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researched by:**
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Well, Are We There Yet?

EDC Today is an independent publication on current information and issues in Electronic Clinical Systems (ECS) strategies and technologies for the Biotechnology and Pharmaceutical (Biopharma) industry. Each month we examine topics related to ECS theory, technology, practice, or implementation.

EDC Management understands that many Biopharma companies are looking for a comprehensive technological solution to the sometimes-vexing problem of efficiently conducting, databasing, analyzing, and submitting the results of, a clinical trial. As computer technology changes by leaps and bounds seemingly by the minute, one would expect to see, around the corner or in a yet-unsearched corner, such a solution to Biopharmas' business requirements. Unfortunately, it seems that such a solution still does not exist.

In this issue, we bring to your attention and respond to an article written by Ronald S. Waife found in the Association of Clinical Research Professionals' (ACRP) members-only publication of The Monitor dated December 2005 and titled "Technology Today: Are We There Yet?"¹ In doing so, we hope to discover why technology hasn't yet provided a truly successful solution and what might be done to expedite the journey down the tortured road that leads to nirvana, that is, the creation of a comprehensive technological solution to processing Biopharmas' clinical trials.

Introduction

Recently, in the ACRP's publication of The Monitor, Ronald S. Waife wrote a very interesting article titled "Technology Today: Are We There Yet?" In this article the author raises a number of questions and makes a number of compelling points. He states that Biopharmas, that is clinical research professionals specifically, are anxiously looking for computer technology that addresses their many needs and he feels that, and we here at EDC Management fully concur, none of the current technology is completely satisfactory. Mr. Waife thinks that while none of the current technology is completely satisfactory, the most modern of the technology is closer to addressing Biopharmas' needs than it was 5-10 years ago.

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What Are the Requirements?

According to Waife, even with the "basic components of the products and services," the leading vendors have failed to meet their users' needs let alone reach perfection. So what would be considered perfection? Waife defines the technological goal, that is, the perfection desired, as an application that is "an integrated R&D IT whole" having a universal, shared through-out the entire application, "common interface", which supports "spontaneous reporting" and having a robust and clearly defined and sharable/transformable repository (i.e., clinical trials database plus metadata). Furthermore, Waife states, the "basic vision" for Biopharma software should be that it be "easy to use, unobtrusive" (i.e., not have features that interfere with or impede day-to-day work), "fast, intuitive" (i.e., be easy to learn and to figure out functions), "comprehensive, multi-dimensional" (i.e., horizontally span organizational boundaries and requirements), "flexible, and reliable" (meaning, of course, bug free.) So in a nutshell, paraphrasing Waife, the perfection means that functionally, all gathered information "(about patients, investigators, laboratory testing, operational metrics) should be available" for instantaneous ad hoc reporting. Further, Waife says, the perfect solution should alert its users "to problems, dangers, issues, and to [things that are good to know]". And if that wasn't ambitious enough, users "should be able to access, [securely, all of] this information, according to [their] role, from any computer anywhere [in the world]."

In addition to all of the above, the perfect solution would also include the caveat that, again paraphrasing Waife, "all of this should happen without [the user needing to know] anything about [the biopharmas' software and hardware] vendors because the application "simply and consistently works" helping the user get their work done.

Whew! Is this indeed reasonable? After all, hardware and networking (connectivity and internet) have made a lot of progress over the past 5-10 years but Biopharma software seems to be slow to improve. So slow in fact, that many Biopharmas seem to have, according to Waife, greatly lowered expectations for software, both in utility and quality.

Why Doesn't the Technology Meet the Requirements?

So who is to blame, entirely or in part, for causing the problem? And more importantly, how can the problem be addressed?

Waife lays part of the blame on the size of the Biopharma software market. He asks us to recognize that the Biopharma software market in terms of the number of users is very small. There are only several hundred buyers. Contrast that with the several billion users of Microsoft Windows. Such a small niche-market gives vendors little incentive to produce packaged software tools aimed at Biopharmas' rather specific and somewhat difficult to meet needs. As a result, Waife feels, and we at EDC Management fully concur, that many software vendors are under-capitalized. Add to the mix confused, conflicting user "requirements" (or are these better termed "expectations"?) for the software aggravated by vaguely defined regulatory compliance requirements (e.g., what should an audit trail consist of?) and you get more than one person scratching their heads while trying to determine what the software should do, how it should do it, and how it will be paid for.

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Waife states in his article that a possible approach to addressing the problem is having the Biopharma industry form a coalition to fund and specify development of standard industry-wide usable application. This CDISC-like group would do far more than CDISC as it would bring consensus amongst the various biopharmas as to their needs and requirements combined with the funding to devise and implement one or more long overdue software solutions.

We at EDC Management have long pondered about value proposition of clinical software. We feel that the value of the software, if it worked well, is, in dollar terms, far more than biopharmas would seem to consider paying for it. What seems lost in the market pricing process is the understanding that the clinical research process is a core, very needed process for a biopharma. A biopharma would have no sales without an approved drug to sell. How much is a successful IT solution worth to such a company? How much is the perfection as defined by Waife worth? Surely, such software is worth much more than the hundreds of thousands typically spent on clinical research software.

