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*Adaptive design could also mean that products make it to the market more efficiently, and more people benefit from effective therapies earlier than today. It could mean that, at the end of the trial, doctors have more information to guide treatments to those patients more likely to experience a benefit.*

*Scott Gottlieb, MD, Former Deputy Commissioner for Medical and Scientific Affairs, U.S. FDA*

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## Benefits of adaptive design

- Expend fewer resources on failed products
- Critical decisions pushed earlier in the development process
- Redirect spending onto products with greater probability of success
- Faster detection of safety issues
- Patients not unnecessarily exposed to non-efficacious drugs
- Enrollment of unnecessarily large numbers of patients avoided
- Earlier and less productive aspects of clinical trials expedited (e.g. dose finding)

## Adaptive design is transforming clinical trials

Traditional clinical trials, in which a protocol is designed according to certain assumptions and strictly followed throughout the study, have numerous inefficiencies. Because there is no opportunity for researchers to adapt a protocol to reflect their increasing understanding of a drug as a trial progresses, the outcome may be inconclusive if the initial assumptions prove incorrect.

In addition, traditional trials are extremely time-consuming because the results are not known until the final patient has completed the study, and additional ethical approval is required for each protocol amendment. Traditional studies are also more expensive because futile studies are allowed to continue since the information needed to stop a study is not known and sample sizes may be unnecessarily large.

For some time, the concept of adaptive clinical trial design has been debated as an exciting alternative. Now that technology has caught up with theory, this alternative approach promises to dramatically reduce the time and expense of drug development, revolutionizing the way clinical research is conducted.

## Adaptive design – a challenge and a unique opportunity

The potential benefits of adaptive trials are exciting, greatly enhancing the drug development process by requiring fewer patients and a reduced time to meet study endpoints. However, adaptive trials are challenging to implement. They must be designed carefully before they begin, with full scenario planning (including stoppage rules, decision trees and other important details) agreed beforehand with regulatory authorities. Once a trial of this type is ongoing, operational speed and outstanding project management are vital. When undertaking such a large and complex project, the benefit of having a partner that offers the necessary experience, expertise and guidance cannot be underestimated.

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*Adaptive design can speed up the process of drug development or can be used to allocate resources more efficiently without lowering regulatory standards.*

*EMA, Committee for Medicinal Products for Human Use, Reflection Paper, March 23, 2006*

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## The Kendle difference

Kendle's extensive experience and understanding of adaptive trial design will give you confidence that your study is in the most capable hands possible. Whether you're conducting a large, global study or a small, regional trial, we can tailor our strategy to fit any sized program, using our rapid database lock to lock databases in days rather than weeks.

Rapid database lock is possible only through the use of Electronic Data Capture (EDC). At Kendle, we are at the forefront of the EDC revolution and our statisticians are highly trained and knowledgeable in this field, with strong international expertise. Kendle has practical knowledge of leading EDC software packages, a dedicated EDC Support Centre and the experience of hundreds of successfully completed EDC trials.

At Kendle, we recognise that the success of an adaptive clinical trial depends on the seamless integration of a number of functions – biometrics, clinical research, data management, drug supply and clinical operations – and this requires strong project management and the total commitment of all functions involved. Kendle's project leaders are unique in their expertise in managing the outsourcing relationship to ensure maximum efficiencies and successful delivery of every project. With our track record in delivering countless projects successfully during our 28 year history, our team is uniquely qualified to meet the challenges of adaptive design in clinical trials.

### For more information

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

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