



Site Contract Management from Syneos Health

Speeding Site Start Up with
Optimized Processes



Site Contracts negotiations can sometimes feel like they were designed to cause headaches. The best plans of the most experienced project trial team can quickly be tested by an unexpected budget dispute, an esoteric legal issue, or the absence of a seemingly mundane bit of site documentation needed to finalize some element of a site's clinical trial agreement. Worse still, the process of working to resolve an issue during site contract negotiations often seems to be an impossible task—with the right decision-maker or the necessary information just out of reach while precious time on a study is lost.

Contracts negotiation does take time as well, and unexpected issues do frequently limit how quickly the entire startup process can be completed. A delay in the contract management step can threaten to extend the timelines for activations across multiple sites. Since any delay in the startup phase can impact patient enrollment, it's no stretch to say that a misaligned approach to site contracts can jeopardize a team's ability to meet its study's milestones.

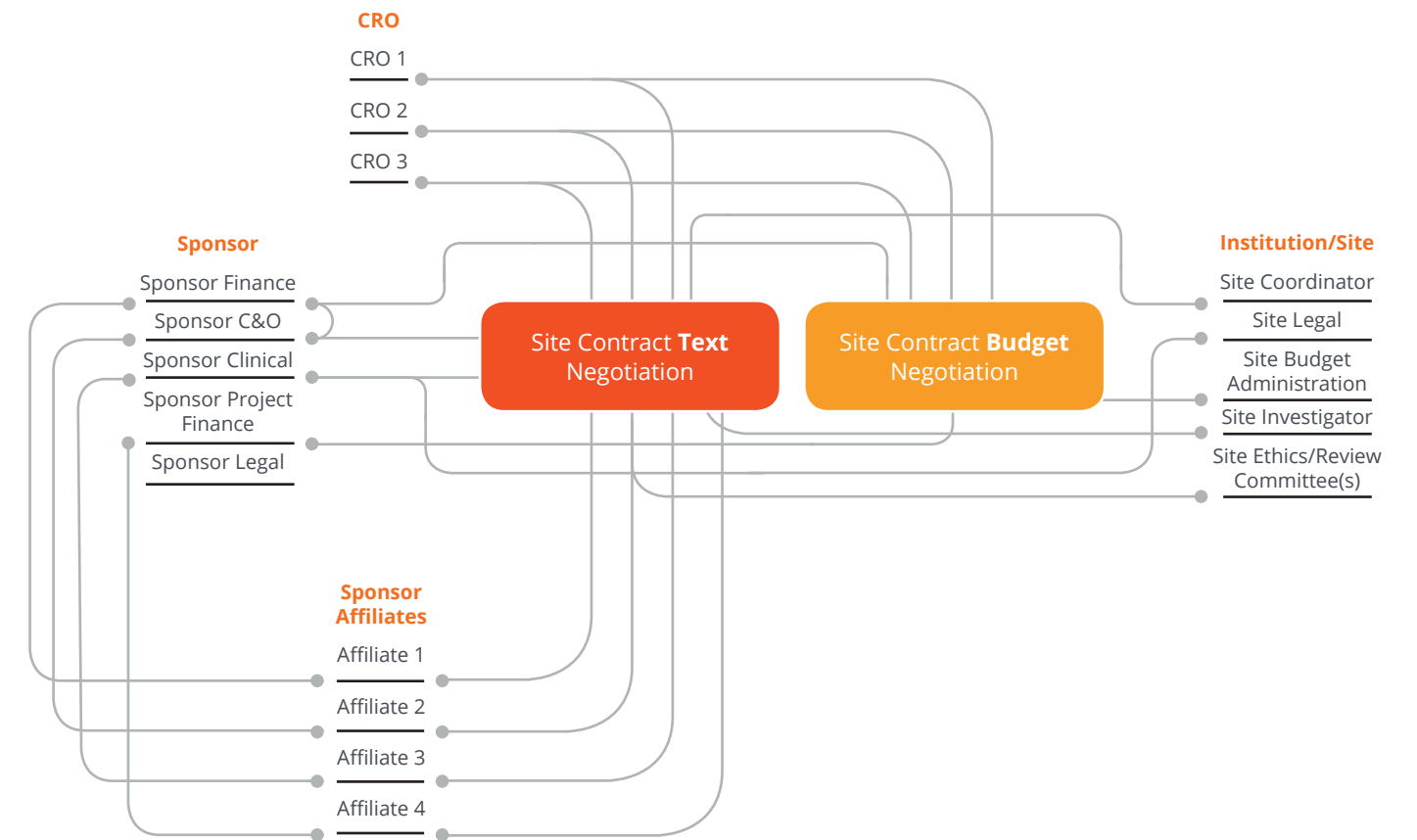
If the process seems cumbersome, then it might actually be. At Syneos Health, we know that negotiation of a site contract is a relatively simple process, which often has an

