

# Selecting an EDC Vendor in the Life Sciences Industry

## Navigating an IT market that is becoming commoditized

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### SUMMARY

#### Catalyst

The safety and efficacy of new drugs are increasingly being questioned by the public, and this has given rise to demand for longer, more comprehensive, global clinical trials from regulatory agencies. In response to the globalization of clinical studies and the increase in patient data, life sciences companies are adopting electronic data capture (EDC) solutions to more accurately collect, clean, validate, and manage clinical data across hundreds of investigator sites. Although the recession hampered uptake of EDC, companies are back on track and eager to become paperless, but the selection process has been difficult due to a large and diverse vendor landscape. In this report, Ovum evaluates a number of EDC solutions to assist life sciences companies select an IT solution that is increasingly becoming commoditized.

#### Ovum view

Clinical research is the most time-consuming and costly process in the pharmaceutical (pharma) product lifecycle. As a means to streamline clinical operations and create efficiencies across the trial process, pharma, and biotechnology (biotech) companies are beginning to look at e-clinical technologies. Most often, EDC is seen as the stepping-stone for further e-clinical IT adoption. The comfort level of EDC has increased significantly over the past five years, yet there is still quite a bit of confusion among life sciences companies about which solution is the best option for their needs. Out of necessity, companies started to adopt various e-clinical technologies from different vendors,

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which resulted in an IT infrastructure of best-of-breed point solutions that were difficult to integrate, and therefore created many redundancies and errors in the data. Over the past two to three years, companies have started to realize that EDC and other e-clinical technologies are beginning to become standardized, and instead of best-of breed, an interoperable e-clinical platform is of the utmost importance. Ovum concurs with this viewpoint. In the EDC market specifically, there are not too many game-changers where a new feature is going to wow the life sciences market. Therefore, the selection of the EDC solution will be much more dependent on the vendor's knowledge of clinical trial processes, the maturity of the vendor, the customer service and support, and lastly, what else can the vendor provide down the road, such as the vendor's vision of the e-clinical market and its innovative nature. Life sciences companies are looking for a long-term partner, so a vendor's product roadmap and future vision of the e-clinical market will be important to the decision-making process when selecting an EDC solution.

### **Key messages**

- Spending on EDC will continue, but will peak over the next couple of years
- EDC adoption will increase among small and mid-sized pharma/biotech companies
- As clinical study designers become more comfortable with the process change brought on by EDC, more companies will bring design control in-house
- EDC will become one "module2 within an interoperable e-clinical platform rather than a stand-alone solution
- EDC will become more tethered to non-clinical technologies
- Analytics will start to play a bigger role within EDC systems



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## MARKET DEVELOPMENTS

### EDC is the first step to paperless clinical trials

Clinical research, which ultimately determines if a drug is safe and effective to treat humans with a specific affliction/illness, is the most expensive phase of the drug discovery and development process. While cost-cutting is a high priority, the importance of clinical trials makes it difficult to do so. Over the past five years, more and more life sciences companies have realized that the best way to increase productivity, maximize efficiency, and reduce time and costs of conducting clinical trials is to adopt e-clinical technology solutions.

Although EDC systems have existed for over 25 years, their implementation and usage has been quite low, primarily due to poorly designed systems, lack of budget, and minimal end-user buy-in. However, as the clinical trial process becomes more complex due to increasing government regulations, growing safety concerns, financial instability, and globalization, end-user attitudes toward EDC are changing for the positive, particularly since the solutions have become much more advanced than their first-generation versions, eliminating many of the issues that early adopters had with these systems. EDC is often considered the flagship e-clinical product because it provides the greatest improvements in data accuracy and efficiency. Once EDC proves to be a success, Ovum believes that end users will feel more comfortable adopting other e-clinical solutions, which is why investment in the right EDC solution is so important to ensure the company's e-clinical strategy moves forward.

The EDC market has been somewhat segmented between the different sectors of life sciences. At one end of the spectrum, there is big pharma/biotech with numerous drug candidate programs and multiple global trials running simultaneously at any given time. At the other end are small pharma and biotech companies that have one or two potential candidate drugs that are targeted to a small, niche population. While the basic EDC functionality needed by clinical trials stakeholders is the same, the smaller companies will not require as substantial an infrastructure or back-end database as the larger companies. In addition, the level of services could also differ significantly between the two ends of the spectrum. While vendors will typically price their solutions based on the size and complexity of each individual trial, the size and experience of the life sciences organization could impact the delivery model and have a bearing on whether the fee is license or subscription-based. Furthermore, the size of the company may also impact the decision to opt for an EDC that has basic functionality of other e-clinical solutions, rather than implementing each product separately.



The purpose of this report is to help pharma/biotech companies and contract research organizations (CROs) evaluate the numerous EDC vendors in the market. Overall, the solutions available today are a vast improvement on what has been offered in the past, and in many respects, the major elements of EDC are becoming common across all solutions. The key to a good solution is that it is a web-based or software-as-a-service (SaaS) solution that takes into consideration clinical research workflows using intuitive interfaces and the most up-to-date technology. While many EDC solutions have evolved to become more user-friendly, many vendors have neglected to update the technology and are selling a solution based on technology that is old and no longer sustainable. Unsophisticated interfaces and a lack of a vision for an integrated e-clinical platform are telltale signs of this. While vendors in this evaluation generally scored highly for usability and flexibility, they need to continue to improve their end-user interface or they will lose out to their competitors. Ovum also believes that as the e-clinical technology market matures, a good EDC will simply be one component of an interoperable e-clinical platform, rather than a stand-alone solution. This will allow solutions to share data seamlessly and reduce redundancy in data, decreasing some of the inaccuracies caused by inputting the same data in multiple systems.

In general, Ovum expects the following developments to occur in the EDC market over the next 12-36 months:

- Spending on EDC will continue, but will peak over the next couple of years.
- EDC adoption will increase among small and mid-sized pharma/biotech companies.
- As clinical study designers become more comfortable with the process change brought on by EDC, more companies will bring design control in-house.
- EDC will become one “module” within an interoperable e-clinical platform rather than a stand-alone solution.
- EDC will become more tethered to non-clinical technologies.
- Analytics will start playing a bigger role within EDC systems.

#### **Spending on EDC will continue, but will peak over the next couple of years**

While many pharma companies projected that they will be running 100% of their trials using EDC by 2012, this goal is unlikely to be achieved because numerous IT projects were put in hold in response to the economic crisis over the past two to three years. However, many IT projects, including the conversion from paper to EDC, are back on track. Therefore, Ovum expects a spike in the number new EDC implementations through 2015, but it will then start to fall again once a large number of the life sciences companies become repeat customers rather than new adopters. In addition, Ovum foresees a drop in EDC adoption due to an increase in outsourcing clinical trials



to CROs, which are likely to already have their own systems in place. Lastly, the adoption of stand-alone EDC solutions will decrease as more companies opt for an integrated e-clinical platform.

### **EDC adoption will increase among small and mid-sized pharma/biotech companies**

Historically, small and mid-sized companies rarely conducted large clinical trials because larger companies (big pharma) often acquired companies that showed promising drugs in early research stages or they licensed the drugs and paid for the clinical trials. However, as pharma's R&D costs increase while drug pipelines and sales decrease, larger companies are being much more cautious about which potential drugs to invest in. They are therefore seeking more data (late-stage R&D data), which is increasing the need for small and mid-sized life sciences companies to conduct clinical trials, and adopt EDC. This shift in the R&D market will result in the growth of e-clinical vendors that target small and mid-sized enterprises (SMEs), and it is likely that their growth will be more pronounced than that of vendors catering to larger life sciences companies, many of which have already adopted EDC.

### **More companies will bring design control in-house**

One of the major differences between paper and EDC is the process involved with building a clinical study. The adoption of EDC front-loads this process drastically. In the traditional, paper-based system, the patient recruitment process could begin even before the study protocol was developed, while the design of the case report forms (CRFs), the approval of the final protocol, and the creation of the database and validation checks were carried out in parallel. CRFs could be added or modified at any time during the trial, since it would only be a matter of replacing a sheet of paper. By contrast, an EDC system requires that all aspects of the design, including every electronic CRF (eCRF) that could potentially be used, be finalized and included in the database before a single patient can be enrolled. In addition, mid-study additions or modifications, while possible, are not always an easy task, and could be quite costly, depending on the contract sponsors have with their EDC vendor. Because this new process takes some time to get familiar with and understand, the majority of EDC vendors build the clinical trial database and the eCRFs associated with the study for their customers as part of the EDC implementation. However, as companies become more accustomed to the process, Ovum believes they will start to request that the trial design responsibilities be given to them so that they have more control of the study build and mid-study change processes. While most EDC vendors have or are in the process of developing a study designer application, it will still be a while before the larger life sciences community opts for this option because it takes a special skill set to design, build, and manage a clinical study. The more likely case is that sponsors and CROs will want access to this module so that they can make mid-study changes more easily. Regardless of how and when they choose to



adopt the study designer tool, the demand for it will increase and vendors will need to be prepared by having the appropriate training services and support in place.

