TECHSOL
LIFE SCIENCES

Biopharmaceutical Clinical Development Services and Scientific Process Solutions

How We Help Sponsors

With our extensive clinical research experience across various therapeutic areas, Techsol offers full-range Clinical Research Services with a focus to deliver high quality, regulatory compliant and cost-effective clinical development results. We partner with sponsors as a trusted scientific solutions provider to bring novel medicines faster to the market by using a combination of sound quality driven processes and latest technology innovation.

We have deep scientific, technology and regulatory knowledge to formulate the right study design, selection of a suitable reference product, coordinating with stakeholders, laying pathways for regulatory approvals, completing patient recruitment as per inclusion and exclusion criteria, evaluating statistical considerations based on immunogenicity and safety, timely coordination amongst stakeholders and so on to successfully complete different types of biopharmaceutical clinical trials.

Our Clinical Research Services

Medical Writing

Our team has broad scientific expertise to research, develop, and deliver medical writing services across the clinical development lifecycle. Right from providing knowledge support for the study design of new class of treatments, to expediting the submission and approval of Clinical Trial Applications, we have proven capabilities to provide high-quality scientific content.

Our Expertise:

- Conducting bridging trials and clamp studies
- Broad knowledge on various therapeutic areas
- Thorough practical experience in crafting medical literature based on Biosimilar guidelines
- Study Protocols for Phases I to IV studies
- Investigator Brochures and Informed consent documents (ICD)
- Clinical Study Reports public disclosure
- Clinical and non-clinical sections of the CTD
- Patient Safety Narratives, CO & NCO overviews

Pre-Clinical & Early Development

Establishing the safety profile of a medicinal product is a crucial step and we understand the nuances to get accurate results to account for drug pharmacology (PK/PD), biological activity, maximum tolerated dose (MTD) and so on.

Following are our key specialties for Biopharma clinical studies:

- Toxicology Studies
- Safety Pharmacology Assessment
- Bio-Analytical Services

Clinical Research & Development

As a continuum to early phase development, we have the expertise to complete safety assessment, dosage, and efficacy determination by conducting Phase I, II and III clinical studies.

With Techsol's interconnected hospital and healthcare organizations network, we have a broad outreach to a wide variety of targeted patient populations, qualified principal investigators, and site personnel to timely achieve subject recruitment and complete the study conduct phase in a regulatory compliant manner.

Our Expertise

Study Feasibility, Site / Investigator Selection

- Patient Pool Discovery
- Site and Investigator Selection
- Site Qualification
- Site CDA /NDA Agreements

Study Initiation

- Facilitating investigator meeting
- GCP training to site staff
- IEC/IRB submission and approvals
- CTRI registration
- Protocol training
- TMF Setup and maintenance

Study Planning and Startup

- Site Readiness Planning
- Protocol Development
- Budget Planning & Allocation
- Vendor Selection

- Safety management training
- Preparation and implementation of study specific monitoring plans
- Conduct study initiation visits (SIV)
- Site Activation

Clinical Study Conduct

- Subject Recruitment and Retention

- Risk based monitoring / Centralized monitoring
- Trial Master File (TMF) Management
- In-house Investigator Site File (ISF)
- Randomization, Blinding/Unblinding
- Drug Accountability / IP Management
- Site coordination and management
- Central Labs Management
- Clinical trial supplies and management
- Manage adverse event reporting and documentation
- Source data verification (SDV) and quality checks at sites
- Subject Compensation
- Investigator Payments
- Protocol deviations/violations
- Regulatory, IRB / IEC Communications
- Oversee Site performance and compliance
- Site readiness for Audits & Regulatory Inspections

Study Close-out

- Track Drug Accountability
- Complete pending payments
- Study Documents Archival
- Site-Closeout Execution
- Preparation of Clinical Study Report

Clinical Data Management

Techsol provides centralized clinical data management services for Phase I to Phase IV clinical studies across various therapeutic areas with a comprehensive risk-based and value-focused data management plan. We are committed to providing the highest data quality, integrity, and security for our clients in meeting 21 CFR part 11, GAMP 5 and HIPAA requirements.

Using industry-leading electronic data capture (EDC) technologies, we provide end-to-end clinical data management support starting from eCRF design to database lock and final study archival.

We have supported clients to execute clinical data management on the following Electronic Data Capture and Medical Coding systems:

- Oracle Inform, Oracle Clinical, Remote Data Capture, Thesaurus Management System
- Medidata Rave, ClinSpark for Early Phase Clinical Trials

Our Expertise

- DMP Preparation
- CRF Designing
- CRF Annotation
- eCRF Designing
- Data Entry Screen testing
- Edit check/DVP Development
- DVP Testing
- Preparation of eCRF filling guidelines
- UAT Execution
- Database Go-Live
- Data cleaning
- Query management
- QC activities
- Medical Coding
- SAE reconciliation

Biostatistics & SAS Programming

We been working for more than 15 years in NDA/ BLA/PMA submission and actively interacting with FDA, EMEA and PMDA working groups.

