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TOWARDS AN IMPROVED APPROACH TO THE METHODICAL PLANNING OF NON-COMMERCIAL CLINICAL TRIAL PROJECTS

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Purpose: The subject of this study is driven by the extensive necessity to enhance the efficiency of clinical trial project management. The objective of this article is to provide a comprehensive overview of the essential characteristics that should define a planning method that can be adapted to the specifics of non-commercial clinical trial (NCT) projects.
Design/methodology/approach: The objectives of the study were achieved by examining a variety of alternative characteristics that the NCT project planning method may possess. A multi-criteria analysis (morphological analysis) was employed.
Findings: The result of the analyses carried out is a summary of the attributes of the NCT project planning method. A total of 19 characteristics were identified as being essential for the NCT project planning method. These include the application of classical methodology, the agile methodological approach and the hybrid approach to project management. This study provides a foundation for subsequent empirical research in this area.
Research limitations/implications: The research has been limited to NCT projects; it is worth conducting similar analyses for commercial projects. The set of features in the article may not be complete. Other factors should be considered.
Practical implications: The majority of extant literature pertains to medical issues; this research, which focuses on considerations from the fields of management and quality sciences, responds to an unmet need on the part of NCT project management theorists and practitioners. The findings of the study have the potential to enhance the efficiency of the project planning process and to optimise the organisation of research teams' work. Furthermore, they can also be valuable for commercial clinical trials.
Originality/value: The results of this study have a significant impact on the efficiency and effectiveness of research preparation in medicine, which is an important source of new knowledge, develops treatment methods and increases people's standard of living. The study fills the gap that is the deficiency of research on improving the efficiency and effectiveness of conducting clinical research projects. The results of the study may be of use not only to management but also to medical staff and researchers.
Keywords: planning method, non-commercial, project management, clinical trial
Category of the paper: research paper.

1. Introduction

Clinical trials represent a pivotal component within the pharmaceutical market and the healthcare sector. Conducting such trials is imperative for advancements in medical science, the development of innovative new treatments, prevention and patient care. A project-based approach is highly recommended, as the development of new medicines involves unique, complex, costly and lengthy projects that require expertise and interdisciplinary collaboration between clinical researchers and scientists associated with many different disciplines. As research confirms, the implementation of project management methodologies has been demonstrated to exert a positive influence in a number of domains within healthcare management, such as the timely accomplishment of organisational goals, cost-containment, and the enhancement of quality (Dobin, Lazar, 2020).

Planning and managing clinical trials, including non-commercial clinical trial (NCT) projects, is usually not easy and requires project management competencies (Sonstein et al., 2022; Mitchell et al., 2022). It has been noted that there are challenges associated with the low efficiency of the implementation of clinical trials, and there is a need to establish a body of good practice in the planning and management of projects in the area of drug development, clinical pharmacology (i.e. the development, evaluation and clinical use of pharmaceutical products) (Harpum et al., 2010; Grudzinskas et al., 2022). In the search for appropriate clinical trial management methods, competence standards for clinical trial project management professionals are constantly developing (Sonstein et al., 2024; Jones et al., 2024).

In the healthcare sector, an increasing interest in the utilisation of project approaches has been observed. However, the existing project management methodologies are not always sufficiently familiar to the healthcare community and do not always meet their expectations (Lunkka et al., 2019). Popular and universal project management methodologies are only partly adaptable to the specificities and needs of healthcare projects and it is sometimes necessary to combine the project approach with other management methods e.g. oriented towards change management or for practitioners to adapt intuitive and improvised approaches not related to specific management concepts and approaches (Gordon, Pollack, 2018).

It is pointed out that good planning of a clinical trial is a very important factor in the success of this type of project (Kim et al., 2023) and recent research on the organisational culture of health sector units in Poland indicates a clear need for health care systems in Poland and worldwide to systematically increase the efficiency of their functioning (Domańska-Szaruga, Jończyk, Knap-Stefaniuk, 2024).

