

## Insider Insights: ClearTrial

CWWeekly's semi-monthly company profile feature, Insider insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Mike Soenen, President and CEO of ClearTrial.

**Q** Based on your previous experience at Kraft Foods, Andersen Consulting and the success of ClearTrial, why has it taken so long for the clinical trials industry, particularly sponsors and CROs, to do a better cost benchmarking and real-world planning compared to other industries?

**A** The primary reason other industries have gone there before and pharma is only now having to wrestle with this is quite simple. We did not have to be efficient in this industry until five years ago. The margins and protections the industry had gave it the ability to be less conscious about being efficient. Time was always an issue, but we could spend a lot more than we can today. Financial resources aren't there anymore the way they use to be. Today it's productivity initiatives. And that is what is driving the efficiency initiative that we are solving at ClearTrial.

Change is the main driver, but there are many sub-drivers like patent protection compression in first-to-market exclusivity. There is generic competition driving prices down and regulation around price controls—all kinds of things that provide pressure on the revenue side. Now there is nowhere for that pressure to go except upstream into the R&D side. That's what's driving all these productivity initiatives.

From my 23 years of experience, there is a common thread in my helping companies, especially those with complex pricing and contract management issues, like the biopharmaceutical industry. It is to make significant efficiency gains by streamlining their business operations across not only their internal functions but also their external operations.

**Q** If spreadsheets are the old vinyl records of I.T. and cloud computing is the new state-of-the-art, what kinds of efficiencies, cost savings, simulations, flexibilities and other benefits do you see for the computing future of the clinical trials industry?

**Headquarters:** Westmont, Ill. (moving to Chicago March 2011)

**Total Worldwide Employment:** 50

**Description:** Provides Clinical Trial Operations (CTO) software, an integrated system for clinical operations planning, forecasting, outsourcing and project tracking. It helps biopharmaceutical, medical device companies and CROs streamline their clinical operations from plan to payment.

**Officers:** Mike Soenen, President, CEO

Michael Bruns, COO

Andrew Grygiel, VP, Marketing & Product Management

Richard Zecca, VP, Sales

**Offices:** 4 (Chicago, Philadelphia, San Francisco and Munich, Germany)

**Domain expertise:** Clinical operations, clinical outsourcing, clinical finance and clinical project management

**Year founded:** 2004

**Website:** [www.cleartrial.com](http://www.cleartrial.com)

**A** The biopharmaceutical industry will now have to make more informed decisions more quickly. Already, you are seeing it as some of the large pharma companies are rationalizing their pipelines, getting out of certain therapeutic areas, making hard choices and decisions on what they will and will not focus on. That same decision making is now driving down into the R&D operations in terms of how they attack clinical studies. So the ability to rapidly simulate, for example, what costs would be and what the time schedule will be, whether it's Approach A or Approach B or any one of multiple scenarios, is important for making decisions off accurate information. And you have to do them quickly. You can no longer wait a week, as somebody else will beat you to the punch. You still need to be accurate. And those are the capabilities that have existed in other industries for years. We need the tools to be doing it in the clinic today.

**Q** ClearTrial's Study Cost & Optimization Service software is billed as being able



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to identify dramatic study cost and time line reductions. What is the biggest and most common expense areas that can be reduced?

**A** While it varies by the type of study, monitoring, site management and project management are three buckets in which there is a lot of room for efficiencies. For example, one customer was in discussions with its CRO about how best to run the study. Our customer, the sponsor, was looking at the study model the CRO recommended, but in the ClearTrial software. And it became glaringly apparent that there were some inefficiencies in the operational approach the CRO was recommending. In this case it was monitoring. It went back to that CRO and suggested slightly different strategies that affected a few cost drivers but reduced the cost of the study by 10 percent.

This was a fairly complex oncology study. The CRO came back within 24 hours and lowered its bid. The sponsor saved enough money to fund another phase I study. To redeploy that capital and fund another study is the big win. And that is becoming increasingly more important now that we are moving offshore with global studies and a lot of global clinical trial operations. Those three activity buckets—monitoring, site management and project management—are becoming more complex, especially on a global scale.

**Q** You began selling to sponsors, but as CROs grow by taking more pharmaceutical and biotechnology outsourcing, Clear-Trial is seeking to be impartial. How do you view your company in the center between sponsors and CROs?

**A** We are in the middle—essentially as the enabler. We have no interest in the

profitability of the study and no interest in under-charging, so we are very much neutral as it pertains to budgeting and forecasting. But I think the bigger thing to note here is what ClearTrial is really enabling. In our position, between sponsor and CRO, the bigger win here for everybody is the fact that ClearTrial is the platform on which CROs and sponsors can collaborate to find



**“ClearTrial is the platform on which CROs and sponsors can collaborate to find the operational efficiencies to drive significant savings and productivity gains that these companies need to survive in today’s economy.”**

*Mike Soenen, President and CEO, ClearTrial*

the operational efficiencies that are going to drive significant savings and productivity gains that these companies need to survive in today’s economy. That’s the bigger win.

Yes, it starts with budgeting and forecasting, but it is much bigger than that. It’s operational planning and finding and optimizing the operational design of a study so that both parties win. If software can help you find more efficient ways to run the study, the CRO is not expending as many resources and the cost, correspondingly, comes down for the sponsor while the CRO’s margins remain intact. Everybody wins while costs are lowered. ClearTrial is the enabling platform that operationalizes that strategy.

**Q** Your software can account for clinical trial cost differences and compute the impact of slightly faster recruitment in one country over another. What other software planning advances are you being asked to consider that will speed clinical trials?

**A** There are three things I see as recurring themes based on the customers I

speaking with every year. The first is this trend among the larger pharmaceutical companies that are reorganizing to global clinical operations. One of the top pharma companies, who is a customer, just announced a reorganization in that direction. It was going to use us as the platform to roll out and enable that global clinical operation. There is a thirst to be able to track its studies against the plan. That’s been a gaping hole in the market in terms of the software that serves the clinical trials industry. Everybody does a good job tracking everything but nobody has the integrated planning systems.

A second is reforecasting, especially change orders.

The market is waking up to this need, especially with the

change order that has plagued this industry. With ClearTrial that is one thing we enable—the visibility for where you should be, as well as where you are, so you can make an informed decision on what degree you need to course correct.

The third is collaboration. We’ve been working with one customer, a top 10 pharma, and it is frequently thinking about how it interacts with CROs. It has a very collaborative approach and is looking at ClearTrial as the method by which it can basically conduct collaborative planning with that CRO. That means leaning on what the CRO is good at, coupling that with what it—the sponsor—is good at and doing it on one single platform on a global basis. It went through an exercise in validating ClearTrial and it gave the CRO a pretty complex study to estimate. It took the CRO about a week to come back with one scenario. Our customer sat down and in 30 minutes modeled out his study and compared the two side by side. We came in at \$34 million and the CRO at \$35 million. It was a pretty compelling example of what they can do together. 