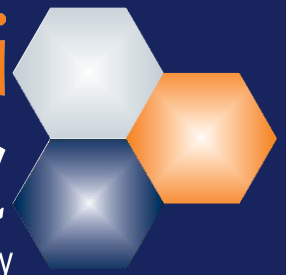


Sapthagiri
Clintrac
Evolving Tomorrow's Therapies Today



**Find your
right service
partner**

COMPLETE



- ▶ **Phase I-IV Studies**
- ▶ **Device Studies**
- ▶ **Registration Studies**
- ▶ **Marketing Studies**
- ▶ **Outcome Studies**
- ▶ **Epidemiology Studies**
- ▶ **Nutraceutical & Herbal Studies**
- ▶ **Cosmeceutical Studies**



ABOUT US:

Sapthagiri Clintrac private limited (**Sapthagiri Clintrac**) is part of GD Group of companies owing business encompassing education, healthcare, information technology, hospitality, infrastructure, power and mining.

Sapthagiri Clintrac founded in 2011 is a privately owned Clinical research services company with its business office in Bangalore, India. We provide a wide range of services, primarily in the areas of Clinical trials and CT-Bioavailability & Bioequivalence studies and early & late phase clinical development.. Our service offerings support to Pharmaceutical, Biotech and Device companies significantly enhance their R & D objectives.

Sapthagiri Clintrac is committed to Quality Clinical Research and is strategically located in the premises of 1000-bedded Super specialty Sapthagiri Institute of Medical Sciences and Research Center, Bangalore. Sapthagiri Clintrac works with companies across India for conducting Clinical trials and PK|PD studies involving Pharmaceutical, Biological, and Medical Device products.

Sapthagiri Clintrac operates in adherence to national and international regulatory requirements. We are committed to quality, efficiency, confidentiality and competitiveness to foster long term partnerships with clients – we strive to complete projects with defined timelines maintaining high quality data and within budget.

We also provide high quality and cost-effective medical transcription services. Clintrac committed to Produce quality transcription and reduce turn around time. Sapthagiri Clintrac consistently delivers medical transcription services with minimal to zero errors, fast turnaround times and exceptional customer services



Sri. G. Dayanand
Chairman & Managing Director

Leadership Team:

Chairperson and managing Director: Mr.G.D Dayanand successfully has established a golden age for all the ventures and has made a mark as a successful business entrepreneur. He has established two professional colleges for Technology and Medicine- Sapthagiri College of Engineering and **Sapthagiri Institute of Medical Sciences and Research Centre**. he is the quintessential entrepreneur with many successful ventures .

This successful entrepreneur also ventured many business under the GD group of companies includes Hospitality (Solitaire -4 star hotel),information technology, Healthcare(Sapthagiri multi specialty and super specialty Hospital),Mining, infrastructure and commercial.

Vice Chairman: Mr. G.D Balaji is Chief Executive officer of G.D Group. He is the son of Mr.G.D Dayanand, a graduate in international business, has taken over many responsibilities to steer the group into newer realms of business expansion. A strategic corporate culture that clearly reflects in his rich capability in inspiring leadership and quality service at every level.

OUR MISSION:

To be the leading Clinical Research service provider as judged by the quality of its leadership and people partnerships, productivity through NDAs To be the first choice of clinical research service provider, by offering innovative solutions and comprehensive services in the development value chain and To leverage the India advantage whilst maintaining global quality standards and speed.



OUR VISION:

To be preferred as most trusted resource for the Contract Research services To emerge as a leading and most admired global Clinical Research Organization whilst creating value for its customers .



Every project is assured our complete focus and is conducted to the highest level of regulatory standards.



Site management

Sapthagiri Clintrac SMO offers the following distinct capabilities.

- ◆ Network of experienced Physicians, Coordinators and study nurses
- ◆ GCP trained Investigators and Coordinators.
- ◆ Dedicated full time Clinical Research Coordinators experienced in working with Pharmaceutical Companies and Contract Research Organizations
- ◆ Access to patient pool of 700 out patients and 400 in patients maximizing patient target achievement
- ◆ Patient identification, screening and recruitment
- ◆ EDC and query management, trial master file; Quality Source documentation upkeep, Investigational Product (IP) and supplies accountability
- ◆ Maintenance of CRFs, TMF and Patient Source documents
- ◆ Patient visit follow-up and compliance assistance
- ◆ Help optimize monitoring and reduce cost of poor quality data
- ◆ Support to monitoring visits and Audits and Inspections

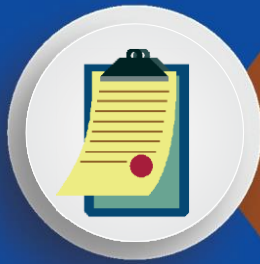


Facilities

Sapthagiri Clintrac SMO is characteristically well equipped with:

- ◆ 1000 Bedded Hospital facility & super specialty with the world class Medical infrastructure
- ◆ 24*7 ICU facility
- ◆ Pharmacy services
- ◆ Approach to Institutional Ethics committee
- ◆ Access to patient Data Base with the positive attitude towards research
- ◆ Access to ISO 2008 certified local laboratory which is under process of NABL certification
- ◆ Latest technologies for workflow
- ◆ Infrastructure suitable for conducting trials
- ◆ Study Documentation storage facility- Dedicated Cupboards with the lock and key, secured from unauthorized individuals.
- ◆ Dedicated monitoring rooms for CRO /Sponsor Representatives
- ◆ Drug Storage Area with restricted access to unauthorized Individuals
- ◆ Sampling area for the trial patients
- ◆ Study documents archival facility





Project Management and Clinical Operations

Our project managers provide a single point of contact, manage budgets to minimize change orders, keep you informed through frequent communications and clear customized reports, identify issues and proactively prepare solutions and take ownership of your project and all its deliverables.