Therefore, the objective of the study was to identify the appropriate characteristics for a planning method that would be suitable for non-commercial clinical trial (NCT) projects. The objectives of the study were achieved by analysing a number of alternative characteristics that a planning method for NCT projects may have. A multi-criteria analysis was employed

to achieve this objective. The resultant analysis provided a comprehensive summary of the attributes of the NCT project planning method, incorporating the application of classical methodology, the agile methodological approach, and the hybrid approach to project management. The paper is constituted by a lead-in to the topic of clinical research project management, an explanation of basic concepts and a review of recent literature on the subject. This is followed by a discussion of the chosen research method – multi-criteria analysis, i.e. the morphological method. Subsequently, the procedure for determining the features of the planning method is presented. The paper concludes with a presentation of conclusions and recommendations for directions of further research.

2. Project management of non-commercial clinical trials

A clinical trial is defined as any study conducted in human subjects with the objective of discovering or confirming the clinical, pharmacological, including pharmacodynamic, effects of one or more investigational medicinal products. Alternatively, a clinical trial may be conducted to identify adverse reactions to one or more investigational medicinal products. Additionally, a clinical trial may be conducted to follow the absorption, distribution, metabolism and excretion of one or more investigational medicinal products with a view to their safety and efficacy (Pharmaceutical Law).

The fundamental classification system divides clinical trials into two broad categories: commercial and non-commercial. Commercial trials are those involving the pharmaceutical industry, usually in the role of trial sponsor. Conversely, a non-commercial clinical trial (NCT) is conducted without the involvement of the pharmaceutical industry. The fundamental premise underlying the conception of an NCT is that the data collected during the course of the trial cannot be utilised for the purpose of obtaining marketing authorisation for designated medicinal products, nor can it be employed to amend extant authorisations. Non-commercial clinical trials can be conducted in an academic setting, where the objective is to gain knowledge of the mechanism of action, efficacy and pharmacokinetics of a drug (Wąsik, Kuczur, 2016). It is important to note that non-commercial clinical trial projects are undertakings for which the trial sponsor, e.g. a university without the assistance of the pharmaceutical industry, has to provide all the necessary resources itself (Finger et al., 2011).

In order to facilitate an understanding of the organisation of a non-commercial clinical trial project in attributional terms, the following example is provided. Prior to the initiation of the planning phase for a clinical trial project, the principal investigator, in collaboration with the sponsor, is responsible for establishing a small working group. This group should comprise investigators, as well as at least one statistician and an individual with expertise in clinical trial methodology. The steering committee is responsible for all significant decisions regarding

the initiation, execution, and termination of the trial. The sponsor is the entity responsible for the trial in question and may also be the funding organisation. The coordinating and data centres are responsible for the day-to-day tasks of running the trial, including randomisation processes, data collection and circulation, reviewing current documentation, and organising monitoring visits to study sites. The endpoint validation committee is tasked with the review of the documentation prepared by the coordination centre for the trial endpoints. The safety assessment committee has the responsibility of communicating with the steering committee and the medical agencies (e.g. EMA or FDA) in the event of any irregularities in the design of the non-commercial clinical trial (Boissel, 2014).

A commonly accepted, general definition of a project posits that a project constitutes a sequence of unique, complex and interrelated tasks that share a common objective, are delivered to a fixed deadline and within a fixed budget, and comply with preset requirements (Kerzner, 2018; Wysocki, 2019). Furthermore, M. Trocki (2003) emphasises that a project constitutes a unique undertaking, executed by a team, distinct from the repetitive activities of the organisation, and employing specialised methods and techniques.

