

Example of Project in the Pharmacometrics Group

Title

Development of a methodology for guiding the dose range and number of dose strengths to be made available to patients.

Background

In drug therapy, it is common that a dosing regimen is modified or treatment is stopped due to lack of efficacy or adverse events. The response of individual patients to a treatment varies greatly and for many patients a dose below or above the initially prescribed dose may be more appropriate. With a wider range of doses available for a given drug, the probability of achieving treatment success through titration of the dose increases, provided that treatment response can be used to guide dose changes. A pertinent question in drug development is how the proportion of patients that benefit from treatment increases with the range and number of doses that are made available for a to-be-marketed product.

Objective

To develop of a methodology for guiding the dose range and number of dose strengths to be made available to patients. Secondly, to assess how within-subject variability in treatment response impacts the dose range and number of doses.

Methodology

Through *in silico* simulation in NONMEM, the distribution of the optimal dose in individual patients will be determined in the presence of inter-and intra-subject variability in the shape of the dose-response relationship. Relevant examples of dose-response information will be retrieved from the literature.

Contact: Trine Meldgaard Lund trine.lund@sund.ku.dk