Ovum Decision Matrix: Selecting a CTMS Solution, 2013–14
SUMMARY

Catalyst

The complexity and cost of conducting clinical trials has been steadily increasing and is threatening the profitability of drug candidates and the economic feasibility of drug discovery research projects. The industry has to lower these costs, particularly as governments and payers of healthcare are looking to lower the cost of providing care and the cost of pharmaceuticals. Furthermore, the development stage of the drug lifecycle is increasingly being viewed by life sciences organizations as a potential source of competitive advantage. Organizations are seeking to reduce the cycle times that drug candidates take to either fail or reach the market. In today’s competitive therapeutic areas, first-mover advantage can result in significant financial rewards. Concurrently, pharmaceutical manufacturers are increasingly sourcing the execution and management of clinical trials from external third parties, driving growth in the small to medium-sized enterprise (SME) segment of the clinical trial management systems (CTMS) market.

This Decision Matrix looks at the five top CTMS vendors and compares their products to help life science organizations better understand the CTMS vendor landscape.

Ovum view

The CTMS market is evolving and moving rapidly to keep up with the rate of change within the industry. The industry is demanding far greater standardization, out-of-the-box functionality, SaaS-based solutions, and greater flexibility in pricing and licensing options. These demands are a reaction to increasing complexity in the operating environment and the trials themselves. Pharmaceutical companies are outsourcing more clinical trial execution to contract organizations to increase sourcing flexibility and to focus on higher value activities such as drug discovery. With personalized medicine and increasing regulatory requirements, clinical trials are becoming more and more complicated. These issues, combined with near-real-time report demands, mean contract and academic organizations are increasing their adoption of CTMS solutions. Ovum expects this outsourcing trend to continue with a proliferation of specialty clinical research organizations (CROs) and academic research organizations (AROs). This segment of the market will continue to show above-average growth. Furthermore, the competitive intensity of the CTMS market will grow as vendors continue to invest heavily in developing their solutions.

Key findings

- The costs associated with clinical trials continue to increase, threatening the overall profitability of novel medications.
- Clinical trials have become more complex as medical research and drug therapy move toward personalized or precision medicine.
- The increased complexity, cost, and geographical sprawl of clinical trials is driving the need for IT to facilitate the execution and completion of trials more cost effectively.
- Large IT vendors are building or integrating e-clinical suites that include CTMS.
- The focus is on price and modularity to adapt to the evolution in the marketplace.
Methodology

Vendor selection

The CTMS market can be divided into different categories based on size, functional breadth, and client focus:

- Firstly, there are a handful of large vendors: Oracle, Medidata, and Parexel. Then there are a series of smaller vendors, of which Ovum has selected two that are growing rapidly in the market: BioClinica and Bio-Optronics.
- Another segmentation of the vendors divides the competitive landscape into two camps: those vendors that offer a more comprehensive end-to-end suite of e-clinical solutions including electronic data capture (EDC) and the smaller vendors that offer point CTMS solutions.
- Lastly, there are vendors that provide functionality for clinical trial sites and those that offer solutions that cater to both sites and enterprises. In this Decision Matrix, Ovum has selected the largest vendors in the market that offer end-to-end suites of e-clinical applications (with the exception of Bio-Optronics) and vendors that cater to both clinical trial sites and life science enterprises.

Technology assessment

In this assessment dimension we analyzed a number of features and functionalities that provide differentiation between the leading solutions in the marketplace:

- Usability/ease of use – the extent to which each vendor’s solution can be configured to accommodate the different functional needs of client organizations. Examples include the ability to configure role-defined workspaces or dashboards, and multilingual and currency support.
- Flexibility – the variety of pricing and licensing options that the vendor makes available for organizations, and each solution’s ability to scale to meet the changing needs of client organizations.
- Breadth of offering – the ability of the solution to support the different business activities and processes of the different stakeholders in the management of clinical trials.
- Development roadmap – the vendor’s commitment and resources to further developing the solution. This includes not only functional and technical innovation but also licensing and pricing innovation.
- Reporting and analytics – the extent to which the solution provides sufficiently robust tools and capabilities to evaluate and optimize sales and marketing campaigns.

