



WHITE PAPER

EDC in Clinical Trials: A Benchmark Analysis of Oracle RDC

Sponsored by: Oracle

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EXECUTIVE SUMMARY

As the volume of information collected in clinical trials continues to grow, data collection and management is becoming a priority for pharmaceutical and biotech companies. Capturing data in a more accurate and timely fashion is a critical component to reducing time to market for potential new drugs. Companies are aggressively moving from pilot electronic data capture (EDC) implementations to enterprisewide adoption strategies. A Health Industry Insights survey conducted in 3Q05 demonstrates that the successful completion of pilot EDC implementations will green-light deployment of EDC in new clinical trials within 12 months. This trend exists across small, midsize, and large contract research organizations (CROs) as well as biotech and pharmaceutical companies.

As companies increase their utilization of EDC and proceed further along with EDC adoption, an increasing number of benefits begin to present themselves and become commonplace. The research presented in this white paper, conducted by Health Industry Insights and sponsored by Oracle, shows that the use of EDC within clinical trials yields several benefits that lead to time savings, cost reductions, and increased efficiencies. More specifically, these benefits include:

- Reduction in time from last patient visit to database release
- Reduction in the number of required queries
- Efficiency gains from the reuse of forms
- Reduction in site-monitoring costs
- Reduction in project management costs
- Reduction in time surrounding patient enrollment tracking

This white paper also introduces Health Industry Insights' four-stage EDC Maturity Model as a framework to describe the factors that impact EDC adoption. To develop the research data, we took an interview-based approach to determine the quantitative and qualitative data that demonstrates the value proposition of moving from paper to EDC.



METHODOLOGY

The objectives of this white paper are to examine and develop estimates of benchmark metrics for using EDC in the clinical trial process. To create the primary research necessary to accomplish these objectives, Health Industry Insights developed a set of questions tailored to derive time and cost savings gained from using EDC versus a traditional paper-based approach. A series of in-depth interviews was conducted with individuals involved in the management and operation of Phase I, II, III, and IV studies within CROs and pharmaceutical companies. In contacting these targeted clinical trial professionals, we aimed to speak with a variety of environments to get a distribution of samples. Health Industry Insights interviewed four customers using Oracle's Remote Data Capture (RDC) from companies of various sizes — small to large — and organization types — pharmaceutical and CRO. The results of those interviews are presented in the Study Findings and Case Studies sections of this document.

Throughout this study, Health Industry Insights deliberately chose what we believe to be conservative estimates for assumptions used to build the benchmarks. The case studies may show dramatic performance in some areas and lower-than-expected results in other areas. Each company must take into account its own situation and market when estimating existing or potential benchmark metrics.

IN THIS WHITE PAPER

This white paper presents data from a recent study conducted by Health Industry Insights and sponsored by Oracle. The study is aimed at understanding and evaluating the value proposition for the use of EDC within clinical trials. The white paper includes the following sections:

- ☒ **Situation Overview:** The Situation Overview section provides a review of the current market forces and recent trends in the clinical trial space.
- ☒ **Maturity Model:** The Maturity Model section presents a theoretical framework developed by Health Industry Insights to assist end users in determining an average benchmark for using EDC over paper.
- ☒ **Study Findings:** The Study Findings section presents both qualitative and quantitative data derived from interviews with four Oracle customers.
- ☒ **Case Studies:** The Case Studies section highlights four examples of companies that are using Oracle RDC at varying levels within their clinical trials and the benefits each has achieved. Where possible, each benefit is compared with the benchmark predicted by the EDC Maturity Model or, if available, with the average benchmark noted in Health Industry Insights' larger study of 21 companies titled *EDC in Clinical Trials: An ROI Analysis* (Health Industry Insights #HI200611, February 2006).