#### **EDC will become one “module” within an interoperable e-clinical platform**

In order for life sciences companies to reduce the redundancies that currently exist between EDC and other e-clinical point solutions, they must be built on a unified architecture with a single foundation at the core. While each solution could work as a stand-alone product, the interoperable framework provided by the unified architecture would give a more seamless environment for end users and would also ease maintenance for the IT department. In addition, it would offer a single solution that would span the entire clinical trial lifecycle, ensuring that all relevant data associated with the various aspects of a study was in one location. Instead of each technology being a separate solution, there would be “plug-and-play” modules of an e-clinical platform in which they could be activated and “turned on” within days, if not hours, allowing life sciences companies to use and pay for only the solutions they need, when they need them. Ovum's vision may seem simplistic and idealistic, but vendors will need to explore how they can develop this unified e-clinical platform that the industry is increasingly demanding.

#### **EDC will become more tethered to non-clinical technologies**

While it is important for the numerous e-clinical technologies to be integrated into a seamless environment, it is just as important to connect non-clinical technologies, such as safety and signal detection applications and electronic health records (EHRs), to the clinical IT infrastructure. As trials become more complex, the number of stakeholders that touch information associated with a clinical study is also increasing. However, groups not directly involved with conducting clinical trials often do not have access to e-clinical technologies and data. These key stakeholders have their own IT solutions that they must interact with on a regular basis, and adding an e-clinical application to their already cluttered workflow would simply add an unwanted burden on them. Instead, what needs to exist are integrations between e-clinical technologies and non-clinical technologies so that non-clinical stakeholders (the patients' physicians, regulators, and drug safety scientists and monitors) can still access trial data, but within their own systems.

#### **Analytics will start playing a bigger role within EDC systems**

As life sciences companies adopt EDC, they are generating and storing mounds of valuable patient data that often only get analyzed for the specific trial it came from. However, there is significant benefit to look at the data across studies, and to do this, Ovum believes companies need to start leveraging analytics and business intelligence (BI) tools. The use of BI can provide study managers with much greater insight into how the clinical trials are operating, or analytics can

provide data managers with the right tools to look at patient data across studies for things such as safety signals. The use of BI and analytics is a relatively new concept for the life sciences industry in general, let alone in clinical trials, but it is one that has a lot of potential to grow rapidly.

## THE EDC INDUSTRY SOLUTIONS GUIDE

The EDC market includes a long list of vendors that has made the selection process somewhat difficult, but there has been recent, significant consolidation within the market. In this industry solutions guide, Ovum provides a summary of EDC vendors' capabilities based on a quantitative assessment of their influence in the market, the quality of and breadth of the technology features they offer, and their role in evolving and delivering innovation in the e-clinical technology market. The vendors profiled in this report (see Table 1) are at the forefront of the pack, gaining market share and confidence from the life sciences industry and the CRO community. This report aims to provide further insight for clinical trial sponsors and CROs looking to purchase a solution, helping them to understand the differences between some of the top EDC vendors. The detailed scores underpinning the Industry Solution Guide can be found on individual vendor assessments and in Table 3 in the Appendix.

**Table 1: Technology vendors featured in the EDC industry solutions guide**

BioClinica  
DATATRAK  
Medidata Solutions  
Merge Healthcare  
Nextrials  
OmniComm Systems  
Oracle (Oracle Inform and Oracle RDC)  
Perceptive Informatics

Source: Ovum

OVUM

The decision to purchase one EDC solution over another and realizing value from an EDC deployment should be based on a broad array of factors, including but not limited to the degree of alignment between the solution's features and functionality, and the specific objectives of the sponsor's clinical trials patient data capture strategy. As a result, Ovum's recommendations (see

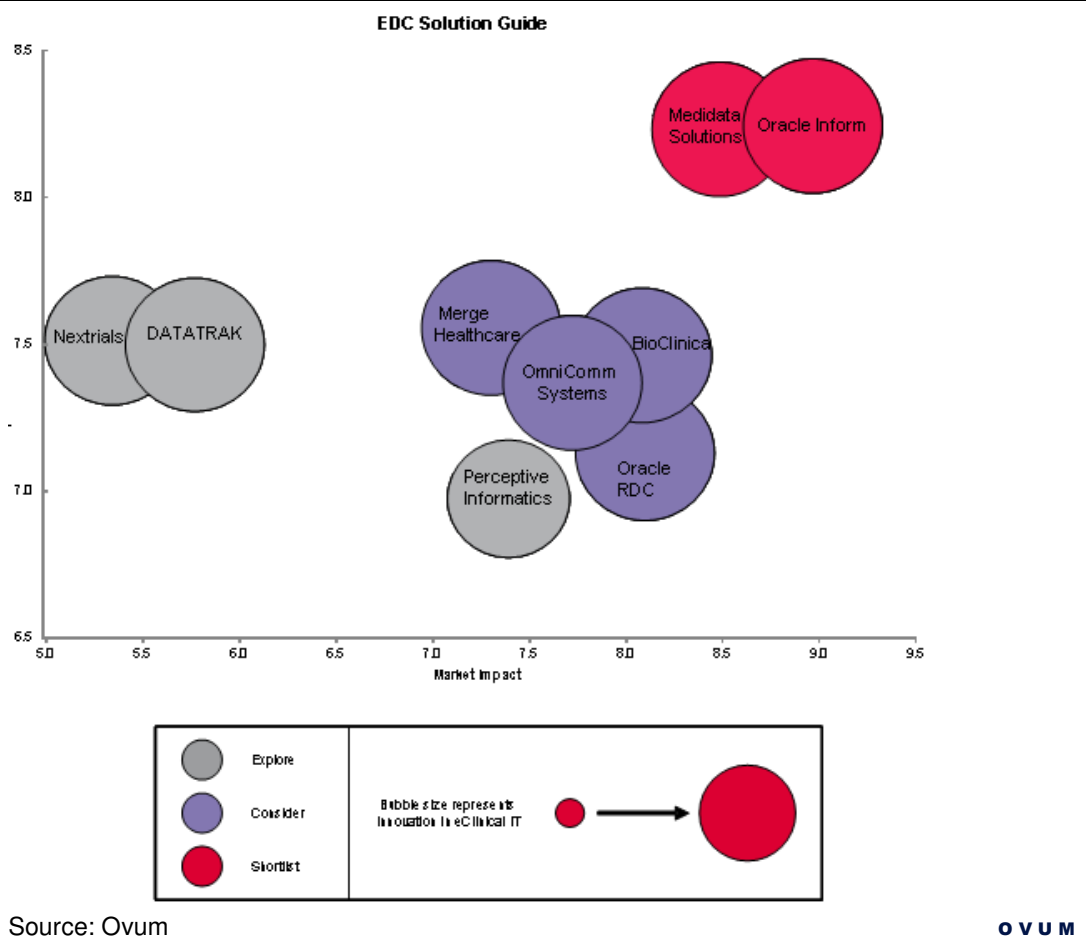


Figure 1 and Table 2) should be considered only within the context of a life sciences company's specific solution requirements.

The following definitions are used for each of these recommendations:

- **Shortlist:** these vendors' products and services should always be placed on a company's shortlist for EDC selection. This category represents the leading solutions that Ovum believes are worthy of a place on most technology selection shortlists. Each vendor has established a commanding market position with a product that is widely accepted as best of breed.
- **Consider:** the vendors in this category have good market positioning, and are selling and marketing the product well. The product offers competitive functionality and good price/performance, and should be considered as part of the technology selection process.
- **Explore:** solutions in this category have less broad applicability, and may have limitations in terms of the product's functionality, or the vendor's execution capability. However, they will still be suitable for meeting specific requirements and may be worth exploring as part of the technology selection process.