Execution

In this dimension, we review the capability of the solution around the following key areas:

- Interoperability – how easily the solution/service can be integrated into the organization’s operations, relative to the demand for integration for the project.
- Innovation – this can be a key differentiator in the value that an enterprise achieves from a software or services implementation.
- Deployment – various deployment issues including time, industries, services, and support.
- Professional services – the availability of sufficiently skilled professional services teams to support implementation and provide strategic advisory services around relationship management.

**Market impact**

Market impact is measured across the following five categories:

- Revenues – each solution’s global revenues are calculated as a percentage of the market leader’s.
- Revenue growth – each solution’s revenue growth estimate for the next 12 months is calculated as a percentage of the growth rate of the fastest-growing solution in the market.
- Total life sciences revenues – revenues attributable to the vendor’s life sciences industry vertical.
- Geographical penetration – Ovum determines each solution’s revenues in three regions: the Americas, EMEA, and Asia-Pacific. These revenues are calculated as a percentage of the market-leading solution’s revenues in each region.
- Market segmentation coverage – Ovum determines each vendor’s presence in the different market segments for the clinical trial ecosystem. Market segmentation is defined by both type and size of organization. The vendor’s overall company market segmentation score is a representation of its coverage of the different segments.

**Ovum ratings**

- **Market Leader:** This category represents the leading solutions that we believe are worthy of a place on most technology selection shortlists. The vendor has established a commanding market position with a product that is widely accepted as best-of-breed.
- **Market Challenger:** The solutions in this category have a good market positioning and the companies are selling and marketing the product well. The products offer competitive functionality, a good price-performance proposition, and should be considered as part of the technology selection.

**MARKET AND SOLUTION ANALYSIS**

E-clinical is becoming increasingly important as the industry seeks to reduce costs

**Overall profitability of novel medications is under threat due to increased cost and complexity of trials**

The pharmaceutical industry is undergoing tremendous change in response to revenue and efficacy pressures. Healthcare payers are demanding more value from their medications and higher degrees of efficacy over existing medications. Payers are making mandatory price reductions to the cost of medications, thus lowering the profit margin for biopharmaceuticals. Clinical trials have become more complex, and will continue to do so. Medical research and drug therapy is moving toward personalized or precision medicine: drug therapies are designed to treat more specific patient profiles.
than the blockbusters of the past, and require the implementation of more procedures. According to Tufts Center for the Study of Drug Development, the average number of procedures per protocol in 2002 was 106, compared to 167 in 2012 (source: Getz et al. Variability in Protocol Design Complexity by Phase and Therapeutic Area, Drug information Journal, 2011 45(4); 413-420).

This shift has far-reaching implications for the industry and particularly for clinical trials. Smaller target patient populations for medicines mean smaller clinical trials, but sourcing those patients will be much harder. Running more but smaller trials also inhibits the realization of economies of scale, as certain fixed costs are incurred regardless of the number of patient participants. The smaller eventual target patient population also means a much smaller market in terms of revenue for approved drugs. The costs associated with running trials therefore need to come down for projects to be economically viable.

In response to this, biopharma companies have been making significant changes to their business and operating models. Clinical trials are increasingly being conducted outside of the US to lower operational costs and increase the pool of patients from which to recruit trial participants. However, this geographic sprawl increases the operational complexity of clinical trials, and the added logistics increases costs, undermining the value proposition of international patient recruitment.