SITUATION OVERVIEW

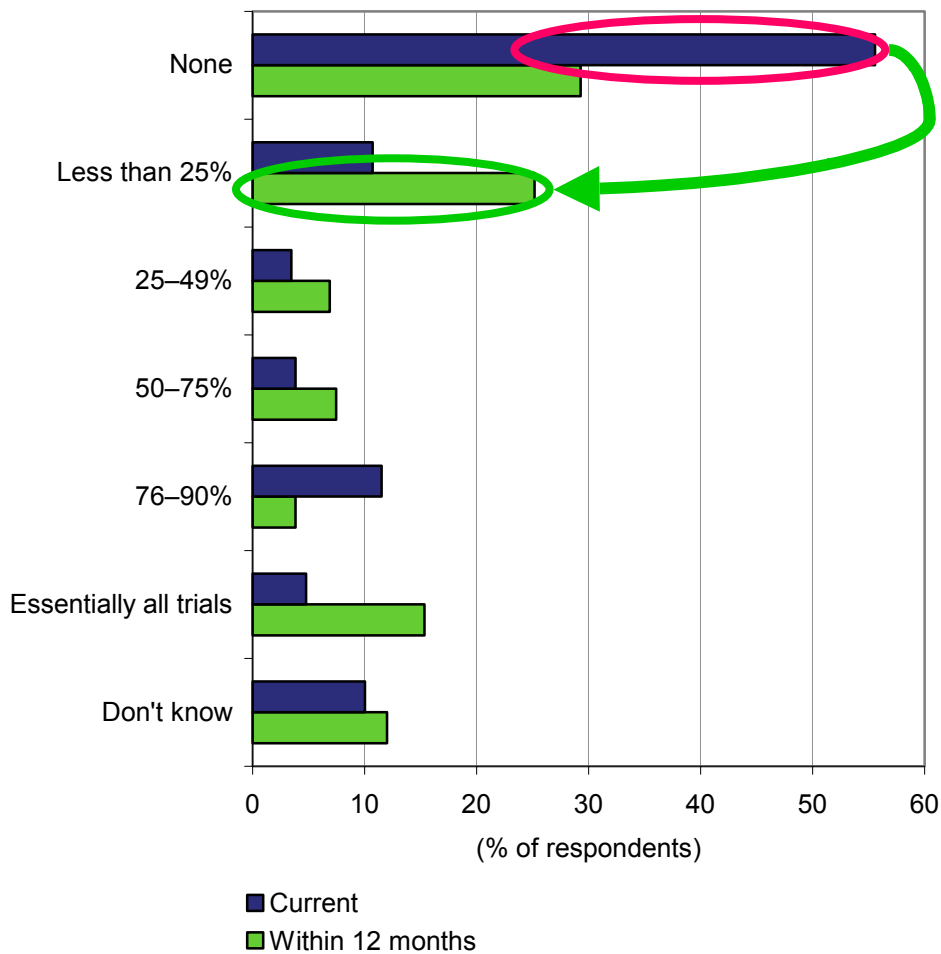
Data collection and management within clinical trials is a priority for pharmaceutical and biotech companies. Capturing data in a more accurate and timely fashion is critical to reducing time to market for new drugs and containing costs. Companies are aggressively moving from pilot EDC implementations to enterprisewide adoption strategies. Figure 1 illustrates the market's desire to embrace EDC.

As companies move further along the EDC adoption curve, time savings, reduced costs, and increased efficiencies from EDC utilization are becoming commonplace and more companies are realizing the value that EDC tools hold in store for them.

FIGURE 1

Current and Expected Levels of EDC Use in Clinical Trials

Q. Please indicate your company's current and expected levels of EDC use in clinical trials in 12 months.



Source: Health Industry Insights' 3Q05 Leading Indicators in Life Science IT Spending Survey

CHALLENGES

As with any technology, there are potential challenges to adoption and full realization of the benefits expected by the system. This document illustrates the benefits of migrating from paper to EDC, such as cost reductions, time savings, and gained efficiencies. While these benefits are very attractive, life science companies should also recognize the challenges they may face on the road to EDC adoption. Some of these challenges may include:

- ☒ Companies with a long history of conducting paper-based trials could face cultural adoption barriers, placing great importance on change management.
- ☒ EDC setup time at the front end of clinical trials can take up to twice as long with some EDC solutions that have less intuitive design capabilities and involve groups such as data management much sooner in the study build process.
- ☒ With the additional data structure put in place with EDC, some companies may initially experience increased difficulty surrounding the ability to implement midstudy changes.
- ☒ Efficiency gains may not appear immediately. Organizations must be vigilant as well as patient as they become more accustomed to using EDC and can reuse forms and edit checks to reduce process redundancy.

