KRIGER RESEARCH GROUP INTERNATIONAL
www.kriger.com

CLINICAL TRIALS

Kriger Research International

Kriger Research Group International provides clinical research services for pharmaceutical and biotechnology product development from phase II through phase IV for US, Canadian, European and multinational pharmaceutical companies. KRGI is your way to high quality design, conduct and analysis of clinical trials.

Our staff, zealously live and breathe their projects, providing meticulous attention to the details. They ensure that executions are crisp, timely, and accurate.

You receive truly personal service - and our senior management gives you their attention.

Member of the International Biopharmaceutical Association

Kriger Research International - Headquarters

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Please contact us for a free consultation on your projects.

In order to set a teleconference with our clinical research team and/or submission of request for proposal, please contact; Julie Locke, Director of Business Development Phone: +1 . 905 . 918 . 2727 Email: j.locke@krgi.org

CRO Products and Services

Clinical Monitoring

KRGI commits to provide sponsor with highly qualified regional based Clinical Research Associates which substantially reduces the overall cost of the project and ensures its timely completion. We have experienced staff in most geographical regions. This sets KRGI apart from other CRO-s that might not have such extended capabilities.

KRGI CRA-s perform comprehensive site management and monitoring activities to include the following types of monitoring visits:

- Pre study qualification visits
- Initiation visits
- Interim monitoring visits
- Close out visits

All activities are performed in accordance with ICH-GCP to ensure all investigational sites are compliant with all applicable regulations and protocol requirements.

- **The paramount responsibility of KRGI CRA-s is to ensure timely subjects recruitment, patient rights, safety and data integrity.**

In addition to on-site responsibilities each CRA is responsible for site management documentation and follow-up activities to ensure that site staff remains motivated and focused.

In summary the KRGI CRA plays a major role in the successful conduct of a study. The relationship developed between the CRA and the site staff is such that there is a focus on open effective communication with the CRA providing training and support thus ensuring patient safety, data quality and maximizing patient enrolment.

Medical Monitoring:

- Medical Monitoring (including 24/7 Medical Monitor coverage)
- Enhancement of regulatory compliance.
- Clarifying inclusion/exclusion criteria with the investigator.
- Providing consultation for potential safety issues or medical concerns regarding the clinical study.

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Regulatory Affairs

Clinical trial registration/licensing

Our experience encompasses obtaining clinical trial approvals and registration of new chemical, biological entities and medical devices. We can also provide assistance with post-registration activities, such as variations and renewals.

Regulatory submissions

Our regulatory team includes professionals with over 20 years of experience in dealings with FDA.(USA), TPD (Canada) , EMEA (European Union). TGA - Therapeutic Goods Administration and similar agencies in other countries.

Safety reporting

Patient safety and regulatory compliance are our primary concerns when conducting clinical studies. We work closely with our client's own drug safety department to provide safety surveillance and prompt, accurate reporting of serious adverse events.

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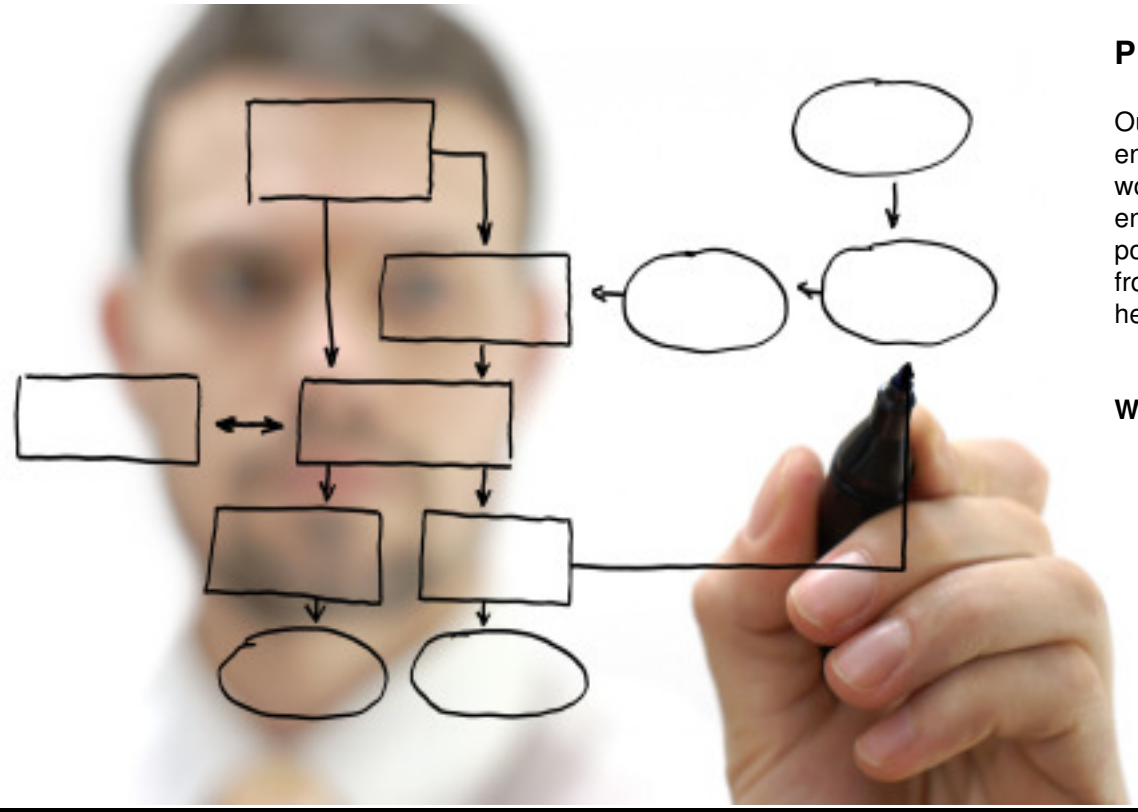
Clinical Trial Management



