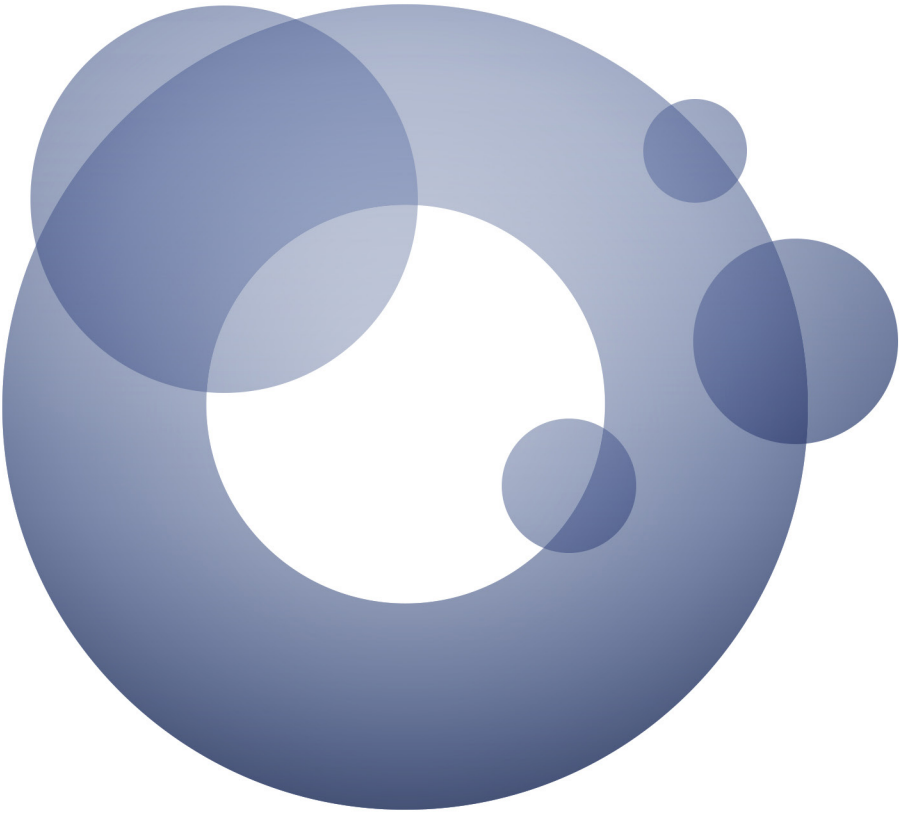
MIDD

The Power of a Quantitative Framework



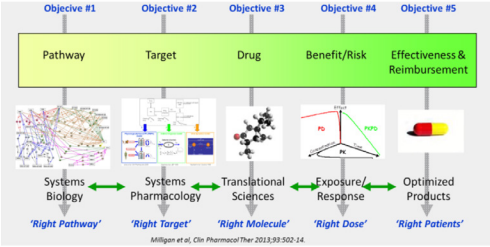
Pharmetheus

Pharmacometrics Consulting Services

Model Informed Drug Development

Pharmetheus colleagues have considerable expertise in establishing, formalizing and maintaining a "MIDD mindset" within Pharmaceutical Companies (1).

Of great importance was the development of a culture of collaboration across statisticians, clinical pharmacologists, and clinicians.



The collaboration underpinned the development of a quantitative framework where a variety of modeling approaches (population pharmacokinetics, exposure-response analysis, physiologically based pharmacokinetic modeling, clinical trial design etc.) were integrated to most effectively and efficiently support and inform development program strategies and decisions.

The integration of "fit for purpose" models can be used throughout the product life-cycle to inform a range of important strategic directions and minimize trial and compound uncertainties.

Sources of Trial/Compound Uncertainties	Potential Quantitative Approach
Changes to formulations/dosing frequency	PK/PD Models
Changes to duration of treatment	Longitudinal Models
Changes to study "success" criteria	Design & Trial Execution Models
Changes to endpoint of interest	Translational Models
Changes to dose, sequence, schedule, combinations	Disease, PBPK, PBPK/PD and System Models
Changes to populations	Disease, PBPK, PBPK/PD and (Multiscale) System Models
Changes to indication characteristics and/or competitive landscape	(Model Based) Meta Analytic Models
Changes to differentiation/transition criteria through research/development/registration/reimbursement...	Decision Theoretic Models

At Pharmetheus we have the blend of expertise to enhance MIDD at the trial, compound and/or organizational level. We offer a range of MIDD services tailored to your needs, such as:

- Presentations focused on MIDD awareness.
- Workshops focused on MIDD implementation.
- Workshops focused on MIDD application within particular therapeutic areas.
- Scientific advice at the analysis, trial and compound levels.
- Review of development programs.
- Delivery of a range of MIDD components in a "fit for purpose" manner.

1) Milligan et al, Clin Pharmacol Ther 2013;93:502-14