One reads about “Blockbuster” drugs, that is, drugs that garner a billion dollars in sales per year², a figure that translates into the oft-heard million dollars a day a drug can be worth (i.e., in sales, not net profit) after it is approved. That “million dollars a day” is used as incentive by those in the biopharma industry to expedite the completion of clinical trials, as every day sooner is a million dollars to be made. One can ponder if software that trimmed days or weeks off the approval process was worth some percentage of that million dollars (for each day and for each drug it was used for!). Obviously, this isn’t quite the case, as one also reads that the cost of drug development, that is, the cost of bringing such a blockbuster drug to market, is argued to be in the one to two billion dollar range.³ Taking this into consideration, one assumes that biopharmas make no profit at all, at least for the first year or so a drug is on the market. However, looking at things from another angle, one could ponder how to price software that reduced the drug development cost by any significant amount. Even a seemingly insignificant one percent (1%) improvement (i.e., cost reduction) would mean a savings of tens of millions of dollars. It was further noticed that the money spent on marketing and advertising a drug in the first year or so after approval can amount to anywhere from \$40 million to \$150 million.⁴ We at EDC Management are left believing that the money is there and that a “successful”, let alone “perfect”, application that met Biopharmas’ needs and that brought a blockbuster drug to market, would be worth at least several million dollars per buyer.

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But Would Money Be Enough To Solve The Problem With Biopharma Software?

EDC Management suspects that part of Ron Waife's reasoning for a coalition (i.e., a "super-group") formed from the industry to generate a requirements document and to fund an improvement to a Biopharma IT solution, explicitly or implicitly, might mean restricting coalition membership to qualified persons. In order to make progress, it may well be necessary to remove the unqualified but assumed "stakeholders" from the process, as these people are often opinioned and in a position to obstruct specification or even minor process changes, when they are not truly qualified to offer creative or constructive input. It is uncomfortable to say, in the corporate world, that corporate politics and unqualified "voters" hold powerful and perhaps unmerited sway. There is a need for those involved in the clinical research arena to realize that they are respected professionals in a field other than clinical software.

EDC Management believes that there is quite a bit of merit to the thought presented by Waife that Biopharmas are "selfish" in guarding what they think are unique solutions, and therefore a competitive advantage, to age old (and perhaps intractable) challenges that clinical trials make on software. However, discerning what is and what isn't a competitive advantage is not an easy task.

Further, we believe that fear, uncertainty, and doubt (FUD) is a larger part of the problem of developing satisfactory software. There are at least three groups of people involved in the mix: The FDA, Vendors, and Biopharmas, all of which have groups of people that are involved in some way with deciding how software should work, irrespective of their qualification and technical understanding. FUD has an enormous hold on the Biopharma world.

For example, the fear of failing an FDA audit might lead the Clinical Data Manager to insist that "the audit trail" produced by the Clinical Data Management System be such that it will pass a hypothetical audit. However, what will or won't fail is uncertain at best, and possibly unknown altogether since the FDA regulation that covers the matter is not at all specific in terminology, thus everyone, the Clinical Data Manager, the software vendor, and possibly even the FDA auditor, is left in doubt.

Further confounding the problem is the abuse and misuse of language – for example, Biopharma software can, at best, be called "FDA regulation compliance capable" and cannot be called "compliant". Thus one wonders who might be the more ill-informed, the representative from the Biopharma asking a vendor salesperson if their software is "fully compliant" or the vendor's salesperson telling a prospective buyer that their software has always been "fully compliant"! It's little items such as this, piled ever higher on the pile, that add up to a situation that should drive someone tasked with buying or developing Biopharma software to reach for the bottle of Aspirin or Tylenol in exasperation.

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Conclusion

In the December 2005 issue of the Monitor magazine, Waife raises a number of points about clinical software, and basically states that the software should work a lot better than it does.

There are a number of reasons why Biopharma software does not work as well as it might reasonably be expected to, one of which being that there are too many different vendors, some of which have come into existence to satisfy the need for one specific biopharma company that in turn, paid for the development of the software. There being too many vendors, in turn, leads to many of them being under-capitalized. Another reason for the problem stems from the fact that too many people have too many different ideas about what the software should do, making any software development difficult and the end result most likely a “buggy” and non-user-friendly application.

Waife suggests an industry consortium to develop a joint software applications requirements document and fund the development of a standard, universal application, arguing that Biopharmas really gain competitive advantage in the efficiency they bring to standard clinical trials processes.

We at EDC Management suggest that more money than that spent on clinical trial software is available for improving it, and that it is in the Biopharmas’ business interest to fund such improvements. Furthermore, we feel that a large amount of FUD, with its various roots, is what is really causing the trouble with obtaining good high quality clinical trials software.

We urge our readers to consider joining the ACRP if they haven’t already to gain access to Monitor articles and other benefits. We would like to thank Mr. Waife for writing and having published a compelling, insightful article on the state of Biopharma computerization efforts.

Resources

¹ Ronald S. Waife, “Technology Today: Are We There Yet?” *The Monitor*, Dec. 2005: 79-81.

² http://en.wikipedia.org/wiki/Blockbuster_drug

³ <http://www.drugresearcher.com/news/printNewsBis.asp?id=48314>

⁴ <http://www.bizjournals.com/triangle/stories/2005/02/21/daily23.html>



Who's behind the research?

Our lead researcher, Kirk Mousley, PhD received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

Karl Mousley received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).



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