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

Publication Date: 10 Jul 2014 | Product code: IT0010-000195

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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.

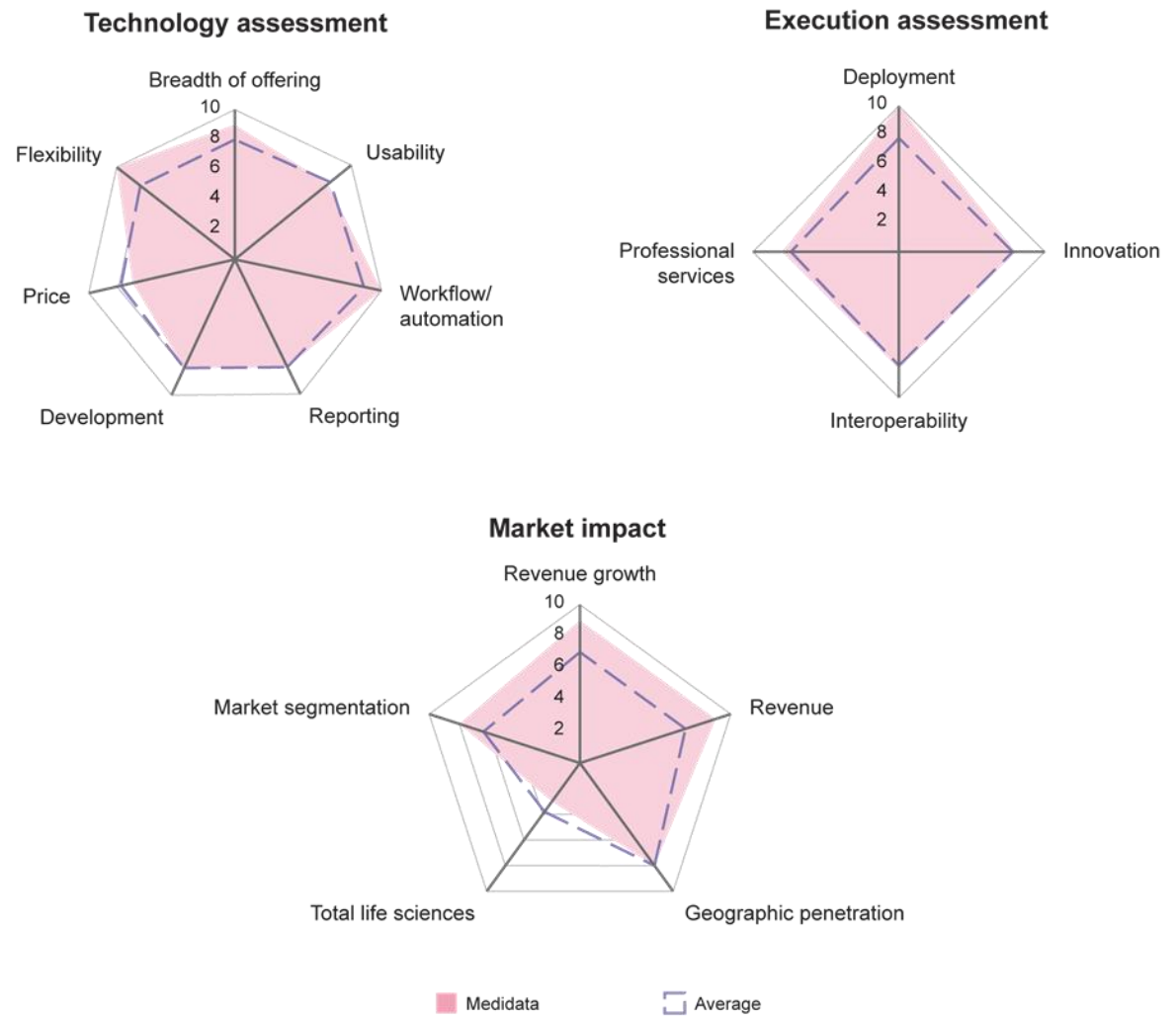
Ovum ratings

- **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.

