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ДОГОВІРНІ МЕХАНІЗМИ УПРАВЛІННЯ РИЗИКАМИ ПРИ ВЗАЄМОДІЇ СПОНСОРА/КДО У ПРОЄКТАХ КЛІНІЧНИХ ВИПРОБУВАНЬ

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CONTRACTUAL MECHANISMS FOR RISK MANAGEMENT IN SPONSOR/CRO INTERACTION IN CLINICAL TRIAL PROJECTS

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Анотація. *Метою роботи є комплексний аналіз договірних механізмів ефективного управління ризиками у взаємодії між спонсором та контрактною дослідницькою організацією (КДО) у межах проєктів клінічних випробувань (КВ). Особливу увагу приділено порівнянню переваг, недоліків та потенційних ризиків двох домінуючих моделей аутсорсингу - Full Service (FS) та Full Service Provider (FSP), включно з їхніми підтипами та практичними аспектами застосування.*

Дослідження виконано на основі системного огляду сучасних наукових і професійних публікацій, даних галузевої статистики та ринкових звітів, зокрема дослідження Tufts CSDD/ICON, аналітики Contract Pharma, Applied Clinical Trials та інших джерел. Проведено детальний розбір варіантів моделі FS (Fixed Price, Fee for Service, Fixed Unit Price-Based, Fixed Unit Price-Milestone) та моделі FSP із урахуванням фінансово-правових інструментів, ключових положень документа Statement of Work (SOW) та системи ключових індикаторів ризику (KRI), які забезпечують ефективний контроль і своєчасне коригування умов співпраці.

Моделі FS відзначаються гнучкістю у формуванні фінансових зобов'язань, але вразливі до ризиків затримок та конфліктів мотивацій сторін. Модель FSP демонструє вищу економічну ефективність, довгостроковість взаємодії, можливість швидкого перерозподілу ресурсів між проєктами та глибшу інтеграцію процесів, але може стикатися з проблемами подвійного підпорядкування персоналу та зниженням мотивації. У роботі сформульовано набір критично важливих положень контрактів - чіткий розподіл ролей і відповідальності, адаптивні схеми оплат, заздалегідь визначені порогові значення ризиків, які дозволяють мінімізувати поширені ризики. Запропоновано окремі умови для моделей FS з поетапною оплатою (milestone) у разі затримок, спричинених факторами, що не залежать від КДО, з метою забезпечення їхньої фінансової стабільності.

Запропоновані підходи можуть бути використані спонсорами та КДО для вибору оптимальної моделі аутсорсингу, підготовки збалансованого контракту і впровадження ефективних фінансово-правових механізмів стимулювання. Їх застосування сприятиме зменшенню кількості затримок, контролю витрат, підвищенню мотивації партнерів і забезпеченню стабільності виконання КВ. У підсумку це зміцнює взаємодовіру сторін, підвищує результативність проєктів і гарантує безпеку та якість досліджень.

Ключові слова: *управління ризиками, контракт, комунікація, клінічні випробування, КДО, спонсор, зміни.*
Формул: 0, рис.:1, табл.:1, бібл.: 10

Abstract. *The study aims to analyze contractual mechanisms for effective risk management in Sponsor–Contract Research Organization (CRO) interaction within clinical trial (CT) projects, with emphasis on the comparative advantages, disadvantages, and risks of the two dominant outsourcing models – Full Service (FS) and Full Service Provider (FSP).*

The research is based on a comparative review of outsourcing models described in recent industry publications, empirical studies, and professional sources, including Tufts CSDD/ICON data, market reports, and specialized literature. The analysis covers key FS variants (Fixed Price, Fee for Service, Fixed Unit Price-Based, and Fixed Unit Price-Milestone) as well as the FSP model, paying special attention to financial–legal instruments, Statement of Work (SOW) clauses, and systems of key risk indicators (KRIs).

FS models are characterized by flexibility in structuring financial obligations but face challenges of misaligned incentives, dependence on rigid milestone schedules, and vulnerability to project delays. FSP offers advantages of cost efficiency, resource reallocation, long-term engagement, and deeper integration into Sponsor processes but carries the risks of reduced CRO motivation, dual reporting conflicts, and heavy dependence on Sponsor oversight. The study identifies essential SOW elements that mitigate typical risks, such as clear role allocation, adaptive payment schedules, predefined KRIs, and provisions for milestone-based models that account for Sponsor-driven delays or external factors (supply, regulatory, or protocol changes).

