Cognigen

A SIMULATIONS PLUS COMPANY

www.simulations-plus.com
(NASDAQ: SLP)

Cognigen uses the tools of pharmacometrics, embedded in a highly developed enterprise infrastructure, to support decision-making at critical points in drug research and development. We provide comprehensive pharmacometric analysis and support services emphasizing exploratory analyses, PBPK modeling (GastroPlus®), PK/PD modeling, statistical modeling, and clinical trial simulations focused on dose and dose regimen selection and justification.

Pharmacometric Analyses and Support

- Analysis plan development
- Optimal study design support
- PK/PD sampling strategy development
- Literature review and meta-analysis
- Physiologically based PK modeling (GastroPlus)
- Population PK and PK/PD model development
- Exposure-response analyses
- Exploratory and formal covariate evaluation
- Clinical trial simulations
- Technical report writing for inclusion in regulatory submissions
- Expert review/forensic pharmacometrics
- Dose selection and justification support, including wording for labeling statements

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

Pharmacometric Training and Education

- Introductory population PK/PD modeling course, with hands-on, interactive experiences
- Intermediate-level didactic population PK/PD modeling course
- Custom-built workshops incorporating NONMEM- and/or Monolix-based modules

Quantitative Clinical Pharmacology Consulting Services and Support

- Embedded clinical pharmacology and pharmacometrics team member support, with flexible arrangement for required extent of commitment
- Gap analyses at research and development milestones
- Noncompartmental and associated statistical analyses
- Guidance regarding clinical pharmacology development plans, incorporating M&S
- 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, related CTD sections, PIPs, and PSPs
- Collaboration on strategic direction for regulatory interactions and support for regulatory response preparation
- Abstract, manuscript, and poster preparation

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