

Center with or Without a Coordinator? The Coordinator as an Integral Part of a Research Team

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Abstract: The entire clinical trial process is a perfectly orchestrated team. It took many years before centers started hiring clinical trial coordinators. The centers that decided to do so noted not only positive aspects from the technical side of the study, but also from the side of the participants - which are the patients. The aim of the publication was to collect literature data showing the work of the coordinator in the centers and its impact on increasing the effectiveness of the study. The comparison additionally included the importance of the coordinator's role on patient recruitment and perceptions. The centers analyzed, showed the impact of the coordinator on their center's research at approximately: 99.1% in China (knowledge of patient rights), 80% in Italy (increasing the quality of the clinical trial conducted) and 70% in South Korea (impact on reducing patient withdrawal of consent). Those teams that worked without the support of a coordinator gained less trust among patients, which affected recruitment and retention of participants. The coordinator's influence on study management resulted in better organization of the study. Conclusions reached can support the development of centers and thus clinical trials around the world. Hiring a coordinator not only has an impact on improving the management of the study, but also on increasing the number of patients included, and thus increasing the therapeutic options in medicine. This paper aims to compile existing literature concerning the responsibilities of clinical trial coordinators and subsequently advocate for the value they bring to enhancing the efficacy and efficiency of clinical trials.

Keywords: study coordinator, clinical research, clinical trials, management, patients

Introduction

Clinical trials constitute a fundamental aspect of modern medicine, aimed at the development of new treatments and drugs. Due to their experimental nature, they may involve certain risks for their participants, both healthy volunteers and those with medical conditions. Participation in a clinical trial is upon written and aware consent of the patient, with the provision to withdraw from the medical trial at any point.

It depends on the stage of the study. The entire process of a clinical trial is a team that ideally works together to create opportunities to actively conduct such a trial at a given site.¹ The idea starts in the laboratory. After a series of tests by scientists, the most promising experimental therapies are selected, which, when transferred to clinical trials, are conducted in stages. Through these stages, the risk and efficacy results of the chosen experimental treatment are obtained. [FDA]

The phases of clinical development are divided into Phase I, II, III and IV.

Phase I (pharmacology in humans "first use in humans") - preliminary studies on the safety and pharmacological properties of the drug involving about 50–100 healthy subjects. Phase II (treatment studies) - dose-finding studies, preliminary analysis of the safety and efficacy of the drug of about 300–600 patients with a specific ailment. Phase III (confirmation of therapeutic effect) - the longest and most costly phase from about 1000 to 3000 participants. The goal is to confirm the safety efficacy of the drug which allows registration and marketing. Phase IV ("post-authorization studies" product life cycle management) - further studies after registration of the drug to confirm its long-term efficacy and safety.

Based on the above criteria, we can define clinical trials in two categories. The first relates to drugs and the phases of their study, and the second relates to those without whom it would not be possible, namely the patients and the entire clinical trial team. In order for each phase of the study to take place outside of the drug, we need study participants (depending on the phase) who are healthy or sick.²

According to the global clinical trials database located at ClinicalTrials.gov, there are currently (as of May 2023) more than 67,000 clinical trials with active recruitment. To date, the database has collected more than 333,000 clinical trials in 209 countries (since 2008, September).

According to a report by the Office for the Registration of Medicinal Products for Devices, Medical Devices and Biomedical Products, the number of clinical trials is growing every year. To protect the safety and rights of those participating in clinical trials and to ensure the reliability of the data obtained, Good Clinical Practice (GCP) rules have been developed and implemented. The GCP rules also make it possible to limit the number of patients in clinical trials, since the results of a single trial are recognized by all drug registration organizations.

The Principles of Good Clinical Practice (GCP) are the international ethical and scientific standard for clinical research. They define the proper planning, conduct, documentation and publication of the results of clinical trials conducted with human subjects. Following GCP principles is a kind of public guarantee of proper protection of human rights. Maintaining the safety and well-being of those participating in the study, in accordance with the principles adopted in the Declaration of Helsinki, guarantees respect for the rights of each participant. Consequently, also the reliability of clinical trial data.

