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INTEGRATED RISK-BASED HUMAN RESOURCE MANAGEMENT IN THE CLINICAL TRIAL PROJECT ORGANIZATIONS

The article is dedicated to strategic human resource management in clinical research organizations. It addresses the problem of staffing shortages among Clinical Research. Associates (CRAs). The authors propose an integrated, risk-oriented approach to personnel management. High staff turnover and a shortage of specialists with specific competencies pose significant risks, threatening the budget, quality, and deadlines of clinical research projects. The proposed method, called sequential-parallel engagement, involves phased training and support of junior CRAs by senior colleagues. This approach promotes gradual development of competencies, increases motivation, and helps retain staff within the organization. The method also allows for reducing sponsor and contract research organization (CRO) costs, as well as decreasing the workload on Senior CRAs. The model is effective provided there is a clear understanding of the seriousness of risks, transparency in the sponsor-CRO relationship, proper planning, alignment, and adherence to the sequential processes and requirements of ICH GCP. The economic part of the article demonstrates that training mid-level CRAs can replace Senior CRAs, reducing monitoring visit costs by nearly 63% after just four months of the implementation.

Keywords: *human resource management, human resource risks, communication, trainings, competence, organization.*

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ІНТЕГРОВАНЕ РИЗИК-ОРІЄНТОВАНЕ УПРАВЛІННЯ ЛЮДСЬКИМИ РЕСУРСАМИ В ОРГАНІЗАЦІЯХ ПРОЄКТІВ КЛІНІЧНИХ ДОСЛІДЖЕНЬ

Статтю присвячено стратегічному управлінню людськими ресурсами в організаціях, що займаються клінічними дослідженнями. У ній розглядається проблема нестачі персоналу серед моніторів клінічних досліджень (Clinical Research Associates, CRA). Автори пропонують інтегрований, ризик-орієнтований підхід до управління персоналом. Висока плинність кадрів і дефіцит фахівців із необхідними компетенціями становлять суттєві ризики, які загрожують бюджету, якості та термінам виконання проєктів клінічних досліджень. Запропонований метод, що отримав назву «послідовно-паралельне залучення», передбачає поетапне навчання і підтримку молодших моніторів з боку досвідченіших колег. Такий підхід сприяє поступовому розвитку компетенцій, підвищенню мотивації та утриманню персоналу в межах організації.Метод також дозволяє знизити витрати спонсора та контрактної дослідницької організації (КДО), а також зменшити навантаження на старших моніторів. Модель є ефективною за умови чіткого розуміння серйозності ризиків, прозорості у взаєминах між спонсором і КДО, належного планування, узгодженості та дотримання послідовних процесів і вимог ICH GCP. Економічна частина статті демонструє, що навчання моніторів середнього рівня може частково замінити старших моніторів, зменшуючи витрати на моніторингові візити майже на 63% вже через чотири місяці впровадження.

Ключові слова: *управління людськими ресурсами, ризики персоналу, комунікація, навчання, компетентність, організація.*

Рис.1, Табл.0, Літ.10.

The Problem Statement

The pharmaceutical industry involved in developing new drugs is currently experiencing a period of increasing complexity, the intensification of regulatory requirements, the accelerated digitalization of processes and longer timelines for scientific projects. High staff turnover and specific requirements for monitor experience elevate the risk of a shortage of monitors, especially experienced specialists with specialized competencies. Difficulties in onboarding new employees, which require significant resources and time, compel organizations to seek sustainable human resource management models. The CRA plays a critical operational role, serving as the liaison between the trial sponsor and clinical sites. The absence of a strategic CRA reserve leads to risks such as declining research quality, delays, and increased project budgets. An integrated, risk-oriented approach to personnel management can serve as a solution by accounting for potential personnel losses and ensuring project continuity. At the meantime, a stable staff increases the competitiveness of the organization.

