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Patient safety remains among our highest priorities at Kendle. With increasingly complex safety regulations worldwide, our global network of experts ensures both regulatory compliance as well as patient health and welfare.

*Ken Hintze, PhD, Vice President
Clinical Safety and Pharmacology*

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Preview Kendle's capabilities

- Global Adverse Event (AE) management for clinical trials
- Expertise in serious and non-serious AE management systems
- Assessment and evaluation of events and reportability to appropriate regulatory authorities
- Coding of medical history, concomitant medications, Adverse Drug Reactions (ADRs), etc, using MedDRA, WhoDrug and other coding dictionaries
- Preparation and submission of safety reports
- Preparation of alert letters
- Medical Serious Adverse Event (SAE) review and monitoring
- Customer safety reports including trend analyses
- Experience handling legacy cases from acquired products
- Electronic adjudication system and process for endpoints of interest

Providing robust safety data to inspire confidence

The number of recent high-profile pharmaceutical product withdrawals due to safety issues has made drug safety an area of growing concern for both physicians and patients.

More than ever before, biopharmaceutical companies are recognizing the importance of robust and accurate safety data, not only to smooth the passage of the drug to market, but also to provide reassurance and restore confidence among physicians and patients alike.

The Kendle difference

Kendle's team of more than 180 safety experts, including doctors, nurses, pharmacists and degreed life scientists, as well as data-entry specialists, spans all major regions of the globe and offers local expertise.

Our experienced staff work closely with Kendle's Global Medical Affairs group to provide customers with comprehensive medical monitoring and safety services and ensure all events are reported in a timely manner.

Clinical safety

Our experts have a thorough knowledge of ongoing developments in drug safety monitoring and reporting and can provide complete, consistent and rapid assessments of all SAEs and AEs throughout a product's lifecycle, from concept through Phases I to IV and on to successful commercialization.

At Kendle, we pride ourselves on the flexibility of the service we offer and will select the most appropriate of our robust safety solutions to handle your particular situation. We are able to offer either a full service package or individual services as requested and can work under our own Standard Operating Procedures and conventions or those of our customers. No task is too big or too small – we tailor our services to your clinical safety needs.

Kendle is proficient in the full spectrum of safety database systems and can maintain databases internally or work within a customer's system via secure network connections. We accept AE reports directly or from our customers and enter them either into your tracking system or our own state-of-the-art ARGUS safety management system to generate regulatory reports.

We also have considerable experience working with medical devices as well as drugs, and are expert in the particulars of generic products.

Our staff has experience in the management of SAEs in many therapeutic areas, including oncology, CNS, cardiology, metabolic diseases and arthritis/pain, and more.

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 safety database, allowing them to process data anywhere in the world. Our global network allows our customers to decide where SAEs are reported, either from each individual country or from a central location.

Kendle has world-class, global scientific therapeutic expertise, with an international network of certified medical doctors who are experienced in all key therapeutic areas.

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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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For more information

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

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