



Our strategy for regulatory success

With so much of a drug's development time consumed by clinical trials, it's important to shorten regulatory approval times to speed up the R&D expense recovery process. Ideally, a company will look at the complete picture up front to create a clinical development program that anticipates regulatory issues and also addresses the entire product life cycle. But where does the complete picture come from? That's where Kendle steps in.

Preview Kendle's capabilities

- Design of clinical programs
- Design of individual clinical trial protocols
- Review of programs to provide opinions on whether they will meet International Conference on Harmonization (ICH) guidelines and expectations of individual regulatory agencies
- Gap analysis to evaluate robustness of completed work to date
- Preparation of product information and drug labeling to provide focus for clinical development programs
- Preparation of plans linking preclinical and Chemistry, Manufacturing and Controls development to ensure they support the clinical development program

Proof that partnerships work

Vascular Biogenics Ltd., based in Israel, needed assistance in planning a development program for its anti-inflammatory product, which it believed could be used in multiple indications. The company approached Kendle to work with it on a strategic clinical plan to assess different proof-of-concept protocols for the product.

Kendle drew on its expertise from around the world to help prepare a comprehensive plan, including several different indications for the new compound. "I could tell from the very first draft of the plan, Kendle just got it," commented Vascular Biogenics' Vice President of Clinical Development. The plan included synopses, timelines, study designs and costs for six Phase IIA proof-of-concept studies and one Phase IIB proof-of-concept study. Vascular Biogenics was delighted with the outcome of its partnership with Kendle, and is deciding which recommendations to adopt.

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It was a pleasure to work with Kendle's global strategic consulting group – the team was very responsive. The entire process was well designed and managed and the end product was good. When you have all of that put together, you feel pretty lucky.

Vice President of Clinical Development
Vascular Biogenics Ltd.

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The Kendle difference

We know our customers need to develop clinical development strategies that are rapid, cost-effective and deliver product claims superior to the current and emerging competition. We also understand the underlying need of any clinical development program is to maximize the chance of regulatory success. That's why we recently implemented a Global Strategic Consulting Group consisting of elite physicians, clinical scientists, regulatory specialists and statisticians. This group of more than 100 individuals was formed to assist customers with strategic planning of the regulatory and clinical elements of their development programs.



Kendle regulatory consultants are a friendly and responsive group of people to work with. You feel like they have a real stake in your project, that they're part of the project team and derive excitement and personal satisfaction from your success. We look forward to working with them in the future.

Director of Regulatory Affairs and Quality
AcruX



Our clinical and regulatory experts work on many programs across wide geographic regions, frequently interacting with regulatory agencies. They are familiar with the unwritten concerns and challenges of a clinical development program. Accordingly, our experts have valuable insights into recent successes and failures in clinical development and can therefore model strategic designs to make your program a success.

In fact, Kendle literally wrote the book on strategic clinical development planning. "Strategic Clinical Development Planning: Designing Programs for Winning Products," written by William Sietsema, PhD, Vice President, U.S. Regulatory Consulting and Submissions at Kendle, has now become the standard by which clinical programs are designed.

As part of our full life cycle management capabilities we can provide strategic planning for switching your product to "behind-the-counter" or "over-the-counter" presentations. Through a unique mix of technical writing and skillful arguments, we tailor each switch application to the issues at hand (e.g., a first-in-class switch) and individual countries' switch criteria.

Speed of response is critical

When AcruX in Australia decided to take a project into Phase III, it needed advice from a larger company that could draw on a global team of experts rather than from sole consultants in each major region of interest. The company invited Kendle to advise on the strategic aspects of the project, and was delighted when we suggested innovative ideas that provided viable options to speed the project to market. AcruX has been delighted by our flexibility, and the ease with which our consultants can adapt to changing project priorities.

For more information

about Kendle's expertise in global strategic clinical development planning, please contact us at info@kendle.com or at one of the telephone numbers below:

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