Review of Recent Research and Publications

The issues of clinical team stability in clinical trial organizations lie across several dimensions — industry requirements, the scale of the problem within the industry, causes of staff turnover, CRA motivation to acquire new competencies and remain loyal to the organization, integrated risk and personnel management, and the effectiveness of collaboration between the sponsor and CRO within the organizational structure. According to ICH GCP E6(R2), a monitor must be approved by the sponsor and be capable of performing 17 key functions [1]. At the same time, a number of studies by The National Center for Biotechnology Information, Tufts CSDD, and ACRP [2], [3], [4], [5] highlight the scale of the issue, factors contributing to high turnover rates, the unwillingness of organizations to hire specialists without specific competencies, and methods for retaining monitors within

both the organization and research project. Additionally, several works [6], [8], [9] emphasize the importance of building a communicative environment, transparence, motivation in employee retention, as well as improving their work efficiency.

Main Material

The organization of a clinical trial (CT) project for new medicinal products is a complex, multi-layered structure involving many stakeholders, starting with the sponsor (a biopharmaceutical company), the key service provider (Contract Research Organization, CRO), local regulators, vendors providing specific services, healthcare institutions, investigators, and patients or healthy volunteers (hereafter referred to as CT participants). All of them form a temporary organization, often represented across multiple countries.