incredibly high number of unintentional complications. With multiple stakeholders requiring review, legal policies and risk profiles; as well as scientific committee reviews to navigate and escalation hand-offs for approval documentation—there is a wide range of sources where complications can arise during a negotiation. This is why so many Sponsors have entrusted Syneos Health to build a dedicated team with customized tools and processes to provide functional site contracts management services in alignment with their unique R&D strategies and needs. We can help to streamline negotiations and ensure that contract and budget executions are no longer the rate-limiting factor in how quickly patient enrollment can begin.

Contract Management: A Lengthy, Complex Process

Charting the workflows, interdependencies and steps involved in managing site contracts as part of the study start-up phase results in a “spaghetti diagram” that reveals the intricate process along with the thorough planning necessary for it all to run smoothly. (See Figure 1.)

Figure 1: The Inherent Complexity of Site Contract Negotiations



Underlying the need for all of these touchpoints and back-and-forth negotiations is the fact that the contract is a critical document for so many stakeholders in institutions and study sponsors alike.

From the protection of confidential information, to the liability of both parties, and the financial arrangements for the cost of the study's conduct, a clinical trial agreement covers all of the elements of the study, and the investigator's participation hinges on it. Hashing out the details of the contract involves:



Gaining agreement from multiple parties. Multiple disciplines from multiple entities are involved in discussing, reviewing and approving study contracts, such as financial, legal, clinical functions, study sponsor/site, Contract Research Organizations (CROs), ethics/review committees, among others.



Answering questions about the protocol. The contract's budgetary review is the first real test of the study design and the protocol itself. Sites interpret the activities outlined on the study from a financial perspective and ask for clarification, etc. This takes time and coordination between negotiators and clinical teams.



Negotiating over grant amounts. The vast majority of delays in gaining agreement on contract terms relates to negotiations over grant amounts rather than over other contract terms and legal language. Sites rarely accept the first offer that is made to them. Negotiations typically become very granular and nuanced as the site and sponsor work together to agree on reimbursement for specific procedures of the protocol (i.e., costs for procedures such as EKG or blood draw; costs for administrative duties such as record archiving, study set up, team training).



Having a global footprint for global studies. Managing contracts for global studies necessitates having "feet on the ground" in those countries where the study will be conducted. Negotiations can take place using the local language within the time zone and with knowledge of local conditions and practices.



Navigating the tensions between corporate and study-level concerns. Contracts contain elements that must be decided upon by various stakeholders (legal, financial and clinical), sponsors and CROs who may not be study-level staff. The staff assigned to the study site (who may or may not have legal/budgetary expertise), must then seek the same level of guidance from their internal stakeholders as compromises are sought. The availability and flexibility of the various decision makers increases the administrative complexity of conducting a negotiation.

