



KAI Research, Inc., An Altarum Company Clinical Data Management and IT Services

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 (CRO) with an in-depth knowledge of all aspects of clinical data management. In business since 1986, KAI has established a reputation for providing efficient, innovative, responsive, and thorough data management solutions and IT services to the pharmaceutical and biotechnology industries.

KAI's clinical data management experts provide unrivaled responsiveness, flexibility, and high quality

Clinical data management has been a cornerstone of KAI clinical research services for more than 24 years. KAI has honed its data management skills and processes to consistently deliver clinical database applications of the highest quality. The KAI clinical data management staff is well versed in good clinical data management practices and has strong technical, programming, and communication skills.

Whether your clinical trial is a multi-site study with thousands of subjects or a single site Phase I study, KAI's clinical data management team will provide a flexible approach that is:

- ▲ Accurate
- ▲ Accessible
- ▲ Reproducible
- ▲ Customized, and
- ▲ Timely and cost-efficient

Clinical data management team

The KAI clinical data management team members:

- ▲ Are highly skilled staff members with health care and/or data management backgrounds and senior staff anchoring each assigned clinical study;
- ▲ Serve as architects and implementers of clinical trial information management systems for pharmaceutical companies and National Institutes of Health (NIH)-sponsored studies; and
- ▲ Are active members of the Clinical Data Inter-

change Standards Consortium (CDISC), the Drug Information Association, the Society for Clinical Trials, and the Society for Clinical Data Management.

Data collection that meets clients' needs

Whether you are looking for a system that supports electronic data capture (EDC) or paper, KAI understands that navigating today's data collection and submission landscape can be complicated. Well-informed decisions about your study's data can save time and money later in your program. KAI clinical data management experts can advise you on the best path for your study and can implement data collection and formatting strategies to maximize your investment.

EDC: KAI can recommend an EDC strategy for your program by using our validated clinical data management system, SmartStudy®™. The staff has extensive experience providing clinical data management services by using EDC and can collaborate with you to ensure that the system meets your program's needs. KAI staff will guarantee that the system customization and validation checks are deployed quickly, sites and users are trained on the system, and results are available in a clean database.

Paper-based data capture: If paper is the best choice for your program, KAI offers robust data collection using paper case report forms (CRFs). SmartStudy®™ provides:

- ▲ Fast and flexible setup,
- ▲ Consistently clean data,
- ▲ A CRF inventory,
- ▲ Tracking of forms by participant at the page level,
- ▲ True independent double data entry with a third-party referee, and
- ▲ Strong custom reporting

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Data formats and Food and Drug Administration submissions: Need advice on the best format for your data? KAI's data managers are experts in data standards including clinical data acquisition standards harmonization (CDASH), the study data tabulation model (SDTM), or your own standard. KAI can evaluate your entire program to help you determine the best format for your project's data and expedite the eventual creation and approval of your submission package. KAI can also convert legacy data to the most current standards.

Statistical support

KAI statisticians and statistical programmers are experienced in developing statistical analysis plans and data management plans and creating tables and listings for submission to regulatory agencies. They are also experienced in creating verified CDISC SDTM files. In addition, KAI supports data and safety monitoring boards for various NIH institutes providing statistical expertise and safety reports. All statistical programmers have advanced degrees in statistics or information management and are continually updating their SAS, statistics, or data management knowledge.

Randomization services

KAI provides two methods of randomizing patients:

- ▲ An Interactive Voice Recognition System (IVRS) and
- ▲ A Web-based randomization system

Both systems link directly to KAI's EDC and study management system, allowing for confirmation of IVRS-provided information against the database. These systems are 21 CFR 11 compliant and can be used separately or jointly (sharing the same database). Reports from this system can be viewed from study Web portals, and the randomization database can be linked to the EDC system.

Web portals

KAI can create secure study specific Web portals that provide the sites, principal investigator, and sponsor with immediate access to reports and documents such as the protocol, user manual, manual of operations, and meeting notes. These portals can also provide forums, calendars, and newsletters. Access rights are tightly controlled so that information is provided on a need-to-know basis.

KAI's comprehensive clinical data management and IT services include

- ▲ Clinical data management consulting;
- ▲ CRF or electronic CRF design;
- ▲ Database development and deployment;
- ▲ Data entry and tracking;
- ▲ Customized clinical data management programming;
- ▲ Knowledge and use of current data standards (SDTM, CDASH, and CDISC);
- ▲ Interim analysis readiness;
- ▲ External data integration;
- ▲ Medical coding (the Medical Dictionary for Regulatory Activities and the National Cancer Institute's Common Terminology Criteria for Adverse Events);
- ▲ Reconciliation of clinical and safety databases;
- ▲ Customized reporting and data listings by using business objects, SQL reports, and SAS;
- ▲ Database closeout and delivery; and
- ▲ Certified Oracle and Microsoft SQL database administrators on staff.

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

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