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In the next issue of
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FDA

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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 TodayTM 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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Market Update

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.

Now that it is officially the year 2004, it is time to look at the EDC market and see what the New Year has brought in. In this issue, we update our assessment of the adoption rates of EDC, and present news and information from various vendors themselves. A key addition to this issue is an update on technology beyond EDC, such as patient diaries, handheld computers, and tablet PCs. We also examine some new possibilities of direct capture of clinical data from electronic medical records.

Introduction

Electronic Clinical Systems (ECS) are continuing to make in-roads in the clinical data arena. While Biopharmas may be slow in adopting new technologies, we believe they will continue to be pressured to find better and faster ways of processing and analyzing clinical data. Improving the clinical data handling area of clinical trials will involve a mixture of newer technologies and changing business practices and processes.

In this issue we attempt to determine what has taken place in the EDC market in the past year. We review our estimated EDC adoption rates from *EDC Today*TM, Issue 15, "State of EDC", and update our view of the adoption rate.¹

Then we delve more deeply into what is happening with EDC Vendors. The information we present is extracted from various EDC Vendor press releases; so all this information is publicly available. In addition to presenting financial and customer-related news, we also present any available information about ongoing vendor product development and refinement.

We examine some continuing roadblocks to ECS adoption and we examine how technology can, in fact, help Biopharmas in the adoption process itself.



Next we touch upon a few hot technology areas such as tablet computing and electronic medical records. We highlight information presented by Briggs Morrison of Merck and Co. at a recent ACRP conference.

Finally, we conclude with an assessment of what we expect to see in the upcoming year.

Review of market

In our past issues (*EDC Today™ Issue 15 and EDC In Depth Issue 1.2*) we estimated EDC usage by calculating the number of customers that were using EDC Vendors and divided that number by an estimate of the number of Biopharmas. In June 2003, we estimated there were 2000-2500 Biopharmas and that there were about 420 EDC Customers, giving us an adoption rate of 20 to 25 percent. This figure agreed closely with other published estimates.

As the New Year opens, our estimate of the number of Biopharmas remains at about 2,000 to 2,500. While it appears that there are about 50 or 60 new biotech companies², we believe the increase in the total number of Biopharmas in the past year has been relatively small. Looking at the EDC customer numbers, we estimate there were only a handful of new EDC adopters at the end of last year. So we estimate that the adoption rate has not changed significantly and remains at about 20 to 25 percent.

Sales of EDC products appear to have been relatively flat in the 4th quarter of 2003. We suspect that this is due to the fact that most companies do not buy major software at the end of year for budgetary reasons. However, there is an apparent increase in sales in the global market, specifically the European market. So what happened to the US adoption rate? Is the US market saturated? We don't believe this is the case. Perhaps the FDA's apparent temporary retreat on 21 CFR Part 11 requirements (see *EDC Today™, Issue 17, "FDA Withdraws Guidance for Industry 21 CFR Part 11"*) removed some of the pressure on US Biopharmas to update their Clinical data capture software.³ Perhaps, the large number of EDC vendors and an expected upcoming shakeout amongst them has a number of Biopharmas taking a wait-and-see approach. Perhaps too, there is a growing perception that EDC doesn't fully deliver what is needed. Or perhaps it is just a continued resistance to change within the Biopharmaceutical industry.

Certainly the news that several EDC vendor companies are reportedly looking to be purchased by another company would make one pause. Moreover, some EDC vendors (e.g., Mitchell Bayer, Senior Vice President of Medidata) expect further market consolidation and shakeouts. One could argue too, that technology is changing so fast that it has a paralyzing effect on those trying to adopt the most effective of the newest developments. We think that newer technology promises even greater changes over the next couple years than those seen in the past. Mobile computing is now "over the horizon" and the new year promises more changes as we move deeper into the wireless age.

(continued on page 3)



EDC Vendor News and Updates

EDC Management does not endorse any specific vendor or EDC solution. What follows is a cross-section sampling of news reported in 2003 from a large number of EDC vendors. For further information, please see the individual vendors' websites.