With an in-depth knowledge on regulatory guidelines such as ICH GCP, ICH E9 and data standards such as CDISC, CDASH and SDTM, our team of SAS Programmers can deliver clean, accurate and enriched data sets that can be be used for determining the safety and efficacy of medicinal products.

Our Expertise

- Study design
- Sample size calculation
- Randomization
- Preparation of Statistical analysis plans (SAP)
- Creation of Mock shells
- Final TLFs
- Interim Analysis
- Preparation of Statistical Analysis Report (SAR)
- Perform blind data review checks
- Risk benefit reports

Regulatory Affairs

Evaluating the readiness state of a regulatory submission requires meticulous planning and continuous team coordination. At Techsol, we have teams unified with our proprietary digital collaboration platform to facilitate fast and streamlined process execution.

Our expertise in data submissions, and knowledge of data exchange standards allows fast and accurate data submissions to global regulatory bodies. Techsol's Regulatory Center of Excellence (rCOE) strives to keep all our clients updated on the latest updates and changes across different types of GxP and Data Privacy regulations. Our team evaluates business process risks and recommends ideal best practices for adapting and implementing enterprise-wide compliance actions.

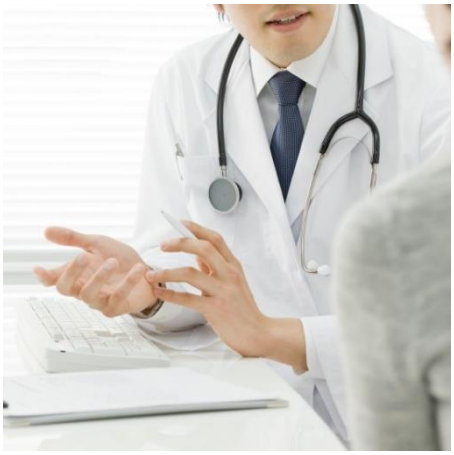
With an extensive GxP regulatory experience, Techsol has been helping several global companies to strategize and evolve continuously from a compliance perspective right from product development to commercialization.

Pharmacovigilance

With our presence across the globe our global pharmacovigilance team is capable of handling large case volumes, complex multi-center and multi-national safety operations with a combination of offshore and onshore teams. We offer independent PV Services or integrated with global medical information and regulatory services.

How We Help

- Case Processing & Regulatory Reporting
- Global Literature Search & Analysis
- Periodic Aggregate Reporting
- Signal Management, Detection & Analysis
- Safety Management Plan (SMP) Development
- Clinical Pharmacovigilance (PV) Auditing Services
- EudraVigiliance Services
- EU QPPV & LPPVS
- PSMF Management



GxP Technology Platforms and Managed Services

We provide extensive technology consulting services and fully-managed platforms for Electronic Data Capture, Medical Coding, Clinical Trial Management, Drug Safety, pharmacovigilance and Post-marketing Surveillance to global sponsors as a standalone offering. All our solutions are validated to account for global regulatory compliance (FDA 21 CFR Part 11, EU Annex 11, etc.)

Why Techsol

- Extensive experience in managing different types of biologics clinical studies
- Access to a broad patient pool network

- Deep scientific knowledge that drives risk-based clinical development
- Technology and infrastructure to deliver results in a transparent and regulatory compliant manner
- Designing a strategy apt for the Product Lifecycle
- Knowledge support for the study design of new class of treatments
- Expediting submission and approval of Clinical Trial Applications
- Designing patient recruitment strategies to achieve on-time subject recruitment
- Engaging with patients to eliminate subject dropout
- Eliminating and reducing protocol deviations and non-compliance
- Streamlining on-time site-investigator and vendor payments, staying within budget, payments transparency
- Establishing comprehensive quality, risk, and compliance oversight
- Regulatory compliant source data and trial data management
- Adherence to data standards and applicable regulations

About Us

Techsol Life Sciences specializes in offering value-focused clinical development functional services powered with innovative GxP technology solutions to global pharmaceutical, life sciences, and healthcare companies.

We provide full-range of Clinical Trial Services, Pharmacovigilance, Medical Device MDR Compliance and Regulatory Services by strictly adhering to ICH-GCP, US FDA, EMA and comply with national and international regulations; dedicated to a high level of protocol compliance and proactive communication.

Our functional teams have extensive experience in handling of end-to-end complex global trials. Our clinical operations team, project management and quality teams constantly strive to ensure that study requirements, regulatory compliance and study timelines are met without comprising quality.

Our Locations

United States	India	South Korea
Techsol Life Sciences 101 College Road East Princeton 08540 New Jersey USA	Techsol Life Sciences Private Limited Level – 4, Lorven Tiara, Survey No.34, Kothaguda Circle, Kondapur, Hyderabad, Telangana 500084	Techsol Korea Private Limited #318-R313, H Business Park Bldg. Beobwon-ro 9-gil 26, Songpa-gu, Seoul