The findings provide Sponsors and CROs with concrete recommendations on selecting appropriate outsourcing models, preparing balanced SOWs, and implementing contractual incentives (bonuses, penalties, interim payments) that sustain CRO motivation, reduce delays, and ensure financial stability. Properly designed contractual frameworks strengthen mutual trust, improve project outcomes, safeguard patient safety, and contribute to the resilience and quality of clinical research in an increasingly complex regulatory and competitive environment.

Keywords: *risk management, contract, communication, clinical trials, CRO, Sponsor, changes.*

Formulas: 0; fig.: 1, tab.: 1, bibl.: 10

Problem Statement. The rapid growth of the global CRO market, increasing complexity of clinical trial (CT) protocols, and stricter regulatory requirements have significantly raised the importance of selecting adequate outsourcing models and contractual frameworks for Sponsor–CRO cooperation. Errors in model choice or poorly detailed contracts can lead to delays in patient recruitment, budget overruns, misaligned incentives, and even compromise the quality and safety of research. Although Full Service (FS) and Full Service Provider (FSP) outsourcing models dominate industry practice, existing literature often analyzes them mainly from operational or financial perspectives, while insufficient attention is given to integrated contractual risk management. This creates a gap in practical recommendations for structuring Statements of Work (SOWs), defining key risk indicators (KRIs), and balancing financial–legal instruments. Addressing this gap is crucial for ensuring resilience, sustainability, and efficiency of modern CT projects.

Analysis of recent research and publications. Recent studies highlight growing adoption of the FSP model, citing cost efficiency and flexibility. Tufts CSDD/ICON (2023) found differing model use by project complexity and scope. Literature covers FS models' financial structures, yet less attention is paid to integrated contractual risk management across models. PPD (2022) confirms the rising share of FSP outsourcing This gap underlines the need for practical SOW-based solutions, while Moat (2023) examines the evolution of Sponsor/CRO relationships and their strategic implications. Markey, Howitt, El Mansouri & Schwartzenberg (2024) demonstrate through machine learning analysis of over 16,000 trials that CT complexity is steadily increasing, necessitating adaptive management approaches, reports steady CRO market growth and the expanding role of outsourcing. Hughes & Turner (2006) outline financial structures of FS models, still relevant for understanding contractual incentives. Mac Garvey (2020) and Henderson (2020) describe the evolution and advantages of FSP, highlighting cost savings and operational flexibility, provide comparative performance data, revealing model-specific trends in timelines, budgets, and usage in complex protocols. Saeed (2024) focuses on understanding key contractual agreements in CTs, emphasizing the SOW's role in defining deliverables, payments, and risk allocation. Collectively, these sources underscore the need for integrated, contract-driven risk management across outsourcing models to improve CT efficiency and resilience.

Formulation of the goal and methods of the research. The research methodology is based on the application of several complementary scientific approaches. First, a systematic literature review was conducted to identify and synthesize current knowledge on outsourcing models in clinical trial management, with a focus on contractual mechanisms and risk mitigation strategies. Second, a comparative analysis was applied to evaluate the structural, financial, and organizational differences between Full Service (FS) and Full Service Provider (FSP)

models, including their subtypes such as Fixed Price, Fee for Service, and Milestone-based schemes. Third, content analysis of professional publications and contractual frameworks was carried out to extract critical elements of Statements of Work (SOWs), clauses, and Key Risk Indicators (KRIs). Finally, secondary data analysis of empirical evidence and industry statistics was performed, drawing upon recognized sources such as Tufts CSDD/ICON benchmarking studies, Contract Pharma industry reports, and Applied Clinical Trials analytics. The combination of these methods ensured triangulation of results, increased validity of conclusions, and allowed the development of the practice-oriented recommendations for effective Sponsor/CRO interaction in clinical trial projects.

