CASE STUDY BRIEF:

Coastal Pediatric Research

Achieving increased efficiency, improved time management, and elimination of duplicate work

OVERVIEW

Coastal Pediatric Research (CPR) based in Charleston, SC, had considered implementing an eRegulatory solution. But the site seriously questioned if it would be just a "shiny" IT system they could show to their sponsors to appear progressive or could it be an exremely beneficial investment for the site.

The site asked their sponsors and CROs for feedback: Would they be open to using the system at their site? Would it make site visits more productive in terms of previewing the patient data versus the regulatory piece? Would it make their own work any easier?

"Our Sponsor, CRO and CRAs were more open to the possibility than we had anticipated," said Julia Brenner, MHA, finance and regulatory manager for Coastal Pediatric Research. "That was really the trigger for us to move forward with eRegulatory."

THE SELECTION PROCESS

CPR outlined what they actually wanted a solution to provide:

- **21 CFR Part 11 compliance.**
- **User friendly for all CPR research staff and partners.** All of the site's coordinators manage the regulatory component of their studies versus a separate regulatory coordinator.
- **Regulatory binder structure flexibility.**
- **Elimination of duplicate work.**
- **Ability to streamline staff signatures.**
- **Integration with their CTMS**.

After seeing a demo of Complion's eRegulatory solution, CPR was quite confident it would meet all their requirements.

COMPLION ADVANTAGES

- **Accessible from anywhere.** The web-based application can be securely accessed on a computer anywhere internet connectivity is available with eSignature capability from phones/ smartphones/mobile devices.
- **Multi-site access.** A document is filed at one site and is instantly accessible at another.
- **Remote monitoring.** Easily share only relevant binders with monitors through controlled view-only access.
- **Compliance and audit readiness.** Documents can be organized in a familiar "binder" interface to enable key information to be easily searched. An automatic audit trail provides access to viewing and modification history. Documents can be easily compiled into a single formatted PDF with one click.
- **One "source of the truth".** A document is uploaded only once and is then accessible from all relevant binders wherever it's accessed. Revisions are automatically updated from wherever the document is filed and accessed.
- **Efficient filing, monitoring, and signing of documents.** Documents are easily imported directly into the system from scanners, email, or other digital sources. Through standardized naming conventions for each document type and pre-configured binder templates, consistency and standardization is created across all sites and all trials. There are no lost or misplaced documents.
- **Integration with other site systems.** Complion augments and is compatible with existing systems that manage institutional review boards (IRB), trial databases, patient registries, billing, coverage analysis, Electronic Data Capture (EDC), biospecimens and/or staff tracking.
- **Search capabilities.** Complion's document attributes enable the file to be easily searchable and automatically filed in all relevant binders.
- **Configurable user permissions.** Actions and access for binders and documents is role-based at the individual user level. Additionally, documents can be easily shared/ unshared for review and task assignments. Tasks and reminders can be set for each reviewer.

IMPLEMENTATION

There were a few things CPR needed to determine before implementing Complion:

- **Develop an understanding of the site infrastructure.** What type of hardware and software systems were already in place? What was the composition of the staff and what would their user roles be within the eRegulatory system? Would coordinators have access to everything, or would they need admin responsibilities to edit major parts of the binder?
- **Develop workflows.** Determine the timelines and what would be set as the precedent for filing documents. How would all the documents be named in the system?
- **Create and edit SOPs for eRegulatory system and validation.** Who would be using the system, and how would signatures be streamlined?

CPR had to take a good look at their current process and determine how they could make improvements in the workflows to adopt an eRegulatory system. As a result, they had to edit their SOPs quite a bit to help phase out paper binders.

> *"With Complion, our coordinators achieved a 40 percent reduction in time spent on regulatory document management -- time that can now be spent on recruitment and patient visits."*
>
> **- Julia Brenner, Finance and Regulatory Manager**
> **Coastal Pediatric Research**

The site began by setting up strategic goals for timelines and document competition. They discovered they were investing a great deal of time keeping track of when GCPs and CVs of investigators and site staff would expire. As CPR grew larger and the number of studies they were conducting increased, it was evident that someone's CV or GCP training would expire before they had ample time to renew.

"That was one area where we set up a report in Complion on the back end to help the credentialing department see the status of CVs, medical licenses, or GCP training. The department now had enough visibility to begin reminders well before expirations occurred," Brenner pointed out.

Another area of concern: turnaround time on signatures. As a large pediatric group with several research sites, it would often take as long as 5 days to gather the required signatures. CPR set a goal of 48 hours to collect them, and several months after implementation, they were now within that timeframe.

"We also had to rethink how we were going to complete our regulatory documentation without duplication of efforts," said Brenner. "We often printed out email correspondence, filed it in the paper binder, and then copied that email and placed it on our internal server."

This was one of the hardest steps for CPR; to break a cycle everyone was accustomed to and would be so easy to fall back into -- where the process was primarily paper based -- and rethinking how to complete documentation electronically without duplication [using paper files].

Brenner shares an example: "We get requests to send regulatory documents electronically or to send the most recent 1572. We remind our monitors that they have access to Complion and can pull that information or download the source at any time."

DESIGNING THE BINDER TEMPLATE

"This step was quite a challenge," Brenner admits. "I suggest devoting time and effort toward this part of the process to really finetune the template to your needs. It's especially important during the initial phase to gain input from key stakeholders and end users regarding what items should be in the template."

For CPR, the regulatory binder really needed to be a catchall for every study since they not only conduct vaccine studies, but also drug studies, baby formula studies, and device studies.

"There are instances where some regulatory documentation applies to one study, but not necessarily to another," Brenner explains. "That was an important consideration when it was time to define our regulatory binder template."

THE BEST TIME FOR IMPLEMENTATION

As Brenner points out, there really is no best time to implement an eRegulatory solution. Her team was at a point in time when they were beginning a new group of studies. So, they just jumped in and started using Complion right away.

CPR determined moving forward, all new studies would be in Complion and previous studies that were expected to close within the year would be finished in a paper regulatory binder.

"It wasn't a smooth process but setting a standard that future studies would be managed electronically was a big accomplishment for us," Brenner shared.

TRAINING CONSIDERATIONS

When training on an eRegulatory system, it's important to consider your site's infrastructure and the staff's bandwidth for training.

CPR designated a certified coordinator to serve as their super user who Brenner trained on Complion. That coordinator then trained all the other coordinators on their individual studies that would be in the system. As a result, CPR was able to get all coordinators trained and using Complion for their studies about six months after implementation.

"Complion has done an awesome job of providing us with training resources," Brenner noted. "For instance, they provided us with language for our SOPs that made the onboarding process much simpler. Further, they provided several valuable resources like a sponsor success letter, contract language, and budget negotiation tips for getting the system covered.

"We really didn't think a vendor would offer these resources," Brenner said. "It's something Complion automatically provided. It confirmed we had chosen the right vendor for our eRegulatory system."

SUMMARY

With Complion's eRegulatory solution, CPR has not only increased their efficiency, but has also greatly improved their time management, and eliminated duplicate work.

Brenner adds: "If you ever question if you've made the right decision moving forward with an eRegulatory system, just take a look at the reduction in hours and how satisfied the staff is because their work is now so much easier."

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