

**Based on research by:**

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**Written by:**

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In the next issue of  
**EDC Today:**

Careers in EDC: Keeping  
up with Changing  
Technologies

**About EDC Management:**

EDC Management is the leader in Clinical and Data Management and Electronic Data Capture (EDC) consulting services for the biopharmaceutical industry. EDC Management publishes well-researched and timely information about Electronic Data Capture technologies and processes through *EDC Today*<sup>TM</sup> and *EDC In Depth*. We do not sell or endorse any specific EDC software application or vendor. Improve process today; position for tomorrow.

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## State of EDC

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

*To assist organizations making the transition from paper-based clinical trials to EDC-facilitated trials, our fifteenth issue takes a look at the current usage rate and the predicted adoption (or pull back) rate for EDC across the Biopharma Industry, and highlights some EDC vendor consolidations, set backs, and failures. We then discuss EDC product evolution, including the expansion of features beyond those that have been previously considered an integral part of an EDC product, and touch upon EDC vendors' embracing CDISC standards (and why!) Finally, a note: in order to keep us in sync with the EDC industry on the whole, EDC Management is undergoing changes too!*

## Introduction

In April of 2002, EDC Management introduced its *EDC Today* publication with a feature entitled "The Emergence and Adoption of Electronic Data Capture (EDC) in Clinical Trials Data Collection". In that issue, we assessed EDC usage and adoption rates across the biopharma industry. A year has now gone by, and in a very rapidly changing technological arena, a lot has transpired. This issue sets out to bring our assessment up-to-date and discuss some of the changes and adjustments the industry has undergone in the past year. This issue will also point, when relevant, to previously published *EDC Today* issues that have discussed trends in the industry or explained some of the more technical concepts.

## EDC Usage Rate Across The Biopharma Industry

A year ago, we reported that the accepted EDC usage rate estimate was 4-5%. We cited a number of studies to support this assessment, and our numbers were more or less in agreement with numbers presented at conferences throughout the year.

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Today, however, according to Mark D. Uehling, a writer for Bio-IT World, “In the past year, some of the largest Biopharmas – Novartis, Wyeth, Bayer, and Roche – have finally reported greater confidence in EDC.”<sup>1</sup>

This greater confidence is one factor contributing to a larger base of EDC users. Uehling also quotes Kenneth Getz, saying:

“‘Adoption is increasing rapidly,’ said Kenneth Getz, founder of CenterWatch, a leading clinical trials publication and Web site, during the recent Bio-IT World Expo. ‘EDC is being used extensively in one out of four projects.’”<sup>1</sup>

In our *EDC In Depth* Research Report Issue No 1.2 “Current State of Clinical Trials Data Collection,” we presented a calculation of EDC use based on the size of the biopharma market, and the number of clients reported by representative vendors:

“Given that there are about 20 vendors, of which Phase Forward might be one of the larger ones and DataTrak might be about average size, that would yield a very rough estimate of approximately 240 customers. This rough figure indicates about 10% of the industry has actually purchased EDC software.”<sup>2</sup>

Surprisingly, however, Phase Forward stated in a press release dated May 19, 2003 that, “More than 300 companies worldwide use Phase Forward solutions.”<sup>3</sup> This represents an increase from 140 companies previously reported in our research report. While the current number of DataTrak clients could not be found in a search of public records, their quarterly report for the first quarter of 2003 indicates about an 80% increase in revenue.<sup>4</sup> If we apply that increase to the number of customers they reported last year, we could estimate 21 customers for DataTrak. Using our same formula, there would be a rough estimate of a total of 420 EDC customers (out of an estimated 2,000 to 2,500 companies). This would yield a usage rate of about 20 to 25%.

If we take the conservative number and assume the current EDC usage rate is about 20%, this shows a 15% increase over last year. This is a solid growth in usage, but not nearly the 30% expected by some in the industry who thought the usage rate would hit 80-100% by the year 2005.

## **Predicted Adoption Rate**

Although growth will continue to be driven by a general acceptance of EDC technology, it will also be driven by more end user acceptance and involvement, particularly as investigator sites become more computer literate.

