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IN SEARCH OF A HIDDEN CLINICAL RESEARCH PROJECT MANAGER – AN EXAMPLE OF NON-COMMERCIAL ORGANIZATIONS IN POLAND

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Purpose: The objective of this study is to examine which roles are responsible for managing non-commercial clinical trials. A further objective is to assess the adequacy of the current recommendations concerning project management at the model Clinical Research Support Centre in Poland.
Design/methodology/approach: The theoretical scope of the study encompasses issues related to methodical project management and key roles in the management of non-commercial clinical trials. The research method employed is desktop research and in-depth analysis of scientific sources and current standards set by industry organisations in the healthcare sector.
Findings: The findings demonstrate the existence of numerous analogous terms that describe the roles of a non-commercial clinical trial manager, including but not limited to clinical trial coordinator, clinical trial associate, principal investigator, clinical trial manager and research project manager. It has been identified a very general overview of current recommendations and guidelines regarding the requirements for managers of non-commercial clinical trials, as well as imprecisely formulated job descriptions. Moreover, the result of the work is a conclusion that will act as a recommendation for implementing changes in the model Clinical Research Support Centre in Poland.
Research limitations/implications: The present study was grounded in extant literature on the subject, in addition to official documentation (legal regulations, guidelines, recommendations, good practices). Market information, in the form of job offers for management positions in clinical research projects, was not a factor in the study.
Practical implications: The present study offers a valuable resource for decision-makers and legislators by proposing a methodical approach to clinical trial management and enhancing work efficiency through the focus on qualified management staff.
Originality/value: This work addresses a significant gap in the literature by providing a systematic review of the roles of clinical trial managers. The paper presents a comparative analysis of the responsibilities of a non-commercial clinical trial manager in the context of methodological guidelines, including PMBOK, PRINCE2, AgilePM, and Scrum.
Keywords: project management, project manager, non-commercial, clinical research, clinical trials.
Category of the paper: research paper.

1. Introduction

The modern pharmaceutical market is developing dynamically due to the ageing population, its increasing wealth, and the emergence of new diseases (e.g. those caused by the SARS-CoV-2 virus). The most important factors in this development are the growth of innovative activities and the production, commercialisation and sale of increasingly new medicinal products whose effectiveness in achieving the desired therapeutic effects is confirmed by research, development and clinical trials. Recent publications highlight their role in generating high-quality evidence for health policy and medical practice (Ellis et al., 2025; Wen et al., 2025; Akinbolade et al., 2025).

A clinical trial is a prospective scientific study in which participants are assigned to one or more interventions (e.g. drugs, procedures, devices, diagnostic procedures or behavioural interventions) to assess their impact on health outcomes (WHO, 2025). Clinical trials can be small, preliminary studies or randomised controlled trials designed to evaluate safety and efficacy. They are carefully designed, reviewed and approved prior to commencement and involve the testing of new therapies, devices or preventive procedures.

The ICH-GCP guidelines (latest version E6(R3), 2025) and EU regulations (Regulation EU 536/2014) set out the requirements for conducting clinical trials, the priority of participant safety, and the mechanisms for approval and supervision.

A non-commercial clinical trial, otherwise referred to as an investigator-initiated trial (IIT), is a trial that has been designed and initiated by a researcher (university, research institute, scientific society, or public entity) in response to a scientific question of clinical or social importance, rather than primarily for commercial product development. Typically, these initiatives are sponsored by non-profit organisations or public entities, with funding frequently derived from public sources, grants, or non-profit organisations (Del Álamo et al., 2024).

In the context of EU legal and operational documents, this concept is recognised and distinguished from industry-led research; it does not automatically imply less rigour, with regulatory requirements proportionate to risk still applying (European Parliament, 2014).

The term "clinical trials" is characterised by specific features, including but not limited to the following: a clearly defined objective, a defined timeframe, a specified budget, a defined scope, a defined group of stakeholders, and a defined set of risks. In practice, project management methodologies and techniques, such as planning, scheduling, risk management, CPM/PERT, agile/hybrid, and digital tools, are increasingly being applied to clinical trials (Gumber et al., 2024; Peralta, Sánchez-Santiago, 2024).

The following observations have been made (Wang et al., 2025):

– Clinical trials are characterised as project-based, requiring meticulous planning encompassing a protocol, schedule, and budget. These trials are initiated with a defined objective, commonly referred to as a research question or a specific clinical outcome,

and are subject to various constraints in terms of resources, including staff, budget, and equipment. The temporal aspect of clinical trials, characterised by the initiation, progression, and conclusion of specific projects, is another salient feature. Consequently, clinical trials align with the conventional characteristics of a project, encompassing the necessity for thorough planning, the establishment of a defined objective, and the allocation of resources in accordance with the stipulated budget and equipment.

- Project management tools and techniques are utilised in the management of clinical research projects, encompassing domains such as process organisation, role allocation, administrative process optimisation, regulatory compliance oversight, and the coordination of multiple studies concurrently.

It is evident that clinical trials, encompassing both commercial and non-commercial domains, are characterised by the hallmarks of a project (Doganov, Yanev, 2006; Farrell, Kenyon, Shakur, 2010). Consequently, the effective implementation of these trials necessitates the integration of professional project management principles and tools. The hallmarks of such initiatives include a clearly delineated objective, a defined temporal framework, specified resources, a team with clearly defined roles, and the necessity for continuous coordination of activities and risk management. Consequently, a project-based approach is imperative to ensure structure, transparency, and predictability of activities. The role of the project manager becomes of particular significance in this context. The project manager is responsible for planning, scheduling, monitoring progress, managing an interdisciplinary team, and identifying and controlling risks that may affect the safety of participants and the quality of data. The extent to which the project manager is adequately prepared and demonstrates competence has been shown to have a significant impact on the success of a clinical trial, with the result that it is more likely to be conducted in an efficient, ethical, and regulatory-compliant manner.

Furthermore, recent studies highlight that the Research Project Manager plays a pivotal role in all phases of the collaborative research project, from the ideation stage through to transformation and execution, post-execution and project closure (Barbosa et al., 2025).

Other research findings at the intersection of health sciences and management sciences indicate that it is worthwhile to introduce managerial and strategic (management) roles into health-related projects (Carman, Pendergrass, 2025).

The objective of the present study is to make a comparison between the roles of a project manager as defined in a selection of project management methodologies (PRINCE2, AgilePM, PMBOK Guide) and the roles and positions found in non-commercial clinical research projects. The work is descriptive and comparative in nature and is based on an analysis of extant sources, including industry documents and publicly available materials.

