



# CLINEX RESEARCH SERVICE

Clinical Trial Site Management Organization (SMO)  
Full-Service SMO Solutions

SUPPORTING QUALITY ETHICS & COMPLIANCE IN CLINICAL RESEARCH

# Clinical Trial Support Services

- ▶ Clinex Research Service is a Clinical Trial Site Management Organization (SMO) in Belagavi, providing comprehensive administrative, regulatory, and operational support to clinical trial sites.
- ▶ We Support Phase II – IV Clinical Trials & assist investigators in conducting ethical, compliant and high- quality clinical research in accordance with Ich-GCP guidelines.
- ▶ Clinex Research Service prepares clinical trial sites and supports investigators to conduct ethical and compliant research.
- ▶ We provide customized services to help our client reach the appropriate study population.
- ▶ Our SMO services help keep patients engaged and actively participating in our client's trials, while also streamlining patient intake and retention at clinical sites.

# Reducing Clinical Site Workloads.

- ▶ Clinex Research Service supports clinical trials with an experienced Clinical Research Coordinators (CRC's)
- ▶ CRC's help to improve the quality of clinical trials, while reducing the workload of the clinical staff.
- ▶ Our CRCs ensure that patients recruited for trials are suitable as per protocol and site requirements and provide comprehensive trial support across multiple therapeutic areas.

# Our Edge in CRC Services

- ▶ Flexible clinical trial management support with acknowledge and expertise.
- ▶ CRC's are deployed to work onsite and provide full support to medical institution to improve the quality of clinical trials.
- ▶ CRC's with knowledge and experience of clinical trials in wide range of therapeutic areas to reduce workload of clinical trial operation.
- ▶ With strong ethics, expertise and dedication, Clinex Research Service can manage potential compliance risk related to clinical trials.
- ▶ Effective management of potential protocol and GCP compliance risks

# Manage contracts, Support Regulatory Inspection and More

- ▶ Clinex provides clinical site administration support for clinical trial preparation and execution.
- ▶ Prepare sites for clinical trials.
- ▶ Manage IEC/IRB submissions and reviews.
- ▶ Prepare and manage trial documents.
- ▶ Manage invoices and financial documentation.
- ▶ Support audits and regulatory inspections.

# Our Edge in Clinical Site Administration

- ▶ Comprehensive operational support for clinical trial sites
- ▶ Identification and coordination with suitable medical institutions
- ▶ Support in clinical trial preparation activities
- ▶ Preparation and management of documents in alignment with ICH-GCP

# Services

- ▶ Patient eligibility support.
- ▶ Informed Consent Process support.
- ▶ Management of patient's visits/follow-ups and testing schedules.
- ▶ Clinical trial material management.
- ▶ Support in CRF / eCRF preparation.
- ▶ Support to Clinical Research Associates (CRAs).
- ▶ Audit and regulatory inspection support

# Services (Administrative & Regulatory)

- ▶ Request initiation of clinical trials by medical institutions.
- ▶ Preparation and execution of clinical trial contracts.
- ▶ Invoice management.
- ▶ Preparation and maintenance of essential documents.
- ▶ IEC/IRB arrangement and coordination.
- ▶ Support IEC/IRB review processes.

# Clinical Trial SMO Services for a Variety of Study Areas

- ▶ General Medicine
- ▶ Gastroenterology
- ▶ Urology
- ▶ Surgery
- ▶ Orthopaedics
- ▶ Ophthalmology
- ▶ Gynaecology
- ▶ Pulmonary
- ▶ Neurology
- ▶ Psychiatry
- ▶ Paediatrics
- ▶ Dermatology
- ▶ ENT



## ❑ **Extensive Experience in Therapeutic Areas**

- ▶ Clinex Research Service supports clinical trials across a wide range of therapeutic areas with experienced research professionals, ensuring quality data and regulatory compliance.

## ❑ **Clinical Sites**

- ▶ Clinical trial sites supported by Clinex Research Service include both government and private medical institutions.

## ❑ **Laboratory Services**

- ▶ Clinex collaborates with NABL-accredited laboratories to provide:
- ▶ Pathology & Radiology investigations (\_As per protocol requirements\_)

# Contact Details

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THANK YOU 😊