



## Case Study

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# RUNNING A VIRTUAL NETWORK: OPTIMED

Using CRIO's powerful enterprise system, Optimed Research has pioneered a new, centralized delivery model for clinical research services. This model has the potential to transform the industry and bring investigational products to market quicker.

## Building a research practice

Dr. Christine Ebert-Santos of Ebert Family Clinic, a pediatric practice in Frisco, Colorado had always wanted to do clinical research, but found it difficult to break into the industry. An accomplished physician and academic researcher, Dr. Ebert-Santos had limited experience as a principal investigator in interventional clinical trials and did not have the staff or resources to secure and operate studies.

Therefore, when Dr. Ebert-Santos heard about Optimed Research, Ltd., a centralized trial management organization, she was intrigued. "Their business model is to provide a full range of support for both research-experienced and research-naïve sites," she explains. "They bring a lot of expertise in areas we lacked, allowing me to focus on the clinical aspects of the trial."

Under the partnership, Dr. Ebert-Santos serves as principal investigator and directly employs and manages the clinical research coordinators. This gives her control of the trial operations while ensuring a tight relationship between the PI and staff.

Optimed provides all the other services, including: sourcing studies; negotiating budgets; training the staff; implementing site-level SOP's; managing the eRegulatory binders; designing and publishing the eSource templates; QC'ing completed source; entering source data into EDC systems; running advertising campaigns; and managing the finances.

## The virtual management model

Optimed started as a single research site in 1999 in Columbus, Ohio, and grew to be one of the largest free-standing sites in the area. In 2013, a new management team came in to identify ways to grow the business further.

"We realized pretty quickly that we've saturated the local market, and there was limited upside unless we expanded geographically," said Dustin Caldwell, Optimed's Director of Strategic Development.





However, the challenge with expanding to sites is how to do so without taking on too much staff. “In the traditional model,” explained Dustin, “the only work that’s done centrally is business development, contract negotiation and invoicing. The bulk of the work is operational, requiring a heavy footprint at each site.” This requires that each local site achieve a certain size threshold before becoming sustainable.

Optimed pioneered a new-to-the-industry operating model. Instead of maintaining large, de-centralized staff at multiple locations, it would utilize technology to centralize every task except research visits, which would be done by local investigators utilizing their own coordinator staff. This gave the investigators more control, and incentive, to grow the business, and allowed them to transition existing clinical staff to research roles on a part-time basis during ramp-up.





The result is more standardization, economies of scale at the center, and leaner sites. “This model allows both the investigator and us to earn profits much sooner than the traditional model,” said Dustin.

The model was perfected and rolled out in 2017; within a year, Optimed was able to activate 11 investigators around the country in 7 therapeutic areas, as far away as Hawaii.

## BEFORE

Activity	 Center	 Site 1	 Site 2	 Site 3
Business Development	Source / Negotiate			
Regulatory Binders		Performed Onsite		
Source Template Design		Performed Onsite		
Patient Recruiting	Centralized	Local Recruiting		
Data Collection		Performed Onsite		
Quality Control	Traveling QC	Performed Onsite		
EDC Entry		Performed Onsite		
Financial Management	Invoice / Reconcile	Activity Entry		

## AFTER

Activity	 Center	 Site 1	 Site 2	 Site 3
[No Title] Business Development	Source / Negotiate			
Regulatory Binders	Centralized			
Source Template Design	Centralized			
Patient Recruiting	Centralized	Local recruiting		
Data Collection		Performed Onsite (with guardrails)		
Quality Control	Centralized			
EDC Entry	Centralized			
Financial Management	Centralized			

## Technology, and CRIO in particular, paved the way

What enabled this shift was the rise of affordable commercial software built for research sites. After a comprehensive search, Optimed chose CRIO as its eSource and CTMS platform.

“With CRIO, we can build source templates quickly and easily, with real-time alerts that guide the user as he or she fills out source,” explained Dustin. That allows the coordinator – many of whom are relatively new to research – to work more efficiently, with fewer mistakes and deviations.

Meaghan Ziegler, a coordinator at Dr. Ebert-Santo’s site, found CRIO to be very intuitive and helpful. “I have a lot of experience on the clinical side, but am relatively new to research,” she explained. “With CRIO, the system really helped get me up the learning curve because it would tell me when I needed to do certain things, and flagged data entries that presented potential deviations.”

Once the visit is complete, Optimed’s team performs Quality Control. “Our team can see the data instantly,” said Dustin, “and leave queries directed to the coordinator, investigator, or both.” These queries appear in the users’ dashboards.

After QC, the Optimed team enters the data into EDC. “By centralizing EDC entry, we achieve not only economies of scale, but we take control over a critical and highly visible chokepoint in the process,” said Annie Schertzer, Optimed’s Director of Site Intelligence. With control over EDC, Optimed can ensure high performance on two critical metrics sponsors use to evaluate site performance – timeliness of data entry, and number of queries per entry.

Finally, CRIO’s integrated Finance module allows the Optimed Finance team to send out invoices without having to rely on local coordinators’ updating a CTMS or Excel spreadsheet. That’s because CRIO’s Finance module is integrated with eSource, so receivables, invoiceables and payables are automatically created as the data is being captured.

“We do not leave any money on the table,” points out Annie. “That means we can deliver more value for our affiliate sites, with less local workload and virtually no invoicing inaccuracies.”

Dustin puts CRIO’s role in Optimed’s business model this way: “Literally without CRIO very few of these efficiencies would be possible. The system is very intuitive, comprehensive and seamlessly integrated. It’s easy to use, easy to train staff on, and facilitates remote oversight that has historically been impossible.”

## Conclusion: the future of research

With the rise of Electronic Health Records, many physicians now have access to large patient populations that they can pre-screen for complex protocols. However, very few are actively engaged in research; even those that are experienced often struggle with issues of achieving scale or dealing with cyclicalities.

This is why Dustin believes Optimed’s business model is the wave of the future. “We are able to deliver high quality operational support to both research-naïve and experienced investigators, thus enabling research that might not otherwise get done,” he said. That means investigators can leverage their patient relationships and clinical skills to help sponsors with the ever-growing challenge of patient recruitment. “It’s truly a win-win for everyone involved, from the sponsor/CRO to the investigator to the patient.”

Dr. Ebert-Santos puts it this way: “Without Optimed, and their technology-driven support, we would not be able to recruit our patients or deliver high quality data to sponsors. Technology-centered partnerships like the one we have with Optimed could really help the industry achieve better enrollment, thus leading to faster time to market for critical life-saving therapies.”

## ABOUT THE PROFILE



*Dustin Caldwell is Director of Strategic Development for Optimed Research, a Columbus, Ohio-based site with an extensive and growing network of managed partner-sites. Dustin is responsible for managing sponsor and investigator relationships and sourcing studies for the network.*