A qualitative approach, underpinned by document analysis (desk research), was employed. This method facilitates the systematic collection and interpretation of information characterising both the formal requirements of selected methodologies and the practical roles

found in the clinical research environment. The paper discusses the case of a model Clinical Research Support Center developed by the Medical Research Agency in Poland.

2. Literature review

The following literature review is divided into two complementary areas. The first of these concerns managerial roles as defined in selected leading international project management standards and methodologies. The second area of focus in this text is on the analysis of the role of the project manager in clinical research projects, with particular emphasis on the specific nature of research and regulated projects.

2.1. Managerial roles in selected leading project management standards

Internationally recognised project management methodologies, including the PMBOK Guide, PRINCE2, and agile methodologies, establish consistent standards for project execution across diverse sectors. The definition of key processes, knowledge areas, and project artefacts is fundamental to ensuring transparency, control, and repeatability of activities (Liebert, 2017; Brzozowski, 2020).

Furthermore, they provide a robust foundation for precisely defining the role of a project manager. This is achieved by describing their responsibilities in terms of planning, communication, stakeholder management, risk management, quality management, budget management, and team management. Consequently, the role of the project manager is not only clearly delineated, but also comparable across organisations and industries, thereby promoting professionalisation and enhancing project effectiveness (Jamali, Oveisi, 2016; Zubon, Taher, 2022). This section of the study examines a selection of leading project management methodologies and their approach to the role of the project manager. The primary focus of this analysis is on competency requirements and responsibilities.

The project manager's competencies in planning, organising, allocating resources, using PM tools, and dealing with interpersonal and contextual factors are identified as "key elements" in determining the success of a project. This gives the project manager a pivotal role, connecting the project's objectives with its daily execution. The project manager is entrusted with the responsibility of establishing structure, maintaining order, facilitating communication, and adapting to evolving circumstances (Gasemagha, Kowang, 2021). The primary functions of a project manager are presented in Table 1.

Harold Kerzner (2022), a leading authority in the field of project management, defines a project manager as a person who is responsible for planning, organising, directing, and controlling project resources in order to achieve project objectives in accordance with the agreed scope, time, budget, and quality. In Kerzner's classic approach, a project manager is:

- the single point of responsibility for project implementation,
- the person coordinating the activities of an interdisciplinary team,
- the negotiator in contacts with stakeholders and management,
- the leader responsible for communication, motivation, and conflict resolution,
- a risk and change manager,
- a person supervising the integration of all project processes.

Table 1.
Primary functions of a project manager

Planning project activities The project manager bears responsibility for the planning of all project activities, including the schedule, task distribution, and resource allocation. In addition, the project manager assesses team members' competencies and assigns tasks appropriately.	**Project team management** The ability to manage people effectively is pivotal. The manager must assess the skills of team members, divide roles and tasks, motivate, coordinate activities, and monitor the team's work.
Application of project management tools and techniques It is imperative to emphasise that the adept utilisation of PM techniques and tools (e.g., methodologies, planning, control, and monitoring techniques) constitutes a pivotal competency that is instrumental in the success of a project.	**Managing the political and cultural context of a project** In projects – especially those of an organisationally complex or intercultural nature – the manager must demonstrate competence in dealing with issues of organisational politics, stakeholder relations, and cultural differences. This is also a crucial element of project management.

Source: Own elaboration based on Gasemagha, Kowang, 2021.

Kerzner (2022) emphasizes that a project manager must combine technical, organizational, and interpersonal skills, and that their role is to create an environment that enables the project's goals to be achieved — regardless of the organizational or technological complexity of the undertaking.

In accordance with the fundamental principles of management, during the implementation phase of a project, the project manager is required to (Karbownik, 2022):

- maintain intensive communication with the client, senior management, and resource providers,
- monitor and control project work,
- deepen team members' knowledge of the project,
- identify and solve problems,
- delegating tasks,
- involving the team in the decision-making process.

The nature of a project manager's tasks and role is contingent on the approach to project management. In the traditional approach to project management, the project manager's role is to build, motivate and lead the team to achieve goals. This includes planning, budgeting, resource allocation, supervising and managing conflicts. The agile approach uses self-disciplined and self-organising teams of highly competent members with certain personality

traits. Agile project management methods, such as Scrum, do not use a project manager (Karbownik, 2022; Romański, 2025).

The following Table 2. sets out a comparison of the definitions and key responsibilities of a project manager in a selection of project management methodologies, including both traditional approaches (PMBOK, PRINCE2, IPMA) and agile approaches (AgilePM, Scrum). This comparison facilitates an understanding of the differences in assigned roles, tasks and competencies in different project contexts.

Table 2.
A comparison of selected definitions of the role of a project manager

Source	Definition of a project manager	Key highlights/elements of the role
Harold Kerzner (2022)	A project manager is a person responsible for planning, organizing, directing, and controlling resources in order to achieve project objectives in accordance with the scope, schedule, budget, and quality.	– single point of responsibility, – integration of activities and processes, – team, communication, and stakeholder management, – risk and change management, – combining technical, organizational, and interpersonal skills.
PMBOK® Guide 7th ed. (PMI)	The project manager is a person appointed to lead the project team in order to achieve the project's objectives and generate value for stakeholders.	– responsibility for the project team, – ensuring the implementation of PM processes and practices, – leadership, communication, facilitation of cooperation, – supervision of scope, schedule, costs, risks, – focus on value and stakeholders.
PRINCE2®	The project manager is responsible for the day-to-day management of the project and for delivering project products within the tolerances set by the management (Project Board).	– product-based planning, – day-to-day project management, – reporting to the Project Board, – risk, quality, and configuration management, – maintaining documentation and stage control.
IPMA ICB 4.0	A project manager is a professional who applies technical, behavioral, and contextual competencies to achieve project goals in a specific organizational environment.	– broad competency model (29 elements), – emphasis on soft skills: leadership, communication, self-awareness, motivation, – context and stakeholder management, – adaptation of methods to the project environment.
AgilePM (DSDM)	The Project Manager is responsible for planning, monitoring, and coordinating the project, ensuring compliance with business objectives while maintaining Agile flexibility.	– iteration planning, – communication, – risk management, – collaboration with the Agile Team and Business Sponsor, – supervision of the delivery process.
Scrum	Scrum does not provide for the role of project manager; responsibilities are divided between the Scrum Master, Product Owner, and Development Team.	– Scrum Master: facilitation and removal of obstacles, – Product Owner: backlog management Team: product delivery

Source: Own elaboration based on: DSDM Consortium, 2014; International Project Management Association, 2015; AXELOS, 2017; Schwaber, Sutherland, 2020; Project Management Institute, 2021; Kerzner, 2023.