MATURITY MODEL

The use of EDC in clinical trials is rapidly changing, adoption is quickly increasing, and companies are realizing a wide range of benefits depending on their level of EDC adoption. The following four-stage EDC Maturity Model has been developed by Health Industry Insights to provide a framework for companies to benchmark their performance from the use of EDC tools. This model, intended as a general reference, was developed using interview data obtained for this study as well as data incorporated from other sources. Health Industry Insights will continue to develop the metrics presented in the EDC Maturity Model in future research.

Stage 1: Pilot/Single Study

Definition

Companies in the first stage of EDC adoption, referred to as the pilot stage, are actively conducting experimental EDC implementations within a single study or within a very limited number of clinical trials. The primary goal of companies involved in conducting these pilot or single-study EDC implementations is to identify the possible benefits achievable within their own organization. Stage 1 companies are actively investing both time and budget to ensure the benefits from EDC are more than just hype.

Expected Performance Benefits

Table 1 presents expected performance benefits at stage 1.

TABLE 1	
Expected Performance at Stage 1 of EDC Adoption (%)	
Benefit	Stage 1 Performance
Increase data availability	50
Decrease database lock time	45
Decrease number of queries	30
Decrease enrollment tracking time	10
Decrease site visits	5
Increase reuse	–

Source: Health Industry Insights, 2006

Additional Success Criteria

The following criteria were identified as important to successfully move companies from stage 1 to stage 2 in the EDC Maturity Model:

- Deployment options.** The deployment scenario is one of the most critical decisions that face companies evaluating the adoption of EDC. Should a company purchase the solution as a technology transfer, subcontract to a CRO, or utilize a hosted service? Solutions that demonstrate a migration path from completely hosted to customer owned will appeal to a wider range of companies concerned about the risk of premature deployment.
- Interoperability.** In companies with an established technology investment in one or more areas adjacent to EDC (e.g., clinical data management systems [CDMSs], interactive voice response systems [IVRSs], business intelligence [BI], central lab), interoperability is an important criterion for success in the pilot stage. An extensible architecture or native integration with installed applications such as a CDMS may prove to be the deciding factor when deploying EDC across the enterprise.
- Follow-on features.** As companies interact with EDC solutions in the pilot stage, they will uncover important unanticipated feature benefits. The pilot stage provides companies with the opportunity to roll out services they may not have otherwise been able to offer to their users. EDC solutions that provide a wide range of features beyond 21 CFR Part 11–compliant data capture, such as trial management reporting or site/query management, stand to benefit as a de facto standard where no legacy system currently exists.

- ☒ **Customer support.** The ability to support the technology underlying EDC is an obvious necessity. Troubleshooting browser conflicts, network connectivity, firewall issues, and other problems is the mainstay of help desks everywhere. Often overlooked but equally important to the success of a pilot EDC implementation is the ability to support the clinical side of the organization. Investigator sites may need to be provisioned with hardware or trained on regulatory requirements such as 21 CFR Part 11. EDC solutions that provide clinical users with self-help tools or that can offer help desk services that complement the company's own IT staff will increase their chance of survival through the pilot stage.

Stage 2: Limited Standardization

Definition

Companies in the second stage of EDC adoption, referred to as the limited standardization stage, have moved past piloting EDC and have recognized its value potential in their organization. Stage 2 customers seek to test the solution's ability to fully scale and are assessing its reliability. They typically expand EDC deployment to other trial phases or different therapeutic areas.

These companies are now using EDC in 10–75% of their existing clinical trials. Paper-based data capture exists in 25–90% of current trials, sometimes concurrently with EDC use, but reliance on paper-based practices is steadily declining. Tight integration between EDC and a limited number of other important clinical systems, such as CDMSs, ediaries, IVRSs, document management systems, or compliance monitoring systems, exists in stage 2.

