CRIO

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Case Study

APRIL 2018 | CASE STUDY

CRIO FINANCE WOULD HAVE NETTED OVER $50K ON A SINGLE STUDY

Regeneris Medical performed an audit of their financials on a high-enrolling study and discovered over $50,000, or nearly 10% of potential revenue, was uninvoiced. Had they used the CRIO eSource system integrated with Finance, they would have easily captured all this nearly-missed revenue.

Growing too fast for Finance

Regeneris Medical is a clinical research site in North Attleborough, MA affiliated with Tristan Health, a primary and urgent care facility. Led by Dr. Ryan Welter, Regeneris Medical performs studies across multiple therapeutic areas.

Dr. Welter decided to grow the clinical research practice, and as a result the site took on several high enrolling studies. However, the administrative functions couldn't keep up. The coordinators were too busy processing patients to track procedures accurately.

To manage the newfound growth, Dr. Welter brought in Alex Wang, an experienced site director. One of the first things Alex did was sign up for the Clinical Research IO platform. "I had used the CRIO system at my last site," said Alex, "so I knew first-hand how much it can help site operations."

On one major study, the close-out visit was approaching. Alex had no familiarity with the study but could tell from the packed binder full of financial notes and receipts that the site's tracking systems were not well organized.

"I knew we were leaving money on the table, but I had no idea how much, and I did not have the time to examine it myself," said Alex, so he hired outside auditors to take stock.

Over $50,000 unbilled

The audit team huddled around a conference table for several days poring over stacks of binders. In all, the site had randomized nearly 40 subjects, so the volume of paper was staggering. By the end of their engagement, the team had identified over $50,000 that was never invoiced. This represented nearly 10% of the site's total earnings.

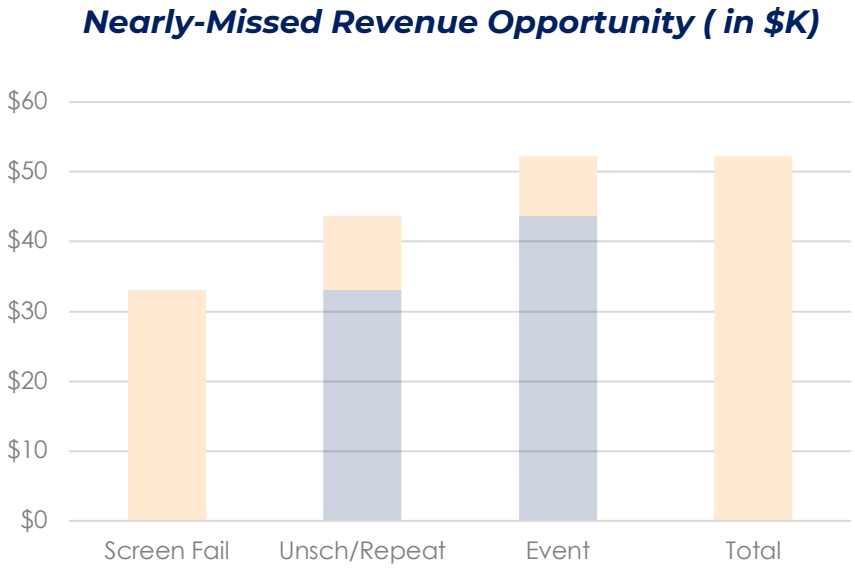
First, the site never fully invoiced for procedures on Screen Fail patients. In some cases, the site had only received the patient stipend but not the clinical procedures; in others, it had received all the clinical procedures but not the stipend. Even worse, it hadn't invoiced for the full number of Screen Failures it was entitled to.

Second, the site was not invoicing for all the unscheduled and repeat procedures performed. The team found procedures associated with repeat labs, ECGs and Informed Consents that were never invoiced. The re-consents in particular were significant since the study had several amendments.

With paper source, it was especially hard to track these events. In one instance, the team realized that an Unscheduled Visit had occurred because they found a handwritten, barely legible progress note from the coordinator that a patient had come in on a separate day for a lab re-draw.

Third, the site had missed key opportunities to invoice for repeat events such as the purchase of clinical supplies or advertising.

Fortunately, the audit team was able to produce invoices and itemizations Alex could use to collect the funds – just as the study was about to close. But the audit wasn't free, and it was a stressful event for Alex and the PI.



CRIO would have caught almost all of it

Alex tested the findings against the CRIO system and found that the CRIO system would have captured 95% of the missed invoicing opportunities. That's because the system's Finance module *tracks receivables while the data is being collected*. For instance, if a coordinator responds "Yes" to the question "Was a repeat ECG performed?", the system knows that a repeat ECG was done and creates an invoiceable event for it. Because this is done in real-time, the site has complete, up-to-date visibility into their receivables at all time.

The CRIO system offers a complete workflow solution. So once an invoiceable event is created, it goes into a holding pen, where it can be added easily to an invoice customized with the site's logo. Once the invoice is saved, the system starts tracking how many days outstanding it is and provides various receivable reports to the end user.

The only part that CRIO might not have captured are the events that occur outside of visits, such as purchases of clinical supplies. Those kinds of events necessarily rely on staff diligence for tracking.

"We had no idea how much money we were leaving on the table," said Dr. Welter. "It's unfortunate but these sponsor contracts can get pretty complicated, and if you're not extremely organized, you will let receivables slip through the cracks. And when you do well and get busy, that's when the tracking system becomes the most stressed."

"With CRIO," he continued, "we don't have to worry about any of that. We just do our jobs, and just by doing our jobs the system is tracking all our receivables for us. We spend *less* time focused on Finance, but we end up collecting *more* revenue because nothing is missed. You can have your cake and eat it too."

Conclusion

Even Alex was surprised at the findings. "At my prior site, they were just getting started with CRIO Finance when I left, so I never had the chance to learn how powerful it really is," he said. "To anyone thinking of buying the CRIO system, I say it's a no-brainer. Besides all the efficiency and quality gains, the system will capture all the hard-to-track revenue and basically pay for itself through that alone. Why wouldn't you use this system?"