Presentation of the main research material. It is difficult to imagine the modern drug development industry in general, and clinical trial (CT) projects in particular, as the work of a single biopharmaceutical company (hereinafter – Sponsor) performing all functions itself – project management, start-up, monitoring, medical writing, preparation of a statistical plan, etc. The trend toward increasing complexity of CT projects due to a more competitive environment and changes in industry regulations (Markey et al., 2024) forces Sponsors to look for reliable partners to whom part of the responsibilities can be delegated.

The main partner for the Sponsor is the Contract Research Organization (CRO), which provides a wide range of services to pharmaceutical and medical companies, as well as to governments, academic, and research organizations. These services can cover all phases of the CT project life cycle, and given CROs' global scale and therapeutic expertise, they are often able to do this more cost-effectively, saving time for the Sponsor. The global CRO market grows annually by 10.7%, reaching /$76.6 billion in 2023 with a forecast of /$127.3 billion by 2028 (Vecchione, 2023). Therefore, the outsourcing/management model, motivation, and communication between Sponsor and CRO often become key factors for project success.

In the past decade, two competing outsourcing models have dominated: *Full Service* (FS) and *Full Service Provider* (FSP). Each has its advantages and disadvantages. In the FSP model, the Sponsor outsources a required number of CRO staff with specific competencies, paying a fixed monthly *FTE (full-time equivalent)* fee or for 160 hours per month, using the Sponsor's own procedures and electronic tools such as *CTMS and training systems*. In the FS model, the CRO's standard operating procedures are mostly used. The FS pricing model is more complex: invoices can be based on hourly rates for outsourced human resources or by defined business process units (*unit-based*), per completed project milestone, or for the entire project. There are also *intermediate, hybrid models*. The scope and type of requested/provided services can vary for both models, as can the type of outsourcing – tactical, strategic, or project-based (PPD, 2023).

The FSP model has developed over the last 15–20 years. In a 2007 study of Sponsor–CRO contractual and financial relationships, the authors described only basic FS models, without mentioning FSP. However, their descriptions of each FS model's advantages and risks remain relevant today (Hughes, 2006):

–***Fixed price*** – the total project cost is fixed, considering all required activities to achieve the goals. Payment in long projects is made in parts upon completion of major milestones. In small projects, payment is made at CT completion – very convenient for the Sponsor. However, the Sponsor should be prepared for making decisions quickly under CRO pressure to complete tasks promptly. For the CRO, any delays – from the Sponsor or vendors – pose a risk, as staff salaries must still be paid to retain personnel and maintain quality, while service fees remain unchanged. High risk of contract renegotiation for both parties. Change orders are used to adjust for possible delays.

–***Fee for service*** – The CRO reports monthly or quarterly for services provided,

expressed in hours (with a pre-agreed rate), spent by CRO specialists on project tasks. This approach involves significant delegation of authority to the CRO, is highly flexible, and convenient for managing risks and changes. Although the model allows easy tracking of project performance, the CRO's increased authority can cause mistrust. Budgets often get exceeded due to misaligned motivations: CROs may benefit from providing more services, while Sponsors aim to shorten timelines and optimize costs**.**

–***Fixed unit-price-based*** – Similar to Fee for Service, but the CRO invoices for service units with a fixed number of hours per business task. Convenient for planning activities, estimating how many units are needed for larger tasks, and measuring efficiency – despite sometimes lengthy initial negotiations to define units. Risks are similar to Fee for Service, though CROs often have fewer decision-making powers. Motivation issues can still cause conflicts and mistrust.

–***Fixed unit price-milestone/deliverable based*** – A fixed price calculated for the activities needed to achieve a project milestone. Payment is made upon milestone completion. This cooperation offers transparency and fosters positive communication and trust in project management. However, risks similar to Fixed Price remain – rushed decision-making, delays negatively impacting communication, and the possibility of CRO underbidding during tender, leading to loss of motivation. Sponsors should be prepared for one or more *change orders* (Moat, 2023).

–***Full Service Provider*** - in recent years, the FSP model has been growing rapidly. Professional publications indicate a shift towards greater use of FSP (MacGarvey, 2020). Main advantages of FSP over FS include:

1. Cost efficiency - FSP reduces Sponsor costs by eliminating redundant work, avoiding FTE-style hourly rates for human resources, while maintaining project control.

