



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., An Altarum Company Pharmacovigilance and Safety Reporting

KAI Research, Inc. (KAI), an Altarum company, is a contract research organization with an in-depth knowledge of all aspects of pharmacovigilance and clinical safety through our support of both clinical studies and marketed products. In business since 1986, KAI has established a reputation for providing efficient, innovative, responsive, and thorough medical affairs and pharmacovigilance solutions to the pharmaceutical and biotechnology industries.

Full-service thoroughness and small-business responsiveness

The KAI pharmacovigilance and clinical safety team provides support for drug, biologics, and medical device products in a variety of therapeutic areas. Our extensive operational experience allows us to provide project startup; establish uniquely comprehensive pharmacovigilance standard operating procedures; and maintain open, communicative, and collaborative relationships with our clients. KAI's drug safety associates

- ▲ Receive, track, assess, and follow up on spontaneous adverse event reports;
- ▲ Conduct literature reviews for reports of adverse events;
- ▲ Code adverse events using the MedDRA coding dictionary;
- ▲ Prepare individual case safety reports and expedited reports;
- ▲ Prepare periodic safety reports; and
- ▲ Submit completed reports to clients and regulatory authorities both within and outside the United States.

KAI's pharmacovigilance and clinical safety team, in conjunction with our biostatisticians, conduct trend analyses and signal detection of safety data and assist in the development and maintenance of risk evaluation and mitigation strategies, risk management plans, and standard operating procedures.

Professional expertise

Our uniquely productive and qualified team includes nurses, pharmacists, and physicians, all with relevant backgrounds in clinical practice and industry, who are Certified MedDRA Coders (CMCs). The KAI pharmacovigilance and clinical safety team is supported by KAI's administrative, quality assurance, and IT staff.

Versatile, secure electronic safety databases

KAI uses the industry-recognized ARISg™, a commercially available state-of-the-art electronic safety database management system. ARISg™ meets both Food and Drug Administration regulations and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines and allows for electronic submission of Individual Case Safety Reports in E2B format. Our systems provide seamless compatibility with any client-preferred data format and are compatible with any widely used software platform.

Signal Detection/Risk Management

Signal detection at KAI focuses on identifying new patterns in a safety database. This effort ranges from looking for clusters of reports that stand out from the background to applying sophisticated methods involving statistical disproportion. KAI's pharmacovigilance and clinical safety team, along with members of our statistical department, have developed a battery of reports and programs using SAS and Statxact to first identify statistical signals and then evaluate them for medical significance. This comprehensive approach takes advantage of KAI's statistical skills and medical expertise.

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