ClinPro RESEARCH EMPOWERING SOLUTIONS

Your CRO partner for effective Drug Development in India

Can you provide an overview of ClinPro Research?

ClinPro Research, established in Feb 2020 is an ISO 9001:2015 certified, full-service capability CRO, headquartered in Mumbai; India. We cater to the clinical requirements of both domestic and international pharmaceutical companies, biotech companies, medical device companies, ayurvedic and nutraceutical companies with our exceptional suite of solutions, which includes end-to-end project management and functional standalone services as well.

We provide cost effective options to custom-curate the requirements for projects to our prospective and existing clientele.

What is the current state of clinical research in India?

The clinical research industry is a significant parallel of the health care sector. The covid-19 pandemic also brought about a wave of awareness on clinical trials and its relevance in the drug development process. India has accounted for 8.3 per cent share of global clinical trials activity in 2020, and this figure is only going to upsurge with the numerous opportunities this country provides, in terms of skilled medical and paramedical professionals, large and diverse genetic pool of treatment-naive population, lower operational cost, multidisciplinary well-equipped sites and much more!

Furthermore, the regulatory landscape in India has evolved with the new NDCT (New Drugs and Clinical Trials) Rule 2019, to advantageously place India as one of the preferred hubs for conducting clinical trials.

Can you elaborate more on the company's capabilities and services that you provide?

ClinPro Research has accomplished several projects across various domains like Clinical Data Management, End to End Clinical Trial Conduct and Management, Site auditing, Medical Writing, eTMF, Clinical Analytics etc. Our leadership team has over 15 years of robust clinical trial experience across various submissions viz; India, APAC, UK, EU, LATAM and the US. We have core expertise across a gamut of therapeutic indications. Our strong technical acumen enables us to conduct various types of trials like phased trials, patient-based PK studies and BA/BE trials with an appreciative turnaround time and exceptional quality.

Our extended service arm includes medical coding, safety and pharmacovigilance, clinical trial supplies management, biostatistics, strategic consulting etc.

ClinPro Research is now one of the emerging service providers in the clinical trials space. Can you share an insight into the market drivers and the needs that ClinPro is responding to?

Patient enrollment and retention is one of the crucial aspects along with efficient study start up and regulatory barriers in any clinical trial.

Our recruitment specialists assist the PI in providing insights to upkeep with the recruitment

demand. They work closely with the investigator and site staff to identify recruitment challenges (if any) and come up with appropriate resolutions. Our diligent team of CRCs works towards subject retention by meticulously tracking subject visits, enquiring about subject safety and well-being, and being available for their assistance/queries etc. With this, we ensure good subject retention rate and minimal/negligible dropouts.

We expedite study start up process through our pre-assessed network of investigative sites. Each site is evaluated for infrastructure, qualified professionals, potential subject pool, ethics committee availability & compliance etc. prior to enrolling in our network. These factors play pivotal role in hassle free start up and conduct.

Our regulatory advisors are well versed with the Indian regulatory guidelines and have considerable experience in seeking approvals and addressing regulatory queries with excellent turnaround time Thus, enabling us to provide exceptional regulatory compliance for our projects.

TARANNUM KASHMIRI is a seasoned clinical research leader with over 15 years of extensive experience in managing domestic as well as global clinical trials, across a wide spectrum of therapeutic indications. She has strong technical acumen across Clinical Analytics, GCP Auditing, Clinical Data Management and Clinical Operations. Innovation is her inbuilt forte; she has accomplished several cost-effective lean projects during her professional tenure.

AUTHOR BIO

How well prepared is ClinPro Research to support large scale clinical trials?

We have an elaborate network of multispecialty clinical sites; including hospitals, research institutes and laboratories across various urban and suburban locations in the country to open doors to a diverse subject pool. Our team of experienced clinical professionals are adept in managing large scale clinical trials with great ease. We are competent in various e-clinical systems like EDC, CTMS, eTMF, IVRS etc. which aid in seamless execution of large-scale trials. Additionally, comprehensive trials involve smooth coordination and rapport building with a host of third-party vendors. We, at ClinPro are cognizant of this, and have built excellent collaborations and seamless working relations with our vendors, who have been meticulously selected via our robust vendor evaluation and selection process. This empowers us to meet our goal of providing proactive, prompt and proficient services to our customers.

AI has become a focus area for drug R&D. How has ClinPro been responding to this market trend?

As AI and digitalisation have also entered the medical world with a compelling intention to stay and are also the need of the hour, our team of technologically advanced clinical researchers are adopting newer technologies like decentralised trials, virtual and hybrid trials.

Electronic data capture (EDC), Clinical trial management systems (CTMS), electronic patient reported outcome (ePRO), digital wearables are being integrated in data collection, site operations and management to offer an enhanced engagement for the participants and a logistically and economically advantageous experience for us and the sponsors.

How does ClinPro handle challenges like recruitment, poor site performance/response, quality and compliance issues, etc.?

These challenges are the part and parcel for every functional business.

The credit for always being on the forefront for observing and resolving these short comings has to go to our skilled team for their ever so positive approach towards our goals, extensive experience in the industry and zeal to bring about a positive

change in the healthcare industry. We have a robust Quality Management System with well-defined SOPs, work instructions and policies. We have a strong CAPA mechanism to ensure that gaps are addressed on time and not repeated. We also practice predictive analysis to identify potential risks and proactively take preventive measures to evade their occurrence or minimise the impact. In addition to the above, at site level, our QA team conducts in-house site audits to ensure the study is progressing as intended and with the expected quality and compliance.

What is your Unique Selling Proposition (USP) and how would you add value being an emerging CRO?

Our USP is that we provide client-oriented tailor-made solutions, specific to each customer. We are agile and can adapt to a customised approach best fit for the project and the client. Customer delight is our topmost priority, and we go that extra mile to provide cost-effective and quality services with excellent turnaround time. Our team's varied and extensive experience is another asset which keeps us at the forefront. Another unique practice that we follow is that we adopt lean principles on our assignments. We constantly review our processes to eliminate redundant tasks/procedures which proves to be cost effective for our clients and acts as a catalyst for us in meeting/expediting the turnaround time with optimum results.

What are the strategic objectives you envision ClinPro to achieve, over the next couple of years?

We would like to work harder and keep ourselves apprised of the latest nuances in the clinical research field and incorporate them within our services to provide a quality experience to our clients throughout the project and even after. We would like to cater to a wider clientele and welcome the opportunity to provide unmatched services to them.

Making healthcare affordable and accessible to the masses by playing a humble part in accelerating the drug development process is our core goal and we desire to keep working towards it with honesty and integrity.

We look forward to overcoming the roadblocks in this journey and stride past them with our improved performance, teamwork, innovative ideas, customer focus and ineffable passion for clinical research.