

COMPETITIVE ANALYSIS

U.S. Clinical Trial Management Systems 2004 Vendor Analysis: Leadership Grid and Market Shares

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LIFE SCIENCE INSIGHTS OPINION

Clinical trial management systems (CTMSs) help sponsors of clinical trials manage all aspects of clinical study planning, preparation, performance, and reporting. Trial sponsors are increasingly looking to replace homegrown systems or add much-needed functionality to their drug development IT infrastructure, and they have an array of choices for CTMSs to purchase. Life Science Insights' research into the competitive landscape of the CTMS market yields the following findings:

- ☒ The four companies placed in the leadership portion of the grid include Phase Forward, Oracle Clinical, Nextrials, and Medidata. Siebel and SAS are both on the cusp of being in a leadership position but must first meet the challenges of evolving functionality and partnerships before making the move.
 - ☒ Technology buyers should determine the functionality that will give them the best results while carefully watching the financial and operational viability of chosen vendors. The leaders identified in this document have strong functionality and market position, but technology buyers should look first at the fit of an application with their unique business needs before making a final decision.
 - ☒ Current leaders must assess their position and identify weaknesses while emerging players concentrate on their strengths and secure share in the expanding market.
 - ☒ System integrators and partners need to forge key alliances that will help them implement and customize solutions efficiently while meeting the business needs and budgets of a diverse group of pharma and biotech companies. As regulatory requirements and industry dynamics continue to evolve, these partnerships will be increasingly important.
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IN THIS STUDY

This Life Science Insights study examines the U.S. clinical trial management systems competitive market by profiling a variety of market players and provides tools for evaluating CTMS vendor strengths and weaknesses. In addition, it provides analysis of some of the market trends in the clinical trials management space. The companies profiled in this study are compared using Life Science Insights' Leadership Grid.

In *U.S. Clinical Trial Management System 2004–2008 Forecast and Analysis* (IDC #31996, October 2004), Life Science Insights described the market dynamics and size of the U.S. market for clinical trial management systems; each of the vendors identified in this document are profiled here. An in-depth analysis of the competitive position of each of the vendors is conducted, a Leadership Grid demonstrates the relative market position of each player, and a pie chart characterizes the market share of each vendor.

Methodology

In gathering information for this study and selecting companies to profile, Life Science Insights chose to provide a snapshot of a variety of software vendors. Vendors are categorized by the markets they serve as well as their functional and architectural strengths. A brief profile highlighting each vendor's strengths and issues is provided.

The companies profiled here differ in terms of size, company heritage, and approach to the market. Life Science Insights chose the following vendors in an effort to provide a glimpse into the market variations:

- ☒ Advanced Clinical Software (ACS) (www.clinicalsoftware.net)
- ☒ ClickFind's ClickTrials (www.clicktrials.com)
- ☒ ClinSource (www.clinsource.com)
- ☒ DataLabs (www.datalabs.com)
- ☒ eResearch Technology (eRT) (www.ert.com)
- ☒ Medidata (www.medidasolutions.com)
- ☒ Nextrials (www.nextrials.com)
- ☒ Oracle Clinical (www.oracle.com/industries/life_sciences/index.html)
- ☒ Parexel/Perceptive Informatics (formerly Fraser-Williams' IMPACT) (www.parexel.com/products_and_services/advanced_technology.asp)
- ☒ Phase Forward (www.phaseforward.com)
- ☒ SAS Drug Development (www.sas.com/industry/pharma/develop/)

- ☒ Siebel Clinical (www.siebel.com/clinical-crm/solutions-description.shtml)
- ☒ Winchester Business Systems (www.wbsnet.com)

SITUATION OVERVIEW

Introduction

In the sections that follow, the CTMS market is defined and segmented, and key players are defined and described according to their relative market positions.

Market Definition

Clinical trial management systems help manage all aspects of clinical study planning, preparation, performance, and reporting. Clinical trial management systems encompass trial data such as documentation (protocols, case report forms, etc.), patient recruitment and enrollment, investigator relationship management (IRM), monitoring, reporting, and cost tracking. While most vendors offer a subset of functionality, CTMS products might deliver a full spectrum of integrated modules, including the following:

- ☒ Investigator relationship management
- ☒ Investigator and site identification and recruitment
- ☒ Site management (grant payment management, financial disclosure, monitoring enrollment relative to plan, and IRB approval and decision status)
- ☒ Protocol and study documentation preparation
- ☒ Case report form (CRF) development and electronic data capture (EDC)
- ☒ Clinical data management (CDM) including CRF planning and distribution (whether electronic or paper)
- ☒ Financial management including tracking study costs, reimbursing investigators, and paying claims related to study activities
- ☒ Clinical supply management including supply tracking, storage, and shipment
- ☒ Clinical data archiving/warehousing and management
- ☒ Data analysis
- ☒ Monitoring and reporting
- ☒ Adverse event (AE) reporting, tracking, and documentation

Some products may offer a subset of rather than all these modules, but by IDC definition, CTMS applications deliver solutions spanning the clinical trial planning and performance time line, specifically providing functionality in four or more of the functional areas defined above.