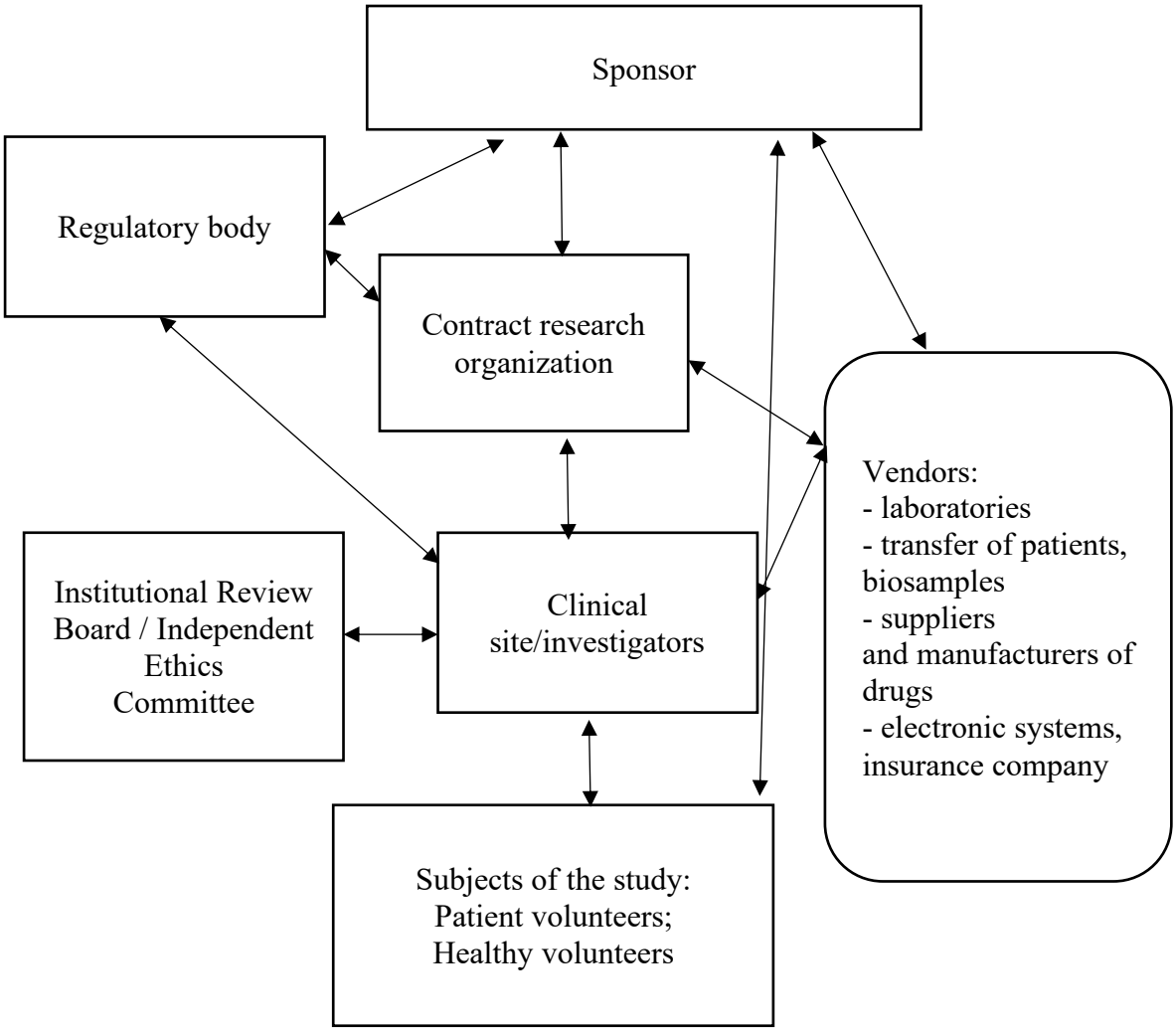

Figure 1 – Created by the author

As shown in Figure 1, the sponsor and CRO are the central elements of the organization. The coordination between these stakeholders and the presence of professional staff in the structure determines the project's success. Clinical trials are unimaginable without CRAs (monitors), whose role is outlined in the international standard ICH GCP E6R2, in effect since 2016. Monitors serve as the sponsor's primary contact at the site, acting as the conduit of requirements to the site, providing feedback to the sponsor on deviations and issues, training site staff, and monitoring protocol compliance, ensuring patient rights and safety, drug management etc. According to the standard, monitors perform 17 key functions [1].

The COVID-19 pandemic and significant changes in the global economy have affected the clinical trials market, leading to acute staffing problems [2]. Globally, the CRA turnover rate reaches 30%, posing a major issue given that most clinical trials last several years and organizations strive to retain staff throughout [3]. On the other hand, organizations often seek employees with at least two years of experience, intensifying the demand for qualified CRAs [4].

Other study`s survey confirm this: only 44% of organizations are willing to hire candidates with less than two years of experience, and only 31% have successfully followed this principle. Furthermore, retention is challenging - only 23% of companies report no difficulties. For the rest, the average annual turnover rate is at least 20%, whereas the salary increases are the primary reason for CRA`s leaving. The second most significant motivational factor is professional development. For 42% of companies, training takes 7 months or longer; for 18%, 1–2 months; 15% take less than a month or 3 - 4 months. Competence is crucial, particularly for complex trials in oncology, rare diseases, or gene therapy. The most effective training types are mentorship (by more experienced colleagues) and individual training (primarily by line managers) [5].

Human resource management challenges—especially related to CRAs—and the desire to retain monitors in CT projects contribute to staff turnover. According to ICH GCP E6(R2), CRAs must be approved by the sponsor (p.40), meaning both CRO and sponsor must evaluate risks related to experience and competencies, especially in complex trials. A sponsor cannot approve a monitor with no experience for a complex oncology protocol based solely on a 10-hour web training. When facing staffing shortages, project teams may be assembled without accounting for potential CRA loss. CROs often face shortages not only of Senior CRAs but also of Junior and CRA II level monitors. Thus, the sponsor and CRO should jointly implement risk-based human resource management throughout the project, considering the annual 20% turnover rate and maintaining a strategic reserve of monitors.

A possible solution could be *the method of sequential-parallel engagement*, based on two principles [6]:

1. The specific responsibilities of a CRA according to ICH GCP E6(R2);

2. A personnel development strategy focused on motivation and incentives that encourage employees to learn, acquire, and subsequently apply knowledge and skills, allowing them to feel like part of the organization in such a way that they do not wish to change jobs to another organization [7], [8].

The complexity of a CT protocol may require experience and specific competencies, but this does not apply to all seventeen tasks. Undoubtedly, neither the Sponsor nor the CRO should allow an inexperienced CRA to train investigators, confirm that trial participants meet the protocol eligibility criteria, or oversee patient safety management, including the handling of serious adverse events. However, 9 out of the 17 functions can be performed (or partially performed) by a CRA with basic competencies, as these tasks are the same for both complex and simple clinical trials. Examples include monitoring the delivery, storage, dispensing, and destruction of the investigational product, overseeing compliance with informed consent procedures, reporting patient recruitment rates to the sponsor, collecting site documents for the trial master file, and others. The specifics of workforce distribution in enterprises with a strong matrix organizational structure, such as CROs are such that line managers (LMs) allocate resources to projects (in our case, CRAs), and one CRA may work on a single project or on several simultaneously. The method of sequential-parallel engagement helps to mitigate such risks in cases where there is no back-up CRA. Since hiring back-up staff in advance just in case a risk arises can be costly for the organization, it makes sense to prepare back-up CRAs from among less experienced employees (CRA I, II), who receive lower salaries and are therefore more cost-effective for both the CRO and the Sponsor.

