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Kendle is extremely flexible. We have had situations where Kendle has stepped in seamlessly to assist us in processing large volumes of data. The only way that this can happen is through good communication and excellent cooperation.

*Vice President, Drug Surveillance and Information
Global pharmaceutical company*

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Preview Kendle's capabilities

- Expertise in Adverse Event (AE) and Serious Adverse Event (SAE) management
- Expertise utilizing multiple AE management systems
- Coding of medical history, concomitant medications, Adverse Drug Reactions (ADRs) using MedDRA, WhoDrug and other ICD coding dictionaries
- Preparation and filing of annual and periodic summary reports
- Data mining/signal detection
- Experience handling legacy cases from acquired products
- Literature review and processing of identified AEs
- Review of litigation documents and processing of AEs
- Creation and filing of pharmacovigilance plans
- Identification and processing of product complaints
- Expertise gathering follow-up and source documents for all levels of SAEs or events of interest

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Kendle's experience in the United States and the professionalism of their team has made outsourcing the safety monitoring of our products easier than we had anticipated.

*Executive Director, Global Patient Safety
Eli Lilly and Company*

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Taking the strain out of post-marketing surveillance

As the success of any drug relies on patients trusting in its safety, the timely collection, analysis and reporting of drug safety data from marketed products is not only a regulatory requirement but also a vital strategic need. Many companies find long-term safety monitoring under tight timeframes burdensome and have to divert resources from other important projects. By outsourcing post-marketing surveillance, you can maintain the necessary ongoing compliance on marketed products while releasing internal resources for less routine duties.

Kendle can assume total or partial responsibility for post-marketing surveillance or help you develop your own policies and procedures to ensure full compliance with global safety reporting.

The Kendle difference

Kendle's team of more than 180 safety experts spans all major regions of the globe, offering local expertise. Our experienced staff includes doctors, nurses, pharmacists, degreed life scientists as well as data-entry specialists. The safety team works closely with Kendle's Medical Affairs group in reviewing AEs to provide customers with comprehensive medical monitoring and safety services.



Post-marketing safety

Our post-marketing safety team has the flexibility and versatility to precisely match your needs. We handle assignments of all sizes, from large, international issues-management projects to small projects involving just a few events per year, and can work with an entire product line or just one drug.

We are able to work under our own Standard Operating Procedures and conventions or our customers', and accept AE reports directly or through our customers. Kendle is proficient in all safety database systems and can maintain databases internally or work within a customer's system via secure network connections. We also have considerable experience working with medical devices, as well as drugs, and are experts in generic products.

Because we are globally connected, we can help you overcome the geographical and language issues inherent with large international projects. We have centers of excellence in nine locations around the world and can localize a global strategy to meet individual country regulations and reporting requirements. Our local experts have a thorough understanding of the particular requirements for safety data reporting in their own regions and have access to Kendle's global regulatory database, allowing them to process data anywhere in the world.

Seamless global management

Eli Lilly and Company initially outsourced activities for management of post-marketing adverse event reports for a few select products to Kendle's Cincinnati office, but quickly became impressed by our adaptability in meeting their needs. The business and IT processes put in place gave the two companies confidence to expand outsourcing, and after a few months Eli Lilly began outsourcing European projects to Kendle as well.

To coordinate the work between the European and U.S. sites of both companies, Kendle has appointed a Global Project Manager, who coordinates and manages the work that is outsourced in both Europe and the United States, ensuring all projects run smoothly and consistently.

We have expertise in the development of post-marketing risk management plans as required in Europe and as needed in other locations, as well.

Kendle has world-class, global scientific therapeutic expertise, with an international network of certified Medical Doctors (MDs) who are experienced in all key therapeutic areas.

Finally, Kendle is an innovator in signal detection methods to drill down to any early warnings of safety issues. Our state-of-the-art software ensures we are at the forefront of this key aspect of post-marketing surveillance.

Flexible data support

For nearly five years, Kendle has handled a major global pharmaceutical company's safety data entry for post-marketing and investigative products. Kendle helps manage fluctuations in data entry need, especially during unexpected increases in AE case volume. Other projects require medical interpretation, source document review and preparation of a clinical narrative. Kendle enters data directly into our customer's database from approximately one-half of its operating units. The company's Vice President, Drug Surveillance and Information commented: "Kendle has been very responsive and we have established a climate where Kendle's support team feel they have been incorporated into our internal data processing team."

For more information

about Kendle's capabilities in post-marketing safety, please contact us at info@kendle.com or at one of the telephone numbers listed below:

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