Further evidence of the momentum behind the development of clinical trials was the addition of The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) GCP established in 2014.

The purpose of the development of the ICH GCP is to define uniform rules for the conduct of clinical drug trials in the member countries of the European Union (EU), Japan and the United States of America. This enables mutual recognition of the data obtained by the relevant authorities in these countries.²

Without a common standard, it would be necessary to repeat the same project in many countries, which would delay the introduction of new, more effective drugs. That's why all drug development organizations and companies make it a priority to follow high ethical standards.³ When they run out of available therapeutic paths they step in: clinical trials. They offer hope to those who have exhausted all therapeutic options or those available on the health care markets are not effective enough. In addition, a patient choosing to participate in a clinical trial gains access to modern therapies that are not financed under guaranteed benefits, as well as higher standards of treatment and detailed diagnostics that comprehensively verify his or her condition in conjunction with the condition being treated.⁴ There is a constantly growing interest in the area of clinical trials because of new and alternative treatments. This provides a new opportunity to receive treatment, and as a result, it becomes extremely important to ensure the quality and efficiency of the clinical trial and adherence to its procedures.¹

Over the last decade, the surge in multi-center clinical trials and the standardization of the clinical trial industry has led to an increased demand for clinical trial coordinators. While this role is well-established in highly developed countries, a significant number of countries and, subsequently, numerous centers are still without mentioned position. In these cases, other medical personnel assume the role of a coordinator alongside their primary responsibilities.⁵

Effective collaboration with the entire study team requires adequate commitment and qualification. In addition to the diversity within the team, the diversity among the patients of the study must also be combined. For these reasons, a coordinator has been identified who, by bringing all the participants together, develops an appropriate path for the effective conduct of the study and, consequently, the effective treatment of the patient. Coordinators are a kind of liaison between each stage of the study and each unit involved in it. They are referred to as integral to the success of a clinical trial because of their extensive involvement and expansive responsibilities to the clinical trial.⁵

According to a survey conducted by the National Cancer Institute Community Oncology Research Program, it was shown that in groups of patients enrolled in clinical trials (in addition to physicians) also identify administrative staff as important participants in the entire clinical trial process. They point to the management role of such people and the

supportive role at each stage of the trial. The supportive role manifests itself in the identification of coordinators and nurses as goalkeepers during the recruitment of older participants to the study.⁶

This paper aims to compile existing literature concerning the responsibilities of clinical trial coordinators and subsequently advocate for the value they bring to enhancing the efficacy and efficiency of clinical trials. Through a comprehensive exploration of the coordinator's role across various stages of a clinical trial, we intend to draw conclusions that can be incorporated as methodologies to enhance the execution and management of clinical trials.

The research criteria were based on the analysis of the literature coverage review methodology using the Scopus (Scoping Review) database and secondary sources. Secondary sources (Infarma and Adamed (large pharmaceutical companies) reports, GCP guidelines) Systematic review - A total of 25 articles and secondary sources were used. The data that were collected from the centers studying the components of improving the efficiency of a clinical trial and the increase in the number of patients included were compared with each other. The compilation allowed a summary conclusion to be drawn through the statistical average of the compared results. Developed a certain method using the guidelines of cross-sectional studies, based on the establishment of the research problem, the focus was on the target population and the available descriptive phenomena already studied. The collected data was used to analyze the mentioned research problem through which the desired conclusions were drawn. Key words mentioned in the article were selected as selection criteria. Keywords: medical trial coordinator, clinical research, clinical trials, center, patients. This resulted in an appropriate selection of articles on the phenomenon under study over the past 10 years (from 2013 to 2023). Such period was chosen because the dynamics of the development of clinical research is significant, which could result in already outdated knowledge with a broader scope. The chosen methodology allows for an objective evaluation in the terms of the methodological rigor of the work and the subsequent use of the results of this review.