VENDOR ANALYSIS - Medidata

Medidata CTMS (Ovum recommendation: Leader)

Figure 10: Medidata radar diagrams



Source: Ovum

Medidata is one of the larger vendors in this space and offers a broad range of e-clinical technologies, including its cloud-based CTMS solution. In 2011 Medidata bought Clinical Force, which was founded in 2004 as a standalone SaaS-based CTMS solution. Medidata has subsequently integrated Clinical Force into its widely adopted EDC solution Rave in the cloud. Medidata has innovated by providing these tools in a modular fashion via a cloud-based platform with a SaaS pricing model. This allows customers greater flexibility to procure the functionality they need rather than paying one price for a large monolithic systems model. The cloud delivery method has lowered the cost barrier for smaller organizations to adopt CTMS solutions and promoted a frequent and rapid upgrade schedule through an agile development methodology.

Single code based and cloud-only delivery result in strong deployment score

Medidata scores highly in the deployment criterion of the Decision Matrix because of the frequent upgrade schedule and rapid deployment model that its cloud platform and agile development methodology afford. Medidata maintains a single code base for its CTMS and, although the implementation in the cloud on Amazon's Web Services platform is multi-instance, all instances share some centralized information, data, and services. Medidata performs three or four upgrades per year, which individual customers can defer for a period as needed. Medidata works with each client to ensure the timing of each upgrade meets their needs. This upgrade schedule enables Medidata to implement customers' desired features more rapidly than the traditional on-premise development lifecycle.

Medidata's CTMS provides single sign-on and out-of-the-box functionality for usability

The solution provides many drop-down and contextual features to support usability, along with customer-defined screens, sophisticated mapping, and configuration tools that improve the efficiency of different roles within the drug development process. These tools enable the auto-compilation of reports and other documents, and the ability to import and export data from other systems via XML and CSV. The solution also comes with 120 standard reports out of the box including cross-study views and dashboards as well as robust tools to configure organization-specific, ad hoc reports based on organizational metrics or procedures. Single sign-on functionality enables users to go in and out of EDC and CTMS with ease.

The financial management aspects of the solution are particularly strong, with robust workflow and automation functionality. Customers can license Medidata's grant planning and contracting modules to send clinical site negotiated costs into the Medidata payment module. Medidata has also developed sophisticated integration between EDC and the Medidata payment module that enables clients to significantly reduce the time necessary to calculate payments. Its tools enable end users to configure new payment setups – a process that would traditionally have required customization by technically skilled professionals.

Cloud-based platform supports strong integration and innovation scores

Medidata has built robust integration tools that support a high level of automation and reduce the need for double entry of trial data. Medidata provides sophisticated integration with its other e-clinical tools, Rave and Balance, but like other enterprise-class solutions can interoperate with other third-party systems. It complies with the industry's CDISC ODM data model to facilitate data sharing.

Medidata CTMS provides a broad range of functionality to support various clinical trial business processes and activities such as study planning, startup, content management for regulatory compliance, monitoring, and financial management.

Medidata is at the forefront of cloud-based innovation for e-clinical services. Future enhancements will include integration with Vault eTMF, Veeva's cloud-based life sciences content management system for electronic trial master file (eTMF) functionality. In this regard, Medidata is moving the industry towards a future consisting of an ecosystem of cloud-based industry-specific solutions interacting together to provide robust and comprehensive solutions for life science organizations. As a result of its modular approach, Medidata was ranked highest for workflow/automation, deployment, and flexibility.

Market impact

Medidata is growing particularly well in the small to mid-sized enterprise (SME) segment of the market. It also scored well in the new client and revenue growth criteria of the market impact assessment. The majority of its customers are in the US, with approximately 20% in Europe and the remaining 10% in the rest of the world. This geographic spread is similar to many of the vendors profiled in this report. Medidata has a sizable install base and enjoys a large share of related e-clinical technologies, particularly in the EDC market with its Rave product. It therefore also scored well in the install base and addressable install base. With respect to big pharma, this market segment has long cycle times when it comes to solutions such as CTMS, which results in low turnover of CTMS solutions.

