Medidata Will Dominate Large Pharma But Will See Little Movement Down Market

Companies: BIOC, DTRK, HPQ, IBM, MDSO, MRGE, ORCL, PRXL

December 13, 2013

Research Question:

Can Medidata successfully stave off competition from established clinical trial software leaders and open-source solutions?

Summary of Findings

➤ Medidata Solutions Inc. (MDSO) and Oracle Corp. (ORCL) will remain leaders in the clinical trial software industry serving large pharma companies and contract research organizations (CROs). However, they will be challenged in moving down market.

➤ The clinical trial software market is highly competitive and price-sensitive, is growing in the midsize and small pharma segment, but is approaching saturation among large pharma companies.

➤ Medidata's strengths in serving the large pharma and CRO market include its substantial customer base, which is reluctant to change vendors. It also benefits from strong name recognition, quality products, highly integrated software and a robust network of commercial partners promoting its software solutions.

➤ Challenges facing Medidata among small to midsize pharma companies include its nontransparent, high pricing, older software design, customer service issues, a lack of focus on the SMB market, and new competitors offering innovation and lower pricing.

➤ More than 15 competitors were discussed as contributing to industry innovation and pricing pressure. Most frequently mentioned were OmniComm Systems Inc., Parexel International Corp. (PRXL), Merge Healthcare Inc. (MRGE), Datatrak International Inc. (DTRK), BioClinica Inc. (BIOC) and Nextrials Inc.

➤ Open-source, cloud and mobile device solutions are generating interest in clinical trial management software, but adoption is tempered by patient privacy, security and regulatory concerns.

	MDSO Can Maintain Large Pharma Share	MDSO Can Expand Down Market
Medidata Customers and Partners	⬆	⬇
Competitors' Customers	⬆	⬇
Competitors	⬆	⬇
Medical R&D Professionals	⬆	⬇
Industry Specialists	⬆	⬇

Silo Summaries

1) Medidata Customers and Partners
Four of the five sources think Medidata can maintain its market share and compete effectively against other clinical trial software providers seeking clients among large pharmaceutical companies. Four sources said Medidata's high price and poor services could prevent it from moving down market to small and midsize pharma companies. Competition is strong from several companies, including BioClinica, OmniComm, Parexel, Hewlett-Packard Co.'s (HPQ) Vertica, XClinical GmbH, Merge, Nextrials, Medrio and Axiom Real-Time Metrics.

2) Competitors' Customers
All four sources described the clinical trial software market as highly competitive, price-sensitive and growing. Medidata was cited as a leading company except by a source in Europe, where it reportedly is not a major player. Oracle is Medidata's leading competitor, and BioClinica touts strong products as well.

3) Competitors
All five sources view both Oracle and Medidata as the clinical trial software market leaders among large pharma companies. Sources described the market as highly competitive, price-sensitive and growing among smaller and midsize pharma companies and in Phase I and IV clinical trials. Medidata is gaining share in the large pharma segment as it has successfully targeted and converted Oracle Phase Forward customers. Medidata's growth in the midmarket will be challenged by its high pricing and by the superior innovation offered by lower-priced competitors like Datatrak, Parexel, Parexel's Datalabs, Nextrials, BioClinica and OmniComm.

4) Medical R&D Professionals
These three sources think Medidata can maintain its leading position based on its easy-to-use and intuitive products. Medidata does face challenges from lower-cost competitors in a market that challenged by slowing growth and smaller clinical trials.

5) Industry Specialists
These four sources agree that Medidata is a leader in providing clinical trial software to large pharma and that it will maintain its market share. The clinical trial industry is experiencing greater competition, and new entrants are offering strong innovation. Medidata's growth will slow in line with the number of opportunities in the large pharma market, and its products are not priced appropriately for smaller pharma companies.

Medidata Solutions Inc.

Background

Software solutions for laboratory and clinical research has enormous potential because of the almost limitless number of compounds to be developed as well as the associated high cost of research. These solutions improve both the cost efficiency and statistical accuracy of clinical trials, especially when compared with conventional paper alternatives. Medidata Solutions is a leader in this growing field, and achieved 27% year-to-year revenue growth in the third quarter. Forty-seven percent of its customers now commit to buying multiple products (compared with 36% a year ago), and the company had 379 customers at the end of the third quarter, up 14% year to year.

In such a rapidly developing industry, proprietary technology is critical to an enterprise's success. Medidata has aggressively invested in developing unique products, including in a cloud-based solution designed to facilitate global pharmaceutical trials. Medidata is lauded for having a better product mix than its competitors, and Rave, its core EDC (electronic data capture) product, is being used to assist in managing clinical research activities.

However, pricing for Medidata solutions is considered nontransparent and high, which will challenge the company is servicing the small to midsize pharma company segment. Also, Medidata may be vulnerable to competition from larger forces in the technology space, such as IBM Corp.'s (IBM) well-established Pharmaceutical Consulting Division, as well as from open-source options from the likes of Clinovo. Both nontraditional competitor groups represent a disruptive force and a potential threat to Medidata's long-term viability.

Current Research
Blueshift Research assessed whether Medidata could defend it market share and expand down market in the face of increasing competition and technology changes. We employed our pattern mining approach to establish six independent silos, comprising 21 primary sources and seven relevant secondary sources focused on the life sciences industry and specifically clinical trial software:
1) Medidata customers and partners (5)
2) Competitors' customers (4)
3) Competitors (5)
4) Medical R&D professionals (3)
5) Industry specialists (4)
6) Secondary sources (7)

Next Steps

Blueshift Research will continue to research the clinical trial software market to determine if Medidata and Oracle can defend and grow sales among large pharma companies. We also will study the midsize and small pharma market to determine which clinical trial software companies are gaining traction and what new technology is being presented and adopted. We will research clinical trial software sales in China. Finally, we will determine whether Medidata can overcome the perception of being too expensive for smaller pharma companies.

Silos

1) Medidata Customers and Partners
Four of the five sources think Medidata can maintain its market share and compete effectively against other clinical trial software providers seeking clients among large pharmaceutical companies. Medidata is innovative and offers a strong platform, highly integrated software and a robust network of commercial partners. The remaining source said Medidata products do not stand out from the competition and that its pricing is becoming an issue. Large pharma companies are

somewhat conservative and resistant to change, which favors incumbent vendors like Medidata. Four sources said Medidata's high price and poor services could prevent it from moving down market to small and midsize pharma companies. Open-source and cloud clinical trial software will be slow to catch on because of patient privacy concerns. Interest in using mobile devices is growing, but again privacy and security present unique industry challenges. Oracle is Medidata's biggest competition in the large pharma market, but competition is strong from several companies, including BioClinica, OmniComm, Parexel, Hewlett-Packard Co.'s (HPQ) Vertica, XClinical GmbH, Merge, Nextrials, Medrio and Axiom Real-Time Metrics Inc.

KEY SILO FINDINGS

Clinical Trial Software Market Conditions
- 3 sources identified the clinical trial software market as highly competitive.
- 1 source said the market is fragmented but added that Medidata and Oracle are the clear leaders and, combined, hold 60%–66% of the market.
- Worldwide, the market is growing. Small and midsize pharma companies are looking for lower-cost solutions than Medidata and Oracle provide.

Medidata Solutions' Advantages and Disadvantages
- Medidata's advantages include being first to market and offering innovation, a strong software platform, highly integrated software and a robust partner network.
- Medidata's disadvantages are its high price and poor customer service.

Medidata Solutions' Growth Opportunities
- Medidata's growth may be limited by its high price. This and its poor service will slow down-market adoption of its products.

Miscellaneous
- Pharma's adoption of cloud-based and mobile solution will be slow as the industry deals with the patient privacy and data security issues.

1. Senior executive of an eClinical consulting company and Medidata partner

Medidata can maintain its lead in the market. Medidata and Oracle each hold approximately 30% of the electronic data capture (EDC) market, and Medidata has the leading product in this space, Rave, despite competition from numerous players. To maintain its current edge, the company will need to enhance its products; expand its portfolio, possibly by buying out smaller competitors; manage pricing; and keep ahead of the competitive curve. Medidata's advantages include a strong platform and a strong network of partners for services, which reduces their overhead. However, the company has grown so quickly that it is increasingly perceived as losing sight of reasonable pricing and customer service. The biggest challenge facing the industry is how to integrate data from various sources and systems into a central hub and translate the data into useable information.

Clinical Trial Software Market Conditions
- "The market is rather fragmented right now, with numerous players in space. There has been some consolidation in the past few years. With low entry barriers, new players continue to come in and try to position themselves."
- "The market is also fragmented from a pricing issue. The top-tier companies can get away with setting higher prices, but there is a lot of negotiation. Prices are kept confidential because they vary from client to client."
- "The top-tier players tend to be inflexible on pricing, while the mid- to lower tiers take a more aggressive approach. On the far extreme, there are the open-source models that you can acquire and develop yourself."
- "Medidata competes directly with Oracle for the EDC market. Both companies combined hold somewhere between 60% to 66%, of this market; they each have about 30%. Oracle offers both Oracle RDC and InForm [obtained when Oracle acquired Phase Forward]. However, InForm is an older product that has some issues. It needs to be redesigned."
- "Parexel, with Perceptive Informatics, and OmniComm both like to think that they are top competitors."

Medidata Solutions' Advantages and Disadvantages
- "Medidata started years ago by an investigator at Columbia [University]. The system was well received, and the company leveraged itself from that point. This marketing differentiator is their biggest advantage. Other products are

competitive from a user's experience. Pharmaceutical companies tend to be very conservative, which provides an advantage to well-established products over newer entrants.

- "Medidata has the strength and technology to continue holding onto a strong portion of the market."
- "Medidata has accredited partners, so they don't have the overhead that some of their competitors have. They have a strong network of services."
- "As far as tech issues go, Medidata has a better platform. They don't have to overcome platform issues."
- "On the negative side, Medidata has grown, and there is a perception that they are not as dedicated to customer service as they once were. They are less flexible and do not provide the same service as before."
- "Their pricing is high, and the industry is becoming more price-conscious. In the short term, they may see their profitability improve if they can convert [Oracle] InForm clients to Rave. It becomes a matter of marketing strategy, whether they want to pursue only the higher-tier customers with greater profit margins but lower volume, or develop a tiered series of offerings that allow them to develop and maintain customers with different price sensitivities."
- "Medidata is not updating its EDC products. Rave is a good product and it works fine now, but the company is not maintaining and enhancing Rave. From a marketing standpoint, customers want a growing product that isn't stale. This is a tough position for a software vendor to be in. It is a balancing act between customer expectations versus product feature bloat."
- "Cloud services get a bit of press, but the definition has become watered down such that many solutions can be considered cloud solutions. Based on the way cloud services are described, the Medidata Rave platform could be viewed as having been a cloud-based solution for a long time. From a pure technology standpoint, there is probably nothing prohibiting Medidata from being used with interfaces and a variety of device types."
- "It is harder for the high-end clients to switch from Medidata to the less-expensive competition. But customers can more easily switch from the less-expensive competitors to Medidata."

