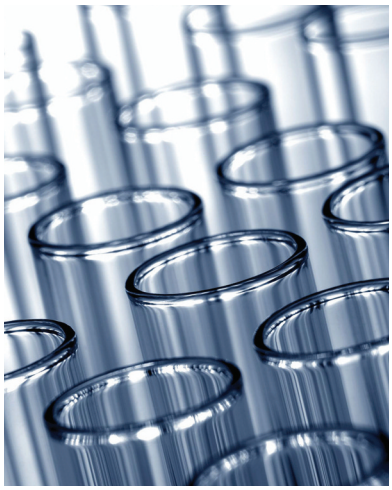
Easing Financial and Business Burdens in Your Clinical Trials

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



CFS CLINICAL

Transforming the Business of Clinical Trials™

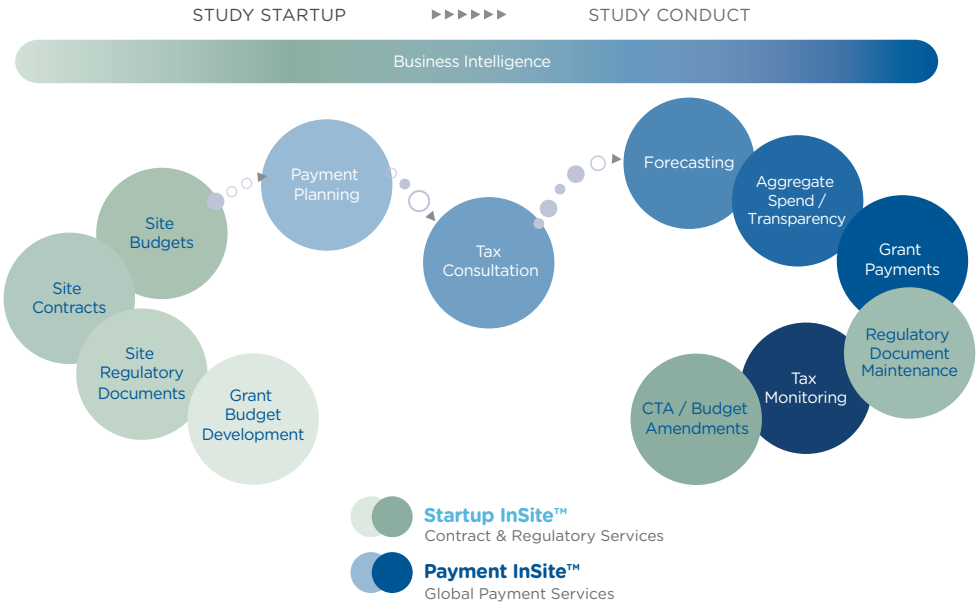
Your Challenges are Complex.

In the race to bring drugs and devices to market, clinical trial sponsors and CROs face bigger challenges than ever before—including mounting pressures to increase profits and decrease spending, stringent financial and regulatory requirements, and cutthroat competition for the best study sites. Meanwhile, sponsor resources are increasingly limited. Already taxed departments are being saddled with responsibilities that fall outside their core functions and expertise. With so much at stake, sponsors simply can't afford second-best business and financial management of clinical trials.

The CFS Solution is Simple.

CFS Clinical is the only company to offer turnkey business and financial management services for clinical trials. We help CROs, biopharmaceutical sponsors, and medical device companies to address today's complex management challenges. We combine the right people, processes, and technologies to streamline and improve the way you manage the business of clinical trials—including site grant budgets, contract negotiation and administration, essential site regulatory documents, and grant payment management.

By leveraging our investments and expertise—including our proprietary CFS InSite™ Platform—you have access to the resources you need when you need them. So you can run your trials with greater consistency, efficiency, speed, and control—addressing compliance and strengthening the critical relationships with your investigators. Ultimately, CFS Clinical empowers sponsors and CROs to bring products to market faster.



Supporting the Full Lifecycle of Clinical Trial Agreements.
CFS Clinical provides services throughout the lifecycle of the clinical trial agreement. Depending on your goals and requirements, your organization can outsource some or all of these business processes to us. The CFS InSite™ Platform supports all of our services, with CFS Startup InSite™ providing support for CFS Contract and Regulatory Services and CFS Payment InSite™ serving as the engine for CFS Global Payment Management.

Initiate Trials More Quickly and Efficiently: CFS Contract and Regulatory Services

CFS Clinical offers a suite of capabilities to help sponsors and CROs dramatically streamline and accelerate the process of initiating a study. CFS Contract and Regulatory Services address the critical contracting, budgeting, and essential site regulatory document requirements for activating clinical trials. By outsourcing these business processes to CFS Clinical, sponsors can initiate studies more quickly and effectively. Our services also enable you to:

Align essential site documents, contracts and payments. Technology-enabled collaboration with enterprise access to site regulatory and contractual documents ensures synchronization of information across essential startup documents. Synergy of documents and robust quality controls expose and mitigate often overlooked risks such as obligating the correct parties.