Clinical Trials in Centers with a Coordinator

The coordinator like support of the entire clinical trial team introduces the basic points for the effective functioning of the trial. The consequences of more effective management, cooperation and coordination help the center achieve better recruitment results, and consequently, more patients can receive treatment of last chance.

The primary responsibilities of clinical research coordinators involve overseeing various activities, regardless of their background. When we observe coordinators, who possess clinical training, they not only manage mentioned responsibilities associated with their role, but are also well-equipped to take on certain investigator duties, effectively serving as sub-investigators. While assuming this dual role can offer advantages, it's crucial to remember the core tasks, that coordinators fulfill: ensuring the seamless progress of clinical trials and upholding data quality.

A clinical trial coordinator is a person hired to support the team and the principal investigator during the conduct of a clinical trial. Most often it is, an employee of the medical centre or it can be externally hired person with the prior approval of the centre. Cooperation with such a large multidisciplinary team requires a common bond - the coordinator. In order to properly carry out the study, coordination is necessary on the clinical, administrative and regulatory levels. Minimum of 2 years of experience in conducting and coordinating clinical trials is necessary here. Training that ensures the quality of the coordinator's work and confirms his/her skills such as Good Clinical Practice (GCP) training, training in proper packaging and shipping of laboratory samples (IATA), *Electronic Case Report Form* (eCRF) training and knowledge of clinical trials. The larger the center is, the more complex the study and thus the greater the demands on the coordinator are. The coordinator must be driven by reliability, organization and a willingness to cooperate in order for the study to run smoothly.

One of the most important qualities of a coordinator is the ability to communicate. For this reason, we can divide these skills into hard and soft skills.

Hard skills: prior clinical and research experience, technical/hands-on clinical skills, research and teaching skills, psychosocial and counseling skills, organizational/ planning/ management skills, ability to balance competing issues.

Soft skills: communication, honesty, respect for people, identification of "ethical" skills.^{5,7-9}

The coordinator's duties encompass a range of activities, including collaborating closely with the principal investigator, discussing the study schedule with patients, participating comprehensively in different aspects during patient visits throughout the study's duration, ensuring the thoroughness of procedures administered to patients, actively assisting in

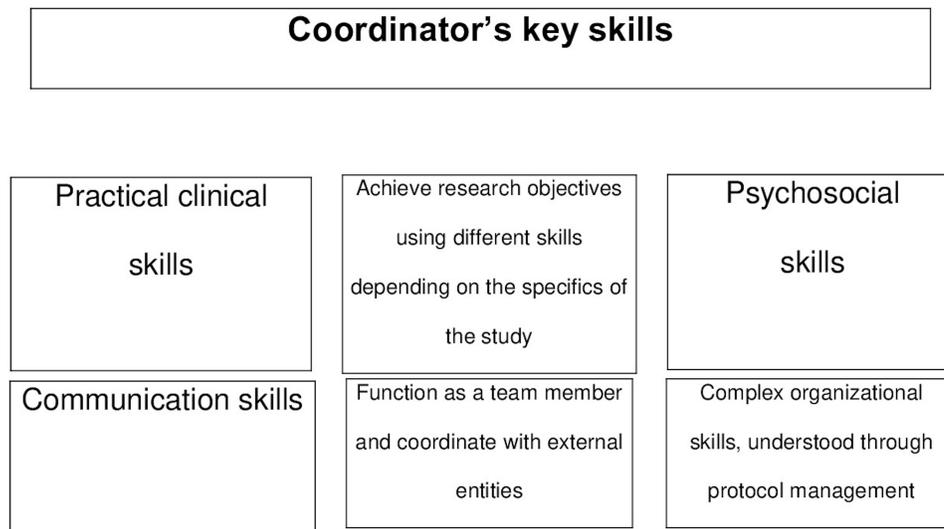


Figure 1 Main role of clinical trial coordinator.

the completion of questionnaires, maintaining accurate source documentation, and upholding the overall quality of the clinical trial (Figure 1).^{10–12}

Important skills among clinical trial coordinators that enable them to conduct research in a safe, ethical and effective manner are appropriate management and team skills. With ethics and participant safety in mind, coordinators execute study steps in accordance with Good Clinical Practice. New regulations and complex new study designs teach professionalism and commitment to every detail of a clinical trial, even the smallest one.