> "Medidata started years ago by an investigator at Columbia [University]. The system was well received, and the company leveraged itself from that point. This marketing differentiator is their biggest advantage. Other products are competitive from a user's experience. Pharmaceutical companies tend to be very conservative, which provides an advantage to well-established products over newer entrants.
>
> *Senior Executive, eClinical Consulting Company & Medidata Partner*

Medidata Solutions' Growth Opportunities

- "The best strategy for Medidata is to whittle away at Oracle InForm's 30% of the EDC market with a tiered pricing strategy."
- "All of the competitors face the biggest challenge of how to translate collected data into information. This will involve integrating their own products to everyone else's products and using a central data exchange hub for better data standards and integration support. You have to have a mindset to manage the transformation of data into information and to support decision making."
- "Medidata is an expensive option. The company grew so quickly. They expect people to accept the prices that they set. But companies will become more price-sensitive. This will play out based on the size of the customers."

Miscellaneous

- "To remain competitive, Medidata will have to enhance their products, expand their portfolio and keep looking to the future. They need to reinvest in markets to improve on the variety of device types."
- "There is a lot of consolidation going on, and Medidata will be forced to play this same game. Medidata is well positioned to steal other businesses, if they are smart about it. They need to continue to acquire other companies and expand. The competitive landscape is moving more toward providers having a suite of products as can be seen with Oracle, [Parexel's] Perceptive Informatics and OmniComm."
- "Oracle has the largest portfolio of any vendor out there, but their products don't 'talk' well together. Oracle has acquired a number of companies over the years. It acquired Phase Forward three years ago, and before that Phase Forward had acquired another clinical life sciences data program, including Clintrial. The company has its own EDC product, a clinical product and a clinical trial management product. They have a mixed bag of products that compete against themselves. Oracle needs to integrate. They have been talking about integration though the use of Oracle Fusion for a long time, but real progress is limited."

2. Business manager, consultant and Medidata user advising CROs and pharmaceutical clients

Medidata is "the Apple" of the eClinical technology solutions market. The company is (and promotes itself as) very innovative. Medidata makes its users feel like the company has a broad, cutting-edge view of industry needs, most notably integrated solutions.

Clinical Trial Software Market Conditions
- "As systems become more compatible and comparable, companies can easily switch vendors. This makes for a more competitive market and price flexibility. It's not like 10 years ago where you invested in an expensive system. There are more choices today. This has an effect on prices as well."
- "Integration of data is what's driving the market. It's no longer about just capturing the data, but now there's the need for an integrated data landscaped where data is captured, loaded and analyzed on one platform. Long ago there was a front-end data capture and a back-end data analysis, but now that's merging. Medidata is quite active in this area."
- "Because tools are integrating, they are becoming more user-friendly. The smaller companies like XClinical are coming forward with systems built around the user's perspective, not the data analysis's. These tools are also built around the latest data standards."
- "OmniComm is a player in this area. Datatrak is basically gone from the market."
- "Economics are definitely a driver in this marketplace. Big pharma is looking to cut costs by outsourcing more and more functions to CROs. Today a pharma company could have a huge stable of CROs all working together because the technology is more and more compatible."

Medidata Solutions' Advantages and Disadvantages
- "Medidata remains on top because they're innovative and also have great marketing. They are really good at marketing themselves. They're like the Apple of this industry. I went to their user group meeting in Italy recently and they do a big show; they have an Apple-like keynote presentation about how innovative they're being. You really get the feeling that they're driving the marketplace and thinking a little bit broader than the competition. Medidata is always trying to present something new, yet they should still focus more on enhancing their established products in their established markets."
- "Medidata is the top player in Europe. Oracle bought Phase Forward in 2010 and that grew their footprint, but the driver and market leader is still Medidata."

Medidata Solutions' Growth Opportunities
- "Fewer and fewer CROs have their own homebrewed clinical trial technology systems and are instead purchasing systems like Medidata. Big and medium CROs used to think that they could save money by building their own systems, but the associated costs, like making sure the system is up and running 24/7, are steep today. I try to convince clients to buy a suite of products built on established data standards.

Miscellaneous
- "Cloud is the buzzword now, but most of companies are storing their data in some offsite computer center anyway. Gone are the times when pharma had large onsite data centers. Yet the hurdles in this industry, especially the laws that define where medical and health data can be stored, are hampering the benefits of cloud and software-as-a-service that other industries enjoy."

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>
> *Business Manager, Consultant & Medidata User*

3. Senior clinical data manager who uses Rave at a West Coast pharmaceutical company

Medidata can maintain its position as one of the three top clinical trial software companies because it has multiyear contracts with numerous large pharma companies. Big pharmas tend to remain entrenched in familiar platforms and make changes slowly. However, Medidata's higher prices and poor service prevent the company from penetrating the smaller pharma companies. A number of smaller software companies offer better products and service at lower prices.

Clinical Trial Software Market Conditions

▪ "The market in general is definitely competitive. There are three big companies—Medidata, Oracle and [Parexel's Perceptive [Informatics]—competing for market share of the big pharmas."

▪ "There are not a lot of midrange companies, but there are a lot of smaller companies where everyone else is scrambling to be No. 4. These companies would include Merge, Nextrials, Medrio and Axiom."

Medidata Solutions' Advantages and Disadvantages

▪ "Medidata software is not the best, but it is not the worst. There are a few disadvantages. Rave is functional but not the most current. It works well enough, but there are shortcomings on the service provided. I've worked in two companies with different Medidata packages. The project managers they provide are pretty poor, the response team is poor, the quality of work is poor."

▪ "As far as service goes, Medidata does not match up to the smaller [software] companies. But they make a lot of money on their services."

▪ "The Rave platform is the most mature product; the others aren't as mature. Rave doesn't usually break. Once you get your study built, it will run pretty well. However, the Medidata CTMS [clinical trial management software] is very buggy."

▪ "There is lots of talk about mobile devices, but I haven't seen a lot of requests. I would not use it to log in and look at data. It may be a good idea, but it is not adopted yet, and with hospitals, less so."

> "Medidata's prices are too high, and this is a threat to getting smaller companies. I worked at a smaller company that used Medidata, and we had to eventually look at the other options. The smaller options can beat Medidata on all fronts for price and service.
>
> *Senior Clinical Data Manager*
> *Uses Rave at a Pharmaceutical Co.*

Medidata Solutions' Growth Opportunities

▪ "EDC is very much a commodity. Medidata will have a hard time serving small companies if they don't provide better service. So far they have been doing acquisitions to increase market share."

▪ "Medidata's prices are too high, and this is a threat to getting smaller companies. I worked at a smaller company that used Medidata, and we had to eventually look at the other options. The smaller options can beat Medidata on all fronts for price and service."

Miscellaneous

▪ "Medidata can maintain its dominance. They are an enterprise that deals with big pharma companies with multiyear studies. If you are entrenched in the top 10 pharmas, much like Medidata is, then that structure doesn't change. Big pharmas don't change platforms very quickly. It will be awhile before this paradigm shifts."

▪ "It is hard for the midsized [software] companies to survive; they get acquired."

4. Biostatistics and data manager at a South Central pharmaceutical company

Medidata will continue to capture the market with large pharma companies, but this segment eventually will reach a saturation point. Also, Medidata offers a top integrated software suite, but its products are overpriced and its customer service is so bad that this source has started to address related problems. Most smaller companies cannot afford Medidata, and those that use its software can easily drop the company for a less-expensive program with better service. Open-source platforms will not be adopted by this market for as long as 15 years because of confidentiality issues. However, the source cited a need for data capture software for tablets, which are being embraced by physicians.

Clinical Trial Software Market Conditions

▪ "From a global standpoint, the market is growing. There is a need for the services that Medidata offers and for data capture. Medidata is big; people want to talk about them, and you hear more about Medidata."

▪ "Oracle is the biggest competitor, with Phase Forward. HP has started getting involved with the Vertica analytic platform. There are also companies developing digital pens, which capture information as you write. Then they are plugged into a computer with a USB."

Medidata Solutions' Advantages and Disadvantages

▪ "Medidata offers one of the best integrated packages of software. It's their biggest advantage, to offer a whole integration of EDC, how to build protocol studies, take measurements, etc.—an entire electronic firing system."

- "On the negative side are price and customer service. Their pricing is quite expensive and is based on different phases of a trial over the course of a few years. But most companies don't plan that far in advance. And the price goes up if you don't meet a certain number of trials. The price can be very daunting over the course of a study."
- "When they were first starting out, Medidata's customer service was actually good. But now Medidata has horrible customer service. It is very hard to call them. … We started taking this over ourselves. They aren't hard problems, they are all simple things. But Medidata hasn't taken care of them."
- "We use the Medidata customer service site, but they have a bit of a turnover here. We've been working with them for five years, and we've never had the same project manager. Their turnover rate is very high."
- "We are going from paper-based to electronic right now. There is still a lot of resistance to going electronic. The cloud is not growing very fast in this field, and it will be a considerable time, possibly 10 to 15 years, before its usage becomes widespread. People are worried about security and patient confidentiality. They are afraid of being sued. The cloud scares the daylights out of clinicians because they don't know where the data is. There is a sense of comfort having data right next to you in a filing cabinet. Whatever system is in place has to be very secure, and there has to be a lot of education on this."
- "We are also way behind the curve on tablets and cell phones. We do use mobile for some studies going to the FDA [Food and Drug Administration]. We had to develop our own mobile data capture system because it was not available."
- "Doctors really like tablets; it's the right fit for them. They don't feel separated from a computer, and they don't equate the cloud with the tablet in their lap. One doctor just 'ate' up a study we had on using a tablet."

Medidata Solutions' Growth Opportunities

- "Where their growth will come from is a good question. Big pharma has deep pockets, but unfortunately there are a lot of midsized companies. Medidata has priced themselves out of that particular segment. They need to have a product without a lot of bells and whistles for the small companies so that they can grow into Medidata."
- "There aren't any tablets with SaaS [software-as-a-service] although some Google apps have SaaS. We need more skills in tablets. This is a missing piece that Medidata could target although it would require a lot of luck to get a mobile device going in this field."
- "A small company cannot buy software data management if the price is set too high. When I worked with another company, Rave was 20% to 30% of the entire cost of our study. That was unexpectedly high. Companies set a study budget, and it is hard to increase the proportion of money they will spend. It is also costly to advertise and get patients in the trials, so this cuts into the budget too. The high cost of software slowed down enrollment."