Streamline negotiations and document completion. CFS Clinical's proprietary system, Startup InSite™, enables global lifecycle management of all essential startup documents, from CTAs to informed consents and CVs. The system tracks project and site information, key negotiated items stratified by budget and contract clauses, document auditing with version control, negotiation and document status, and eSignatures. The results: faster, more effective contract and essential site document reviews and less frustration among sites and sponsors alike.

Improve budget management. Experienced budget development and negotiation experts leverage IMS GrantPlan® and our large proprietary internal database of procedure costs to maintain fair market value (FMV) standards.

Reduce risk through standardization. Through site profiling, we eliminate negotiations in a vacuum— promoting consistency of terms with each of your sites and throughout your study portfolio. Further, proven controls ensure payments are in accord with contracts, enabling you to stay in compliance with SOX regulations and ready for Sunshine and global aggregate spend reporting.

Enjoy complete transparency. Available 24/7, the CFS Startup InSite™ project dashboard provides unprecedented visibility into the activation status of your investigator sites. Simply log into the dashboard at any time for easy task management and real-time statuses of every contract, budget, amendment and essential site document.

Improve compliance. Our expert team, powered by Startup InSite™, engages your sites to complete forms correctly and accurately per applicable regulations. Moreover, a robust quality system with multi-tier QC review delivers audit-ready documents ready for integration into your eTMF. CFS delivers a careful balance of speed and quality.

Enhance investigator relationships. Startup InSite™ auto-generates contract and essential site documents with data from our enterprise-wide database. Investigators appreciate this approach, which avoids redundancy and accelerates study startup.

Improve Financial Management of Clinical Trials: CFS Global Payment Services

CFS Clinical has built the CFS Payment InSite™ system to properly calculate and efficiently administer payments to investigator sites — enabling your organization to more effectively manage business intelligence and remain in compliance with aggregate spend and transparency requirements. Our highly controlled, fully integrated payment-processing environment allows us to manage grant payments and pass-through expenses for investigative sites around the world. We deliver payments through electronic funds transfer (EFT) and provide detailed reports to payees in their local language and currency. CFS Global Payment Services benefit your organization by empowering you to:

Improve financial control. Our innovative software and rigorous processes allow you to precisely calculate your monthly spend. With that insight, you can make just-in-time payments and better manage your trial budget. Accurate, real-time accruals and reporting enhance business intelligence—while electronic billing transactions and straight-through processing enable superior financial control. Moreover, as a result CFS Clinical's adoption of SSAE 16 SOC 1 Type II compliance as part of our control environment, we help meet our client's Sarbanes-Oxley Act requirements regarding Service Organizations.

Enhance investigator relationships. Investigators appreciate being paid accurately, on time and with true transparency. CFS Clinical's automated data extraction process allows us to do that—paying investigators quickly for their activities. Outside North America, CFS Clinical's advanced invoicing process and payment tracking further eases your site's burden. Your investigators are guided with automated alerts to our site portal to see details of their payments.

Improve compliance. CFS Payment InSite™ generates reports around both investigative sites and individual investigators—improving your compliance with federal (Sunshine Act), state and growing global aggregate spend reporting requirements.

Accelerate cycle times. When you work with CFS Clinical, investigative sites are paid based on the data they submit. Our approach encourages investigative sites to input trial data quickly and accurately, which supports greater productivity and faster trial results.

People & Process POWERED BY CFS CLINICAL InSite™

TRANSPARENCY THROUGH OUTSOURCING

- Real-Time Dashboards for Sponsors, Sites, CROs
- Enhanced Traceability for Payments & Documents
- Electronic Workflow
- Auto-Document Creation
- eSignature

Enhanced Business Intelligence: Grant Payment Reporting and Transparent Study Startup Features

The CFS InSite™ technology platform, which serves as the backbone for CFS Clinical's investigator payment and study startup services, provides unparalleled access to business intelligence, with operational transparency and enhanced reporting, for today and further expansion into the future. This includes real-time access to:

Enhanced Investigator Grant Payment Reporting

- Detailed forecasting of your investigator grant spend
- Valuable "What if" analysis for pre-trial and active study planning
- Cash flow statements to manage grant cash requirements
- Actual vs. forecast reporting based on planned and current enrollment trends
- Variance reporting – How far did the trial stray from plan?

Transparent Study Startup

- Metric driven site selection – understand what sites are routinely requesting & how long it is taking to get them up and running
- Enhanced document tracking – dashboards for Sites, Sponsors and CROs keep everyone on course

Tax and Contracting Consulting Service: Tax Expertise for Paying Your International Sites

CFS Clinical provides enhanced tax and contracting consulting for clients to sort out the vast complexities of paying investigators globally. CFS experts help you build your global grant payment strategy to minimize financial risk and manage your tax exposure.

- Value Added Tax (VAT): Due diligence including applicability, local legislation and validations of invoices with the latest regulations.
- Withholding Tax (WHT): Due diligence including applicability, collection of compliance documents and filing.
- Foreign Exchange: Due diligence including applicability and development of process flow to comply where needed.
- Clinical Trial Agreements (CTA's): How to favorably structure CTA's to streamline international payments and manage financial risk.

CFS CLINICAL

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