A clinical trial meets all requirements of the project definition (Doganov, Yanev, 2006; Farrell et al., 2010). The specific features of clinical trial projects are as follows: the definition of objectives in the planning phase, the identification of resources necessary to achieve the planned objectives, the planning of activities to achieve these objectives, the continuous monitoring of the progress of the work and its effects on the basis of clear performance criteria, the ongoing evaluation, the closure of the project if the objectives are achieved or cannot be achieved, the implementation of the activities in accordance with a clinical trial protocol prepared in advance and the use of this document as the basis for monitoring the progress of the project (Goodarzynejad, Babamahmoodi, 2015).

In accordance with the clinical trial project management model, five distinct stages can be identified. The initial stage is the definition of the project objectives, i.e. the identification of the objectives, synthesis of current knowledge, information about the drug substance (drug product and other products), scope of work, budget and implementation period. Subsequent to this initial stage, a feasibility study is conducted, which involves an analysis of the viability of implementing the project, an assessment of the availability of resources, including researchers, specialist doctors, and suitable sites (medical centres), and an estimate of the accessibility of technical equipment. In the third stage, resources are allocated, with the principal investigator being hired, researchers (medical staff), patients and volunteers for the study being recruited, sites being recruited, and drugs being ordered (including organising their transport). The penultimate stage is characterised by the initiation of project implementation, encompassing the baseline phase. This phase includes treatment, ongoing monitoring of progress and compliance with the protocol, and safety monitoring (adverse events). The final stage of the project is closure, which

includes the final visit, the organisation of all the data and information obtained, the performance of statistical analyses, the preparation of the final report and the writing of scientific publications (Grzeszczyk, Zawada, 2020).

The present paper is concerned with the planning stage of non-commercial clinical trials, which is defined as the preparatory phase preceding the initiation of the primary research. It encompasses a range of activities, including the identification of the research problem, the review of extant literature, the formulation of a research question, the development of a hypothesis, the determination of the study design, the identification of the target population, and the procurement of informed consent for participation. This stage also involves the establishment of collaborations with experts and the assessment of the overall feasibility of the proposed study. Prior to the initiation of the scientific investigation, researchers must determine the most appropriate data collection strategy, sampling techniques, and statistical analysis methods. Following the formulation of a working hypothesis and its subsequent reformulation as a null and alternative hypothesis, the subsequent step involves deciding on the type of study required to answer the research question and the most suitable methods to implement it (Kiani et al., 2022; Karunarathna et al., 2024).

The research emphasises that the project manager plays a pivotal role in the effective planing, organisation and implementation of optimal processes for the control and monitoring of a clinical trial. The critical steps involved in the planning phase of a clinical trial encompass a range of activities, including the conceptualisation of the study, the review of existing literature, the identification of the problem to be addressed, the formulation of an abstract, the selection of investigators, the development of a protocol, the identification of funding sources, and the creation of a patient consent form, along with numerous additional tasks (Kandi, Vadakedath, 2023).

A comprehensive discourse on the management of clinical research projects can be found in the extensive literature on the subject (Hackshaw, 2009; Friedman et al., 2015; Brody, 2016; Wright, 2017; Chew, 2019).

3. Selected research directions for clinical trial project planning

While there are a number of studies that address methodological approaches to the management of clinical trials, these do not directly relate to management and instead focus on medical aspects. However, the concept of adaptability is frequently utilised, interpreted as an extended and flexible design of clinical trials (Granholm et al., 2023). Adaptive studies are characterised by the implementation of adaptive (transitional) analyses, which are employed for the purpose of adjusting the target sample size, updating allocation coefficients, or initiating the early termination of the study in the event of the fulfilment of a predefined statistical decision rule

(Burnett et al., 2020). Nevertheless, the management of clinical trial projects is addressed through the utilisation of the concept of adaptability in order to facilitate the decision-making process during the planning phase of the projects (Grzeszczyk, Zawada, 2024).

