www.pharmatechoutlook.com MAY - 2020 ISSN 2644-2787

pharma TECH O

eClinical Trial Management Edition

Rick Arlow, CEO

Rendering Clinical Research Pandemic-proof

Complion

$15

pharma TECH OUTLOOK TOP 10
eCLINICAL
TRIAL MANAGEMENT
SOLUTION PROVIDERS - 2020

Complion

Rendering Clinical Research Pandemic-proof

Cities and countries enact shelter-in-place policies, shuttering businesses while cancelling conferences and events, the COVID-19 pandemic has really upended the globe. While many measures have been taken in the name of social distancing, much attention—and rightly so—is focused on the drugs that biopharma industry is developing to treat COVID-19. Evidently, the ongoing pandemic is clearly, immediately, and drastically changing the way clinical research is being conducted.

Clinical trials demand patient travel, doctors, and clinical space—all pinched by the rapid spread of COVID-19. These delays could extend an already lengthy process to get drugs to market. And they may cut off a lifeline for patients willing to try a drug before it gets regulatory approval. The need of the hour is for solutions that allow staff involved on all sides of this equation—sites, sponsors and CROs—to do their work effectively and efficiently even while needing to distance from one another. And that's where Complion comes in. "As a research community,

RICK ARLOW,
CEO

especially now, we believe that the industry cannot afford to stop this work or sacrifice the quality of the work until the pandemic is controlled," says Rick Arlow, the CEO of Complion.

A leading eRegulatory solution for high-performing clinical research sites, Complion has remained focused on site regulatory document management while enhancing its solutions for sponsors and monitors involved in that process and responsible for the final submission. "We are here to help provide innovative and urgent solutions for trials during this time, including those specific to COVID-19, to help ensure high quality and cost-effective monitoring," says Arlow.

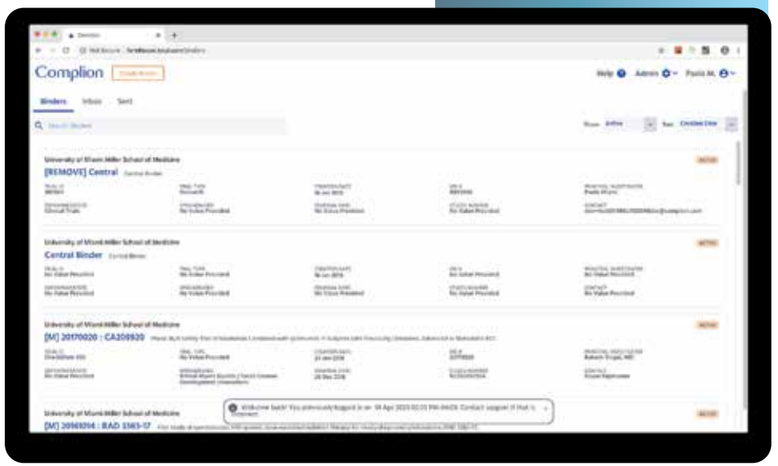
Delivering Future-Proof Services

A key factor that has been powering Complion's focus toward understanding the current situation and evolution has been its relentless pursuit to listen to the industry and its clients. From the day that Arlow realized the power of emerging technologies and broke the status quo of managing site regulatory documents, Complion has evolved past just digitizing site regulatory document management into leveraging technology to completely transform how critical documents are managed and reviewed throughout a study. "As we speak with pharmaceutical companies, we have found that they try to push down document portals and eRegulatory solutions on the site that the sponsor has created to best suit the sponsor's needs," he mentions.

Though this approach makes sense from the sponsor's perspective, this has historically been unsuccessful as it leads to chaos at the site due to a multitude of sponsor-specific portals, new technology to learn constantly, and difficulty in dealing with internal staff changes and re-trainings.

Coupled with this, the redundancies in the documentation process at the research site often lead researchers to frustration and take focus away from the trial. This also creates a fragmented document management process that affects reimbursements of funds and makes it difficult for sponsors to have good oversight on the trial. "To this end, we believe that the industry is best served by a solution that focuses on empowering sites and provides sponsors the insight they need along the way to increase confidence in the completeness of these documents and submission-readiness at the end of the study," says Arlow.

> **We are here to help provide innovative and urgent solutions for trials during this time, including those specific to COVID-19, to help ensure high quality and cost-effective remote monitoring**



Built by Clinical Researchers for Clinical Researchers

To empower sites with consistent internal processes across studies, Complion offers a comprehensive eRegulatory and document management platform that improves trial efficiency, compliance, and transparency for research sites and sponsors. A key point here is the fact that even though the sponsors are accountable for these documents at final submission, the site is responsible for the work of managing the documents over the course of the study. "Through the platform and our process, we enable the highest level accuracy of documentation—and in the process of doing so, facilitate real-time collection of correct and approved documents," mentions Arlow. Complion has various features that help ensure consistency, guaranteeing high-quality regulatory document management, and simplifies internal processes.