Medical and Safety Services

Our experts who are medically qualified and work in close collaboration with therapeutic expertise doctors who work at our Medical Institute at different level contributes to medical writing involves:-

- Clinical protocols
- Clinical study reports (CSR), investigators' safety/efficacy summaries (ISS/IES)
- Publication manuscripts and literature reviews



Data Management

We provides a full range of in-house paper and electronic data capture services, including, but not limited to:

- ◆ Case report forms (CRF) and eCRF design, review tracking and processing
- ◆ Database design and testing
- ◆ Double-data entry and QC
- ◆ Query generation and processing
- ◆ Electronic data integration and transfer
- ◆ Serious AE reconciliation

Biostatistics

Our expert biostatisticians produce statistical analysis plans that are compliant with International Conference on Harmonisation (ICH) guidelines. We are regularly called up on for our expert, reliable consultation in the full range of biostatistical issues. Our services include statistical protocol development, statistical analysis plans, and pre-clinical analysis and data presentations, regulatory submissions and statistical consulting.



Key strengths

- ◆ Best in class Infrastructure, in house network of GCP trained physicians /Investigators & patient access
- ◆ Experienced and well trained Technical team
- ◆ Clintrac attached with **1000 Bedded** multi specialty and super specialty Hospital facility access to large diversity of patient population
- ◆ Clintrac established under Sapthagiri Institute of medical Sciences and Research centre with research background and to access therapeutic expert investigators
- ◆ Approach to Institutional ethics Committee registered with **Drug controller general of India(DCGI)** and **U.S. Department of Health and Human Services**
- ◆ Our site Sapthagiri Hospital is registered under WHO: D&B D-U-N-S Number 87-235-2736 and with GDUFA Self Identification FEI: 3012275212
- ◆ Access to well equipped Medical College and Hospital Research laboratory –ISO certified.
- ◆ **Sound Business Acumen with Financial strength**
- ◆ Network of experienced Physicians, Coordinators and study nurses. GCP trained Investigators & Site team



Our registrations & Certifications :

Ethics Committee

- ◆ With DCGI: ECR/583/Inst/KA/2014
- ◆ FDA(OHRP): IRB00010606

Sapthagiri Hospital

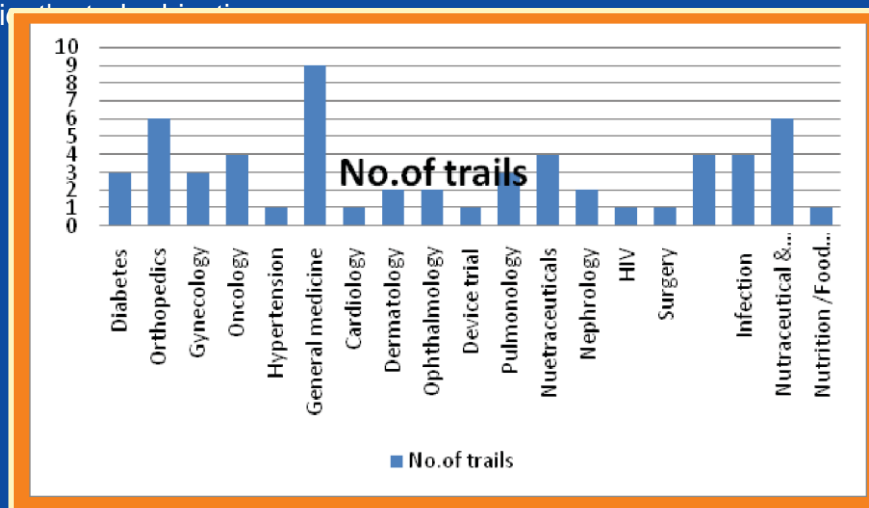
- ◆ USFDA Registration : D&B D-U-N-S number:87-235-2736
- ◆ Sapthagiri clintrac is certified under ISO : 2009-2015
- ◆ **National Accreditation Board of Hospitals: NABH**

Registrations

Therapeutic Insights

Our in-house experts and professionals have worked on various therapeutic areas including but not limited to oncology, diabetes, cardiovascular etc. In depth knowledge coupled with experience in all key therapeutic areas enables our team to align resources to the client's needs.

Therapeutic insights Snapshot of our experience in different therapeutic areas



We've worked
with a diverse
sponsor base.

How can we
help you?





Sapthagiri Clintrac. Pvt. Ltd

**Contact Us: Sapthagiri Institute Of Medical Science & Research Centre
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