



## Easing the way for clinical development

The seamless coordination of nonclinical and clinical studies is vital to ensure timely and cost-effective drug development. To move your product efficiently through the nonclinical stages of development, you'll require a carefully considered program that is right the first time. It is important to avoid repeat investigations or delays because of a lack of internal staff availability or because essential studies have been omitted.

## Preview Kendle's capabilities

- Program design and strategic advice
- Gap analysis of existing data
- Advice on likely regulatory agency views
- Regulatory agency meeting organization
- Briefing document preparation
- All types of regulatory document preparation and review
- Literature reviews and data summaries
- Protocol and study design
- Comparative quotes and placement advice
- Good Laboratory Practice (GLP) audits and study monitoring
- Data interpretation and review of study documents

## Forming a first-rate partnership

When UMD Inc. encountered difficulties responding to a U.S. Food and Drug Administration question related to a toxicology aspect of its Phase II program for an intravaginal product for dysmenorrhoea, it approached Kendle for help. Our toxicology experts were able to swiftly resolve the issue with the FDA and provide further input on study design and evaluation of the toxicology report. UMD was particularly impressed with our ability to respond rapidly to relatively complex queries. The customer was so pleased with Kendle's response to this initial inquiry, it has continued to consult with us on a range of nonclinical and clinical issues, building a very successful, ongoing relationship.

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*If you e-mailed Kendle a question in the afternoon, you'd have a response the following morning. And not just a one-line answer – they were very thorough and all their information was correct.*

*Director, Regulatory Affairs and Clinical  
UMD Inc.*

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## The Kendle difference

Kendle provides a full nonclinical consulting service for small molecules, biologicals, vaccines and devices. We offer well-designed nonclinical programs that smooth the path for clinical development and help get your product to market rapidly. Our advice is prompt, reliable, up to date and can be integrated into the clinical development plan. Importantly, our guidance is independent of nonclinical service providers.

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*I was most impressed by their experience and real grasp of the current regulatory environment, which has changed greatly over the years with the development of new osteoporosis drugs.*

*Vice President of Clinical Development  
Metabolic Pharmaceuticals Ltd.*

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We have experienced and knowledgeable toxicologists on three continents who can create study designs, programs and regulatory documents that are acceptable throughout the world, enabling customers, particularly those outside the European Union and United States, to enter foreign markets. Furthermore, we can help you find the most cost-effective location to conduct a study, and with our worldwide network, we can provide study monitoring wherever the study is placed.

We have the flexibility to adapt to your needs, whether it is providing a comprehensive regulatory submission service – coordinated with our quality and clinical services – or handling an occasional inquiry. Our practiced staff can stand in for, or simply support, your own toxicologists. We also have the capacity to respond to day-to-day issues and problems as they arise.

## Experienced in preclinical planning

When Australian biotechnology company Metabolic Pharmaceuticals Ltd. needed help to develop its potential new osteoporosis product, it approached the Kendle office in Melbourne. We prepared a detailed clinical development plan for the new product that addressed all regulatory issues as well as nonclinical and clinical proposals, detailed budgets and timeframes. We were able to draw on our experience of developing similar development plans for large, traditional pharmaceutical companies as well as detailed knowledge of the current regulatory climate for osteoporosis products.

## For more information

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

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