**Figure 1: Performance of EDC vendors included in the industry solutions guide**



<b>Table 2: Recommendations for EDC vendors in the industry solution guide</b>		
<b>Shortlist</b>	<b>Consider</b>	<b>Explore</b>
Medidata Solutions	BioClinica	DATATRAK
Oracle Inform	Merge Healthcare	Nextrials
	OmniComm Systems	Perceptive Informatics
	Oracle RDC	

Source: Ovum OVUM

### Market leaders: Medidata Solutions and Oracle Inform

Ovum’s EDC shortlist is unexpected. The two vendors that made this list: Medidata Solutions and Oracle Inform have established strong brand names in the EDC market and have long been the tier-1 solution providers for e-clinical technologies. Across the areas of market impact, technology assessment, and innovation in e-clinical technologies, both Medidata and Oracle Health Sciences have demonstrated their market-leading position. Ovum therefore recommends that sponsors and CROs place these technology vendors on their shortlist when selecting an EDC solution.

- Medidata Solutions has a well-established presence in the clinical trials space, due primarily to its flagship SaaS-based EDC solution, Rave. With a significant installed base, Medidata has developed its product so that it is appealing and scalable to all segments of the life sciences industry, including big pharma as well as smaller pharma and biotech companies. In addition to the SaaS offering, Ovum believes that what sets Medidata apart is its consulting and advisory group, a necessity for EDC adopters. In order to target each life sciences sector, Medidata has created a first-class services group that focuses on each individual sector so that companies, regardless of size, feel they are getting personalized attention from a vendor that truly understands the nuances of their market.
- When evaluating EDC solutions, Oracle Health Sciences Inform GTM (Oracle Inform) is typically high on every organization’s list, which is why it has the largest EDC install base. The Oracle Inform platform and its supporting modules have grown to include a number of e-clinical as well as safety solutions that work together to improve a sponsor’s ability to collect, manage, and monitor clinical data. With significant



investment made in integrating its comprehensive list of offerings, sponsors and CROs are capable of working with one vendor for all their e-clinical and safety IT needs. Consistently a leader in this market, Ovum believes this vendor will remain a pioneer in the e-clinical space.

### **The challengers: BioClinica, Merge Healthcare, OmniComm Systems, and Oracle RDC**

Due to the varied needs of organizations within the life sciences industry, the EDC market is quite diverse, giving companies, particularly SMEs, considerable choice when selecting a solution. While BioClinica, Merge Healthcare, OmniComm Systems, and Oracle RDC did not make the shortlist, these vendors offer compelling solutions, and depending on the company's clinical research needs, may prove to be the best solution for a particular life sciences company. Ovum therefore strongly recommends that companies consider these vendors when purchasing an EDC solution.

- BioClinica is a strong, well-rounded vendor in the EDC market. Its Express EDC solution scored well on market impact and has shown significant growth over the past couple of years. After acquiring several e-clinical technology vendors and rebranding itself as BioClinica, the vendor has made significant investment in developing a robust EDC platform that is user-friendly and flexible. Life sciences companies will benefit from BioClinica's product suite, which includes an IVRS, a CTMS, a supply forecasting tool, and a digital imaging solution, a technology that is becoming more important in clinical trials yet few vendors offer. Ovum believes that BioClinica's EDC system, once fully integrated with its other products, will provide customers with a user-friendly, seamless e-clinical environment.
- Merge Healthcare entered the e-clinical market with the acquisition of etrials Worldwide in 2009, which had been a provider of e-clinical solutions for over 20 years. To further its eClinical footprint, Merge also acquired Kika Medical in December 2010. Ovum believes that Merge's global reach will help it increase adoption of its EDC technology. Merge's healthcare customer base also gives it an advantage in reaching a new audience with its e-clinical solutions. Merge offers a robust EDC system with many features that are generally unexpected from a vendor of this size. However, in the short term, Merge Healthcare may have to put greater emphasis on better marketing itself as a vendor in the e-clinical market, not just healthcare, to ensure its expected growth stays on track.

- OmniComm Systems is a relatively small e-clinical software and services provider, when compared to the market leaders, but has shown tremendous growth over the past five years. With an impressive EDC install base and an active CRO program, OmniComm is a good example of the phrase "size does not matter". While OmniComm's EDC product, TrialMaster, may not be as well known as some of its larger competitors' products, it offers much more than just the basics. Companies that value customer service will be pleased with OmniComm. Combine this with an EDC solution that is cost-effective and a suite of e-clinical products that are currently being integrated into an interoperable platform, and companies will find a long-term partner in OmniComm.
- Oracle is a leading vendor in the life sciences market and has invested a great amount of resources to develop its Oracle Remote Data Capture (Oracle RDC) solution, which provides a rich set of features for collecting and managing patient data. Oracle's global footprint has enabled it to market its solution worldwide, attracting big pharma and large CROs. The difference with Oracle's RDC solution is its on-premise delivery model, which may shut out SMEs that do not have the infrastructure or resources to support it. While Oracle RDC may not be for everyone due to the delivery model, Ovum believes it should be considered because of its e-clinical vision and its capability of making that vision come true.

### **Emerging competitors: DATATRAK, Nextrials, and Perceptive Informatics**

While the EDC market is relatively mature, there are still opportunities for smaller, more niche, emerging vendors to become strong competitors in this space. DATATRAK and Nextrials are small fish in a big pond, but hold their own in the competitive EDC market. Perceptive Informatics has an established suite of e-clinical solutions, of which EDC is only one product. All of these vendors have robust technology platforms. Ovum therefore recommends that life sciences companies and CROs explore these vendors when purchasing an EDC solution.

- A lesser known vendor in the EDC market, DATATRAK, is a strong contender due to its technology platform. It offers a unified e-clinical software suite, DATATRAK ONE, which provides end users with an interoperable environment in which clinical researchers are provided with the necessary tools to design, deliver, and manage their clinical trials. Because few life sciences companies are prepared to "throw away" investments already made in e-clinical solutions to replace them entirely with the DATATRAK ONE platform, DATATRAK offers an alternative implementation option in which it integrates its individual products and the existing applications using industry standards and DATATRAK Exchange. For those that are just starting the evaluation



process, DATATRAK offers a cost-effective option for an entire clinical research suite of products.

- Nextrials is a comparatively small, privately owned e-clinical company founded in 1999. Nextrials' size has been attractive to smaller companies that prefer to work with similarly sized vendors rather than a vendor whose client base consists largely of big and mid-sized pharma companies. Unlike its competitors in this evaluation, Nextrials is unique in that it has only one product: its EDC solution, Prism. While this strategy has contributed to Nextrials' low market impact scores, it has also allowed the vendor to focus all of its resources on improving and evolving its technology platform as well as integrating EHRs, something Ovum believes could have a huge impact on patient recruitment and patient care during/after clinical trials.
- Perceptive Informatics is the technology subsidiary of Parexel International, a leading global CRO. Having access to a wealth of clinical trials knowledge and expertise from its parent company gives Perceptive an advantage over other e-clinical vendors. In addition, the use of Perceptive's DataLabs EDC solution by Parexel also gives the vendor exposure to life sciences companies that are using the CRO's services. Through several acquisitions, Perceptive has built up a strong e-clinical product portfolio, which combined with Parexel's CRO services, provides companies with a one-stop-shop for all their clinical research needs. Ovum sees Perceptive Informatics as a perfect candidate for life sciences companies that are looking to meld technology with clinical trials expertise for a complete end-to-end solution, or for small and mid-sized CROs seeking to leverage a robust e-clinical platform in their business.



## MARKET LEADERS

Although Medidata and Oracle Inform stand out significantly from their competitors, the other vendors selected for this report are very strong EDC solution providers, especially in the small and mid-sized life sciences markets. However, in order to better understand each of the vendor's particular strengths and weaknesses, it is important to consider the evaluation categories (market impact, technology assessment, and innovation in e-clinical IT) separately. In the section below, Ovum highlights the market leaders for each category and discusses the sub-criteria within the assessment area.

