



The guide to a successful CRO partnership

WHITEPAPER

SGS

Abstract

Outsourcing is becoming increasingly popular in the pharmaceutical and biopharmaceutical market, both as a way to reduce operational costs and to gain access to therapeutic trial expertise. Contract Research Organizations (CROs) have evolved into a multibillion-dollar market that loyally serves the pharmaceutical and biopharmaceutical industry, academia, and research and development organizations. A successful sponsor-CRO relationship relies heavily on communication and relationship management to ensure a shared vision is molded and adhered to. An overly casual approach to such a relationship can have adverse effects, reducing efficiency and the speed at which the project is completed. Partnering with the right CRO is therefore a fundamentally important step toward success. In this whitepaper, “The guide to a successful CRO partnership”, we discuss the array of benefits a partnership with the right CRO provides you.

Introduction

Pharmaceutical and biopharmaceutical companies are under immense pressure to transform life-changing scientific research into new treatments, all whilst reducing operational costs and improving efficiency.

Studies suggest that strategic partnerships between drug developers and CROs can significantly reduce the time it takes for a drug to get to market – by up to 30%. Whereas in the past sponsors would look at “hiring” a CRO, over the past decade, CROs have developed and evolved from just being vendors to collaborators. Although the sponsors still “hire” CROs, the valued work is obtained through a cooperative partnership.

The structure of CRO/site-sponsor partnerships is diverse, and success has been mixed. Many pharmaceutical and biopharmaceutical companies struggle to ensure that these partnerships are beneficial despite investments and commitments.

Setting up a mutually beneficial sponsor-CRO partnership can be difficult and requires a build-up of trust, consistency and a commitment to a certain volume of work – a trio of traits many struggle to perfect.

This paper looks at the benefits of partnering with a two-in-one site and CRO such as SGS Health Science. We describe a framework that can be used to improve our relationship with future sponsors and help sponsors navigate through the array of services we provide to ensure the efficient running of their trial(s).



Benefits of a partnership with the right CRO

The benefits of engaging in a strategic partnership with the right CRO are vital to ensuring optimal performance. In turn, optimal performance translates into resource and trial efficiency, cost reduction, and most importantly, a successful study. When a partnership is successful, both parties benefit from a range of outcomes.

The best way to maximize the benefits of the partnership is by ensuring effective communication and transparency – sharing ideas and knowledge to achieve the desired results.

At SGS, we promise you a partnership that will benefit you in a number of areas:

1. Preparation

Preparation is the most time-consuming phase in building a clinical trial but is absolutely critical. And it is also key when partnering with a CRO or Clinical Pharmacology Unit (CPU). For sponsors, preparation allows time to understand and implement the expertise of the CRO into a trial, whereas for a CRO, preparation is essential with a view to understanding the goals, limitations and expectations of the sponsor. Sponsors want a cost-effective, efficient trial, and they must share their “wants” with their new partners. It has been noted that certain sponsor-CRO partnerships turn sour because of misaligned expectations. We believe that the best way to align expectations with partners is through transparency. Transparency allows sponsors to understand the ability of the CRO to meet expectations. Sponsors can learn about the site, the team of experts available and how the team utilizes resources to efficiently carry out trials.

Trust is another crucial factor that determines a collaboration’s success. Trust grows slowly over time when both parties demonstrate the right intentions, communicate effectively and achieve positive results. The more trust between partners, the faster the process will be. Early positive results increase trust within partnerships. In turn, this benefits future trials.

The current molecule market remains stagnant, but the number of molecules in development continues to increase, creating significant productivity challenges that can be overcome with a strong, strategic CRO partnership. By strictly adhering to local guidelines and implementing knowledge and resources obtained from previous trials, we will work with you to fulfill your business needs.

2. Protocol discussions

Gathering feedback from ethical committees and health authorities from previous trials is crucial with a view to ensuring that all variables, especially if missed in previous trials, are implemented in current work. In a partnership, these past experiences can be used to adapt new protocols. This reduces the risk of receiving a non-approval. For instance, inclusion and

exclusion criteria that caused issues in earlier trials can be rediscussed with the data from these trials. We’re here to help you get from molecule to market in an efficient, timely manner. We implement adaptations to speed up the process whilst maintaining operational feasibility.

3. Operational tasks

Each trial uses its own tests and equipment to ensure trialists' safety and meet pharmacological objectives. Therefore, clinical study teams must usually hold separate discussions for each new trial to determine what's required and whether this is feasible. When working in a partnership, however, the same tests and equipment can be used for multiple trials. Training can be a one-time activity – once the staff has experience conducting one trial, they can use these learnings going forward. The same principle applies to devising communication plans, risk management plans and monitoring plans, as well as setting up project reports. No longer will clinical study teams have to develop these from scratch when beginning each new trial, thereby increasing efficiency and minimizing hassle. We have the necessary resources already in place.

Clinical trials are complex exercises that rely on consistency, time management and equipment to run efficiently. We are consistent with the couriers, vendors and equipment we use. Consistency leads to fewer errors and more efficient work. However, we are flexible and will adapt to using other equipment if desired by the sponsor.

CROs should have a quality system that documents processes, procedures and responsibilities for carrying out trials. A relationship with the right CRO promises a team of competent staff who have a great knowledge of the applicable Standard Operating Procedures (SOPs) designed to improve safety, quality and efficiency. As our partner, you can familiarize yourself with these SOPs and better prepare for your next trial's operational requirements.