Systems that manage this spectrum of information must be compliant with the FDA's 21 CFR Part 11 regulation in order to ensure that protocols, investigator brochures, CRFs, CTM information, and clinical data remains attributable, traceable, and controlled. This assurance is provided in CTMSs by underlying content management systems (CMSs) that themselves are Part 11 compliant, but they must be coupled with adequate training and documentation of the entire system's configuration and stability. Only vendors and applications that meet these criteria are included in this forecast.

In addition, role-based security at the enterprise level that meets 21 CFR Part 11 and HIPAA guidelines is a prerequisite for CTMS systems. The CDISC standard was developed by the Clinical Data Interchange Standards Consortium, supported by many large industry organizations, and provides data interchange standards to support the clinical trial industry. While CDISC compatibility is only beginning to be a feature of some systems, compatibility with CDISC and other standards is increasingly growing in importance and serving as a differentiator between systems. Management of electronic documents associated with a trial, or interoperability with document management systems, is key to CTMSs.

Leadership Grid

The Life Science Insights Leadership Grid is typically constructed with two main elements in mind:

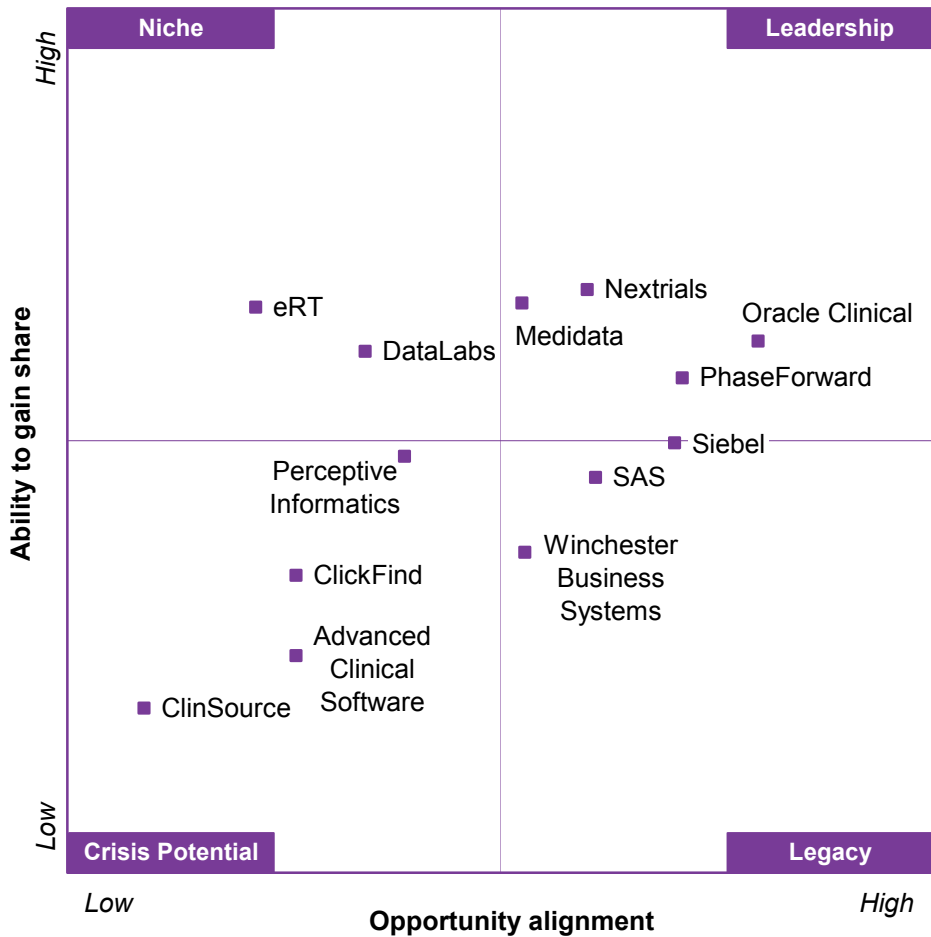
- ☒ **Opportunity alignment on the x-axis.** This is an assessment of how well the company's portfolio and capability matches what Life Science Insights believes to be key customer requirements in the selected market. Each element is scored on a scale of 1 to 10 in which 10 denotes a perfect fit. The aggregated scores are then plotted along the x-axis.