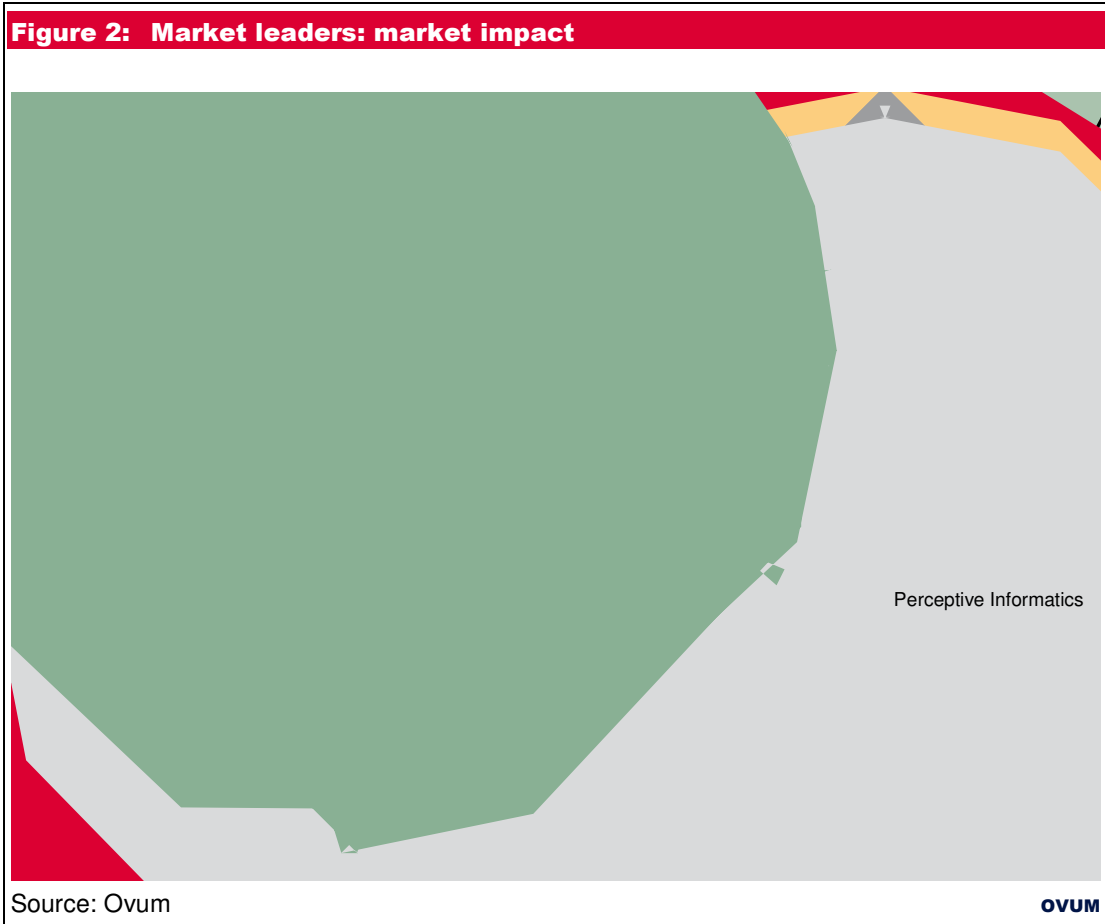
### Market leaders: market impact

Market impact was measured purely by figures, sometimes provided by the company, at other times estimated from publicly available documents and data. EDC installed base refers to the number of unique-named EDC customers the vendor has. The solution addressable installed base is the number of unique-named life sciences IT customers. Geographic research includes the number of unique-named life sciences customers outside of the US. Revenue growth is defined as year-on-year EDC revenue growth and EDC revenue as the overall revenue for the EDC solution. New customers refer to the number of new unique-named life sciences customers in 2010. Pharma/biotech clients and CRO clients refer to the number of unique-named customers within each segment. E-clinical solutions refer to the number of other e-clinical solutions the vendor offers, such as CTMS, IVRS, and ePRO.

Oracle Inform, Medidata, and BioClinica lead in market impact (see Figure 2). Oracle Inform unsurprisingly dominates in every market impact category, particularly EDC installed base, EDC revenue, and pharma/biotech clients. Medidata also received top scores for every market impact category and is probably Oracle Inform's biggest competitor. However, not to be overlooked is BioClinica, a vendor that is creeping to the top with strong scores in EDC installed base, revenue and new customer growth and pharma/biotech clients.

While Oracle Inform, Medidata, and BioClinica had the highest market impact scores, other vendors were not shut out in this section. For example, smaller vendors such as Merge Healthcare and OmniComm Systems had strong revenue growth and an impressive list of CRO clients. Meanwhile, larger vendors such as Oracle RDC and Perceptive Informatics have robust suites of e-clinical solutions and large customer bases that could potentially become EDC adopters. While the larger, multinational companies have an advantage in the market impact section, small and mid-sized vendors are more likely to lead in terms of revenue growth and new customers, two areas that indicate future growth. In addition, as more and more small and mid-sized pharma and

biotech companies conduct clinical trials, they are increasingly adopting EDC, especially those offered by smaller vendors whose business values and operations, in many ways, mirror those of the SMEs.



### Market leaders: technology assessment

The technology assessment section of the solutions guide evaluates the features of the EDC solutions. It should be noted that the demonstrations for the evaluation were conducted in spring 2011 and some vendors may have released newer versions of their EDC systems with improved/updated features and functionality since the demos. The first category is usability and

flexibility in which the main focus is user-friendliness of the user interface, but the assessment also takes into consideration how well the solution configures to provide role-based or user-based views and workspaces as well as authorizations and access to patient data. On a related topic, Ovum also looked at workflow management to assess how easy it is for clinical trials stakeholders to adopt EDC into their daily activities, such as automated to-do lists and checklists, easy to read dashboards, notification alerts, and design tools to build new studies and make mid-study changes. Because EDC is becoming common, most vendors scored highly in these two categories, though some stand out more than others, and improvements can certainly be made in all solutions. In addition, the time to implement and deploy the solution, as well as the average cost and value of EDC were also considered. To clarify, a higher score for implementation/deployment time relates to lower implementation/deployment times and a higher score in cost means a lower average contract price and greater value for the solution. Since EDC usage is highly dependent on the vendor's ability to support study/database design and build, professional services was evaluated. With the market moving toward an interoperable e-clinical platform where EDC is one component, integration is also another important consideration. Lastly, Ovum evaluated each solution's supporting tools, which, while not mandatory, are essential to create a more seamless work environment. These include a trial designer/builder, and reporting and exporting tools.

Unlike with the market impact section, the market leaders in the technology assessment category were harder to separate (see Figure 3). While Medidata and Oracle Inform had the highest overall average, several vendors had very impressive scores for many of the categories. Surprisingly, DATATRAK and Nextrials, the two smallest vendors in this solutions guide that did not qualify as a leader for any of the market impact categories, showed great strength in the technology assessment - proof that you do not need to be a large multinational company with the highest revenue intake to have a good product.

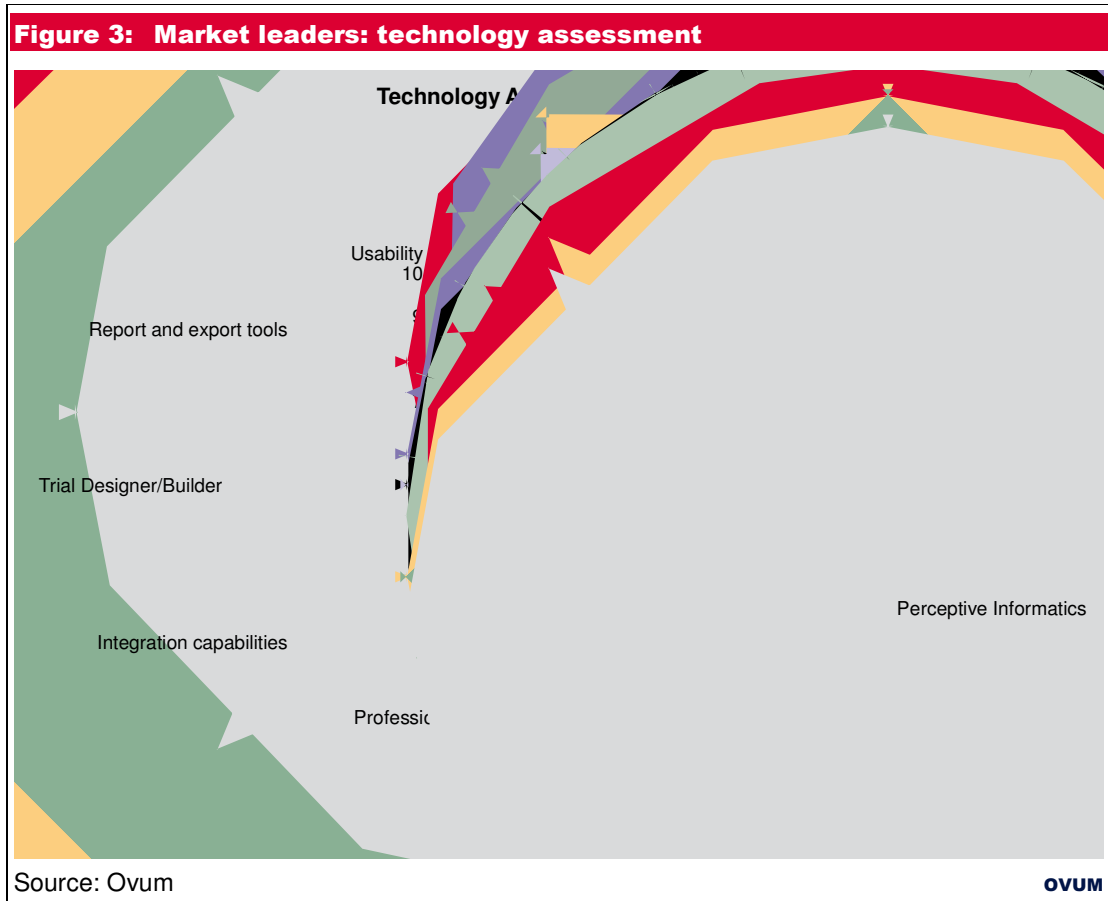
Medidata and Oracle Inform were the best performers overall in the technology assessment. The two categories where neither vendor scored highly are implementation/deployment and cost. Much of this could be attributed to the fact that Medidata and Oracle Inform target big pharma/biotech companies that generally run larger, more complex, global clinical trials, which would in turn result in longer study build times and duration of trials, and therefore greater costs. In addition, these larger clients are usually less sensitive to implementation costs or may have a stronger appetite for costly customizations and other services work. This is not to say that Medidata and Oracle Inform do not support trials that are simpler and shorter, or that other vendors do not have clients running complex trials.

