The Most Powerful Study Management Software? - The One That People Actually Use

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Some years ago, I saw a TV commercial with a business manager standing at a second floor observation window overlooking the cubicled offices of his staff. He remarked to an associate, "Do you know which computer is the most powerful?" After a brief pause, the manager said, "The one that people actually use." That image and that thought came back to me recently during the American College of Toxicology conference in Indian Wells, California. I talked with a number of manufacturers and contract research organizations (CROs) in the pharmaceutical, bio-technology and pesticide arena about the various software products that they use for data collection, reporting, and general study management. Their responses ranged as follows:

Dilemmas Facing Scientists Using Study Management Software

- We use product X to manage our mammalian toxicology studies, but not for alternative toxicology, genetic toxicology, or eco-toxicology. When asked why, they indicated that product X was too difficult to use. Their experience using this product for mammalian toxicology was so painful that it has discouraged them from even attempting to use it for other toxicology study types.
- We use product Y, but we are four versions behind. Will you be upgrading? No. Why? In part due to the cost of the license upgrade per se, but primarily because it will take us a full year to re-validate on every computer. It is not cost effective for us to upgrade. With these heavy costs, plus the general difficulty of use - it just does not make good business sense.
- Do you use the reporting function of product Z? Yes, but reporting is a painful process and is very slow.
- Do you use the reporting function of product Z? No. We have used this product for four and one-half years for data collection, but we have never developed a report using it. Why? The reporting functionality is too cumbersome to use and takes too long. We can put data into product Z, but it is very difficult to get it back out. Therefore, we use Word, cut and paste, and cobble things together.
- Relative to another product--- the dashboard looks like that of an Airbus A-300. I need a GPS to navigate the software.
- We have been validating for a year, but I am not sure how the product will work yet. Why? What was demonstrated does not appear to be what was installed.

What Is Wrong Here?

It appears these products were built without a true understanding or consideration of the scientist user and their needs. Although the products do what they were designed to do --- more or less --- and are samples; observations to be made are observations; and timing of application, sampling, or observation is timing. Most, if not all, of these are inherent in any given study type. Most importantly, it is totally irrelevant whether the test system (the object or material against which this test or experiment is being conducted) is a whole animal, a tissue, a plant, or an automobile tire. The names or labels of the above steps or items may change, but not the underlying logic of the research process.

perhaps more training could lessen the problem --- some --- in the end, the products are not meeting the needs of the user. Why? Some products seem to be built specifically for use by IT as they support the scientist. Others try to put everything conceivable into one product, all integrated, and inter-dependent. Utopia! Right? Often not. Products can be predefined and integrated to the point that the user's hands are tied. He or she must use all of the product's components, and use them in the order and manner the software designer conceived the research process to flow, not the way the scientist needs or wants to conduct the study.

Back to Basics - Understanding the Scientist's Study Management Needs

Generally, a study director is more interested in managing his or her study than in managing the laboratory and all associated instrumentation. They are interested in "my study" from protocol development through study design, notebook design and data capture, analysis, and reporting.

The Scientific Process

Consider the hierarchy of project, study, experiment. A project could be, for example, an area of research such as oncology, or all the work associated with a given compound. A project may contain one or more studies. A study may contain one or more experiments. An experiment is a unique "test" with a unique set of results / data. This logic does not change with each study type, but serves as the basis for all studies. Further, this logic is the first foundational step to forge a common relational thread among the data within the database.

Consider further, the logic and flow of the scientific process. There are few fundamental differences among study types. Although the names by which they are referred may differ by company, study type, etc., the material to be tested is test material; treatment applied is treatment; dosage or rate is dosage or rate; samples to be collected

Managing Multiple Study Types

From the scientist's perspective, why would software developers not build products with greater flexibility to accommodate multiple study types? Why have different products or modules for "different" study types when the logic and the flow of the study process is largely the same for all studies? The scientist easily tires of learning

new software, and their management easily tires of purchasing and validating largely redundant but different products or modules to accommodate the few differences among study types. Pharmas and CROs increasingly recognize the value of, and prefer, products that provide the capability and flexibility to accommodate multiple study types.