A number of studies have been conducted in the field of non-commercial clinical trial project planning. Among these studies are those focusing on the utilisation of the Hierarchical Interaction Network (HINT). This network is employed to enhance the efficacy of prediction in clinical trials prior to initiation, thus enabling the allocation of greater resources to trials with a higher probability of success, thereby circumventing inevitable failures (Chen et al., 2024). Furthermore, Generative Large Language Models (LLMs) have been utilised in the design of inclusion criteria for clinical trials, constituting an essential element of the protocol and a critical factor in the success of clinical trial projects (Wang et al., 2023).

A range of analytical approaches is being used to facilitate the planning of clinical trials. These include methods to improve the efficiency of managerial decisions in uncertain circumstances, which are made using a multi-stage stochastic programming formulation (Colvin, Maravelias, 2010), and methods to plan a clinical trial based on decision analytic modelling (Keim-Malpass et al., 2023).

The domain of clinical trial project planning includes the aspect of data management, which is integral to the effective execution of research endeavours. The Data Management Plan (DMP) is a crucial element that ensures the systematic and uniform execution of data management operations, thereby maintaining data integrity and facilitating the successful conduct of the study (Maroju et al., 2024).

4. Selected methods and standards for planning clinical trial projects

As stated in the introduction, the management of clinical trial projects adheres to the same standards as the management of other types of projects. The growing importance of projects in the field of clinical research is a phenomenon that is referred to as projectization (Juchniewicz, 2018). This approach entails the extension of project management methodologies to various internal organisational issues, thereby signifying a transition towards a management paradigm that is characterised by projects (Stabryła, 2006). The strong similarity in the approach of clinical research project management theory to R&D projects, as indicated by the literature review, allows for the use of both traditional and agile methodological approaches.

As clinical research is considered to be a type of research and development project, universal management methods and standards are applicable to projects in the healthcare sector and to clinical trial projects. The leading approaches are those developed by organisations such as PMI (Project Management Institute), APM (Association for Project Management), IPMA (International Project Management Association) and Scrum Alliance (Strojny, Szmigiel, 2015).

The PMI methodology, for instance, outlines five phases of the project life cycle (initiating, defining and planning, executing, monitoring performance and closing), and these phases can also be applied to healthcare, pharmaceutical and clinical trial projects (Schwalbe, Furlong, 2017). Recently, there has been a particular focus on agile approaches (Griffiths et al., 2020; Ewings et al., 2022).

In addition to universal methodologies, a number of professional and design standards that are used in clinical trial practice for project management purposes should be noted. One such example is Good Manufacturing Practice, which defines the correct manufacturing procedures to support quality management in production engineering under conditions of considerable technological expertise required and high variability in the characteristics of the products to be obtained (Rahalkar et al., 2022). Furthermore, Good Clinical Practice is a constantly evolving field, with ongoing refinement aimed at enhancing the analysis and risk assessments of non-commercial clinical trials conducted by academic research centres (Le Marsney et al., 2022). Methodological support is also provided by Good Scientific Practice. Among the guidelines formulated are recommendations for the efficient and timely publication of complete results of non-commercial clinical trials, which are sometimes problematic (Riedel et al., 2022). Addressing concerns regarding risks and hazards is facilitated by enhancing Good Pharmacovigilance Practices (Holm et al., 2022).

A formal approach to planning and the use of specialised methods is particularly warranted, and its proper execution can have a positive impact on the results obtained, especially in the case of long-term (strategic) planning of projects with significant risks. However, the agile approaches recommended for such projects suggest less focus on implementing formal planning principles and methods at the beginning of the project (Zwikael, Gilchrist, 2021).

The discourse on clinical trial project management draws attention to best practice in planning such projects, which includes elements such as scope management, estimation, change control, scheduling, resource management, budgeting and performance management (Stewart-Long, 2010).

Research indicates that promising results can be achieved through the combination of multiple solutions, which are improvised and intuitive, and the improvement of change management, especially in the early stages of the project life cycle (Gordon, Pollack, 2018). In particular, it is crucial to improve the implementation of the planning phase of clinical trial projects (Farrell, Kenyon, 2014).