Recommendation: Market leader

Ovum has rated Medidata's CTMS solution as one of the market leaders due to its breadth of offering, visionary modularized cloud-based platform approach to e-clinical solutions, and its market share.

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.

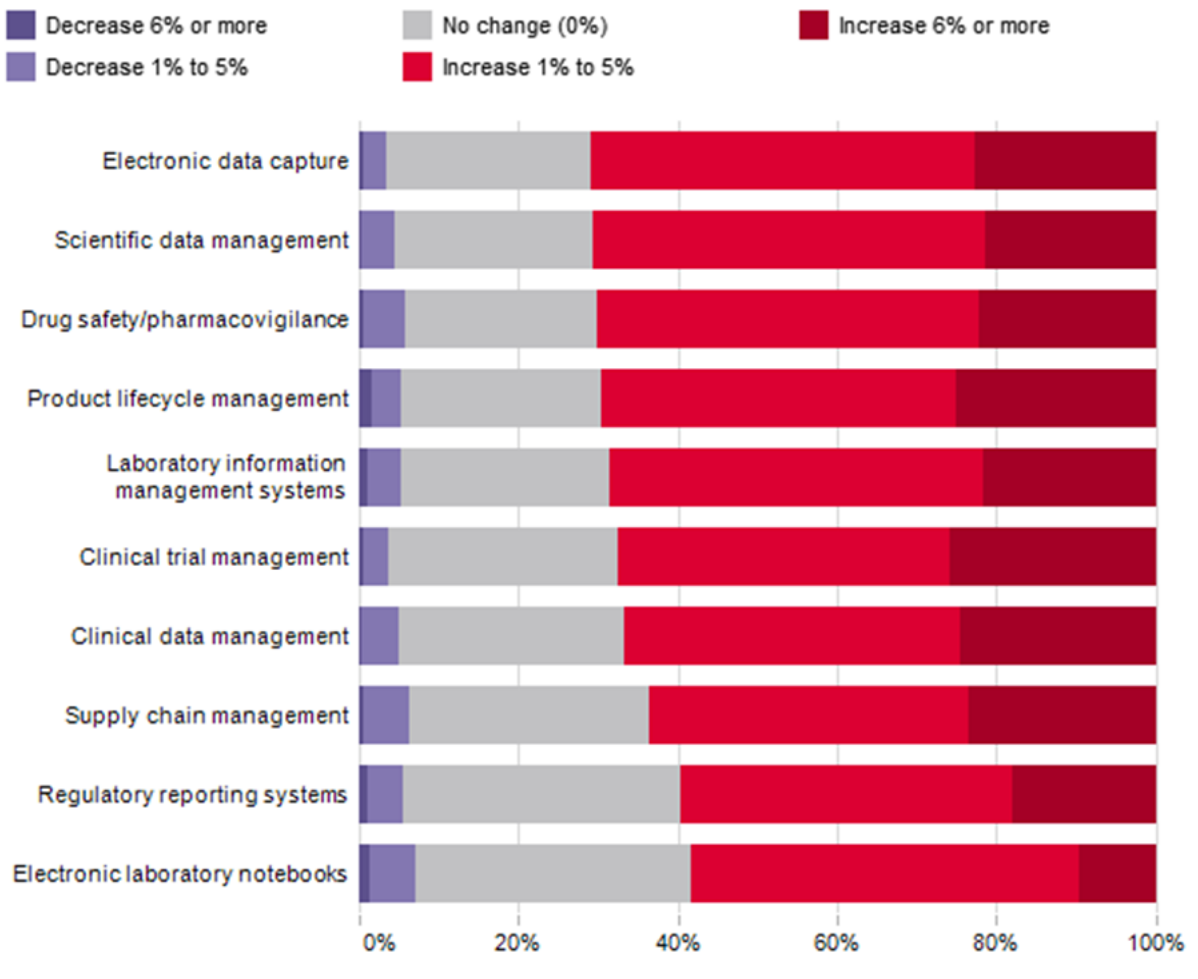
In response to this, biopharma companies have been making significant changes to their business and operating models. Clinical trials are increasingly being conducted outside of the US to lower operational costs and increase the pool of patients from which to recruit trial participants. However,

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.

