MORE EREGULATORY EXPERIENCES:
EMBRACING A PAPERLESS PROCESS

A Complion Feature Article
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Embracing a Paperless Process
A Complion Feature Article

The point at which an organization arrives at the decision to transition from a paper-based research study management process to an electronic document management solution is the end of one journey and the beginning of another. Dustin Caldwell and Neal Surasky have been down that sometimes rocky path and completed the transition. And like seasoned travelers, Dustin and Neal have gained experience along the way that they are willing to share. This article presents their unique perspectives on that transition, from the early motivation, to challenges faced in working toward completion.

Dustin is the director of operations for OptiMed Research, a clinical research organization based in Columbus, Ohio. Founded in 1999, OptiMed is focused primarily on allergies and immunology.

Neal is the data manager and quality assurance coordinator for the Chesapeake Research Group near Baltimore, Maryland. CRG is focused on post-bunionectomy analgesic trials, and has recently expanded to include post-abdominoplasty studies.

Rationale: Why Make the Change?

An site’s decision to migrate to a paperless system is typically driven by the realization that relying on a paper-based, manual system in today’s research and regulatory environment is a bit like relying on a horse and buggy for your morning commute.

Dustin Caldwell is reluctant to refer to paper-based systems in clinical research as “antiquated.” But if the shoe fits...

His organization, OptiMed Research, recognized the need to update all aspects of its operation. “Moving toward a paperless system in regulatory was a big draw for us,” Dustin says. “We have an entire regulatory room that is nothing but binders. We have anywhere from 25 to 30 trials ongoing at a time.” Those trials include cardiac outcome studies that can continue for up to eight years. “You can imagine, with correspondence and everything, how cumbersome that all gets.”

The ever-growing mountain of paper made it clear that something had to change. “A more streamlined process really appealed to us,” Dustin says, “and that was one of the biggest early draws for us,” for the Complion platform.

“The accumulation of tons and tons of papers, big binders that we have to store, essentially indefinitely, was really creating a lot of trouble.”
Neal Surasky and Chesapeake Research Group were living under the shadow of their own growing mountain of paper. Neal says. “We saw electronic storage and electronic document handling as a great solution to what we were experiencing.”

Even the smallest change in organizational processes and systems can unleash significant resistance among stakeholders. Comfort with old systems, however inefficient, can cloud judgment and blind them to the need for change.

In Dustin’s case, he confesses to being on the front line of that resistance, rejecting Complion’s initial contact on the basis of assumptions regarding stakeholder objections. “I said no because I was afraid that the CRAs and the sponsors wouldn’t accept this,” Dustin admits. But Complion persisted, presenting information on how the system worked, and on its regulatory compliance. Dustin’s resistance evaporated, the process aided by what he saw happening elsewhere in the industry.

“At about the same time, I’d been introduced to another group that was doing work primarily for sponsors and CROs,” Dustin explains. “They were trying to get CROs to adopt an eReg system that they would force the sites to use. I saw that it was happening in places in the industry. I just hadn’t seen it happening this way.” The realization that the industry had caught up to eRegulatory cleared the way for Dustin and his OptiMed Research colleagues to make the transition.
“Everything really fell into place once we realized that this was something that the industry would allow us to do,” Dustin says.

Of course, every situation is unique. Neal and his colleagues at Chesapeake Research Group weren’t concerned about CRA or sponsor reactions. “We just thought they would accept it because we were doing it,” Neal explains. “As we entered into further discussions, we realized very early on that everything they were doing was 21 CFR 11 compliant and that we really had nothing to worry about in terms of regulatory compliance.”

The bigger challenge for Chesapeake was staff members. Given varying degrees of technical savvy among PIs, “we were concerned about how that would work and about integrating new technology into their everyday activities,” Neal explains. Some of those concerns were well-founded. “Early on we had to handhold one of our PIs through it.”

But any initial resistance or discomfort gave way to acceptance and appreciation. The PIs and others have embraced the system. “The challenges we thought we might encounter never panned out,” says Neal.