- ☒ **Ability to gain market share on the y-axis.** This is an assessment of how well the company is positioned to address the market opportunity and typically looks at sales and marketing capabilities, brand perception, and the portfolio of partnerships.

The Leadership Grid provided as Figure 1 identifies the competitive positioning of the leading vendors in the U.S. market. Within the grid, competitors are placed into four quadrants: leadership, niche, crisis potential, and legacy. This categorization is done on the basis of the vendor's growth potential and alignment of product and service offerings with the needs of the market. This grid includes a small number of vendors offering clinical trial management systems; those vendors not included in the grid can evaluate their own strategy and functionality on the basis of the discussion that follows to gain insight into their own market position.

FIGURE 1

Life Science Insights Leadership Grid: Clinical Trial Management Systems Market



Source: Life Science Insights, 2004

Leadership

The four companies placed in the *leadership* portion of the grid are Phase Forward, Oracle Clinical, Nextrials, and Medidata:

- ☒ **Phase Forward.** Phase Forward is placed in the leadership portion of the grid on the basis of its current position as a market leader. It has strong EDC functionality and appeal as a financially stable, proven vendor. With a large existing client base, the vendor must avoid complacency in order to grow its share as the market expands. Current development projects are aimed at integrating existing product lines with each other, and expanding the range of functionality, including Cognos integration, will also be important for Phase Forward's continued competitiveness.

- ☒ **Oracle Clinical.** Oracle Clinical is placed in the leadership portion of the grid on the basis of its current position as a market leader. It has strong hybrid trial and trial management functionality and appeal as a financially stable, proven vendor. Oracle has a large existing client base but must continue to build its EDC platform and relationships in order to increase its share as the market expands. Its EDC module, RDC, is relatively new and still awaiting widespread market acceptance.

- ☒ **Nextrials.** Nextrials is placed in the leadership portion of the grid on the basis of the strength of its extensive product offering and an estimate of the company's potential to build additional market share as the market grows. After a number of years of intensive development activity following the company's founding, the product offering is highly evolved and comprehensive. Functions include EDC, a safety module, supply capabilities, lab data management and enrollment, and randomization capabilities. This company stands out in recent competitive situations as a result of its innovative and broad functionality set, clear and simple user interface, and sound architecture.

- ☒ **Medidata.** Medidata is placed in the leadership portion of the grid on the basis of the strength of its clinical data management and EDC product offerings, positioning, ease of interfacing, and an estimate of the company's potential to build additional market share. Medidata's holistic view of the clinical trial process has made the product's architecture well suited to interfacing with other applications in an Internet-based trial environment. The simple yet powerful user interface compares well with other applications in the market. Medidata's strategy was to enter the market early with a narrow but strong functionality set. However, Medidata lacks functional components, such as a safety module, that would make it more competitive.

Niche

eResearch Technology and **DataLabs** are placed in the *niche* portion of the grid on the basis of their highly targeted product offerings. Both these companies have applications closely targeted at specific client needs and compete strongly against less targeted solutions in accounts where their specific strengths are highly valued.

Legacy

SAS and **Winchester Business Systems** are placed in the *legacy* portion of the grid. While SAS Drug Development presents a strong opportunity for the company, its historical positioning sets it firmly in the data analysis portion of clinical trial management, and it must grow its penetration outside this space to enter the leadership quadrant. Winchester Business Systems sits in the legacy quadrant as a result of the limited market for its Lotus Domino platform.

Crisis Potential

Several vendors lie in the *crisis potential* space. It is our opinion that these vendors need to closely examine and adjust their business models, positioning, and product direction to succeed in this highly competitive market and move toward leadership positions.

Calculation of Leadership Grid

The factors that were weighted to determine the company's ability to gain share included:

- ☒ **Current market share.** Current market share was a factor in the ability to gain future market share and was estimated based on end-user survey data and published as well as estimated software license revenue.
- ☒ **Breadth of product offering.** The relative breadth of the vendor's product offering within the varying sets of functionality that characterize CTMS systems was considered.
- ☒ **General appeal.** The general appeal of the vendor's functionality set and positioning as it effects the ability to gain share and market dominance over the next 18 months were considered, based on a number of metrics.