Miscellaneous

- "Medidata can stave off competitors if it continues to get into the larger pharma companies, the Abbotts and Pfizers. These are the companies that can afford Medidata's prices. But once Medidata establishes itself with the bigger companies, it will reach a limit."
- "The biggest hurdle would be in attracting smaller pharma companies. A lot of the smaller pharmas use the larger companies' data systems, but they aren't really long-term customers. They can easily go away. Smaller software companies could steal Medidata's business away by targeting smaller pharmaceuticals, which are happy to have a low-cost data collection solution."

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>
> *Biostatistics & Data Manager*
> *South Central Pharmaceutical Co.*

5. Associate director of clinical research for a large pharmaceutical company and Medidata customer

Medidata will need to continue making good products and offering good service to stay competitive. The market will remain challenging because pharma companies are developing more difficult, specialized drugs. Price will be an issue, especially for smaller companies. Larger companies usually have preferred providers, but the source's firm changes software every year. The scientists are not involved with the decision process and appear not to have a vested interest in one particular brand. Data is heading toward cloud services, but Medidata's cloud offerings does not stand out. Mobile apps have increased the accuracy of patient input.

Medidata Solutions Inc.

Clinical Trial Software Market Conditions
- "The market is very competitive, and it is becoming increasingly challenging. All the easy drugs have been identified. The drugs that are needed now are very specialized. It is hard to find and recruit patients for related studies. We have a challenging time of this."
- "Sometimes we use Medidata, but this changes from year to year. We are using Rave now. It all depends on what we subscribe to for the year. The scientists don't make that decision; I don't even know who does."
- "Besides Medidata, we use Oracle and BioClinica. Oracle is big around here."

Medidata Solutions' Advantages and Disadvantages
- "I'm not really sure about Medidata's pluses and minuses. I have not heard any complaints, and I don't really deal with customer service. Truthfully, we don't really pay attention to the type of software we use."
- "The cloud helps everyone; that's where data is going. I trust the cloud, but I have no use for it. It is not for me but for people further downstream. We use other clouds for other services, but we don't necessarily use it day-to-day. Medidata's cloud service does not stand out."
- "Mobile apps are interesting. Patients in our studies use mobile apps, and we find that their input is more accurate. They give input right at the moment, what they are feeling right then. They just jot down the information as it happens, which is more accurate than waiting for a while to try and remember how you were feeling."

Medidata Solutions' Growth Opportunities
- "For any company to grow in this market, they need to be the very best, to prove their successes, and to back up the successes with data. You also need to have a good team to sell success."
- "The competition is fierce for resources. Less-expensive products will be considered, especially by smaller companies. Larger companies sometimes have preferred providers, and it is harder to change brands. It is easier to make changes in a smaller company. However, we are large, and we do change."

Miscellaneous
- "For any company to stave off competition, it all comes down to the product and the people. This is a very competitive market, and it will always be competitive."

2) Competitors' Customers

All four sources described the clinical trial software market as highly competitive, price-sensitive and growing. Medidata was cited as a leading company except by a source in Europe, where it reportedly is not a major player. Oracle is Medidata's leading competitor, and BioClinica touts strong products as well. Medidata offers a clinical trial software solution that is innovative, user-friendly and highly integrated. It also has cloud and mobile device options. One source said Medidata has price flexibility that would help it to market to second-tier pharma companies. Competition is fierce. Some smaller companies boast strong innovation, including Medtrials Inc., CluePoints, Perceptive Informatics' (Parexel) ePro, and CRF Health.

KEY SILO FINDINGS

Clinical Trial Software Market Conditions
- All 4 sources described the market as competitive, price-sensitive and growing, particularly among small to midsize pharma companies.

Medidata Solutions' Advantages and Disadvantages
- Medidata offers an innovative, user-friendly, highly integrated, cross-platform clinical trial software solution.

Medidata Solutions' Growth Opportunities
- Growth opportunities exist with large pharma, which is abandoning homegrown, in-house clinical trial software, and with midsized and small companies.

Miscellaneous
- Cloud and mobile solutions are creating interest, but adoption is limited.

Medidata Solutions Inc.

1. Clinical trial management specialist at a pharma company

This source has prior experience at two top pharma companies and said Medidata is well entrenched and has room to grow within large pharmas that have not converted from homemade systems, and within lower-tier companies. Her previous employer took several years to convert to Medidata's system, while her current employer is not yet using the company.

Clinical Trial Software Market Conditions
- "There are so many more trials today because the government requires so much more. … The market is much more limited for [vendors selling] EDC tools and for IVRS [interactive voice response system] or CTMS tools. They're pretty saturated within the industry."
- "Medidata is the leading company because it's a more use-friendly tool. There aren't many complaints from users adopting the technology. There was good feedback when using [Oracle's] Phase Forward's full suite of products, but the whole suite is expensive. Most companies don't have the money to buy all of it."

Medidata Solutions' Advantages and Disadvantages
- "In the field, people are really excited to be able to connect to the cloud, and that is very helpful."
- "Mobile integration does play an important role. It's the piece where people can connect anywhere with anyone. Each company wants to be doing it."

Medidata Solutions' Growth Opportunities
- "Medidata has good market share now. I don't think the market is changing that fast, and where they are, they're entrenched. There doesn't seem to be another [competitive] option right at this time. … They have to offer some kind of benefit to switch, and there's no reason to switch."
- "There are a significant number of [pharma] companies that haven't converted yet. … Some of those large pharma companies still have homemade systems that don't match with any other systems. It took [my last employer] a full three years to adopt the full Medidata technology. There's growth in second-tier companies, like our company where we don't use Medidata."
- "I believe they're offering that price flexibility. There should be a price differential. Larger companies can afford more than smaller companies. You still have to provide some kind of service or pay for use."

Miscellaneous
- "Oracle does have more clout; they're good at selling products. I don't know that they're easier to use, but if they do a good job selling, I think that where they work best. Many of the lower-tier companies, I think there's a lot more growth."

> "Medidata is the leading company because it's a more use-friendly tool. There aren't many complaints from users adopting the technology.
>
> *Clinical Trial Management Specialist*
> *Pharma Company*

2. Clinical data scientist who uses Oracle's Phase Forward at a large East Coast drug company

Medidata has tough competition with Oracle's Phase Forward and products from Medtrials. This scientist has doubts about the cloud's security in storing data, and has no need for mobile capability. Oracle software is very good, and the source will not be converting to any other brand. She worked with Medidata when it was first introduced; at the time, the product had many flaws. It is to Medidata's credit that it is now one of the top companies in the field. To grow, the company will need to bring in more pharma business and CROs.

Clinical Trial Software Market Conditions
- "This market is really growing, and it is very competitive. The software is very pricey depending on the level of support. I don't know the exact figures."
- "The top three companies are Medtrials; Medidata, which I used several years ago; and Oracle or Phase Forward, which I'm using now. These are the names you hear most often."
- "The company I'm at already had Oracle in place. It works for what we need.

> "The top three companies are Medtrials; Medidata, which I used several years ago; and Oracle or Phase Forward, which I'm using now. These are the names you hear most often.
>
> *Clinical Data Scientist*
> *Uses Oracle's Phase Forward*

There has been no talk of changing to another product, nor is there a need to do so."
- "Oracle has been a good program, and we are not considering changing to Medidata."

Medidata Solutions' Advantages and Disadvantages
- "I worked with Medidata when it first came out. They were pretty new and pretty terrible. It was very cumbersome to set up and difficult for site users. I can't think of any positives. We had Medidata for a year-long trial, and I hated it. The company did not go with it."
- "I'm not in contact with people who use Medidata now, so I can't say if they have worked out the bugs."
- "Medidata seems to have done pretty good because they are still around."

Medidata Solutions' Growth Opportunities
- "Medidata will have to bring in more pharma business and CROs."
- "I don't buy the products, so I have no idea how much it costs, except to say that the software is a lot of money."

Miscellaneous
- "I really can't say how well Medidata will do. They must have improved things to be around this long."
- "The cloud does not sound like an advantage for us. I would be concerned with data storage in the cloud. I would be worried about the security of confidential data. As far as I know, Oracle doesn't even have a cloud system. We have not even discussed this kind of storage."
- "I don't have need of a mobile device to store our data. For our work, I'm not sure if this would be a competitive edge."

3. Experienced clinical trial manager with pharmaceutical and medical device clients throughout Europe

Clinical trial management is evolving toward mobile and the cloud. Wireless devices are able to transmit data directly to clinical records in the cloud, facilitating collaboration and saving time and money. Small companies, not the large players, offer these tools.

Clinical Trial Software Market Conditions
- "I have 11 clients right now running clinical trials, and they're all using either Oracle or [its] InForm. Those are the two major players, not Medidata—at least not in Europe."
- "Oracle is not doing mobile or anything that's innovative. Oracle is only adopting the same program that's been here the last 10 years to some slightly newer features. It's the same Oracle, only trimmed down and cheaper."
- "The only driver at the moment in clinical trial management is financial. Companies are getting less and less money to perform studies, so they are looking to do them as cheaply as possible."
- "No one is going to use suites or bundles of tools; it would be too expensive."
- "Mobile and cloud are the exciting developments in the clinical trial space. With new wireless data devices, data can be transmitted to a secure private cloud environment directly from the patient's bedside. Mobile will cut down on time, on human error from manually inputting data, and on costs."

Medidata Solutions' Advantages and Disadvantages
- N/A

Medidata Solutions' Growth Opportunities
- N/A

Miscellaneous
- "Wide use of the cloud should have been here already, but no one will allow it. Approval of patient and medical data placed in a new environment is scary. Everyone had to weigh in: the FDA, the medical ethics panels."

> "I have 11 clients right now running clinical trials, and they're all using either Oracle or [its] InForm. Those are the two major players, not Medidata—at least not in Europe.
>
> *Experienced Clinical Trial Manager*
> *Europe*

4. Experienced business development director in clinical trial management and software

This source is a former director at BioClinica and Parexel and offered insights into both the business and technology sides of clinical trials worldwide. He said innovation is slow to gain a foothold in the conservative pharma marketplace.

Still, innovative technology companies have the opportunity to drive adoption of cloud and mobile solutions as pharma and healthcare companies look to shave costs and streamline operations.

