



Easing Financial and Business Burdens in Your Clinical Trials

Discover how you can drive success with best-in-class solutions from Clinical Financial Services.



Clinical Financial Services

Today's Clinical Trials Are Complex

Clinical trial sponsors face bigger challenges than ever before in the race to bring drugs and devices to market, from mounting pressures to increase profits and decrease spending to stringent financial and regulatory requirements to cut-throat competition for the best study sites. At the same time, sponsor resources are becoming more limited, with already taxed departments saddled with increasing responsibilities that fall well outside their core functions and expertise. With so much at stake in this ultra-competitive industry, sponsors simply can't afford second-best business and financial management of their clinical trials.

The CFS Solution Is Simple

As the only company in the clinical trials industry that offers turnkey business and financial management services for clinical trials, Clinical Financial Services (CFS) helps biopharmaceutical sponsors and medical device companies meet today's burgeoning management challenges. Our team brings a keen understanding of the clinical trial process, including trial budgets and agreements, contract negotiation and administration, regulatory documentation, and finance and accounting.

Our unique domain expertise, efficient business processes and innovative technology bring increased consistency, faster speed, better compliance and more financial control to your clinical trials. Our global capabilities reduce costs and accelerate cycle times, empowering you to bring your products to market faster. Outsourced services from CFS give you access to resources when you need them, easing the day-to-day burden throughout your organization and offering an excellent return on your investment.

SITE ACTIVATION SERVICES

The process of getting investigative sites activated by efficiently collecting their regulatory documentation is critical to the successful initiation of any study. Headed by a dedicated team focused solely on managing the start-up activities of your clinical trial, Site Activation Services from CFS make the clinical trial activation process quicker, more efficient and less complicated for your team, allowing them to focus on other critical trial activities. The benefits of our service include:

Faster study cycle times: By shortening the study initiation process, we maximize the number of sites that are "enrollment ready" at the first-patient-in date.



Enhanced investigator relationships: Pre-populating regulatory and financial disclosure documents with investigator data from our enterprise-wide database avoids redundancy and speeds completion of this paperwork, alleviating investigator frustration and improving site satisfaction with your organization.

Complete transparency: Available 24/7, the CFS project dashboard provides unprecedented visibility into the activation status of your investigator sites. Simply log in to the dashboard at any time to access the status of every regulatory document.

Improved compliance: Our Financial Disclosure Team works with your investigative sites to complete financial disclosure forms and ensure that the information is consistent and compliant with 21CFR Part 54. By cross-referencing the information with that provided on form FDA 1572, we document all potential conflicts of interest and ensure data integrity.

GLOBAL CONTRACT MANAGEMENT SERVICES

The initiation of any clinical study hinges on the efficient execution of trial agreements between sponsors and investigative sites. With Global Contract Management Services, CFS can manage



the complete lifecycle of your clinical trial agreements, from creation, negotiation and electronic signature to storage,

compliance and analytics. Our highly experienced people and advanced systems offer significant benefits:

Accelerated cycle times: We leverage contractual information based on previous studies and track relevant information for future contract negotiations, immensely speeding trial activation. Our project dashboard offers a clear view of every contract change as it happens, allowing you to manage your trials with confidence and at your convenience.

Better budget management: We use cost benchmarking databases and our large proprietary internal database of procedure costs to negotiate grant budgets with investigative sites and maintain fair market value standards for grants.

Streamlined negotiations: Our proprietary online Negotiation Tracking System tracks project and vendor information, key negotiated items stratified by budget and contract clauses, red-lined agreements with version control and negotiation status—greatly facilitating contract reviews and decreasing both site and sponsor frustration.

Risk management and standardization: Because we know what sites are requesting with each successive engagement across your portfolio, we eliminate negotiations made in a vacuum and help you implement consistency of terms and conditions across your sites. We ensure that what you pay out is actually captured in the contract, so you remain in compliance with standard and Sarbanes-Oxley financial audit regulations.

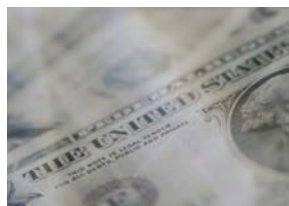
Global legal support: CFS offers centralized access to legal support in more than 60 countries worldwide, with expertise in both contract negotiations and tax regulations.

GLOBAL PAYMENT MANAGEMENT SERVICES

Managing grant payments in clinical trials is a complex endeavor that requires integrated technologies to properly calculate and efficiently administer payments to investigative sites. Global Payment Management Services from CFS make it easier for your organization to manage business intelligence and remain in compliance with federal aggregate spend requirements. Our highly controlled and fully integrated payment-processing environment allows us to manage grant payments and pass-through expenses for investigative sites around the world quickly and accurately via electronic funds transfer (EFT), with detailed reports provided to payees in their local language and currency. Our service benefits your organization in many ways:

Improved financial control:

Our innovative software and rigorous processes allow you to precisely calculate your monthly spend, so you make just-in-time payments and can better manage your trial budget. Accurate, real-time accruals and reporting enhance business intelligence, and electronic billing transactions and straight-through processing enable superior financial control. With SAS 70 standards as part of our control environment, our internal controls meet Sarbanes-Oxley Section 404 requirements.



Improved investigator relationships: CFS helps you significantly improve relationships with investigative sites because we pay investigators on time and with true transparency. Our automated data extraction process allows us to pay investigators monthly for patient visits and pass-through activity, and our site portal shows investigators exactly what they are being paid for.

Better compliance: Our protocol-specific sponsor portal generates reports around both investigative sites and individual investigators, improving your compliance with federal (Sunshine Act) and state aggregate spend reporting requirements.

Accelerated cycle times: Investigative sites are incentivized to input trial data quickly because they are paid via data extracted from those entries. This improved productivity means you get trial results more quickly.

How can we ease your burden?

Contact CFS today to learn more about how our triad of business and financial management services can help you streamline operations and improve your bottom line.



Clinical Financial Services

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