In summary, Kerzner emphasises integration, control, and the role of the manager as the "central point of responsibility". The PMBOK methodology is predicated on the principles of value creation and effective team leadership, with a focus on best practices and a flexible

approach. The PRINCE2 framework places significant emphasis on the role of the manager as the operational leader of the project, with responsibility to report to the Project Board and deliver products within prescribed tolerances. The IPMA model is distinguished by a broad competency framework encompassing both the hard and soft aspects of management.

2.2. The role of project manager in clinical research projects

The Core Competency Framework, published by the Joint Task Force for Clinical Trial Competency (which is responsible for updating the scientific and methodological basis for conducting clinical trials), clearly recommends the need to develop the project management skills of people working in this field (Sonstein et al., 2022). The planning and management of clinical trials, including non-commercial clinical trials (NCTs), is a complex process that typically demands a range of competencies. Recent studies have highlighted a significant shortage of adequately trained management staff at research centres conducting such trials (Mitchell et al., 2022).

It has been posited that clinical trials meet the requisite criteria to be classified as projects. The specific characteristics of clinical research projects include, above all: the establishment of objectives at the planning stage, the identification of the resources necessary to achieve the planned objectives, the proper planning of activities adequate to achieve these objectives, the continuous monitoring of work progress and results based on clear performance criteria, the ongoing evaluation, the project closure if the objectives are achieved or cannot be achieved, the implementation of activities in accordance with a pre-prepared clinical trial protocol, and the use of this document as a basis for monitoring project progress (Goodarzynejad, Babamahmoodi, 2015).

In accordance with the universal PMI methodology, the project life cycle is comprised of five phases (initiation, definition and planning, execution, performance monitoring, and closure). In the context of healthcare projects conducted within the pharmaceutical market and clinical trials, analogous stages can also be applied (Schwalbe, Furlong, 2017).

When discussing the organisation of a non-commercial clinical trial in terms of attributes, the following example can be used. Prior to the initiation of a clinical trial project, the principal investigator and the sponsor of the trial are obliged to establish a small working group. This working group should consist of investigators, a statistician, and an individual with experience in clinical trial methodology. The steering committee is responsible for all significant decisions pertaining to the initiation, management, and cessation of the trial. The sponsor is the entity that assumes responsibility for the trial, which may also be the funding organisation. The coordination centre and data centre are responsible for the day-to-day tasks of conducting the trial, including randomisation, data collection and circulation, review of ongoing documentation, and organisation of monitoring visits to trial sites. The endpoint validation committee is responsible for verifying the documentation prepared by the coordination centre regarding the study endpoints. The safety assessment committee is

responsible for liaising with the steering committee and medical agencies (e.g., EMA or FDA), providing information regarding any irregularities in the non-commercial clinical trial project (Boissel, 2004).

Recent studies (Barbosa et al., 2025) have highlighted a paucity of clarity and consensus with regard to the role of research project managers in collaborative research projects, as well as an absence of a widely accepted definition of what the position of research project manager should and should not entail.

As Ernø-Kjølhede (1999) has demonstrated, the function of research project manager is situated at the intersection of Research Management and Administration and Project Management.

Research Project Manager typically exerts minimal formal authority over project members/participants (Ernø-Kjølhede, 2000). In contradistinction to the prevailing paradigm of general project management, in which the Project Manager (PM) typically reports directly to the governing body or funder, the Research Project Manager (RPM) frequently collaborates with the Project Manager/Scientific Manager or Principal Investigator (PI). This PI is typically a visionary who, prior to the initiation of the project, establishes a project consortium comprising organisations collaborating on a designated joint research project and secures funding, often with the support of the Research Manager and Administrator. It should be noted that, although the same individual may sometimes fulfil both the roles of Principal Investigator and Research Project Manager, these roles are distinct and interrelated, thus forming a dynamic leadership duo. The RPM is concerned with management principles, regulations, and contract details, ensuring that the project fulfils its obligations to the funder, while the PI is responsible for scientific direction and decision-making. The success of the project is contingent on the effective fulfilment of both roles, with internal communication being of paramount importance. The RPM is charged with the facilitation of this process (Ernø-Kjølhede, 1999).

Research Project Managers constitute a discrete yet interconnected component of the research administration framework. The role of the aforementioned parties encompasses several fundamental elements, which are outlined below (Barbosa et al., 2025):

- The implementation and support of projects that span multiple phases of the life cycle is a responsibility that falls upon these individuals.
- They are assigned to specific projects on a permanent basis, playing a proactive role in them. They respond to the needs of the principal investigator (PI), but also initiate activities independently, using their knowledge.
- These individuals are not typically academic staff members. In instances where they assume dual roles, they undertake project activities in a manner that is distinct from their academic responsibilities.
- The role description of the project manager corresponds to the definitions of project management and is formally recognised (e.g., by the funding institution or central university units).

- It is imperative that the requirements of the grantors and institutions are reconciled with the needs of the PI, the consortium, and the project objectives, while adhering to the established rules, procedures, and regulations.
- Their approach is characterised by a holistic perspective, encompassing multiple areas of expertise and collaboration with diverse project partners.

During the implementation phase of a research (clinical trial) project, the research project manager is responsible for tasks such as: Project Phase Planning, Funding entity knowledge, Contract Management, Consortium Management, Budget Management, Risk Management, Progress Tracking, Reporting, Quality Management, Evaluation and Assessment, Change Management, Impact Assessment, Management Communication within the Project. In addition, the research project manager may also have additional responsibilities: Data Management, Compliance and Ethics, IP Management and Exploitation, Communications and Dissemination, Stakeholder Management, Procurement Management, Resource Management, Gender dimension (Barbosa et al., 2025). The authors cited here claim that the successful coordination of a collaborative research project necessitates a proficient Research Project Manager, a dedicated and enthusiastic Principal Investigator, along with a group of collaborating partners, and constant dialogue among the professionals involved in the project life cycle support.