ABOUT THE PROFILE

Alex is the Director of Clinical Research at Regeneris Medical. Prior to that, he was a coordinator and site director at another facility. He began his career as a petrochemical engineer and holds a master's degree in Engineering. He grew up in China in a family of engineers. After following in those footsteps, he transitioned to clinical research after a recently approved medication saved his life during school. He is passionate about helping patients and contributing to rigorous and patient-centered clinical research.

Case Study

MARCH 2018 | CASE STUDY

CRAS FAVOR CRIO OVER PAPER BY 3:1 MARGINS ON KEY DIMENSIONS

One CRA discovered the benefits of the CRIO system and introduced it to other sites on the trial. The CRAs favorable impressions were confirmed in a subsequent survey of CRA users of the CRIO system, who favored CRIO over paper on promoting data integrity, compliance, and rigorous QC by a 3:1 margin.

A site on CRIO

Sin Park is a CRA for MOE Therapeutics, a small device manufacturer running a Phase 3 trial. Of his six sites, he noticed something different about one of them, which also happened to be the highest performer: Instead of the usual paper binders, this site was using the Clinical Research IO (CRIO) eSource system to collect data.

“I can log in any time and see the data,” said Sin. “I know exactly what is going on with the site. If I have any questions or comments, I can leave a query, and I know the site will see it. I don’t have to write a sticky note and wonder if it is going to get read or not.”

Remote monitoring was especially helpful because it meant he didn’t have to travel as often to the site. “If all my sites were on CRIO, I could do a lot more of my work from a central location, and that would save significant cost for the sponsor, and time for myself,” said Sin.

Not only was there value in the transparency and remote access, but the site’s data quality was substantially better than at the other sites. Sin later learned from the site that this was due to the edit checks and other quality safeguards built into the system. “The way the template was laid out – it was very easy for me to follow the workflow, confirm compliance, and review the procedures and results.”

Convinced of the system’s value, Sin worked directly with CRIO to have tablets, the software and the template given to two other sites. When two new sites were brought on, they came on agreeing to utilize the CRIO system.

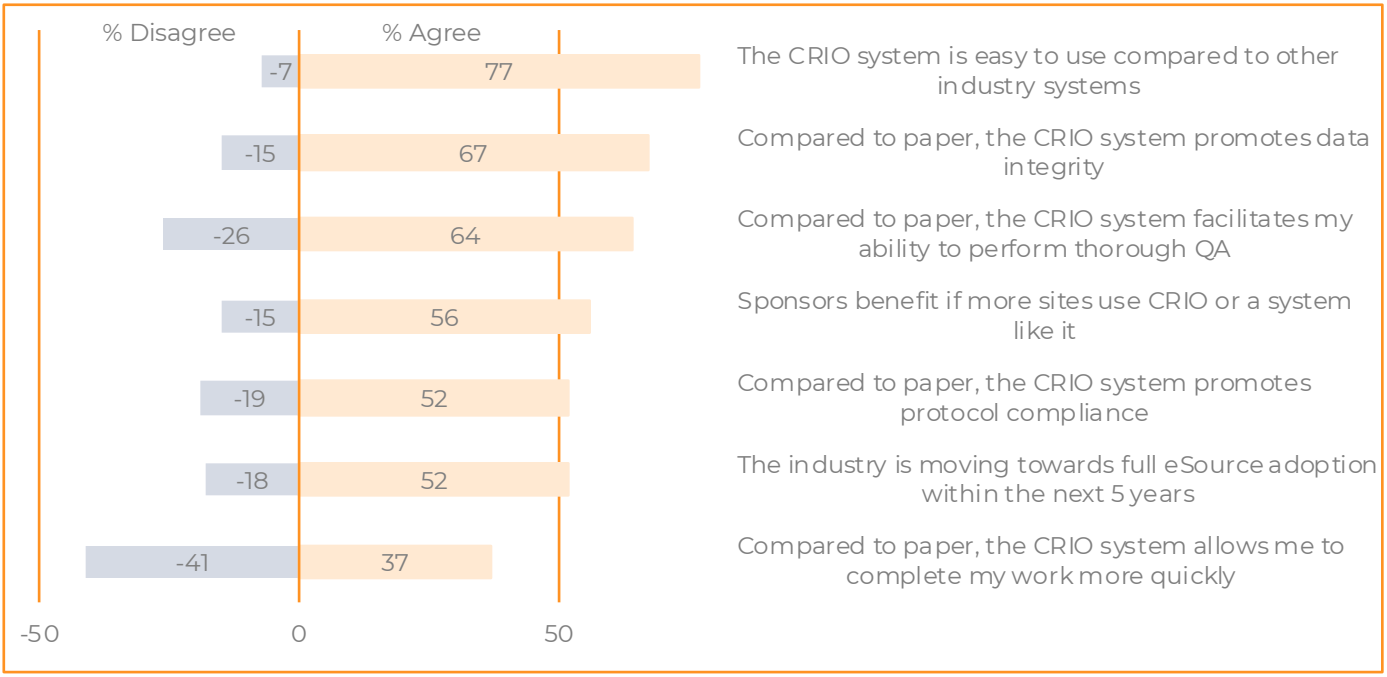
“If I were starting a trial today,” said Sin, “I would choose only sites that are using or are willing to use the CRIO system.”

CRAs favor CRIO over paper by 3:1 margins

Sin's experience is not unique. Clinical Research IO commissioned a third-party market research firm to survey its CRA users on their experience working with the system, and those results reflected widespread favorability to the system.

On several key attributes, CRAs reported CRIO as being superior to paper binders by margins of 3 to 1.

Responses of CRIO CRA-users



On the question of what better promotes data integrity, CRAs favored CRIO over paper by 67%-15% (4.5:1 margin). On the question of which facilitates rigorous QC, CRIO beat paper by 64-26 (2:5). On the question of which promotes protocol compliance, CRIO beat paper by 52%-19% (2:7).