The scoring for opportunity alignment reflected the following:

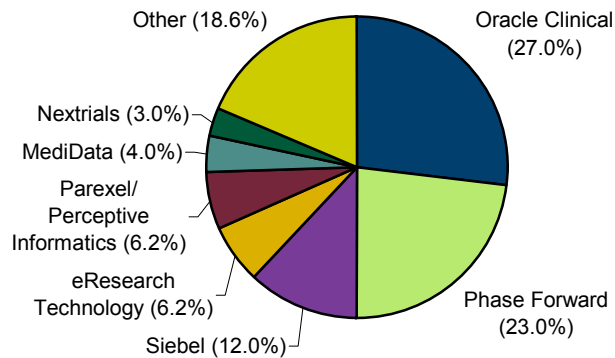
- ☒ **EDC functionality.** The strength of proprietary and partner offerings was assessed, with weight given to the ease of interoperability.
- ☒ **Project management, supply, and financial management functionality.** The strength and breadth of proprietary and partner functionality were assessed, with weight given to the ease of interoperability.
- ☒ **Ease of interfacing.** The ease with which the application and data source interact with third-party applications was assessed.
- ☒ **Nature of product architecture.** While a variety of configurations were included in the products analyzed, this category emphasized the functional advantages of Internet-based applications, applications with remote functionality, and applications with relatively small obstacles to regulatory validation.
- ☒ **Product positioning.** The fit and success of the products' positioning with the target market and the fit of the product's functionality with the target market were assessed.
- ☒ **Flexibility and configurability.** The ability of applications to be reconfigured to support a variety of trial workflows without custom programming was assessed.

Market Share

Figure 2 describes the relative market shares of the top 7 participants in the commercial, vendor-supplied CTMS space. According to our estimates, these vendors make up 60% of the CTMS market, while an additional 40% of systems are homegrown, custom-developed systems. This data is based on supply-side data from the vendors as well as demand-side data collected from the clinical trials segment of Life Science Insights' *Leading Indicators in Life Science* study.

FIGURE 2

U.S. Software License Revenue Share by Clinical Trial Management Systems Vendor, 2004



Note: This figure describes the 60% of the total CTMS market that is supplied by vendors.

Source: Life Science Insights, 2004

Market Strategies

Products included in this forecast are segmented by the type of organization to which they are marketed. CTMS systems are marketed to three main segments:

- Commercial pharmaceutical and biotechnology companies
- Research sites, site management organizations (SMOs), and academic and government institutions
- Contract research organizations (CROs)

While the uses of CTMSs in these three environments can be similar, these are specific functions and tools developed to meet the needs of particular users in their environment. This has created a de facto functional segmentation for CTMS products.

Table 1 classifies vendors according to the segments served. The characteristics of functionality marketed to these segments are described below.

TABLE 1			
Selected U.S. Clinical Trial Management Systems Vendors Segmented by Dominant Customer Type			
	Commercial Pharma and Biotech	Research, Academic, and Government	CROs
Advanced Clinical Software		Primary	
ClickTrials	Growing		Primary
ClinSource	Primary, medical devices		
DataLabs	Primary		Growing
eResearch Technology	Primary	Strong	
Medidata	Primary		
Nextrials	Primary		
Oracle Clinical	Primary	Strong	Strong
Parexel/Perceptive Informatics	Primary		
Phase Forward	Primary	Strong	Strong
Siebel	Primary		Strong
Winchester Business Systems			Primary

Note: Primary indicates the target market for a product, strong indicates a secondary market in which the vendor has appreciable market share and functionality, and growing indicates a target market in which a vendor is gaining strength.

Source: Life Science Insights, 2004

Pharmaceutical and Biotech Companies

Pharma and biotech companies are the ultimate sponsors of trials, whether they are conducted by clinical staff inside the company, CROs, or academic researchers. Pharma and biotech companies are responsible for monitoring the activities of any research conducted on their marketed pharmaceuticals and compounds in development, reporting adverse events to regulators, and assembling the data necessary for regulatory application completion. Their relationships with researchers are critical to success, whether they are internal, at partner CROs, or external to the company. The CTMS systems designed for use by pharma and biotech companies reflect these priorities.

CTMS functions important to pharma and biotech companies include:

- Central management of trial costs and timely payments to sites and investigators
- A "dashboard" or similar environment to tracking enrollment and study progress across multiple sites and/or studies for a particular drug, a therapeutic area, or an entire corporation
- Functions that allow sponsors to spot and manage potential delays before they become severe
- Managing relationships with sites, CROs, SMOs, and investigators
- Clinical trial supply management

As the largest segment of the CTMS market, pharma and biotech companies are supported by the largest, most visible vendors in the space. Oracle, PhaseForward, and Siebel all have significant footprints in this segment. Smaller vendors serving niches within this market include Medidata and Outcome, a leader in Phase IV trial management.