The sponsor of a non-commercial clinical trial may delegate its project management responsibilities to third-party organizations. Clinical Trial Units (CTUs; also called academic Clinical Research Organizations) are non-profit organisations that support academic investigators and sponsors. They raise awareness of national challenges and create a more favourable environment for clinical research. CTUs are usually linked to university medical schools, health care units or university hospitals. Their main function is to support research-active clinicians in planning and executing patient-oriented research projects and advancing the quality of clinical research (Batuca, Maia, 2024).

Trial management procedures/responsibilities that are common across all trials are usually defined in the standard operating procedures (SOPs). For example, the Standard Operating Procedure (SOP) developed by the Cambridge Clinical Trials Unit (2024) concerning the organisation and launch of Clinical Trial of Investigational Medicinal Product describes the step-by-step process of starting up/setting up a CTIMP trial, i.e., all activities from the moment funding is granted to the activation of the first (lead) centre. This SOP delineates the composition of the clinical trial project team as follows: The Chief Investigator, Principal Investigator, Clinical Trials Coordinator, Data Manager and Research Nurse at the coordinating site are to be identified and delegated by the CI and/or Sponsor. The sponsor is defined as a person, company, institution or organisation that assumes responsibility for the initiation, management and/or financing of a clinical trial. This example demonstrates that clinical trial projects (including non-commercial ones) do not explicitly provide for the role of a project manager, but often only for a trial coordinator.

The management of diverse multidisciplinary teams to run clinical trials is challenging. An organisational structure must be defined, with three committees typically overseeing trials: Trial Management Board, Trial Steering Committee and Data and Safety Monitoring Board (DSMB). The Trial Management Board's role is to lead and oversee clinical trials, focusing on practical execution, resource allocation, problem-solving and handling administrative components. Responsibilities include (Batuca, Maia, 2024):

- liaising between sponsors and research teams,
- hiring and training staff,
- ensuring awareness of roles and responsibilities,
- coordinating research teams,
- tracking finances,
- ensuring regulatory compliance, subject safety and data quality,
- tracking subject recruitment and retention,
- Adverse Event (AE) documentation and reporting,
- oversight of drug storage and use,
- data management – data collection, Electronic Data Capture (EDC),
- renewing financial and regulatory approvals.

The group includes the Chief Investigator, the Trial Manager, the Statistician, the Database Manager, the Database Programmer, Pharmacist, Health Economist and one or two site Principal Investigators.

The list of tasks of a clinical research project manager may also include (Nagy, 2024):

- plan creation for tasks, including deliverables, measures, timescales, strategy and tactics,
- establishment of responsibilities, objectives, accountabilities and measures by agreement and delegation,
- setting of standards, quality, time and reporting parameters,
- controlling and maintenance of activities against parameters,
- maintenance of overall performance against the plan,
- reporting on progress towards the group's aims,
- reviewing, re-assessing and adjusting plans, methods and targets as necessary,
- liaising with stakeholders, including team members, project specialists, the project coordinator and the project leader.

In addition, the (non-commercial clinical trial) project manager's duties are (Batuca, Maia, 2024):

- define all activities required to produce project deliverables,
- define the activities' order or sequence and relationship,
- establish the required resources,
- estimate the duration of activities.

In practice, there are often two roles: project manager and project coordinator (research). A project manager is responsible for the success of a project. A project coordinator supports the project manager and ensures the project runs smoothly. This includes scheduling meetings, maintaining documentation and coordinating activities. The project coordinator ensures everyone is on the same page and communication flows smoothly (Nagy, 2024). Therefore, the coordinator's role is less significant than that of the project manager, as they are not responsible for making decisions about the course of the project. The tasks and responsibilities of the project leader, manager and coordinator complement each other. Ideally, these roles should be taken on by different stakeholders, as assuming all of them can lead to confusion, communication difficulties, overload and burnout. However, these roles can be centralised in the hands of one person (Nagy, 2024).

In the pharmaceutical industry, the role of a project manager is defined more broadly, but still in line with the general definition in management science. As indicated by Ahmed (2022) the project manager plays an important role in the pharmaceutical industry, not only by strategising the organisation's marketing strategy for products, but also by implementing it. From pre-launch and launch campaigning to post-launch marketing, every aspect is handled thoroughly by the project manager. Every product in the pharmaceutical industry goes through the typical four phases of the life cycle: introduction, growth, saturation and decline, or the stable phase. Project management and sales are responsible for an organization's revenue targets. In the pharmaceutical industry, a project manager's responsibilities typically encompass (Ahmed, 2022):

- defining the project,
- selecting the team and overseeing organization,
- planning, scheduling and monitoring progress,
- handling problems and making decisions using prototypes,
- obtaining senior management approval and overseeing operations,
- managing proactive changes in real time.

Regulation (EU) No 536/2014 and ICH E6(R3) establish the fundamental legal and quality framework for conducting clinical trials in the European Union and internationally, but both acts differ significantly from typical project management documents. EU Regulation No 536/2014 (Official Journal of the European Union, 2014) is a legal act that regulates the formal aspects of clinical trials on medicinal products. In particular, it establishes the rules for notification, defines the key terms ('sponsor', 'protocol', 'clinical trial'), and outlines the obligations of state authorities, the procedures for authorisation, and the requirements for the protection of trial participants. Throughout the text of the Regulation, there are no references to the concept of 'project' in the management sense, and the term 'management' appears only in the context of the obligations of the clinical trial sponsor and its responsibility for initiating, financing, organising and supervising the trial. This corresponds to the practice of supervising

the research process, rather than the general principles of conducting scientific research or investment projects.

The ICH E6(R3) GCP guideline (European Medicines Agency, 2025), a document prepared by the International Conference on Harmonisation, provides detailed quality principles for the design, conduct, monitoring, analysis and reporting of clinical trials. The purpose of this guideline is to ensure the protection of the rights, safety and well-being of participants, as well as the reliability of data. While the document organises processes and assigns responsibilities (in particular to the sponsor and investigators), it does not utilise the term 'project' as a conceptual category specific to project management, nor does it define project structures or phases. In the context of GCP, management explicitly refers to the implementation of a quality management system, the oversight of risk, and the assignment of responsibilities within a clinical trial. These functions are necessary for the compliant conduct of a trial; however, they do not constitute a described project management methodology.

Consequently, although clinical trials meet many of the criteria for a project in practice (unique objective, limited duration, complex stakeholder structure and high risk), in the regulatory documents analysed, they are conceptualised primarily as a process regulated and controlled in terms of compliance, safety and data quality, rather than as a project in the management sense. The existence of this conceptual gap serves to underscore the necessity for the utilisation of project management expertise in the design of organisational structures, coordination mechanisms and controls for the conduct of clinical trials, without compromising legal requirements and GCP guidelines.