The only question where the two systems were at parity was the one on which was faster to work with "I attribute that to the fact that CRAs are used to working with paper binders, and haven't had as much experience with our system," said Raymond Nomizu, CRIO's Co-Founder. "The fact we're at parity at all is pretty good."

eSource as the future

Two results in particular were telling. First, 56% of CRAs agreed and only 15% disagreed with the statement that "Sponsors would be better off if more sites used CRIO or a system like it." Second, 52% agreed and only 18% disagreed that "eSource will become the predominant mode of collecting data in the next 5 years."

Taken together, it reveals that CRAs as a whole believe eSource is not only beneficial to sponsors, but that the industry is headed in that direction.

Conclusion

Sin is not surprised by the results. "I supposed there are many CRAs who haven't given much thought to eSource and I'm sure many might be hesitant with it when presented as a concept," said Sin. "But when a CRA is exposed to CRIO, I can't imagine why they wouldn't embrace it, and this survey shows that."

ABOUT THE PROFILE

Sin is an engineer at MOE Medical Devices. His educational background is in biology, mechanical engineering and biomedical engineering. After working in academia, he now works for a medical device startup as the mechanical engineer, microbiologist and CRA for clinical studies. He a technophile and spends a good amount of time trying to optimize his productivity.

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MAY 2018 | CASE STUDY

AN INVESTIGATOR-CENTRIC EMR

Dr. Clark of Charlottesville Medical Research Center discovered that CRIO is unlike the EMR he had in his medical practice that used to slow him down. CRIO has enabled him to save time, improve the performance of his site, and earn multiple levels of return. Overall, he spends less time in CRIO than he did in the EMR, and the time spent is much more value added.

From medicine to clinical research

From 1997 to 2015, Dr. Clark operated a solo Internal Medicine practice in Charlottesville, VA. In 2013, to avoid Medicare pricing penalties, he moved his practice from paper charts to Electronic Medical Records (EMR).

The EMR system ended up creating more work for Dr. Clark. The EMR workflow was unintuitive and tedious. Under heightened insurance scrutiny, he found himself writing much more detailed notes to justify billing procedures. He'd finish clinic at 5:00, then work until 8:30 documenting in the EMR.

During this time, Dr. Clark was a part-time Investigator at Charlottesville Medical Research Center. In 2016, he quit medicine, purchased the research site, and became a full-time Investigator and site owner.

Going electronic with CRIO

Dr. Clark's site ran smoothly. His site was considered a high performer. As a full-time Investigator, Dr. Clark was always available to see patients, write and sign notes, meet CRAs, and oversee trials. He saw little reason to change.

Thus, when one of his staff members suggested he look at CRIO, his first reaction was "No way!" After hearing his colleague's enthusiasm, he cautiously entertained a demo.

"I was really impressed with how intuitive the system was," said Dr. Clark. "It was clearly built with a deep understanding of a research site's needs."

Cautious from his EMR experience, Dr. Clark performed extensive due diligence. He attended a workshop hosted by CRIO and spoke with several CRIO clients. Even then, he struggled with justifying the cost associated with CRIO.

Finally, Dr. Clark decided to take the plunge. He signed up for CRIO's monthly CTMS module and opted for the pay-as-you-go pricing plan on eSource, giving him the flexibility to scale back if it didn't work out.

Within months, Dr. Clark's enrolling studies were all on the CRIO system. "My only regret," said Dr. Clark, "is that I didn't listen and jump in earlier."

Not your typical EMR

Dr. Clark's experience with CRIO was radically different from his experience with EMR systems.

The contrast with EMR starts with the fundamental purpose of each system. CRIO's goal is to make research seamless. It does not add or create new workflows; instead, it facilitates them by automating the repetitive tasks. EMR systems, on the other hand, came about in the context of a strong government-led push to control costs; it introduces new workflows and is designed to standardize medical practices and coding.

"With CRIO, I really feel like I'm in control of my operation versus an EMR controlling me and my operation," said Dr. Clark. "CRIO makes it like an air traffic controller overseeing, from one location, several studies occurring at the same time. EMR, on the other hand, was disempowering and always made me feel like I had no control".

Unlike with the EMR, Dr. Clark spends only an hour per day in CRIO, and he spends that hour performing true oversight. "Before CRIO, for instance, I would instruct the coordinator to do something and hope she did it. Now, I can log in and make sure all procedures are completed per Protocol because all source documents are in front of me and not down the hall in someone else's office. I can review the data several times over the course of the trial, ensuring continual oversight."

CRIO vs. Electronic Medical Record system

	CRIO	*EMR*
Industry	Clinical research	Health care delivery
Purpose	Empower Investigators	Enable cost control and insurance and regulatory oversight
Physician hours per day	1.0	3.5
How time is spent	Management / oversight	Note-taking

Paying for itself many times over

Dr. Clark says the system pays for itself many times over.

First, it has freed up time to spend on recruiting. With CRIO, the coordinators are done with data collection when the visit is over. Because of that, they are re-allocating time towards recruiting. They call and screen previous research patients they have relationships with. This augments recruiting capacity and leverages the coordinators' knowledge and personal relationships. As a result, Charlottesville Medical Research recruits more patients per study.

Second, it has enabled his site to take on more studies. Before, Dr. Clark would sometimes turn away studies because he was at capacity. “With CRIO, I save so much time that sometimes at 3 pm I’m looking for things to do,” he said. “Now, I have capacity to take on more studies, and I don’t have to turn away something that could otherwise be financially rewarding.”

Third, it has strengthened his value proposition with sponsors. Since using CRIO, Dr. Clark reports that the CRAs have all been very positive about it. Most of the time, when they are issuing queries, Dr. Clark answers them in real-time. “There are times when the monitors leave and we literally have no follow-ups,” said Dr. Clark. “My monitors are telling me they want to work with our site in the future. That will give me an edge on site selection for the next study.”

Fourth – and most significantly for Dr. Clark – the system provides peace of mind. “In research, one error can cause a lot of bad consequences like an audit, loss of business, etc. With CRIO, I know I have a much lower chance of something like that happening. I can go to sleep at night knowing we have quality under control. This is my livelihood, so there is no price tag to that peace of mind.”