[<https://mrctcenter.org/clinical-trial-competency>]

Beyond the logistical needs essential for the effective management of a clinical trial, there's an important human factor to consider—the principal investigator. This individual holds the responsibility for selecting and including members within the research team. A study conducted by the Mayo Clinic in late 2017 and the early months of 2018 revealed a significant insight. The decision of coordinators to remain in the study has been made, despite modest compensation, often hinged on the Principal Investigator (PI). The PI's personal rapport and influence played a crucial role in retaining coordinators within the study.

The depth of connection and authority vested in the Principal Investigator displayed a strong correlation with the coordinator's continued involvement in the study. Developed countries like North America, Spain, and Germany also adopt an additional role alongside the coordinator—the research nurse. According to the abovementioned, nurses were taking charge of overseeing nursing activities at the center, ensuring the quality and accuracy of procedures performed. However, it's important to note that this position is not synonymous with the coordinator's role.²

With the growing regulatory demands placed upon clinical trials, there has been a corresponding rise in expectations for team members, including clinical trial coordinators. Undertaking the role of a study coordinator now requires additional skills, training, and an enhanced grasp of medical knowledge. However, the increased responsibilities and workload have not necessarily led to heightened job satisfaction among coordinators. Consequently, some individuals opt to resign from this position to the less stressful and demanding ones.⁵

The challenges associated with study procedures weigh not only on the patients but also on the entire process of conducting the study. The intricacy of the study directly impacts the difficulty of recruiting and retaining patients over the long term.¹³ The competence of a clinical trial coordinator extends beyond mere trial management. These specific skills involve blending coordination with the adept handling of study logistics and patient interactions. The scope of tasks falling under the coordinator's purview is influenced by factors such as principal investigator, study specifics, or the nature of the center.⁷

Drawing lessons from a Korean study, it's evident that the involvement of other team members (such as research nurses or clinical research coordinators) in educating and assisting patients during trials can lead to around 30% of patients returning for subsequent clinical trial participation.⁸ In 2015 study encompassing 319 centers in Italy (115 responses), the crucial role played by a coordinator in oncology research was underscored. Even the presence of just one coordinator at a center was shown to double the continuation of ongoing research.¹⁰

A more recent study from 2022, involving 435 coordinators across 20 centers in China, highlighted that medical trials coordinators were particularly attentive to patients' rights (95%) and safety (99.1%) when choosing to participate and while engaged in the study. They exhibited active involvement in the study's ethical considerations (59.6%) due to the extensive training provided as part of their role at the center.¹²

All the studies presented describe the coordinator in a similar way. In addition to the nomenclature: "coordinator" we can find such terms as "manager" or "clinical research coordinator". Despite the lack of systematization of the job title, the presented profession is similar in each job description and tasks. The differences we can see are only due to the responsibilities of the center, the specifics of the study or the sense of unity with the team or principal investigator. The tasks that coordinators perform overlap, and each skill description strives to create a common definition of this team member. The responsibility that a coordinator has influences the perception of his or her job. Coordinators are more likely to define the job as difficult and demanding.^{5,8,14,15}

Clinical Trials in Centers Without a Coordinator

The implications of functioning at a center without the support of a coordinator are mostly a risk to the effectiveness of the study and the team. The coordinator's support along the patient-physician line is key to increasing patient confidence in the decision to participate in the study. Collaboration with the principal investigator is an important part of increasing patient recruitment. Without the coordinator's presence at the center, his or her roles are taken over by the principal investigator or a dedicated nurse.