Despite the growing importance of non-commercial clinical trials in Poland, a significant research gap remains in scientific literature and system documents regarding the precise definition of the position, role, and function of the project manager in clinical trial projects. This issue is further complicated by the inconsistency of the terminology used. Terminology related to clinical project management is used ambiguously and interpreted in different ways, both in organisational practice and in scientific studies. This paper aims to contribute to the existing body of knowledge by addressing the research gap identified in the field. It also seeks to stimulate discussion on the validity of current legal regulations and public guidelines of organisations supporting non-commercial clinical research projects in Poland.

3. Method

The objective of the present study is to make a comparison between the roles of a project manager as defined in a selection of project management methodologies (PRINCE2, AgilePM, PMBOK Guide) and the roles and positions found in non-commercial clinical research projects.

The work is descriptive and comparative in nature and is based on an analysis of extant sources – industry documents and publicly available materials.

A qualitative approach, underpinned by document analysis (desk research), was employed. Desk research, as one of the non-reactive research methods, inherits all the textbook advantages of non-reactive research. According to Babbie (2003) there are three non-reactive methods of data analysis. These are content analysis, analysis of existing statistical data and historical-comparative analyses. Desk research may be considered as a combination, or even the essence, of these methods. A comprehensive desk research analysis is conducted, incorporating content analysis from the initial stage of source identification, alongside extensive utilisation of existing statistical data. Cross-sectional analyses and comparisons of historical data are also performed (Bednarowska, 2015).

This method facilitates the systematic collection and interpretation of information characterising both the formal requirements of selected methodologies and the practical roles found in the clinical research environment.

The present study is of a secondary nature and is based on sources that have already been developed, thus enabling the compilation of dispersed information and the creation of a synthetic comparative model.

The analysis took into account official and publicly available publications: PRINCE2 – Managing Successful Projects with PRINCE2 and AXELOS materials on roles and responsibilities; AgilePM – AgilePM Handbook and DSDM Consortium guides defining roles in agile projects; PMBOK Guide – selected chapters of the PMBOK Guide (e.g. versions 6 and 7), in particular the section on roles, project manager competencies and areas of responsibility. For each methodology, the following were identified: role titles, duties, decision-making responsibilities, required and key competencies, the role's place in the project structure.

The following categories of sources were used to collect data:

- The present corpus of scientific publications focuses on the roles of project managers (and associated positions) in research projects, with a particular emphasis on clinical research projects and projects in the pharmaceutical industry.
- A comprehensive compendium of job descriptions and regulations for entities can be found on the websites of universities, clinical research centres and research institutes.
- The documentation encompassed within this category includes industry and regulatory documents, such as those from the ECRIN and EUPATI repositories, along with guidelines stipulated by the GCP. Additionally, the subject matter encompasses charts that delineate the respective responsibilities of sponsors and research teams.
- Industry reports are documents that concern the organisation of processes in non-commercial research. Such reports are published by international clinical research networks, for example reports on the role of Trial Manager and Project Manager in NCTN, NCRI and ECRIN.

The analysis focused on determining: role nomenclature, scope of responsibility, decision-making areas, relationships with other team members (PI, Sponsor, Monitor, CRA, Data Manager), degree of compliance or differences with project methodologies.

Document analysis is a suitable method for several reasons. The normality of project methodologies is evident in the formalised and publicly described roles, responsibilities and areas of competence presented by PRINCE2, AgilePM and PMBOK. This data can be obtained without the need for field research. The public nature of clinical trial data is a key consideration in the realm of academic research and commercial clinical trials. Academic institutions, research centres and entities conducting non-commercial clinical trials are required to publish a range of materials, including job descriptions (e.g. Project Manager, Clinical Project Manager, Trial Coordinator, Sponsor Representative), recruitment materials and regulatory documents. The potential for cross-sector comparisons is evident. Document analysis is an efficient method for building a comparative matrix of roles between the 'classic' project sector and clinical projects. In clinical projects, role structures often do not correspond to methodologies in terms of nomenclature.

Research based on document analysis is subject to certain limitations. The diversity of nomenclature employed by clinical trial units has the potential to impede the process of achieving comprehensive standardisation of roles. It has been observed that certain job descriptions are not entirely transparent, with some institutions imposing limitations on the extent to which duties are delineated. Systemic differences between countries may have implications for the scope of responsibility of the Project Manager in clinical trials. Document analysis does not permit an evaluation of the actual performance of roles; it examines declarations, not operational practice. These limitations do not nullify the value of the study, but rather highlight the necessity for caution in interpretation.

The adopted methodology enables a systematic and reliable comparison of the roles of a project manager in three key project management methodologies with roles occurring in non-commercial clinical trials. The analysis of documentation facilitates not only the identification of similarities and differences, but also addresses a research gap concerning the application of formal project methodologies in the specific context of clinical trials.

4. Results – The case of non-commercial clinical trial projects in Poland

Non-commercial clinical research projects in Poland are carried out by a variety of entities, including universities or other scientific institutions authorised to award academic degrees, healthcare entities, researchers (doctors), patient organisations, organisations of researchers or other natural or legal persons, or organisational units without legal personality. The activities

carried out are not aimed at making a profit related to the conduct and organisation of clinical trials, as well as the manufacture or marketing of medicinal products.

In addition, non-commercial clinical trials (NCTs) are conducted without the involvement of the pharmaceutical industry. The fundamental principle of NCTs is that the data collected cannot be utilised to obtain marketing authorisation for designated medicinal products or to effect modifications to extant authorisations (Wąsik, Kuczur, 2016).

The Medical Research Agency (2024) in Poland (*Agencja Badań Medycznych*, ABM) has developed guidelines for entities that have or plan to establish a Clinical Research Support Centre (*Centrum Wsparcia Badań Klinicznych*, CWBK) within their structures. Operating as a shared services model, CWBK provides comprehensive and systematic support for the implementation of both commercial and non-commercial clinical trials. Its main area of activity is conducting clinical trials, including contracting and budgeting, as well as managing processes in accordance with established procedures. In order to achieve these objectives, it is necessary to employ qualified staff and establish the appropriate infrastructure.

