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Kendle is accountable and provides timely responses. The company is flexible enough to accommodate our requests without losing integrity.

*Manager, Medical Research & Strategy
Global pharmaceutical company*

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Preview Kendle's capabilities

Kendle has the expertise to provide the following Late Stage services in all major therapeutic areas:

Phase IIIB Trials

- New indications
- New formulations
- Head-to-head comparative studies
- Medical outcomes

Phase IV Studies

- Health outcomes research
- Quality of life
- Expanded access program

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This was a very complicated, nine-year oncology study. Kendle's Lead Clinical Research Associate managed all hurdles quickly and efficiently.

*Study Manager
Global pharmaceutical company*

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Extending the life cycle

Continued execution of well-conducted, scientifically rigorous clinical studies following license approval is an increasingly important stage of the pharmaceutical development life cycle. While a product may be tested in a few thousand patients to gain license approval, post-license studies conducted in the general patient population can involve many times this number, providing invaluable additional safety data. Furthermore, as new product pipelines become leaner and blockbuster drugs harder to find, companies are working harder to extend the life cycle of their existing products through late stage development and commercialization.

The Kendle difference

Kendle has an integrated late stage study management team of experienced biopharmaceutical industry and clinical development professionals. We offer proactive, creative and collaborative services that combine your scientific and commercialization objectives while maintaining regulatory compliance.

Our 25+ years of experience includes designing and conducting more than 600 Phase IIIB/IV clinical trials worldwide and recruiting more than 1.5 million patients. We pride ourselves on strong, experienced project leadership and our ability to provide targeted feasibility and contingency plans to ensure trials are completed to the highest quality standards and within the specified timeframe.



Phase IIIB/IV studies

Our global reach and experience enables us to conduct large international studies and access specific patient populations globally, while using our local expertise to meet national requirements. Our locally based Clinical Research Associates (CRAs) monitor sites in their home countries, providing regional expertise in regulatory requirements, fluency in local languages and customs and the benefit of established investigator relationships. These highly trained and experienced associates work on no more than two studies at any one time, enabling them to develop detailed knowledge of each study, including protocol, disease indication, study tools and processes.

Involvement in the study design phase enables us to offer cost efficiencies related to Case Report Form (CRF) content and data capture. We also can provide site support through our On-site Monitoring Group, achieving further efficiencies through a hybrid approach of on-site and centralized monitoring activities.

Kendle's innovative approaches to megatrial management bring further significant cost efficiencies. Our well-established site selection group is expert in rapid start-up and retention. We supplement on-site monitoring with in-house site management, enabling strong project oversight while at the same time reducing expenses.

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I have nothing but good things to say about the Kendle Project Leader and monitoring team. They always have gone above and beyond to keep us informed with study updates and issues. Because of the Kendle Project Leader's vast knowledge in leading trials, I have gained valuable experience. She is diplomatic, level-headed and at all times respectful.

*Clinical Study Manager
Global pharmaceutical company*

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A comprehensive package

Our late stage services range from study design consultation to completion of the final study report, and include:

- Investigator meeting planning services to maximize cost efficiencies in global studies
- Patient Access and Retention solutions, providing support to physicians to help with patient recruitment and retention
- Data and Safety Monitoring Board (DSMB) management and endpoint adjudication using Kendle's proprietary electronic endpoint adjudication system
- Data management solutions, including Electronic Data Capture (EDC) for faster and more efficient data collection and cleaning
- Trial management and reporting systems to provide timely and comprehensive study status reports and information
- Web reporting tools providing customers flexibility in tracking study progress

For more information

about Kendle's expertise in conducting Phase IIIB/IV trials, please contact us at info@kendle.com or at one of the telephone numbers below:

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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

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