DrugDev
do more trials

Driving ROI: The Case for Investing in Contract & Site Regulatory Document Management Services

With tight timelines and complicated regulatory documentation requirements, getting a clinical trial up and running quickly is easier said than done. Key milestones can be achieved only after the successful negotiation of clinical trial agreements and completion of essential regulatory documents. Many clinical trials are hindered by inefficient, labor-intensive processes. Prolonged, inefficient activation can hamper investigator satisfaction and, ultimately, have a negative bottom-line impact for sponsors and CROs. In addition, the Sunshine Act is heightening the importance of financial disclosure in clinical trials. Without a robust financial disclosure strategy, sponsors cannot ensure that physician self-reported financial disclosure data are aligned with the payment data being reported through the Sunshine Act, increasing financial and regulatory risk.

The goal of this study and white paper is to highlight examples of the operational and business benefits that can be realized when outsourcing clinical trial agreements and regulatory document management to a standalone service provider. The impact of investing in contract and site regulatory document management services is not only strategic but also measurable. Research conducted by independent research firm, the Hobson Group, consisting of five in-depth interviews with DrugDev customers, found that DrugDev's combination of technology and relationships addressed customer challenges and delivered measurable results and a compelling return on investment (ROI).

Contract & Regulatory Document Management Challenges

Reducing the time spent on administrative tasks associated with clinical trial agreements and essential site regulatory documents, while increasing the speed with which sites are activated was a key goal for many customers. The effort to get sites activated, creating required contracts and essential site regulatory documents, which often included a lot of duplicate effort and redundancies, negotiating with sites, and chasing down completed documents from the sites, was still significant when handled with largely manual processes and procedures.

Another key pain point often noted was the effort required by the site personnel to get all of the documentation completed, which not only added to the time required to activate a site but could also lead to frustration on the site's part. Given the critical role that investigator sites play in the clinical research activities of sponsor companies, as well as the fact that sites are often being used by a sponsor for multiple studies, ensuring site satisfaction and strong site relationships was a key focus area for customers.

Beyond the operational challenges with their prior approaches, customers also noted that effective budget management for each study could be difficult. Challenges included not only defining appropriate budget parameters for negotiation, which ensures that budgets represent fair market value for the research procedures being performed, but also having the negotiators stay within these budgets to avoid budget creep and multiple exception requests during the contracting process.

Finally, compliance was a key concern for customers. Ensuring that all required procedures were being followed, all documentation and contracts met regulatory requirements, and investigator budgets are within fair market value guidelines, could be difficult to do when manual processes were being used which could be time consuming and error-prone. At a minimum, compliance errors could result in added time being spent to correct them, but they could also potentially result in other penalties such as fines.

DrugDev
do more trials

Customers identified benefits of a contract and regulatory document management solution from DrugDev in four key areas: increased operational efficiencies, enhanced investigator relationships, improved budget management, and strengthened compliance.

Increased Operational Efficiencies

Reduce time spent managing clinical trial agreements and site regulatory documents. When clinical trial agreements (CTAs) and site regulatory documents need to be created anew for each site participating in a study, the process can be extremely time consuming, taking study team time away from other important study tasks. DrugDev's Startup InSite™ technology platform automates the creation and distribution of contractual and site regulatory documents. Sites are provided with a set of documents that are pre-populated with investigator data from DrugDev's enterprise-wide database, avoiding redundancy and dramatically decreasing the time it takes for study teams to create and manage the paperwork required for the sites to complete to become enrollment-ready.

Would need at least two additional FTE if contracts were being managed internally, instead of being handled by DrugDev. — Director, Contracting Services

Reduce time needed to get executed CTAs and site regulatory documents back from the sites. When the process of managing the back and forth between the sponsor and the site for the CTA and site regulatory documents is handled manually, it is extremely difficult to accurately track the status of these documents, extending the time needed to get the sites activated. Startup InSite™ enables global lifecycle management of all essential start-up documents, from CTAs to informed consents and CVs. The system tracks project and site information, real time document and negotiation status, and key negotiated items stratified by budget and contract clauses. In addition, the system provides a robust audit log, document version control, eSignature capability.