The model CWBK includes the following basic, mandatory positions: two management staff positions, three clinical trial coordination positions and one project management position. The CWBK management team oversees three main areas of activity, each responsible for specific processes: contracting; budgeting; administrative management of research; and supervision of the research coordination process. Clinical trial coordinators should be responsible for the ongoing verification of quality indicators in trials, such as the number of outstanding queries, the number of incomplete CRF pages, issues relating to the quality of medical documentation and discrepancies in the accounting of investigational medicinal products. Their other responsibilities include planning, organising and supervising the various stages of clinical trials, as well as managing time and resources.

CWBK provides dedicated project management staff who are responsible for preparing grant applications and acquiring new research projects for the centre, as well as assisting researchers with their applications. The competences and expected results of the project manager are as follows (Medical Research Agency, 2024):

- Preparing documentation related to the implementation of the project, including drawing up funding applications for non-commercial research together with the required attachments.
- Developing, supervising and updating documents necessary to initiate and conduct a clinical trial, including the trial protocol, laboratory instructions, risk management plan, trial monitoring plan, safety management plan, forms and SOPs.
- Taking responsibility for communication with external service providers (e.g. pharmaceutical manufacturers and other clinical centres).
- Resolving ongoing issues during the trial.
- Directly cooperating with institutions to obtain the necessary data to prepare a funding application.

- Processing applications at the formal and substantive assessment stages.
- Preparing information, reports and summaries on the progress and implementation of projects.
- Preparing a package of documentation for submission to the Bioethics Committee and Office for Registration of Medicinal Products, Medical Devices and Biocidal Products / Clinical Trials Information System.
- The ability to think analytically and draw conclusions.

The minimum requirements for the position of clinical research project manager include only: higher education; one year of experience working in an R&D department or participation in the preparation of five applications for funding for projects financed from national or European funds in the field of R&D; intermediate level of English.

Furthermore, according to the model Clinical Research Support Centre, the project team for a non-commercial clinical trial should primarily comprise (Medical Research Agency, 2024):

- investigators and co-investigators,
- nurses,
- pharmacists,
- laboratory diagnostician,
- clinical trial monitor, and
- a medical writer.

The CWBK Model Standard, promoted by ABM, stipulates that centres must meet organisational and procedural requirements that are appropriate to the complexity of the research. Since clinical trials, especially multi-centre non-commercial or commercial ones, are complex undertakings requiring planning, resources, schedules, supervision, communication and coordination, it is logical that effectively implementing these requires someone to perform the analogous function of a 'project manager'. In practice, the CWBK model creates structures in which individuals are responsible for designing and managing trials.

Examples from other research organisations in Poland show that it is possible and worthwhile to plan the management of non-commercial clinical trials in such a way as to separate the roles of project manager and principal investigator. For example, in one of its main competitions for funding innovative projects, the National Centre for Research and Development recommends (by preparing an appropriate grant application form) separating the roles of R&D manager and R&D module manager (Narodowe Centrum Badań i Rozwoju, 2025). The R&D manager can be compared to the principal investigator in clinical trials, while the R&D module manager can be compared to the project manager.

The most significant stakeholders in non-commercial clinical trials are as follows (elements of the organisational structure of the environment) (Grzeszczyk, Zawada, 2024):

- Trial Sponsor – the entity providing financial backing for the initiation of a trial. In the context of commercial trials, this role is typically assumed by a pharmaceutical company. Conversely, in the case of non-commercial trials, scientific institutions or other research institutions frequently serve as the sponsor. Furthermore, a researcher may also act as a clinical trial sponsor.
- A Contract Research Organisation (CRO) – the entity that conducts a given clinical trial on behalf of the sponsor. The CRO often employs a clinical trial coordinator, clinical trial associate, data manager, biostatistician and other specialists.
- Research centres – the facilities designated for the conduct of clinical trials. Such centres may be located within hospitals or medical clinics.
- Medical staff/researchers – doctors engaged in research activities, with the principal investigator being a salient example. Additionally, the term encompasses nurses and pharmacists involved in research endeavours.
- Study participants – individuals who engage in the study in the capacity of either patients (i.e. persons afflicted by a specified illness) or healthy volunteers.
- Bioethics Committee – the independent institution that provides an opinion on a given clinical trial, with particular emphasis on its legitimacy, feasibility, and the safety of its participants. Similarly, the term "Ethics Committee" denotes an independent institution that performs a similar function in the context of clinical trials.
- Public administration bodies – the institutions that have been charged with the responsibility of overseeing, providing opinions on and approving (i.e. enabling the commencement of) clinical trials. In addition to this, they are also tasked with ensuring that the research project is conducted in accordance with the prevailing legislation.

A comprehensive delineation of the pivotal roles within non-commercial clinical research projects, accompanied by a delineation of task equivalents according to project management methodologies (classical and agile), is presented in the following Table 3.

Table 3.
Clinical roles translated into project roles according to PRINCE2, PMBOK and AgilePM

Role in a clinical trial (non-commercial)	Typical tasks in a clinical trial	Equivalent project role – PRINCE2	Equivalent project role – PMBOK	Equivalent project role – AgilePM
Principal Investigator (PI)	Scientific responsibility, protocol compliance, substantive supervision	Executive (if acting as benefit owner) or Senior User (recipient of scientific value)	Sponsor or Key Stakeholder	Business Sponsor / Business Visionary

Cont. table 3.

Sub-Investigator (Sub-I)	PI support, medical responsibility	Senior User (joint responsibility for requirements)	Stakeholder (Subject Matter Expert)	Business Advisor
Study Coordinator / Clinical Trial Coordinator	Operational coordination of the study, documentation, visit schedule	Team Manager (manages the work area)	Project Coordinator / Project Team Member	Team Member
Project Manager (Clinical PM – if present in the trial structure)	Scope, schedule, risk and communication management	Project Manager	Project Manager (PMBOK roles are process-based, but the PM is responsible for integration)	Project Manager / AgilePM
Data Manager	EDC support, data quality, validation, cleaning	Team Manager or Specialist Role	Specialist / SME (Quality, Data)	Technical Coordinator or Solution Developer
Clinical Research Associate (CRA)	Data monitoring, compliance verification, follow-up visits	Team Manager / Quality Reviewer	Quality Assurance / Control Specialist	Technical Advisor
Regulatory Specialist	Bioethics committee approvals, regulatory documentation	Project Assurance (quality and compliance perspective)	Compliance Specialist / Stakeholder	Business/Technical Advisor
Study Nurse / Research Nurse	Implementation of research procedures, patient support	Team Member	Project Team Member	Team Member
Biostatistician	Randomisation, statistical analysis	Senior Supplier (expert responsibility)	SME (Subject Matter Expert)	Technical Advisor / Solution Developer
Pharmacist / IMP Manager	Medicinal product management, IMP preparation	Supplier / Team Manager	Procurement / SME	Technical Coordinator
Ethics Committee (as stakeholder unit)	Ethical supervision, protocol approval	Project Board – Project Assurance (external)	External Stakeholder	Business Sponsor (advisory role, non-operational)
Academic sponsor (university, institute)	Funding, formal responsibility	Executive	Sponsor	Business Sponsor

Source: Own elaboration based on: DSDM Consortium, 2014; International Project Management Association, 2015; AXELOS, 2017; Schwaber, Sutherland, 2020; Project Management Institute, 2021; Kerzner, 2023; Grzeszczyk, Zawada, 2024.

