



## Clinical Trial Knowledge Platform: The Road To Compliance

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Regulatory scrutiny in clinical research has intensified in recent years, and there are no signs that the intensity of the regulatory environment is abating. In the context of increased outsourcing of clinical study activity to CROs, inspectors are showing an increased interest in evidence of the sponsor fulfilling their remaining oversight obligations. One step to improving the success rate of clinical trials while protecting data integrity and patient safety may lie in better attempts to ensure compliance and streamline clinical trial oversight.

Implementing efficient processes to ensure and maintain GCP compliance is necessary - and mandatory by nature - but ensuring that procedures and team trainings are followed and completed can be complex, time-consuming, and sometimes get in the way of focusing on the job at hand: curing diseases and improving patient's lives.

In concrete terms, how can sponsors disseminate information about a new study procedure to the study team in an efficient and compliant manner? How can one review if and when the team has been trained on a protocol? How can one ensure that sites are best prepared for inspections and audits during or after the study? Implementing the right technology platform could be the answer.

This white paper by James Denmark, CEO & Founder at myClin, describes how this Clinical Trial Knowledge Platform allows for a more auto-documented, data-driven clinical trial oversight, while transforming how clinical study teams communicate and collaborate. myClin allows sponsors, CROs, and sites to access study training, distribute essential documents and track study milestones in a central, secure, and private environment.

"Implementing myClin could be the solution to improving inspection readiness for clinical sites."



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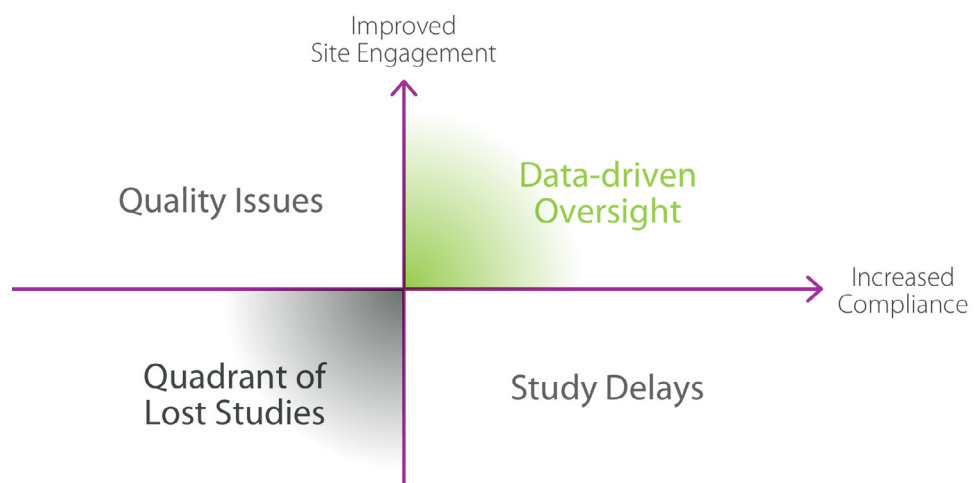
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## The Inception Of The Clinical Trial Knowledge Platform

The team of clinical research veterans that created myClin in 2008 drew from years of experience delivering clinical operations services and building eClinical systems. Initially developing clinical trial portals to facilitate document sharing and communication within a given clinical study, the team quickly realized portals were lacking the collaboration aspect and engaging features necessary for teams to ask important questions, receive answers, information or trainings. Sponsors also didn't have a solution to effortlessly track information and knowledge transfers across the study team – one of the keys to clinical trial oversight.

myClin was thus created as a solution to streamline team communication and provide a private and secure forum for sites and sponsors to collaborate. Kathy Goin, Vice President of Clinical Operations at Trevena, illustrates how the platform made this possible. "I went on a site-initiation visit with a monitor recently, and the site was pounding the monitor with technical questions about the protocol, pointing out a loophole in the inclusion/exclusion criteria," Goin recalls. "In the past, that monitor would have had to make his way back to the office and go back through the chain of command to get the answers, and it would have taken a lot of time. But he was able to put the questions on myClin and within 24 hours the scientists had answers for all to see, which helped all the other sites."

In many cases, the system replaces emails – which are difficult to track and inefficient – with a single, secure, and private communication channel. myClin centralizes the team communications and documents in a compliant platform where sponsors can manage access to confidential study information and distribute information in a more secure, documented way.



Soon enough, the myClin team realized that the platform was not only enhancing collaboration and engagement but provided an unmatched auto-documented, data-driven clinical trial oversight, with no additional efforts from the team. By using the platform, sponsors and sites were de facto audit-ready since they can instantly review which sites have completed on-boarding processes, training sessions, and have knowledge of essential study information or milestones.

## Five Ways For myClin to Increase Compliance

- **Personalized Knowledge Feed:** myClin presents each study team member with a personalized knowledge feed that centralizes the latest posts for their clinical study. There is no learning curve. The posts are ordered chronologically and divided in four pre-defined types: News, Documents, Events, and Training. The knowledge can flow seamlessly and securely across the team, without wasting time in duplicate, isolated and non-compliant email or messaging systems.
- **Trackable Sharing & Filing:** Users hit “File It” for new posts once they have read and understood announcements, training, or documents. They can also post comments and questions so you can easily clarify each piece of information for the whole team. Filing an item automatically adds it to a virtual study file for that site so easing the record keeping obligation for sites. The “File It” feature also makes it easy to review which sites have received information content, seeing who is up to speed or behind and planning operational interventions accordingly. Sponsors can reach full compliance faster and be more confident about the state of their study.
- **Audit-Ready Study Files:** By nature, study correspondence, training, events, and updates relevant to each site are recorded on myClin. The system also reminds users of unfiled items and uses various ways to “nudge” people into compliance. myClin acts as a real-time, central team knowledge repository which simplifies study file management but also dramatically increases preparedness for audits.
- **Real-Time Trial Oversight:** myClin provides study teams with secure, central, and personalized access to essential information and documents relevant to your study, and a communication channel to ask important questions and receive answers faster. Visual dashboards let users review information and knowledge transfers at any time, achieving the most accurate, data-driven clinical trial oversight and reaching real, demonstrable compliance.
- **Cloud-Based Technology:** myClin is a cloud-based and 21 CFR Part 11 compliant system. It is accessible in real-time and fully compatible with any devices, desktop, tablet, or mobile. It doesn't require any installation and can seamlessly adapt to the size of your team.

*myClin is the leading Clinical Trial Knowledge Platform, offering a transformative collaboration channel and the most documented, data-driven clinical trial oversight. The company's mission is to leverage technology to enhance participation, engagement, collaboration, and compliance in clinical trials. The team of clinical research veterans that created myClin in 2008 brought deep experience delivering clinical operations services and building feature-rich eClinical systems. Since then, myClin has been used across all phases of research, in global bio-pharmaceutical and device studies with thousands of clinical users. myClin is headquartered in Philadelphia, PA, with offices in San Francisco, CA, and the UK.*