cencora
PharmaLex

Complete clinical biometric solutions

Elevate your medical product development with PharmaLex's biometric services

Embark on a journey of innovation and excellence with PharmaLex's Data Strategy and quantitative sciences team. We specialize in delivering comprehensive biometric services tailored to supporting the entire lifecycle of medical product development.

End-to-end excellence

From early research to study completion and beyond, our team supports you across every stage of your project. With expertise spanning study design, data collection, analysis, interpretation, and reporting, we are your trusted partner from start to finish.

Global reach, local expertise

While our experts can handle projects globally, we prioritize local oversight for enhanced responsiveness to regional health authorities. Your dedicated local project lead provides ongoing oversight, quick turnaround and timely communication while focusing on accuracy and compliance with regulations every step of the way.

Collaborative partnership

At PharmaLex, collaboration is key. We work closely with you to understand your unique needs and objectives, delivering accurate and timely execution within budget. Your success is our priority, and we are committed to delivering results that exceed expectations.

Expertise network

Behind our biometric team lies a broad network of experts including regulatory affairs, pharmacovigilance, market access and more, with experience across different medical product types and therapeutic areas, including cell and gene therapies. Benefit from a wealth of knowledge and experience as we navigate the complexities of medical product development together.

Experience the difference with PharmaLex – where expertise, dedication, and innovation propel your projects forward!

Study design and planning

- Data and statistical strategies in clinical programs
- Statistical input for protocol development
- Complex innovative trial design including Bayesian statistics
- Statistical analysis plans
- Sample size determination
- Randomization plans
- Modeling and simulation
- Biomarker-driven clinical trial design and experimental design within trials
- Regulatory strategy support
- Integrated summaries of safety and effectiveness (ISS/ISE)

Data management

- CRF development
- CDASH standard datasets
- EDC Database build and validation
- Data capture and processing including cleaning, validation, and coding
- Data import and data export specification preparation
- Third party data integration
- Supporting interim analysis and data safety meetings
- Risk-based monitoring
- Archival

Data mapping / Data migration services

- Conversion of legacy data to CDISC compliant datasets
- CDISC compliant datasets for ISS/ISE

Analysis and reporting of clinical trials

- SDTM mappings and ADaM derivations
- Tables, figures, and listings programming
- Interim and final statistical analysis
- Statistical analysis reports and clinical study reports
- Data monitoring committee (DMC) and data safety monitoring Board (DSMB)
- Define.xml and analysis data reviewer's guide

Contact us
www.pharmalex.com/contact-us