Clinical Trial Software Market Conditions
- "The clinical trial software market is very broad today. There's room for both the big players with suites of integrated tools and the small players with more innovative or more cost-sensitive products."
- "Large pharma customers are investing in integrated tool solutions from companies like Oracle because they cannot only integrate all of their healthcare applications but their business functions that may also run on Oracle. Smaller pharma companies look to the smaller tech companies that are more flexible on product and price."
- "Oracle has the best overall story in the market; whether they can deliver is another question. Medidata is just about there even with Oracle as well. These two are the big players, and I couldn't say which is in the lead right now. It's hard to pick a strong third-place player. BioClinica is doing some really good things; they have a lot of interest in their EDC solution and success with their IVRS solution, and they all integrate well together. Still in the running are OmniComm, Datatrak and Merge Healthcare."
- "We work with whichever technology solution clients have in place, but if we're doing work internally, we use the Oracle for data management and BioClinica for clinical trials. Going forward, we may reevaluate some of the Oracle EDC products or we may look at smaller players because we're looking to cut costs as well."

Medidata Solutions' Advantages and Disadvantages
- "I haven't see a lot that's new and interesting in the last three or six months in clinical trial software. I think Medidata continues to be probably one of the more innovative companies. It has a vision to have a lot of cross platforms and an integrated suite of products that addresses a lot of the needs in the pharma industry."

Medidata Solutions' Growth Opportunities
- "There's also a lot of interest now in analytics. CluePoints has an interesting tool for data analytics, analyzing risk-point monitoring, looking for fraudulent data or incorrect data."
- "I haven't seen a lot of companies with really prominent mobile solutions other than the ePro vendors Exco InTouch or CRF Health."
- "I haven't seen anybody taking the mobile solution to the EDC arena—a lot of talk about it but no implemented solutions. Maybe because a lot of the barriers in the academic sites, barriers with FDA guidance, etc. Mobile isn't mature enough yet."
- "[In terms of innovation] there's eClinical using tablets to collect patient data directly and bridge the electronic health record and the EDC part of it, but they've been around awhile and haven't yet made any real progress in getting across the chasm to be more mainstream. Tablets can also be used to recruit and prescreen patients."
- "Going forward, anything that can bridge EDC and electronic health records gap will be important."

Miscellaneous
- "Pharma needs to make a true evaluation of the risk involved in the cloud and SaaS. There's a higher perceived risk of data integrity and security than there really is."

> "I haven't see a lot that's new and interesting in the last three or six months in clinical trial software. I think Medidata continues to be probably one of the more innovative companies. It has a vision to have a lot of cross platforms and an integrated suite of products that addresses a lot of the needs in the pharma industry.
>
> *Business Development Director w/ Clinical Trial Management Expertise*

3) Competitors

All five sources view both Oracle and Medidata as the clinical trial software market leaders among large pharma companies. Sources described the market as highly competitive, price-sensitive and growing among smaller and midsize pharma companies and in Phase I and IV clinical trials. Medidata is gaining share in the large pharma segment as it has successfully targeted and converted Oracle Phase Forward customers. Medidata's strengths are its name recognition, data integration and cloud and mobile offerings. One source noted that the top 20 pharma companies already have chosen their clinical trial software so future growth in this market will be limited. Medidata's growth in the midmarket will be challenged by its high pricing and by the superior innovation offered by lower-priced competitors like Datatrak, Parexel, Parexel's Datalabs, Nextrials, BioClinica and OmniComm.

KEY SILO FINDINGS

Clinical Trial Software Market Conditions
- All 5 sources described the market as highly competitive, price-sensitive, eager for innovation and migrating to smaller companies and earlier Phase I and II trials.

Medidata Solutions' Advantages and Disadvantages
- Medidata's strengths include name recognition, strong data integration, and cloud and mobile offerings.
- Medidata's disadvantages are its high price, smaller competitors offering more innovation, and a lack of focus on midsize and small pharma companies.

Medidata Solutions' Growth Opportunities
- Growth is expected in China given the number of clinical trials, the midsized and small pharma market and the expansion of clinical software use in Phase I and II trials.

Miscellaneous
- SaaS and hosted platform service are growing in the clinical trial software market.
- Patient-direct communication, patient data input and use of mobile devices are growing.

1. Product support manager at a West Coast medical record and clinical trial software tool company

Medidata should be able to fight off competition in the future. Its biggest competitor, Oracle, offers older software and is not focused on the medical software field. Medidata is targeting Oracle while ignoring middle-tier and newer competitors that are more innovative. If Medidata loses market share to these companies, it will be forced to lower its pricing. Medidata's advantages are its name recognition, market share and cash flow. Its disadvantages include antiquated software and a neglected customer support system. Software companies tout the cloud advantage because it is less expensive, but big pharma distrusts the cloud. Mobile devices will be become prevalent but not a game-changer. Growth for Medidata will come from sales to China.

Clinical Trial Software Market Conditions
- "Right now you have your two big players: [Oracle's] Phase Forward is No. 1, and Medidata, who is aggressively pursuing the top spot, is No. 2. They have the lion's share of the market right now."
- "Datatrak, Datalabs and OmniComm are the middle-tier group that is fighting to take market share from Medidata. Medidata isn't too focused on them because they are going after Oracle, and for some reason Oracle is letting their software get older and older. Oracle does not seem to be too focused on the medical software field."
- "[As far as leaders] if you go by market share, obviously you go with Medidata. If you're going with innovation, I would go with Nextrials for EHR to EDC data migration or OmniComm for remote-based monitoring."

Medidata Solutions' Advantages and Disadvantages
- "The advantages of Medidata are name recognition, market share, and ability to throw large sums of cash at software problems."
- "The disadvantages are that once you've signed a contract with them, unless you're big pharma you quickly are forgotten as Medidata continues to search for new clients to drive them. They also have older antiquated software."
- "I don't think [the cloud is an advantage]. More and more companies are going to go this way because it's cheaper. However, you can run into some problems. When your data is in the cloud, there is always the perception that your data is at risk, and perception is everything."
- "I don't see big pharma embracing open-source solutions."
- "Mobile devices are going to be more and more prevalent in the clinical settings, but I don't see it as a game-changer."
- "Medidata can maintain a strong market position. They have a ridiculous amount of market share, they have a lot of capital to buy up new technology if they encounter an impending threat, and no one has been fired yet for going with Medidata."

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>
> *Product Support Manager, Medical Record & Clinical Trial Software Co.*

Medidata Solutions' Growth Opportunities
- "Medidata growth will come from overseas. China is going to be huge."
- "[Medidata can continue to push its high pricing] for the foreseeable future. They are the big dogs right now. When they start losing market share, they will have to drop the price."

Miscellaneous
- "I do [think Medidata can fight off competition]. The only thing that I think can kill them is if a competitor can create new technology that changes the industry."

2. Director of an open-source software company

Medidata will face a difficult time in moving to lower-tier customers once top-tier pharma becomes saturated. Although this source's company is not a direct competitor, open-source options will be considered more as Medidata expands down market.

Clinical Trial Software Market Conditions
- "It's getting more price-sensitive, and it's getting more competitive in the smaller EDC business. Because we're an open-source solution, it does offer prospective clients solutions that aren't that expensive, although I don't know if you would consider us a Medidata competitor."
- "Medidata's niche has been the larger pharma companies where they offer a huge robust solution that is very expensive, when the rest doing small research—some of the CROs or academic organizations—don't have that kind of funding, they're looking for another solution."
- "Definitely, Medidata's Rave and Oracle stand on top. Oracle is taking a beating all over the place. In the smaller market we're all vying for pole position with different pricing models and marketing. Depending on needs, some just need an EDC or a CTMS or some just looking for ancillary products or randomizing or medical coding."

Medidata Solutions' Advantages and Disadvantages
- "Just the fact their revenue allows them to develop some very robust, proprietary products is an advantage and a hindrance. … You can't fight with Medidata because of their size."
- "The cloud solutions are pretty much across the board as an offering; to be able to have access on the cloud [is important]. I don't see a difference between the big and small players with that. It depends on where in the world you are. We're very global and worldwide."
- "There are a limited number of large pharma companies on the planet. Those companies will have procured Medidata, and that market is becoming saturated. As there's more downward movement [to lower-tier companies], they will be challenged just because of their pricing. Proprietary systems tend to run high in cost. They're going to have a hard time because they're used to getting these large contracts. They're playing against companies whose whole strategy is based on a lower-cost solution and who will ask themselves, 'Do we go with a proprietary system or go with open-source solutions?'"
- "With open source, we have this huge community out there helping to develop. We have very tight control of our data, and there's no difference with patient security. We handle all the phases of clinical research, and we're global. People can download our free version, and we can train people on-site to become a super-user. We have the cloud, and we have validation support."

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>
> *Director, Open-source Software Co.*

Medidata Solutions' Growth Opportunities
- "Medidata has to move downward, or there's nowhere to go. They have to change their model and their offerings. … But they may have to strip away functionality to work with companies that don't have that kind of funding."

Miscellaneous
- "They would have a difficult time increasing their market based on their current model."

3. 23-year veteran of clinical data management at one of the world's largest CROs

Although the major players, such as Oracle, dominate the clinical trial software market, more smaller companies are entering the market and with new innovations that prompt the established players to respond. Mobile, cloud and integrated devices are the trends to watch.

Clinical Trial Software Market Conditions
- "We see, as a market trend, companies looking more at how to imbed patients directly into the clinical trial data stream. The trend is to facilitate patients to monitor themselves and have more data electronically transmitted."
- "One newer aspect of clinical trial software is to facilitate direct communication with patients. For example, a patient's electronic diary may sync with the clinical trial software platform via a smartphone or special device."
- "Down the road, we'll also see the integration of medical devices into the clinical trial data platform. For example, in a diabetes trial a patient may no longer need to input the measurements from their glucose meter into clinical trial data platform; the glucose meter itself may sync with the platform."
- "I've noticed a couple of small players come into the industry and bring innovations, such as mobile connections. I couldn't say if these small players can challenge the larger companies, such as Oracle, for market share, but they will influence the market overall."
- "Another trend in clinical trial software is the further integration of various types of technologies into one platform, like Oracle's suite of eClinical applications. Parexel is also moving in this direction: combining components such as EDC, trial supply management systems, electronic patient diaries and others. Sooner or later all of these platforms will migrate to one."
- "Larger pharmaceutical companies are moving to SaaS rather than purchasing software from providers. Although the industry still has concerns about data security with cloud solutions, I see a clear trend toward hosted platforms."