Conclusion

To physicians who may be struggling with the upfront investment required for CRIO, Dr. Clark offers this advice: “There is no ‘cost’ to this. You simply cannot do research effectively without CRIO. Though we were a very good site, having CRIO has made us a fantastic site on so many different levels, and that’s priceless.”

ABOUT THE PROFILE

Dr. James Clark completed his residency in Internal Medicine at the University of Virginia followed by a fellowship in Primary Care Sports Medicine at the Cleveland Clinic. He moved to Charlottesville in 1997 where he was in private practice and was the President of Medfit Wellness Center, a full-service wellness center. In 2002, Dr. Clark became an investigator for Charlottesville Medical Research Center and has completed over 100 clinical trials. In 2016 he assumed the role of Owner and Medical Director of the site.

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Case Study

MARCH 2018 | CASE STUDY

MITIGATING 50% OF DEVIATIONS: MEDEX HEALTHCARE RESEARCH

Medex Healthcare Research uses Clinical Research IO's workflow-based eSource tool to reduce protocol deviations, thus reducing exposure for their Principal Investigators. An auditor's review of the system confirmed that the system has safeguards against 50% of the most common audit findings.

From EDC to CRIO

Medex Healthcare Research, Inc. is a three-site, multi-therapeutic network with facilities in New York, St. Louis and Chicago. It was founded by Dr. James Greenwald, who serves as the network's CEO and the New York site's Principal Investigator.

In 2010, Dr. Greenwald decided to move to electronic source. After a review of market-based solutions, his team settled on a popular electronic data capture (EDC) system used by many sponsors.

Moving to electronic source allowed him to collaborate with, and oversee the work of, his investigators, as well as enhance data integrity and quality. Dr. Greenwald deployed the system on over 100 studies without any resistance from sponsors, or from the FDA, who audited one of the studies it was deployed on.

However, the EDC system was primarily designed as a data repository and was not optimized for real-time, site-based data collection. Designing studies was not easy, and Dr. Greenwald relied on outside programmers for configuration.

When Dr. Greenwald saw an early, pre-release version of the CRIO system, he immediately grasped its value. "The CRIO system is easier to navigate, and we could build the studies ourselves," he said.

What impressed him the most was that the system had a lot of workflows customized for research. These workflows provided further protections against protocol deviations.

For example, when a user schedules a subject for the next visit, the system takes them to a calendar where the days that are in window are color coded. It then can send text reminders ahead of the visit, not just for the appointment but for compliance-related matters such as fasting or medication changes.

"The overall goal of the CRIO software is to facilitate protocol and GCP compliance at every step of the process. That's important because it reduces protocol deviations, which, from a Principal Investigator perspective, are extremely high risk," he said.

While electronic systems inherently improve data transparency and accuracy, they cannot eliminate all protocol deviations, which can be caused by gaps in workflow outside of data capture. Once it occurs, a protocol deviation cannot be "undone", or easily corrected with a late entry.

"Rightly or wrongly, Principal Investigators are personally liable for the conduct of the study, even on matters that are reasonably handled by others," said Dr. Greenwald. "Any system that reduces protocol deviations provides protection for the Principal Investigator."

Dr. Greenwald signed up for the system shortly after its initial release.

An auditor's view

The Clinical Research IO team wanted to quantify the impact of its system on protocol deviations. To do this, it retained ClinPharm Network, a clinical research quality consulting firm, to perform an evaluation of the system.

The firm compiled a list of the most frequent audit findings from their past 47 audits. For each finding, CRIO and the firm reviewed whether the system had a safeguard that would help prevent the occurrence of the finding.

To qualify as a safeguard, the feature had to offer a level of protection that could not be matched in a paper-based environment. For example, the CRIO software system has an Informed Consent version tracking feature. When the user uploads a new version of the Informed Consent, the system will invoke the associated ICF procedure and prompt the user with the most current version at each subject's next visit. This feature provides a level of protection that cannot be replicated in a paper-based environment since it's impossible to "bring" a hard copy ICF version into the source visit with only one action (i.e., upload).

The study concluded that CRIO has a safeguard against 50% of the most common audit findings.

Sample audit findings with CRIO safeguards

Finding	CRIO safeguard(s)
Inclusion of subjects that do not meet eligibility criteria	Real-time alerts; forced completion of I/E criteria; auto-calculations
Screening log not kept up to date, especially with screen failures	Automated screening log
Lack of documentation on the consent process for each consent/re-consent	Separate ICF procedure tied to each consent; automated version tracking; ability to track multiple ICF's
Inconsistent documentation of weight from visit to visit	Use of "history" view which provides immediate recall of trendline data

Conclusion

Dr. Greenwald knew from experience and intuition that the CRIO system reduces protocol deviations. As a result, he was not surprised by the 50% figure the auditor identified. “So much of what happens at a site can be improved upon through automation,” he said. “In this day and age, every Principal Investigator should be giving strong consideration to how they can use technology to facilitate oversight of their studies. It’s important not just from an efficiency and convenience perspective, but from a basic risk management perspective.”

ABOUT THE PROFILE

Dr. Greenwald is CEO and Medical Director of Medex Healthcare Research, which he founded in 2000. Past positions include Medical Director of a network of medical testing sites and Assistant Professor at Washington University School of Medicine. He has an MD and PhD from Ohio State University, and completed his residency at Johns Hopkins.

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Case Study

APRIL 2018 | CASE STUDY

QUADRUPLING REVENUE FROM CRIO

Summit Clinical Research started as a single-coordinator practice. Through CRIO, it was able to increase revenue by nearly four-fold in only two years – with a lot more growth potential left.

Single coordinator practice at full capacity

Owned and operated by Barbara Wilson, Summit Clinical Research is an independent research organization that runs clinical trials for the Athens Gastroenterology Association in Athens, GA, accessing the practice's 50,000-person database. The site started in December, 2015. By March, 2017 Barbara was running at full capacity.

"As the sole person responsible for trials, I had to do everything. I was my own coordinator, my own data entry specialist, my own QC, my own Finance person," she said.

Due to the lack of support, Barbara's maximum visit processing capacity was 2 patients per day – and only on days not set aside for administrative work. "Overall, I was doing about 5 visits per week," she said.