Dealing with individuals who are unwell stands as a paramount challenge faced by healthcare workers each day. Establishing trust with these patients stands out as a crucial attribute for a clinical research coordinator.⁹ The initial point of contact for a patient is entered by doctor. A study conducted across 4 centers in South Korea revealed, that nearly all respondents (97%) learned about trial details from their physician, and the doctor was one of the few individuals they could place their trust in.⁸ However, a noteworthy aspect highlighted in this study pertains to comprehending and potentially declining consent for study participation—more than half of the respondents faced this challenge. While strong trust in their physician is significant, it does not always solely influence a patient's decision to participate in a clinical trial. Throughout the study, participants need to maintain confidence during whole process.

The principal investigator bears ultimate responsibility for overseeing the entire course of the clinical trial at in the medical centre. This encompasses team selection and the critical duty of safeguarding the well-being of study participants.^{2,13}

In a survey conducted in France in 2021, a significant finding was that the central role in shaping the study's ultimate objectives, assumptions regarding participant recruitment, and decisions concerning study closure, was played by the principal investigator. Researchers tended to express a more optimistic outlook on these matters in relation to their own studies, rather than a pessimistic one. Notably, researchers who assumed the role of principal investigator in a clinical trial tended to speak positively about their experience in conducting the trial.

Among the primary concerns voiced by investigators were an underestimation of the time required to complete the study and inaccurate projections for participant recruitment. The survey revealed that about 50% of respondents leaned towards a negative outlook. Some investigators harbored doubts, reflecting a lack of confidence in their ability to recruit an adequate number of patients. Intriguingly, one in five principal investigators admitted to expecting exclusively positive outcomes from their studies; however, the study's findings suggested that the principal investigator's pessimistic stance was actually linked to more accurate predictions in terms of recruitment.¹⁶

Substituting a study coordinator with a nurse introduces the risk of the nurse overlooking study aspects due to time constraints and an abundance of nursing responsibilities. Consequently, the nurse's absence inessential training in early career often leads to concerns about their ability to comprehend the study's numerous and intricate procedures.¹⁷

In centers where coordinators are not employed, patients' motivation to join such studies frequently stems from seeing tangible evidence in the form of fellow patients undergoing treatment. Increasingly, trial participants are beginning to perceive a "mission" in contributing to the advancement of more effective treatments, underscoring their dedication to this cause.¹⁸

Features of the Coordinator That Affect the Progress of Recruitment and Research

Patient recruitment is one of the most important stages of conducting a clinical trial. Responsibility for the entire trial belongs to the principal investigator; however, his cooperation with the clinical trial coordinator significantly affects the progress of this stage. The coordinator's key skills such as organizational, communication and coordination skills, increase the rate of patient inclusion in the trial.

The original role of coordinators back in the 1990s appears different based on available data. Historical records from Japan depict coordinators primarily engaged in promoting clinical trials rather than their current management responsibilities. The amalgamation of numerous training sessions undergone by coordinators has significantly expanded the scope of opportunities within this profession. In contemporary times, the knowledge acquired from diverse training courses proves particularly invaluable in interactions with the most demanding stakeholder—the patient.¹⁹

The study conducted by Spanish researchers in 2004 outlined the distinct roles and influential domains of coordinators. One notable sphere involved active participation in clinical trial endeavors, particularly in assisting clinical trial investigators during the patient recruitment phase. Alongside administrative duties throughout the trial, coordinators often shoulder responsibilities to aid recruiters—these recruiters are investigators proactively seeking eligible patients. Researchers in Italy have pinpointed the essential traits characterizing an effective coordinator: hands-on experience with clinical trials, proficiency in Good Clinical Practice, adept communication skills, and the ability to proficiently manage both the team and the trial.²⁰ The comprehensive array of skills encompassed by coordinators stands as pivotal to their multifaceted contributions within the research team.

The most commonly recurring skills are those shown in [Figure 2](#).

The journey that patient undergoes can often be bewildering. Factors like "the white coat syndrome" or getting lost in the unfamiliar layout of a hospital compound their apprehension. Yet, even these situations seem relatively trivial when compared to the decision to partake in a clinical trial.