Research Sites and Academic and Government Institutions

Research sites and academic and government institutions constitute a secondary market for clinical trial and site management software. These institutions are faced with conducting trials with multiple sponsors and subsequently, multiple systems, and often seek out a single system with which to consolidate the research operations of the institution. In addition, these systems are used to support research projects at the institutional level, particularly in the teaching hospital setting. While these projects may be subsidized or otherwise sponsored by pharma and biotech companies, they are directed by academic professionals. Functions of these systems include:

- Enable the efficient management of multiple trials at different stages, with different sponsors and multiple researchers
- Build protocols and construct budgets at the site level
- Coordinate patient visits and procedures
- Monitor revenue, profitability, and contract milestones
- Track reimbursement of professionals by commercial clinical trial sponsors
- Follow recruitment activities and conduct analysis of their effectiveness
- Facilitate activities of the institutional review board

Typically these applications do not include their own EDC capabilities because trial participants are likely required to use the EDC systems put in place by sponsors or CROs. However, this is expected to change as standard communication protocols for the conduction of trials, particularly CDISC, emerge and interfacing between EDC and

trial management becomes simpler. As this happens, these research site management tools may begin to centralize EDC for multiple trials while transferring loading data into the sponsor or CRO's trial database or EDC system. This will allow more academic and other types of clinical research facilities to use their own management systems yet share data with external systems under controlled, secure circumstances.

An example of a vendor that specializes in serving this market is Advanced Clinical Software (see its profile the Vendor Profiles section). Phosco, a United Kingdom-based open source offering, provides EDC capabilities to European academic researchers in a specialized system of this type. While many large CTMS vendors such as Siebel, Oracle, and SAS provide this market with applications, they typically do not offer specialized functionality or are priced too high for any but the largest clinical research centers.

Contract Research Organizations

Contract research organizations seek to organize trial activities conducted by multiple clients while maximizing the productivity of clinical research staff. For CROs, the ability to communicate to sponsors up-to-date information on trial progress at each site, enrollment, and interim data results is crucial to maintaining good relationships with clinical trial sponsors. For this reason, the CTMS systems used by CROs focus on these functions, providing a trial "dashboard" view that is often accessible at both the CRO data manager and trial manager levels and often directly by the sponsor.

In systems designed for use by CROs, the following functions are important:

- Tracking of enrollment and progress of trials in reports and metrics easily made available to sponsors, whether by direct access to the CTMS system or by reporting
- Tracking of costs associated with trials, often including time and expense tracking for contractors
- Maintenance of a trial database containing the clinical data for the trial in a format easily shared with sponsors
- Project planning and management, data management planning
- Staff allocation
- Management of change order issues by sponsors

ClickFind's ClickTrials application and Winchester Business Systems' Protocol Manager CTMSs are examples of vendor applications optimized to serve CROs in their trial management activities. DataLabs is another vendor aiming at the CRO user segment.

FUTURE OUTLOOK

Vendor Profiles

The vendor profiles that follow provide brief descriptions of CTMS vendors that have been identified and characterized using the definition discussed in the Market Definition section of this study. The selection is by no means intended to be all-inclusive, and the profiles do not provide complete descriptions but characterize the vendor in relation to the market factors discussed in this document.

Advanced Clinical Software

Advanced Clinical Software was founded in 1993, is privately held, and focuses on providing research sites and academic institutions with applications that allow its clients to:

- Manage budgets, payments, and reimbursement for trial activities
- Schedule and track patient visits and procedures
- Track revenue, profitability, and contract milestones
- Follow and analyze recruitment efforts

ACS provides two products: Study Manager and Study Manager Web Edition. These two products provide CTMSs with two different architectures that allow sites to manage multiple trials in one place. ACS' stated future development strategy is to add EDC capabilities to the application via development or partnership. Standardized data collection via protocols such as CDISC are expected to be important for this company. The company claims to have 1,500 users, which appear to be mostly at academic institutions.

ClickFind's ClickTrials

ClickTrials is a specialty vendor that partners with CROs to provide EDC and related clinical trial management services. This small United States-based company, which has about 20 employees, is currently poised to grow. ClickTrials' product is the eClinical Platform, which provides a number of clinical research management tools.

ClickTrials' functionality is directed at CROs and is frequently licensed to CROs in private-label arrangements. As a CRO's technology partner, ClickTrials provides technological expertise as well as programming to customize the application, data management and other service assistance, training, and technical support. The system is XML based, with a no-footprint client architecture that simplifies validation at the clinical site. The system has collaboration functions to support trial team relationships in a role-based security environment. An innovative server caching system keeps page-turn times down while allowing for highly complex edit checks on CRFs. A workflow design tool accommodates the existing processes of CRO clients. ClickTrials has experience working with digitized electrocardiogram data.

