cencora
PharmaLex

Statistical support for clinical development

Empower your clinical development journey with PharmaLex's expertise

Many companies face challenges in managing complex trial designs, interpreting diverse datasets, and meeting regulatory expectations – especially in fields like rare diseases and pediatric studies. Navigating this complicated landscape demands deep clinical development experience and knowledge.

Why choose PharmaLex's statistics and data science team?

Our team specializes in innovative trial design (including Bayesian methodology), translational and precision medicine, pharmacometrics, and data science across the entire clinical journey. From study design to end-to-end biometrics services and clinical trial reporting, we have you covered.

Experience innovation in clinical trial design

Our experts thrive on challenges, having supported studies across most therapeutic areas in both established and novel product categories. Our team works closely with health authorities to pioneer new approaches and innovative designs, including Bayesian statistics.

Over two decades of biomarker study excellence

With more than 20 years of experience in designing and analyzing biomarker studies, our industry-leading team helps to accelerate the execution of your project. We collaborate with the clinical team, biomarker scientists, and clinical pharmacology experts to answer questions such as mechanism of action, target engagement, and patient stratification while leveraging our specialties in real-world data, omics, and machine learning.

Cencora PharmaLex – where expertise meets innovation!

Innovative trial design

- Bayesian adaptive design
- Early phase dose-finding design
- Seamless design for clinical trials
- Strategy and design for biomarker-driven enrichment trials
- Master protocols with basket, umbrella, or platform design
- Use of real-world data in study design
- Design for rare disease and pediatric studies
- Trial design using synthetic control arms
- Supporting novel approaches in discussions with regulatory bodies

Pharmacometrics

- Non-compartmental pharmacokinetic (PK) analysis
- Population Pharmacokinetic/pharmacodynamic (POP PK/PD) modeling
- Joint model- and mechanism-based models: biomarker, pharmacology, disease progression
- Support of translational activities: interspecies, preclinical-clinical, pediatric extrapolation
- Design definition and optimization through extensive model-based clinical trial simulations

Translational and precision medicine

- Mechanism-based early development (susceptibility or response biomarkers) and patient-centric late development (predictive and prognostic biomarkers)
- Patient stratification
- Statistical support for the development of companion diagnostics
- Multi-omics profiling and digital biomarkers
- Exploratory biomarker analysis, reporting and interpretation

Clinical data science

- Multi-phase & multi-TA experience
- Data visualization
- Interim and final statistical analysis
- Predictive modeling using statistics and machine learning and AI Automation in R/SAS programming
- Template programs for dataset creation and reporting

Contact us
www.pharmalex.com/contact-us