21 CFR Part 11 Compliance: Misconceptions and Misunderstandings

Incorrect assumptions that form the basis for initial resistance to implementing an electronic solution can be caused, in part, by misconceptions and general misunderstanding among certain sites regarding 21 CFR Part 11 regulations.
Neal believes that, among sites, there is a correlation between understanding of 21 CFR compliance and experience with electronic signatures and electronic document management. “I don’t think that people who are not handling electronic documents, regulatory or otherwise, really have that good of a grasp,” of 21 CFR Part 11, Neal says. “But I think that the system really helps to alleviate all of that. Everything it does is 21 CFR 11 compliant,” he says. “The system is designed so that regardless of staff understanding, they’re being compliant anyway. It has to be that way.”

Related: [Ensuring Compliance with Part 11: A Site’s Perspective](#)

Dustin’s experience is similar to Neal’s. But Dustin observes that understanding of 21 CFR Part 11 correlates more to responsibilities within a site. “Our operations are very compartmentalized,” Dustin says. “We have one person that is just our regulatory and compliance officer. We have another person who does operations,” and related activities.

When first approached by Complion, Dustin didn’t handle regulatory. “So I had this vague notion of how compliance worked as far as what the industry would and would not accept. I think that was the stumbling block for us,” Dustin admits. “But once you go through the training and you’re exposed to the software and the system and the way it works, it all becomes very intuitive, and it’s something that you just accept at face value. It’s all part of living compliant.”

**System Validation in Clinical Research: What, Why, and Who is Responsible?**

“I’ve always been a big proponent of the idea that no one person knows everything about everything,” says Neal. “We’re supposed to be able to surround ourselves with the people and the systems that know the things that we don’t. That being said, having been working in Complion’s platform for a while, I know what it does, I know what it can do, and I know how it does it for the most part. But the people around me generally don’t.”

That unfamiliarity can lead to questions about whether the system is doing what it is supposed to do. System validation is the process by which such questions are resolved.


“Validation is a way for us to be able to show whomever, whether it’s somebody within our company, somebody who is…"
monitoring for a CRO, or even sponsor, that our claims to Part 11 compliance, and our claims that the system is able to do this or to do that are valid,” says Neal. Validation offers proof that the system “can actually do what we say it’s going to do.”

Validation verifies and documents that the system does what it claims to do. “It’s extensive,” observes Neal. “And it’s really good to see that as we go through and evaluate each element of the system and document that it’s accurate and true to what it claims to be able to do, that we have an incredible system at our fingertips.”

Dustin’s experience with validation parallels Neal’s. “This is not a ‘take our word for it, it’s all good’ kind of a system. It allows you to empirically demonstrate that the system does what it says it’s going to do, that it is compliant. And you have documentation demonstrating that. If your monitors or others have questions, here’s the proof,” Dustin says.

Dustin notes an added benefit to the validation process. “Going through some of these system checks and updates and validations gives the people that are working with the system at the site level an opportunity to really learn it,” he says. “When you go back through and you do these system updates, you get a new look at the system each time. You get these walkthroughs that explain how you’re doing things and why you’re doing things. So not only does it provide an opportunity to demonstrate it to the sponsor, the CRO, or the monitor that the system is compliant, but it helps you to understand why it’s compliant and gives you peace of mind and understanding that what you’re doing is on the up and up.”

Leveraging Web-based Tools for Multi-Site and Remote Teams

In adopting a web-based, paperless system, organizations free themselves from the physical limitations imposed by paper. For Dustin and OptiMed Research, that meant that the organization was now free to avail itself of resources distributed across multiple locations.

“This was actually the real draw for us,” Dustin says. “We have a very compartmentalized operation with very specific departments.” These are spread across a large primary location and several smaller sites. Implementing a regulatory and document system made it possible to connect those various departments, regardless of their physical location. “We can keep our operations small and manageable and then have everything centralized to that main location.”

“In effect, it provided a gestalt that kept everything together without having to reinvent the wheel at every additional site.”
Connecting various locations in this manner “gave us was the opportunity to leverage some of our resources at our primary site location and centralize some of those practices, such as recruitment and eRegulatory, without having to increase our payroll costs or put more strain on someone like a coordinator.” Dustin explains.

With a paperless system, coordinators outside of OptiMed’s central location don’t do any regulatory work. “They’re hired, they coordinate, and all they have to worry about is doing the study itself. All the regulatory is taken care of back at our central location, along with recruitment,” Dustin says. “This allowed us to really leverage what we already had in place and grow and keep continuity in our operations.”

