Drug Discovery & Development

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By Elizabeth Tolchin

Software that Handles Pre-Clinical Studies 7/21/05

iAdvantage Software Inc., Cary, N.C., recently introduced e-Study, a completely Web-based system that integrates pre-clinical study design, e-notebook design, data collection, and data reporting.

The software, they say, allows scientists from the same or separate sites to design study templates, access study data, record their findings, and pull supporting data into one secure database. Members of the team can then access the information and generate reports in a more automated way.

“The product is specifically designed towards the pre-clinical or development space,” says Ron Thompson, PhD, executive vice president, iAdvantage. “It is not for the discovery or clinical stage. It is for the *in vivo* stage prior to clinical study. This is where the bottleneck is in the discovery and development process.”

The e-Study software is divided into three modules. The first is e-Study Publisher, which is where users design templates for generating reports in the word processing software of their choice (including Microsoft Word and WordPerfect). These report templates are then available for use and revision.

The second module is e-Study Notebook where researchers can control the organization and presentation of the data collection forms in their online electronic notebooks. The scientists create their own templates that can be reused for future studies.

The final piece is e-Study Manager, a Web-based graphical interface for the definition of test articles, test systems, trial locations, treatments, samples, and observations. The system meets the requirements for 21 CFR Part 11 compliance.

e-Study evolved out of iAdvantage’s original CRO business in which the company provided services for managing studies. “Whereas many of our competitors’ software focuses on managing a laboratory, our software focuses on managing the study, which can be out of one laboratory or many laboratories,” says Thompson. “Products that are focused on managing the laboratory are very weak in study design.”

The product provides powerful tools for designing studies, he says, such as randomizing animals and assigning them to various treatment regimes. “Out of that you can design a laboratory notebook that captures all of the data that you want. All of this data sits in an Oracle database where it can be pulled into reports.”

“We fully expect with the flexibility and logic built into this product, scientists can create design study temples themselves without IT support,” says Thompson. “We also estimate that this product will save those who are responsible for designing studies and writing reports between 50% and 80% of their time.”

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