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>
> *Veteran of Clinical Data Management*
> *One of the Largest CROs*

Medidata Solutions' Advantages and Disadvantages
- "We have our own proprietary software, but we have clients that use Medidata. The client selects the software."

Medidata Solutions' Growth Opportunities
- N/A

Miscellaneous
- N/A

4. VP of a competitor

Medidata did well in capitalizing on the uncertainty surround Oracle's Phase Forward merger, but now it must compete more in the underserved Phase I and Phase IV markets to continue their growth, which will be difficult with its current pricing. Medidata also has successfully marketed its cloud solutions and has excelled in data integration.

Clinical Trial Software Market Conditions
- "Phase I and Phase IV are underserved markets, along with diagnostics and animal health. I also see a lot of need for integration of systems, particularly in smaller or midsize customers."
- "When Phase Forward was purchased by Oracle, that was a big consolidation in a pretty conservative market. It was a big shakeup that Medidata took good advantage of."
- "Another big change in development is adoption of SaaS. Medidata is embracing SaaS and cloud computing, particularly in their marketing and messaging. But they're mostly operating with the same technology they always have, and don't appear to be making any major shift to implement a true SaaS solution."
- "Medidata and Oracle are by far in the lead. In the earlier phase markets, we also see OmniComm and a few others. Perceptive Informatics is also a prominent provider in the market. Perceptive has done a poor job with branding, but

they have a sizeable chunk of the market. In terms of SaaS competition there are Medrio, Merge and MedNet [Solutions Inc.]."

Medidata Solutions' Advantages and Disadvantages

- "Advantages are they're market leaders. People go to them as the big players in the market. They're doing interesting things with data integration where they look at trends, such as what are indicators of a trial going well. They publish those and use that data for thought leadership and content marketing. Those are advantages. Disadvantage: Their pricing model is very expensive when price pressure is going down, not up. EClinical will become cheaper over time."
- "From the cloud perspective, they use this term slightly differently than we think it should be. They're doing a good job of marketing as a cloud solution, but they're not delivering it. They don't have a licensed subscription model, and it's not a clearly differentiated technology platform. We're biased because we believe we have a different, true cloud model."
- "I'm a little ignorant of what they're doing with mobile offerings. I hear a lot of need for that, especially in Phase III and IV to get clear data from patients. It's a definite trend, but everyone is struggling how to best do it."

Medidata Solutions' Growth Opportunities

- "I don't think there's any way they can continue the same rate of growth of the last three years for the next 10. The big growth driver was the shift from Oracle due to the Phase Forward acquisition. They have to find a way into Phase I, Phase IV and other markets like diagnostics that aren't currently served at all. Those are opportunities for them. But they don't have a competitive way to get into Phase I. SaaS solutions are cheaper and faster, to start with. They're struggling to do it with their current offerings. I don't know how Medidata can go into a small biotech company for the Phase I or Phase IV work, given their current offerings. I see acquisition of more agile technologies for the early and late-phase markets as a potential growth areas."

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>
> *VP of a Competitor*

- "Maybe they can tweak more revenue out of where they're installed or come up with new technology such as mobile data collection as a strategy. I know they're well established in the U.S. and in Europe, but I'm not sure about Asia, where there may be growth opportunity."
- "We do see them offering some price flexibility, but I don't know how much is taking a price reduction to get into, for example, a Phase II trial versus making a strategic change in pricing structure."

Miscellaneous

- "When looking at how they are doing versus Oracle, they're doing a much more adept job. Medidata has done a good job by taking care of the uncertainty in the market around the Phase Forward/Oracle merger. Their growth outside their core market might come from acquisitions or investments in noncore areas. As for open source, outside of the academic space, which is where we often see open source, we don't compete a lot against it. It could become more important if the industry takes a shift, but we're not seeing open source as a major competitor right now."

5. President of a top 10 competitor

Because of its product diversification, cloud solutions, growth overseas and attrition from Oracle customers, Medidata will continue its record growth for the next several years. However, longer term it will face market share loss if it does not address its EDC product with new software releases. OmniComm, BioClinica and Perceptive Informatics are other growing EDC companies.

Clinical Trial Software Market Conditions

- "It's always been competitive, but it's getting more competitive in the upper tier. There are 40 or 50 EDC companies that do what we do. The top four to five are getting the lion's share of the business, but the number of companies is going down due to mergers or going out of business."
- "There's always been pressure to be price-sensitive because trials are getting more complex, cost is going up and companies looking to reduce cost see purchasing of software as one way."
- "Medidata is the market leader although Oracle has more market share because of their two products. But Medidata is quickly becoming No. 1. In EDC, Oracle is No. 1, Medidata No. 2 but will pass Oracle soon. Then there's a big drop-

off before the second tier. Leading those four or five are OmniComm, then BioClinica and Perceptive [Informatics], a division of Parexel. Datatrak is No. 6, but they're down to 35 people. Depending on what product lines you're talking about, there's also Merge."

Medidata Solutions' Advantages and Disadvantages

- "Medidata's advantage is their exposure beyond just EDC; they've diversified with CTMS, IVRS, fringe technologies. They've done a great job growing their company, but they've almost taken their eye off the ball with only one software release in four and a half years with their EDC. … We've had three major EDC releases in the last three years. They're getting a little too big and not focusing on ECD, thinking they have won that battle. A disadvantage is they're very expensive. Small and midsized struggle to pay their bills."

- "Their eClinical cloud offers one-stop shopping in the cloud, but we feel companies are looking at the best EDC."

- "Most companies are making a concerted effort to develop cell phone apps that are lot more intuitive than a web app, so that's a big push right now. … Medidata is doing the right thing by working toward that market."

Medidata Solutions' Growth Opportunities

- "Most of the companies, the top 20 certainly, have pretty much picked a vendor. You won't see too many new customers because they've already settled on their EDC vendor, but where you see their opportunity is stealing customers from Oracle. With the merger a lot of customers for Oracle and Phase Forward/InForm are struggling. When their contract is up, they'll go over to Medidata. … Oracle's and Medidata's contracts tend to be three, four or five years. It's tough for major pharma companies to switch, but they'll look at Medidata."

- "The last few years, they and other companies have made a push into Asia because a lot of clinical trials struggle to find patients. Medidata has a presence in Asia and the Pacific Rim, as do we. There's a lot of growth potential."

> *They're still very expensive. They're charging too much, but they're getting away with it because they're considered the leader. You can't argue with their success, but whether that can continue remains to be seen. Eventually the industry will wake up and see Medidata has let their products get a little outdated.*
>
> *President, Top 10 Competitor*

- "They're still very expensive. They're charging too much, but they're getting away with it because they're considered the leader. You can't argue with their success, but whether that can continue remains to be seen. Eventually the industry will wake up and see Medidata has let their products get a little outdated. We're thinking the same thing. Maybe they're doing the same mistake Oracle did."

Miscellaneous

- "For the next few years, because of their diversication and offering the cloud, they'll continue to see that growth. But if they ignore their roots and don't put more into their EDC flagship product, it will bite them."

- "Open source comprises 1% of the market, and anyone who submits data to the FDA generally doesn't use open source as there are questions whether it's truly validated. I do think Medidata can continue their growth because they're diversifying and the industry is getting more complex: more trials, more clinical trial complexity with the FDA exerting more scrutiny over safety and making tougher decisions. The industry is still growing, and Medidata can maintain their growth. Even if the industry flattens, they'll grow because of their new offerings."

4) Medical R&D Professionals

These three sources think Medidata can maintain its leading position based on its easy-to-use and intuitive products. Oracle is Medidata's main competition but offers less innovation and fewer robust solutions. Medidata does face challenges from lower-cost competitors in a market that challenged by slowing growth and smaller clinical trials.

KEY SILO FINDINGS

Clinical Trial Software Market Conditions

- 3 sources said the market is competitive and that demand is increasing from midsize and small pharma companies.
- 2 sources think Oracle is the leading software provider to large pharma, but both Medidata and Oracle are at risk of losing share to lower-cost competitors.

Medidata Solutions' Advantages and Disadvantages
- 1 source said Medidata's incumbent position in large pharma is an advantage.
- 1 source said Medidata offers easy-to-use, intuitive, web-based solutions with good support people and a solid business plan.
- 1 source thinks Medidata has outdated software, poor customer service and non-transparent high pricing policies.

Medidata Solutions' Growth Opportunities
- Growth of clinical trials in the large pharma market segment is slowing, which will challenge Medidata.
- Small pharma is priced out of using Medidata or Oracle software.

Miscellaneous
- N/A

1. R&D project manager at a major CRO

This CRO uses Medidata and Oracle's Phase Forward for 90% of its projects. Medidata has a strong competitive advantage: Familiarity with its EDC platform keeps current customers loyal. Still, the company does face slower growthbecause of a dwindling number of top-tier pharma projects and potential cost-cutting by new competitors.

Clinical Trial Software Market Conditions
- "Company sponsors want to use EDC. Very small sponsors—Tier II and III pharma—want to use it, but it's not always cost-effective, and they go back to paper or to Oracle's clinical electronic database, which was the industry standard prior to three to four years ago."
- "Our big sponsors have used a number of EDC, but 90% are using Medidata's Rave or Oracle's Phase Forward. There's also an open source, but I'm not that familiar. … I was going to use a small company until they ended up losing their business. I liked their simplified version."

Medidata Solutions' Advantages and Disadvantages
- "I worked for Medidata directly five years ago as a project manager when they were a growing company. The last year they've gone public, and based on their record, they're doing well. … I think they do have a competitive advantage and am not surprised to see them at No. 1."
- "Many sites already know how to use the Medidata EDC platform. This keeps them from having to learn another platform, which is a selling point for continued use."
- "Oracle and Medidata tend to drive each other. Without Oracle, Medidata wouldn't have as much advanced technology. You need a good competitor."

> **Many sites already know how to use the Medidata EDC platform. This keeps them from having to learn another platform, which is a selling point for continued use.**
>
> *R&D Project Manager, Major CRO*

Medidata Solutions' Growth Opportunities
- "It's not going to grow as fast. There's not that many Tier I and II coming on the market that can use it. But as people come up with new studies and go away from paper studies, whether they can absorb those studies remains to be seen."
- "Large sponsors like to share and move around. I have a Tier I plan where the company is using a number of vendors because they think it's important to help these companies and see who has a more user-friendly product."
- "The primary use of EDC is for the people who enter the data at the sites. Sites can be resistant to learning how to enter new systems. But as entry becomes more portal-friendly and as things tend to standardize, all offerings will be easier to enter."