This system's optimization for the CRO environment gives it strong data export/mining capabilities for metadata extraction as well as built-in reports and ad hoc reporting capabilities. Increasingly, the company is targeting the direct-to-sponsor market as important to its future growth.

ClinSource

ClinSource is a Europe-based EDC and CTMS vendor that specializes in supporting electronic clinical trials for medical device manufacturers, which comprise the majority of its clients. Its flagship product is called TrialXS. TrialXS has four modules that address trial management, electronic clinical data capture, CRF design and versioning, reporting, statistical analysis, and data verification.

DataLabs

DataLabs, a Microsoft partner, offers a system rooted in software technology. The company's focus is directed primarily at creating a low-cost EDC environment that requires little to no process reengineering to implement. Its low price point is designed to be leveraged profitably through partnerships. DataLabs is a closely held, privately financed company poised for growth in 2004. DataLabs currently has 35 employees and expects to double in size by year-end. Prior to mid-2003, DataLabs provided technology to Merck under an exclusive arrangement, supporting its United States-based trials, primarily in the Phase IV area but with pilot programs in other phases.

DataLabs' focus on Microsoft-based software technology includes innovative use of Visio, which provides DataLabs' users with a graphical trial design environment for building CRFs and workflows using their existing processes. The system is organized to support rapid transaction speeds and has a zero-footprint client/server architecture that simplifies validation efforts at trial sites. XML technology and CDISC support guide the company's partnership-based growth strategy. The company's current focus is on building its integration capabilities and partnerships with CROs with a future strategy that would incorporate expanding CTMS capabilities in a .NET/InfoPath environment.

eResearch Technology

eResearch Technology was founded in 1977 and has been publicly traded since 1997. The company offers niche expertise in the management of cardiac safety data, specifically centralized electrocardiographic services. eRT was a leader in developing technology required for digitally extracting and storing ECG information for use in measurement of the QT interval in Phase I trials. This has become an important NDA component as the FDA seeks data on this biomarker in Phase I to help rule out the possibility of cardiac adverse events resulting from a new drug. Along with the FDA, the International Conference on Harmonization (ICH) is also in the process of making the QT interval prolongation reporting an international requirement. In addition, eRT provides embedded technology to Siemens Medical Solutions via a partnership agreement signed in 2003.

eRT also licenses software to support clinical data management and offer EDC capabilities.

Medidata

Medidata was founded in 1999 and focuses on ease of use and implementation as its key strengths. Medidata's RAVE platform provides clinical research professionals with a workflow tool that accomplishes study design, implementation, EDC, and trial management. An emphasis is placed on customizability and reusable components.

The privately held company has been experiencing strong growth, more than doubling in size in both 2002 and 2003, and it was named to Deloitte Technology's Fast 500 and Fast 50 in New York in 2003. As of May 2004, the company indicated that it had managed 85 EDC trials.

Nextrials

Nextrials was founded in 1999 by a management team of former Genentech executives and is privately held. The company offers its clients both software, including the Prism CTMS, and CRO services in selected, strategic engagements. The Prism CTMS includes EDC functionality and is targeted toward small and medium-sized biotech and pharma companies yet also has a number of clients in the medical device space. The application is currently available only as an ASP, but the company states that a solution that would enable onsite installation via a technology transfer arrangement is in development.

The CTMS is built entirely in XML, and the company places an emphasis on participation in CDISC development, with future CDISC compatibility as a differentiator. Specialty features include interfaces that allow the system to access laboratory data, online randomization, supply tracking functionality within the application that pulls data from third-party enterprise supply chain management applications, and an adverse event reporting system that produces Medwatch-format reports, with international capabilities on the development horizon. Prism offers file-level interoperability with SAS, and statistical analysis and predictive modeling services are available via the CRO arm of the company.

Nextrials has pulled together an impressive functionality set after a few years in operation, largely enabled by the XML-based environment. Prism's elegant and innovative toolset also shows well in a product demonstration environment. This makes it a strong challenger in the CTMS and EDC market, where competitive buyers in pharma and biotech are always open to a new tool that has the potential to add a technological edge to their trials.

Oracle

Oracle's product family is built around the Oracle Clinical application, which supports paper and hybrid clinical trials, but it also includes newer applications for electronic data capture and adverse event reporting. While the products support clinical processes, Oracle has successfully leveraged its corporate strengths in creating and maintaining enterprise software technology with the Clinical application.

