18 YEARS OF EXCELLENCE IN RESEARCH

cliantha® research

MEDICAL SERVICES

The Medical Services team is integral to Cliantha's success. The services include Medical Writing, Medical Monitoring, Pharmacovigilance Services, Feasibility Studies, discussion with KOLs and other documents involving study data.

Medical Oversight	Medical Writing	Regulatory Writing	Scientific Writing
• Medical overview of trials including eligibility review • Training of Study Teams and sites • SEC meetings at DCGI • On site Medical monitoring • Central Monitoring	• Protocol • Clinical Study Report • Informed Consent Documents • Subject Diary • Investigator's brochure	• eCTD modules (Module 2.4, 2.5 etc) • Briefing documents for regulatory authorities • Pre-IND, IND submission dossiers • Biosimilar and NDDS clinical development plans • 505(b)(2) program development plans	• Manuscript writing • Conference abstracts & Presentations • Meta-analysis • Web synopses (Clintrial.gov, EU clinical register etc)

Our Medical Services team works seamlessly with other teams:

- Investigators
- Clinical Trials Management Team
- PKBS group
- Data Management
- Bioanalytical

Highlights:

- Well experienced team with knowledge of Phase I-IV studies
- In-depth knowledge of various therapeutic areas
- Prolific exposure to regulatory requirements
- Experience of more than 20 successful subject expert committee meetings at DCGI
- Expertise in identifying various medical risks in data monitoring and providing solutions