

Overcoming Clinical Trial Site Activation Obstacles

Discover how Site Activation Services from CFS can help you accelerate cycle times, improve investigator relationships, and manage compliance requirements in your clinical trials.



THE OBSTACLES YOU FACE

With tight timelines and complicated regulatory documentation requirements, getting a clinical trial up and running quickly is easier said than done. Key trial milestones—from drug shipment and IRB approval to patient randomization—can only be achieved after the successful negotiation of clinical trial agreements and completion of essential regulatory documents.

In addition, the passing of the Sunshine Act has heightened the importance of financial disclosure in clinical trials. Without a robust financial disclosure compliance strategy in place, sponsors cannot ensure that physician self-reported financial disclosure data are aligned with the payment data being reported through the Sunshine Act, leading to potential discrepancies

in these data that increase your financial and regulatory risk.

For many clinical trials, inefficient and laborious processes, from lengthy contract negotiations to redundancy and lack of quality control in regulatory and financial disclosure documentation, hinder the ability of investigative sites to meet enrollment deadlines. Addressing today's complex site activation requirements using manual processes is time-consuming, error prone, and risky for your organization. Moreover, ongoing dissatisfaction on the part of investigative sites with the inadequacies of the activation process has the potential to damage sponsor-site partnerships and thwart the success of future trials.

OUR SOLUTION, YOUR ADVANTAGE

Clinical Financial Services (CFS) offers a comprehensive suite of Site Activation Services that make the arduous clinical trial start-up process quicker, more efficient and less complicated. With an experienced team dedicated solely to managing the activation tasks of your trial and a technologically advanced project dashboard available 24/7 that gives you near-time visibility into the status of every document, we help you accelerate cycle times, ensure compliance, minimize financial risk and improve relationships with investigative sites. Additionally, when you outsource your clinical trial start-up activities to CFS, you free up internal resources that can be redeployed to other critical trial activities.

Our Innovations Accelerate Your Cycle Times.

Outsourcing your site activation tasks to CFS enables you to exceed your trial start-up deadlines. By shortening the study initiation process, we maximize the number of sites that are activated and “enrollment ready” when the enrollment phase of the trial begins, allowing you to complete trials sooner and ultimately bring your product to market faster.

Our Efficiencies Enhance Your Investigator Relationships.

Activating a clinical trial is a complicated process, with contracts that must be executed and regulatory documents that must be properly completed and collected before enrollment can begin. Outsourcing this work to our team of experts enables you to complete these processes efficiently through an advanced online repository. Through our enterprise-wide database, we provide investigators with pre-populated regulatory documentation that avoids manual data redundancy and dramatically speeds the time it takes for sites to complete this paperwork. This process is instrumental in alleviating frustration and enhancing site satisfaction with your organization.

Our Processes Improve Your Compliance.

Quality assurance is part and parcel of clinical research. Streamlining and automating the site activation process of clinical trials—from contract and budget negotiations to regulatory and financial disclosure documentation—positions your organization to manage compliance requirements quickly, efficiently and cost-effectively. Our automated processes, which leverage existing investigative site information, enable prompt collection of essential regulatory documents and rigorous quality assurance audits to ensure the accuracy of information.

The CFS Financial Disclosure Compliance Team works with your investigative sites to complete financial disclosure forms and ensure that the information is consistent and compliant with 21CFR Part 54 and your internal SOPs. We identify and document any potential conflicts of interest and ensure data integrity by cross-referencing the information with that provided on Form FDA 1572. We offer complete transparency by allowing you to log in to our online project dashboard at any time for an up-to-the-minute status of your trial’s start-up activities.

HOW CAN WE SERVE YOU?

In addition to our Site Activation Services, CFS offers Global Contract Management and Global Payment Management Services. This triad of business and financial service offerings helps clinical trial sponsors speed the initiation and completion of studies, enhance investigator relationship management, operate more efficiently and cost-effectively, and meet today’s complex compliance requirements.

Contact us today to learn how we can help your organization overcome its clinical trial obstacles.



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