Undoubtedly, this method serves as a preventive measure against the risk of insufficient monitoring resources in a clinical trial. This risk should be escalated to the sponsor and may require certain adjustments to the business process of the "Monitoring Visit," and potentially changes to the monitoring plan itself. Once the procedures are defined and sponsor approval is obtained, implementation can begin. This includes four steps:

Step 1: At the start of the project, the Project Manager (PM) submits a request to the LM of each country for a specific number of monitors, in accordance with the contract. The contract defines the CRA workload in FTE (Full-Time Equivalent), which is approximately 160 hours per month, along with the required experience and competencies in the relevant therapeutic area—oncology, pulmonology, or any other as needed;

Step 2: The LM reviews the protocol requirements and the availability of monitors with the necessary competencies, and submits the CRA's CV to the Project Manager. If the contract calls for 2 FTEs, the team composition can be formed in several ways: two full-time CRAs dedicated solely to the new project; or one full-time CRA and two CRAs working at 0.5 FTE each, who are also involved in other studies; or three or more CRAs with partial allocation across different projects. *Separately, the Line Manager (LM) submits a list of monitors with basic competencies to form the back-up staff.* A good practice is to provide multiple CVs so the sponsor has a choice. In complex projects, the sponsor typically prefers experienced personnel (Senior CRA), although exceptions may occur;

Step 3: The PM from the CRO reviews and approves the proposed candidates and submits them for sponsor approval;

Step 4: Sponsor`s approval.

At the initial stage, the PM and LM from the CRO discuss the possibility of involving CRA I or II, who lack experience in clinical trials within the given therapeutic indication, into the study. Junior monitor`s initial role would be limited to performing 9 out of the 17 standard CRA functions that are common to all clinical trials. These tasks are unlikely to impact data quality and, therefore, are not expected to meet resistance from the sponsor. Following this, the PM submits the back-up CRA candidate for sponsor approval, clearly indicating the specific functions that the back-up CRA will perform at the site. From this point on, the back-up CRA undergoes initial training on the protocol, procedures, disease specifics, and therapy, with accompanying assessments and tests. Once the PM/LM confirm the back-up CRA's readiness for partial participation in the study, the CRA begins accompanying the primary site monitor on monitoring visits. This approach is compliant with both ICH GCP and standard operating procedures. During these co-visits, the back-up CRA assists the Senior CRA by taking over routine tasks such as document collection, updating laboratory reference ranges, monitoring investigational product receipt, dispensing, balance, storage, and reviewing the site file. This allows the primary CRA to focus on more critical aspects such as source data verification, assessment of patient eligibility against inclusion criteria, and patient safety oversight. These activities significantly help the back-up CRA develop an understanding of the protocol structure, patient visit schedules, and features of working with electronic systems. Approximately 10% of the time is spent in joint monitoring, during which the Senior CRA leads by example, answers questions, and assigns small tasks in new areas for the back-up CRA - thus facilitating gradual competency development.

With each monitoring visit, the number of functions performed by the back-up CRA gradually increases until they fully acquire the competencies required to manage the ongoing clinical trial. The PM and LM oversee the progress, document training activities, and inform the sponsor of any changes, thereby steadily expanding the range of responsibilities assigned to the back-up CRA. Thus, the mentorship provided by the Senior CRA—an experienced member of the clinical team—along with individual training from the LM and PM, and ongoing communication with site staff, contributes to the progressive development

of the back-up CRA's competencies. Joint monitoring visits with the Senior CRA may continue during this process. The training scope is pre-planned by the LM, PM, and the primary CRA. The training process and the results achieved are reflected in the monitoring report, ensuring that the PM, LM, and sponsor remain consistently informed about the CRA's development. The scope of involvement is gradually expanded until the LM, PM, Senior CRA, and possibly the sponsor unanimously agree that the back-up CRA is ready to become the primary CRA at one of the clinical sites with a small number of enrolled patients—providing an opportunity to consolidate their newly acquired competencies independently.