BioClinica, DATATRAK, Merge, Oracle RDC, and Nextrials did well in the technology assessment, achieving high scores in four of the eight categories. BioClinica scored well in



implementation/deployment, cost, and professional services, with the top score in professional services. DATATRAK ranked highly in workflow management, cost, and trial designer/builder. Merge scored well in workflow management, implementation/deployment, and reporting and exporting tools. Oracle's RDC solution is successful in workflow management, integration capabilities, and trial designer/builder, in which it got top rank for its integration capabilities and its trial designer/builder tool. Meanwhile, Nextrials did well in usability and flexibility, implementation/deployment, and cost.

The remaining vendors also made their mark in the technology assessment. OmniComm did well in the cost and professional services categories, with the highest scores for average cost of the solution. Lastly, Perceptive did well in the workflow management category. Therefore, while EDC is becoming highly commoditized, there is still a significant differentiation among EDC vendors in terms of technology and where each vendor excels, giving life sciences companies some flexibility in choosing a solution that best fits their own criteria.



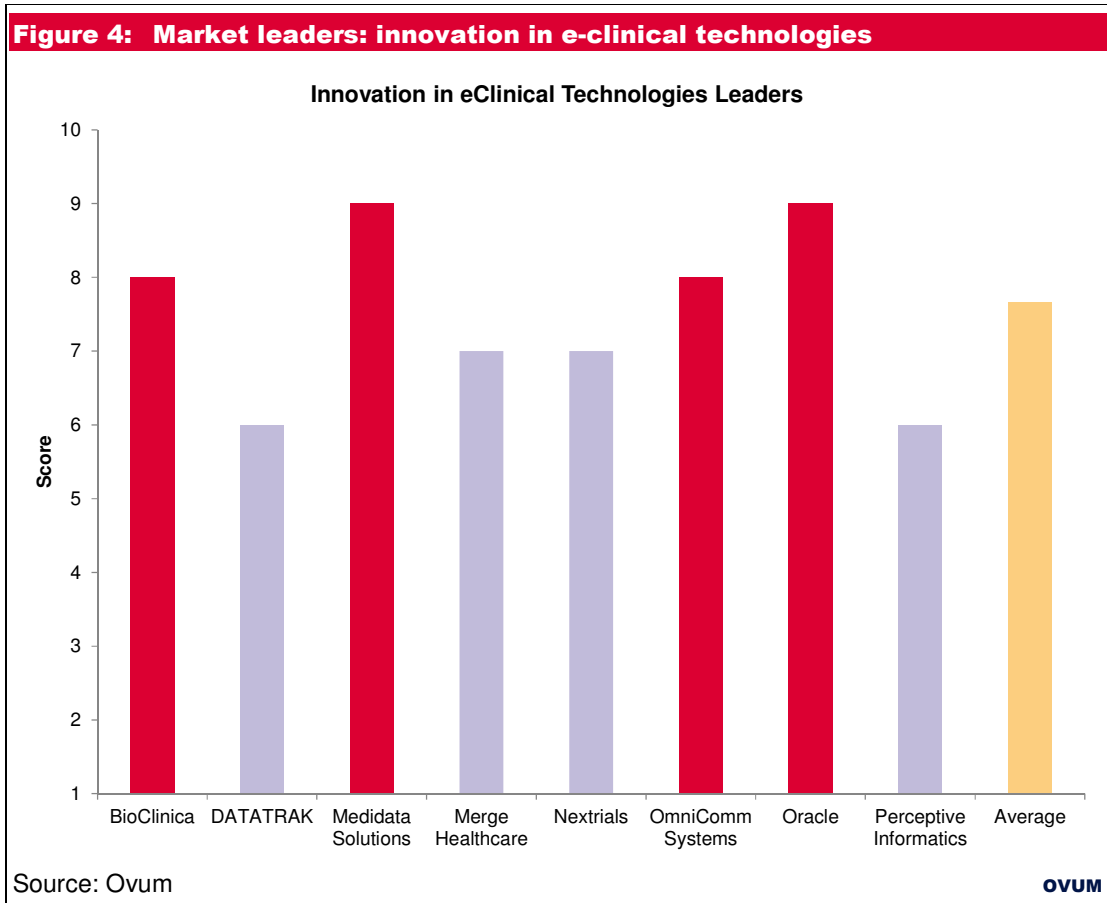
### Market leaders: innovation in e-clinical IT

EDC systems have evolved significantly over the past 20 years. Due to the standardization of clinical trials processes and workflows, EDC solutions themselves have become very similar, and Ovum estimates that 80% to 85% of most EDCs are analogous to each other. Ovum believes it is therefore very important for vendors to make the remaining 15% to 20% as different and innovative as possible to ensure their product stands out. These innovations range from something simple like adding a new feature that clients are asking for, to integrating EDC with other e-clinical technologies to create an interoperable platform, to integrating EDC with non-clinical technologies



such as safety solutions or EHRs to help bridge the life sciences and healthcare industries, to offering analytics to enable sponsors to gain better insight from their clinical data. With the many layers of innovation possible, vendors are judged on how they have influenced the development of EDC, what they are currently doing to evolve the EDC and the overall e-clinical market, the risks vendors are willing to take, and their vision for the future of EDC and e-clinical technologies.

All the vendors in this solutions guide are committed to delivering innovation and have had a hand in shaping the current EDC solution to some extent. While each vendor's future roadmap and vision of innovation differs, Ovum believes that some vendors (shown in red in Figure 4), stand out more than others because they are willing to take the risk to deliver on their vision and be pioneers, rather than wait for someone else to try it first to see if the strategy is successful. These vendors include Medidata, Oracle (Oracle Inform and Oracle RDC were combined as Oracle for this category because the vendor's e-clinical vision and strategy will apply to both solutions), BioClinica, and OmniComm. Medidata ranked highly due its investment in R&D as well as its commitment to continuously provide new and innovative features and products that will ease the management of clinical trials. Oracle's access to its other horizontal products such as middleware and identity and security solutions, combined with its considerable R&D resources and creative development team, make it a top candidate for delivering innovation in e-clinical IT. BioClinica scored well in this category for its imaging solutions, and its foresight around EDC-EHR integrations and leveraging forecasting tools. Lastly, OmniComm received high scores for investing in the development of an EDC-EHR integration, though not publicized or commercialized, as well as beginning to look at how analytics could potentially advance clinical research. Because the level and type of innovation will differ greatly among vendors, life sciences companies should consider the vendors' future roadmaps to ensure that they partner with an EDC provider that has a similar vision of how EDC and e-clinical technologies should be used and advanced.