Expected Performance Benefits

Table 2 presents expected performance benefits at stage 2.

TABLE 2

Expected Performance at Stage 2 of EDC Adoption (%)

Benefit	Stage 1 Performance	Stage 2 Performance	Total Performance Through Stage 2
Increase data availability	50	25	75
Decrease database lock time	45	10	55
Decrease number of queries	30	10	40
Decrease enrollment tracking time	10	35	45
Decrease site visits	5	20	25
Increase reuse	–	30	30

Source: Health Industry Insights, 2006

Additional Success Criteria

The following criteria were identified as important to successfully move companies from stage 2 to stage 3 in the EDC Maturity Model:

- ☒ **Reuse component.** Reuse is often stated as a key benefit derived from the use of EDC solutions. However, the benefits of reuse become apparent only after several trials have been initiated using EDC. The learning curve can be quite steep with EDC. A successful EDC solution will catalog successful forms, edit checks, and so forth, making them easily retrievable and editable for reuse in other trials.
- ☒ **Scalability.** In stage 2, companies attempt to test the solution with production data from multiple trials. Speed and performance as measured by page turns or record lookup are key metrics. Solutions that can demonstrate a near-flat response curve as the system grows will benefit from continued user satisfaction.
- ☒ **Reliability.** Without question, the overall reliability of the EDC solution is a critical requirement for all stages of EDC deployment. Reliability is especially important in stage 2 as customers initiate new, larger trials and their dependence on the solution grows. Solutions that can demonstrate consistent reliability and effectively recover from a wide degree of system outages will obtain the level of user satisfaction necessary to deploy EDC enterprisewide.
- ☒ **Deployment migration.** After successfully moving out of the pilot stage, companies may decide to redeploy the solution from a single-study license to an enterprise license. Some larger customers may further look to bring the EDC solution in-house in the form of a technology transfer. Solutions that afford easy migration from completely hosted to customer-owned deployments can gain momentum.
- ☒ **Interoperability.** As the EDC solution is deployed to a larger number of groups within the organization, the need to integrate with an adjacent technology (e.g., CDMSs, IVRSs, BI, central lab) may increase. As in stage 1, interoperability can be an important criterion for continued success. An extensible architecture or native integration with installed applications such as IVRSs may prove to be the deciding factor when deploying EDC across the enterprise.
- ☒ **Professional services.** Help desk support will continue to be required in stage 2. However, the need for a responsive, capable professional services team that can expand the solution to meet additional clinical requirements is critical.

Stage 3: Standardization

Definition

Companies in the third stage of EDC adoption, referred to as the standardization stage, have standardized on EDC for all new trials over all phases and therapeutic areas. Most clinical trials using paper are doing so only because they began prior to initial EDC implementation and are grandfathered until they conclude. There is a high level of integration between EDC and other systems such as CTMSs, laboratory systems, project management systems, payment systems, and IVRSs. During this stage, companies commit to a preferred EDC solution vendor and willingly entertain discussions about forming long-term partnerships with vendors.

Expected Performance Benefits

Table 3 presents expected performance benefits at stage 3.

TABLE 3				
Expected Performance at Stage 3 of EDC Adoption (%)				
Benefit	Stage 1 Performance	Stage 2 Performance	Stage 3 Performance	Total Performance Through Stage 3
Increase data availability	50	25	10	85
Decrease database lock time	45	10	10	65
Decrease number of queries	30	10	15	55
Decrease enrollment tracking time	10	35	15	60
Decrease site visits	5	20	15	40
Increase reuse	–	30	20	50

Source: Health Industry Insights, 2006

Additional Success Criteria

The following criteria were identified as important to successfully move companies from stage 3 to stage 4 in the EDC Maturity Model:

- Flexibility.** Customers in stage 3 have proven the value of EDC in their business and continue to see benefits in a number of areas as described above. Stage 3 customers may find that EDC solutions that offer additional feature flexibility, such as those found in CTMS or performance monitoring, replace those solutions in the eclinical ecosystem.
- Professional services.** The support needs generated by the extension of EDC solutions beyond simple data capture may require a significant investment in the customer's internal technical staff or in additional professional services offered by the vendor. The need for a responsive, capable professional services team that can expand the solution to meet additional clinical requirements is critical.
- Vendor stability.** Customers in stage 3 have committed to a preferred EDC solutions vendor. The vendor's ability to demonstrate a solid, viable business model that will sustain a long-term partnership with its customers is key.