Figure 1: Life science firms' IT spending plans for life science-specific solutions

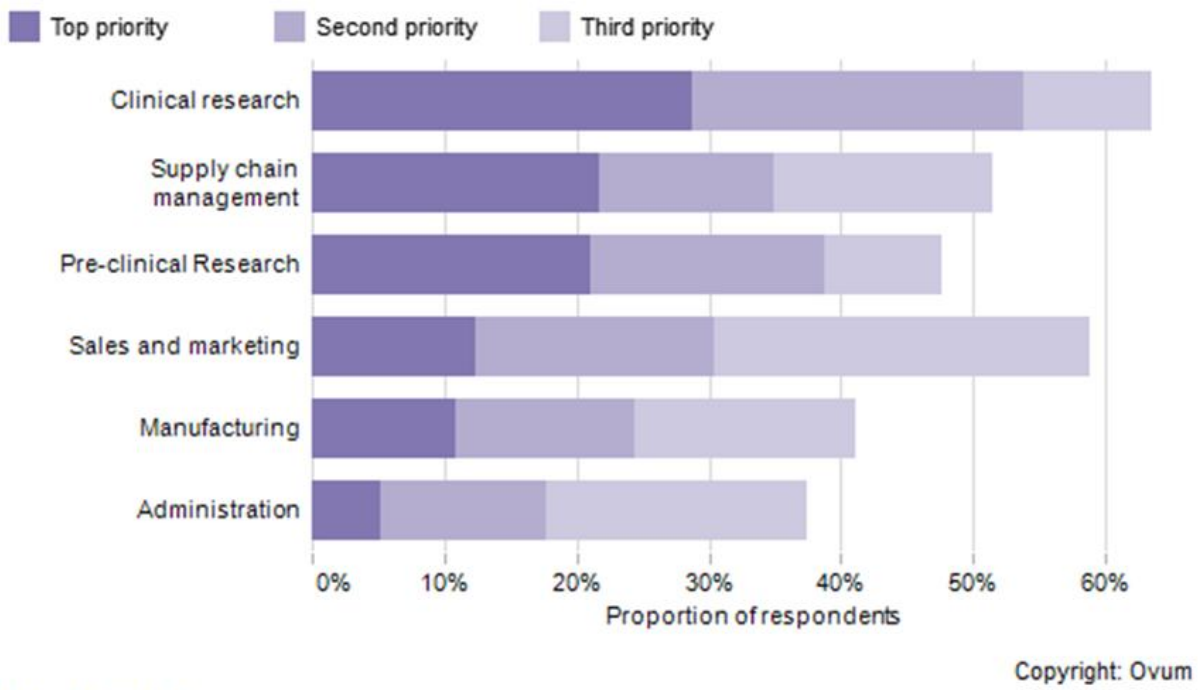


Sample size: 322
Question: What are your IT spending plans for each of the above systems during the next 18 months?
Vertical: Life sciences. Life sciences org type: All. Country: All. Enterprise size: All.

Source: Ovum ICT Enterprise Insights

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.

Figure 2: Life science firms' top three IT projects by drug lifecycle stage



Sample size: 323
Question: In what business areas will your top 3 IT projects be during the next 18 months in terms of total investment value?
Vertical: Life sciences. Life sciences org type: All. Country: All. Enterprise size: All

Source: Ovum ICT Enterprise Insights

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 realtime 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.