5. Research method

The identification of the anticipated characteristics that are deemed to be possessed by an NCT project planning method is regarded as a problem of identifying the optimal solution

for planning NCT projects. One of the combinatorial methods, belonging to the pragmatic stream of heuristic methods – the method of morphological analysis (Zwicky, 1967) – is applied to solve this planning challenge.

Morphological analysis is characterised by its logical-analytic approach, with creative solutions to problems being sought and achieved through a systematic analysis of all possible solutions (Ujwary-Gil, 2003). The utility of this approach is not confined to any specific field of human activity; rather, it is applicable to all areas, both practical and scientific. Its applications include the study of organisational and legal forms of organisations, external and internal organisational structures, management processes, methods supporting organisational problem solving, activities in projects to analyse and select the appropriate form of project organisation, and the creation of conditions for appropriate methodological support in project management processes (Trocki, Wyrozębski, 2014).

A morphological analysis consists of three consecutive phases (Kozina, 2017):

- problem identification phase - is devoted to identifying the boundaries of the problem and defining it rigorously;
- problem analysis phase - is devoted to extracting the relevant parameters or features that characterise the problem (e.g. factors, functions, elements). Subsequently, variants of the identified parameters are identified;
- problem synthesis phase - consists of sorting out all the parameters and identifying possible combinations of them. Then, the combinations are analysed and evaluated in terms of an overall solution to the problem. Finally, those solutions that are most viable and valuable are selected.

6. Proposed features of the NCT project planning method

In this study, Zwicky's method of morphological analysis was employed to identify the expected characteristics that an NCT project planning method should possess. Firstly, the problem to be solved was formulated: what should the NCT project planning method be characterrised by, so that it is best adapted to the peculiarities of this type of project and enables efficient project implementation, saving the time required for project planning? Secondly, a comprehensive literature analysis was conducted to identify the problem variables, i.e. the main elements (features) determining the solution, and the possible values of these elements (manifestations of the features). Consequently, a list was formulated in which the ordered features and the manifestations of these features were included:

A: Type of organisational structure:

1. Linear.
2. Linear and staff.

3. Linear and staff with functional cells.
4. Functional.
5. Matrix.

B: Regulations/standardization:
1. Detailed, explicit.
2. Detailed, alternative.
3. Framework.
4. Heuristic.
5. None.

C: Division of tasks:
1. Elementary partial work.
2. Exchangeable sub-work.
3. Sequences of operations.
4. Natural parts of the work process.
5. Implementation of the entire work process.

D: Project initiation:
1. General principles of project initiation.
2. Framework for project initiation with key decision points.
3. Detailed procedures and documentation for project initiation.
4. Not relevant/not present.

E: Project definition, definition of project objectives, constraints and requirements:
1. General assumptions of project parameters.
2. Framework definition of project parameters.
3. Detailed and precise definition of project assumptions, objectives, constraints.
4. Not relevant/not present.

F: Project structuring and scope management:
1. Definition of the project framework and general project control rules.
2. Full identification of the project scope and definition of its verification rules.
3. Detailed description of the components of the project scope and a precise procedure.
4. Not relevant/not present.

G: Project flow planning as a function of time:
1. Framework planning of the project flow at a high level of generality.
2. Project flow planning at medium level of detail.
3. Detailed planning of the project flow as a function of time.
4. Not relevant/not present.

H: Project documentation:
1. Low degree of project documentation (basic project documentation).
2. Medium degree of project documentation (framework documentation, basic reporting).
3. High degree of project documentation (complete and comprehensive documentation).

4. Not present.

I: Frequency of projects:
1. Occasionally.
2. Regularly (from time to time).
3. Continuously.

J: Repeatability of projects:
1. Never.
2. Occasionally.
3. Regular.
4. From time to time.
5. Continuous.

K: Number of simultaneous projects:
1. One.
2. Several.
3. Several dozens.

