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*The data management and biostatistical group have been fabulous. Kendle's associates are responsive to our needs and go above and beyond to ensure that quality expectations and timelines are met.*

*Senior Manager, Post Marketing Research  
MGI PHARMA Inc.*

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## Preview Kendle's capabilities

- Comprehensive statistical analysis plans
- Data reviews and data summarization, including customized data displays
- Data Monitoring Committee and/or blinded data review meetings, with interim analysis reports
- Sequential analyses including stoppage rules and sample size re-estimation
- CDISC SDTM and ADaM, and support implementation of CDASH data collection standards
- Pharmacokinetics, exploratory analyses, outcomes research, health economics, patient registries and (pharmaco-)epidemiology research
- Consultation/statistical leadership on clinical development plans and individual study design and protocols
- Inferential analyses, including use of modern missing data imputation techniques
- Randomization (including centralized, interactive and adaptive procedures)
- Submission support, meta-analyses and integrated summaries of safety/efficacy for Common Technical Documents (CTDs), regulatory guidance, strategic planning and statistical representation for meetings with regulatory authorities
- Stand-alone statistical reports and/or statistical input and review of clinical study reports
- Electronic CRF tabulations according to regulatory guidance

## Making your data work harder

The considerable cost of a clinical trial demands optimal trial design and the resulting data to capitalize on investment. The results Kendle delivers support rapid and scientifically endorsed decisions and all analyses conducted are accurate and able to withstand the scrutiny of regulatory authorities. Furthermore, we deliver data and analyses swiftly to avoid delays in development.

Our experts are proficient in the use of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and Analysis Data Models (ADaM), with experience in both individual studies and pooled data for submission to the U.S. Food and Drug Administration (FDA). In fact, one of our customers proudly presented the standards developed by Kendle at the 2007 European CDISC Interchange Meeting ("Evaluation and Implementation of Different Strategies to Create ADaM datasets – Experience Gained from a CRO Perspective").

## The Kendle difference

The large size and depth of experience of Kendle's Biostatistics group sets us apart from other CROs, allowing us to provide sound statistical guidance and input at every stage of a product's development. Whether you're conducting a large, global study or a small, regional trial, our Biostatistics group can support any sized study.

Our group is expert in randomization methods, data collection instrument design and data cleaning. In addition, our active engagement plan allows us to take a holistic view of your study, anticipating possible challenges and planning for them while consistently delivering high-quality statistical outputs.

We can work to either our own SOPs or to yours, and all of our outputs are validated using independent programming and reviewed by programmers and Biostatisticians, giving you complete confidence in the quality of the results.

Our team also has considerable experience with paper and electronic CTD submission and we have submitted more than 25 New Drug Applications (NDA) and 90 Marketing Authorization Applications (MAA). We also have a wealth of experience in the development of Integrated Summaries of Safety and Efficacy (ISS/ISE).

By partnering with you from the outset, we ensure that we are both working toward the same goal and that we understand your project thoroughly.

At the end of the day, we're not just the group that analyzes your data; we're a contributing member of your team.

## Creative approaches, overcoming obstacles

When Kendle began working on the New Drug Application (NDA) submission for an endocrinology product for a global pharmaceutical company, we discovered much of the data was around 10 years old and available in differing formats. Close cooperation among the different parties (including another CRO) was therefore essential, as Kendle was responsible for the cardiac safety analysis plan and also commented on the efficacy and safety analysis plan. After the dossier was successfully submitted on time, Kendle was asked to perform the FDA-required 120-day update.

The customer was so delighted with the success of this project that Kendle was asked to also prepare a Biologic License Application (BLA) for a neurology product.

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*Kendle has always delivered both in attitude and performance in challenging situations.*

Senior Manager, Post Marketing Research  
MGI PHARMA Inc.

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## For more information

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

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