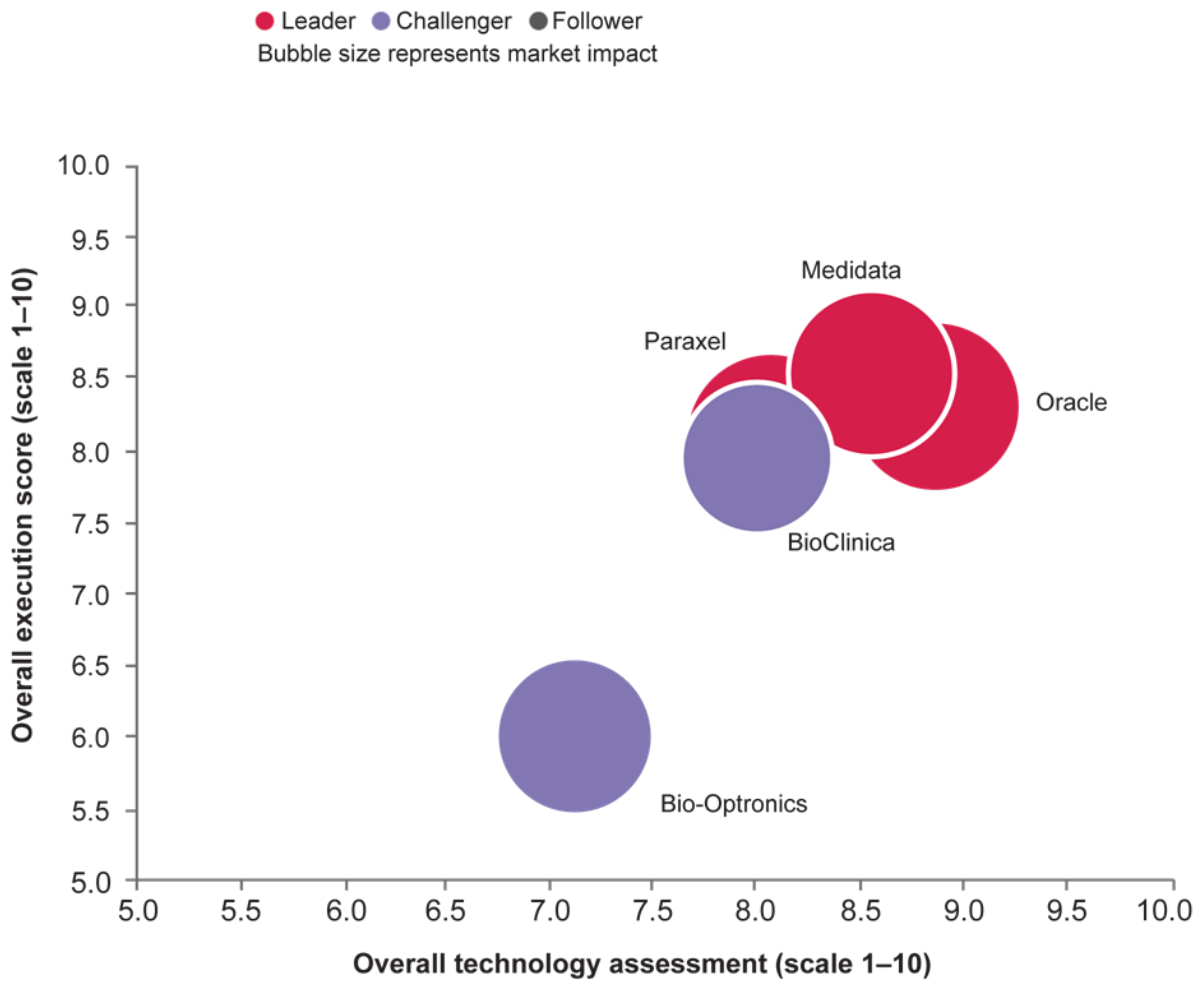
Ovum Decision Matrix: CTMS, 2013–14

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.