Acumen Healthcare Solutions

- Enhanced its TracIt2k® online system and its portal interface to provide better trial tracking and reporting.⁴

DataLabs

- Reported new major customers/studies for its DataLabsXC product on July 8, 2003 and September 22, 2003.⁵

DataTrak

- Application Service Provider (ASP)-model DATATRAK EDC™ Version 3.2 is being used globally.⁶
- Reported improved revenue but continues to lose money.⁷

eResearch Technology

- Continued to update its eRT Enterprise EDC/eResearch Community offerings.
- Announced Guidant Corporation's Cardiac Rhythm Management division was deploying its solutions on January 12, 2004.⁸

etrials

- In August of 2003, announced that it signed a contract worth \$3.7 million with a US-based "top-tier" Biotech Company. The contract covers conducting a Phase III study to be run at 600 sites in 17 countries and includes nearly 14,000 subjects using its QuickStudy Capture™ EDC technology.
- Participated in 400 clinical trials in more than 50 countries, including 11 trials that resulted in New Drug Applications (NDAs) / Biological License Applications (BLAs.)
- Announced it had closed its offering of Series A preferred stock after securing an additional \$2.5 million. Total investment is \$5 million.
- Announced its first profitable month and an end-of-year backlog growth of 250%.⁹

Lifetree Technology

- Announced it had been awarded a National Institute of Child Health and Human Development (NICHD) Contract, and its Department of Health and Human Services (DHHS) contract had been renewed in October 2003. Both contracts use ICTM, LifeTree's EDC platform.
- Released ICTM version 4.0.¹⁰

(continued on page 4)



Medidata Solutions, Inc.

- In October 2003, announced that it had experienced 11 consecutive quarters of growth.
- Claims to have been involved in over 50 studies.¹¹

Megasoft

- Announced the availability of Acceliant, its EDC offering which it obtained when it purchased Enmed.¹²

Omnicom

- On December 3, 2003, announced that Kos Pharmaceuticals, Inc. had selected its TrialMaster[®] solution to provide electronic data capture (EDC) service and support for an upcoming hypercholesterolemia clinical trial.
- In November 2003, announced the availability of its new TrialMaster[®] Archive, a self-contained program that allows the clinical trial sponsor to view all trial data in the captured format.¹³

Oracle

- On December 10, 2003, released Oracle Clinical/Remote Data Capture (RDC) version 4.5. This release is touted as “a major new release featuring advances in usability, form design and support for international trials. Pfizer Inc co-sponsored the development of this new release and has taken a license to the new release for use with future clinical trials.”¹⁴

Phase Forward

- On November 3, 2003, reported about 10 major customers signed in 2003 including Eli Lilly and Company.
- Claims its InForm[™] EDC product has been used in more than 400 trials at 85 countries by 12,000 clinical sites.
- Claims its products (i.e., Clintrial[™], InForm[™], and Clintrace[™]) and services are used by 11 of the top 15 pharmaceutical companies.
- Relocated its corporate headquarters to a larger building on December 15, 2003.¹⁵

PHT Corporation

- On January 13, 2003, announced that a global Pharmaceutical company had selected PHT Wireless LogPad[®], an electronic patient diary solution, for an upcoming phase II pain trial.
- On January 6, 2003, announced that the Beth Israel Medical Center was deploying PHT’s LogPad[®] in a Phase III study on lower back pain.¹⁶

Target Health

- Offered its ASP-model e*CRF.¹⁷

ViPS

- Acquired CB Technologies.
- Offered MetaTrial[®] EDC and myMetaTrial Portal solutions.¹⁸

(continued on page 5)



Adoption Difficulties (Roadblocks)

EDC adoption is still facing some resistance from people at Biopharmas who feel investigators and other investigator site personnel won't use it. However, seeing how most modern hospital sites have become completely computerized in their day-to-day activities, it's hard to fathom this attitude. Other sites, such as smaller physician offices, are becoming increasingly more computerized too. Granted, there remain a lot of people for which paper is best for what they are doing, but as computing becomes increasingly mobile, the last remaining strong appeals of paper (i.e., its "portability" and "permanency") will diminish. We have a nagging suspicion that the resistance to EDC lies not at the sites, but at the sponsor — amongst those that manage clinical trials and its data.

