

Pharmacometric analyses

The Power of Integration



Pharmacometric analyses

The population approach to the analysis of pharmacokinetic and pharmacodynamic data is based on the integration of information; across repeated measures, between patients, across studies and even across drug development programs.

Short timelines is a challenge in the development of new drugs. We can build models to guide the

design of the next study, making sure you get the information you need for internal and regulatory decision making in a timely manner.

With the reproducible analysis and reporting environment developed at Pharmetheus, submission ready reports can be produced with high efficiency and fast turn-around after data base release.

Population Pharmacokinetic analysis is a powerful tool to:

- Understand the pharmacokinetics in all patients.
- Assess covariates (e.g., body weight, age, sex, and race) and vulnerable populations (e.g., reduced liver or kidney function).
- Assess the impact of DDIs.

Combined with a Population Pharmacodynamic analysis it will also allow you to:

- Identify the relationship between drug exposure and efficacy, safety and/or biomarkers.
- Optimize the design of future studies.
- Make informed recommendations regarding posology and avoid unnecessary label restrictions.

At Pharmetheus we have experience working with a wide range of pharmacometric approaches:

- The analysis of discrete data (e.g., time-to-event and count data).
- Mechanism based PK modeling (e.g., enzyme induction/inhibition, target mediated drug disposition and complex absorption).
- Mechanism based model building in different therapeutic areas (e.g., neuroscience, diabetes, oncology, inflammation, infectious disease and respiratory disease).
- Translational modeling (e.g., pre-clinical to clinical and adult to pediatric populations)

