SimulationsPlus

Cognigen | DILIsym Services | Lixoft

www.simulations-plus.com

(NASDAQ: SLP)

Cognigen is comprised of expert data programmers, Clinical Pharmacologists, pharmacometricians and project managers. Together, we provide high-quality analysis & support services including non-compartmental PK analysis, population PK and PK/PD modeling, PBPK modeling in GastroPlus®, and statistical modeling, focusing on your critical drug development decisions. We have extensive experience with regulatory submissions (including Real-Time Oncology Reviews), and a rigorous Quality Management System that has been vetted in numerous client audits.

Kevin Dykstra, Ph.D.
Vice President, Consulting Services

Pharmacometric Analyses and Support

- Dose selection and justification support, including wording for labeling statements
- Non-Compartmental PK Analysis, Population PK and PK/PD model development, exposure-response analyses, PBPK modeling
- Clinical trial simulations to support optimal study design

Joel Owen, Ph.D.
Vice President, Pharmacometric Services

Clinical Pharmacology Consulting Services and Support

- Embedded clinical pharmacology team member support, with flexible extent of commitment
- Analysis and simulations to support FIH dosing, bioequivalence, pediatric scaling, DDIs, optimal clinical trial designs, and benefit/risk assessments
- Collaboration and support on strategic direction for regulatory interactions and regulatory response preparation

Darcy Hitchcock, MBA
Director, Quality Management and Data Programming

Data Assembly and Programming Services

- Comprehensive data programming and analysis-ready dataset creation
- Real-time data assembly with blinded reporting for data monitoring committee review
- Exploratory graphical and tabular analysis

Jill Fiedler-Kelly, M.S.
President, Cognigen Corporation

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

Cognigen

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