Stage 4: Enterprise Deployment

Definition

Companies in the fourth stage of EDC adoption, referred to as the enterprise deployment stage, have standardized enterprisewide on a single integrated EDC solution. All clinical management systems are fully integrated with the EDC system. All note taking is done directly in the system, and all signatures are done electronically. A small number of clinical trials, or certain portions of a trial, may still require the use of paper. EDC solutions found in stage 4 provide hybrid paper/electronic features that support a limited number of paper records.

Expected Performance Benefits

Table 4 presents expected performance benefits at stage 4.

TABLE 4

Expected Performance at Stage 4 of EDC Adoption (%)

Benefit	Stage 1 Performance	Stage 2 Performance	Stage 3 Performance	Stage 4 Performance	Total Performance Through Stage 4
Increase data availability	50	25	10	5	90
Decrease database lock time	45	10	10	10	75
Decrease number of queries	30	10	15	15	70
Decrease enrollment tracking time	10	35	15	5	65
Decrease site visits	5	20	15	20	60
Increase reuse	–	30	20	30	80

Source: Health Industry Insights, 2006

Additional Success Criteria

The following criteria were identified as important to companies to successfully complete stage 4 of the EDC Maturity Model:

- Best practices codified.** Customers in stage 4 have built a library of experience. EDC solutions found in stage 4 provide customers with a foundation of best practice workflows and process tools. Study build decreases from months to weeks, and the critical path items for study start-up revert to clinical and protocol milestones. Institutional review board (IRB) approval becomes the critical path item, and the time from approval to first patient randomization goes to near zero.

- ☒ **Productivity.** The benefits of EDC are clearly visible in stage 4 companies. The investigator site, clinical research associate (CRA), or study coordinator invests no appreciable time or effort in resolving queries resulting from data entry errors. The data is cleaner sooner. With the increase in available time, data managers spend less time generating queries and devote more time to trial analytics.
- ☒ **Vendor stability.** Customers in stage 4 have committed to a preferred EDC solutions vendor. The vendor's ability to demonstrate a solid, viable business model that will sustain a long-term partnership with its customers is key.

STUDY FINDINGS

This section presents both qualitative and quantitative data derived from interviews with four Oracle customers.

Qualitative Expectations of EDC

Qualitative data collected during this study consisted of input from four interviewees, all users of Oracle RDC. The titles of interviewees for this study included president, director, and vice president. The following sections summarize the qualitative benefits experienced by all of the companies interviewed. Qualitative benefits not consistently cited by all interviewees can be found in the case studies.

EDC Purchasing Goals

Those interviewed as part of the study explained that the original intent to purchase EDC was fueled by several benefits expected from the adoption of the technology. Those benefits included:

- ☒ Ability to perform interim or ad hoc data analysis earlier within trials, leading to early trial conclusion
- ☒ Reduction in time from protocol approval to database becoming live
- ☒ Reduction in time from last patient visit to database lock
- ☒ Increase in capacity for clinical operations
- ☒ Reduction of overall clinical trial cost

Cost reduction, although it was noted as an expected benefit, was the least mentioned motive for purchasing an EDC system. However, the ability to save time and effort over the duration of the trial, especially at the end, was a key emphasis. As one clinical manager we spoke with stated when discussing the time it takes to lock the database, "[With EDC], it's like going from a few weeks to a few days."