Complion ensures that each document is stored a single time in the platform and then uses smart logic behind the scenes to provide access to them through individual relevant study binders within the software or quick search functions. The platform simplifies identifying what needs action by incorporating tasks and workflows within the software, such as FDA compliant e-signature workflows. Complion also clearly shows expiring documents with upcoming capability to set document expectations for studies to also clearly and automatically show missing documents. Altogether, it reduces more than 40 percent of the time spent on regulatory tasks at sites, allowing clients to truly focus on patients and get work done much faster.

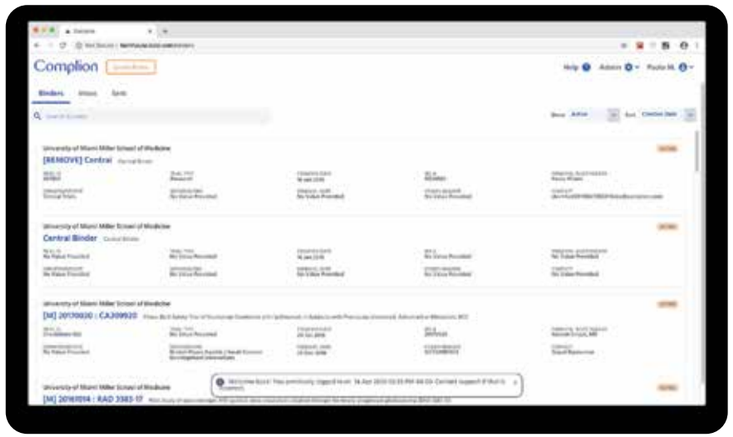
Streamlining Operations and Improving Compliance

Being the pioneers of the Site eRegulatory technology and having a site-focused approach, Complion makes regulatory documents easier to retrieve, whether by an internal staff member or an external monitor, and eliminates confusion around document versions and duplicate documents. This specifically helps ensure that monitors can find precisely the documents they need within the platform without needing assistance from internal staff. This is also helpful during staff turnover and multiple site staff needing to access the same document.

The platform then identifies what's missing, expected, and due-to-expire without the need to be onsite or even ask the site questions. "We then empower the collection of the right documents in real-time to produce a complete, timely, and quality TMF. The software knows to specifically show current, approved versions of documents, eliminating issues brought about by duplicate documents," says Arlow. This functionality boosts CRA's productivity by enabling junior or offshore staff to complete the tasks, and the platform's remote access allows sponsors to satisfy their oversight requirements. Its real-time ongoing review feature nips issues in the bud sooner before they can balloon into additional costs and change orders for unplanned visits onsite during closeouts, audits, and inspections.

Quoting an example, Arlow mentions how his company helped the University of Miami Sylvester Comprehensive Cancer Center in reducing the risk of non-compliance while increasing its staff efficiency, and decreasing material costs. Complion provided them with a centralized solution, which reduced the center's redundant storage of research related documents. "The goal of this project was to prevent compliance issues by proactively addressing the challenges identified with document management and redundancy," says Arlow.

After Miami conducted official internal studies of the success of the system, they found that the number of observations by monitors was reduced by a staggering 88%. And with a number of different departments and satellite operations involved in the platform they still were able to nearly immediately reduce document redundancy by 91 percent across all included operations. Miami also noted how Complion helps enable "an open research culture by providing stakeholders access to regulatory documents without manual requests."



Aligning With the Ever-evolving Clinical Research Space

Over the years, Complion has scripted many such success stories by transforming the way clinical trial documentation is maintained. Powering Complion's journey is a strong team of clinical research and software development experts who continue to improve the platform and processes in response to the clients' needs.

The company has over 7,000 trials currently being managed within the system including a number of current COVID-19 trials, and over 10,000 monitors have accessed Complion, working with sites that leverage its platform.

Having carved a unique niche in the industry, Complion is excited to work with major sponsors and CROs and provide them with the monitoring and oversight solutions they need for site regulatory document management.

For the future, Complion plans to continue building on its already powerful multi-site, multi-institution solution capabilities—including solutions for better staff management as well as additional document and process insight such that users do not have to search within specific documents to understand the work that needs to be done. The company will also build out extensive solutions for monitors and sponsors to leverage its platform internally to collect, distribute, review, and report on site regulations. "As we continue to enhance our platform, we will continue to invest in developing solutions that will empower staff at sites, sponsors, and CROs to work wherever they are, even when they cannot be on site," concludes Arlow.