Syneos Health's Site Contract Management: Success Factors

Syneos Health's contract managers can greatly improve the contract management process. This may seem counterintuitive given that the number of parties involved in contract negotiations adds to the challenge. However, because we are experienced in, and dedicated to, site contracting management, we have developed practices, tools and approaches to optimize the process. We know how to build consensus, accelerate the work through standardization and ease the administrative burden on decision makers.

Our approach to accelerating the site contract management process includes:

- **Establishing a playbook or "fallback document."** This lays out the sponsor's particular legal strategy behind specific contract language. It indicates areas where there is flexibility to compromise versus those that are non-negotiable, specifies the sponsor's fallback positions and indicates where the sponsor draws their "red lines." Having these parameters ironed out before we enter into negotiations on behalf of the sponsor reduces the number of escalations required to get approval for decisions. Consequently, it dramatically streamlines the process. Such a fallback document can be created after an in-depth discussion with the sponsor and is a hallmark of our Kick-Off process when establishing new Functional Service Provider (FSP) engagements.
- **Developing global standards and templates for legal text and budgeting.** Often negotiations with sites are conducted on an ad hoc basis, per study, but it is ideal to standardize certain contract elements and approaches across a company's portfolio. While there will, of course, be nuanced differences from one study to the next, there can be some standardization in tools, approaches and values used. This gives sponsors a consistent basis to manage agreements based within their own financial processes and risk profiles, and eliminates the need to establish new contract templates at the outset of a new study.
- **Referencing fair market value data.** Relying on data on the established fair market value for sites' work eases the process of creating study budgets and reduces the back and forth with sites over costs. Cost is the contractual item that sites push back on most often during negotiations. Building out a study's investigator grant budget based on objective data strengthens sponsor's negotiating position, and allows for a greater level of financial control across its portfolio.
- **Leveraging our geographic reach.** Relying on our global footprint of in-country negotiators allows us to retain local expertise, awareness of the regulatory environment and active site relationships to help drive negotiations and deliver agreements. Pairing that footprint with a team of Sponsor-dedicated study leads helps us to drive standardized portfolio-level policies, practices, tools and efficiencies to the local level in any region that a trial takes us. Finally, by centralizing appropriate high-volume tasks such as maintenance, amendments and review in near-shore low-cost centers reduces direct costs, standardizes quality controls and eases constraints by reducing workloads in the core delivery team.
- **Using technology to track progress.** A well-implemented site activation workflow management system allows our specialists to track progress and report to stakeholders on the sponsor and study teams with real-time, in-depth visibility into the negotiation's progress. Additionally, the ability to connect the site contracting process with the other parts of site activation is essential to a coordinated startup.

Contract Management Efficiencies: Dramatically Reduced Contracting Times

In turning to Syneos Health to manage contracts, a sponsor can realize a number of significant benefits, starting with reduced contract negotiation timelines.

On a portfolio level, implementation of our methodologies has allowed sponsors to beat their targeted industry benchmarks for median negotiation cycle times by as much as 36 percent.