**Building up clinical IT is the top priority**

Biopharmaceutical companies are looking to technology to transform the drug development process. According to Ovum’s annual survey of life sciences IT decision-makers, IT budgets are up and expected to continue to increase (see Figure 1). This demonstrates the increasing importance that the industry places on the technological enablement of business transformation.
Ovum's survey respondents rated clinical development as the IT project with the highest priority over the next 18 months (see Figure 2). This further demonstrates the importance of the development stage of the drug lifecycle and IT's potential to transform operations through automation and decision support.
Greater unity is required across the trial participants as trial complexity increases

All of these challenges and complexities are making the design, planning, and execution of clinical trials more difficult. Managing clinical trials using past methods, with siloed data and spreadsheets, will not be adequate in this new environment. The new breed of CTMS acts as a central intelligence hub for clinical trials, facilitating collaboration and promoting unison among the different groups that need to coordinate to complete a successful trial. Greater IT automation and maturity across the drug development lifecycle enables further optimization of the lifecycle through the application of business intelligence (BI) and advanced analytics. CTMS also plays an important role in this regard, as one component in a suite of e-clinical applications that capture important trial-related information and metadata. This data can be fed into clinical data warehouses for further analysis, providing greater optimization of trial procedures and studies.

The industry is moving toward real-time information for better decision making

One goal is to get as close to real-time as possible, so that all the daily activities of a particular trial or study can be rapidly updated and made available to the different participants. Uncoordinated efforts and decisions based on outdated information lead to inefficiency and lost time. Therefore, all stakeholders are looking to increase their IT to further automate activities such as clinical data capture, which, in turn, improves data quality by reducing human data input errors. The adoption of specific systems built for these purposes helps to centralize data and reduce “versioning” issues, which occur as a result of using spreadsheets as a capture and tracking tool.
Electronic data capture (EDC) systems help to automatically capture trial-related data from the investigator sites, and electronic trial master file (eTMF) solutions act as a centralized repository for trial-related documentation. A CTMS solution must interact with these different e-clinical systems in order to extract the relevant pieces of information. This then provides insight into the current operational status of the trial for the different groups responsible for orchestrating and executing it. By centralizing the information into one application, the different groups can work together in greater unison than if they used diverse systems and tools.

- With CTMS, trial supply and logistics can be better optimized with good and timely data.
- Trial managers can more accurately reallocate resources to areas of the trial that need better support and reduce resources allocated to lower-risk areas. In this regard, the CTMS solution helps to support risk-based monitoring of trial sites.
- By centralizing trial data and information, clinical research associates can be more effectively deployed to monitor only those sites that need to be monitored. In the past, industry practice was to monitor all trial sites. However, this was not particularly cost-effective and in many cases resulted in overkill. Now, CTMS solutions help to manage, coordinate, and track activity only in those sites that need to be monitored.

CTMS market developments

Two newcomers challenge the two large incumbents

Two vendors, Oracle and Parexel, have historically dominated the CTMS market. These vendors offer robust and comprehensive enterprise-class solutions. However, two newcomers, BioClinica and Medidata, have brought to the market innovative solutions and approaches to CTMS. BioClinica’s novel approach uses Microsoft Office applications and Sharepoint as a user interface to facilitate greater user adoption. Medidata has taken a cloud-based, modularized platform approach. This allows customers to more accurately procure what they need with out-of-the-box integration with their cloud-based EDC solution. All the other major vendors have followed suit by providing out-of-the-box integration with their EDC solutions and private cloud deployment options. However, Medidata remains the lone cloud-only provider profiled in this Decision Matrix.

Large IT vendors are building or integrating e-clinical suites that include CTMS

CTMS was once a catch-all solution area for business activities and processes that were not handled by other applications. This led to the widespread adoption of Siebel CTMS, largely due to its breadth of offering and extensive toolkit that enabled large organizations to build additional functionality into the implementation. Siebel’s flexibility and configurability also enabled large organizations to use a single solution to manage the variety of different types of clinical trials. The downside to this approach, however, is that it has led to highly customized on-premise implementations within the install base.