Figure 3: Ovum Decision Matrix: CTMS 2013–14



Source: Ovum

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

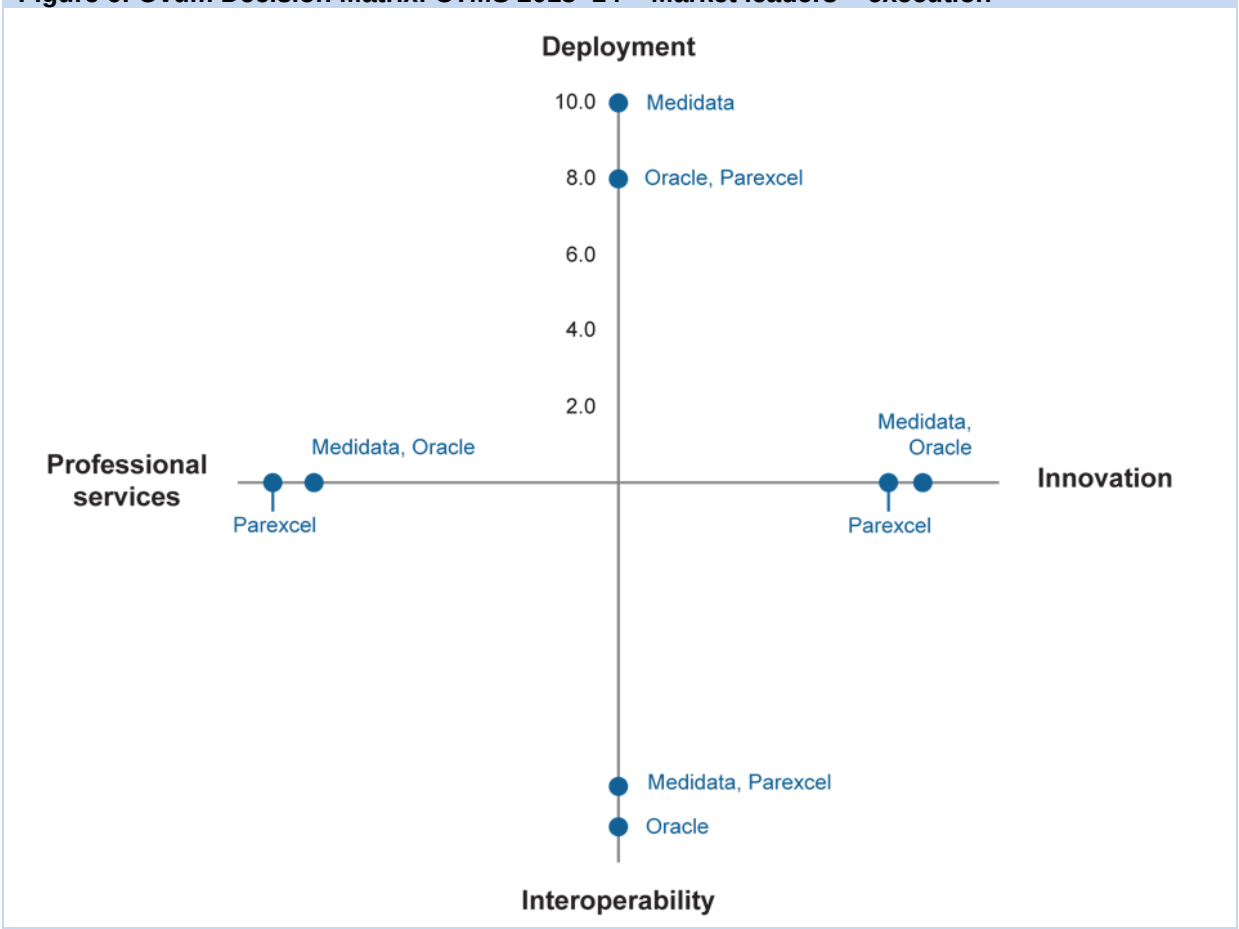
Market leaders	Market challengers
Oracle	BioClinica
Medidata	Bio-Optronics
Parexel	