L: Linking projects:
1. Programmes.
2. Portfolio.
3. Not present.

M: Project size (budget, time, workload):
1. Small.
2. Medium.
3. Large

N: Fixed: time, budget, workload:
1. Fully.
2. Partially.
3. Not defined.

O: Scope of project in relation to organisation's scope of activities:
1. Fragmentary.
2. Partial.
3. Comprehensive.

P: Compatibility of project and organisation competences:
1. Fully.
2. Partial.
3. None.

Q: Clarity of purpose:
1. Fully stated.
2. Partially clear.
3. Slightly clear.

4. Not clear.

R: Knowledge of results:

1. Results are known.
2. Results are known to a large extent.
3. Results are known to a moderate extent.
4. Not known.

S: Degree of user/customer involvement:

1. High.
2. Medium.
3. Low.
4. None.

Following this, solution variants were created (Table 1).

Table 1.
Features and manifestations of the features of the NCT project planning method

Features	Possible values				
A	1	2	3	4	5
B	1	2	3	4	5
C	1	2	3	4	5
D	1	2	3	4	
E	1	2	3	4	
F	1	2	3	4	
G	1	2	3	4	
H	1	2	3	4	
I	1	2	3		
J	1	2	3	4	5
K	1	2	3		
L	1	2	3		
M	1	2	3		
N	1	2	3		
O	1	2	3		
P	1	2	3		
Q	1	2	3	4	
R	1	2	3	4	
S	1	2	3	4	

Source: Author's own study.

Finally, the developed variants were evaluated, and the optimal solution was selected (marked in grey in Table 1).

As illustrated in Table 2, the following section summarises the most advantageous feature values of the NCT project planning method. The organisational structure of a clinical research organisation corresponds to a line-team structure. This organisational arrangement consists

of a project manager and the teams that report to the project manager (along with line managers). The staff cells that support the work of the teams are specialists from different fields, including law, medicine and information and communication technology, who perform advisory functions. The level of applicable regulations and standards for the implementation of clinical trial projects, in any form, can be considered very high – the project sponsor is obliged to comply with the requirements enshrined in numerous legal regulations.

Scientific research units, scientific institutes, medical universities and other clinical research bodies are involved in unique projects and carry them out regularly and continuously as a statutory task. Due to their scope and cost, these projects are most often small to medium-sized and are often long-term initiatives. Organisations often undertake multiple projects simultaneously; however, these projects are not systematically integrated into portfolios or programmes. Research work is divided into elementary units and activities, but due to the nature of research work, i.e. the unpredictability of its results, it is not possible to fully determine the time, budget and workload of individual tasks.

Clinical trial projects are defined by their coverage of a scientific and research area that represents a specific component of the overall activity of the unit (sponsor) conducting the trial. To illustrate this point, consider a clinical trial project within the therapeutic area of cardiology, where the efficacy of one or two drugs for hypertension is being investigated. In contrast, the competence of the project and the organisation is fully compatible. With regard to the initiation and planning of NCT projects, detailed procedures are not available. Instead, a project initiation framework with key decision points prevails. Examples of such key decision points include the necessity for a feasibility study, a research protocol, or obtaining approval from the Regulatory Authority to initiate a study. Given the unique nature of each project, an individualised approach is necessary, resulting in a paucity of detailed instructions on the aforementioned elements. The documentation related to project initiation and planning is prepared in a manner tailored to the type, purpose and specificity of the research project each time.

The definition of the project, its objectives, constraints and requirements is somewhat divergent. These elements are defined with great precision and detail. For instance, the criteria for the inclusion and exclusion of participants (patients) from a study are explicitly delineated, with justifications derived from scientific and medical considerations that are applicable throughout the research project. The subsequent elements of the study are also defined in detail: the characteristics of the components and the scope of the project, and the detailed procedure for its control; the planning of the flow of project activities over time; and the overall documentation of the project. A further notable characteristic of NCT projects is that their objectives are partially specified and the results are known to a moderate degree. This characterisation is substantiated by the observation that a considerable proportion of clinical trials evaluate the efficacy of a specific treatment therapy, among other factors. However, the extent of efficacy remains uncertain, and the outcomes may not align with the initial expectations. A distinguishing feature of NCT projects is the high level of customer involvement, defined as users or recipients of

the project's outcome. This customer involvement is a fundamental aspect of the planning methodology for such projects.