Increasingly, Oracle is expanding beyond EDC to develop (or acquire) a suite of point solutions that may be integrated into a full CTMS. This developing suite holds promise as a CTMS. Current functionality resides in the electronic data capture, case

report form, adverse event reporting, and study monitoring and reporting areas. Additional functionality is available via partnerships and integration. Oracle's Clinical tool is highly regarded for supporting paper and hybrid trials. Oracle also offers its RDC tool, which was introduced in 2003 and is rapidly gaining market share, to support electronic trials. The SiteWorks acquisition provided project, site, and financial management tools to Oracle users.

Parexel/Perceptive Informatics (Formerly Fraser-Williams' IMPACT)

The International Management Package for Administration of Clinical Trials (IMPACT) application suite was formerly available through Fraser-Williams but is now offered by Perceptive Informatics, a division of CRO Parexel. IMPACT supports planning (integrates with Microsoft Project), documentation, clinical payments, and deliverables (provides an investigator portal to manage clinical site recruitment, enrollment, document preparation). IMPACT is compatible with interactive voice response (IVR) systems, imaging review and storage applications, and INITIATOR and INVESTIGATOR packages. There are currently 14,000 users globally.

Phase Forward

Phase Forward's core competency is in EDC, but with some basic project management functionality built into the product and the recent announcement of an integration with Cognos' ReportNet (product release expected by end of 2004) expanding the vendor's reporting and financial management capability, it is evolving into a more fully functioned clinical trial management system vendor. Phase Forward's hurdles are mostly around internal issues and the continued drive to better integrate the existing products with each other. However, for sponsors already using Phase Forward's EDC solution, the opportunity to move to CTMS functionality while staying with this vendor's technology appears to be emerging. Phase Forward has full functionality in its core EDC, CRF, and AE reporting applications. Its strong client base makes it a leader in EDC.

SAS Drug Development

SAS' statistical applications have been the industry standard in analysis of clinical trial data for a number of years. SAS transfer files are a part of every new drug application submitted to the FDA, which is also a SAS user. With this strong base in analysis of clinical data, SAS built the Drug Development suite to manage the process of conducting clinical trials. While the Drug Development application does not include EDC capabilities, SAS is partnering with vendors including eTrials and Constella to provide a clinical trial data management solution.

The SAS application targets the analysis of trial metadata, allowing companies to actively monitor the progress of trials and proactively address problems. It also allows for site-level planning and prediction of performance. Advanced pharmacovigilance capabilities take advantage of SAS' strengths in data analysis. When used in conjunction with EDC, SAS Drug Development provides a low-cost CDMS in which trial data can be analyzed and the required SAS transfer files prepared for regulatory submission, without use of a third application.

Siebel Clinical

Siebel Clinical's portal architecture helps track, profile, and manage investigator sites and personnel and manage clinical sites through calendars, trip report templates, payment management tools, and study manager tools such as CRF templates to help manage data collection and study report templates.

Winchester Business Systems

Winchester Business Systems is a privately held niche provider of CTMS software and services to a client base consisting primarily of CROs. Its Protocol Manager CTMS product uses a top-down approach to clinical trial management, providing visibility of the entire trial process to authorized users, as designated using a role-based access model. Functionality includes IRM, subject recruiting, site monitoring, project management, document management, supply management, financial management of trial activities, and time and expense reporting for CRO services.

What makes Winchester unique is its platform: The program resides entirely within the Lotus Notes/Domino platform. This low-cost platform is well-suited for clinical trials. Winchester markets the application via partnerships with both IBM and Lotus. Extensive services include a sophisticated model for implementation support and regulatory validation for both its software and hardware (IBM hardware reseller).

ESSENTIAL GUIDANCE

Life Science Insights places vendors on the Leadership Grid in an effort to quantify their strengths and weaknesses in comparison with competing vendors and market expectations. The Leadership Grid should be used as a tool for examining the product offerings and positioning of vendors and their products and services. Life Science Insights believes that CTMS vendors will introduce new functionality and interoperability between systems that could significantly change available product offerings, and that the content of this Leadership Grid has the potential to change dramatically in the near term as vendors customize solutions to better match customer needs. Buyers of CTMS systems should take the following into account:

- ☒ Growing price pressure is expected to cause erosion in application pricing as sponsors look to licensing arrangements such as hosting and ASPs to lower the entry cost for applications, creating additional competition. As this happens, we expect application pricing to remain constant or fall as a result of competitive pricing.
- ☒ A highly competitive market will force all vendors to refine their products and services in order to compete effectively and meet the increasing demands of trial sponsors.
- ☒ Suppliers and integrators in the CTMS market should be encouraged by the forecast 13% CAGR expected in the market. With software license revenue of \$190 million in 2003, significant growth opportunities are available for current vendors and emerging competitors. We believe this growth in the coming years will lead to an increase in the importance of partnerships between vendors and

relationships with third-party providers of complementary applications and services.

