CRK-CRO ®
Clinical Research Key

St. Mary's Mission Hospital,
Nairobi, Kenya
+254 740410277
www.crk-cro.com
contact@crk-cro.com

CRO Services

Your Trusted Full-Service CRO Partner in Kenya

Clinical Trial Planning & Design

Strategic Clinical Trial Planning & Design

Effective clinical trial planning and design are **critical for success**. That's why we ensure **every stage of your product's clinical development** is **comprehensively covered**, guiding you from **study inception to regulatory approval**.

Our Key Services:

1. **Clinical Development Plans**
   We develop **comprehensive clinical development plans** to **optimize trial success** and ensure seamless execution.

2. **Scientific Advice Meeting Preparation**
   We organize **scientific advice meetings** to help you **present your study design**, address **regulatory inquiries**, and streamline your **regulatory approval process**.

3. **Regulatory Guidance Review & Advisory**
   Our experts conduct **in-depth evaluations of regulatory guidance documents**, staying updated with **changing rules and regulations**. We provide **strategic insights** to ensure your trial design aligns with **current regulatory expectations**.

4. **Statistics-Related Regulatory Support**
   With extensive expertise in **statistics-related regulatory issues**, we help design **robust methodologies** and address **statistical concerns** raised by regulatory authorities.

5. **Market Authorization Support**
   Our team works **closely with you** to compile and submit **regulatory applications**, ensuring full compliance with **regional regulatory requirements**.

02 Project Management

Clinical Trial Expert Project Management

Effective clinical trial planning and design are critical foundations for success, with project management as the cornerstone of a well-executed study. Our commitment is to ensure seamless coordination and optimized resource utilization to keep your study on track.

Our proactive project managers anticipate and overcome challenges with tailored solutions, maintaining the highest standards of quality and efficiency.

We provide meticulous oversight, precise scheduling, routine status updates, extensive patient tracking, and key performance metrics throughout the trial.

Our Project Management Services Include:

- Develop and manage project management plans;
- Meet enrollment targets;
- Control of clinical study execution;
- Risk management: fast identification and communication;
- Maintain excellent team communication;
- Ensure timely delivery of project milestones.

03 Study Start-up

Navigating **today's clinical trial landscape** can be **challenging**, with unique **hurdles to overcome** and **critical milestones to achieve**. At **CRK Clinical Research Key**, we **understand these complexities** and are committed to **guiding you through every stage** of the process.

We specialize in delivering **highly tailored and precisely defined study start-up strategies**. Our approach is founded on **a deep understanding of study specifications and client needs**, ensuring **every detail is carefully planned and executed** for optimal results.

Our **dedicated team of experts**, including **feasibility specialists, site management professionals, and regulatory affairs managers**, works collaboratively to **turn ambitious timelines into tangible realities**.

Partner with us for strategic, efficient, and successful clinical trial execution.

Our comprehensive study start-up 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 aspect 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

Comprehensive Clinical Monitoring for High-Quality Research

At **CRK Clinical Research Key**, we understand the **critical role of clinical monitoring** in the **research and development process**. To ensure excellence, we have assembled a team of **highly skilled professionals** with **extensive experience and expertise** to oversee every aspect of your study.

We are committed to delivering **tailored clinical monitoring solutions** that align seamlessly with your **study protocols and requirements**, maintaining the **highest standards of quality and compliance** throughout the trial.

Why Partner with CRK for Clinical Monitoring?

By choosing CRK for **clinical monitoring**, you gain access to a **comprehensive approach** that includes **rigorous site visits, meticulous data review, and proactive risk management strategies**. Our team fosters **transparent communication and collaboration** with all stakeholders, ensuring a **seamless and efficient** monitoring process from **start to finish**.

Our Clinical Monitoring Services Include:

- Expert site identification and selection support, including on-site or remote pre-study visits
- Verification to ensure participant rights and safety
- Monitoring to confirm data integrity and regulatory compliance
- Training for investigative site staff
- Informed consent/document translation, validation, and back-translation
- Preparation and submission of regulatory and ethics review board documents
- Timely submission of protocols, consent forms, and other essential documents
- Warehousing of pharmaceuticals, IP management, and clinical study material oversight
- Reporting and documentation of protocol deviations
- Regular, in-depth reporting to keep you informed

Medical Monitoring

Expert Medical Monitoring for Clinical Trial Support

Our medical monitoring services are designed to provide comprehensive support to study sites by addressing critical inquiries related to your clinical trial. This includes reporting safety concerns, responding to patient care coordination queries, analyzing safety trends, and more.