Miscellaneous
- "Let me give you an analogy: MySpace was overcome by Facebook; why wouldn't something like that happen in the future? Competition and changing technology make other company successes very possible. For example, it costs $4,000 to $5,000 to maintain the database. They have thousands of studies going on that [Medidata] is getting that fee, just for keeping the database open. Why wouldn't another company come into that market with a less-expensive model?"

2. Clinical data project manager at a Southern CRO

To maintain share in this competitive market, Medidata will need to address its poor customer service, lack of communication, older software and nontransparent, high pricing. The source did praise Medidata's Rave. EDC is ideal for open-source solutions, and the source believes the platform is secure.

Clinical Trial Software Market Conditions
- "The market is becoming more competitive."
- "Oracle is the main competitor. Its InForm is a smaller program, and it doesn't have all the bells and whistles."

Medidata Solutions' Advantages and Disadvantages
- "On the positive side, Medidata's software is easy to use, intuitive, robust and flexible. You can meet most client's needs with Rave."
- "On the negative side, their customer service is not on top of known log issues. They don't update their documents frequently, or the updates are botched. We try to improve on this for our clients."
- "We haven't fully optimized the cloud or CRF health solution. Various people can have different data access, and this is fairly straightforward. That's expected with EDC. My experience with the cloud is limited to Rave, and it is working well. The cloud seems secure,"
- "We don't use mobile devices."

Medidata Solutions' Growth Opportunities
- "To maintain growth, Medidata needs to continue to improve its software and to be more reliable with updates. They also need to maintain the issues log more thoroughly and communicate in detail to the client."
- "I get a lot of feedback that Medidata's prices are too high. We propose Rave to clients, but smaller companies can't pay that price. The costs aren't transparent either. They vary from company to company, and we can't even estimate costs for a client."
- "One company I worked with used Rave. After three years, they decided they needed to seek a less costly software, and they did leave Medidata."

Miscellaneous
- "Medidata can stave off competition, but it needs to take care of current problems."

> I get a lot of feedback that Medidata's prices are too high. We propose Rave to clients, but smaller companies can't pay that price. The costs aren't transparent either. They vary from company to company, and we can't even estimate costs for a client.
>
> *Clinical Data Project Manager*
> *Southern CRO*

3. Project manager and senior business analyst at a Southern data management company

Medidata will have no problem competing with Oracle. Medidata sells end-to-end package solutions, which customers appreciate. Oracle, however, is in business to only sell software. Rave is easier to use than Phase Forward. Money for the cloud does not flow freely because of security worries, but data in the cloud is more secure. The source was unsure where Medidata would gain future share. It should be concerned that the era of blockbuster drugs is over; the number of big pharma companies is limited; and some of these companies are content to patch software from different companies rather than buy a new end-to-end solution.

Clinical Trial Software Market Conditions
- "This market is growing."
- "I've worked on a lot of pharma studies, and a lot of them have used Rave. I used Oracle before Rave. Oracle has not updated their software; rather they bought out Phase Forward."

Medidata Solutions' Advantages and Disadvantages
- "Medidata has the largest pharmaceutical companies."
- "Rave is web-based and an easier program to use than Oracle. I worked on a team to design studies, and it was very intuitive, excellent."
- "Medidata has used the cloud before; they have been connected to the wireless network. But the cloud could be a problem for Medidata if the money is not flowing freely. Everyone is worried about privacy and security. There is always a risk to having data in the cloud, but people get used to it. Data is safer in the cloud than in a locked room."

- "If Medidata can maintain excellent products, they will maintain a strong position. They have excellent products, good people and a good business plan."

Medidata Solutions' Growth Opportunities

- "Medidata is in a position much like Apple. What do they do next? Introduce new products? An extension of their CTMS will allow download to the FDA."
- "Medidata needs to be concerned that there are a limited number of big pharma companies out there. Right now there is a growth phase, but after that, then what do you do?"
- "It is easier for Medidata to sell a whole solution, and they depend on companies to want an end-to-end solution."
- "A company's budget and what they have in place determine what programs they will buy. Big companies want full solutions, but they may use different programs working together to get there. Merck has a hodgepodge of software, and it takes more people to run their system than to work with paper."

Miscellaneous

- "Medidata will have no problem competing with Oracle. Medidata offers solutions, and people prefer this. They have a better direction and train their own people with their own products. But Oracle just wants to sell software. There is a difference."

> "If Medidata can maintain excellent products, they will maintain a strong position. They have excellent products, good people and a good business plan.
>
> *Project Manager & Sr. Business Analyst*
> *Southern Data Management Company*

5) Industry Specialists

These four sources agree that Medidata is a leader in providing clinical trial software to large pharma and that it will maintain its market share. One source said its largest competitor, Oracle, has developed a negative reputation because of poor customer support and unimpressive products. The clinical trial industry is experiencing greater competition, and new entrants are offering strong innovation. Their challenge is to gain the attention and trust of large pharma, but for now they are making progress in servicing the small to midsize pharma market. Medidata's growth will slow in line with the number of opportunities in the large pharma market, and its products are not priced appropriately for smaller pharma companies. One source said Medidata needs to develop a "Light" version for the small pharma companies. Clinical trial software companies worth noting are BioClinica, Nextrials, Clinovo, Datatrak, Clinical DataFax Systems Inc., Merge, Parexel's Datalabs, and OmniComm.

KEY SILO FINDINGS

Clinical Trial Software Market Conditions

- 4 sources described the clinical trial software market as competitive, with increasing innovation and pricing pressure coming from new companies.
- Large pharma companies are slow to change; however, the second-tier market is growing and looking for lower-cost, innovative solutions.

Medidata Solutions' Advantages and Disadvantages

- Medidata's strengths are its name recognition and stability as a company. 2 sources also cited the company's good products, good service and customer communication.
- 2 sources discussed Medidata's nontransparent, high pricing, slow software, lack of innovation and unresponsiveness to small pharma companies.

Medidata Solutions' Growth Opportunities

- Growth in the clinical trial software market is expected outside the United States and from the small and midsize pharma market.
- Growth in the large pharma company market segment is slowing.

Miscellaneous

- Private cloud use, mobile devices and open-source solutions are growing despite FDA, privacy and security concerns.

1. Large technology company's director of life sciences consulting to pharmaceutical clients

Medidata's Rave is in demand among large pharma companies, but its other tools and suite concept are slow to gain traction. Large pharmas are skeptical of suite solutions. Also, since Medidata's tools are mostly acquisitions, they are not tightly integrated. Still, one large pharma client recently replaced an Oracle stable of tools with the Medidata suite.

Clinical Trial Software Market Conditions
- "Medidata is making headway in terms of market share with EDC arena. They are seeing some success with their coding application [Medidata Coder] but making little headway with IVRS or CTMS. Their traction in these areas within large pharma is very limited."
- "Currently in the clinical development space, we seeing the big software players like Oracle dominate, but we're also seeing more entry by smaller players depending on the type of tool."
- "Medidata's tools are marketed as standalone, but typically are not used as standalone but rather with the core EDC solution, Rave. Rave has increased in market popularity and seems more popular than Oracle InForm."
- "Big pharma has, until recently, ignored these smaller players, but we are seeing increased interest by big pharma in smaller software providers. An example is in the EDC where smaller players like Datatrak, Merge and Datalabs are getting increased traction that we didn't see before within big pharma. There are probably 10 smaller players out there, but they don't yet have a large pharma pedigree. Their market tends to be the midsize and smaller pharma companies, biotechs and medical device companies."
- "The smaller solution providers are perceived to have newer and more modern technology, whereas the big software providers often have difficulty modifying their platforms to the newest technologies. The appeal of smaller companies is also that clients have greater influence on them, and there's a cost advantage of smaller companies. We have some large pharma clients that want to go with small companies and their solutions for these reasons."
- "You're seeing more SaaS-type solutions where pricing is based on your output, not a license. We're seeing that coming into the market."

Medidata Solutions' Advantages and Disadvantages
- "One client company bought the whole Medidata suite and is in the process of eliminating industry-standard solutions like Oracle Siebel and replacing it with the relatively unknown CTMS solution from Medidata. It's the only company I know that's bought everything from Medidata and is now attempting to implement it."
- "Medidata's suite of products are mostly acquisitions and do not have a large pharma footprint right now. Oracle has a more mature suite of solutions when it comes to large pharma, but Oracle's 'integrated' solution is not really very integrated. Oracle, too, has acquired smaller companies and has bought their way to their current pharma footprint and then attempted to retrofit their suite of tools to enable easier integration."
- "Datatrak has a fully integrated solution where customers can turn off the options they don't want to use. You could argue that it creates a lot of weight to the solution although initial views seems to indicate this does not impact performance."
- "Medidata has experienced serious growth for a number of years. They have entrepreneurial leadership, but they are beginning to struggle with growth issues. There are a number of large pharma who say Medidata isn't receptive. There's the perception that neither of the big two EDC providers' technology is on the frontline of innovation."

Medidata Solutions' Growth Opportunities

> " Big pharma has, until recently, ignored these smaller players, but we are seeing increased interest by big pharma in smaller software providers. There are probably 10 smaller players out there, but they don't yet have a large pharma pedigree. Their market tends to be the midsize and smaller pharma companies, biotechs and medical device companies.
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> *Director of Life Sciences, Consulting*
> *Pharmaceutical Clients*
> *Large Technology Company*

> " Medidata has experienced serious growth for a number of years. They have entrepreneurial leadership, but they are beginning to struggle with growth issues. There are a number of large pharma who say Medidata isn't receptive. There's the perception that neither of the big two EDC providers' technology is on the frontline of innovation.
>
> *Director of Life Sciences, Consulting*
> *Pharmaceutical Clients*
> *Large Technology Company*

- "Large pharma isn't looking to buy a large suite of tools but rather wants best-of-breed applications that they can integrate with other solutions. Most tools are bought as individual solutions and integrated by the customer within their clinical development landscape. The one-stop shop for eClinical solutions is weak at the moment."
- "Business process as a service is a coming up where pharma can buy the service and technology solutions together in a subscription model."
- "The biggest thing right now is the risk-based monitoring. Everyone is touting a risk-based monitoring system, but very few have customers or even actual production solutions. You're even seeing risk-based monitoring solutions from some nontypical providers, including IMS."

Miscellaneous

- "Clients have the expectation that cloud solutions will result in cost savings, but we haven't seen the benefits for large pharma yet. Big pharma's idea of cloud is often to have a private cloud and other security considerations and, therefore, often to not realize the cost benefits they anticipated. I have a large client that wants cloud, but they won't allow a real cloud environment to be implemented because of concerns over data control."