Using CRIO to bootstrap the business

While looking for more efficient ways to run her operation, Barbara received a call from a representative of Clinical Research IO. "The idea seemed very interesting," said Barbara, so she agreed to a product demonstration.

When she saw the demo, she knew immediately the product was for her. "I loved how it automated everything," said Barbara, "I could see its potential right away." She signed a contract that day, and within a week she was up and running.

"The customer support team was fantastic," she said. "They were very professional in the way they conducted their training and supported me throughout the implementation process. Plus, the system is so easy to use it didn't take a lot for me to figure out how to use it."

Barbara started seeing immediate benefits. She describes some of the ways the system saves her time:

- It's easier and faster to build study templates because of the system's built-in, customizable library of procedure templates. When she modifies a procedure, it ripples all the way across the study.
- It eliminates the need to create paper binders, track Informed Consent versions, fill in subject headers, etc.

- It improves her own accuracy and ensures she completes all data fields. The findings from her monitor letters went down by 60%.
- She can work from home, accessing the system anytime she needs to.

Barbara's maximum visit capacity per day doubled, from 2 to 4 patients. She soon found herself able to process 10 visits per week instead of 5.

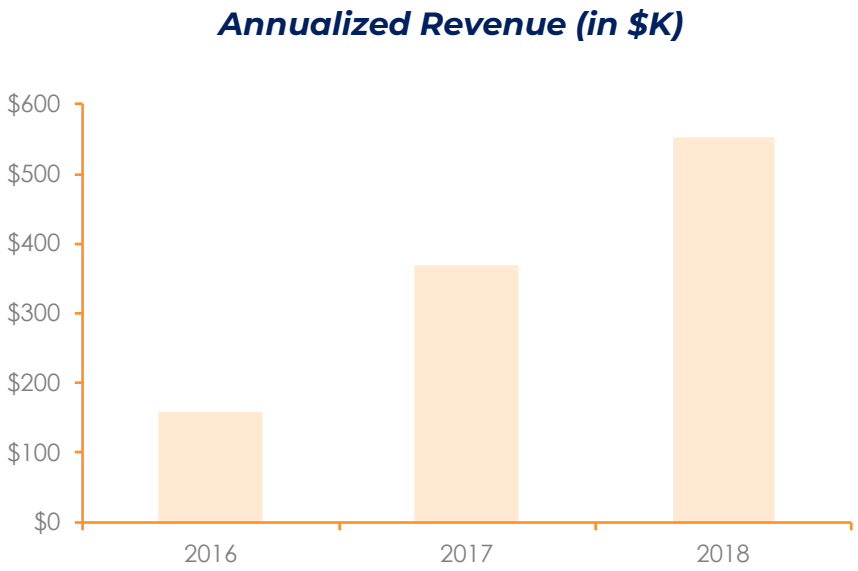
Adding a coordinator

The additional visit volume translated directly into additional revenue. When she forecast the revenue impact from this added visit volume, Barbara realized she was able to hire a new coordinator – only two months after starting CRIO.

Even here, CRIO helped. "Without CRIO, I would have stuck to an experienced coordinator, and they are hard to find," said Barbara. "But the system automates everything, so it makes it a lot easier to bring someone new on and get them up and running."

She hired a recent college graduate, and together the two-person team now processes 15 visits per week.

This vast increase of visit volume has had a direct impact on revenue. From 2016 through 2018, Barbara projects her revenue will increase from about $150K in 2016 to about $550K in 2018.



CRAs have embraced the change

Barbara reports that not only is her business more profitable and stable, but her pipeline has improved because the monitors are impressed with the technology and the quality of the work that results. "Most of the monitors have

really embraced the technology in a positive way," she said. "In fact, one was actually familiar with it from another site he had worked with. It's gratifying to see how the system is spreading like that."

Barbara noticed that the monitors didn't need to spend as much time on-site. "They might leave in the middle of the afternoon instead of staying the full day," she said. She attributes that to the reduced workload from higher quality and the ability to work the night before from their hotel rooms.

As a high enroller, Summit Clinical Research went through two sponsor audits – with no findings related to the system. In one case, the sponsor was so impressed with the technology that when a Vice President was in the area, he visited her site just to look at the software.

Barbara says that the technology has even improved civility. "One monitor I had could sometimes be really nasty. Because the 'stickies' are electronic, however, her queries in CRIO are always very professional," she said.

Conclusion

Barbara is planning to expand her services to encompass more neighboring physicians. CRIO will make this site expansion much easier to do, since she'll be able to monitor work remotely. Barbara summarizes her experience with CRIO this way: "CRIO has literally transformed my site. Before, I was a single coordinator working all the time to keep up with the demands of research. Now, I'm able to carry a much greater load of business, and I have a platform for expansion."

ABOUT THE PROFILE

Barbara is the owner of Summit Clinical Research in Athens, GA. Barbara has over 10 years of experience as a Clinical Research Coordinator, Clinical Research Associate, and as a Site Manager. She has a MS in Clinical Research and Management from Drexel College of Medicine and a BS in Public Health from South University. She was a third-class petty officer in the US Navy and has worked as a phlebotomist and lab technician.

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Case Study

DECEMBER 2018 | CASE STUDY

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
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 cyclicality.

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.

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Case Study

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MARCH 2018 | CASE STUDY

70% OF STICKIES ELIMINATED: QUALITY CLINICAL RESEARCH

After adopting the CRIO eSource system, Quality Clinical Research reduced their count of internal and external data quality findings by over 70%, resulting in significant efficiencies, more satisfied staff and CRA's, greater flexibility to recruit and expand, and a stronger business development pipeline.

Quality at Quality

Quality Clinical Research is an Omaha, NE based research site network with six Principal Investigators who recruit from the community. The site works with the individual PI practices for recruitment, and has five coordinators, four additional staff members, and two executives.

Tricia Harrison, Owner and President of Quality Clinical Research, had developed a robust internal QC process. After a coordinator completes a visit, she or he leaves the binder on the Principal Investigator's desk. The PI reviews and signs off, then hands the binder to Data Entry for EDC input, who then hands off to Quality Control for source data verification.