Coordinators, often stationed at the forefront of patient care, play a pivotal role in recognizing the primary influences on participation and patient attrition. In line with a study conducted in South Korea, the most prevalent barriers for

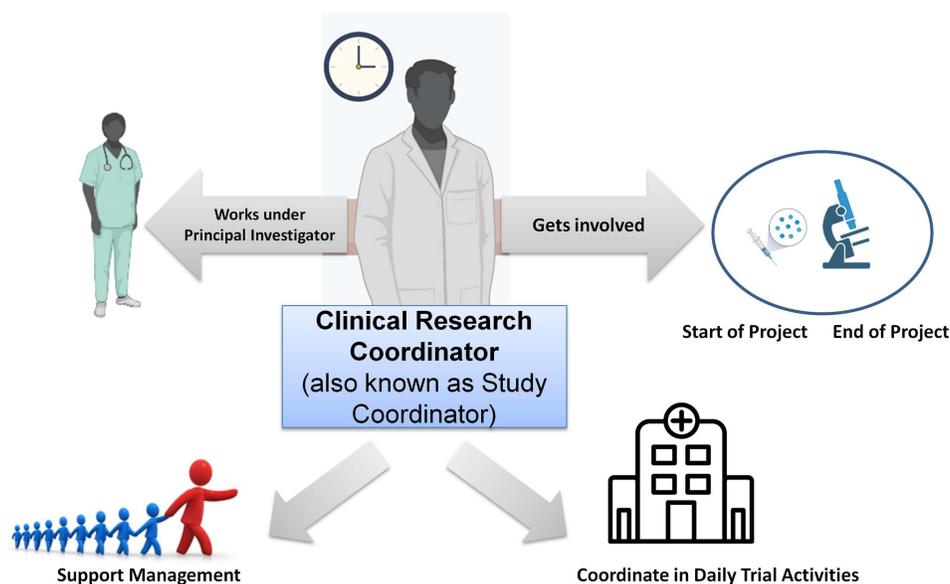


Figure 2 Key skills of a clinical trial coordinator.

oncology patients who potentially meet the criteria for clinical trial involvement include the clinical trial protocol itself (involving frequent lab tests and hospital visits), communication hurdles, cultural beliefs, financial constraints, patient condition (performance status and comorbidities), and physician engagement. Frequently, the resolution of these barriers can be as simple as fostering collaboration between the patient and the medical team.⁸

Guidelines based on Good Clinical Practice (GCP) serve to mitigate the risks tied to participating in clinical trials. GCP training assumes a pivotal role in trial execution and is deemed essential for those entrusted with data collection and maintaining its integrity—namely, clinical trial coordinators.

Highlighting this, the newly established EORTC CRC Group (European Organisation for Research and Treatment of Cancer Clinical Research Coordinator Group) operates with the primary objectives of positively impacting clinical trial quality and establishing criteria and benchmarks for implementing and conducting clinical protocols in adherence to Good Clinical Practice principles.¹⁴ Functioning as the European Organization for Research and Treatment of Pain, the EORTC is dedicated to advancing the development, coordination, and execution of clinical trials across Europe, with the overarching aim of enhancing cancer treatment standards and, consequently, addressing the challenges pertaining to patient survival and quality of life in this medical realm. The EORTC CRC Group focuses particularly on elevating the competencies of coordinators along the path of cancer patients, emphasizing comprehensive support during oncology patients' participation and meticulous study execution in alignment with the protocol.²¹

Among clinical trial participants, a prevalent term to describe coordinators is “the attorney” Coordinators are seen as attorneys for the patients involved, despite the complexities this role entails when it comes to assisting with decisions that ultimately rest with the trial participant. Patients tend to seek the coordinator's advice and anticipate both logistical and personal backing. In these scenarios, the coordinator must maintain their role within the study and clarify, sometimes blurred, but still boundaries between their role and the role of the patient.⁹