Consider one common EDC configuration, the Application Service Provider (ASP), which over the past year has slowly caught on. Dan Muse, a writer for IT Management states that:

“One reason why the ASP model has not achieved faster adoption rates may lie with the customers themselves. Slowly, however, barriers to entry are coming down. Many companies interviewed pointed to internal tactical hurdles such as loss of control, retraining or eliminating workers, and sunk costs (i.e., money already invested in running software in-house).”<sup>5</sup>

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However, according to Harris N. Miller, the president of the Information Technology Association of America:

“While the name may change, the ASP model is here to stay. Customers in our report all found that the benefits to outsourcing to an ASP, such as freedom to focus on core mission and cost savings, far outweighed any tactical hurdles in the decision to outsource.”<sup>5</sup>

EDC Vendors have put out recent press releases about signing up new clients. While this could indicate that the market is still growing, in some cases these clients are not new to EDC but have just changed vendors in search of one that better suits their needs. For instance, DataTrak International, Inc. announced on June 3, 2003, that it had added a new multibillion-dollar North American client. It turns out that this client has simply changed its EDC vendor.<sup>6</sup>

Other EDC vendors have made similar announcements of large trials. Etrials claims that their QuickStudy Capture™ electronic data capture technology used in a recently conducted clinical trial was the largest “paperless” acute care clinical trial in their company history. We view this report as an indication that EDC has become an acceptable technology.<sup>7</sup>

However, there are still factors keeping the growth rate from accelerating. In fact, we are aware of several biopharmas that have pulled back from EDC initiatives, and are going back to traditional clinical data processing. These clients have stated that they have not been able to measure any real benefits of EDC. As one example, Briggs Morrison, VP of Worldwide Clinical Data Processing at Merck and Co., stated that Merck did not see a noticeable benefit to EDC. They will continue using EDC, but not as the sole method of collecting clinical trial data.<sup>8</sup>

Thus, we believe that over the next year, the factors affecting the growth rate of EDC adoption will largely offset one another, and the net affect will be a continuation of the current slower-than-predicted growth. We feel that at the moment, there is no widespread belief by biopharmas that EDC is the clinical trial data capture solution to adopt. It will take a collection of improved metrics and published success stories before the growth rate will accelerate.

## **EDC Vendor Consolidation/Failures**

Last year we predicted that an EDC vendor shakeout would take place. We believe the biopharma industry could support twice as many EDC vendors as it now supports in Clinical Data Management System vendors.<sup>9</sup> If this is the case, then perhaps 5 to 10 major EDC vendors will remain in this market space. Signs of consolidation are indeed apparent. Mark Uehling writes:

“Getz ticked off trials vendors that have recently...entered bankruptcy court (CB Technology), laid off staff (e-trials), or slashed salaries (Arracel).

[This] upheaval — along with persisting doubts about the technology — has made big companies nervous. ‘I’m seeing a lot of companies that are even more cautious about

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implementing these solutions than they were 18 months ago,' Getz said. 'We are seeing companies experiment with other vendors. They are still shopping around. It's an immature environment, and there is limited loyalty between the industry and the vendor.'"<sup>1</sup>

Publicly traded DataTrak International moved from the NASDAQ main board to the small caps funds. While some industry commentators see this "delisting" as an alarming thing, it appears to us, in reality, to be a minor adjustment.

We continue to believe that more market consolidation is inevitable and that this will continue to be an impediment to more widespread adoption of EDC technology.

### **EDC Product Improvements**

EDC products are becoming more scalable and robust. As an example, DataTrak reported on May 27, 2003 that they had set "new records for worldwide EDC implementations." They say that huge eCRFs can and are being handled - "[A recently implemented] 700-page eCRF included a phenomenal 4,720 individual rules and formulas that could be applied to each patient."<sup>10</sup>

Other EDC vendors have made similar announcements of large trials.