This process provided controls over data quality but was inefficient and often highly reactive. When a problem is discovered, for instance, the person reviewing it has to affix a sticky to the binder and pass it back to the Coordinator for troubleshooting. As a result, the cycle could take a long time, with multiple loopbacks.

"The basic problem with this approach," said Tricia, "is that we're correcting a lot of mistakes after the fact, instead of catching them upfront. We needed to find a way to prevent the errors from happening in the first place."

Workflow

When Tricia learned of the Clinical Research IO eSource system, her first thought was, "The sponsor should pay for it." But after one too many mishaps, she re-evaluated her initial reaction. When she and one of her senior coordinators saw the CRIO system at a conference, they decided to move forward.

CRIO's impact on operations

The system had an almost immediate impact on quality. "At first, we had to get used to collecting data in a different way," said Nicole Cureton, one of the senior coordinators. "But then we realized that the system was making our jobs so much easier. We were being more thorough with our visits and finishing up our source by the time the patient left."

Nicole articulates a lot of ways the system reduces errors and saves time during the visit:

- All signatures and dates for attribution are automated through the audit trail.
- Blank data fields are flagged for completion by the coordinator.
- Formulas are auto-calculated and current time-stamps are added with one click.
- Medication spellings are standardized.
- Procedures can be completed simultaneously by different people; for example, the Investigator could be performing the physical while the coordinator is completing IP compliance.

"I leave every night with a clean desk," said Nicole. "I no longer have nightmares of wondering if I had finished source or needing to double check it."

"Our monitors have really embraced this," continued Nicole, "because they can perform remote monitoring much more easily, and when they leave a comment, it's electronic so they can always see it. We used to get into disputes sometimes because they would say they left a sticky, but we didn't see it."

The same basic review process (coordinator → investigator → data entry → QC) still happens, but now it's done electronically, with no passing of binders. Using the system's Commenting feature, staff members communicate with each other without having to affix stickies. Because there is no longer a linear path for the binders – i.e., forward or backward – all stakeholders can work on their tasks iteratively and in parallel, meaning the entire cycle is compressed.

Quantifying impact

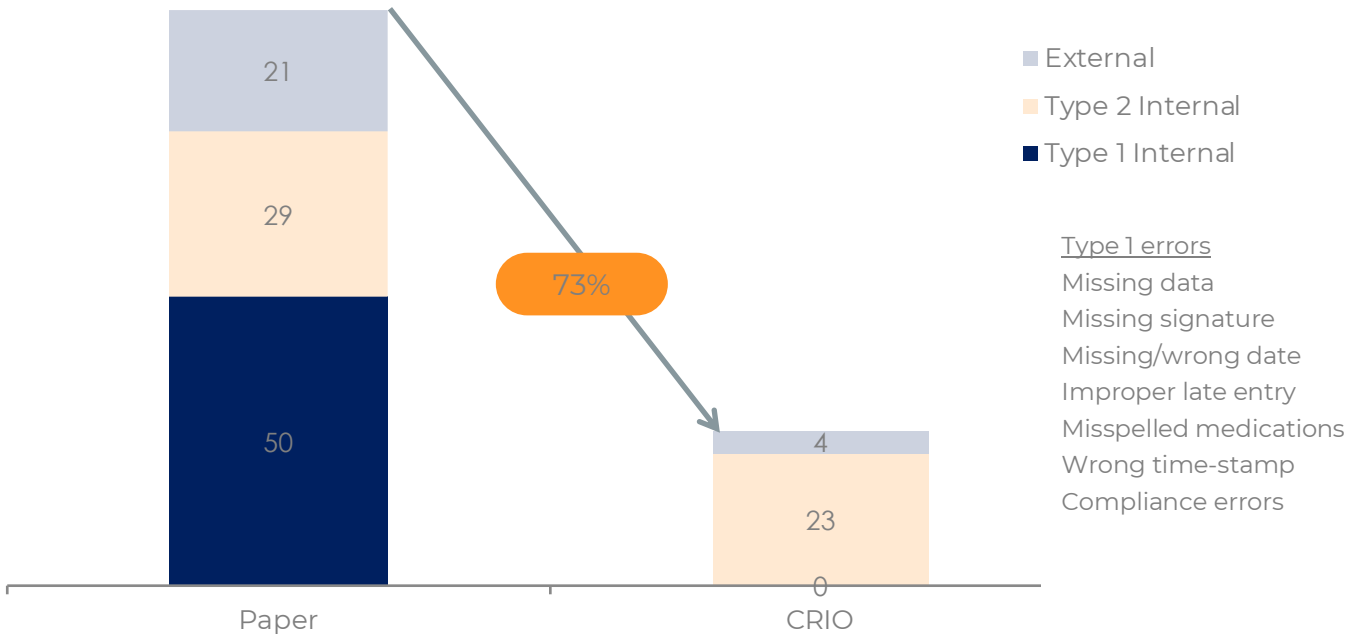
Tricia recently measured the impact CRIO has had in improving data quality. She compared the number of "stickies" on a set of studies conducted on paper vs. the number of comments (electronic stickies) on a set of studies conducted in CRIO. The pre- and post-CRIO studies were comparable in length and complexity.

She found an overall reduction of over 70% in stickies. This was in large part due to the significant decrease in errors associated with missing data fields, time-stamps, calculations, spelling mistakes and other easily automated items. These types of errors, which can be called "Type 1" errors, were eliminated *entirely*.

Other stickies are more judgment based, such as an inconsistency in observations across procedures, or the lack of a progress note to document a deviation. These errors, which can be called "Type 2" errors, still went down by 20% post-CRIO. Tricia attributes this decline to the fact that the PI's find it easier to review source online and are thus able to perform more thorough annotation and review before the electronic binders get reviewed by internal QC staff.

The impact didn't just end there. Tricia found that the number of *CRA* findings went down by80%, for many of the same reasons as outlined above. Her site has earned the praise of CRA's, many of whom have come to view the CRIO system very positively.