2. Independent clinical services consultant on the East Coast

Medidata ranks second only to Oracle's Phase Forward. To ward off competitors, Medidata must be in the limelight by offering technology that reduces management time, responsibility and cost. The company would benefit from continuing to develop cloud and social media coverage. These areas will become increasingly important as European researchers push for data sharing. The company also needs to carefully watch customers and competitors to determine appropriate pricing strategies. Medidata always has focused on customer service, but it has limited experience with clinical trials. The source wonders how Medidata will segment the market.

Clinical Trial Software Market Conditions

- "This market could do a better job of using social media to optimize the clinical development process. There are good apps for the healthcare industry, and we should follow suit."
- "It is expensive to develop drugs, and companies should work with technology to reduce time, cost, management and responsibility."
- "Oracle's Phase Forward is definitely at the top, hands down. It is more expensive and is hard for startups to afford. Medidata and the others follow."

Medidata Solutions' Advantages and Disadvantages

- "Medidata is very focused on customer service and improving their products based on customer feedback. It is all about customization. They also have the expertise in-house to develop software. On the negative side, Medidata doesn't have folks with experience in clinical trials, and that prevents them from understanding the challenges of the trials."
- "The bio IT world has a corner on the cloud market. I'm not sure if Medidata is advancing in this area, but they are keeping up with the industry."
- "Is the cloud hard to trust? There is some insecurity there. Patient and research data are definitely confidential in the United States. However, in Europe, they want data to be shared, visible, particularly with regard to safety. European researchers tend to focus on patients more, but the United States doesn't do this until it is presenting to the FDA."
- "I'm not really sure if clinical software is going toward mobile just yet although cell phones, iPads are where it will probably head."
- "Medidata definitely has an edge over competitors. They have excellent customer service. They take feedback in consideration and always try to improve their products. They have been doing this for years."

Medidata Solutions' Growth Opportunities

- "Medidata and the other customers will continue to grow if they expand outside of the United States. They will also need to acquire companies that are not in their portfolio and new products."

> "Medidata can stave off the competition. But they must keep up with the competitors; they can't be looked at as someone in the background. Right now they are not slipping in the background, but they can't fight off Oracle and its Phase Forward product.
>
> *Independent Clinical Services Consultant, East Coast*

- "Medidata is taking a gamble by keeping its pricing high. The small companies can't afford to pay their prices, although there are companies that will pay a high price. Medidata will need to balance itself within the market. This means looking carefully at customers and competition."

Miscellaneous
- "Medidata can stave off the competition. But they must keep up with the competitors; they can't be looked at as someone in the background. Right now they are not slipping in the background, but they can't fight off Oracle and its Phase Forward product."
- "I'd be interested in knowing who's Medidata going after. Small to medium biotech? Or large pharmas? How are they segmenting this market? A few years ago they had a lot of software engineers on staff and were doing a lot of data analysis."

3. Manager of clinical data for several companies, including Medidata

Medidata may not grow, but it will maintain in this competitive niche market. The biggest competitor, Oracle, is developing a negative reputation, and other EDC players are small. Companies are careful about the software they use and how they use it, fearing possible FDA admonishment. Still, the source believes companies are being overly cautious. Tablet apps are being developed to track patient data although the FDA prefers more objective data. Medidata will need to rewrite its products from the ground up in order to update and integrate them. It also should consider a less-expensive product for smaller companies.

Clinical Trial Software Market Conditions
- "It's a pretty competitive market right now, but it is not a super-big industry. It is really a small niche market."
- "The opportunity is out there, but there is a certain stodginess to the industry. No one wants to rock the FDA's boat, so companies are very careful about the software they use. But the FDA doesn't care if you validate the software, and people are being more sensitive than they need to be."
- "Medidata and Oracle are the big two. A few years ago, I was unimpressed with Oracle's Phase Forward. They do not have good customer support, and they are developing a shoddy reputation. They have had a rough period the last five years."
- "After the big two follow a number of smaller players. We are using two others now, which we evaluated a few months ago. Smaller competitors that come to mind include BioClinica Express in Pennsylvania; Nextrials in California; Clinovo, which adopted an open source and was developed for academia and the government; Datatrak; DataFax in Southern California; and OmniComm. I've stumbled across a few others; it is not hard to develop EDC software."

> **Medidata needs to offer a cost-competitive solution for small companies, a Medidata Light.**
>
> *Manager of Clinical Data for Several Companies, Including Medidata*

Medidata Solutions' Advantages and Disadvantages
- "Medidata is a big company. It is stable, solid and covers all EDC basics. Because it is a dominant player, a lot of people know the company."
- "Medidata software is expensive, and it can be slow. It is also a mixed bag on who you get as a Medidata project manager. Some are better than others."
- "We are paying one-third to one-half the price for our current software than we paid for Medidata software. It's the same set-up time. It doesn't always work the way we want it, and Rave has all the bells and whistles."
- "Rave is trying to be a one-stop shop. We haven't used much integration, but some software works better than others."
- "The cloud is not a regulated industry, You need to have security around the data, have it tightly controlled. Some folks may be uncomfortable with this because it is new. But the FDA is not alarmed, and the concern is small and diminishing. Few companies have software on their own servers, and no one has an issue with this."
- "BioClinica has a new EDC system that is a mobile app; I'm not sure about Medidata. Their new version is on a tablet, and we give patients tablets. We are finding that patient input is more accurate when they record data on the tablet in real time, rather than later, on paper. But a study in California showed that patient-reported outcomes do not carry much weight. The FDA wants objective measures."
- "Medidata dominates the EDC market, and will continue to do so, but it is close to saturation."

Medidata Solutions' Growth Opportunities

- "I'm not sure how much Medidata can grow, but they can maintain. Medidata can serve other areas such as drug safety, clinical trial management, study design systems. They need to integrate their products, but to do this, they will need to rewrite the products from the ground up rather than Band-Aid them together."
- "Medidata does have price flexibility. They negotiate large volumes and give quantity discounts. Price is probably not an issue for them because they target big companies, provide integration and more functionality. They can justify the higher prices, and customers get what they pay for."
- "Medidata needs to offer a cost-competitive solution for small companies, a Medidata Light."

Miscellaneous
- "Medidata will keep strong. No one else will blow them out of the water."

4. Clinical data management consultant with 25 years' experience

Medidata has been unresponsive and unattainable to the small companies this source consults. Its bids have been four to five times higher than the awarded bids. Also, its pricing is not transparent, and he has seen widely varying pricing based on what customers can pay. Still, Medidata has an excellent product and is a clear market leader.

Clinical Trial Software Market Conditions
- "Standardization and risk-based monitoring are important trends. FDA is pretty much saying it's mandatory. And more integration, not just EDC but full-featured products where a company like Medidata can say, 'We're doing everything.'"
- "I'm a big believer in the open source. Using ODM [operational data model] you can move data between systems. That's where open source is taking us and where standards are taking us. It takes some time, but you can pick up Rave and move it to open source."
- "Oracle and [Medidata's Rave] are the two recognized names. I like OmniComm, have had excellent success with Merge who is going to be a significant competitor. Perceptive Informatics, Datatrak are others. I think a lot of the small ones are growing."

Medidata Solutions' Advantages and Disadvantages
- "I love Medidata's product. I'm an intermediate user and have done development with it. I like the product a lot. I'm primarily a technical consultant to small companies, helping to manage contracting. I work with the little guys. For them, I've found Medidata to be unattainable and unresponsive. It could be they're satisfied enough with their Pfizer and Merck business. Johnson & Johnson uses Medidata a lot."
- "I've sent some bids, and Medidata's was four to five times higher than competitors. Their bid for a Phase III trial of four to five months duration was $350,000 versus $50,000 to 75,000 for the same services. We didn't need the bells and whistles of their system."
- "Their size and their breadth are advantages. There's little they can't do, and they have the global aspect and support. There's a lot of interest for trials to share anonymous medication data, size of trial or amount of time to enter data. Medidata has their clinical business analytics where they're giving info about what others are doing to be able to judge your own performance."
- "The negative is their responsiveness, when so much of the market is the little guys."
- "I haven't had experience with their cloud. My clients do typical EDC and paper. ... I don't know about their mobile offering."
- "They can [maintain a strong market position], but I also have a vested interest in the open source. Medidata has endorsed the standards while Oracle has not embraced the industry standards, so Medidata is confident they have enough business to do that. I've worked more with [IBM's] Encapture and Clinovo.com, which took OpenClinica's version and made a more well-rounded model that small companies can use."

Medidata Solutions' Growth Opportunities
- "It's hard to measure by customers when there are so many mergers and splits. I would be more interested in number of studies. Medidata has some big clients such as Johnson & Johnson, big CROs, and some have 100 trials

> "I've sent some bids, and Medidata's was four to five times higher than competitors. Their bid for a Phase III trial of four to five months duration was $350,000 versus $50,000 to 75,000 for the same services. We didn't need the bells and whistles of their system.
>
> *Clinical Data Management Consultant ,25 years' experience*

themselves. They have tremendous name recognition. I'm not sure [of their growth potential], but they need to be nimble enough for the small players—though I don't see that they want to."

- "They do not release a pricing model like some of the others do, listing hosting fees, licensing fees, etc. Oracle has that model, Merge has that model. Medidata has a very closed model. They do fluctuate on price a lot and price based on what the customer can pay. They don't have transparency."

- "A small provider said to me that he could pretty much match them feature for feature but he couldn't spend enough on advertising to get the name recognition Medidata has."

Miscellaneous

- "They would have a difficult time increasing their market based on their current model."

Secondary Sources

The following seven secondary sources highlighted the shift toward outsourcing clinical trials and using cloud-based solutions, the rise in competition for cloud-based clinical trial solutions, interest in Medidata solutions, and a new trial from Medidata.

INDUSTRY

The following two sources centered on the rise of outsourced clinical trials as the industry booms and cloud-based solutions becoming increasingly attractive as a means to lower clinical trial costs and to ease increased FDA regulations.

➤ **Nov. 21 Formedix article**
Outsourced clinical trials are becoming increasingly popular and currently make up 40% of all drug development. The outsourcing market is set to double by 2016 to $60 billion based on trials being conducted 30% faster than in-house methods.

- "We all know that the end-to-end clinical trial process is becoming more complex and more heavily regulated, week on week, by authorities such as the FDA. We regularly learn of customers and industry professionals who are outsourcing to Contract Research Organizations (CROs) to undertake their studies, and it is becoming increasingly more popular—around 40% of drug development is currently outsourced."