Source: Ovum

MARKET LEADERS

Market leaders: execution

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

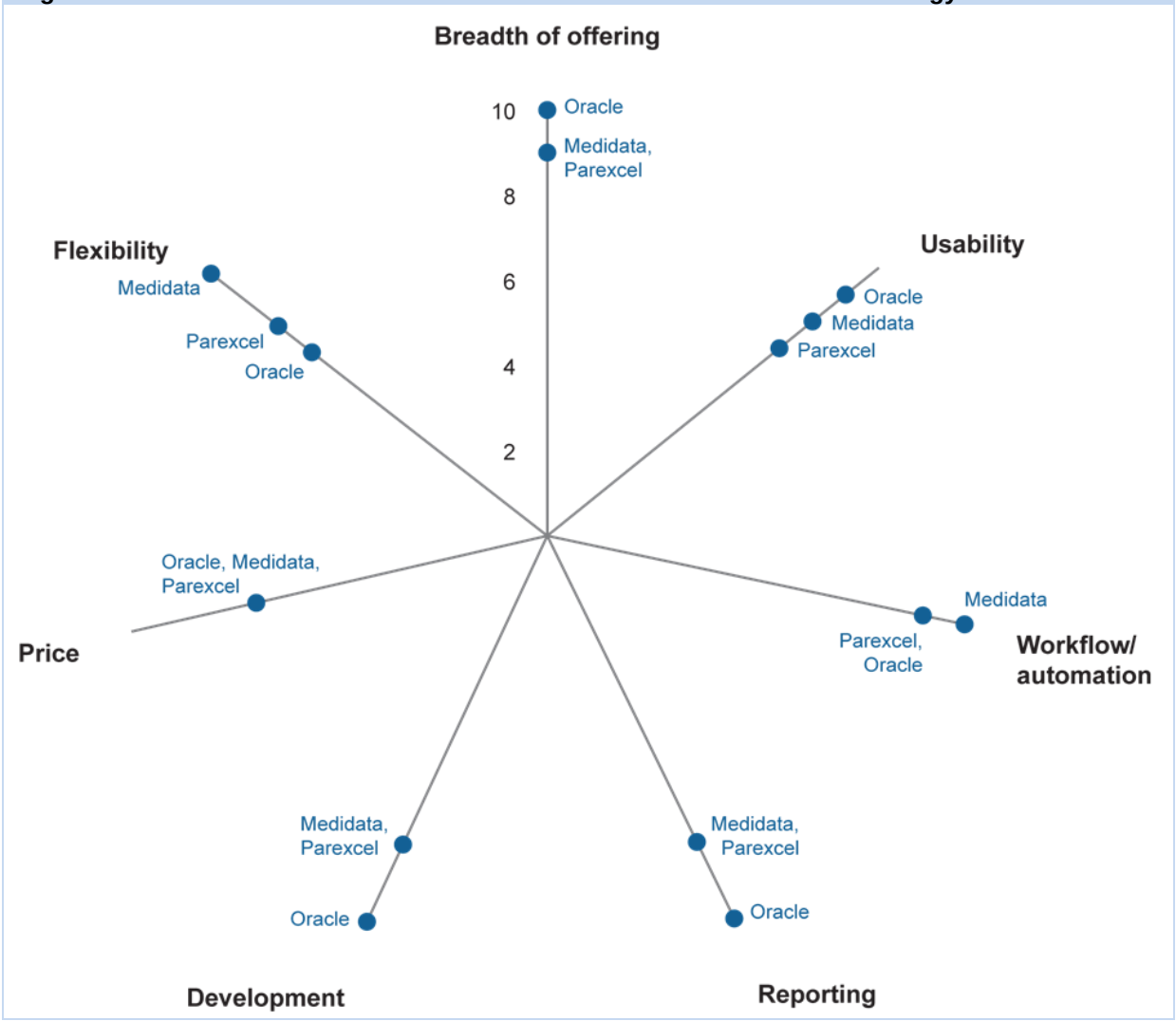


Source: Ovum

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.