Decline in number of quality findings (indexed to 100)



Between the internal and external findings, Quality Clinical Research experienced a 73% decline in overall "stickies" per visit. This means substantially less re-work and clean-up, freeing up resources and allowing coordinators to focus more time on value-added activities such as patient recruitment or retention.

Translating to business advantage

Seneca Harrison, the site's CEO, puts CRIO's impact in business terms.

"First, we have been able to grow our operations with one less person than we would normally have had," he said. "Between the employee savings and the paper supply cost avoided, we literally come out ahead on a P&L basis. CRIO is not a cost item but a savings generator."

"Second, we've improved our standing with CRA's. We routinely get feedback from our monitors about how good our data is, and that increases our chances of winning future studies. It strengthens our pipeline."

"Third, this system has given us the flexibility to expand. We can now take on more PI's and indications easily, allowing us to diversify and grow our top-line."

Conclusion

Tricia summarizes her experience with CRIO this way: "I totally understand why someone would be hesitant to make the jump. I was very nervous at the outset, especially since I don't consider myself computer savvy, but in hindsight, I can't fully express how much the system has improved our operations and business. I don't think anyone can run a multi-specialty, growing site operation effectively without eSource, especially a system of the caliber of CRIO."

ABOUT THE PROFILE

As the owner and president of Quality Clinical Research since 2004, Tricia Harrison is both diligent in her practice and committed to the profession. Tricia has been in the medical field for nearly twenty years, attending both Metropolitan Community College and Creighton University in Omaha Nebraska. She was named "Woman of the Year" by the National Association of Professional Women in 2012 and is an active member of The Association of Clinical Research Professionals and the Society of Clinical Research Sites. She spends her free time volunteering with Habitat for Humanity, donating to several community organizations, mentoring youth girls, and spending time with her husband and their two children.

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Case Study

MARCH 2018 | CASE STUDY

32% TIME SAVINGS: PALM BEACH CLINICAL RESEARCH

In a carefully controlled time study, Palm Beach Research determined that it saves a third of coordinator time through the CRIO system, leading to increased ability to screen patients and manage peak recruiting times.

Adopting eSource: Pilot study

Palm Beach Research Center, in South Florida, is a freestanding site with approximately 25 employees, 2 lead investigators, and 10 study coordinators. It conducts 20-30 studies pear year in family practice, pain management, and internal medicine.

Because the site is often a high enroller, it has very busy periods, which used to lead to quality issues and recruiting bottlenecks. As a result, David Scott, the site's CEO, had been looking for an eSource solution as a way to enhance efficiency.

A couple senior managers met CRIO at a conference. They were immediately impressed with how easy to use and intuitive the system was. "These were long-time veterans who have seen a lot of things, so they have a healthy degree of skepticism," said David. "So when they came back gushing about the system, I knew I had to take it seriously." After more due diligence, David decided to pilot it on a phase 3 migraine trial in the fall of 2016.

To measure efficiency gains, David implemented time tracking on the site's pilot study, comparing the results to an earlier, paper-based study with very similar procedures. David was able to measure visit time with precision because his processes capture check-in and check-out times for patients. For other tasks, such as EDC entry and Quality Assurance, David relied on staff interviews and estimates.

Impact

Based on data from 40 visits, the site experienced 32% overall time savings on visit completion, EDC entry and QC, from 194 to 124 minutes per visit in total. The following are staff documented time savings by function.

1. **Visit conduct (baseline visit) – 29% reduction**
   Paper: 104 minutes
   CRIO: 74 minutes

The actual length of the visit went down due to a variety of factors, including:

- No need to print and assemble binders

- Easier to navigate the questions
- Automated calculations (eg, BMI, inches to cm, age)
- No need to fill in subject headers or attribution information

2. **EDC entry per visit – 17% reduction**
   Paper: 30 minutes
   CRIO: 25 minutes

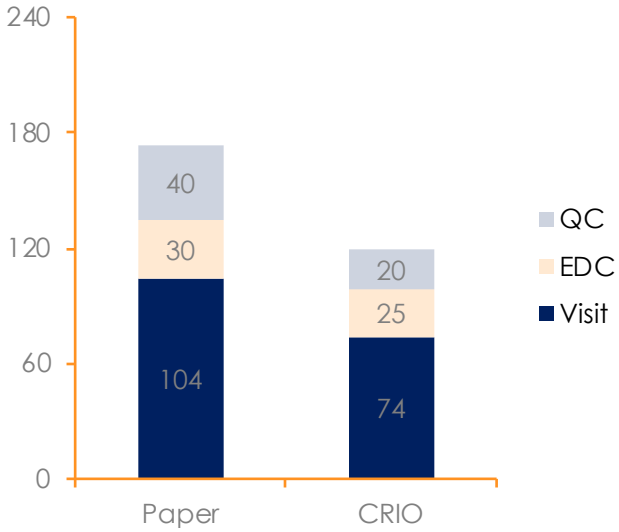
To facilitate EDC entry, the site employed dual monitors for their data entry personnel. The data entry specialist scrolls down the visit on one screen and transcribes required values into the EDC system on the other. The staff finds it easier and faster to enter data this way because they do not have to retrieve paper binders, flip through pages, or decipher illegible handwriting. They also do not encounter nearly as many data gaps that require subsequent clarification.

3. **QC and corrections per visit – 50% reduction**
   Paper: 40 minutes
   CRIO: 20 minutes

The QC staff find it easier to use the system because they no longer have to handle paper binders, decipher handwriting, or affix post-it notes. Instead, QC staff simply scrolls down the page and uses a point-and-click method to leave virtual "stickies". The system makes it easier to identify missing data fields, as those are highlighted in red.

The site realized major time savings from the reduction in the number of "stickies" by an estimated 80%. QC staff report that fields are rarely left blank or have obviously mistyped values due to the multiple controls the system has built in. Fewer data issues mean significant "downstream" time savings for both the QC reviewer and the original coordinator.

Average minutes per Screening Visit, all activities



CRIO vs. paper-based study

Conclusion

Palm Beach Research Center was one of the first sites to utilize the system. Since then, it has gone full eSource and incorporated CRIO's recruiting and finance modules. The site today has much greater capacity to process patients, and the two QC members are now spending most of their time on non-QC activities such as business development or recruiting support.