Project Management

Our project management team works closely with the scientific team to ensure the smooth progression of your clinical trial. Our Project Managers work effectively and diligently to manage all critical aspects of the study to ensure on-time delivery of results, within budget and with the highest possible quality output. Our team will work with you on all aspects of the trial from the first regulatory submissions through to closeout and final reporting to help you and your project succeed.

We provide:

- Frequent and timely reports to our sponsors.
- Training for CRA-s and site personnel on the protocol, CRF-s, SOP's, ICH- GCP.
- Constant review of CRA-s work to assure highest standards and consistency
- Management of Budget and Project Timelines

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Quality Assurance

Investigative Sites Audit

- o We verify that the protocol is performed according to Good Clinical Practices (GCP) and International Commission on Harmonization (ICH) standards and the sponsor's or CRO-'s Standard Operating Procedures (SOPs).
- o Review the informed consent content and process
- o Review records and procedures concerning interactions with the IRB.
- o Review records and procedures concerning drug accountability
- o Inspect study-required facilities and equipment
- o We verify that the data collected in a representative sample of Case Report Forms (CRF-s) are supported by source documents.
- o Assess compliance with internal SOPs
- o Study documentation audit
- o Verify that the protocol is performed according to GCP and ICH standards.
- o Review records and procedures for site visits
- o Review study file documentation
- o Ensure internal systems used in the conduct of clinical trials are correct, including SOPs for Adverse Experience (AE) reporting, supplies distribution, and data handling.
- o Assess compliance with internal SOPs
- o Compare study report versus the protocol, CRF-s, and database.
- o Ensure internal consistency in reports
- o Preparation for regulatory inspection

Covering:

- o Trial master file audits
- o Central laboratory audits
- o System audits
- o Data base audits
- o Site audits
- o Final clinical report audits

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Data Management

Our clinical data management team is using the most advanced and comprehensive clinical data management software available and according to the highest regulatory standards to ensure auditable GCP quality results, and with the required levels of efficiency to keep your drug development and medical device programs on track.

Our data management services include:

- Web-based e-trials
- Electronic Data Capture in full compliance with 21CFR part 11
- Case Report Form annotation and Data Handling Manual
- Blind and independent double data entry
- On-demand comprehensive data validation reports
- Full electronic Audit Trail
- Computer-generated and fully tracked Data Clarification Forms (queries).
- Autoencoders for MedDRA, WHO adverse events and medications, COSTART, or your custom dictionary
- Database export to custom ASCII or SAS-AE with code list libraries and variable labels
- CRF scanning
- Archival to CD-ROM
- Reconciliation of safety database vs. study database

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Therapeutic areas of expertise

KRGI specializes both in new drugs and medical devices clinical trials

- Anesthesiology
- Dental/Maxillofacial Surgery
- Dialysis
- Gastroenterology
- Immunology/ Infectious Diseases
- Nephrology/Urology
- Obstetrics/Gynecology
- Ophthalmology
- Pain Management
- Pediatrics/Neonatology
- Pulmonary/Respiratory Diseases
- Rheumatology
- Transplantology
- and some other areas
- Cardiovascular
- Dermatology/ Plastic Surgery
- Endocrinology
- Hematology
- Musculoskeletal
- Neurology
- Oncology
- Otolaryngology
- Pharmacology/Toxicology
- Psychiatry/Psychology
- Respiratory
- Spinal Cord Trauma
- Trauma/Emergency Medicine

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GCP, CRA, Clinical Data Management, Quality Assurance, Marketing and Management Training Programs

Kriger Research Group International is a leader in providing professional development programs for clinical research professionals. These programs are designed to provide a focused course of study for individuals seeking to position themselves in the clinical research and pharmaceutical trials industry as a clinical research associate, clinical research coordinator and data management specialists. They also provide knowledge and skills of clinical excellence in monitoring scientific studies toward the advancement of knowledge and improvement of health.

Regarding training please review:

http://www.krigerinternational.com

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