With the recent downsizing of many Information Technology (IT) staffs, there may be a lack of staff savvy enough to perform EDC deployments. Clinical Research Associates, Clinical Data Associates, and Clinical Data Managers may not be learning how the new technology works and keeping up with it. With technologic change, there is a whole new jargon and set of tools in which to become proficient. Biopharmas may not be keeping their staff's skills up-to-date. We suspect the range of skills needed to effectively conduct clinical studies using EDC overwhelms the staffs at smaller Biopharmas. Therefore, there is a need at a number of Biopharmas, especially smaller ones, for a lot of technical support (i.e., "hand-holding") from EDC vendors.

Many EDC vendors provide supporting consulting services, and some provide hosted EDC software using an Application Services Provider (ASP) model. Although these may help minimize the need for IT savvy staff, there is still a need for knowledgeable database design and analysis programming staff. Of course, moving beyond that, a Biopharma can contract with a Contract Research Organization (CRO), which has the IT people capable of running EDC trials.

In addition, as we discussed in *EDC Today*TM, Issue 18, "*EDC and Biopharma Careers – Using Portals and Workflow to Help With Job Functional Changes*," portal technology can actually assist both site personnel and biopharma personnel in making necessary changes in their job functions to match the shift from paper-based to electronic-based clinical data collection.¹⁹ In fact, a number of EDC vendors offer portal products which link to their EDC product.

Potential Hot Growth Areas

We feel that there are two areas in the eClinical arena that will grow enormously over the next few years — electronic patient diaries and mobile healthcare computing.

In fact, electronic diaries (See *EDC Today*TM, Issue 19, "*eClinical and Patient Diaries*" for more details) are being aggressively adopted.²⁰ The increasing demand for measuring Quality of Life improvements by Healthcare insurers has spurred an increase in studies that include patient diaries.

(continued on page 6)



Mobile healthcare computing - healthcare professionals using mobile computers such as palm pilots, Windows CE platforms, and recently, an even newer technology, the Tablet PC – may eventually replace healthcare professional’s use of paper for many activities. The key to the mobile computer revolution will be eCharts replacing paper charts. Briggs Morrison from Merck and Co. is advocating direct entry from patient charts.²¹ Certain Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations and concerns centered on patient privacy will have to be addressed, but the hope is that capturing data as it is recorded on the patient’s chart, will provide not only “one-time” data entry but also information in real-time. Development will need to be done so that data needed for clinical trials can be “layered” on the data capture system used for the patient’s care and billing at the investigator sites.

Tablet PCs may be the wave of the future. These PCs reprise the early “pen-based” computers but the technology has come a long way. Recent offerings, such as Eclipsys’ Sunrise Clinical Manager, provide inpatient clinical data repository (CDR), order entry, results reporting and care provider charting and documentation software.²² On Dec. 1, 2003, McKesson Information Solutions announced the availability of its Horizon Cardiology™, a comprehensive, image-enabled workflow solution designed for the workflow and imaging needs of cardiology departments.²³ These products can be run on a wireless, pen-based tablet PC computer. Within a few years, mobile computing may become truly practical and widespread.

Conclusions

We believe that Electronic Clinical Systems (ECS) are continuing to make in-roads in the clinical data arena. While Biopharmas may be slow in adopting new technologies, we believe they will continue to be pressured to find better and faster ways of processing and analyzing clinical data. Furthermore, we believe that some Biopharmas will need to beef up their IT staffs and improve the skills held by their clinical team members.

While we believe that the current adoption rate for EDC was relatively unchanged in the past 6 months, we feel that the resistance to change is within the Biopharma’s clinical departments and not within the investigator sites.

The news provided by EDC vendors seems mostly positive – product offerings continue to evolve and become increasingly refined. More takeovers and mergers can be expected, and for those remaining vendors, profitability (and thus corporate longevity) seems assured. The rate of technologic change, however, will not allow any EDC vendor to rest on their laurels.

New technology such as mobile computing (including Tablet PCs), electronic patient diaries, and electronic medical records may be the “break-through” technology needed to bring EDC into the realm of common day-to-day processing. More development is needed before electronic records are created and used “everywhere.”

(continued on page 7)



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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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