EDC Selection Criteria

The EDC vendor selection process within the companies included in this study was based on five key decision criteria, according to those interviewed. Those criteria, in order of importance, were:

1. Ease of use
2. Integration with Oracle Clinical
3. Cost
4. Architecture
5. Financial stability of vendor

Ease of use was cited as the most heavily weighted decision factor in EDC system selection. This criterion includes user interface (UI) attractiveness and time to productivity with regard to system training. In terms of architecture, thin client was the most desired choice, followed by EDC systems that have both online and offline capabilities. The average system selection process included a vendor-completed RFI, demo, and short pilot project.

Quantitative Aspects of Benchmark Performance

The four companies using Oracle RDC that were interviewed in this study consistently cited five main categories in which they had realized a definitive performance increase based on their EDC investments. Those categories were form reuse, query reduction, database locking, project management, and site monitoring. Beyond these categories, companies also cited an increase in data availability and data quality (which improved the data analysis process) as benefits realized, but they were often unable to quantify these gains. Not all companies surveyed had formally computed their EDC benefits; however, those that had averaged an overall 17.5% clinical trial cost reduction from EDC (see Table 5).

Quantitative data collected during this study consisted of input from four interviewees, all users of Oracle RDC. The titles of interviewees for this study included president, director, and vice president. The following sections summarize the qualitative benefits experienced by all of the companies interviewed.

TABLE 5

Summary Data: Benefits from EDC in Clinical Trials

Area of Benefit	Average Benefit
Data availability	71.0% increase in data availability
Form reuse	58.0% reusability
Query reduction	53.3% fewer queries
Database locking	56.6% time reduction
Project management	25.0% cost reduction
Site monitoring	20.0% cost reduction
Overall	17.5% cost reduction

n = 4 (customers of Oracle RDC)

Source: Health Industry Insights, 2006

Data Availability

Delays in the availability of visit data can have a profound effect on the conduct of a clinical trial. The use of EDC can dramatically improve insight into critical areas such as patient recruitment tracking and safety. On average, companies using Oracle RDC reported a 71.0% increase in the speed with which visit data is posted to the database and available for reporting.

Form Reuse

Some companies reported that the creation and design of forms during the first few trials of EDC adoption could be time-consuming. However, efficiencies gained over the long term from their reusability easily justify the up-front time investment. On average, companies using Oracle RDC reported 58.0% reusability of case report forms (CRFs) and edit checks.

Query Reduction

Edit checks built into forms provide an up-front filter for all information entered in the system. Rather than requiring several weeks to resolve on paper, all information is resolved automatically in real time. Above and beyond the data quality improvements that result, this process drastically reduces the number of open queries later in the trial. On average, companies using Oracle RDC reported that they experienced a 53.3% reduction in the number of queries.

Database Locking

Because of the natural efficiencies gained from managing data electronically, as well as the increased data quality resulting from edit checks, companies are able to reduce the amount of time from last patient visit to the time the database is locked and released. On average, companies using Oracle RDC experienced a 56.6% time reduction for database lock.

Project Management

Elimination of data management in paper-based form has resulted in time savings associated with the project management of clinical trials. The ability to research and retrieve source data on a specific site or subject is dramatically increased through the use of EDC tools. Creating protocol deviations or notes to file, for example, takes far less time. On average, companies using Oracle RDC experienced a 25.0% reduction in project management costs.

Site Monitoring

Site visits are expensive and time-consuming. With remote access to site data, monitors are able to review data from their home or office and make decisions about when and where to go based on information that has been entered into the system. The result is fewer site visits. Further, with proactive review of trial data, site visits become more productive because data is readily available and easily searchable. On average, companies experienced a 20.0% reduction in site-monitoring costs.

CASE STUDIES

The following case studies highlight the results experienced by the four Oracle customers interviewed in this study. The case studies depict companies of differing sizes to showcase the full spectrum of benefits experienced by companies deploying EDC. Where possible, each benefit is compared with the performance predicted by the EDC Maturity Model or, if available, with the performance in Health Industry Insights' larger study of 21 companies titled *EDC in Clinical Trials: An ROI Analysis* (Health Industry Insights #HI200611, February 2006).

