MEDIcept Clinical Research Organization (CRO) Services

For better results, trust us with your next clinical trial!

MEDIcept has a global clinical team supporting clinical trials and post market studies for device, IVD, pharma and combination products. Our team of experienced clinical operations professionals has the necessary expertise and understanding of the medical industry's complex clinical trial development and management process to successfully support your clinical trial efforts, from concept inception, through all phases to post-approval. We integrate firsthand clinical expertise with a deep understanding of current regulatory requirements and client expectations to develop the most effective management plan and execution of the clinical trial for your successful product launch.

MEDICEPT

Trusted Solutions, Rapid Response

We offer customized study design and management based on your needs regardless of your product development stage. Our team of clinical trial professionals has extensive experience with first-in-human (FIH), feasibility, pivotal, long-term follow-up, post-approval, post-market, and phase I-IV studies and registries. First-in-human and feasibility studies are essential for early product experience and require stringent regulatory and safety oversight. Crucial steps for all clinical trials, but especially for our pre-revenue start-up clients.

Our clinical trial consulting services include:

- Clinical Planning and Strategy
- Clinical Operations
- Clinical Trial Management
- Vendor Selection and Management
- Data Management / Statistics
- Safety Management
- Vendor/Clinical Sites Audits
- Medical Writing
- Clinical Regulatory Strategy and Submissions

Clinical Planning & Strategy

The strategy and planning of clinical trials is dependent on the regulatory strategy such as the indication for use for the product, risk level of the product, and patient population. MEDIcept Clinical works conjointly with regulatory to define the clinical strategy most appropriate for your product and its intended use. Trials considered for pre-market clinical trials as well as post-market studies are:

Pre-Market

Feasibility Studies/First-in-Human: critical for products and procedures that are high risk and/or have never been tested in humans. These studies provide important insight into the product's safety.

Studies intended for Regulatory Submissions: whether pharma or device studies are intended to demonstrate the safety and performance of the product and are carefully designed to demonstrate statistical significance.

Post-Market

Post-Approval: mandated by the regulatory authority after an initial conditional approval is granted to assess long term safety and performance.

Post-Market/Registries: intended by Client to ensure post market safety surveillance, enhance the cleared or approved product with publications, or for marketing purposes.

We are skilled to prepare a clinical trial plan design, with accelerated but realistic timelines, and cost-efficient support for multiple types of products and studies from early phase to late phase.

Clinical Operations

Responsible for planning and executing clinical trials from protocol design and trial execution to patient safety support, to protocol compliance, data quality and timely dissemination of results. Together, our Clinical team has over 100 years of experience in complex studies conducted globally.

Clinical Trial Management

Our dedicated study team of talented professionals have many years of experience managing all aspects of a trial from study feasibility to close-out, with excellent training and relationships with the sites and Clients.

Study Feasibility

Study Feasibility is one of the most critical steps to identify and select sites that are the right fit for your specific study.

Finding the best sites and investigators in your therapeutic area are invaluable for a successful trial. MEDIcept has worked with hundreds of investigators and sites. MEDIcept can also help with GLP animal studies to ensure early safety and efficacy.

Study Start-up

MEDIcept's team has a long history of relationships with regulatory authorities and IRBs, domestic international, local, and centralized regulatory and/or IRB/EC submissions. Our team has experience in the protocol design, endpoint identification, input into inclusion/exclusion criteria statistical and safety planning, data collection (eCRF), and EDC design. We create Informed Consent Form(s) (ICF), Patient Recruitment Material, and provide electronic Trial Master File (eTMF) support. We proactively work with sites to manage budgets and contract negotiations.

Clinical Project Management

MEDIcept is committed to your clinical trial!

Clinical Project Management

We, focus on timelines, budgets, and clinical outcomes, and collaborating with sponsors to ensure critical milestones are met. We manage study reporting, adverse events, protocol deviations, and data entry/query resolution metrics to keep you informed of your clinical trial progress.

Clinical Trial Monitoring

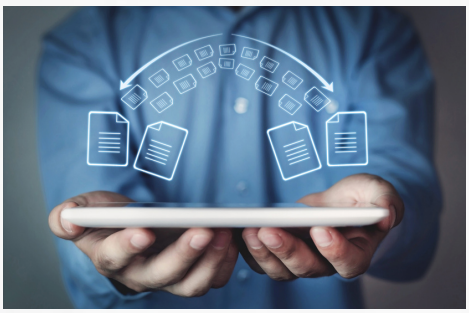
Monitoring is essential to ensure patient safety, especially in today's remote clinical trials environment. MEDIcept provides onsite and remote monitoring, as well as oversight of sponsor and investigator site files to ensure compliance with industry expectations and regulatory standards.

Vendor & System Management

MEDIcept formed strategic partnerships with trusted vendors including laboratories, Imaging, Central Readers, and Centralized Equipment Providers, to support your clinical trials. We offer a full clinical system ecosystem for EDC, eTMF, CTMS, ePRO, IxRS, eConsent, Safety monitoring, and management.

Data Management & Statistics

MEDIcept efficiently develops appropriate Case Report Forms, validates electronic data capture systems, manages data from development to database lock, and ensures integration with other systems such as laboratories Imaging, Central Readers, ePRO, IxRS to support your clinical trials. Our team has experience in complex study development and statistical methodologies, and our SAS programmers can support all your study needs for different products, both pre- and post-market studies/registries.



Safety Management

MEDIcept supports your safety needs by creating Safety management plans and processes, defining study-specific Adverse Events according to regulatory guidelines, and assembling safety committees such as Data Safety Monitoring Boards (DSMBs) or Clinical Event Committees (CECs). We review and discuss adverse event (AE) listings and report and follow-up with investigators on serious adverse events (SAE).

Vendor/Clinical Trial Audit & Inspections

MEDIcept provides remote internal and external sponsor and vendor inspections and audits to confirm compliance with industry expectations and regulatory standards. We can assist sponsors in preparation for audits and inspections, provide support during the process, and oversee corrective actions if necessary.

Medical Writing

Our experts support your clinical evaluation reports (CERs) with a successful track record for all CERs and all Class devices submitted under Medical Device Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC). We write clinical study protocols and reports and assist with training and marketing materials development, and provide conference and manuscript writing support.

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