An eISF solution to help CROs during COVID-19 challenges

Providing increased quality, reduced operational costs and improved profitability

CROs have been contending with the cost containment and quality improvement of site monitoring. The review and collection of site regulatory and other essential documents; i.e., the "binders", has been a particularly aggravating challenge particularly due to the COVID-19 pandemic. CRAs are grounded, they can't travel to sites, and are spending hours on the phone with sites trying to review and collect documents. As a result, they feel they have no real solution available to them. This is extremely unproductive, particularly with the focus on cost mitigation and reduction.

CROs are scrambling to figure out how to work with sites to remotely complete document review and collection to the highest quality standards. Long after travel restrictions are lifted due to COVID-19, it will continue to be imperative for CROs to provide an eISF solution to their sites and staff to enable effective site monitoring and document collection.

In light of the pandemic, there is an increasing demand for studies. Recent travel restrictions are challenging CROs to continue providing the highest level of quality service electronically and remotely to maintain operation and patient safety. In order to recognize the highest return on investment for CROs, it's imperative to provide the correct eISF tool to sites to enable adoption and facilitate effective monitoring and document collection.

The Complion's eISF solution is that tool. It enables a streamlined process and creates opportunity for CROs to reduce their operating costs as it relates to these following labor-intensive tasks:

- Distribution of site regulatory documents;
- Catching site regulatory document errors prior to the potential of costs increasing further downstream;
- Site monitoring cost; and
- Collection of site regulatory documents.

With Complion's eISF solution, these highly clerical tasks -- which often require **at minimum 20% of CRA time** -- are simplified/automated or can be assigned to less senior roles without site visits.

The best-in-breed, cloud-based platform provides a place to centrally store documents to prove collection and ensure completeness while providing additional oversight at research sites throughout the entire clinical trial process. And the time a monitor spends checking documents is greatly reduced. All factors which further leverage the benefits of eRegulatory.

CRAs and CTAs get the tools they need in a more organized manner to review site regulatory documents for completeness, prove contemporaneous checks to satisfy oversight requirements, and collect the correct documents from the site. The time a CTA spends reviewing, resolving and collecting site documents is greatly reduced. Errors and missing documents are identified in real-time based on site workflows which enables quick resolution by CRAs and CTAs. The result: Fewer delayed close outs, audit/inspection findings or unplanned change orders.

CROs see many benefits with Complion eISF

- **Increased quality** by identifying and tracking issue resolution;
- **Accommodation of oversight requirements** with real-time collection of correct and approved documents;
- **Cost containment** by eliminating unplanned visits for site closeouts, audits and inspections;
- **Boosted CRA productivity** by enabling remote and/or more junior staff to consistently resolve issues earlier with less costs; and
- **Improved site productivity, partnerships and inspection readiness.**

Complion is successful at getting sites to adopt and utilize our eISF solution because it's designed for the sites with purpose-built site regulatory and remote monitoring. Specifically, replacing "binders" by walking sites through the process to ensure every regulatory requirement is met. This improves site audit-readiness, and increases site productivity.

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 eISF 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 eISF PARTNER. CALL US TODAY.

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