



Quinlan Life Sciences India

Delivering High Quality Research





Introduction

QUINLAN LIFESCIENCES INDIA (QLS-India), has an extensive experience and a highly qualified staff that allows covering a wide area related to clinical research from Phase I to Phase IV studies.

QUINLAN LIFESCIENCES INDIA offers flexible and customized services that meet project and the client needs. We are capable of carrying out the entire project, from the protocol designing, study coordination, data management, and statistical analysis to its final report. We also can adapt ourselves to the level of assisting the requirements of our client. This flexibility allows working together with the client's staff, or separately, creating a completely integrated project team in accordance with the corporate culture of the client.

- QLS India, is an independent company with young Entrepreneurial Research Organization that provides wide range of contract research management services to pharmaceuticals, Nutraceuticals, Medical Device, Cosmeceuticals, Biotech and Life Sciences industry.
- The Staff working with us are highly qualified, experienced and motivated, all having Science and Medical background and in addition trained with ICH-GCP in Clinical Research.
- All the Investigative sites have well ICH-GCP trained and experienced Principal investigator`s who are conducting clinical trials for more than 10 years.
- We have our Corporate Office at Panjim, GOA.
- Services that we offer are Clinical Trial Management (phase I to IV), Site Management, Clinical Data Management, Bio-statistics and medical Writing

Pharmacovigilance

- Case intake
- Medical coding
- Safety narrative writing
- Assessment of seriousness, causality, and expectedness
- Medical review
- Regulatory reporting

Clinical Data Management

- Data Management Plan Database Design & Validation
- Data Entry & Verification CRF Tracking
- Medical Coding
- Discrepancy Management
- SAE Reconciliation
- Database Lock

Bio-Analytical Studies

- Protocol development
- Studies on Conventional/modified release formulations
- Studies under fasting or fed conditions
- Volunteer screening
- Method development, Validation and Analysis
- Pharmacokinetic Analysis

Clinical Trial Management Study (Phase I to IV)

- Designing of Protocol, CRF, ICF and IB.
- Feasibility & Regulatory Approvals
- Investigator Recruitment & Training Site Identification
- Pre-Study & Site Initiation visit.
- Patient Enrolment, Medical & Site Monitoring.
- Information reporting on safety.

Medical Device

- Designing & initial Feasibility Stage.
- Assist in Verification and validation.
- Design appropriate Pre-clinical and Clinical trial studies.
- Assist in Regulatory approval/clearance.
- Post marketing activities.

Bio-Statistics

- Analysis plan Sample size Calculation
- Randomization Schedule CRF Annotation
- Blinding code Generation Interim Analysis
- Final Statistical Analysis Analytical
- Reporting Services

Medical Writing

- Protocol Design
- Investigator Brochure Design
- CRF Design ICF Design
- Final study Report
- Medical Manuscripts
- Patient Dairy
- Safety & SAE Narratives



Site Management Capability

- 43 sites all over India with almost 60 CRC
- 110 hospitals conducting trials for us in India.
- Capacity to offer several quality sites by telephone call
- Capacity to coordinate studies from Phase I to Phase IV
- Capacity to coordinate hospital and outpatient studies
- Wide database of highly qualified investigators who are experienced and enthusiastic
- Clinical trial coordinators who work full time and have experience
- Full national coverage

- Close working relationships with IEC/IRB and foundations
- Access to wide patient populations with cultural diversity
- Efficient and centralized contractual and budget solutions
- Long-standing, stable relationships with a high number of public and private institutions
- In case of emergency, we provide sites within 72 hours through our fast recruitment process
- Optimization of patient recruitment to support the efforts of the local site
- Efficient, stable and beneficial work relationships with the investigational sites for both parties

Investigator Site Network in India :

- | | | | |
|--------------|--------------|----------------|-----------------|
| - Ahmedabad | - Chandigarh | - Kakinada | - Patna |
| - Aurangabad | - Guwahati | - Kolkata | - Rajahmundry |
| - Bangalore | - Gulbarga | - Kurnool | - Satara |
| - Bhopal | - Gurgaon | - Ludhiana | - Surat |
| - Belgaum | - Goa | - Lucknow | - Tirupati |
| - Chennai | - Ghaziabad | - Manipal | - Trivandrum |
| - Chennai | - Hyderabad | - Mysore | - Visakhapatnam |
| - Calicut | - Hubli | - Mumbai | - Vijayawada |
| - Cochin | - Indore | - Noida | - Varanasi |
| - Guntur | - Jaipur | - Navi Mumbai. | - Vellore |
| - Faridabad | - Jalgaon | - New Delhi | |

Therapeutic Area

- | | |
|----------------------------------|----------------------------------|
| - Cardiology/Vascular Diseases | - Nephrology/Urology |
| - AIDS/HIV | - Pulmonary/Respiratory Diseases |
| - Dermatology | - Dental |
| - Gastroenterology | - Rheumatology |
| - Gerontology | - Neurology |
| - Endocrinology | - Oncology |
| - Hematology | - Pediatrics |
| - Immunology/Infectious Diseases | - Ophthalmology |
| - Psychiatry | - Vaccines |

Corporate Office at Goa:

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