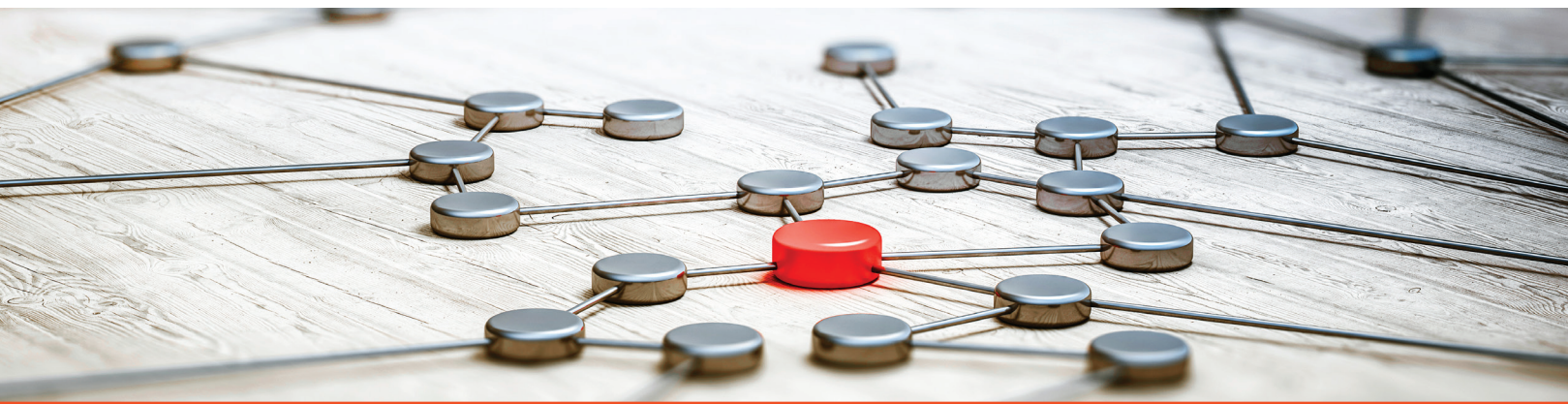
By reducing contracting startup timelines by several weeks, the work stream can be removed from the critical path of startup activities; in other words, contracting will no longer be the process that dictates how long startup will take. This has a significant cost benefit, as it is well established that every day of delay in getting a product to market represents a loss of opportunity cost in the millions. Other savings—both direct and indirect—can amount to about 45 percent of contracting costs over time.

Just as with FSP arrangements in other functional areas, the practice offers staffing flexibility to adjust resources up or down, depending on needs. Syneos Health provides access to a wide pool of experienced, trained professionals who provide coverage across therapeutic areas, time zones and geographies for scalability as needed.

In standardizing processes and streamlining the back and forth of negotiating we can reduce the burden on the sponsor's legal team, which may not be staffed to accommodate negotiations with hundreds of sites across multiple studies. At the same time, management oversight is minimized as our expert teams can be trusted to proceed under established guidelines, and use efficient and effective systems and processes.

A frequently overlooked benefit is that by improving the contracting process, sponsors can improve their relationship with sites, as contract negotiations are often the site's first experience with a sponsor. Inefficiencies can cause frustration at sites affecting the sponsor's long-term image with the site. A study published in the *Journal of Clinical Research Best Practices* suggests that this is an area ripe for improvement. The study found that sites rated seven of the world's leading pharmaceutical companies as only average on "turns clinical trial agreement drafts around quickly." On a scale of 1-5 (five being the highest) scores ranged from 2.20 to 3.05.

Source: Goldfarb, Norman M, "Site Ratings of Sponsors and CROs," *Journal of Clinical Research Best Practices*, July 2019, Vol 15, No 7.



The FSP Maturity Model: The Relationship that Keeps on Giving

Working with Syneos Health to develop a scalable, global site contract management solution is a process that typically evolves in phases over a number of years as trust and familiarity grow between both parties.

Once engaged, Syneos Health can immediately reduce the sponsor's direct costs (labor) by approximately 25 percent. As the relationship matures, we can achieve substantial indirect savings by centralizing tasks, aggregating delivery across functions, streamlining work flow, improving processes and even potentially using low-cost centers when appropriate. These steps can realize an additional 20 percent savings, on average, for a new cost basis of 42 percent to 48 percent of the original. (See Figure 2.) While it's notable that achieving this level of savings can take eight to 10 years, the pace of advancement along this maturity curve is primarily driven by the sponsor's appetite for change, rather than by our capabilities.