The new system also allows OptiMed to maintain a streamlined operation by making it easier to identify problem areas across the various sites. As Dustin explains, “it’s allowed us to help them by centralizing a lot of the practices that they may be struggling with back to our primary site. The sites can then focus on operations directly on the ground at the site level.”

Dustin identifies those factors as critical in OptiMed’s mission to streamline its multi-site operation. “In a lot of ways it allowed us to continue to work the way that we wanted to work
without having to adopt new practices,” he says. “In effect, it provided a gestalt that kept everything together without having to reinvent the wheel at every additional site.”

Neal and Chesapeake Research Group had their own unique situation. Rather than remote sites, CRG relies on a network of remote individuals to handle various responsibilities. “Our site manager is off site,” Neal explains. “One of our PIs is actually off site, and I can’t tell you the number of times when, prior to transferring to the eReg system, certain signatures would have to wait. This doctor was out of town, this doctor was on vacation. In Complion, “we can invite all these people to be part of this, and it doesn’t matter where they are.”

A web-based system eliminates the barriers of both distance and time. “If I have a PI that’s out or on vacation and we have, for example, an SAE report that needs to be signed and sent, I can just text him and say, ‘hey, check the website,’” Neal explains.

“Even more impressive is the correspondence feature that allows you to upload a document that needs to be signed and send it directly to the person whose signature is needed,” Neal says. “It has made waiting for signatures essentially obsolete. As long as they’re able to access their phone and click a link, they can do what they need to do.”

Dustin echoes Neal’s assessment of Complion’s eSignatures capability as essential. “It’s a real game changer in a lot of ways,” he says. “It makes things so much easier when you don’t have to transport documents back and forth and try and catch the physician when he’s in the office.” That helps to shrink turnaround time, “which obviously makes the sponsors much happier when they’re not sitting around waiting for signatures.”

**Beyond Regulatory: Document Management**
While the platform provides secure storage of eRegulatory documents, it also provides the means to manage all clinical trial documents, from study setup through long-term archiving. Neal and Dustin and their respective organizations found their own unique paths to implementing those features. “I’m the kind of guy who, once we start doing something, I want to jump in all the way,” Neal admits. “I want to access every feature. I want to use everything that we can possibly use.” But as one person in a large organization, Neal had to rein in his enthusiasm just a bit. For instance, CRG’s adoption of eSignatures was a more gradual process. “In fact, we’re still not using the Complion platform for delegation of authority. I’m still in the process of trying to convince some people that’s the way to go.”

In contrast, CRG’s implementation of the storage aspect happened quickly. “The correspondence is key,” Neal says. “If you have a document that needs to be signed, signatures can actually take a number of different forms.” For example, putting a signature on a 1572 form indicates approval of that 1572.

“We have a practice in which every follow-up letter from a monitor is reviewed and signed by the PI for that particular trial,” Neal says. “The platform allows for an eSignature to mean just that the PI reviewed the document.” That feature has been particularly helpful, according to Neal.

“Uploading those documents and sending them through correspondence was really, really helpful,” Neal explains, “However, one of my favorite features is the add-on for Microsoft Outlook. With this add-on, every single email can be sent from my Outlook into the system and directly into the specific binder for that particular trial.”

That feature has eliminated the need for Neal to manually review and organize countless paper documents. “That all goes away with this system,” he explains. “It’s just uploaded immediately, and it’s so easy.”

The feature is particularly valuable in situations involving correspondence that applies to more than one study. Neal offers this example: “If you have a sponsor for which you are running two different studies at the same time and one email refers to both of them, it’s so easy to just send it to both binders rather than make copies and file them in two different regulatory binders.”
The days of needing two or three four-inch binders to hold correspondence for a single trial are gone. "Complion makes it all go so, so easy," Neal says. He describes a recent situation in which a monitor for a study that had just closed asked for all of the correspondence for that trial so she could upload it to her sponsor’s master file. “In about five minutes, rather than having three, four binders worth of stuff, all the correspondence for the entire study from the time it began to the time it closed was saved in a single 150 megabyte file that I could just put up on an FTP site and send to her. It was amazing.”

While CRG initially thought the electronic system might cause difficulties with audits, those difficulties never materialized, thanks to the system’s ability to download all trial information into a single file. “I really appreciate the system for that,” Neal says.