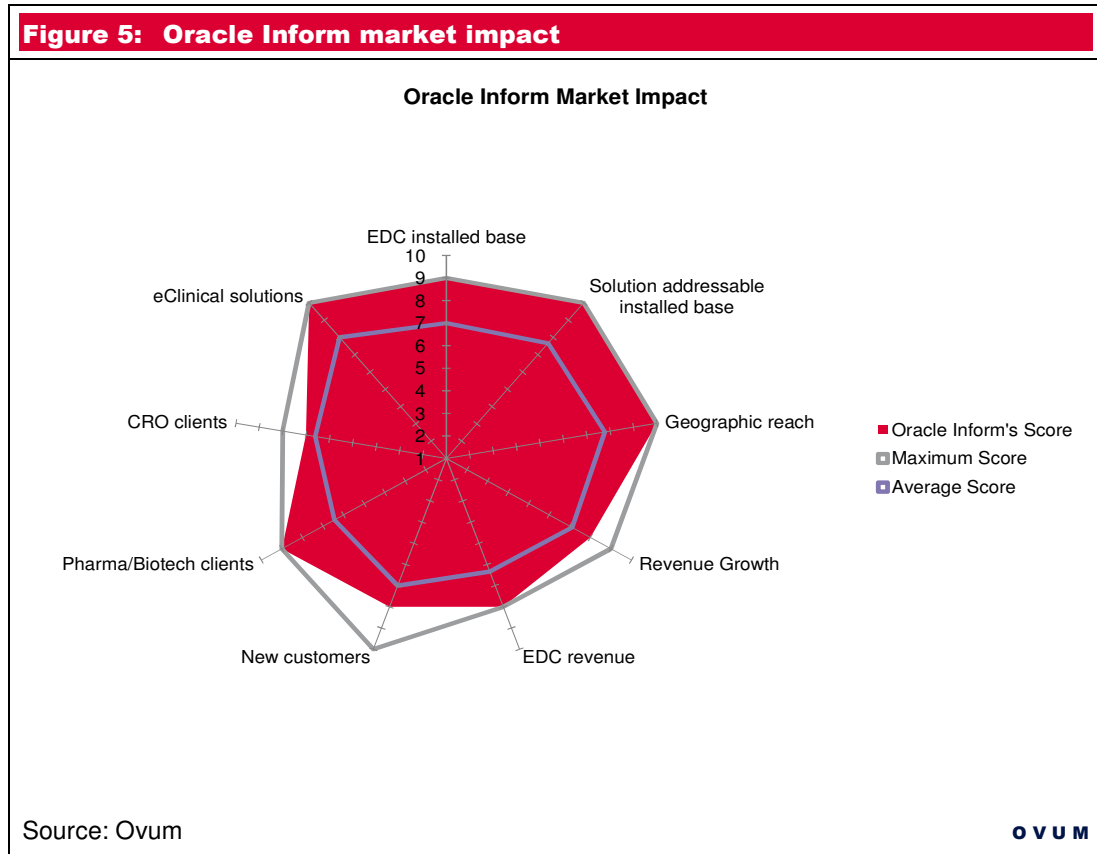


## VENDOR ANALYSIS

### Oracle Inform

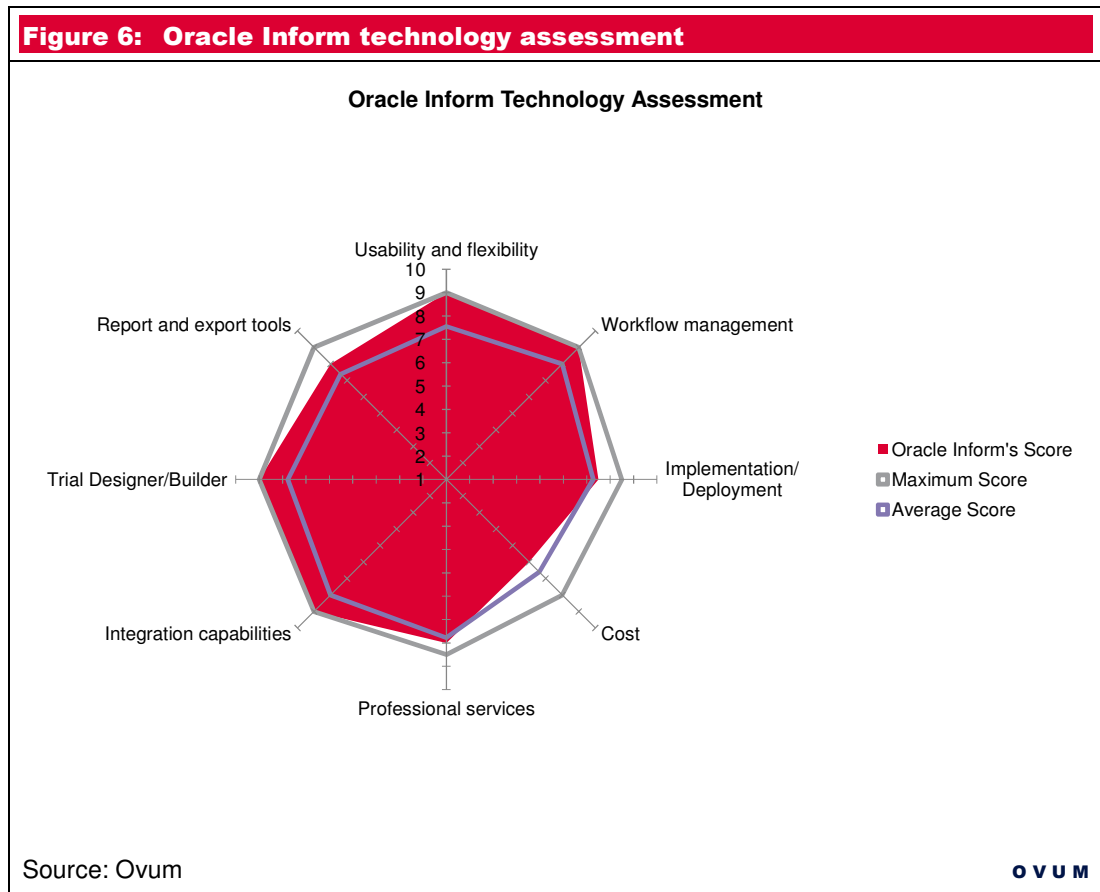
Based in Redwood Shores, California, Oracle is a leading technology provider to the life sciences market, offering enterprise applications and industry-specific solutions that span the pharma product lifecycle. In 2010, Oracle acquired Phase Forward whose e-clinical and safety product portfolio augmented Oracle's existing products. As a result, Oracle now offers two EDC solutions, Oracle RDC and the SaaS-based Oracle Health Sciences Inform GTM (Oracle Inform). In addition to Oracle Inform and its supporting modules, Oracle expanded its portfolio to include, among others, a CDMS, an IVRS, an ePRO, a clinical data repository, and a safety suite. Combined with its services organization, Oracle can boast an end-to-end e-clinical offering.

**Figure 5: Oracle Inform market impact**



Oracle Inform received above average scores in every category, and scored the highest in two-thirds of them (see Figure 17). Oracle Inform has by far the largest EDC installed base and a large solution addressable installed base. Oracle Inform has been used by pharma and biotech companies of all sizes around the world, backed by significant EDC revenue (based on Ovum estimates) to show for it. Its CRO client base may seem low in comparison, but this is due to the market the vendor targeted. Oracle Inform's growth in revenue and new customers, though still high, may have slowed slightly due to the acquisition and ensuing uncertainty about the product's future. However, now that Oracle has stated that Oracle Inform will be a key part of the its e-clinical portfolio, Ovum believes the growth in revenue and new customers will increase.

**Figure 6: Oracle Inform technology assessment**





Tied as the leading EDC (see Figure 18), Oracle Inform received top marks for half the technology assessment categories: usability and flexibility, workflow management, integration capabilities and trial designer/builder. Oracle Inform includes many standard features and functionality but then takes it up a notch. Some examples are: a real-time data viewer for data managers; easy to read and understand dashboards based on traffic light colors; the ability for end users to exchange comments outside of the eCRF; and the ability to complete tasks in bulk. In addition to integrations with Oracle's other e-clinical and safety solutions, Oracle Inform is integrated with many third-party systems. Ovum finds Oracle's trial designer, which has drag-and-drop functionality and a "storyboard" interface that allows the designer to visualize the study, to be quite savvy. Oracle Inform also scored high on report and export tools, which continue to be expanded on a regular basis. Oracle Inform's professional services group is on par with the rest of the industry, but it remains to be seen how the acquisition will affect the services group. Oracle Inform did not score as high on implementation/deployment time and cost. This is likely due to the differences in client needs and study demands from Oracle's varied customer base. The significant diversification in studies also affects the average cost of Oracle Inform.