R&D Challenges Driving Improved Data Automation

There are a number of R&D challenges that argue strongly for the continued improvement and automation of study design, data collection, analysis, and reporting. These include:

- Continued economic pressure to develop new products and to do so faster and more cost effectively. Fewer candidates failing in clinical trials.
- Difficulty aggregating, reporting, and sharing research data.
- Inherent inefficiencies in paper systems and nonintegrated "islands of automation".
- Lack of security and data integrity resulting from paper processes and disjointed systems.
- Competing demand by scientists for IT resources. IT spending in the research and development areas is increasing. However, business management and finance will continue to consume the major portion of these IT resources.
- Cumbersome, inflexible tools with limited capability that help, but often fall short of the real needs of the scientists.
- Demand for standardization of electronic study management platforms across disciplines and study types.

Progress is being made, but priority should continue to be placed on developing resources to meet these R&D challenges. In fact, software, hardware, and internet technology is available to a greater extent today than we as an industry are fully utilizing. In almost all situations, there is no good reason not to collect data electronically. In order for it to be accessible and of real value, much of the data collected on paper is later transcribed into an electronic format anyway --- leading to transcription errors and multiple QA steps. If instead, the data are collected electronically, it can be saved directly into a relational database making it readily accessible to be reported out both now and later in any number of formats based on the scientist's needs.

Regulatory Acceptance of Electronic Data Capture

Regulatory authorities around the world are now, and will increasingly, recognize and accept that data entered electronically with an audit trail reflecting user name and password, time and date stamp for both initial entry as well as any revision of the data, is equally, if not more, valid and secure than data entered directly on to paper. Given proper systems for access permissions and audit trails, arguments against the validity and security of data captured electronically will not stand the test of time.

IT – Overextended

The scientists and their management understand better than anyone the technical and regulatory requirements of the studies that they are charged to conduct. There is no logical reason for the scientist user to be without the necessary tools to build their own study design, data collection templates, and report templates electronically. IT personnel must keep the computer systems serviced and operating properly, and should retain responsibility for maintenance and structure of data bases. Given these responsibilities, plus the demands of management and finance, IT should not have to be distracted from their core responsibilities to implement or tweak data collection forms and data report templates nor to develop a myriad of macros to patch work the functionality needed by the scientist. The scientist user knows technically what is required for the study from the perspective of the regulator, the specific client, the reporting requirements, and, most importantly, the overall scientific process. Understandably, the scientists are asking for the ability to control their study and to stop the back-and-forth dialog and associated costs and time delays when control of their research process is too dependent on IT.

Freedom with Web-based Systems

Not that the scientists necessarily want to work during their vacation, but they do want access to their study and study results at anytime, from any computer, from any where. To allow them to manage their studies in a more timely and efficient manner, they want the freedom from being tied to "their computer" and from the restriction of having their computer tied up repeatedly with software installation, validation, maintenance, upgrades, and re-validation. Technology is available today from web-based systems that not only provide this freedom, but also accommodate wireless and off-line functionality allowing the scientist complete freedom to move un-tethered around the laboratory, or from lab to lab, or office to lab, with a laptop, tablet PC, etc. while still maintaining full data security. Scalability is also simplified with web-based systems as there is no software to install and validate on each individual computer as new users are added. Rather, issuance of a user name and password adds a user.

Reporting Data Out – Easily

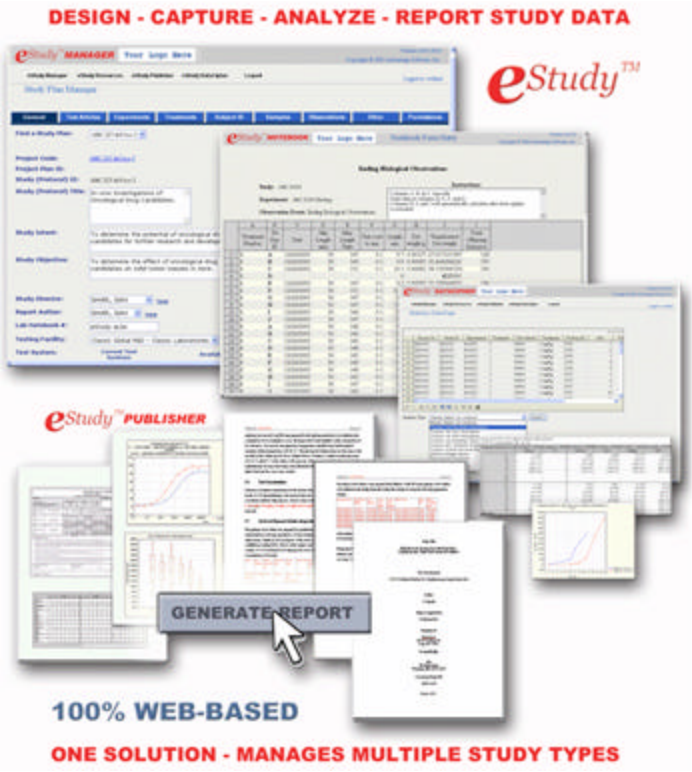
Most scientists will confirm to you that reporting dilemmas have long haunted them. The problems of difficulty accessing data, limited reporting formats, having to learn multiple, complex reporting tools, having to aggregate multiple piece-meal report elements into a final report, and the inherent time delays associated with the above are endemic in the industry. The scientists and their management do not simply want data in. Rather, they want to report out data results quickly and easily in the format of their choice, i.e. in theformat that the regulators, their client, and they themselves prefer. The technology is available today to enable the scientists to design their report templates without IT involvement, and to access multiple data sources simultaneously to pull single data points, text, tables, and images and into a single draft report- - - and this can be done in seconds or minutes, not weeks or months.

