Clinical Services

LANDRICH GROUP

From Strategy to Study Close-Out
Comprehensive Clinical Excellence at Every Step

Why Do You Need Us?

With 30+ years of global clinical operations and regulatory expertise, the Landrich Group provides strategic and hands-on support to guide your Phase I through IV studies from concept to completion. We help you navigate clinical trial planning, vendor and site oversight, and day-to-day execution while staying aligned with GCP principles, sponsor responsibilities, and global regulatory expectations. Whether you're preparing for a Phase I trial or scaling for global market entry, we keep your team compliant, efficient, and inspection-ready.

Clinical Strategy & Regulatory Readiness:

- FDA Pre-IDE/Pre-IND and regulatory meeting support
- Global study planning and development timelines
- Development of protocols, study plans, and essential documentation
- Regulatory pathways and risk mitigation guidance

Study Management & Oversight:

- Site and CRO/vendor identification, qualification, and oversight
- Ethics submissions and IRB coordination
- Site initiation, training, and ongoing engagement
- Trial supply management and IP accountability
- Issue tracking and resolution coordination

Clinical Software Solutions & Technology Support:

- Support selection and qualification of systems such as:
  - Electronic Data Capture (EDC)
  - eTMF (electronic Trial Master File)
  - CTMS (Clinical Trial Management System)
- Ensure system setup aligns with operational workflows and GCP compliance
- Coordinate training, testing, and system oversight in collaboration with vendors

Monitoring & Site Support:

- Conduct GCP-compliant site monitoring (on-site and remote)
- Track Protocol Deviations and implement CAPAs
- Perform source document verification and resolve Case Report Form (CRF) queries
- Manage visit reports, follow-up letters, and inspection preparation

Close-Out & Final Reporting

- Trial close-out activities and reconciliation
- Final site documentation review and archival
- Coordination with data management and biostatistics for report completion
- Support final CSR development and submission readiness

Post Study Regulatory Support

- Operations and support on BIMO and Regulatory Review process

We streamline complex clinical development with expert, end-to-end operational and regulatory support—so you can stay focused on innovation while we ensure execution with quality, compliance, and efficiency

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