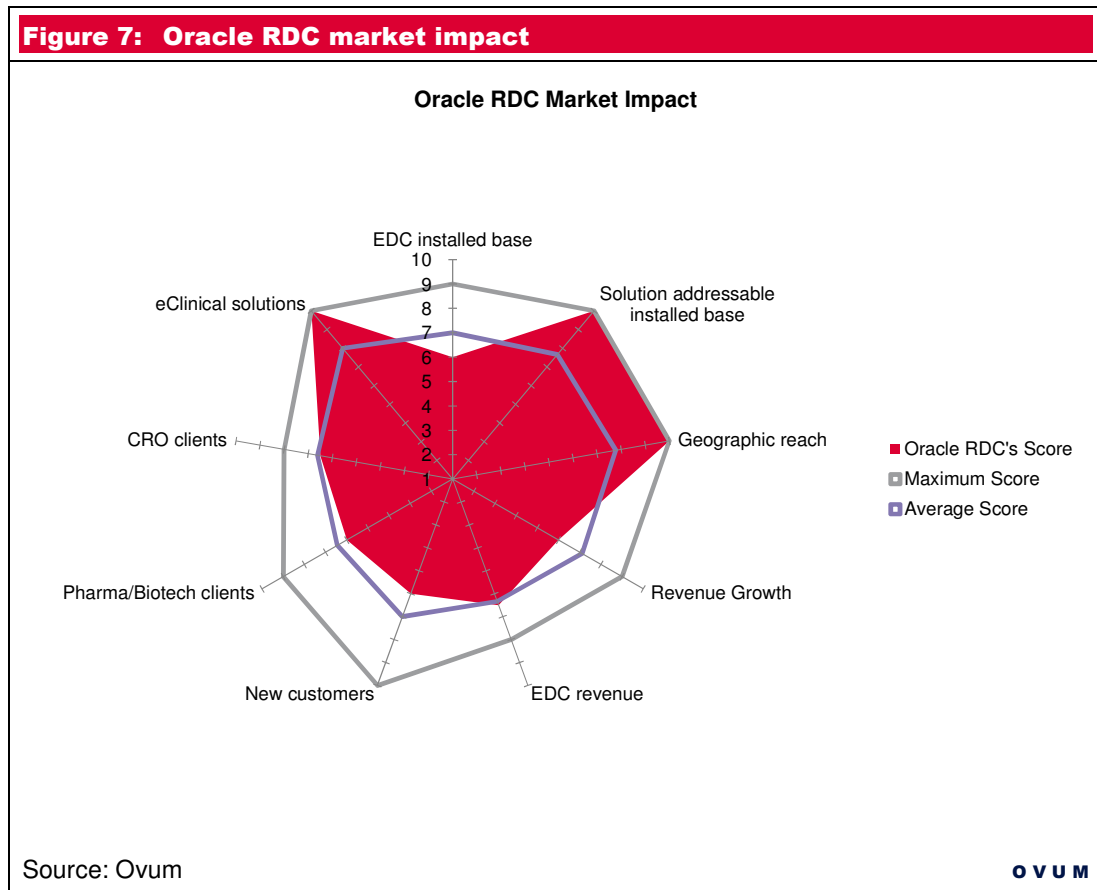
Moving forward, Oracle aims to more tightly integrate all of its e-clinical and safety solutions and to develop a platform that allows for single sign-on and seamless data exchange between the different systems. Oracle stands out for its analytics solution which has improved significantly since its launch. The vendor is also doing some work in the area of bringing signal detection technology to clinical trials, something Ovum believes has been lacking and strongly supports. Therefore, Oracle is considered an innovator in the e-clinical market, scoring 9 out of 10.

#### **Recommendation: Shortlist**

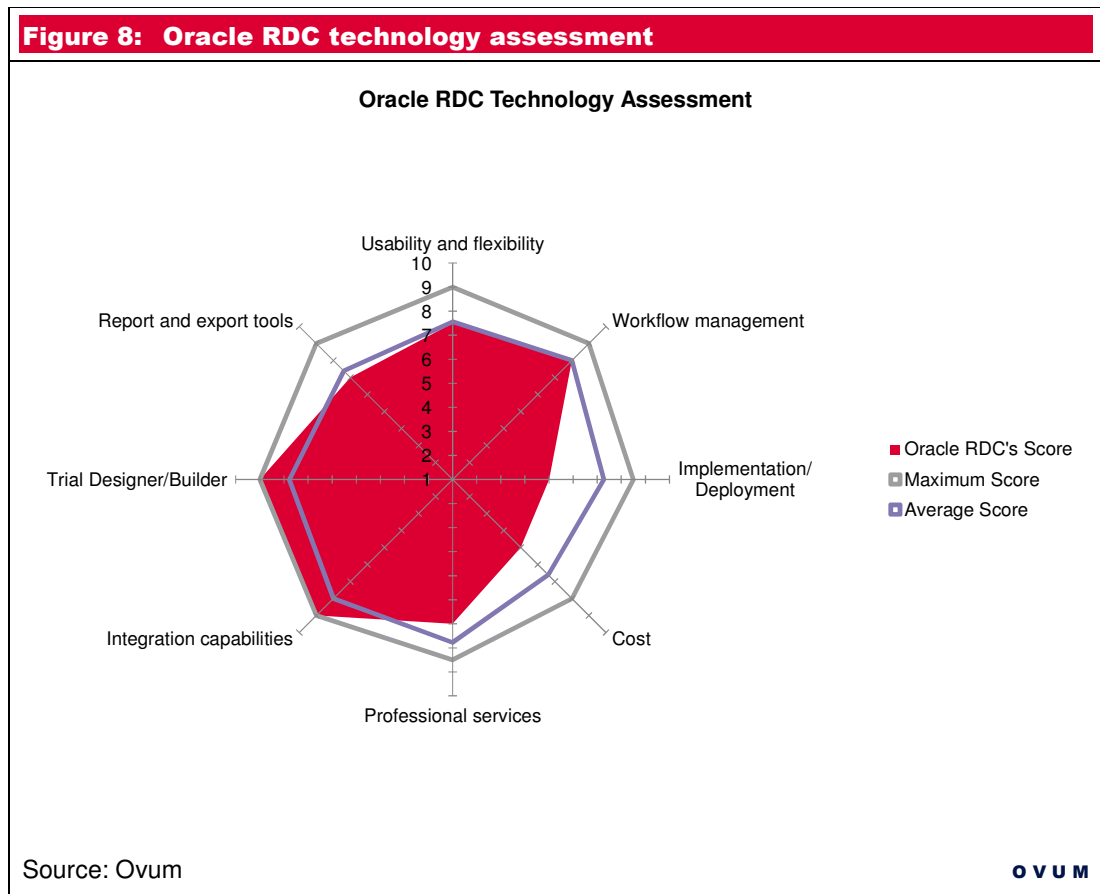
Oracle Inform has been a leading EDC solution for several years, and Ovum believes it will continue to be so. The combination of Oracle Inform's rich features, Oracle's expertise in clinical research, its track record with global customers and its continued focus on innovation in the e-clinical space are all reasons why Ovum believes that Oracle Inform should be shortlisted when evaluating EDC solutions.

## Oracle RDC

With its headquarters in Redwood Shores, California, Oracle is an international supplier of enterprise software. Within the life sciences sector, Oracle offers industry-specific solutions across the pharma value chain, including e-clinical technologies such as EDC, CDMS, CTMS, data warehousing and analytics. While known for its CDMS and CTMS solutions, Oracle's EDC solution, Oracle Remote Data Capture (Oracle RDC), has a solid customer base that includes many big pharma companies and large CROs. In addition, Oracle offers a range of services such as consulting, study design and build, data management, and systems integration, most of which are provided by global partners.



Oracle is a leading vendor in the life sciences space, and it is therefore no surprise that it received top marks in a few market impact categories (see Figure 19). Oracle undoubtedly has the largest health sciences customer base to which it could potentially provide its Oracle RDC solution. In addition, the Oracle brand has global recognition, resulting in customers worldwide. Oracle also offers a wide-ranging e-clinical product portfolio, which was made stronger by the Phase Forward acquisition. Although Oracle RDC is reasonably comprehensive and has strong functionality, Ovum believes the leading reason the installed base of Oracle RDC is lower is due to its on-premise model, which limits the number of life sciences companies that can implement and support it.