These heavily customized solutions are difficult to upgrade and have come to represent a single source of failure due to the extensive downtimes to perform system maintenance and upgrades. In certain cases this has led to significant impact on clinical operations as these systems have grown to cover and support a wide range of business activities and processes. This has led to a trend towards greater modularity to mitigate this vulnerability in CTMS solutions.
Mergers and acquisitions and evolution of e-clinical technologies

This trend towards modularity has been reinforced by merger and acquisition activity across the life sciences ecosystem and by the evolution of e-clinical specific solutions. Many organizations, particularly larger pharmaceutical and contract research organizations, have a very fragmented internal e-clinical software infrastructure, because their acquisitions have created a patchwork of e-clinical solutions in different operational and functional areas of the organization. Additionally, over time, point solutions that focus on a specific business process within drug development have been emerging. In some cases, these point solutions are better than or augment core CTMS functionality. In either case, customers are demanding a greater degree of interoperability from their CTMS providers to allow them to use new and existing tools and technologies to improve efficiency and automation.

Focus on price and modularity

As biotech and pharmaceutical manufacturers continue to source more drug development resources externally, the provider ecosystem becomes more diffuse. Contract research organizations are growing not only in size but also in number and geographic location: more specialty contract organizations are being created to respond to the advancement of personalized medicine; and more contract research organizations are being created in emerging markets due to the geographic sprawl of clinical trials in search of patient populations. With the increased complexity in trial protocols due to personalized medicine, and increased requirements from payers and regulatory bodies, more organizations are looking to CTMS solutions to help manage this complexity.

These structural changes within the industry, together with evolving medical practices and increased regulatory requirements, are influencing the CTMS market. The industry is demanding greater flexibility in terms of pricing and licensing options and in the procurement of application functionality within the e-clinical solution area.

Ovum Decision Matrix: CTMS, 2013–14

The market for CTMS solutions can be segmented in a number of ways. In this Decision Matrix, we have selected five top solutions, with a bias towards those that cater to the needs of large life sciences organizations.

Figure 3 provides a summary of each CTMS vendor’s capabilities based on a quantitative assessment of their influence in the market, execution, and technical capabilities. The scores underpinning the Decision Matrix can be found in each of the individual vendor assessments and in Table 2 in the Appendix.

Realizing the value from a CTMS deployment is dependent on the solution’s ability to execute the organization’s overall trial operation strategy. A decision to purchase a specific solution should be based on a broad array of factors, including, but not limited to, the degree of alignment between the solution’s functionality and the specific objectives of the organization’s relationship management strategy. As a result, Ovum’s recommendations should be considered only within the context of a life sciences company’s specific solution requirements.
The vendors chosen for this report represent the top five vendors in this solution area. As such, Figure 3 shows the highly clustered quantitative scoring of the profiled vendors. This also reflects the increasing maturity of the solution area, as the top vendors offer similar core capabilities and functionality. Oracle is slightly ahead of the other vendors in terms of breadth of offering and development roadmap. The market leaders for this report are Oracle, Medidata, and Parexel. The market challengers are BioClinica and Bio-Optronics, both of which are demonstrating significant growth.

Table 1: Ovum Decision Matrix: CTMS 2013–14

<table>
<thead>
<tr>
<th>Market leaders</th>
<th>Market challengers</th>
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<tbody>
<tr>
<td>Oracle</td>
<td>BioClinica</td>
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<tr>
<td>Parexel</td>
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Source: Ovum
MARKET LEADERS

Market leaders: technology

Usability and interoperability are the two most important criteria for a CTMS solution. Good usability is required to deliver strong return on investment (ROI). As trials are becoming increasingly complex, trial managers and research associates have to track many items as the trial progresses. Automation such as alerting, workflows, templates, and milestones all facilitate greater efficiency in trial execution and better decision making. Interoperability is particularly important not only due to the fragmented e-clinical infrastructure landscape but also because there are so many different existing and emerging solutions within the clinical trial space. Life sciences organizations are also wary of being tied into one particular vendor for their entire e-clinical suite unless they can effectively realize sufficient ROI. It is a juxtaposition: on the one hand life sciences organizations are wary of a single point of failure and vendor lock-in, yet many recognize the improved efficiency of integrated end-to-end platforms. It is usually easier to integrate e-clinical systems from the same vendor than solutions from different vendors.
vendors that rely on web services. Furthermore, as the industry moves towards risk-based monitoring of trial sites, reporting and analytics is becoming a much greater priority in order to support mobile clinical research associates.

