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Selecting a contract type between the sponsor and CRO in clinical trials projects

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Abstract: Clinical research projects of new pharmaceuticals sponsored by pharmaceutical companies increasingly rely on Contract Research Organizations (CROs). CROs are becoming the primary long-term partners of the sponsors. The correct choice of outsourcing type significantly influences project motivation and success, yet it can also be a substantial risk factor and cause.

Keywords: project management, risks, communication, budget.

Introduction

Clinical research projects are conducted according to strictly regulated industry rules or standard operating procedures of organizations. This often results in the approved form of the contract or Master Service Agreement (MSA) remaining unchanged from study to study. The created and approved budget is often incorporated into this form without consideration of the project specifics, stakeholders involved,

or significant risk factors that may emerge during budget development. Communication among stakeholders can become routine as a result, potentially leading to more significant project risks.

Analysis of recent research and publications

The article utilized the clinical research industry standard ICH. Guideline for good clinical practice E6(R2) (ICH GCP E6(R2), 2016). Types of outsourcing, types of contracts, and risks associated with each type of contract are described in John R. Vogel's work (Vogel, 2007). The specifics of budget formation were studied based on "Outsourcing Clinical Development: Strategies for Working with CROs and Other Partners" by Jane E. Winter and Jane Baguley (Winter, Baguley, 2006).

Formulation of the purpose

The aim of the following work is to study the process of forming Master Service Agreements (MSAs) and budgets for clinical research projects, as well as the risks associated with careless budget formation and insufficient communication among stakeholders.

Research Results

The essence of CRO outsourcing is that the Sponsor transfers some or all project activities related to conducting clinical trials to the CRO. This approach minimizes fixed costs and eliminates the need to acquire expensive expertise when entering a new therapeutic indication. Depending on the volume of activities delegated, John R. Vogel identifies 3 types of relationships between the Sponsor and CRO (Vogel, 2007):

- Tactical outsourcing
- Project outsourcing
- Strategic outsourcing

Broadly speaking, these strategies differ in the volume of work that the sponsor delegates to the CRO. Within this list, Project outsourcing entails the largest volume, whereas Tactical outsourcing involves a smaller amount. Additionally, Tactical outsourcing is more commonly applied in later stages of research. Strategic outsourcing represents something in between.

At the stage when the sponsor has already chosen a partner to conduct the research, the project team of the CRO will need to create a budget that will serve as the basis for the contract or MSA, as well as determine the type of contract. The book describes 4 types of contracts between the Sponsor and CRO:

1. Fixed price – fixed fee for a specific scope of work throughout the entire project.
2. Fee for service – payment for time spent by a specialist. FTE (Full-Time Equivalent) - CRO and the sponsor agree, determining the cost per hour of the specialist's work, and CRO periodically invoices for the work performed.
3. Fixed unit-base price – also known as Functional Services Provider (FSP), the sponsor requests a certain number of specialists to perform tasks in various areas such as selection, initiation, closeout, monitoring, and site management. CRO and the sponsor agree, determining the cost per unit.
4. Fixed unit price–milestone/deliverables based - CRO and the sponsor agree on milestone achievement criteria. Payment for services rendered occurs upon reaching milestones.

It should be noted that currently there are also hybrid forms of contracts. Thus, the project manager at the CRO must select the appropriate type of contract for the study and be prepared to provide justification

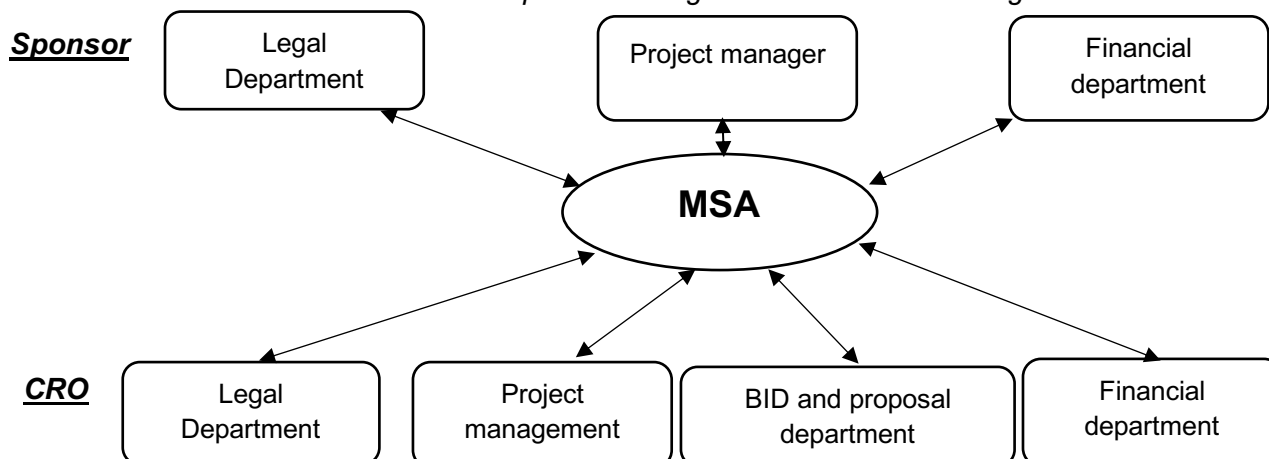
for why such a contract would be the best solution for the project. They should also draft the future MSA budget with details of the required number of FTEs for service tasks. It is important to consider that the budget includes direct costs of the services provided by the CRO, specifying the resources allocated to tasks, as well as indirect costs, which are expenses not directly related to the services, and third-party expenses. Therefore, drafting the budget entails multi-level communication both within the CRO and externally with vendors. It is in the best interest of all stakeholders not to neglect such communication, and an ideal solution would be to document everything possible—email correspondence, minutes of online meetings. Additionally, this is the optimal time to analyze risks within the team, as it will prepare them for negotiations with the sponsor. It is also important to consider that each type of contract, alongside its advantages, carries specific risks for both the sponsor and the CRO during the negotiation stage. Here are some of them:

- ✓ Discussion of the contract can be lengthy—sponsor and CRO project and financial teams face challenging negotiations regarding checkpoints, payment schedules, scope of work, and resources. This risk applies to fixed-price, fixed-unit-price milestone/deliverables-based, and fee-for-service contracts.
- ✓ Research often begins without a signed MSA, which can be a separate risk, particularly disadvantageous for the sponsor, putting them in a weak negotiating position—until key time points are established, CRO may not be in a hurry, whereas time is key for the sponsor. Applicable for fixed-price, fixed-unit-price milestone/deliverables-based, and fee-for-service contracts.
- ✓ Quantitative, qualitative, and temporal changes to services during the project, if any occur. Conditions under which prices, milestones, or other time points may be revised and other factors should be considered. Again, the sponsor finds themselves in an unfavorable negotiating position, as the updated contract discussion must consider CRO interests to avoid motivation loss and subsequent quality loss. Applicable for fixed-price, fixed-unit-price milestone/deliverables-based, and fee-for-service contracts.
- ✓ For fixed-unit-price contracts, motivation loss looks different—such a contract typically does not allow for service unit price changes, which is a major demotivating factor for CROs. It makes sense for the sponsor to consider specifying a bonus in the contract for timely completion of tasks.
- ✓ Possible changes and objective risk factors dependent on sponsor responsibility zone are rarely stipulated in the contract. For example, delays in decision-making, document revision needed for significant protocol amendments submission, which can lead to milestone delays. Not addressing such risks in the contract may lead to conflicts during the research process.
- ✓ For all types of contracts, there is always a relevant risk of out-of-scope activities - what happens if CRO performs more work than planned or provides a service not specified in the specification.

At the final stage of preparing the draft, the Project Manager will need to discuss it with lawyers and financial experts to eliminate potential risks. From a financial perspective, it is noteworthy that budget formation by the Project Manager has a significant characteristic. Winter, Baguley, 2006 highlight that the Project Manager has limited maneuvers to make the study more financially attractive for CROs because the main service units or cost drivers, such as monitoring and site management, will already be defined by this stage, often being key factors in CRO selection. Therefore, it is crucial not to make mistakes in calculating these services and also to include all additional, less significant services to ensure project profitability. In this case, the assistance of a financial specialist can be decisive [Figure 1].

Figure 1

Communication scheme between CRO/Sponsor during clinical trial contract negotiations



Source: author's own development

Conclusions

Ideally, communication and discussion of the future MSA between the sponsor and CRO teams should occur in an atmosphere of trust and openness. Both parties should be prepared to discuss the most sensitive issues and have a list of potential risks in conditions of significant uncertainty to avoid misunderstandings and distrust during the project.

To avoid nasty surprises, the sponsor should try to put themselves in the CRO's shoes, understanding factors that could negatively impact motivation, discussing them openly, and exploring with the contract organization how motivation could be fostered and formalized in the MSA. A system of bonuses and penalties is a suitable tool to mitigate this risk. For the CRO, thorough preparation for negotiations, expertise from relevant departments, and the involvement of lawyers and financial specialists are crucial. It's important to avoid making excessive promises but to have a list of risks identified by the first-hand experience of relevant departments and vendors. Each clinical research project is unique, so both parties should avoid simply filling out an existing contract draft. Instead, they should discuss and include in the MSA as many significant details as possible, such as out-of-scope activities, time and conditions for contract revision and reconciliation, responsibilities for non-performance or avoidance of liability due to reasons beyond the agreement's control.

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