The Agile Approach to Adaptive Research: Optimizing Efficiency in Clinical Development
By Michael J. Rosenberg

Adaptive clinical research is one of the “hot topics” of the day. As a relatively new field, it certainly has its challenges, but it also has the potential for considerable improvements in drug development efficiency. Dr. Rosenberg’s new book, *The Agile Approach to Adaptive Research* first outlines the current state of the pharmaceutical and biotechnology industries, where considerably increased research and development expenditures have not led to a greater number of investigational drugs reaching marketing approval. He then captures the current excitement surrounding adaptive clinical research (also called adaptive design), and provides a very readable introduction to the methodologies involved in implementing such research.

The timeliness of this text is well reflected by the release of the FDA’s draft Guidance for Industry, *Adaptive Design Clinical Trials for Drugs and Biologics*, in the same month as the book’s publication, February 2010. The FDA’s definition of an adaptive design clinical trial in the context of its draft guidance is “a study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from subjects in the study.” An adaptive trial therefore contrasts with the traditional fixed-design trial, in which a study proceeds from start to finish as described in the study protocol without modification.

There are some individuals who would comment that we have long conducted ‘adaptive research’, via the writing of protocol amendments—these documents alter the nature of the remainder of the trial once implemented. However, there is one fundamental and critical difference between true adaptive research and the use of protocol amendments, a difference captured in the FDA’s definition. A true adaptive design provides prospectively planned opportunity for modification of the trial’s remaining stage(s), while protocol amendments are not prospectively planned, and are almost always the result of a problem that could (and arguably should) have been addressed in feasibility studies conducted before writing the original study protocol.

Rosenberg’s book provides information on many aspects of adaptive design, including these three key considerations: sample-size re-estimation, adaptive enrollment, and adaptive monitoring. Any and all adaptations made are the result of appropriately analyzing clinical trial data already collected in the context of prospectively determined decision-making algorithms and various quantitative metrics concerning the trial’s conduct to date that have also been collected and analyzed. Hence, the validity and legitimacy of results obtained at the end of the trial are maintained.

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**The Agile Approach to Adaptive Research**

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**Medidata Solutions President Glen de Vries Named to Crain’s 40 Under 40**

Clinical Trial Technology Innovator Recognized for Industry Leadership and Business Success

NEW YORK - Medidata Solutions (NASDAQ: MDSO), a leading global provider of hosted clinical development solutions, today announced that President and Co-founder Glen de Vries has been named one of Crain’s 40 Under 40, an annual list of rising business stars who have excelled in their respective fields.

De Vries is being honored for his efforts in helping drive Medidata to a position of industry leadership in bringing advanced technologies to the development of drugs and other medical treatments and creating a thriving, profitable enterprise that employs hundreds worldwide.

“Glen’s business and technology vision, combined with his relentless drive to deliver on his personal and professional goals, have been essential to our company’s success,” said Tarek Sherif, CEO of Medidata Solutions. “Glen shapes our vision and product strategy, inspires and mentors our worldwide team and embodies our corporate culture of collaboration with our customers, which is the basis of our business and industry success.”

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