Able to reduce the average time required to get all contracts completed per study by 20-30%.
— Clinical Monitoring Manager

Enhanced Investigator Relationships

Reduce monitor visits due to increased site productivity. When sites are completing the same required start-up documents from scratch when they work on multiple studies with a sponsor, it unnecessarily adds work to the site that could easily be avoided. In addition, a manual, paper based site activation process increases the workload burden of the CRA who is largely responsible for collecting these documents from the site. This not only lengthens the time needed to activate a site, but also increases site monitoring costs. Startup InSite™ auto-generates contract and essential site documents with data from DrugDev's enterprise-wide database and distributes these documents through a secure portal that comes with complete task management so a site can easily manage their site activation "To Do" list. Investigators appreciate this approach, because it eliminates redundant data collection, reduces the time they spend on document completion, and accelerates study startup. This can also result in studies being completed more quickly.

The faster the contracts are complete the more quickly sites can be enrolling patients, moving the study along more quickly as well. — Clinical Agreement Manager

Increase site satisfaction. When sites have to manage the CTA negotiation and complete the site regulatory documents manually it can create a significant amount of administrative work for them, resulting in frustration at the site level, and causing them becoming less engaged. Startup InSite™ customizes these documents for the site and gives them a robust task management toolset, greatly reducing a site's administrative burden and letting them focus on enrolling patients and starting the trial.

DrugDev helps with the sites' perception of us as a sponsor. If we are seen as a sponsor that is easy to work with, who can be trusted to negotiate well and pay in a timely fashion, this can help with site engagement.
—Clinical Monitoring Manager

DrugDev
do more trials

Improved Budget Management

Reduce grant amounts negotiated with the sites. Without a quick and easy way to reference past site contracts/other industry benchmarks, determine fair market value, or access site specific cost information such as a site's current overhead percentage, it can be difficult to ensure the best rates are being negotiated. DrugDev's technology enabled business processes streamline the CTA negotiation process and reduce the number of escalations to the sponsor. Drug Dev's commitment to adhere to the budget parameters established with the sponsor as well as an in-depth knowledge of contract language and their legal implications, minimizes the number of escalations that occur for the same issues.

Have seen exception requests reduced from 50-60% of the time with CROs to less than 20% with DrugDev. — Vendor Manager

Improve overall study costs with better business intelligence. When CTAs are managed and stored separately for each study, it can be very difficult to get a consolidated and timely view of all negotiation history across the enterprise to spot trends, issues, and opportunities in the way contracts are being handled. Enhanced business intelligence leverages metric driven site selection, helping sponsors understand what sites are routinely requesting and how long it is taking to get them up and running, as well as providing enhanced document tracking with dashboards for sites, CROs, and sponsors to stay on course.

We can now easily see all of the data regarding what all of the sites are being paid, and feel comfortable knowing that they are being paid market demand rates, which helps with overall cost improvements. — VP, Development Operations

Strengthened Compliance

Increase transparency of clinical trial agreements and regulatory documents. When contracts and regulatory documents are handled by CROs it can be difficult to obtain an up-to-the-minute status of this critical start-up activity, as well as a clear view of any contract changes, making it harder to manage trials with confidence. DrugDev Startup InSite™ provides 24/7 access to a project dashboard that is updated in real time, giving sponsors unprecedented visibility into the activation status of investigator sites. Simply log into Startup InSite™ and access dashboard at any time for easy task management of escalated documents and real-time status updates of every contract, budget, amendment and essential site document.

There is a much greater comfort level now. We don't have to guess where contracts are at, as we get a regular status report from DrugDev with all of the data we need, giving us a greater level of transparency. — VP, Development Operations

Avoid fines/penalties for non-compliance. When contracts and essential site regulatory documents are handled manually it can be very difficult to track project and site information, key negotiated items and contract clauses, activation status, or ensuring the correct, compliant and current versions of essential site documents have been collected and reviewed. DrugDev maintains robust site profiles which eliminates negotiations in a vacuum, promoting consistency of terms with each site and ensuring that the most current documents are on file. Further, proven controls ensure payments are in accord with contracts, enabling compliance with SOX regulations and readiness for Sunshine and global aggregate spend reporting.

