CRO Services

COMAC MEDICAL

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Project Management

In Comac Medical, we prioritize the importance of effective project management as the cornerstone of successful clinical trials. Our commitment lies in ensuring seamless coordination and efficient resource allocation to keep your study on track.

Our teams operate with a proactive mindset, adept at identifying potential challenges and delivering tailored solutions. With our extensive expertise and track record of professionalism, we are able to provide comprehensive support in critical areas including patient recruitment and retention, financial control, and data quality assurance.

At Comac Medical, we uphold the highest standard of quality and efficiency. Throughout the entire project duration, we offer meticulous oversight, precise coordination, regular status updates, comprehensive patient tracking information, and key performance metrics. Trust us to navigate your clinical trials with precision and dedication.

Services:

- Develop and manage Project Management Plans;
- Achieve enrollment targets;
- Systematic oversight of study execution;
- Risk management: fast identification and communication;
- Maintain excellent team communication;
- Ensure punctual delivery of project milestones.

Study Start-Up

Navigating the landscape of clinical trials can be daunting, with unique hurdles to overcome and milestones to achieve. At Comac Medical, we recognize these challenges and stand ready to guide you through every step of the process.

We are experts in delivering tailored and meticulously defined study start-up strategies to each client and our approach is rooted in a deep understanding of study specifications and individual needs, ensuring that every aspect of the process is carefully considered and executed.

At Comac Medical, we value the collective expertise of our dedicated team comprising feasibility experts, site management specialists, and regulatory affairs managers to transform ambitious timelines into tangible realities.

Our comprehensive services include:

- Development of customized strategies tailored to specific submissions for each country involved.
- Collaboration and alignment with site representatives to streamline processes and ensure seamless operations.
- Provision of comprehensive documentation and training materials, fostering a thorough understanding of every facet of the study.
- Direct management of the study submission process, overseeing document gathering, facilitating reviews, and finalizing contracts.
- Ensuring timely initiation of your trial while adhering to the specified budgetary constraints.

Clinical Monitoring

At Comac Medical, we recognize the pivotal role that Clinical Monitoring plays in the research and development process. With this understanding, we have assembled a team of experienced professionals who contribute extensive knowledge and skill to every project.

Our commitment is to provide tailored clinical monitoring services that align seamlessly with your study specifications and protocols, ensuring the highest standards of quality and compliance throughout the duration of the trial.

By partnering with Comac Medical for your clinical monitoring needs, you can expect a comprehensive approach that encompasses rigorous site visits, meticulous data review, and proactive risk management strategies. Our team is dedicated to fostering open communication and collaboration with all stakeholders involved, facilitating a smooth and efficient monitoring process from start to finish.

Part of the Clinical Monitoring team responsibilities include:

- Expert support for site identification and selection, including on-site or remote pre-study visits;
- Verifying the rights and well-being of clinical study participants;
- Monitoring to confirm safety and data integrity;
- Training of investigational site staff;
- Informed consent/document translation, verification, and back-translation;
- Preparation of regulatory or ethics/review board submissions;
- Timely submission of protocol/consent and other essential documents;
- Warehousing pharmaceuticals, overseeing intellectual property, and managing materials for clinical studies;
- Reporting of protocol digressions;
- Regular and comprehensive reporting to keep you informed..

Our experienced Clinical Research Associates' on-site monitoring visits throughout your study ensure the highest quality review of data and documentation to ensure compliance with regulations.

Medical Monitoring

Our medical monitoring service aims to support the study sites by addressing inquiries related to your study. This may include reporting safety concerns, addressing queries related to patient care coordination, analyzing safety trends and more.

Comac Medical's Medical Monitors are qualified professionals, with more than 20 years of experience in managing and monitoring trials across a large range of therapeutic areas. Our team's primary responsibilities include (but are not limited to):

- Review of relevant patient clinical data;
- Review of medical coding;
- Therapeutic training of operational teams;
- Addressing site, PI, and team medical questions throughout the study;
- Review out-of-range lab values;
- Assessment of significance and reportability;
- Assessment of protocol deviations;
- Medical review of tables/figures/listings;
- Medical review of patient narratives.

Regulatory Affairs

Our experienced Regulatory Affairs team will make sure your health product complies with all legal requirements. We develop tailored regulatory strategies, based on every client's needs and product specifications to ensure all processes align with the global compliance standards. With a focus on precise documentation and keeping up-to-date with changing regulations, we will pave the way for your clinical research success.