David summarizes his experience with CRIO this way: "In the exam room, the system is like an app, not a cumbersome program. It has the look and feel of efficiency, which is what you want. CRIO's system helps sites become much more productive, and that allows them to focus on more value-add activities."

ABOUT THE PROFILE

David Scott is the owner and manager of Palm Beach Research. He has been working full time in clinical research since 1996. He has worked in every segment of the industry, and strives to be a part of high quality, progressive research.

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Case Study

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WORKING OUT OF OFFICE OVER HALF THE TIME: INJURY CARE RESEARCH

After implementing CRIO's eSource and CTMS systems, Injury Care Research became a truly remote work-enabled site, where coordinators and investigators can be maximally productive without always being in the office. A time study revealed that 60% of total employee time is spent outside the core facility.

Remote work-enabled site

Injury Care Research is a site in Boise, ID that does pain and family medicine research. Owned and operated by Jill Heinz and Dr. Richard Radnovich, the site draws on Dr. Radnovich's patient population at his affiliated private practice.

For years, Jill has dreamed of a technology solution that would enable true site-wide remote collaboration. She used Dropbox for common site workflows, and implemented a CTMS and eREG solution, but could not find a satisfactory eSource solution – until she came across Clinical Research IO.

"I really liked the system. It was built exactly the way I would have built it," said Jill. After she moved forward with the system, Injury Care became a fully remote work-enabled site.

Recently, Jill and her staff did a time analysis and determined that only 39% of the work is now being done in the core office – which would not be possible without the technology backbone she has in place.

Off-site procedures

Injury Care frequently does studies that require sending patients to another facility for specialized procedures, where data would need to be collected contemporaneously. Historically, the site's coordinators would visit the facility with paper templates in hand.

"We had to print out source binders and bring them with us in cars," said Bridget, one of the coordinators. This was extremely inefficient and a bit frightening since the source binders could get lost. "One time I forgot to bring the right template, so at the site I had to call up the template on my laptop. But there was no printer access, so I literally had to record the data on sticky notes while reading from a laptop."

With CRIO, staff can visit without printing or carrying paper templates. “Now, I can just bring a tablet over and call up the procedure,” said Bridget.

Better yet, the CRIO system could enable the facility’s local technicians to complete source using CRIO. “With CRIO, I can entrust the on-site staff to do source since it makes it super easy to complete. If there’s a problem or a question, I could look up the source from home and know what’s going on,” said Jill. She is in process of implementing this new workflow model at one of her upcoming studies.

% of Time Spent in Different Locations

	Hrs/Wk	*Core*	*Satellite*	*Travel*	*Home*
Principal Investigator	15	50%	25%	10%	15%
Manager	50	30%	20%	20%	30%
Coordinator 1	30	30%	20%	0%	50%
Coordinator 2	40	60%	20%	0%	20%
Billing	10	10%	0%	0%	90%
Weighted Average		**39%**	19%	8%	34%

Work from travel/home

As the Owner and Director of her site, Jill spends a considerable amount of her time doing business development and community affairs. Dr. Radnovich also has other commitments, including a clinical instruction position at a university and an advisory role at another medical company. Both travel for investigator meetings and conferences.

It isn’t just the firm’s principals that need remote access; it’s the entire staff.

Injury Care Research has a flex model where employees have discretion to set their own schedules. The clinic’s official hours are 9 to 5, and as long as those hours are maintained, and employees coordinate their time off in

advance, employees may craft unique schedules, including work from home. Every 2 weeks, staff submits their timesheets, describing their work hours and what they did.

"A lot of sites would not want to do this," said Jill, "but here's the thing: I know if an employee's output matches their input. What I want to do is hire people with a high degree of initiative, who can operate independently. This gives them flexibility they wouldn't have at other companies and really helps with employee satisfaction and low turnover."

All three of the site's coordinators take advantage of the flex policy. Two are parents or caretakers of young children, and one is a Millennial pursuing school part-time. Several other staff members are part-time contractors, some of whom work almost entirely off-site – for example, the invoicing person and the accountant.

Why remote access is more productive

Remote access gives Injury Care much greater flexibility to respond rapidly to tasks and inquiries. "In research, a lot of things pop up, and some of them can be urgent," said Jill. For instance, a patient may call after-hours to report an AE; a sponsor may want an urgent review of a document; or a deadline for invoice submission may be approaching.

With remote technology, employees can complete tasks in the moment, rather than batching them for completion the next time they're in the office.

Jill gives a perfect example. "The other day our accountant had a question for me about a procedure for an invoice we needed to send out. Without CRIO, I would have had to make a note of the question, then resolve it the next time I was in the office. But as soon as I walk in, I get bombarded with requests and may not get to it. One day could become one week, and one week two weeks, and it doesn't get done. With CRIO, we logged in together and figured out what we needed to do. She got the invoice out right then and there."

Site expansion

Recently, the site decided to do research at a new location that would allow them to tap into a different patient population. Now, coordinators won't have to carry binders back and forth, or work on only one site's studies at a time. In the first few years of the site, this flexibility will be especially important, since it will take time for the revenue to scale to the point where it supports dedicated on-site staff.

"With CRIO, we literally can do research anywhere in the Boise market," said Jill. The technology opens up many new opportunities that she is just now starting to explore.

Conclusion

"The backbone of a good research operation is its team," said Jill. "Employees are becoming more tech savvy and desiring of flexible work arrangements, and CRIO's technology allows me to build and retain the strongest performers. By enabling remote work, it lays the foundation for long-term growth."

ABOUT THE PROFILE

Jill has worked in the research industry for over 17 years and has been involved with numerous clinical research studies, ranging from those funded by the National Cancer Institute, to Investigator Initiated, to Private Industry. She is a Certified Clinical Research Coordinator and Certified Research Contracts Professional. She has a bachelor's degree in Biology and Chemistry and obtained her Master of Health Science from Boise State University. Her favorite task is still meeting with research subjects and overseeing the coordination of clinical trials.