Satisfying the Stakeholders – Scientist, IT and Management

There are a number of stake-holders with interest in successful automation of study management. The scientists want ease of use, flexibility, and better reporting capability. IT departments want quality products on a common platform, products requiring low maintenance and less IT resources, and satisfied users. The pharmaceutical and biotechnology companies and CROs want quality, defensible data that enables faster and better decision making resulting in fewer failures in clinical trials. In addition, they want their personnel to remain focused on their core competencies of research, development and commercialization without the distraction, and often the limitations, of internal software development.

Time and Cost Benefits of Electronic Study Management

Successful implementation of electronic study management, specifically web-based electronic study management, is not adding cost and complexity to the R&D process. Rather, using creative design and leading-edge technology, electronic study management has demonstrated the ability to simplify study management, add flexibility and utility, and reduce the costs and timelines of studies per se, as well as, reduce the cost of training, implementation and maintenance of software systems.



"Currently, the vast majority of in vivo animal studies undertaken by life science research organizations are managed using paper-based notebooks, loose-leaf binders or Excel® spreadsheets," said Mike Elliott, president of Atrium Research and Consulting. "With the goal of streamlining biopharmaceutical R&D, we find this practice to be highly inefficient. Additionally, data from a range of highly automated analysis and collection systems must be transcribed by hand, leading to issues of data quality and throughput. We estimate that these outdated processes increase the costs of pre-clinical research from 15 to 25 percent." At a CRO, for those persons involved in study design, eNotebook design, data management and reporting, iAdvantage Software noted an 80% reduction in time requirements with its eStudy™ and ePublisher™ products versus paper systems; and a 50% reduction in time requirements with its products versus "islands of automation". Although there is less direct time savings associated with electronic data capture per se vs. paper entry (it is difficult to collect observational data easier and faster than with pen and paper), capturing the data electronically and saving the data directly into a relational database enables significant benefits associated with ease of access and subsequent manipulation and reporting of the data. The above time and cost reductions are further supported by a top-ten pharma that indicated that when electronic study management is implemented their internal estimate of time savings from protocol development through reporting, excluding data entry per se, is 67%.

Making the Right Choice!

Increasingly, technology and study management tools are available to allow the study director and those supporting the study to focus on successfully designing and conducting their studies electronically. It is critical that companies choose an electronic study management system that will not only meet their needs today, but one that also has the flexibility, capability, and scalability to grow with the increasing demands they will face tomorrow. Making the right choice initially will dramatically minimize, if not eliminate, the time and cost headaches of multiple, piece-meal systems, multiple implementations, validations and continued re-education of the users. A flexible electronic study management solution that is user-defined and user-controlled is a valuable tool that will do what it is supposed to do --- improve productivity, reduce time-to-results and increase revenue

About iAdvantage Software

iAdvantage Software is dedicated to empowering scientists and management in the pharmaceutical and biotechnology arenas with efficient, web-based electronic study management and reporting tools. Its products eStudy™ and ePublisher™ were designed by scientists for scientists to automate cumbersome tasks and provide flexibility and scalability to its users while operating in a secure, GLP and 21 CFR Part 11 compliant environment.

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