Our Regulatory Affairs team full strategic and operational support includes:

- Communication with the ECs and RAs on a regular basis;
- Preparing, reviewing, and submitting regulatory applications;
- Maintenance of regulatory intelligence;
- Development of regulatory strategies.

Quality Assurance

Our Quality Assurance team is dedicated to applying the highest standards throughout every phase of your clinical trial. We design and implement quality systems, conduct in-depth audits, and ensure regulatory compliance to guarantee the integrity and reliability of your study data. With over two decades of experience in the industry we perform audits of internal systems, processes, departments and all services and procedures related to your study.

Our core Quality Assurance Services include:

- Investigator site audits.
- Quality event management/CAPA.
- Vendor audits.
- System and process audits.
- GLP audits.
- Regulatory inspection preparation support and management.
- Regulatory GxP training.
- Oversight and management of document control.

Clinical Data Management

Our Clinical Data Management team is here to ensure the accurate collection, integration, and availability of your clinical trial data, applying the highest standard of quality at every step. We tailor our Clinical Data Management services to enhance your trials with precision, efficiency, and strict adherence to compliance.

Our comprehensive package of Data Management services focuses on the management of all aspects from rapid data entry to query resolution and Database Lock (DBL).

- CRF Design (Both paper and EDC)
- Configured solutions
- EDC system roles management
- Data cleaning / Query resolution
- Edit checks programming
- Medical and listings review
- Reconciliation of external data
- Database Set-up module (CDASH, SDTM and custom libraries)
- Predictive analytics to empower immediate actions
- Clinical coding with industry standards and client-specific dictionaries

Medical Writing

Medical communication is a key contributor to the regulatory success of a product. Our team of medical writers consists of specialists with both scientific background and therapeutic knowledge. Our package of Medical Writing services includes:

- Protocols and protocol amendments (early phase, late phase, and non-interventional studies)
- Informed Consent Forms and Patient Information Leaflets
- Clinical Study Reports (CSRs)
- Subject and patients narratives
- Investigator Brochures (IBs)
- Literature summaries
- Clinical expert reports

- Scientific manuscripts
  - *Manuscripts*
  - *Abstracts*
  - *Posters*
  - *Meeting publications*
  - *Slide presentations*

Safety & Pharmacovigilance

With a steadfast commitment to ensuring drug safety and regulatory compliance, COMAC Medical offers tailored solutions to support clients throughout the product lifecycle. Combining extensive expertise in pharmacovigilance, risk management, and regulatory affairs, Comac Medical delivers high-quality services backed by advanced technology and innovative methodologies. Our dedication to excellence and continuous development enables clients to navigate complex regulatory landscapes with confidence, ultimately advancing patient safety and public health. We provide:

- Clinical trials safety management
  - *Preparation of SMA*
  - *Full processing of individual cases*
  - *Periodic reports preparation (line listings, DSUR)*

- Post marketing activities
  - *Literature search and review*
  - *Product complaint management*
  - *PSMF Preparation and Maintenance*
  - *Risk-Management, crisis management & consulting (preparation of RMP)*
  - *Qualified Person for Pharmacovigilance (QPPV) in Europe*
  - *Local (Pharmacovigilance) contact person*
  - *Aggregate periodic reporting (PSUR, etc.)*

- Safety Database hosting with electronic regulatory reporting in EudraVigilance
- Global interaction and reporting to Competent Authorities
- Generation of CIOMS Reports
- Product Reporting within XEVMPD

Central & Bioanalytical Lab

Comac Medical's laboratories use advanced equipment and are GCP and GLP compliant. Our labs have responsive teams of experts which work with innovative methods to bring well-timed and high-quality services.

Laboratory Expertise:

Central Clinical Laboratory

- Wide range of technologies and applications (Hematology, Clinical and Special Chemistry, Immunology, Microbiology, Biomarkers assessments)
- Preparation of Laboratory Manuals
- Preparation of laboratory kits and patient forms
- Sample handling, management and storage
- Flexible logistics services
- Shipment Monitoring
- Investigator support
- Dedicated laboratory project management
- Data exporting (incl. STDM compliant format)

Bioanalytical Laboratory

- Regulatory method development and validation (small and large molecules)
- Expertise in different analytical techniques (LBA and LC-MS/MS)
- Expertise in "Fit For Purpose" validation for early phase clinical studies and biomarkers
- Association with industry advisory groups
- GCP and GLP compliance
- Lab data transfer (incl. SDTM format)
- Immunogenicity analysis

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CRO SERVICES V1. 2024