DrugDev is able to provide us with the justification for why the sites are being paid the amounts they are, which is critical to avoiding penalties from the various governing groups as we can now more easily prove compliance with things such as fair market value. — Clinical Monitoring Manager

DrugDev
do more trials

KEY ROI FINDINGS

The value of a contract and regulatory document management solution is immediate and demonstrable. A sample sponsor with the following study portfolio:

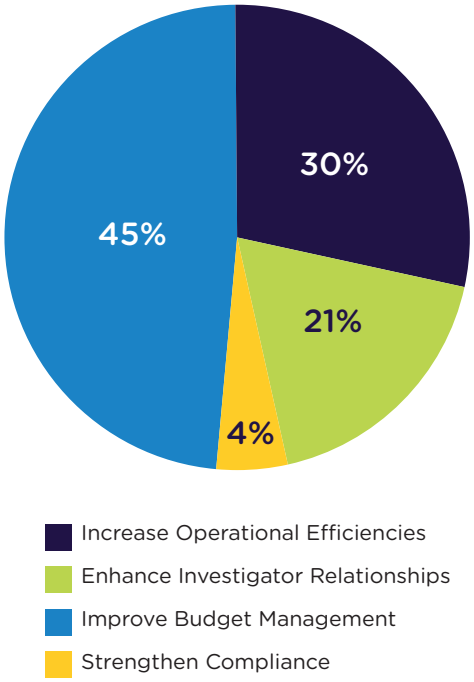
- 5 studies a conducted a year over a period of 5 years, and manages CTA negotiations and essential site regulatory documents internally
- Studies have an average of 140 sites participating sites, with 30% of the sites located outside of North America
- The average study length is 33 months,
- Average site costs are $10K per patient, start-up costs of $25K
- This sponsor can experience $4.6M in savings a year from improved budget management and increased operational efficiencies alone. With enhanced investigator relationships and strengthened compliance, annual benefits can be as much as $6.7M.
- For the sample organization, the three year investment totaling $5.0M generates a positive return in 4.4 months. The three year net present value (NPV) and return on investment (ROI) are strong at $8.8M and 218%, respectively. The key financial metrics for the sample organization were calculated by standard methods and are shown below.

Figure 1: Key Financial Metrics

FINANCIAL METRIC	3-YEAR VALUE
Payback (months)	4.4 months
NPV	$8,782,811
ROI	218%

The chart below shows the extent to which each value driver contributes to the total value of the contract and regulatory document management solution. For the sample organization, improving budget management and increasing operational efficiencies represent the majority of the value.

Figure 2: Benefits by Value Driver



DrugDev
do more trials

About DrugDev

DrugDev simplifies life at the clinical trial site through technology and services that enable sponsors, CROs and investigators to do more trials together. By providing study startup solutions, global payments by CFS Clinical, and a clinical trial optimization platform by TrialNetworks, DrugDev creates and drives standards to improve quality, shorten timelines and reduce cost. In addition, DrugDev maintains the industry's largest global network of opt-in sites actively seeking new trial opportunities, and serves as the third-party host of the pre-competitive Investigator Databank sponsored by Novartis, Janssen, Merck, Lilly and Pfizer. Learn more at drugdev.com

About Hobson & Company

Hobson & Company helps technology vendors and purchasers uncover, quantify and validate the key sources of value driving the adoption of new and emerging technologies. Our focus on robust validation has helped many technology purchasers more objectively evaluate the underlying business case of a new technology, while better understanding which vendors best deliver against the key value drivers. Our well researched, yet easy-to-use ROI and TCO tools have also helped many technology companies better position and justify their unique value proposition. For more information, please visit www.hobsonco.com

1 King Street, London, W6 9HR | uk.office@drugdev.com | +44 208 741 0918
1000 Madison Ave, First Floor, Audubon, PA 19403 | us.office@drugdev.com | +1 888 650 1860