Scenario 1: Large Pharmaceutical

Overview

A large CRO has been using EDC for three years. The company is currently operating 100 clinical trials, 40 of which utilize EDC. It is currently using EDC in Phases II through IV and aims to have all new trials started on EDC going forward. Integration across systems is limited, and esignatures are not fully utilized.

Maturity Model Stage

Standardization (stage 3)

Benefits

- ☒ As clinical data management evolves from batch-oriented to transactional systems, the timeliness of clinical data is critical. This company realized an impressive **95% increase in data availability** compared with the 85% increase predicted in the EDC Maturity Model for companies at the same stage of EDC adoption.
- ☒ Query resolution accounts for a considerable amount of the hidden cost in clinical trials. This company realized a **70% decrease in the number of queries**. This result compares favorably with both the 55% reduction predicted in the EDC Maturity Model for a stage 3 company and the 44.6% performance increase averaged by the other 20 companies in the larger EDC adoption study.
- ☒ While data validation time was not tracked specifically in the study, this company realized a **30% decrease in time to validate data**, a value consistent with that of an organization that has efficient data management processes in place.
- ☒ This company realized a **30% decrease in database lock time for interim analysis**.

Quote

- ☒ "With paper it took over 12 weeks to get 30% of the [visit data] ... [with EDC] we had as much as 80% of the data in-house one week after the patient visit."

Scenario 2: Midsize CRO

Overview

A midsize CRO is currently operating 100 clinical trials, 12 of which utilize EDC. It is currently using EDC in Phases I through III, with a goal of using EDC in 30% of its trials this year and in 80% of its trials within five years. A great deal of emphasis is placed on integrating EDC with its bioanalytics tool for the submission of approval data.

Maturity Model Stage

- ☒ Limited standardization (stage 2)

Benefits

- ☒ The long-term benefits of real-time access to clinical data are just being imagined. This company is well positioned to reap those benefits with an **80% increase in data availability** compared with the 75% performance increase predicted in the EDC Maturity Model for a stage 2 company.
- ☒ This company realized a **75% decrease in database lock time** compared with the 55% performance increase predicted in the EDC Maturity Model and the 46.8% average performance increase realized by the 20 other companies interviewed in the larger EDC adoption study.

- ☒ While many companies could measure the reduction in the overall number of queries, this company went one step further, stating that it had realized a **40% decrease in time to resolve queries**.
- ☒ The **25% decrease in project management time** realized by this company is slightly lower than, but in line with, the 29% reduction realized by the 20 other companies in the larger EDC adoption study.
- ☒ This company stated that it had realized a **25% increase in productivity during site visits**. While this white paper intended to account for only the decrease in the number of site visits, this efficiency gain may be a very meaningful benefit for many CROs.

Quote

- ☒ "[The migration from paper] is easier; [sites] like the interface because it looks like a piece of paper."

Scenario 3: Small CRO

Overview

A small CRO has been using EDC for two years. Of the 45 clinical trials the company is operating primarily in the United States and Europe, two (a Phase II trial and a Phase III trial) are using EDC. Integration exists between EDC, CDMS, and a bioanalytics tool.

Maturity Model Stage

- ☒ Limited standardization (stage 2)

Benefits

- ☒ This company realized an impressive **75–80% decrease in time to database lock**, a process that is historically time-consuming and resource-intensive. The company realized database lock in nearly half the time of the other 20 companies interviewed.
- ☒ The **40–50% increase in data availability** realized by this company in its two clinical trials using EDC is consistent with the performance expected in the EDC Maturity Model for an early stage 2 company.
- ☒ The **50% reduction in the number of queries** realized by the company compares favorably with both the 40% reduction expected for a stage 2 company in the EDC Maturity Model and the 44.6% reduction averaged by the other 20 companies interviewed in the larger EDC adoption study.
- ☒ This company reported that it had attained a **30% reuse of forms and edit checks**, which is consistent with the performance predicted by the EDC Maturity Model for stage 2 companies.