With regard to storage and document management, Dustin’s Complion experience at OptiMed Research once again parallels what Neal has described. “When we first adopted this system, we mostly saw it as storage,” Dustin says. “But we moved beyond that pretty quickly once we realized how powerful the system was and what it could do.”

OptiMed had run into similar problems with correspondence, particularly in ensuring that monitors had access. “We just went through an audit a couple months ago,” Dustin explains, “and correspondence was one of the biggest things that she looked at. She said, ‘I just want to see the narrative, I want to understand the narrative.’ To be able to effectively transport that narrative and put it directly into the system without having to compile and reconfigure a conversation after the fact is extremely helpful.”

**New System, New Process: Embracing Change**

Change is rarely easy, particularly on an organizational level. But then, every organization is unique. For Dustin and Neal and their respective organizations, adopting a paperless process presented each with unique challenges -- and opportunities.

Complion was introduced at OptiMed Research in the context of that organization’s transition to a multi-site operation. “Originally, the idea was that we would take the model that we had already created and the systems and operating procedures already in place and recreate them at each additional site,” Dustin explains. “Of course, regardless of any kind of formula that you may have, when you try to repeat or duplicate a process elsewhere, you’re always going to run into issues, especially when you don’t have

**“This actually allowed us to grow without having to change at all.”**
necessarily the ability to directly oversee or manage the process, which is one of the things that can become troublesome with multi-site or even remote management."

For OptiMed, recreating existing processes and procedures at multiple sites would require either hiring people to fill the necessary roles, or training existing staff at each site to take on new roles. “We didn’t want to hire new regulatory people,” Dustin explains. “Were we going to train our coordinators to handle the regulatory as well? What aspects would they be responsible for?”

The introduction of the new system revealed another, far more efficient solution. “It allowed us to just say no, everything will stay exactly the same,” Dustin says. Rather than duplicating the main site’s resources and processes at each remote location, each location would continue to perform its own unique role. But now, thanks to Complion, the main site and remote locations would be linked together as a distributed, coordinated system. Processes related to regulatory were centralized at the main site, while other processes were handled at the other locations, as determined by the resources available at each. All locations were then connected through Complion, with each location’s unique resources available across the distributed organization. “This actually allowed us to grow without having to change at all,” says Dustin. “That was a big boon for us.”
The system delivered in a similar fashion for Neal and CRG. Even with shifts in staffing, “It has allowed us to continue working with a minimum of hiccups,” Neal says. He and the site manager continues to focus on regulatory, and no one has had to take on additional responsibilities. “We’re moving forward.”

Neal notes that, despite the differences between CRG and OptiMed, the respective experiences are similar. The system “does what it says it’s going to do,” Neal says. “It’s made things easier for both of us.”

**Gaining Staff and Sponsor Acceptance**

While CRG and OptiMed are now enjoying significant benefits from the transition to paperless, that journey was not without hurdles and stumbles. “It wasn’t all wine and roses at first,” says Dustin. The problem was personnel rather than product.

“We had some pushback,” Dustin admits, “and it took a little bit of time to get staff to understand that this was a superior way of doing things, and that this is the future.” But once people had a chance to work with the new system, “those gripes quickly disappeared.”

Those growing pains were nothing new. “We had the same problems when we moved to VoIP phones,” Dustin explains. “We had the same problem when we moved to new database management systems. We had the same problem when we moved. Anytime we make any kind of change in the company, there are voices of dissent.”

However, those voices were no louder in the transition. “I think that’s just the kind of thing that you run into at almost any business when you have people who are established in their processes and in their way of doing things,” Dustin says. “But now everything is cruising along nicely.”

While things are now cruising along just as nicely for Neal and CRG, Neal identifies three specific challenges through which the organization had to navigate.

The first was the decision that had to be made about whether to include in-process trials in the transition to the new system. “One study was close enough to the end that we decided, okay, we’ll just keep it the way it is,” Neal reports. Two other in-process studies were included in the transition. “I’m not sure that was the best way to go,” Neal admits, “because we ended up with partial paper binders and a partial eRegulatory binder. Given a do-over, Neal says he probably would not have included those trials. “Live and learn,” he says.
The second challenge CRG faced grew out of the failure to anticipate external push-back. “We had a sponsor who had set up their trial to use electronic signatures, but it was their electronic signatures,” using a third-party solution, Neal explains.