The technology assessment scores for Oracle RDC were mixed (see Figure 20). Oracle received the top rank for its integration capabilities and its trial designer. Oracle RDC has been integrated with Oracle's other e-clinical and safety solutions, and can also be connected to external systems. Oracle's trial designer application, which has drag-and-drop functionality and a "storyboard" workspace that allows study designers to visualize the clinical trial, is unique. Oracle RDC's usability and flexibility and workflow management scores fall right around the average. While providing many standard features, Oracle RDC has some differentiators, such as eCRFs that have the look and feel of paper CRFs, graphical eCRFs, the ability for authorized users to access multiple studies with a single sign-on, and of course its tight integration with Oracle Clinical. The report and export tools continue to be improved. Oracle RDC did not do as well in the professional services area due to the perception by smaller companies that more attention will be given to larger customers. However, Oracle has a number of partners that can provide these services. While the on-premise model of Oracle RDC has benefits such as the ability to scale up quickly or have more control of the system, it can also mean longer implementation time and cost. The deployment time for each study should decrease once the solution is implemented. An on-premise model tends to bring higher upfront costs associated with infrastructure as well as annual maintenance. However, having greater control over the system and sensitive data is sometimes worth the additional cost.

Moving forward, Oracle aims to more tightly integrate all of its e-clinical and safety solutions and to develop a platform that allows for single sign-on and seamless data exchange between the different systems. Oracle stands out for its analytics solution, which has improved significantly since its launch. The vendor is also doing some work in the area of bringing signal-detection technology to clinical trials, something Ovum believes has been lacking and strongly supports. Therefore, Oracle is considered an innovator in the e-clinical market, scoring 9 out of 10.

**Recommendation: Consider**

Oracle RDC is a solution that Ovum recommends companies consider when evaluating EDC. Partnering with Oracle provides access to not only a full-featured EDC, but also an expansive list of other e-clinical and safety solutions as well as applications that are necessary further down the product lifecycle. While having an on-premise solution could be problematic, third-party hosting should be considered if the delivery model is the only drawback.

## APPENDIX

### Summary scores

<b>Table 3: EDC industry solutions guide: vendor scores summary</b>			
<b>Vendor</b>	<b>Market Impact</b>	<b>Technology Assessment</b>	<b>Innovation in e-clinical IT</b>
BioClinica	7.4	7.4	8.0
DATATRAK	5.7	7.5	6.0
Medidata Solutions	8.5	8.2	9.0
Merge Healthcare	6.8	7.6	7.0
Nextrials	5.4	7.5	7.0
OmniComm Systems	7.2	7.4	8.0
Oracle RDC	7.4	7.2	9.0
Oracle Inform	8.8	8.2	9.0
Perceptive Informatics	6.8	7.0	6.0

Source: Ovum OVUM

### Ovum ratings

- Shortlist – these vendors’ products and services should be placed on a company’s shortlist for EDC selection. This category represents the leading solutions that Ovum believes are worthy of a place on most technology selection shortlists. Each vendor has established a commanding market position with a product that is widely accepted as best of breed.
- Consider – the vendors in this category have good market positioning, and are selling and marketing the product well. The product offers competitive functionality and good price/performance, and should be considered as part of the technology selection process.



- Explore – solutions in this category have less broad applicability, and may have limitations in terms of the product's functionality, or the vendor's execution capability. However, they will still be suitable to meet specific requirements and may be worth exploring as part of the technology selection process.

## Extended methodology

Ovum assesses EDC vendors based on three core categories, each of which consists of specific evaluation criteria. Taken together, these categories and criteria serve as the basis for Ovum's positioning of vendors as shortlist, consider, or explore in the competitive landscape for EDC in the life sciences market.

### Market impact

Ovum analysts use data collected through primary and secondary research to determine each vendor's market impact. Market impact is measured across nine criteria, each of which are scored on a scale of 1-10, with 10 being the highest. Overall market impact is the average of these six scores, which are:

- EDC-installed base: the number of unique-named life sciences companies having purchased the vendor's EDC solution.
- Solution addressable-installed base: the number of unique-named life sciences companies using at least one of the vendor's industry-specific applications.
- Geographic reach: the number of unique-named companies a vendor has under contract outside of the US.
- Revenue growth: each vendor's revenue growth rate from 2009 to 2010.
- EDC revenue: revenue attributable to the vendor's EDC solution.
- New customers: the number of new unique-named life sciences companies that each vendor brought under contract in 2010.
- Pharma/Biotech clients: the number of unique-named pharma and biotech clients that are currently active customers.
- CRO clients: the number of unique-named CRO clients that are currently active customers.
- E-clinical solutions: the number of other e-clinical solutions (non-EDC) the vendor offers as part of its product portfolio.

## Technology assessment

Ovum analysts assign vendors a score from 1-10, with 10 being the highest, for each of the assessment criteria, whereas the overall technology assessment rating is determined by taking the average of these 10 scores. It should be noted that the demonstrations for the evaluation were conducted in spring 2011 and some vendors may have released newer versions of their EDC systems with improved/updated features and functionality since the demos were done. The technology assessment criteria used for the EDC in life sciences industry solutions guide are:

- Usability and flexibility – measures the user-friendliness of the user interface, as well as how well the solution configures to provide role-based or user-based views, workspaces, and access to patient data.
- Workflow management – assesses how easy it is for clinical trials stakeholders to adopt EDC in their daily activities, i.e. automated to-do lists, checklists, dashboards, notification alerts, and design tools.
- Implementation/deployment – how quickly the life sciences company is "up and running" with the solution and is able to start the trial. The higher the score, the lower the implementation/deployment time.
- Cost – the average cost of implementing EDC for a trial and the value for that price. The cost will depend on numerous factors, such as license versus subscription, the size of the trial, the therapeutic area, and the geographic reach. For this category, the higher the rating, the lower the average contract value.
- Professional services – the availability of a sufficiently skilled professional services team that is able to support the solution's implementation as well as provide strategic advisory services around designing clinical studies. It also considers the availability of services during a trial, such as help desk, training, and the ability to conduct mid-study changes quickly.
- Integration capabilities – the ability for the EDC solution to be integrated "with ease" to create a more seamless data exchange between EDC and other e-clinical tools.
- Trial designer/builder – the extent to which the vendor provides a trial designer/builder to its customers, allowing them to build studies themselves or make mid-study changes without relying on the vendor. It also considers how user-friendly the designer tool is and how easy it is for a clinical trial designer to use it.
- Report and export tools – the extent of the standard reporting and exporting tools the vendor provides in the EDC in order to make data reporting/analyzing easier.



## **Innovation in e-clinical IT**

This is the ability for an e-clinical vendor to differentiate and innovate the EDC solution to ensure that it is more than the basic EDC. These innovations range from something simple like adding a new feature that clients are asking for to integrating EDC with other e-clinical technologies to create an interoperable platform to integrating EDC with non-clinical technologies, such as safety solutions or EHRs, to help bridge the life sciences and healthcare industries. Vendors are judged on how they have influenced the development of EDC, what they are currently doing to evolve the EDC and overall e-clinical market, the risks vendors are willing to take, and their vision for the future of EDC and e-clinical technologies.

## **Sources**

Financial analysis – an analysis of vendors' financial performance, taken from annual and quarterly reports, investor presentations, as well as a variety of secondary sources.

Technology analysis – comprehensive product demonstrations conducted in spring 2011 and corporate briefings.

## **Further reading**

- A Day in the Life of a Drug: Data Management Across the Pharma Enterprise, July 2011, OI00133-033
- ePrescribing Brings Change to the Healthcare and Life Sciences Ecosystem, June 2011, OI00133-006
- The Past, Present and Future of e-clinical Technologies, May 2011, OI00133-008
- Oracle Outlines Health Sciences Strategy at Innovation Forum, May 2011, OI00133-010
- Pharma Pushes BI and SaaS Closer to Center Stage, April 2011, OI00133-005
- SDMS - Unstructured Data Management in the Paperless Lab, January 2011, OI00040-002
- 2011 Trends to Watch: Pharmaceutical Technology, November 2010, OI00001-018
- Industry Dynamics: 2010 Guide to the Asia-Pacific Life Sciences Industry, September 2010, OI00013-002

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- Global Life Sciences IT Spending Forecast Model through 2015, August 2010, IMTC0392
- Clinical research: an outsourcing opportunity, March 2010, OVUM052154
- In Pursuit of the Paperless Clinical Trial: A Look at EDC and CTMS, June 2008, DMTC2216

## Abbreviations

CDMS - clinical data management system

CRF / eCRF - case report forms / electronic case report forms

CRO - contract research organization

CTMS - clinical trials management system

EDC - electronic data capture

EHR - electronic health record

ePRO - electronic patient reported outcomes

IVRS - interactive voice response system

RTSM - randomization and trial supply management

SME - small and mid-sized enterprise

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## Ovum Consulting

We hope that the analysis in this brief 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

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