2. Stakeholder engagement - FSP involves long-term, continuous relationships, often with multiple projects in parallel. Using Sponsor SOPs and systems eases oversight, while CRO staff are trained to run several CTs according to Sponsor rules. This allows resource transfer between projects when needed. Regular communication builds close relationships and a shared history of overcoming recruitment difficulties, protocol issues, or database locks (Lamberti, Smith, DiPietro, Barry & Getz, 2023).

For CROs, the advantage is stable contracts. Risks include lower profit margins, reducing motivation; slower career progression for CRO staff in FSP arrangements; and the "dual reporting" communication risk, which can disorient employees. Inadequate Sponsor engagement – a risk for any CT – can be fatal in FSP projects due to the Sponsor's critical oversight role.

A 2023 Tufts CSDD/ICON comparative study showed interesting results: in one of the most labor-intensive services – clinical monitoring – FSP was used in 47% of cases vs. 38% for FSO. However, in complex oncology protocols, FSP was used only 14.8% of the time vs. 51.8% for FSO; the rest used mixed models or Sponsor in-house resources. This suggests Sponsors avoid FSP in complex CTs requiring exceptional specialist expertise. FSO is used more in longer CTs with more countries, sites, and patients. Regarding schedule and budget deviations: 59.3% of FSP projects ended late, 40% over budget; for FSO, the figures were 20% and 50% respectively (Markey et al., 2024). Still, FSP use is growing rapidly – PPD data for 2022 shows the FSO\FSP ratio shifting from 72/28 to 59/41 over three years (PPD, 2022).

So each model has its prerequisites, disadvantages, and risks, as well as conditions where its use is appropriate. Errors in selection or poorly detailed contracts can have serious negative project consequences. The *Statement of Work* (SOW) is the key document defining payment terms, reimbursable expenses, timelines, project scope, success metrics, and risks. The SOW should detail responsibilities, and adding extra details will ease future work. It may also include *Key Risk Indicators* (KRI) to anticipate changes if common risks arise that could threaten the Sponsor–CRO relationship

(Moat, 2023; Saeed, 2024) or project success. KRI in the SOW can determine at what *risk threshold values* changes to the budget (*Change Order*) are mandatory (Figure 1).

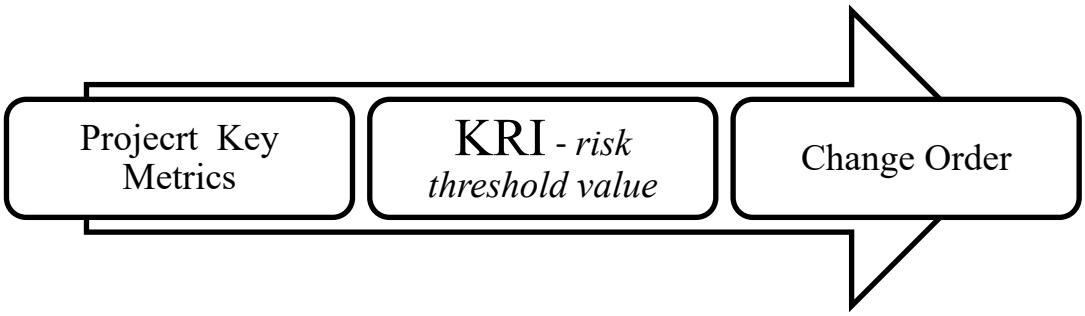

Figure 1. Sequence of factors in decision making about changes in the budget
Source: created by the author

Financial and legal regulation mechanisms – contracts, bonuses, fines, interim payments.

1. ***For FSO Fee for Service, Fixed unit-price-based, and FSP*** – the main risk is that CROs have no incentive to meet deadlines. Since the main risk for a CT project is that, despite all the other advantages, they all do not contribute to the effectiveness of the CRO, first of all, the CRO does not have the motivation to achieve the project's goals within certain deadlines, and sometimes even vice versa, the longer the project lasts, the longer the CRO has a work and receives payment - sometimes, the longer the project lasts, the longer they are paid. Solutions:

a) Bonus payments for timely, high-quality, on-budget milestone completion.

b) Penalties for delays, critical quality issues, or significant budget overruns.

