Biostatistical and Data Management Services

Simplifies Complex Trials with Expert, End-to-END Support

LANDRICH GROUP

Why Do You Need Us?

With 30 + years of extensive experience in biostatistics, design control, clinical study planning, and regulatory submissions, the Landrich Group brings invaluable expertise to every project. We support all stages—from early development to FDA and other National Competent Authority(NCA) regulatory engagement. Whether developing a drug, medical device, or in vitro diagnostic assay, we help clients navigate complex development and achieve global market access. We specialize in preparing high-quality documentation—IDE/IND submissions, Analytical Protocols, Clinical Protocols, Monitoring Plans, Investigational Plans, Clinical Trial Reports and Regulatory Submissions that meets global standards, including U.S. FDA, EU IVDR/MDR, ISO Standards, CLSI and ICH. Our Data Management Team ensure that your clinical data is accurate, traceable, and submission ready. We manage all aspects of data operations from database development through lock, offering full-service support that ensures clean, reliable data and efficient execution and integration across product lifecycles.

Our Value to You

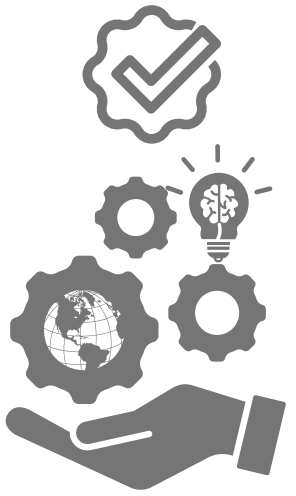
Expert Guidance: Provide comprehensive support across the entire product development lifecycle and support from trial planning to data analysis, with ongoing Biostatistics advice.

Global Regulatory Compliance: Adherence to harmonized global standards, maximizing market access.

Efficient Analysis: Proficient use of R, SAS, SPSS, and Plink for accurate, timely data insights.

Streamlined Processes: Protocol, SOPs, Templates, and Forms to ensure consistency and efficiency.

High-Quality Deliverables: Comprehensive reports and documentation meeting regulatory requirements



Biostatistics Services:

- Study design, statistical consultation, and power/sample size calculations
- Statistical Analysis Plan (SAP) development
- Randomization design and implementation
- Interim and final analyses, tables/listings/figures (TLFs), and CSR input
- Real-world evidence and post-market analyses
- Statistical reports and submission support for FDA, and other National Competent Authorities

Data Management Services

Core Services:

- Develop Data Management Plan (DMP)
- eCRF Development and Programming
- Database Setup, Hosting Oversight, and Status Reporting
- User Acceptance Testing (UAT) and Site Training
- CRF Completion Guidelines

Data Review & Coding:

- Query Generation and Resolution
- Adverse Event (AE) and Concomitant Medication (ConMed) Coding
- Serious Adverse Event (SAE) Reconciliation

Third-Party Oversight:

- Receive and Reconcile Vendor Data (e.g., Randomization, Central Lab, Imaging)
- Third-Party Data Reconciliation

Closeout & Ongoing Support:

- Database Lock and Final Report Preparation
- Clean Data Exports for Analysis and Submission
- Continued Team Participation and Strategic Guidance
- Presentation Support for Investors and Business Development

At the Landrich Group, we simplify complex product development, clinical trials, and regulatory submissions through expert, end-to-end biostatistical and data management support – helping you achieve innovation, compliance, and successful market access.

Contact us for a free consultation at:
admin@landrichgroup.com