
Pharmacometrics Consulting Services