### **Expansion Of Features Beyond EDC**

Some sponsors feel that EDC is just a small segment of what really is needed to improve clinical data processing. These sponsors are looking for more than just EDC. They are looking for management and collaboration tools and tighter integration of clinical software applications. One response to this demand is evident with some vendors offering more portal features in their products. In *EDC Today* Issue 12, we stated:

"While an EDC application need not be part of a portal, portal technology can provide user-friendliness and additional information and support to EDC application users. In much the same way that Internet portals, such as Yahoo! or AltaVista, are gateways to Web content, access portals are browser-based systems that give users a single point of access to an organization's data and software applications from their desktops. This means that all study materials (such as the clinical Protocol, applicable SOPs, guidelines, instructions, and forms) can be located at the Portal."<sup>11</sup>

One example of a vendor's portal product is eResearch Technologies' eResearch Community™. Another is the portal interface to Acumen Healthcare Solutions' TrakIt2k™, which offers study reports and other documents.

*For more information about EDC and portals, please see EDC Today Issue 12, "Portals, and How They Can Make EDC Work Better".*

In addition, to cope with the large increase in the number of users of EDC software over that of existing Clinical Data Management Systems (CDMS), many companies are trying Web-based training. Over-the-Web training products from Centra and WebEx have been used by a number of biopharmas.<sup>12</sup> A number of EDC vendors have also added Web-based training to their product offerings. One of those vendors is DataTrak. According to their website:

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“DATATRAK offers a state-of-the-art, web-based training program for the DATATRAK Entry™ module. It is self-paced, offers proof of training, and has an assessment at the end of the course.”<sup>10</sup>

DataTrak stated that large numbers of people are being trained to use its product:

“Additional records were established for the training of users in multiple countries. The new achievements pertained to the number of people trained in a single study using the Internet and also included a cumulative number of users instructed with live training.”<sup>10</sup>

Features like autoencoding Adverse Experiences and laboratory value standardization are being added to EDC product offerings as well:

“...verbatim terminology is not particularly usable when analyzing clinical data, a variety of computer-based coding methods and dictionaries have been developed to encode such terminology for AE's and medications. The automation of this time-consuming manual process is a definite business advantage”<sup>13</sup>

Therefore, features like autoencoding Adverse Experiences and laboratory value standardization are being added to EDC product offerings.

*For more information about common “auxiliary” systems please see EDC Today Issue 11, “EDC and Legacy Clinical Data Management System Integration”.*

## **CDISC**

More EDC vendors are embracing CDISC, especially the ASP vendors, who see the use of CDISC data models as a means of overcoming issues related to data transfer between themselves and Biopharma sponsors. These issues include things like the lack of uniformity in data item (sometimes known as “question”) metadata definitions and lack of “upload support” into the sponsor’s clinical trials database.

CDISC data models have been gaining acceptance in an industry that has traditionally had problems embracing and using standards. Part of the driving factor is the proliferation of “contract” vendors. Another part is the emergence of tools such as XML that allow for convenient definition of standards.<sup>14</sup>

*For more information about CDISC please see EDC Today Issue 8, “Data Transfer Standards: How to Leverage Your Investment in EDC”.*

## **Conclusions**

EDC usage has risen in the past year. The rate of adoption, while not as large as predicted, is still significant. We have examined some of the factors such as increased acceptance of EDC technology, increase in EDC product robustness, and an increase in EDC-related management and collaboration features.

However, we have seen some pull back due to the lack of measurable benefits of EDC. We believe that continued development of metrics that show significant benefits will be required to contribute to better acceptance of EDC. Certainly EDC will continue to be examined for return on investment in the coming year.

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Meanwhile, with vendor maturation and market consolidations, time will bring forward the best of the vendors. While that is happening we will continue to see a maturation and evolution of their products. There appears to be more desire on the part of EDC vendors to offer a more complete data management solution and also a solution that is CDISC data model compliant.

## EDC Management Expands Its Focus

EDC Management is evolving with the market. The EDC market is embracing greater functionality beyond just data collection. Many EDC vendors offer management tools and reports along with their EDC product. The movement could broadly be termed as an evolution into Electronic Clinical Systems. To embrace the electronic clinical arena, EDC Management is expanding its focus to match the ever-widening definition of the products produced by the EDC vendors.

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## Who's behind the research?

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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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