An eISF solution for COVID-19 clinical trials designed with Sponsors in mind

Providing increased quality, contained costs and fulfilled oversight requirements

The review and collection of site regulatory and other essential documents while containing costs and improving quality of site monitoring has always been a major challenge. Sponsors are scrambling to figure out how to work with sites to remotely complete document review and collection to the highest quality standards.

With the pandemic, CRAs can't travel to sites and are spending hours on the phone with sites trying to review and collect documents. In addition with the increasing demand for COVID-19 studies, the majority of sponsors are looking at ways to modify site monitoring practices.

As a result, several questions have surfaced:

- How are things such as protocol changes and deviations going to be documented?
- If the process requires "wet-ink" signatures, what are the alternative methods of demonstrating approvals?
- Site staff is spread across multiple locations making it challenging to obtain the required information efficiently. If adjustments to a clinical program requires new team members, how will the team rosters, CVs, qualification documentation, training and Delegations of Duties log (or equivalent) be revised efficiently?

When Sponsors work with multiple CROs, they often receive information in a variety of formats which impacts effective study management. The solution is a cloud-based technology platform that streamlines collaboration between Sponsors and CROs, and at the same time standardizes data views and workflows. The result: time savings and efficiencies across the entire clinical research value chain.

Long after travel restrictions are lifted, it will still be imperative for Sponsors to provide a solution to their sites and staff that enables effective site monitoring and document collection, particularly during the pandemic when the majority of work needs to be done remotely.

To recognize the highest return on investment for Sponsors, it's essential to identify a best-in-breed partner that specializes in clinical research and eSite Reg and can provide the right eISF tool to sites to facilitate effective monitoring and document collection.

The Complion eISF solution addresses all these challenges while improving quality and containing the cost of site monitoring with on-time accurate TMFs and real-time oversight into site regulatory requirements.

Additionally, the highly clerical tasks typically performed by CROs can be simplified/automated or assigned to less senior roles without site visits which can greatly reduce costs associated with the CRA/CTA workforce.

Sponsors 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.**

CRAs and CTAs get the tools they need to review site regulatory documents for completeness, 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. The result: Fewer delayed close outs, audit/inspection findings or unplanned change orders.

Complion is successful at getting sites to adopt and utilize our eISF system because it's built for the sites. By achieving site utilization, Sponsors achieve their other goals of increased quality through accurate submissions; improved TMF quality, completeness, and timeliness; and enhanced oversight with real-time visibility and accessibility of sites.

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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