- ☒ The company reported a **15% reduction in the number of site visits**, which is consistent with that of a company early in stage 2 of the EDC Maturity Model's adoption curve.
- ☒ Another benefit realized by the company, and certainly a positive contributor to its impressive performance increase in database lock, was the **25–30% decrease in time to validate data** by using EDC.

Quote

- ☒ "Improved efficiency, better data ... sites are getting more and more used to [using EDC] and beginning to expect [those benefits] now."

Scenario 4: Midsize CRO

Overview

A midsize CRO has been using EDC for over three years. The company is currently operating well over 100 clinical trials, approximately 20 of which are using EDC. However, as the most important indication of its adoption of EDC, the company rolls out all new trials using EDC. Tight integration exists between EDC and CDMS, thesaurus management, and a bioanalytics tool.

Maturity Model Stage

- ☒ Limited standardization (stage 2)

Benefits

- ☒ The company reported a **greater than 70% increase in data availability**, which is consistent with the 75% performance increase expected in the EDC Maturity Model.
- ☒ The **45% reduction in the number of queries** realized by the company compares favorably with the 44.6% reduction averaged by the other 20 companies interviewed in the larger EDC adoption study.
- ☒ This company realized a **50% decrease in database lock time** compared with the 55% performance increase predicted in the EDC Maturity Model and the 46.8% average performance increase realized by the 20 other companies interviewed in the larger EDC adoption study.

Quote

- ☒ "We have a global library [that is] reused for different forms and different projects."

CONCLUSION

The results of this study, coupled with the benefits predicted in the Maturity Model section of the white paper, demonstrate the performance increases available to companies as they continue to deploy Oracle RDC for use in their clinical trials. The exceptionally high reuse of CRF pages and edit checks reported by customers of Oracle RDC indicates that Oracle's EDC solution has become an integral component of the clinical trials conducted by these companies.

The research presented in this study consistently cites lack of adoption at investigator sites as one of the greatest obstacles to successfully deploying EDC in clinical trials. Oracle RDC's use of CRF pages, whose layout can be made consistent with paper CRFs and which utilize a widely accepted client technology in Adobe Acrobat, greatly improves the adoption of EDC at investigator sites that are migrating from paper-based studies to EDC.

Oracle RDC customers expressed confidence in rolling out the application because of the tight level of integration with other Oracle applications such as Oracle Clinical and Oracle Discoverer. As one customer stated, "Data quality is built in the system, timelines are shorter, cost is down, and quality is better — I think we've won all the way around."

LEARN MORE

Related Research

- ☒ *U.S. Clinical Trial Management Systems 2006–2010 Forecast and Analysis* (Health Industry Insights #HI201214, April 2006)
- ☒ *Linking Clinical Research and Electronic Health Records* (Health Industry Insights #HI201078, March 2006)
- ☒ *1Q06 Leading Indicators in Life Science IT Spending Survey* (Health Industry Insights #HI10024, March 2006)
- ☒ *EDC in Clinical Trials: An ROI Analysis* (Health Industry Insights #HI200611, February 2006)

DEFINITIONS AND ACRONYM GLOSSARY

- ☒ **Case report form (CRF).** The paper or electronic form that is used to collect data in clinical trials
- ☒ **Data availability.** The point at which clinical data is posted to the database and available for reporting
- ☒ **Database lock.** The data cleaning and query resolution process as well as preparation of the database for submission

- ☒ **Edit check.** A logic check applied during data entry that is designed to detect out-of-range values, missing fields that are required, or any inconsistencies with other data elements in the system
- ☒ **Electronic data capture (EDC).** A method for using computers and other devices to electronically capture and store data generated during the conduction of clinical trials
- ☒ **Interactive voice response (IVR).** An automated voice or key recognition system typically used to collect trial data, randomize subjects, and allow sites to request drug and study supplies
- ☒ **Patient enrollment tracking.** The duration from patient screening and randomization to the availability of data from the patient's first visit (See data availability.)
- ☒ **Queries.** Management of data clarification form (DCF) entries as well as clinical alerts and site issues
- ☒ **Site visits.** Travel to and from an investigator site by a clinical monitor

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