An eReg solution for COVID-19 clinical trials designed with Sites in mind

Providing increased quality, reduced operational costs and improved profitability

The COVID-19 pandemic has drastically changed the way clinical research is being conducted. For some Sites this means holding operations. For others, it means the burden of work is heavier and much more pressing. Some Sites may be involved in COVID-19 vaccine trials, some of which may be virtual. Others are trying to continue the trials that can't afford to be stopped amid strict practices of distancing and quarantining.

Monitoring trials of all types, virtual or not, requires endless phone calls, emails and virtual meetings –- even more than prior to the pandemic. Some Sites have cancelled monitor appointments or are spending several hours or days on the phone with monitors. In regard to regulatory documentation, monitors should be able to review it without interrupting work by coordinators – doing so remotely and digitally.

In light of all this, important documents still need to be managed, updated, shared and signed. Protocol training needs to be completed. All these tasks should be able to be completed easily, digitally, wherever clinical or regulatory staff are located, including getting compliant signatures.

For those Sites that have had to slow work or delay research, the onslaught of work whenever this pandemic is finally controlled will become undaunting.

Sites are struggling to provide the infrastructure necessary to enable the process to run efficiently while ensuring trials are progressing smoothly. This has made it imperative for sites to identify and quickly implement a Site eReg solution that allows effective and efficient management of regulatory documents, particularly if done remotely.

Complion's Site eReg solution is purpose-built for Sites. With the platform, Sites can experience simpler storage, retrieval and sharing of regulatory documentation as well as compliant e-signatures to help staff easily manage all related work from wherever they are working. The ability to have unlimited users in the system – PIs, hospital staff, regulatory staff or external users such as monitors –makes remote or distanced work and review simple.

With the cloud-based software platform:

- **Documentation can be easily imported** from scanners, email or digital sources directly into the system.
- **One version of the truth.** A document is uploaded once and can be accessible from all relevant binders wherever the document is accessed. Revisions to the document are automatically updated wherever that document is filed and accessed.
- **Gain insight and control through document audit trails.** Every document activity is automatically tracked providing access to viewing and modification history.
- **Gain and ensure consistency.** Standardized naming conventions for every document type and pre-configured templates for binders provides consistency across all sites and all trials.
- **Provide access control.** Individual internal and external users have access to only those binders and specific documents they should have access to.

Sites see many benefits with Complion eReg

- **Better tracking and auditability** of regulatory documents;
- **Ensured compliance** through online monitoring of site regulatory documents;
- **Simpler, more secure sharing and review** of regulatory documents by internal staff/monitors;
- **Improved collaboration** through online review of documents and signature collection; and
- **Eliminated space and costs** associated with paper storage.

- **Easily share/unshare documents** for review and assign tasks like eSignatures. Tasks and appropriate reminders can be set for each reviewer; they're compiled in the system to easily view what still needs completed. Remove staff from tasks, document or binders that are no longer appropriate.
- **Provide remote access to monitors.** Easily share only relevant binders with monitors with controlled view-only access.
- **Multi-site access.** If a document is filed at one site, it is instantly accessible at another and can be accessed from anywhere be it a laptop or desktop computer.

The Complion eReg solution will transform the way Sites currently work, particularly during a time when we are all forced to change the way in which we work. It ensures the highest level of compliance with the least amount of work, so sites can focus on what really matters -- clinical trials.

COMPANY OVERVIEW

Founded by a clinical researcher in an NIH-funded medical scientist training program (MD/PhD) in partnership with leading sites like UCSF and Northwestern, Complion is the leading provider of Site eRegulatory solutions for Sponsors and CROs on over 8,000 trials. With a uniquely singular focus on site regulatory documents and remote monitoring, we partner with Sponsors and CROs to contain the cost and improve the quality of site monitoring.

Our software leverages purpose-built site regulatory workflows to intelligently file, find, share, sign, review and collect site regulatory and essential documents. The result -- previously redundant, manual error-prone work is eliminated.

LET'S BECOME YOUR eREG PARTNER. CALL US TODAY.

800-615-9077

sales@complion.com