

Scaling Clinical Trial Contract Hurdles

Discover how Global Contract Management Services from CFS can help you better manage your clinical trial budget, reduce contractual and financial risk, and accelerate cycle times.



THE HURDLES YOU FACE

Timely development, negotiation and execution of trial agreements with investigative sites is vital for the expeditious activation of any clinical study, with pivotal start-up activities hinging on this process. Yet clinical trials are often stalled from the start due to inadequate investigator budget development and inefficient contract administration and negotiation processes.

Many sponsor companies rely on their own limited investigator grant data when developing a budget. While this approach can provide a realistic view of what the sponsor has historically paid, it does not offer the industry-

wide cost perspective required to achieve fair market value (FMV). Other companies subscribe to cost benchmark databases but lack the expertise to understand and translate the trial protocol into a budget with a clear, executable, and repeatable grant payment schedule that maintains FMV standards.

The clinical trial contract dictates the payments made to investigative sites. Ultimately, inefficient contract management and poor negotiation of grant payments lead to weak financial controls and poor compliance throughout a clinical trial.

OUR SOLUTION, YOUR ADVANTAGE

Clinical Financial Services (CFS) focuses exclusively on the business and financial management of clinical trials, so we truly understand the complexity and importance of effective investigator contracting practices. Global Contract Management Services from CFS are among the most functionally rich and robust services available today to support clinical trials. Our enterprise solution is adaptable and highly scalable to meet the growing demands of pharmaceutical and medical device research and development.

CFS provides complete lifecycle management of your clinical trial agreements, from creation, negotiation and electronic signature to storage, compliance and analytics. We offer unique systems and a dedicated infrastructure to manage data, with a flexible process tailored to meet your organizational requirements. Partnering with CFS empowers you to initiate and complete clinical trials more quickly and cost-effectively while improving investigator relationships and enhancing your status as a sponsor of choice.

Our Knowledge Reduces Your Cycle Times.

Site profiling enables us to leverage contractual information based on previous studies and track relevant data for use in future contract negotiations, speeding trial activation immensely. Our project dashboard offers a clear view of all contract changes as they happen, allowing you to manage your trials with confidence and at your convenience.

Our Insight Improves Your Budget Management.

With access to cost benchmarking databases as well as a large proprietary internal database of procedure costs, we work with you to develop a realistic and fair investigator grant budget and payment schedule supported by current industry data. If you have already developed a budget, CFS experts can provide a consultative review and analysis to ensure that your budget is in line with both protocol requirements and the latest industry trends.

We work diligently to negotiate grant budgets on your behalf within established thresholds and will partner with you when requests are made that fall outside those parameters. Our wide array of data and negotiation techniques minimize the number of budget requests that require your input, allowing your team to remain focused on other crucial study initiation activities.

Our Systems Streamline Your Negotiations.

Maintaining strong financial controls when managing payments to investigative sites begins with execution of the trial contracts. By ensuring that what a sponsor pays out is actually captured in the contract, CFS enables standard and Sarbanes-Oxley financial audit compliance.

The CFS Negotiation Tracking System—a proprietary approval flow system that manages the entire contract lifecycle, including any potential amendments that may occur throughout the life of the project—delivers all of the efficiencies and benefits of contract management processes while leaving you in complete control of the negotiation. This system enables us to track many aspects of the negotiation, including project and vendor information, key negotiated items stratified by budget and contract clauses, red-lined agreements with version control, and negotiation status. What's more, it offers full transparency and a systematic way to facilitate reviews as well as escalation to your team for additional levels of review and approval when needed.

Our Legal Stewardship Helps You Manage Risk.

Our vast legal network—with on-the-ground resources in more than 60 countries—supports contract negotiations around the world with efficiency and clarity, so your legal team is fully prepared to manage risk on an enterprise level. We also ensure that agreements are structured appropriately to handle country-specific tax regulations, so you can feel confident that your documentation will conform to the intricacies of regulations that fall outside your scope of expertise.

HOW CAN WE SERVE YOU?

In addition to our Global Contract Management Services, CFS offers Site Activation 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 scale its clinical trial hurdles.



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