With reference to the functions of the project manager in non-commercial clinical trials, illustrative role summaries can be found in Table 4.

Table 4.
Main roles of the project manager: comparison of methodologies and clinical trials

Area / Role element	PRINCE2 (Project Manager)	PMBOK (Project Manager)	AgilePM (Project Manager / Team Leader)	Clinical trials (NC) – project manager / trial manager / study coordinator
Project planning	full responsibility for the plan	full responsibility for the plan and management of the project triangle	shared with the team, iterative planning	preparation of the study plan, schedule, tasks for the PI and team
Scope management	scope control, deliverables	key area (Scope Management)	iterative scope, determined jointly	defining the operational scope of the study in accordance with the protocol
Schedule management	preparation and control	full responsibility	short-term, iterative plan	preparing the timeline, visits, recruitment, monitoring
Budget management	monitoring and reporting (decisions made by the Executive)	PM responsible for costs and budget	depends on the organisation	most often: budget preparation, grant settlements, but financial decisions formally made by the sponsor/institution
Risk management	formal risk management process	Risk Management central element	adaptive approach to risks	identification of compliance, delay and recruitment risks; GCP compliance
Communication management	full responsibility	Communication Management Plan	strong emphasis on team communication	coordination of PI, clinical team, CRO/monitors, sponsors
Quality Management	in accordance with the Quality Management Approach	Quality Management Plan	team responsibility	Very high responsibility for data quality, compliance with GCP and protocol
Team management	team work control	PM responsible for team leadership	team leader → joint responsibility	often coordinates research, but is not the formal supervisor of the team
Relationship with stakeholders	stakeholder analysis, communication	Stakeholder Engagement	key element of Agile	Cooperation with PI, sponsors, monitors, bioethics committee, hospital pharmacy, laboratory
Decision-making	within the limits of assigned powers	PM makes operational decisions	short-term decisions	operational decisions; clinical and ethical decisions → PI and Sponsor
Documentation	complete project documentation management	full project documentation	minimal, iterative documentation	key role: TMF, protocol, consents, reports, GCP documents

Source: Own elaboration based on: DSDM Consortium, 2014; International Project Management Association, 2015; AXELOS, 2017; Schwaber, Sutherland, 2020; Project Management Institute, 2021; Kerzner, 2023; Grzeszczyk, Zawada, 2024.

A comparative analysis revealed significant similarities between the role of a project manager as defined in the PRINCE2, PMBOK and AgilePM methodologies and the roles performed in non-commercial clinical trials. In both areas, schedule, communication and risk management, as well as team coordination and integration of the activities of multiple stakeholders, are of central importance. The project manager plays a pivotal role in orchestrating the implementation process of the project, ensuring the coherence of operational activities, the seamless flow of information, and the delivery of tasks that meet the requisite standards. This convergence lends further credence to the hypothesis that the fundamental project competencies – planning, progress monitoring, resource management and communication – are universal and retain their relevance in the clinical research environment.

Concurrently, substantial discrepancies have been identified, attributable to the distinct nature of the clinical sector. It is imperative to recognise that clinical research projects are subject to stringent regulatory oversight. Consequently, the project manager is obligated to possess a comprehensive understanding of Good Clinical Practice (GCP) principles, ethical procedures, personal data protection protocols, the reporting of adverse events, and the management of research documentation. In contradistinction to conventional projects, the project manager in clinical trials frequently lacks formal hierarchical authority over the team, assuming instead a coordination and negotiation role. Furthermore, the Principal Investigator retains responsibility for the substantive outcome of the trial, while the project manager's remit is to ensure the organisational, qualitative and regulatory correctness of the trial's implementation. In addition, clinical project structures include specialised roles – such as monitor (CRA), data manager or pharmacovigilance specialist – which have no direct equivalents in traditional project management methodologies. Consequently, there is a requirement for the adaptation of project role models to the realities of medical research.

In summary, the following elements can be identified as the key findings from the analysis:

- Non-commercial clinical research projects conducted in Polish scientific and research units meet the definition of projects.
- Poland has a public organization whose task is to support the conduct of clinical research projects in public healthcare institutions.
- Medical Research Agency (*Agencja Badań Medycznych*, ABM) finances Clinical Research Support Centres (*Centrum Wsparcia Badań Klinicznych*, CWBK), which supports the conduct (management) of clinical research projects (including non-commercial ones) within public healthcare institutions.
- Model CWBK assumes the existence of the following positions: clinical trial coordinator and project manager, indicating the basic responsibilities for these roles.
- It is possible to compare the roles of a clinical trial coordinator and a clinical trial project manager with the recommendations for project management roles formulated by project management methodologies (e.g. PRINCE2, PMBOK, AgilePM).

– In clinical trial management practice (including non-commercial trials), there are many managerial roles (Project Manager, Principal Investigator, Clinical Trial Coordinator) that differ significantly from one another.

5. Discussion

Clinical research represents a significant interdisciplinary domain within the realm of scientific endeavours, underscoring the complexity and multifaceted nature of contemporary scientific pursuits. The implementation of clinical trials, including non-commercial in nature, is characterised by a series of project attributes (including specific objectives, temporal constraints, resource allocation, scope, and stakeholders, as well as risk considerations). It is evident that Project Management (PM) methodologies and techniques, which include planning, scheduling, risk management, CPM/PERT, agile/hybrid methodologies, and the utilisation of digital tools, are being adopted in increasing measure for their application in this domain (Goodarzynejad, Babamahmoodi, 2015; Barbosa et al., 2025).