Experienced Medical Monitors

At CRK Clinical Research Key, our qualified medical monitors bring over 20 years of experience in managing and overseeing clinical trials across diverse therapeutic areas.

Key Responsibilities of Our Medical Monitoring Team:

- Reviewing patient clinical data to ensure accuracy and compliance
- Medical coding review for consistency and regulatory adherence
- Therapeutic training of operational teams to enhance study execution
- Addressing medical queries from study sites, PIs, and research teams throughout the trial
- Reviewing out-of-range lab values and assessing their significance
- Evaluating reportability of safety data for regulatory compliance
- Assessing protocol deviations and providing strategic guidance
- Conducting medical reviews of study tables, figures, and listings
- Performing clinical reviews of patient narratives to ensure comprehensive reporting

06 Regulatory Affairs

Expert Regulatory Affairs Support for Compliance & Success

Our **highly skilled regulatory affairs team** ensures that your **healthcare product** meets all **statutory regulations**. We craft **customized regulatory strategies** tailored to your **specific product and business needs**, ensuring full compliance with **global regulatory standards**.

By maintaining **precise documentation** and staying updated on **evolving regulations**, we pave the way for your **clinical research success**.

Comprehensive Strategic & Operational Regulatory Support

- **Regular communication** with ECs and RAs
- **Preparation, review, and submission** of regulatory applications
- **Maintenance of regulatory expertise and intelligence**
- **Development of effective regulatory strategies**

Quality Assurance

Comprehensive Quality Assurance for Clinical Trials

Our **quality assurance team** is committed to upholding the **highest industry standards** at every phase of your **clinical trial**. We develop and implement **robust quality systems**, conduct **comprehensive audits**, and ensure **regulatory compliance**, safeguarding the **integrity and reliability** of your study data.

With **over two decades of experience**, we conduct **thorough audits** of **internal processes, procedures, departments, and all study-related services** to maintain excellence.

Our Key Quality Assurance Services:

- **Investigator site audits**
- **Quality event management/CAPA**
- **Vendor audits**
- **Process and system audits**
- **Regulatory inspection preparation and support**
- **Regulatory GxP training**
- **Tracking and management of document control**

Clinical Biostatistics

Transforming Clinical Data into Actionable Insights

At **CRK Clinical Research Key**, we specialize in translating **complex clinical data** into **practical, actionable insights**. From **study design to statistical analysis**, our **expert biostatistics team** collaborates closely with your researchers to ensure the **accuracy, integrity, and reliability** of your study results.

Comprehensive Biostatistics Expertise

Our **biostatistics services** encompass a full range of **statistical consulting and programming solutions**, supporting **Phase II-IV clinical trials** across diverse **therapeutic areas**.

Our Key Services Include:

- **Study design & methodology**
- **Data mining techniques**
- **PK (Pharmacokinetics) analysis**
- **Protocol development**, including **sample size and power calculations**
- **Randomization & integration** with **IMP management, IVR & IWR systems**
- **Creation of statistical analysis plans**
- **Statistical consulting & interpretation of results**
- **Interim analysis reporting**
- **Standalone statistical reports & integrated clinical study reports**
- **Cross-study data integration**
- **Preparation of ADaM datasets**
- **SAS® programming**, including:
    - **Analysis database & SAS datasets**
    - **Data tables & listings**
    - **Graphical data presentation**

Clinical Data Management

Seamless Clinical Data Management for Reliable Outcomes

Our clinical data management team ensures the accurate collection, integration, and availability of your clinical trial data, maintaining the highest standards of quality and compliance at every stage. We offer customized data management solutions, enhancing your trials with precision, efficiency, and strict regulatory adherence.

Comprehensive Data Management Services

We oversee all aspects of data management, from rapid data entry to query resolution and database lock (DBL), ensuring smooth and efficient study execution.

Our Key Services Include:

- CRF Design (both paper-based and EDC)
- Tailored data management solutions
- EDC system role management
- Data cleaning & query resolution
- Edit checks programming
- Medical review & listings analysis
- Reconciliation of external data sources
- Database setup module (CDASH, SDTM, and custom libraries)
- Clinical coding using industry standards & client-specific dictionaries

Medical Writing

Expert Medical Writing for Regulatory Success

Medical communication is a **critical factor** in achieving **regulatory approval** for a product. Our **team of expert medical writers** combines **scientific expertise** with **therapeutic knowledge** to deliver **precise, high-quality documentation** tailored to regulatory requirements.