Figure 2: Value Creation as an FSP Relationship Matures

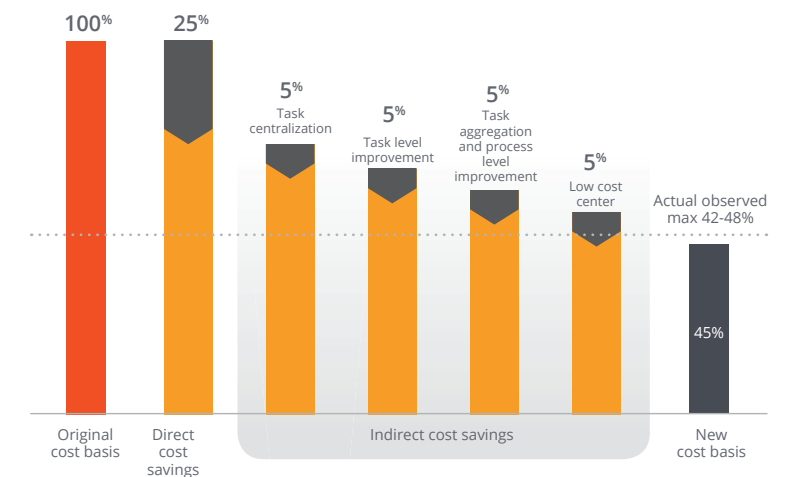
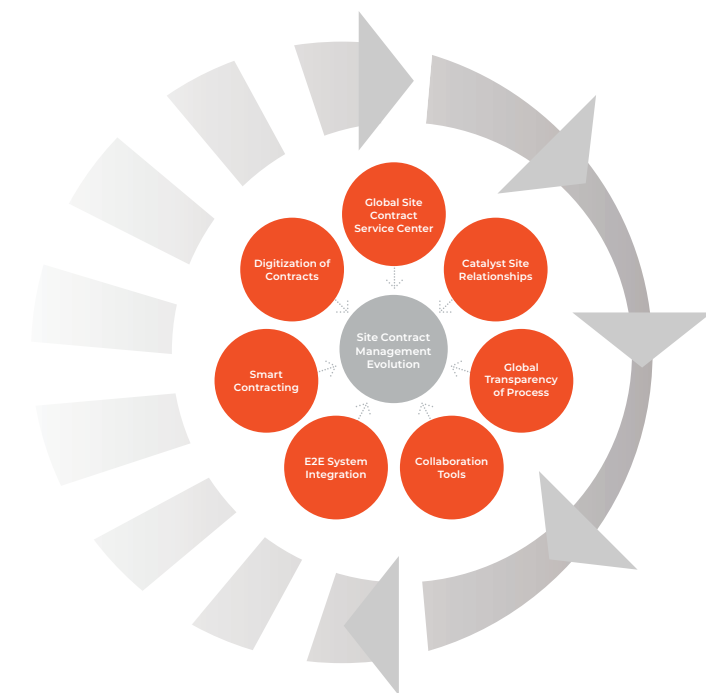


Figure 3: The Evolution of a Scalable Site Contract Management Solution



Establishing a Functional Service Provider Relationship: Start With a Strategic Fit

The overarching focus in establishing a functional service provider relationship should be “strategic fit.” The FSP’s tools, processes and governance should be aligned to the company’s business and development goals, and should reflect the sponsor’s fundamental values and operating principles. The FSP will be representing the sponsor in negotiations, so it is important that the sponsor’s overarching strategy be captured in the FSP’s approach.

At Syneos Health we can ensure this alignment by providing:

- **Dedicated support.** A relationship manager/subject matter expert dedicated to a given business unit with a specialized team devoted to contract management gives the sponsor a key contact who is intimately familiar with the sponsor’s processes and needs.
- **Global footprint.** Contract negotiations take place locally, so it is important to have resources in place wherever trials are being planned. Also, access to talent in low-cost regions is key to realizing the full cost savings potential.
- **Feedback from experience.** A structure can be put in place to capture lessons learned that can drive process improvement across the portfolio. For example, as a sponsor’s legal team makes decisions, we can capture those decisions and review them regularly to be incorporated into a living guidance document. This allows the FSP to represent the sponsor’s legal position with increasing precision over time.
- **Metrics-driven performance.** We track Key Performance Indicators (KPIs) that are jointly established at the beginning of the project to objectively inform FSP governance and shape the relationship for the better over time.
- **Strong workflow management.** This provides visibility to real-time updates on project status, standard templates with the flexibility to be modified as needed, as well as fit-for-purpose software modules to compile, submit, review and track documents.
- **A culture of continuous improvement.** The potential cost savings can only be achieved when the FSP is committed to continuing to find ways to improve the service. Tracking performance and learning from the data is a big part of this.
- **A governance structure.** Our high-performing FSP relationships have regular (at least quarterly) operational meetings to resolve issues, drive process improvement and record lessons learned.

Getting Started: How Best to Work Together

The extent to and pace with which a sponsor turns to professional contract managers within Syneos Health should, of course, match the sponsor’s business strategy, needs and capacity for change. Often, sponsors elect to start in one therapeutic area with the support of Syneos Health liaisons who are therapeutically aligned. Over time, as trust grows and we develop guidance and establish processes, these solutions can be expanded to other therapeutic areas.

An FSP’s KPIs should be built into the structure of the relationship at the outset to ensure that governance can shape processes based on the needs of the sponsor’s organization. If a sponsor’s primary concern is driving consistency and controlling investigator grant spend across therapeutic areas, then the governance should track average negotiated per-patient amount as a percentage over template offered, or average study budget amounts within FMV benchmarks. If the sponsor wants to focus on streamlining legal review timelines, then the percentage of negotiated budgets escalated for sponsor review, or average escalation turnaround times, should be tracked. There is very little that a dedicated FSP team Syneos Health cannot track, but in order to be impactful within the relationship, KPIs should be identified from the outset and structured around a sponsor’s goals.

Whatever shape an FSP engagement takes, the approach adopted should follow all of the best practices of change management, including developing and communicating a vision, getting buy-in from all parties, communicating the value of the change, measuring results and providing feedback on those results. We have the experience to plan that implementation process, the flexibility to fit it to a sponsor’s unique needs and the discipline to execute it with care.

Our metrics-driven approach begins with a delivery plan, uses best-in-class project management methodologies, proactively manages risk and embodies the principles of continuous improvement to deliver faster results.

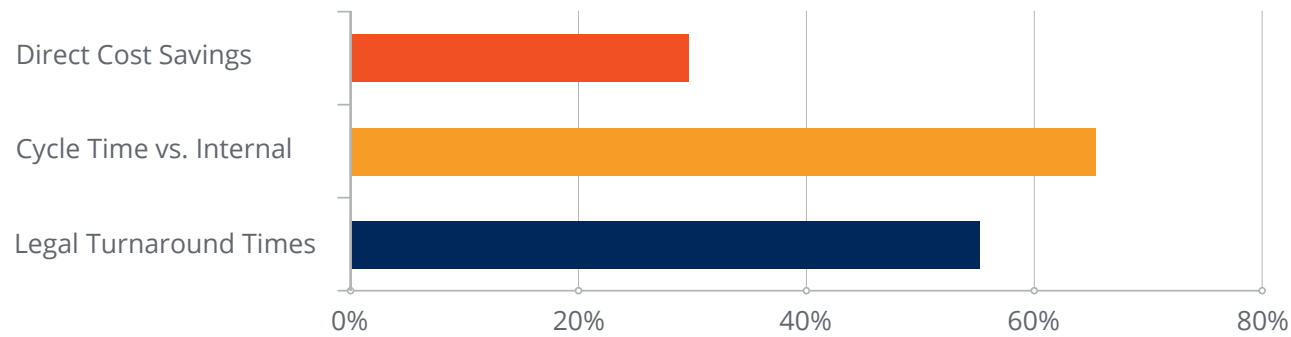
As they embark on an FSP arrangement for contract management, sponsors should:

- **Know their organization’s needs.** Contracting decisions need to fit within a sponsor’s broader risk profile so that the organization’s focus remains on what is important, while lower-risk decisions can be delegated to a contracts team that is appropriately aligned with the sponsor.
- **Be prepared to balance the need for speed with the need to manage the budget.** Determine which contract elements pose the highest risk and concentrate on those. For example, it might not be worth it to delay startup by two weeks while hashing out the cost of one procedure within the protocol.
- **Be amenable to standardization.** Much of the time and cost savings to be realized come from standardizing contract elements and approaches across a company’s portfolio.

A Case in Point: Mid-Sized Global Pharma Improves Legal Team's Efficiency

One mid-sized biotech company's legal team was unable to devote the necessary resources to keep up with the demands of overseeing contract negotiations. The function became a bottleneck in the startup process. Syneos Health built a dedicated contract management team, operating in an FSP model for the company. Our team organized the company's risk profile and legal positions within guidance documents, which reduced the volume of questions that were directed to the legal team. And those that were referred to legal were further along in the process toward a suitable compromise. As a result, only 15 percent of negotiation issues were escalated to the sponsor's lawyers, and their turnaround time was reduced by approximately 56 percent, to less than seven days. This also led to a 66 percent improvement in negotiation cycle times over the first three years of the engagement.