Summary

The collected data effectively bridge the existing gap in defining the coordinator's impact on clinical trials. Across the examined medical centres, the coordinator's significance and influence within clinical trials averaged at a notable: 99.1% in China¹² 80% in Italy¹⁰ and 70% in South Korea.⁸ This substantial influence of a research team member is substantiated by their pivotal attributes that bolster the study's engine, team dynamics, and patient recruitment. Key qualities encompass: experience, a comprehensive grasp of study regulations, and adept communication across all study phases. As the number of clinical trials escalates annually, meticulous attention to every facet of trial orchestration becomes imperative for achieving trial success. Notably, the role of the coordinator was established as a permanent fixture within research teams in Asian countries; however, the same permanence and clarity were harder to ascertain in European settings.^{8,10,12}

Despite a well-established pattern for the coordinator's responsibilities, a misconception about their tasks still persists among the general public. This misconception hinges on the perception of performing routine paper and electronic communication tasks while simultaneously engaging in research activities. In reality, the coordinator's role in clinical trials embodies a multitasking paradigm, involving the identification of frequently recurring and time-intensive tasks.²²

A survey conducted in Canada between 2018 and 2020 shed light on clinical trial coordinators' self-perceptions and job satisfaction. Over 60% of coordinators expressed experiencing a lack of comprehension from others regarding their clinical trial responsibilities. More than 70% of respondents sought clearer delineation of their roles. In contrast to these external challenges, when assessing their own feelings of value, respect, and confidence in their work, nearly 90% of responses affirmed positive sentiments.²³

Drawing insights from data collected in the US, where the role of a clinical trial coordinator is more prevalent than in European countries, it's evident that this role is highly desirable within the clinical trial landscape. An analysis conducted in 2021 highlighted the necessity to enhance the employment of clinical trial coordinators. Projections suggest a 10% increase in demand for coordinators between 2016 and 2026, compared to the preceding decade, underscoring the ongoing requirement for coordinators in clinical trials.¹⁵

In summary, well-executed clinical trials serve as a cornerstone for the healthcare entities, furnishing the knowledge essential to deliver effective, safe, and economically viable treatments.²⁴

Conclusions

In any team, leader is essential, and this principle holds true for clinical trial teams as well. The choice of this leader is on the principal investigator, who decides whether to assume the leadership role or delegate it to the clinical trial coordinator. Beyond this decision, the principal investigator also shoulders the responsibility of overseeing the entire study, spanning from the site to the team, which can often become a considerable burden. A strategic move observed in surveyed centers was to entrust the management function to the clinical trial coordinator. Centers lacking such coordination frequently encounter challenges like diminished recruitment, lower study quality, participant apprehension, and dropouts.¹¹ Conversely, centers with a designated coordinator exhibit superior study organization, streamlined procedures, and enhanced patient care. Moreover, these centers tend to achieve quicker patient recruitment by placing a heightened emphasis on patient engagement by co-researchers, rather than getting bogged down in the organizational aspects of the study.

The aspects that determined the relevance of the coordinator's role in a clinical trial are the conclusions made during the studies conducted in the 3 mentioned centers (China, Italy and South Korea). By clarifying the key responsibilities of the coordinator and his contribution to the coordination of the study, 3 key conclusions were identified.

1. The coordinator, as the person on the patient's 1st line, is best aware of the patient's rights.
2. The coordinator improves the quality of the ongoing clinical trial.
3. Has an impact on reducing consent withdrawals by patients.

In essence, the analysis underscores that centers with coordinators are better organized, achieve faster recruitment, and demonstrate an elevated sense of patient care. The meticulous documentation of the project and the prioritization of study participant safety led to refinements and advancements in diagnostic and treatment protocols across primary and specialized healthcare domains. This outcome significantly contributes to the overall well-being of patients, emphasizing the importance of effective project management and care coordination.¹¹

Disclosure

The authors report no conflicts of interest in this work.

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