



## KAI Research, Inc., An Altarum Company Data Standards and Data Warehousing

*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 data management. In business since 1986, KAI has established a reputation for providing efficient, innovative, responsive, and thorough data standards and data warehousing services to the National Institutes of Health (NIH) and the pharmaceutical industries.

### **KAI's data standards experts enhance study efficiency and timely submissions**

Clinical trial data standardization is one of KAI's strongest capabilities and one of the services most in demand by its clients. The company's distinct advantages are its knowledge of the standards and the tools that it has developed to support their use. The tools that KAI uses create additional time and opportunities to investigate the data. KAI staff experience and expertise improve the likelihood of successful submissions.

KAI's experts understand a wide range of industry data standards and apply them to the needs of individual studies. The skill at supporting and working with such a range of data standards maximizes the ability to meet clients' goals. KAI can collaborate with clients to ensure that the appropriate standard is implemented from the beginning. For existing studies that do not adhere to a specific standard, KAI leverages knowledge, tools, and experience to transform metadata and produce deliverables that conform to an industry-wide or sponsor-specific standard.

The overall deliverable is a submission database that U.S. Food and Drug Administration (FDA) reviewers can use to easily confirm study analyses. This gives regulatory agencies confidence in the submission with fewer queries and an expedited review so that the drug may go to market sooner.

### **KAI is a leader in the development and adoption of CDISC standards, including CDASH, SDTM, and ADaM**

KAI employees have been involved in the creation of the industry-wide Clinical Data Interchange Standards Consortium (CDISC) data standards and continue to participate in the CDISC organization. Because of KAI's early connection with the evolving NIH, biotechnology, and pharmaceutical data standards, it developed industry-leading, CDISC-compliant tools to implement these new standards into its work, further enhancing the efficiency that it brings to clients' programs. KAI can design studies to support the current CDISC standard, a future version, or legacy versions as project needs dictate. These tools allow for submission databases that are consistent across each study and compliant with FDA standards and expectations.

The benefits of CDISC compliance are many, but there are short-term considerations to keep in mind. KAI expertise in CDISC and other data standards will be put to good use in determining the specific needs of your project.

Benefits of data standardization include

- ▲ Increased ability to create easily accessible data collection tools and to reuse study elements,
- ▲ Increased efficiency and quality of data and communication between team members,
- ▲ Facilitation of data aggregation and simplified analysis,
- ▲ Metadata that are easy to understand and reproduce, and
- ▲ Reduced agency review time.

These benefits add up to greater quality in data submissions as well as more efficient reviews, which ultimately streamline clients' clinical trial programs. As the FDA moves toward establishing CDISC as the standard, KAI is positioned to continue as an industry leader in helping clients meet these requirements.

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## Clinical Data Warehousing

In today's clinical trials, data are often stored in multiple databases or data collection systems at contract research organizations (CROs), electronic data capture vendors, sponsors, investigator sites, or laboratories. These databases are often nonstandard and proprietary. KAI can streamline these multiple and divergent data sources into a single, unified data repository. A clinical data warehouse solution provided by KAI will provide a centralized, integrated system for data storage, analysis, reporting, and ad hoc query of clinical data. This solution will enable standardization of clinical data, efficiency in project programming, and data discovery options leading to improvements in the overall drug development process.

KAI's clinical data warehouse repository provides for the construction and maintenance of a centralized data repository; integration of data from multiple data sources, including CROs and other external data vendors; and distribution of data to multiple output channels. Output channels include standard data models in CDISC standards and reports facilitating study submission activities. The solution provides an environment that takes into account the specific FDA regulatory requirements for 21 CFR Part 11 software systems.

Tasks necessary for solution delivery include creating the warehouse data model, converting the data from multiple data formats, and processing the data in an iterative series of steps. Reports on these data will be accomplished through the use of standard SAS programming or Web-based reporting. Additional options include document management solution, change or version control, workflow, and electronic signatures. The result of a clinical data warehouse would be the creation of datasets ready for submission.

## KAI offers the following data warehousing services:

- ▲ Conversion of legacy data into CDISC study data tabulation model-compliant datasets in SAS or XML format; and
- ▲ Data warehouse design and conversion.

KAI can create clinical data workflows that transform chaos into clarity and provide an integrated vision for data collection, management, storage, analysis, review, and submission.

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

**Patti Shugarts**  
COO (Interim)  
301-770-2730  
301-770-4183 fax  
pshugarts@kai-research.com

Altarum Institute  
[www.altarum.org](http://www.altarum.org)