Improvement Over Historical Sponsor Performance

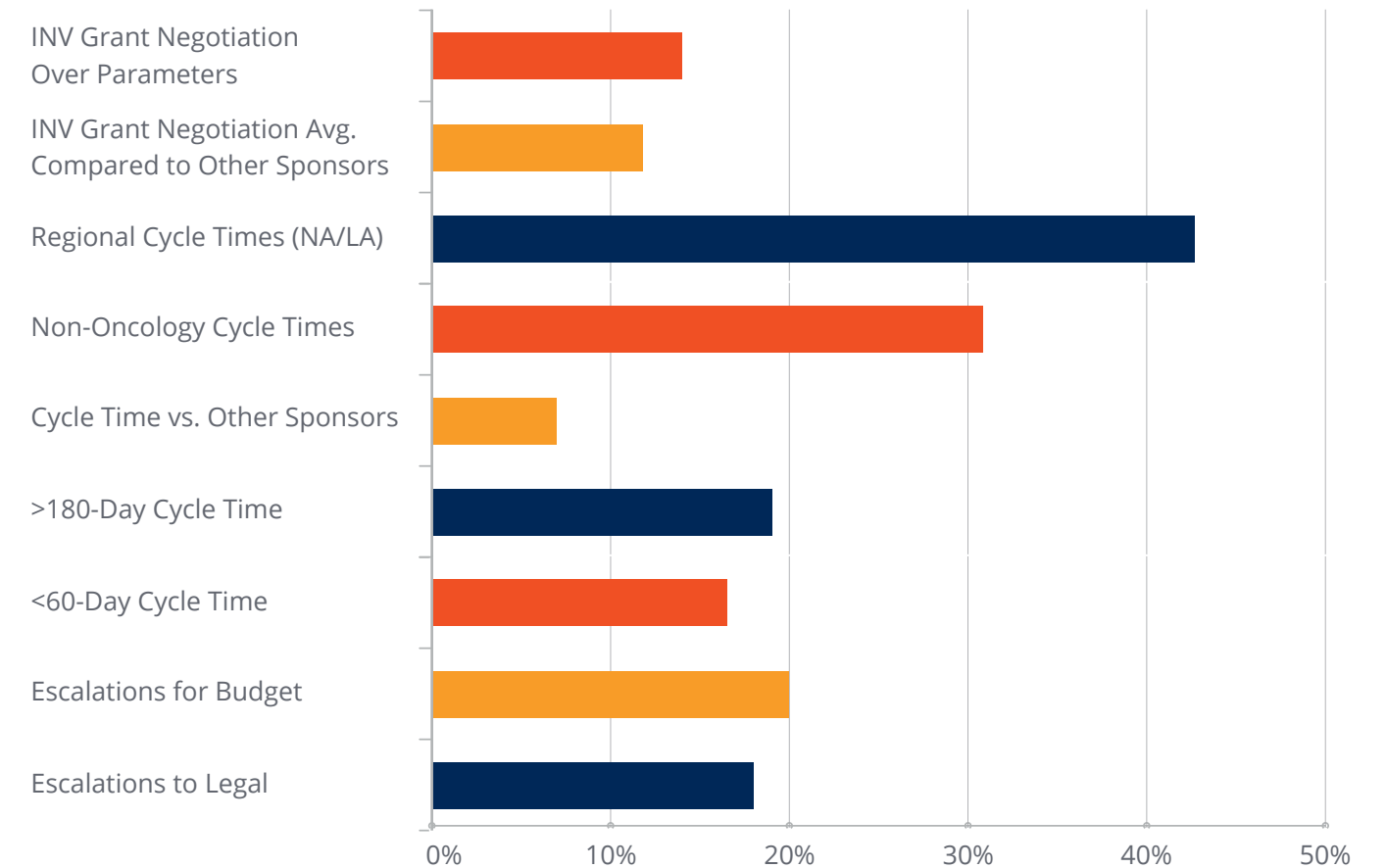


A Case in Point: Global Coverage Delivers Direct and Indirect Cost Savings

In an ongoing engagement with a top-tier pharmaceutical company, Syneos Health's site contract management team focused on streamlining the decision process that is part of site negotiations. By developing comprehensive guidance documents and fallback positions with the client, we were able to reduce the individual instances in which decisions on legal or budgetary matters were escalated. This resulted in:

- A 17 percent reduction in the number of issue escalations to the legal department
- A 25 percent reduction in the number of escalations on budget matters
- Doubling the number of contracts that were settled within 60 days
- A 32 percent drop in the cycle times for the general medicine portfolio

We consulted benchmark pricing to help establish the parameters for offers to sites. Through our subsequent negotiations with sites, we were able to reduce the number of grants that exceeded those parameters from 26 percent to 11 percent.



The Syneos Health Site Contract Management Solution

Syneos Health has pioneered serving as an FSP to the industry, and has amassed significant expertise and experience in performing site contracting successfully across therapeutic areas and geographies. Our clients—who are in the industry's top tier—have been with us for an average of six years, attesting to the long-term nature of these relationships and the ongoing benefits they deliver.

Our solution is not merely a staffing resource that provides personnel to supplement your own resources. Rather, our site contracting management solution draws upon the expertise of a dedicated team of specialists in site engagement to guide the entire process. We consult with you on strategy, help you develop a playbook for negotiations, handle escalations and continually work to improve procedures and results.

The Syneos Health Solution



Faster startup times



Cost savings of around 45%



Reduced burden on the legal team



Reduced oversight



Improved site relations



Flexibility and scalability

600+
Specialized
SMEs

Over **600** specialized site contracts experts in our global footprint

110
Dedicated
FTEs

Over **100** FTEs supporting dedicated Site Contracts FSP engagements

Historically, gaining a signed contract and agreement on a budget with sites has limited how quickly the startup phase of clinical trials can be completed. **Syneos Health specializes in this work and brings practices, tools and approaches that will speed contract negotiations so that sites can be activated sooner.** Sponsors will realize cost savings from speeding the development cycle, as well as from operational efficiencies created by dedicated, external resources. The arrangement will also reduce the burden on the sponsor's legal team and create a positive image of the sponsor with sites. Sponsors should select their FSP provider carefully as the arrangement yields the greatest benefits if allowed to mature over several years.





About Syneos Health

Syneos Health® (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are **shortening the distance from lab to life**® at syneoshealth.com.