Market leaders: technology

Figure 4: Ovum Decision Matrix: CTMS 2013–14 – Market leaders – technology



Source: Ovum

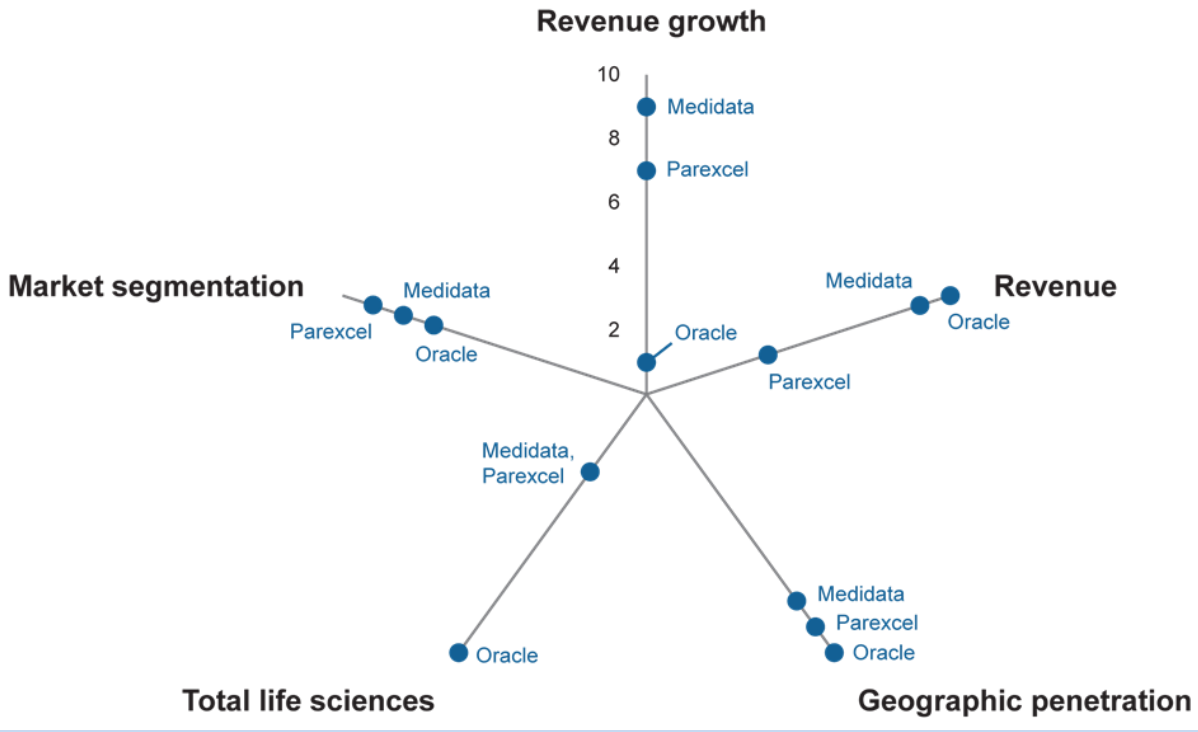
Usability and interoperability are the two most important criteria for a CTMS solution. Good usability is required to deliver strong return on investment (ROI). As trials are becoming increasingly complex, trial managers and research associates have to track many items as the trial progresses. Automation 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 tothe 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 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

Figure 5: Ovum Decision Matrix: CTMS 2013–14 – Market leaders – market impact



Source: Ovum

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.

APPENDIX

Summary of vendor scores

Table 2: Summary of vendor scores

Vendor	Market impact	Technology assessment	Execution
BioClinica	6.0	8.0	7.8
Bio-Optronics	4.8	7.1	6.0
Oracle	7.6	8.9	8.3
Medidata	7.4	8.6	8.5
Parexel	6.4	8.0	8.0

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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We hope that this analysis will help you make informed and imaginative business decisions. If you have further requirements, Ovum's consulting team may be able to help you. For more information about Ovum's consulting capabilities, please contact us directly at consulting@ovum.com.

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