This study's findings, based on analytical processes, demonstrate that a combination of effective preparation and competent project management can substantially enhance the likelihood that a clinical trial will be executed in a manner that is efficient, ethical and compliant with regulatory standards. New insights are presented below, alongside references to earlier scientific works. The majority of the results (relating to the approach to project management) are consistent with the principles of management science and the findings of other authors. Nevertheless, there remains a lack of scientific research concerning the management of non-commercial clinical trials within Polish organisational units.

Documents from the Medical Research Agency (ABM) in Poland and descriptions from the Clinical Research Support Centre (CWBK) indicate that the model CWBK provides for structures and functions that correspond to the role of project manager, which is undoubtedly of great value. This is in line with the findings of other studies cited in this paper (Ernø-Kjølhede, 1999; Sonstein et al., 2022; Batuca, Maia, 2024; Barbosa et al., 2025), which emphasise the importance of appointing a Project Manager / Research Project Manager. Despite the fact that the model standard for Clinical Research Support Centres provides for a project management position, the scope of formal competency requirements for this role remains relatively general and limited mainly to professional experience and knowledge of GCP principles. It is also indicated by other studies (Mitchell et al., 2022) that there is a necessity to improve the competencies of those who manage research projects. In light of the intricacies inherent in non-commercial clinical trials, which are distinguished by a considerable regulatory risk, multi-stakeholder participation, interdisciplinary nature and substantial time and budgetary constraints, it is rational to advocate for a substantial augmentation in competency requirements

in the domain of professional project management. This augmentation should encompass expertise in recognised methodologies, planning tools, risk management, communication and stakeholders.

In consideration of the extant data, it can be deduced that the model CWBK supported by ABM provide for a function that can be interpreted as the role of a project manager – only the function responsible for ‘project management’ is envisaged as a basic position (1 full-time position). However, there is a clear absence of specifics regarding the required competences (knowledge, skills, familiarity with project management methodologies and techniques).

It is important to note that neither the Medical Research Agency documents nor the CWBK Model Standard, in their publicly available definition of 'project manager' as a formal, unified role, contain a publicly available document that states: The necessity for a designated Project Manager within CWBK is essential for the effective management of projects.

A further significant limitation of the current model CWBK is its overly general approach to the competency requirements for individuals performing management functions in clinical projects, which focuses primarily on general experience and knowledge of Good Clinical Practice principles. Meanwhile, the effective management of a complex research project requires advanced, specialist knowledge of project management. This includes the development of work breakdown structures and schedules, cost estimation and control using earned value methods, systematic project risk management, stakeholder and communication management, change control and quality assurance of project processes.

The limitations of the study (i.e. those aspects excluded from the scope) are also recommendations and further research plans. Further in-depth research is recommended, in the form of individual interviews and focus groups, in order to provide a more robust confirmation of the conclusions of this study. It appears imperative to undertake empirical research in the form of observations of the work of teams (individuals) managing non-commercial clinical trials in Poland. In the field of research, the subsequent study could focus on the analysis of the competencies of clinical trial managers, clinical trial coordinators and principal investigators in the domain of project management. When undertaking further research on this topic, it should be noted that the structures and job titles vary, with individuals being referred to as 'research coordinator' or 'project specialist', suggesting that the role may not always be designated 'Project Manager' and that its scope and title may vary.

6. Summary

Non-commercial clinical research projects are of significant importance in the advancement of medical knowledge, the improvement of healthcare quality, and the filling of research gaps. Due to their high organisational complexity, stringent regulatory requirements, multiple

stakeholders, and significant scientific and operational risks, a professional approach is required for the execution of these projects, utilising structured methodologies, tools, and project management techniques. A series of lessons were identified through the course of the analyses.

It is recommended that entities conducting non-commercial clinical trials establish a separate, formally recognised position of research project manager (clinical trial project manager), distinctly separate from both scientific and administrative roles. It is recommended that such a position should be systematically financed by grants from the Medical Research Agency. This approach would ensure employment stability, continuity of organisational competence and professionalisation of clinical trial portfolio management. Consequently, it would increase the effectiveness of project implementation, the quality of supervision and the likelihood of achieving the intended scientific and implementation results.

Despite the fact that the model standard for Clinical Research Support Centres provides for a project management position, awareness of the importance of this role in the research community remains limited. The prevailing approach continues to place the burden of organisational responsibility primarily on the principal investigator or study coordinator. This has resulted in a dispersion of responsibility for the schedule, budget, risks and communication with stakeholders. It is therefore reasonable to formally define the role of clinical trial project manager as a separate function, responsible for the overall integration of project activities, planning, monitoring progress and ensuring that the project is implemented in accordance with strategic and operational objectives.

The results of this research have the potential to be applied in the domain of public management practice. A fundamental condition for the effective implementation of professional project management is the recognition of the position of clinical trial project manager as a reimbursable cost in projects financed by the Medical Research Agency in Poland. This solution will enable project implementing entities to flexibly hire highly qualified experts, including on a contract or interim management basis, without the need for long-term organisational commitments. This will facilitate the transfer of expertise from the commercial market to the non-commercial clinical research sector, increase the stability of project implementation and improve the efficiency of public funds utilisation. The financing management competences of organisations can be directly influenced by grants, thereby reducing the risk of underestimating the organisational costs of projects and enhancing their predictability.

Concurrently, it is imperative that organisational and systemic changes are implemented at the institutional and regulatory level. It is recommended that the Medical Research Agency provide clarification on the CWBK model standard by means of the following measures: firstly, by clearly defining the role of the project manager; secondly, by specifying minimum competence requirements and recommended certifications; and thirdly, by introducing the obligation to use formal project management plans in funded research. The Ministry of Health has the capacity to facilitate the enhancement of project competencies through the

implementation of training programmes, the establishment of career pathways for research project managers, and the integration of project management within clinical research development strategies. Consequently, the legislator should establish a legal framework that facilitates the flexible employment of project experts in public entities and the recognition of management competence costs as an integral component of research project funding. It is asserted that consistent action on these three levels has the potential to significantly increase the organisational maturity of the Polish non-commercial clinical research system, thereby enhancing its competitiveness and efficiency.

In summary, the professionalisation of the role of project manager in non-commercial clinical trials is identified as a key condition for increasing the efficiency, predictability and quality of publicly funded projects. Consequently, there is a compelling rationale for conducting additional empirical research on the impact of project management maturity on clinical trial outcomes, the effective utilisation of funding, and the development of organisational competencies of research centres in Poland.

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