



“

*The Kendle project team exhibited extraordinary cooperation, flexibility and a high level of commitment to providing quality deliverables on a long-standing and complex global trial. It was a pleasure to work with this team.*

*Associate Director, Project Management  
U.S. based global biopharmaceutical company*

”

## Preview Kendle's global full-service capabilities

- Product, disease and specialty registries (e.g., pregnancy, adjudication of outcomes events)
- Study design and protocol development
- Epidemiological oversight for registries
- Staff epidemiologists for study consulting and oversight
- Risk management programs and evaluations
- Regulatory agency negotiations
- Implementation, management and reporting
- Establishment and facilitation of Advisory and Steering Committees
- Endpoint monitoring and evaluation
- Assessment of signals, trends and bias
- Awareness and educational programs (focus groups, surveys)
- On-site monitoring available through Late Stage dedicated CRAs

## Robust clinical evidence in a real-world setting

In today's cautious regulatory environment, observational studies are increasingly carried out in newly approved drugs to demonstrate the effectiveness, safety and tolerability of a product in a clinical practice setting for the purposes of real-world risk management and safety monitoring.

Navigating the peri- and post-approval landscape is challenging as it can be difficult to select the most appropriate study design and research question. Designing a protocol that addresses post-marketing commitments as well as compelling scientific questions also can be daunting, while managing the expectations of regulatory authorities can be intimidating, especially in global studies.

## The Kendle difference

Kendle's Late Stage group leads the industry in conducting safety surveillance and other observational studies. Our experience in developing, implementing and managing safety registries, especially pregnancy registries, is unsurpassed. In addition, we have specific expertise in Patient Related Outcomes and economic questions into observational studies.



## Observational studies

Our staff, of whom nearly 65 percent have more than five years of relevant industry and registry experience, use a variety of methodologies to deliver:

- Post-marketing commitment safety studies
- Cohort studies
- Case-control studies
- Cross-sectional studies
- Product registries
- Disease registries

With our extensive operational experience and data-based decision making processes, we will help you conceive, implement, conduct and analyze your study and its data on time, on budget and within all regulations.

We will work with you to assemble an experienced team of scientists, physicians, and operations experts who will devise a scientifically rigorous and cost-effective approach to meet your needs. Our Regulatory Affairs and Submission experts and project leaders will discuss appropriate study designs that are operationally feasible while still providing robust, rich data to meet regulatory authority requirements as well as publication needs.

As a global organization, Kendle has the infrastructure and expertise to overcome the additional complexity inherent in large observational trials. We have the experience and capacity to address global corporate program needs as well as the individualized marketplace constraints of local affiliates.

Our dedicated On-site Monitoring Group supports the work of our Medical Outcomes team, supplementing on-site monitoring with remote site management services for cost-effective observational trial approaches. The On-site Monitoring Group also provides immediate access to multilingual Clinical Research Associates.

Our expertise in Electronic Data Capture and our Web-based adjudication capabilities allow us to conduct large observational safety studies with maximum efficiency. Our observational registries team is trained to work seamlessly via Kendle's automated events adjudication platform, enabling us to conduct your trial with greater speed and efficiency.

## Automated reporting aids close-out

Kendle's On-site Monitoring Group was responsible for the selection of a large number of previously unused research sites in the United States for a global, full-service megatrial. These sites were supported closely by the On-site Monitoring Group through site selection, regulatory document collection, patient enrollment, data cleaning and site close-out. Each site was assigned to a dedicated in-house CRA, facilitating the development of strong working relationships. The sites were asked to interact with different vendors for patient enrollment, drug supplies, site supplies and laboratory supplies. As a result of our standard processes, automation of reporting among Kendle and the four vendors and assignment of internal leads for the different tasks, the On-site Monitoring Group was able to enroll sites, help sites to enroll and retain subjects, collect and clean data and close-out sites within the project timelines.

## For more information

about Kendle's capabilities in Observational Studies, please contact us at [info@kendle.com](mailto:info@kendle.com) or at one of the telephone numbers below:

**North America** Cincinnati, OH, United States. Tel: +1 513 381 5550

**Europe** Camberley, England. Tel: +44 1276 481 000

**Asia/Pacific** Singapore, Singapore. Tel: +65 6248 4683

**Latin America** Mexico City, Mexico. Tel: +52 55 2169 0300

**Africa** Johannesburg, South Africa. Tel: +27 11 384 0000

