



KAI Research, Inc., An Altarum Company Clinical Trial Management

Altarum Institute integrates independent research and client-centered consulting to deliver comprehensive, systems-based solutions that improve health and health care. A nonprofit, Altarum serves clients in both the public and private sectors.

KAI Research, Inc. (KAI), an Altarum company, is a contract research organization with an in-depth knowledge of all aspects of clinical trial management. In business since 1986, KAI has established a reputation for providing efficient, innovative, responsive, and thorough clinical trial management to the pharmaceutical and biotechnology industries.

KAI brings more than 24 years of unparalleled experience and expertise to clinical trials management. KAI offers a full range of clinical study support in the cycle of clinical study development and implementation from protocol design through successful regulatory approval in an array of therapeutic areas. KAI's skilled scientific and methodological staff manage and analyze studies in all post discovery phases.

KAI's professional staff feature experience in the following therapeutic areas:

- ▲ Central nervous system
- ▲ Dermatology
- ▲ Endocrinology
- ▲ Infectious disease
- ▲ Pain
- ▲ Psychiatric disorders
- ▲ Rheumatology
- ▲ Substance abuse, and
- ▲ Vaccines

In addition to the disease areas, KAI has specialized experience with pediatric and geriatric studies.

Full-service expertise and small-business responsiveness

KAI senior scientists and biostatisticians, along with its project managers and support staff, collaborate in study development, implementation, operations, data analysis, and reports to the U.S. Food and Drug Administration (FDA). The staff supports the sponsor to deliver results in an efficient and cost-effective manner.

Study material development

KAI collaborates with the sponsor in the design and development of the protocol, source documents, case report forms, and study manuals. KAI develops data management, monitoring, drug distribution, sample shipping, and reconciliation plans.

Regulatory compliance

KAI regulatory specialists work with the sponsor to develop the Investigator Brochure and submit the investigational new drug and new drug application documents required by the FDA. KAI works with the site to obtain institutional review board (IRB) approval and to collect and maintain site regulatory documents. The KAI medical writer prepares all reports required by regulatory authorities.

Site management

KAI qualifies, selects, contracts with, and initiates study sites. KAI's experienced project management staff trains, coordinates, and manages site staff to ensure that recruitment, enrollment and randomization, participant safety, and data collection and editing are accomplished in a timely, accurate, and professional manner and in accordance with good clinical practices.

Site monitoring

Geographically dispersed, experienced clinical research associates well versed in design, implementation, collection, and analysis methods provide onsite support to clinical sites to oversee all study activities, ensure study compliance, and protect the safety of study participants. KAI works with the project management team to initiate the sites, perform interim and closeout monitoring, and ensure regulatory compliance.

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Safety and medical monitoring

KAI medical monitors, all degreed health care professionals, have extensive experience serving as medical monitors in a variety of therapeutic areas and managing all aspects of adverse event and serious adverse event receipt, evaluation, and reporting. Medical monitors oversee the safe conduct of studies; advise sites and sponsors on trial-related medical questions or issues; and review reported adverse events, laboratory results, and concomitant medications. KAI's medical monitors prepare reports for the safety monitor, the data and safety monitoring board (DSMB), and the sponsor as well as the FDA.

DSMB support

KAI provides professional support for the DSMB; identifies and invites potential participants; serves as the Executive Secretary; arranges all logistics, including meetings and conference calls; and prepares and distributes meeting materials and minutes. KAI tracks and reimburses all expenses and honoraria.

Vendor management

KAI qualifies, selects, contracts with, and manages laboratories, investigational product suppliers and distributors, central IRBs, and other vendors. KAI maintains a list of preferred vendors, develops a vendor management plan, receives and processes study-related data, processes payments, and closes out the vendor obligations.

Statistical design, analysis, and reporting

KAI's statistician and statistical programming team have both therapeutic and population expertise, applying innovative approaches to statistical issues. They develop the statistical analysis plan, prepare and analyze the data, and report results for both regulatory requirements and manuscript preparation. KAI's team of medical writers assists with both final report preparation and manuscript generation.

Quality assurance

Quality consciousness pervades all aspects of KAI operations, including Investigator and site training, onsite clinical monitoring, data monitoring, and data and regulatory audits. KAI has a staff of experienced auditors who perform quality assurance audits of sites, labs, and other vendors. KAI maintains a suite of Standard Operating Procedures (SOPs) that address all areas of practice. Client-specific SOPs and guidance documents are drafted as necessary to ensure consistent quality work throughout the life of a project.

For further information about KAI Research, Inc., please contact:

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