Table 2.
Summary of selected best features of the NCT project planning method

Features	T / A	Manifestations of the characteristics
Type of organisational structure	T	Linear and staff
Regulations/standardization	T	Detailed, explicit
Division of tasks	A	Elementary partial work
Project initiation	A	Framework for project initiation with key decision points
Project definition, definition of project objectives, constraints and requirements	T	Detailed and precise definition of project assumptions, objectives, constraints and requirements
Project structuring and scope management	T	Detailed description of the components of the project scope and a precise procedure for its control
Project flow planning as a function of time	T	Detailed planning of the project flow as a function of time
Project documentation	T	High degree of project documentation (complete and comprehensive documentation of project progress)
Frequency of projects	T & A	Continuously
Repeatability of projects	T & A	Never
Number of simultaneous projects	T & A	Several
Linking projects	T & A	Not present
Project size (budget, time, workload)	T & A	Small or Medium
Fixed: time, budget, workload	A	Partially
Scope of project in relation to organisation's scope of activities	T & A	Fragmentary
Compatibility of project and organisation competences	T & A	Fully
Clarity of purpose	A	Partially clear
Knowledge of results	A	Results are known to a moderate extent
Degree of user/customer involvement	A	High

Note. T = traditional methodologies, A = agile methodological approach.

Source: Author's own study based on Grzeszczyk, Zawada, 2024.

It is evident that NCT projects are characterised by a high degree of formalisation, being subject to a comprehensive regulatory framework that includes numerous laws and good practice guidelines. The medical research regime requires particular care and documentation of research progress, while maintaining a high degree of transparency. However, NCT projects are characterised by an absence of clarity in their objectives, which are often vague and imprecise (e.g. searching for a substance that could be a cure for a particular disease). Additionally, there is often a lack of clarity in the conditions under which these projects would be conducted. Furthermore, the dynamic nature of the research environment means that it is not possible to accurately predict future activities or outcomes of individual research tasks and steps.

As illustrated in Table 2, the NCT project planning method has the potential to be compatible with traditional and agile methodologies. Within the scope of planned work, a distinction

can be made between tasks that fall under the regime of the clinical trial protocol and those that are not precisely defined. The organisational structure, compliance with standards, the plan, structure, course and documentation of the project correspond to the principles of traditional project management methodologies (e.g. PRINCE2). Conversely, the division of work into specific tasks, in addition to the initiation of the project, which predominantly encompasses the preparation of a study protocol or the submission of a funding application (along with the development of a feasibility study) to a task, can be executed in accordance with the agile methodological approach. The efficacy of agile concepts is substantiated by the observation that clinical trials frequently exhibit a high degree of uncertainty regarding outcomes and involve a significant level of stakeholder engagement (e.g., clinical trial participants, researchers). The remaining characteristics enumerated in Table 2, pertaining to organisational aspects, are consistent with both the classical methodology and the agile methodological approach.

7. Conclusions

The analysis conducted in this article clearly demonstrates that, among the available project planning methods, particularly those employed in R&D project planning, it is not possible to unequivocally identify a single method that exhibits the identified characteristics. Instead, it is possible to search for an alternative method that can be significantly characterised by the required key features.

The absence of universally applicable methodologies, coupled with the ongoing endeavours to cultivate proprietary standards to facilitate the planning of clinical trial projects, underscores the necessity to discern the anticipated characteristics of a methodology for planning such endeavours. This may, in turn, enable the formulation of a sought-after proprietary approach to addressing the planning challenge.