From a technical perspective Oracle ranks highly across the board but heavily customized implementations have complicated ongoing maintenance. The transition to the cloud will help alleviate this issue, as it will give Oracle the opportunity to standardize implementations on its cloud platform. The four large providers that offer enterprise-class solutions are close in terms of functionality provided though. Oracle is a little ahead of the others in terms of breadth of offering and development, but newcomers BioClinical and Medidata are offering an alternative to the traditional CTMS solutions and are experiencing a great deal of success.

Market leaders: market impact

Oracle and Parexel have the largest CTMS market share in terms of users but have been facing stiff competition from Medidata and BioClinica. As a result they have been investing heavily in their respective solutions to defend market share. The SME segment of the market is the fastest growing and Bio-Optronics, Medidata, and BioClinica have been winning the most new, smaller clients. The other vendors are reacting by allowing greater flexibility in terms of functionality licensed, and lowering the number of users required to adopt their solutions or charging on a per-study basis.

From a geographical spread of clients perspective, Oracle has the greatest diversity of all vendors but the other vendors are gaining ground. Bio-Optronics demonstrates good geographic coverage for a small vendor. The SME segment in the emerging markets and academic research organizations will be the focus for most vendors as these segments represent the largest untapped submarkets. These
organizations are growing rapidly as a result of the outsourcing of drug development by larger life sciences organizations. Oracle is the leader in revenues derived from the industry. Its leadership position, while not as strong as in the past, is unlikely to change in the near future.

**Market leaders: execution**

**Figure 6: Ovum Decision Matrix: CTMS 2013–14 – Market leaders – execution**

There is little significant differentiation between the market leaders in terms of execution. Medidata edges out the other two in terms of deployment, due to its single code base and cloud platform. Oracle scores highly in terms of interoperability due to its extensive Siebel toolkit and in professional services because of the breadth and depth of its consulting arm.
Oracle Siebel CTMS (Ovum recommendation: Leader)

Oracle has one of the largest install bases by number of users of CTMS in the life sciences industry. Oracle is uniquely positioned in this market due to its expertise in the life sciences and the breadth of its offerings in eClinica, its ancillary/complementary life sciences specific solutions, and its technical depth in “horizontal” or cross-industry technologies. Coupled with a cloud offering, accelerators to facilitate initial implementation, adherence to best practices and greater flexibility with pricing and licensing options, Oracle is continually developing Siebel CTMS to ensure its market-leading position. Oracle’s support for mobile CRAs, risk-based monitoring platform, and integration with its Clinical Data Analytics product differentiates its offering from the rest of the market. Oracle will create a unique offering in the market should it achieve its longer term vision to further integrate its vast portfolio of clinical solutions.

Oracle communicated its commitment to industry solutions at its recent Industry Connect event in Boston. With recent management changes in the Health Sciences Global Business Unit and
developments with the Siebel CTMS product itself, most notably the Open UI and SaaS deployment option, Ovum feels that Oracle is on the right track to address clients’ concerns. Some large clients have had issues with their upgrade path, largely due to heavy customizations of the base Siebel CTMS install (ironically Siebel’s configurability is one of its strong suits). As such, the development of a SaaS-based install on Oracle’s Health Sciences Cloud will help to standardize and facilitate future maintenance of clients’ implementations.

**New user interface and best-practice accelerators improve usability**

Oracle’s recent product development has improved the usability of the application significantly. The new, open UI provides a much better and more flexible interface, giving the end user and organizations much greater control and providing role-relevant information in a well-designed interface. Usability is further supported by the addition of prebuilt process flows and accelerator configurations that incorporate industry best practices for a variety of trial-related activities such as trip reporting, study setup, and clinical supply planning. Siebel also comes with 200 reports and 13 dashboards out of the box and the company is developing a specific risk-based monitoring dashboard based on the TransCelerate guidelines. Additional UI functionality enables each user to define their own dashboard.

