Population Modeling Capabilities

Principles

Population pharmacokinetic, PK/PD, and exposure-response modeling are the industry standard approaches for modeling clinical, and increasingly non-clinical, pharmacological and safety and efficacy data to inform clinical trial program design and data analysis and interpretation. This meets regulatory requirements and expectations through all drug development phases to submission and beyond. Population PK, or PK/PD modeling uses PK or PD time course data from multiple subjects, potentially across many trials, to describe and simulate the dose, concentration (and PD) time relationship, accounting for the variability in the population. Exposure-response modeling quantifies and simulates the relationships between drug dose, exposure and efficacy or safety endpoints.

Population modeling is used for the following purposes:

- Analyzing PK, PD or PK/PD data from clinical trials, especially trials with sparse PK or PD sampling
- Simulation to help design, select, justify, and optimize dose and regimen through all development phases
- Design, simulate and analyze clinical trials to maximize the probability of success and optimize sample size, trial duration, sampling and assessment schedules, patient selection and trial conditions.
- Support submission and labeling including dose and dose adjustments for special populations, drug-drug interactions, and contra-indications, describing intrinsic and extrinsic factors in PK variability.

Services

- Modeling Dataset Programming
- Analysis Plan Development and Writing
- Exploratory Data Analysis
- Population PK, PK/PD and Exposure-Response Model Development including:
  - Compartmental and Complex Base Model Building
  - Longitudinal, Mechanistic PK/PD and Disease Progression/Placebo Response
  - Covariate Analysis
  - Simulation
- Clinical Trial Simulation
- Visualization (R shiny)
- Submission-Ready Reporting

Computing

Validated Cloud-Based High-Performance Computing (NONMEM/R/Pirana/PsN)