- ☒ An increasing level of customization is expected to become available in off-the-shelf products, and a growing number of vendors will develop the functionality needed to enter the market. Many of these new entrants will come from the EDC space as the market for CTMSs matures and EDC vendors add additional CTMS functionality to remain competitive.
- ☒ Trial sponsors are expected to move from custom and homegrown systems to vendor-supplied systems as the available applications become more competitive and sponsors seek the stability and support of commercially developed applications.

Challenges exist in multiple areas of the market as newly available technology strives to meet the needs of stakeholders. In addition, we expect new challenges to arise in the coming years as vendors and trial sponsors rise to meet the emerging demands, a few of which include:

- ☒ Supporting group sequential and multiarm trial designs
- ☒ Accommodating growing numbers of trials using clinical genomic data
- ☒ Intensifying efforts by sponsors and regulators to extend adverse event reporting into full-spectrum pharmacovigilance
- ☒ Adding CDISC data interchange format compatibility to facilitate interoperability between applications
- ☒ Complying with regulatory requirements
- ☒ Improving the value equation for applications as cost containment pressure continues to intensify in the clinical trial application market

These challenges, as well as those addressed in this document, will drive future developments and provide opportunities to create new leaders in this space.

Clinical Trial Sponsors

Clinical trial sponsors should consider CTMSs as a tool to automate trial processes, increase the efficiency of their trials, improve communication between trial teams, and better manage the finances and logistics of trial operations. This Leadership Grid should serve these sponsors as a tool to assess potential application acquisitions and to help make decisions on new technologies in the CTMS space. While sponsors should consider the market share data quantified in this document when assessing the financial viability and long-term stability of a vendor, the data should not be a deciding factor because there is clearly significant movement going on in this market.

Many clinical trial sponsors have looked at systems in the past but may have been disappointed by vendor offerings or made the decision to develop internally as a result of the need for specialized functionality. While this market is still not at full maturity in terms of functionality offerings for trial sponsors, it is worth reexamining

frequently over the course of the next one to three years as the opportunity to adopt a system that can save in trial management costs but that comes with a lower total cost of ownership than homegrown or custom systems may exist for clinical trial sponsors.

Contract Research Organizations

As CROs enter the age of EDC, they are increasingly under pressure to provide technologically advanced trial services to sponsors that may themselves be averse to technology. CROs need to look at the spectrum of offerings available and select EDC partners and product offerings, taking the guidelines and expectations of their clients into account. While this document considers vendors primarily from the perspective of the functionality needs of pharma and biotech trial sponsors, CROs can use this document to assess the competitive position of individual technology vendors as well as to compare these vendors with their own partners or proprietary offerings.

As CDISC and other data interchange standards emerge, CROs may increasingly be able to cut costs by streamlining systems for EDC and trial management with multiple sponsors but still provide the data and communication that sponsors need, in the formats to which they are accustomed. While many good CTMS systems focused on the needs of CROs exist, the emergence of CDISC should provide the next step for these applications to provide a more complete range of functions that CROs can use to service multiple sponsor organizations.

Vendors

Vendors should note when examining this Leadership Grid that no vendors were placed at the top of the leadership quadrant. The market for CTMSs is still relatively immature, and while existing vendors continue to make progress, the industry still lacks a comprehensive vendor-supplied package for clinical trial management. This product would provide all the needed functionality in a single package, alongside CDISC compatibility and a realistic price that allows sponsors to see a return on systems investments. There is room for improvement in the positioning, product, and service offerings of all of the vendors mentioned, and even those characterized as leaders should avoid complacency.

At this time, the bulk of CTMS spending is spread among a few leaders, with a large number of small vendors working on the edges to innovate with new technology and approaches to problems in clinical trial management, with varying amounts of success. The overall sentiment of end users is mild disappointment as applications supplied by the current market share leaders create some clear efficiencies but often fail to meet a large enough subset of users' needs and requirements.

Life Science Insights expects to see the CTMS market reach a tipping point in the next few years, when some vendors (or combinations of partnering organizations) begin to see and demonstrate clear success with technology. In some cases, the premium pricing of existing, leading CTMS applications has set the bar too high for customer satisfaction, and vendors that are able to deliver at a lower price while still maintaining profitability will have an edge on customer satisfaction. The vendor (or

vendors) that is able to create the full package of CTMS functionality at a reasonable price while responding to user needs will undoubtedly see marked success in the coming years.

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