Siebel CTMS comes with a large number of templates that support efficiency through reusability. Templates are provided for a range of business activities such as trip reports and subject visits. Siebel CTMS also provides strong workflow capabilities.

**SaaS offering and greater flexibility in licensing options**

Oracle is facilitating greater adoption of Siebel CTMS by offering a SaaS-based deployment option and revamping its pricing and licensing options. Oracle is going with the trend in the industry of offering more flexible pricing and licensing options, enabling smaller organizations to adopt Siebel CTMS and allowing organizations greater modularity to procure what they need.

Additionally, there is a lot of flexibility built into the system. There is now a high degree of configurability over the UI. In the financial management module, managers have the flexibility to change fees for certain procedures by site.

**Enterprise-class interoperability**

Like most enterprise-class CTMS solutions, Oracle integrates with other third-party e-clinical and non e-clinical applications by providing a growing library of published web services to support ease of integration and interoperability. Oracle has worked with Qumas to provide a layer that enables Siebel to interact with Qumas’ content management system, and with Greenphire for payments.

**Oracle continues to invest and further develop its CTMS**

Oracle has an impressive development roadmap and is a leading innovator in this solution space. Oracle is the first vendor profiled in this report to have released a mobile app specifically to support mobile clinical research associates in the field. Future enhancements include integration with Oracle’s InForm and Clear trial planning tool. Another innovative addition will leverage Nuance’s voice recognition technology for mobile reps.
Oracle historically has a wide breadth of offering and it continues to enhance with mobility and analytics

Oracle has the greatest breadth of functionality of CTMS solutions on the market. It has released a mobile CRA application that is fed with relevant analytics from Oracle’s clinical data analytics (CDA) product. Siebel CTMS provides all the functionality of an enterprise-class CTMS solution such as financial management, site management, strong investigator relationship management, and multichannel communications functionality.

Market impact

Oracle has a large share of the CTMS market, including most of the top ten pharmaceutical companies and large contract research organizations. Oracle also has broad adoption across different segments of the market and has partners that bundle accelerators to facilitate the adoption of Siebel by smaller organizations.

Recommendation: Market Leader

Oracle is a market leader in this Decision Matrix due to its market share, breadth of offering, and long-term vision. Oracle has great potential with Siebel CTMS and its portfolio of e-clinical and life sciences applications. The challenge for Oracle now is to realize that potential and execute on its vision.

APPENDIX

Summary of vendor scores

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Market impact</th>
<th>Technology assessment</th>
<th>Execution</th>
</tr>
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<tbody>
<tr>
<td>BioClinica</td>
<td>6.0</td>
<td>8.0</td>
<td>7.8</td>
</tr>
<tr>
<td>Bio-Optronics</td>
<td>4.8</td>
<td>7.1</td>
<td>6.0</td>
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<tr>
<td>Oracle</td>
<td>7.6</td>
<td>8.9</td>
<td>8.3</td>
</tr>
<tr>
<td>Medidata</td>
<td>7.4</td>
<td>8.6</td>
<td>8.5</td>
</tr>
<tr>
<td>Parexel</td>
<td>6.4</td>
<td>8.0</td>
<td>8.0</td>
</tr>
</tbody>
</table>

Source: Ovum

Further reading

Clinical Trial Management Systems at the Hub of e-Clinical, IT010-000196 (April 2014)

Cloud in the Life Sciences: Benefits and Barriers to Adoption, IT010-000188 (November 2013)

2014 Trends to Watch: Life Sciences Technology, IT010-000187 (October 2013)

2013 ICT Enterprise Insights in the Life Sciences Industry, IT010-000185 (October 2013)

Global Life Sciences IT Spending Forecast through 2017, IT010-000184 (September 2013)

Business Analytics in the Life Sciences: Market Overview, IT010-000179 (August 2013)

Biopharma and Business Analytics: Essential Tools for Clinical Trials, IT010-000167 (January 2013)
Big Data and Business Analytics: The Right Therapy for the Life Sciences Industry, IT010-000163 (August 2012)

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Ovum Consulting

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