Economic Justification

As previously mentioned, the cost of CRA work is calculated based on FTE, meaning the CRO invoices the sponsor for each hour the CRA works. The monitoring visit process consists of the following sub-processes:

- Visit Preparation (VP)
- Travel Time to and from the site (TT)
- Time spent on-site multiplied by the number of visit days (VT × ND)
- Report Writing (RR) – only for main CRA

By multiplying the total number of hours for these activities by the hourly rate (HR) of the CRA, we get the visit cost (VC):

VC (1 CRA 2-days monitoring visit) = (VP+TT+VT×ND+RR) ×HR

Considering that the only difference in the sub-processes between a Senior CRA and a back-up CRA is that the back-up CRA does not write the report as a co-monitor, the final formula becomes:

VC (2CRA 1-day co-monitoring visit) = Senior CRA (VP + TT + VT× ND + RR) × HR + back-up CRA (VP + TT + VT× ND) × HR - this formula reflects the combined cost of a visit involving both a Senior CRA and a back-up CRA, where the back-up contributes to all steps except report writing. This approach allows cost optimization, especially when back-up CRAs are paid at a lower hourly rate due to their junior status (CRA I/II), making the combined cost more efficient than full reliance on Senior CRAs.

According to data from Indeed, the annual salaries for Clinical Research Associates (CRAs) vary as follows:

- Lowest (Junior CRA): $54,449
- Average (CRA II): $85,986
- Highest (Senior CRA): $135,789 [9].

This distribution can be used as a conditional approximation for the salary levels of Junior, CRA II, and Senior CRA, respectively. To estimate the hourly cost of one specialist's work for a CRO or a sponsor (if the sponsor conducts monitoring using internal resources), the following formula is used:

VC (1 Sr. CRA 2-days monitoring visit) = (2 + 4 + 8 × 2 + 2) × 70.72 $ = ***1 697,28 $.***

VC (2CRA 1-day co-monitoring visit) = (2 + 4 + 8 + 2) × 70.72 $ + (2 + 4 + 8) × 44.78 $ = 1131.52 + 626.92 = ***1 758,44 $.***

These figures can be used to calculate and compare the cost-effectiveness of involving a back-up CRA versus relying solely on a Senior CRA, especially in tasks that do not require advanced expertise. That is, approximately, the cost of both options is almost the same. Returning to the Tufts CSDD study, the average training duration is 4 months. Thus, after 4 months, the former back-up CRA will be capable of conducting the clinical trial as an independent CRA, but now the cost of a two-day visit by the new CRA will be:

Effectiveness: VC (1CRA I, 2-days monitoring visit) = (2 + 4 + 8 × 2 + 2) × 44.78 $ = ***1 074.72 $***. For comparison, the cost of a visit conducted by a Senior CRA is **1,697.28** $. The difference amounts to **622.56 $.**

This approach will also help reduce turnover among back-up CRAs by providing additional motivation and demonstrating trust when employees are entrusted with challenging tasks and receive dedicated time and attention for training. This leads to increased job satisfaction, loyalty, retention, and improved productivity.

Conclusion:

Integrated risk-based human resource management in clinical trials enables proactive prevention of staffing shortages, particularly the high CRA turnover rate. The risk of losing the required number of monitors mid-trial can have serious consequences, primarily affecting project quality, increasing protocol deviations, and jeopardizing patient safety. The sequential-parallel engagement model allows CRA I and II to be involved in complex protocols without requiring external recruitment, which in itself significantly optimizes costs for both the organization and the project. Another clear advantage of this method is its potential to raise the intellectual capacity and competitiveness of the CRO and the sponsor (in cases where the trial is conducted without outsourcing). The motivational component and an atmosphere of trust between the sponsor and CRO, as well as between the PM/LM and CRA, help retain staff within the organization. Involving CRA I and II at early stages also reduces the workload and multitasking burden on senior CRAs, allowing them to focus on critical tasks such as verifying patient eligibility, ensuring patient safety, and conducting investigator training — all of which are especially crucial during the initial patient enrollment phase. The economic justification for the sequential-parallel involvement of junior specialists in complex clinical trial projects shows that during the first four months, the training of CRA I and II requires minimal time investment from the PM and LM. Starting from the fifth month, the cost savings reach 63% for each site assigned to the newly trained CRA.

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