Cognigen uses pharmacometrics, a multidisciplinary scientific approach involving a comprehensive toolbox of mathematical analysis and simulation techniques and technologies, embedded in a highly developed enterprise infrastructure, to support decision-making at critical points in drug research and development. We provide comprehensive, regulatory-ready analysis and support services emphasizing exploratory analyses, population PK/PD modeling, physiologically based PK (PBPK) modeling in GastroPlus®, exposure-response analyses, statistical modeling, and clinical trial simulations focused on optimizing the dosing regimen, target population for treatment, and trial design features for all phases of development.

Our team of expert consultants and data programmers are eager to support your development program by providing the following services:

Pharmacometric Analyses and Support
- Analysis plan development
- Study design support
- PK/PD sampling strategy development
- Literature review and model-based meta-analyses
- PBPK modeling in GastroPlus®
- Population PK, PK/PD, and exposure-response modeling
- Clinical trial simulations
- Technical report writing
- Forensic pharmacometrics

Data Assembly and Programming Services
- Comprehensive data management and analysis-ready dataset creation
- Real-time data assembly, reporting, and error checking
- Exploratory graphical and tabular analysis
- Unblinded support for Data Safety Monitoring Boards
- CDISC compliant dataset creation
- Data definition documentation and preparation of Data Reviewer’s Guides

Pharmaceutical and Clinical Pharmacology Consulting
- Gap analyses at research and development milestones
- Noncompartmental PK analysis and associated statistical analyses
- Embedded clinical pharmacology support
- Clinical pharmacology plan development incorporating modeling and simulation strategies
- Simulations that assist in first-in-human dosing, bioequivalence, pediatric scaling, drug-drug interactions, optimal Phase 3 clinical trial designs, and benefit/risk assessments
- Preparation of regulatory briefing packages and related CTD sections
- Collaboration on strategic direction for regulatory interactions
- Abstract, manuscript, and poster preparation