Such intentions should be stated at CRO selection (bid-defense). Fairness requires also listing risks outside the CRO's control that may still cause delays.

2. ***For FSO Fixed unit price-milestone/deliverable based and Fixed Price*** – Sponsors may not need extra CRO motivation since payment is tied to milestone achievement. However, many CT risks – drug supply delays, lab kit issues, regulatory comments, Sponsor organization delays – are outside CRO control. These can force CROs to maintain staffing longer without extra pay, causing demotivation and reduced engagement. In addition, there is a risk of demotivation of CRO, which will have a negative impact on the severity of CRO, and therefore on the quality of CT, on the safety of patients. Well-conducted negotiations and an SOW allowing payment schedule adjustments for delays not caused by the CRO can prevent this.

The SOW can also list risks that could affect milestone or project timelines, define the applicable protocol version, and state that stricter inclusion/exclusion criteria should be grounds for deadline review. To the reasons listed above, it makes sense to add a version of the protocol in relation to which the agreements are applicable, or to indicate that the complication of the criteria for including and not including patients in the CT should also be considered as a reason for revising the deadlines for completing tasks, in particular, the speed of recruitment of patients (since the clinical centers were selected for the CRO on the basis of old, more feasible criteria). And this looks justified, since CRO plans its resources, pays salaries longer in time, and receives payment later. The risk of delays on the part of the Sponsor is usual - additional wishes of the Client, not previously taken into account in the SOW (change/complication of the criteria for the inclusion of CT patients, addition/complication of procedures in the CT, addition of a comparison arm), problems with suppliers (logistics delays with the delivery of the drug, laboratory kits or problems with electronic systems), communication delays with the approval of documents/forms,

informed consent sites/investigators, amendments to the protocol). It is also reasonable to include a clause allowing partial regular payments in addition to milestone-based ones in case of delays outside CRO control – especially in long projects where milestones may be years apart.

Finally, the SOW should note that all additional activities needed due to risks unrelated to CRO actions but essential for CT goals will be compensated. This helps keep CRO motivation high, especially for small and mid-sized organizations.

Table 1

Financial - Legal regulation mechanisms in CRO–Sponsor contracts

Contract model	Main risk identified	Contractual mechanisms suggested	Key notes
1. **FSO** (*Fee for Service, Fixed Unit-Price-Based*) **FSP**	CRO has little incentive to meet deadlines; prolonged projects increase CRO income, reducing motivation for efficiency.	1) Bonuses for timely, high-quality, and on-budget milestone completion. 2) Penalties for delays, critical quality failures, or budget overruns.	Risks outside CRO's control (e.g., regulatory, logistics, protocol changes) must be recognized to ensure fairness. Intentions should be clarified at bid-defense stage.
2. FSO (*Fixed Unit Price-Milestone/Deliverable-Based, Fixed Price*)	Payment tied strictly to milestones; CRO suffers financial burden if delays are caused by Sponsor or external factors, leading to demotivation.	1) Adaptive payment schedules allowing partial interim payments when delays are beyond CRO control; 2) Contract clauses to revise deadlines if protocol versions inclusion/exclusion criteria change; 3) Compensation for additional tasks arising from Sponsor-driven risks.	Helps maintain CRO motivation and financial stability, especially in long projects with widely spaced milestones. Protects small and mid-size CROs.

Source: created by the author

Conclusions. Both FS and FSP outsourcing models have specific conditions under which they deliver optimal results. Successful implementation depends on accurate model selection, precise SOW drafting, and fair allocation of responsibilities and risks. Incorporating bonuses, penalties, and adaptive payment schedules can sustain CRO motivation and performance. Effective communication structures, clear escalation procedures, and predefined KRIs reduce the likelihood of delays, budget overruns, and quality failures. A well-structured SOW that anticipates foreseeable risks — including those outside the CRO's control — strengthens cooperation and resilience. Ultimately, integrating contractual risk management mechanisms into outsourcing arrangements not only safeguards project efficiency but also enhances trust, stability, and patient safety in clinical research.

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