Comprehensive Medical Writing Services

Our **medical writing solutions** include a wide range of **regulatory and scientific documents**, ensuring clarity, compliance, and effectiveness in **clinical trial communication**.

Regulatory & Study Documents:

- **Protocols & Protocol Amendments** (Early Phase, Late Phase, & Non-Interventional Studies)
- **Informed Consent Forms (ICFs) & Patient Information Leaflets**
- **Clinical Study Reports (CSRs)**
- **Subject Narratives**
- **Investigator Brochures (IBs)**
- **Literature Summaries**
- **Clinical Expert Reports**

Scientific & Publication Writing:

- **Scientific Manuscripts**
- **SMA Preparation**
- **Abstracts & Poster Development**
- **Conference & Meeting Publications**
- **Slide Presentations**

Safety & Pharmacovigilance

Comprehensive Drug Safety & Regulatory Compliance Solutions

With a **steadfast commitment** to **drug safety and regulatory compliance**, **CRK Clinical Research Key** provides **tailored solutions** to support clients throughout the **entire product lifecycle**.

Leveraging **extensive expertise** in **pharmacovigilance, risk management, and regulatory affairs**, CRK delivers **high-quality services** powered by **advanced technology and innovative methodologies**. Our **dedication to excellence** and **continuous improvement** helps clients **navigate complex regulatory landscapes** with confidence, ensuring **patient safety and public health**.

Our Services Include:

Clinical Trials Safety Management:

- **SMA preparation**
- **Full processing of individual cases**
- **Preparation of periodic reports (line listings, DSUR)**

Post-Marketing Activities:

- **SMA preparation**
- **Literature search and review**
- **Product complaint management**
- **PSMF preparation and maintenance**
- **Risk and crisis management consulting (RMP preparation)**
- **Qualified Person for Pharmacovigilance (QPPV) in Europe**
- **Local Pharmacovigilance (PV) contact person**
- **Aggregate periodic reporting (PSUR, etc.)**
- **Safety database hosting & electronic regulatory reporting**
- **Global coordination & reporting to competent authorities**
- **Generation of CIOMS reports**
- **Product reporting within XEVMPD**

Central & Bioanalytical Lab

State-of-the-Art Laboratory Services at CRK

CRK Laboratories are equipped with cutting-edge technology and operate in full compliance with GCP standards. Our labs are staffed by responsive experts who employ innovative techniques to deliver high-quality, timely services.

Our Laboratory Expertise

Central Clinical Laboratory

- Extensive range of technologies and testing (hematology, clinical and special chemistry, immunology, microbiology, and biomarker assessments)
- Laboratory manual development
- Preparation of laboratory kits and patient forms
- Sample handling, management, and storage
- Flexible logistics solutions
- Shipment tracking and monitoring
- Investigator support
- Dedicated laboratory project management
- Data export capabilities (including STDM-compliant formats)

Bioanalytical Laboratory

- Regulatory method development & validation (for small & large molecules)
- Expertise in various analytical techniques (LBA and LC-MS/MS)
- “Fit for Purpose” validation for early-phase clinical trials and biomarkers
- Active involvement in industry advisory boards
- GCP-compliant laboratory operations
- Lab data transfer capabilities (including SDTM format)
- Comprehensive immunogenicity analysis

3 PK/PD and PBPK modelling

Optimizing Drug Development with PK/PD Expertise

A **comprehensive understanding** of how drugs are **absorbed, distributed, metabolized, and excreted** is essential for **making informed decisions** throughout **drug development** and **clinical trial design**.

The Role of Pharmacokinetics (PK) & Pharmacodynamics (PD)

PK/PD studies are **crucial for drug approval**, as nearly **25% of the information on a drug label** is derived from PK/PD data. **Careful planning** and **smart study design** can significantly **accelerate the development process**, ensuring that **safety and efficacy goals** are achieved efficiently.

Our PK/PD Services at CRK Clinical Research Key

We provide **expert guidance** to optimize **study designs**, focusing on:

- **Dose selection**
- **Population selection**
- **Sampling schedules**
- **Drug-drug interactions**

Our Specialized Services Include:

- **PK/PD and PBPK modeling**
- **A dedicated team of clinical pharmacologists and biostatisticians**
- **Utilization of SimBiology software for advanced modeling**

Types of Studies We Support:

- **PK studies in special populations** (hepatic and renal impairment, elderly)
- **Drug-drug interaction studies**
- **Regulatory expertise with EMA & FDA guidelines**