- "With the huge pressure on drug development companies to reduce time and costs in their trials, it is crucial that CROs are able to offer more innovative and cost and time effective solutions to their sponsors."

- "Leading CROs' annual revenue jumped by as much as 10% last year and these companies are under mounting pressure to remain as attractive as possible to current sponsors and potential clients."

- "Infograph information: CRO revenue to double by 2016 to $60 billion."

- "General trials are conducted by CROs are completed 30% quicker than in-house."

➤ **Sept. 9 Applied Clinical Trials Online article**
Cloud-based software solutions for clinical trials and product development are picking up steam because of FDA-initiated regulations and electronic submissions, the increased costs of developing and initiating a clinical trial, the lack of paper used in an Internet process, and the cooperative nature of cloud-based documents.

- "The process of bringing a new molecular entity or device to market has historically been long, costly and both paper and people intensive. Clinical trials play a substantial role in this development process with costs for a single clinical trial potentially reaching $100 million."

- "These high costs are compounded by an inability to totally recoup the investment due to limited patent exclusivity timelines. Because the patent time clock starts ticking very early in the process, there is often only 8 to 13 years to earn back the sums invested in the product's development by the time marketing approvals are obtained."

- "Clinical study startups require intense collaboration among the sponsoring life sciences company, contract research organizations (CROs), investigators, the ethics committees and many other outsourced providers; regulatory oversight on many different levels; and documentation at every step. On average, more than 10,000 different documents over the course of three years are involved in every new trial, which all require time and effort to manage."

- "There is some movement in the life sciences industry away from the slow paper systems that have been used for decades. And, although the spreadsheet era of clinical trial start-up process management is not totally behind us, software systems are appearing as replacements. In fact, 2012 survey data from the DIA TMF Reference Model

group showed a 12 percentage point increase since 2010 in the number of respondents currently planning, building or evaluating an electronic Trial Master File (eTMF). Many of these eTMFs are currently available, but like many eClinical technologies, have now grown into cloud technology."

- "Cloud technology, where software is web-based rather than installed on each individual hard drive or in a sponsor's or CRO's data center, can offer document exchange on demand wherever permissioned users can connect to the Internet. Unlike traditional installed software, cloud technology software does not require the capital or technological support commitment. It offers a pay-as-you-go subscription payment model, is enhanced regularly and relies on a single code base so that everyone is running the latest version all the time."
- "Cloud-based eTMF users can pinpoint missing documents or spot issues such as non-performing sites causing delays, and resolve them proactively."
- "Because many systems can be integrated in the cloud, sponsors can step-up the use of cloud technology to encompass the entire clinical trial process. Instead of many disparate systems, therefore, there is just one, complete eClinical solution."
- "The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) now require electronic submissions of a highly structured, electronic common technical document (eCTD).[5] The FDA also more recently started requiring all submissions labeling to follow a structured product labeling (SPL) format—an overdue step towards more clearly defining the rules for use of electronic systems."
- "All told, these regulatory changes are helping to drive the industry's adoption of eTMF systems in the cloud while successful use of cloud eTMF systems are helping to dispel any concerns around their efficiency. For example, cloud technology solutions can be developed to comply with the FDA's Part 11 regulations out of the box without additional validation or an add-on application, overcoming another concern."

COMPETITION
The following three sources discussed eClinical Insights' entrance into the cloud-based clinical trial software market, Cerner and Claritas Genomics partnering to release a specialized solution, and Datatrak landing a new CRO partner.

➤ **Dec. 11 PBR article**
eClinical Insights is entering the cloud-based clinical trial software market with its eClinical intelligence platform that integrates data from multiple platforms for real-time clinical trial intelligence and workflow.
- "eClinical Insights, a provider of cloud-based clinical trials software, has announced the introduction of its eClinical intelligence platform, a cloud-based platform that provides real-time data insights for clinical trials."
- "eClinical intelligence platform is built upon a eClinical data hub that acquires and integrates data from any clinical system."
- "This platform delivers real-time clinical trial intelligence and workflow capabilities through a suite of cloud-based applications designed to help pharmaceutical, biotech, medical device, and contract research organizations improve the performance of their clinical trials through real-time data sharing and collaboration."
- "The open architecture of the eClinical intelligence platform includes a library of out-of-the-box interfaces to leading EDC technologies, enabling customers to leverage their existing technology investments as integrated components of the eClinical Insights platform."
- "eClinical intelligence platform is powered by a business analytics engine and is delivered through a Software-as-a-Service (SaaS) subscription model."
- "It includes a suite of cloud-based trial management applications that are available on per study basis, and can be turned on and off as needed, on both new and ongoing trials."
- "'With a team that has decades of experience in clinical trials management, and unparalleled experience integrating data from EDC, IVR, ePRO, CTMS, and Central Laboratory systems, we had a unique vantage point from which to solve this challenge.'"

➤ **Dec. 6 Genomeweb article**
Cerner Corp. (CERN) and Claritas Genomics are partnering to launch a cloud-based laboratory information management system for next-generation sequencing-based testing for molecular diagnostics.

- "This week, healthcare technology vendor Cerner and Claritas Genomics, a genetic diagnostic testing company, announced a partnership focused on building tools that will help clinical laboratories advance next-generation sequencing-based testing into the traditional molecular diagnostic setting."
- "Specifically, the partners plan to develop and launch in the next two years a cloud-based laboratory information management system (LIMS) that can handle the data processing and analysis steps required for NGS-based workflows, according to Maki Moussavi, Cerner's senior practice manager for genomic solutions."
- "The LIMS, she told *BioInform* will enable users to integrate the instruments and analysis software that they use as part of their sequencing workflows and help them move sequence data across these systems."
- "Separately, Claritas is implementing [Millennium] Helix, Cerner's laboratory information system for capturing data from traditional molecular diagnostics activities such as SNP testing and cytogenetics as part of its collaboration with the healthcare technology firm. It will use the solution for its non-NGS-based testing activities in addition to helping Cerner develop its new cloud solution, Moussavi said."
- "Meanwhile, Cerner's considering adding new partners to its LIMS development program. According to Moussavi, a number of Helix customers have indicated their interest in branching out into the NGS-based testing arena and the company is currently sorting through potential partnerships."
- "Claritas, for instance, focuses more on pediatric testing 'but we will have other clients who are focused on oncology and other areas and we want to make sure that we are not developing to a particular specialty,' she added. Furthermore, although Cerner is targeting clinical testing laboratories, the LIMS software will also be flexible enough for research use."

➤ **Dec. 3 Broadway World's Geekworld.com** article
Datatrak landed a new CRO partner in SPRI to expand its network and give SPRI the ability to manage clinical trials in one cloud-based solution.
- "DATATRAK International, a leader in developing cloud-based, unified eClinical technologies and delivering related services for the clinical trials industry, today announced its newest CRO Connect Partner, SPRI. SPRI Clinical Trials is a contract research organization that takes a hands-on approach to clinical trial design, planning and management."
- "'In the complex world of drug development, DATATRAK's unified platform provides our clients and our clinical teams alike a single location to review consolidated data. Combining CTMS, EDC, IWR, ePRO and randomization on a single platform provides a seamless solution that works well for a single trial or a global program. The robust platform, industry experienced teams and competitive costs all combine to make this partnership a natural fit for SPRI,' said Amy Rigney, SPRI's President and Chief Operations Officer.'"
- "The DATATRAK Connect Partner Program is collaboration between synergic companies to accelerate the drug development process. The program allows for extended services offerings to cover all areas of the drug development process with the goal of reducing study costs and furthering business development objectives."

MEDIDATA
The following two sources showed a market for Medidata's integrated products and the influence of Medidata's mobile and cloud technologies on patient engagement.

➤ **Oct. 11 Applied Clinical Trials Online** article
Forty-four percent of surveyed organizations are evaluating the integration of interactive response technologies and EDC. Medidata has a good relationship with Applied Clinical Trials Online, giving it another outlet to showcase its products.
- "We've been working with our friends at Medidata on a series of online educational tools on the topic of integrating interactive response technologies (IRT) and electronic data capture (EDC)."
- "The webcast 'IRT-EDC: Are You Ready for a Unified Experience?' yielded some interesting poll results, with 44% of attendees indicating that their organization was 'evaluating the approach' to integration. (See the survey results discussed in the follow-up White Paper, here)."
- "As the industry's cloud-based technology continues to improve, it's easy to imagine the future of integrated and even completely unified tools for clinical trial management."

➤ **Sept. 23 FierceMobile Healthcare** article

Medidata Solutions Inc.

Medidata is conducting its first clinical trial on the effects of mobile and cloud technology on patient engagement. It is using mHealth devices from Withings to monitor physical activity in participants.

- "Medidata Solutions, a provider of cloud-based solutions for clinical research in life sciences, is conducting its first clinical trial to assess the impact of mobile and cloud technology on patient engagement for improving health outcomes in diabetic patients, according to a company announcement."

- "The initial feasibility stage of the study is slated to start in the fourth quarter of 2013 and will be followed by a randomized clinical trial. Endocrinologist Zachary T. Bloomgarden, Clinical Professor of Medicine, Endocrinology, Diabetes and Bone Disease at Mount Sinai Hospital in New York and co-editor of the *Journal of Diabetes*, is the study's principal investigator."

- "Medidata's study will use mHealth devices from Withings, maker of smart devices and applications, that will monitor the physical activity and weight of study participants, providing immediate feedback to participants and providing targeted messaging through wireless links for patient engagement."

- "In addition, Spaulding Clinical Research, a research solution provider and medical device manufacturer, will use its capabilities to enable the mHealth devices to connect to the Medidata Clinical Cloud."

- "'Wireless and personal mobile devices provide opportunities to improve patient engagement because of their ease of use, real-time transmission of data and increased portability and convenience,' said Randy Spaulding, founder and CEO of Spaulding Clinical Research, in a written statement. 'This collaboration is an important step in bringing these benefits to the real world.'"

- "In related news, U.K. researchers from the Universities of Newcastle and Northumbria have developed a prototype personal health monitoring system that uses medical sensors, mobile phones, and cloud computing to help people with Type 1 diabetes."

- "In June, healthcare technology company WellDoc launched the first FDA-cleared mobile prescription therapy for Type 2 diabetes with insurance reimbursement. Called BlueStar, the patient-centered medical product requires a prescription from a licensed healthcare provider and will be 'reimbursed and adjudicated' as a pharmacy benefit similar to other prescription products."

Additional research by Renee Euchner, Linda Richards, Carolynn Schwaar and Mason Rudy

Blueshift RESEARCH 1 Ferry Building, Suite 255, San Francisco, CA 94111 | www.blueshiftideas.com