4. Monitoring activities

Communication and collaboration are key in every partnership. The better you get to know each other, the greater the likelihood that the project will be a success. Fortunately, in a partnership, you generally work with study teams with whom you've previously collaborated. The monitors know the sponsor's expectations and have acquainted themselves with

how the CPU operates. Therefore, they can raise appropriate queries or flag potential concerns, have a better understanding of the timelines involved and can easily discuss issues with the right members of staff. This is a win-win for both parties, increasing efficiency and reducing confusion.



A supportive, clinical partnership

At SGS, we go beyond the norms of a clinical partnership to tackle the ever-increasing obstacles to transforming discoveries into marketed drug products. We do this by offering a clinical, yet supportive partnership. We are a team of problem-solvers, innovators and managers that care about your passion, and strive to meet (and exceed) your expectations.

1. Standardization

Once both parties have reviewed and approved the necessary study documents up front, they can then begin the project. This is perhaps the easiest step in the entire partnership. While it seems like a no-brainer, its importance can't be stressed highly enough – the process outlines critical next steps regarding the study set-up, conduct and close-out. Standardizing documentation (on the project, risk management and monitoring and communication plans) helps to build efficient and interoperable networks that are capable of producing high-quality, safe and reliable data, and streamlining workflow by allowing data to be accrued in a quick, timely manner.

Standardization contributes massively to a trial-specific process. Documents we help you to standardize include the:

- **Risk management plan** – to identify, assess and prioritize risks to mitigate and control any events should they occur
- **Monitoring and project plan** – to identify responsibilities, determine who to contact in the event of safety issues and ensure compliance with the protocol, GCP, regulations and policies
- **Communication plan** – to provide specific communication guidelines for issue escalation and strategy

2. Transparency and realistic expectations

Many typical sponsor-CRO relationships fail to go beyond the transactional nature of the business. However, many sponsors are turning to the world of partnerships with CROs. These partnerships, as mentioned above, are not based on just fee-for-service approaches, but rather offer services, governance approaches and operational integration to ensure long-term commitment and success.

One attribute of these strategic partnerships is transparency. By being transparent, both parties can acknowledge and leverage their differences instead of being hindered by them.

This allows for a set of well-defined SOPs to be put in place, which enhances the trial process' efficiency and trust.

Transparency also allows us to set realistic expectations throughout the life of the study or program. By setting realistic expectations, the CRO and the sponsor can maintain oversight of any trial-related duties, critically review and query interim monitoring reports, and document this review and monitoring process to ensure smoother operation for the future.

3. Master service agreement

A master service agreement between you and the selected CRO is an overarching legal document that establishes the obligations and services expected of both parties in the relationship. This agreement can not only be tailored to trial-specific needs through a work order, but can also allow you to focus on your team, budget and time, as well as address the following:

- Setting out the scope of the parties' activities
- Compliance and compensation obligations
- Call of duty upon a cancellation
- Confidentiality agreements
- The services you want the CRO to provide

Governance strategies

Shared values and objectives, as well as a high level of trust between partners, are critical to the success of a partnership. Once an expectation has been set, additional aspects of an operating strategy can be defined to allow for the smooth running of a process:

- **Key performance indicators (KPIs)** – certain goals and metrics can be used to drive optimal performance. By working with a project manager to set up predefined KPIs as a method of incentivizing efficient work, we can help ensure your project meets business needs.
- **Lessons learned** – a biannual review will be carried out on a continuous basis to identify improvements for the future and to track issues (such as identifying new regulations and adapting current trials to work in accordance with the new regulations).

True partnership

Given the complex nature of clinical studies, sponsors are routinely stretched when it comes to resources. Thus, being transparent and upfront about your expectations prior to the trial can allow you to focus on the added value, we identify how we can exceed your expectations, and most importantly, develop a long-term relationship built on trust and knowledge.

A sponsor-CRO relationship can be rich and rewarding if it is properly established. It can not only produce time efficiencies, but can also facilitate higher-quality data delivery and cost savings. However, these things aren't guaranteed. Both parties must set clear expectations and adhere to the following elements of success:

1. **Communication** – clinical research is incredibly complex, and so good communication between the sponsor and CRO is essential in order to ensure the effective running of the trial. Having a good communication plan that incorporates roles, responsibilities, governance and escalation is crucial for fostering better collaboration.
2. **Pivoting** – identify any issues that may occur during the trial, pivot as soon as possible and tackle the problem.
3. **Consistency** – consistency begets confidence. By being consistent, we highlight the efficiency of our system of operation and build rapport with sites and sponsors.
4. **Trust** – trust allows for true collaboration. Strong trust leads to a higher-achieving environment and allows both parties to feel comfortable with one another.



In summary

The past couple of decades have seen many failed partnerships within the pharmaceutical and biopharmaceutical industry. Sponsors have a choice: They can continue to establish merely transactional relationships with CROs which achieve, at best, mixed results, or they can look to the future and establish a strategic partnership with a CRO that embraces the values of trust, communication and consistency such as SGS Health Science – a collaboration that could be the start of a mutually beneficial long-term relationship.

The role of SGS Health Science

As a mid-sized CRO, we are involved during all aspects of a clinical trial (phase I-IV). We pride ourselves on our end-to-end clinical trial management system, and our status as a trusted partner for biometrics, translating complex clinical trials into drugs for the market.

SGS takes sustainability very seriously; we always ensure that our processes are environmentally friendly. We have established a governance hierarchy to allow us to deal with issues at the appropriate level. Project managers are able to report any issue at a project level to their program managers, who would then establish whether or not the issue can be resolved without further escalation.

Most heads of department are at a functional level and focus on workload, work division, and understanding the framework of your program. They can tackle any issues escalated by the program managers. If they cannot resolve the issue, it is further escalated to the executive level.

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