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On the basis of those electronic signatures, the sponsor initially refused to accept CRG’s decision to go paperless. But CRG held fast. “Perhaps it was a little cocky,” Neal admits, “but we stood up for what we knew was a good system, and we said to ourselves, ‘well, this sponsor will bend to this and they’ll let us do it.’”

But that didn’t play out exactly as CRG expected. Having reached a stalemate, the sponsor declined to use eSignatures at all, insisting on wet signatures on all documents. That continued until a visit from representative from that sponsor coincided with a follow-up call from Lisa Bozza Archer, a Complion account manager.

“I was on the phone with Lisa going through this system, going through any issues we were having, and she asked if I was having any troubles,” Neal explains. “I mentioned the issue with
the sponsor, and it occurred to me that since the sponsor was here, why not bring the sponsor in on the call?"

The sponsor came in, along with a monitor who had been active on the site and had expressed appreciation for the way CRG made use of the system. After a brief overview of the system, the sponsor rep agreed to relay the information to her people.

“I had no hope that there was going to be any change,” says Neal. “But two weeks later, the rep was actually back at our site, and she said ‘oh, by the way, I spoke to our people and after talking with Lisa, we have no problems with your system, we’ll go ahead and use your system for all the signatures.”

It was a big win for CRG. “We never expected to fight the battle,” Neal says. “And it was really comforting to know that we didn’t have to fight that battle alone. Complion has all sorts of documents, all sorts of validation tools, and their staff is more than willing to talk with whomever we feel they should talk with in order to facilitate the transition to their system.”

Since then, Neal reports that CRG has had no other issues with any other sponsors.

The third challenge CRG faced is one that has only recently emerged. “But it’s not a bad challenge to have,” Neal says.

When a study recently closed, one that CRG used Complion to manage, Neal found himself with a thick stack of paperwork, documents he had scanned into the system. “It’s all in there,” Neal says. “But now my challenge is bringing myself to actually get rid of the paper.”

Neal still struggles with that issue. “Part of me is saying I have to still hold onto everything. Part of me is saying, well, the study is done, everything is in the system, let’s just shred this all. I’m sure I’ll figure this out at some point, but I’m not there yet.”

A Matter of Focus: Empowering Sites

Shortly after first their first introduction to a paperless system, Dustin attended a Drug Information Association (DIA) event, where he noticed several booths for eRegulatory systems, shattering his initial skepticism that the industry wasn’t ready to go paperless. “That was my first indication that this is possible,” he says.

But in talking to some of those vendors that day it became clear to Dustin that they were geared towards sponsors and CROs rather than sites.
Nevertheless, Dustin’s curiosity prompted a conversation with Complion. “I said, okay, tell me a little bit more about this.” That was when he learned that Complion is very site-centric. “They spent a lot of time getting our feedback,” Dustin says. “They were very interested to know what was important to us, what we wanted to see, and what we wanted the software to be able to do.”

Dustin was struck by the level of customer support provided as well. “If you get pushback from a sponsor, if you have trouble or questions, they are absolutely on your side,” Dustin says. “There are other document management platforms out there, but nothing that really centers on what the sites want and need in the way that the Complion does.”

Neal agrees. “I think that one of the signs of power is versatility,” he says. While Complion is designed to be used by sites, “I think that it is powerful enough that a sponsor or CRO could also use it. It’s simply a matter of how different things in the system are set up, which is fully customizable based upon need. That makes this particular platform exceptionally powerful.”

**Conclusion**

This article has presented the unique perspectives of two individuals, representing two different organizations, on the transition from paper-based management to the Complion document management system. As the article has demonstrated, Neal and Dustin and their respective organizations each had unique goals in making the transition, and each faced unique challenges in that journey. But as the article demonstrates, there was also considerable common ground. It all adds up to valuable insight for those considering their own transition to a paperless process.
Additional Resources

Explore best practices for managing documents electronically and learn from real-world experiences at similar sites.

eRegulatory Experiences from a Site Without Binders
Jill Heinz of Treasure Valley Clinical Research in Boise, ID. shares the details of her organization’s transition.

Steps to Paperless Clinical Trials: Creating Certified Copies & More
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