In clinical research project management processes, traditional approaches and previously identified life-cycle stages are not always conducive to success. Consequently, new solutions must be sought and research in this area developed. Integrative projects, combining traditional project management methodologies with solutions inspired by different types of concepts, are worthy of consideration.

A significant limitation of the present study is the focus on non-commercial projects, which limits the generalisability of the findings. Analogous analyses should be undertaken for commercial clinical trial projects. Given the theoretical nature of this study, it would be beneficial to carry out a series of empirical studies to verify the postulated features of the NCT project planning method in practical settings. It is possible that the set of features presented in the article may be incomplete. It would be advisable to conduct further research into areas that are relevant to NCT project management and to consider other features of the planning method.

It is evident that the issue under discussion is of interest to researchers worldwide. However, it is important to note the acute lack of methods to support the efficient planning of NCT projects. Such methods would need to take into account the specifics of NCT projects and the needs of experts and project managers. In view of the rapidly expanding discipline of clinical trial project management, particularly in the domain of non-commercial research, there is a compelling rationale for the continuation of research focused on the identification of novel management methodologies or the refinement of extant universal methods.

References

1. Act of 6 September 2001. *Pharmaceutical Law*. Ustawa z dnia 6 września 2001 r. Prawo farmaceutyczne, Dz.U.2017.0.2211 t.j.
2. Boissel, J.-P. (2004). Planning of clinical trials. *Journal of Internal Medicine, 255(4), 427-438.*
3. Brody, T. (2016). *Clinical Trials* (Second Edition). Academic Press. Retrieved from: http://-dx.doi.org/10.1016/B978-0-12-804217-5.00043-6.
4. Burnett, T., Mozgunov, P., Pallmann, P., Villar, S.S., Wheeler, G.M., Jaki, T. (2020). Adding flexibility to clinical trial designs: An example-based guide to the practical use of adaptive designs. *BMC Medicine, 18(1), 352.* Retrieved from: https://doi.org/10.1186/s12-916-020-01808-2.
5. Chew, B.H. (2019). Planning and Conducting Clinical Research: The Whole Process, *Cureus, 11(2), 4112.* Retrieved from: https://doi.org/10.7759/cureus.4112.
6. Chen, T., Lu, Y., Hao, N., Zhang, Y., Rechem, C. V., Chen, J., Fu, T. (2024). *Uncertainty Quantification on Clinical Trial Outcome Prediction* (arXiv:2401.03482). arXiv. Retrieved from: https://doi.org/10.48550/arXiv.2401.03482.
7. Colvin, M., Maravelias, C.T. (2010). Modeling methods and a branch and cut algorithm for pharmaceutical clinical trial planning using stochastic programming. *European Journal of Operational Research, 203(1), 205-215.* Retrieved from: https://doi.org/10.1016/j.ejor.-2009.07.022.
8. Dobin, V.M., Lazar, B. (2020). Project Management and Quality in Healthcare: A Systematic Literature Review. *PM World Journal, IX, I(IX).*
9. Doganov, B.K., Yanev, S. (2006). Implementation *of project management principles in clinical trial process.* In PMI, Global Congress 2006–EMEA.
10. Domańska-Szaruga, B., Jończyk, J.A., Knap-Stefaniuk, A. (2024). Diagnosis of organizational culture of healthcare entities in Poland. *Scientific Papers of Silesian University of Technology Organization and Management Series, 2024(199).* Retrieved from: https://doi.org/10.29119/1641-3466.2024.199.8.

11. Ewings, S., Saunders, G., Jaki, T., Mozgunov, P. (2022). Practical recommendations for implementing a Bayesian adaptive phase I design during a pandemic. *BMC Medical Research Methodology, 22(1).* Retrieved from: https://doi.org/10.1186/s12874-022-01512-0.
12. Farrell, B., Kenyon, S. (2014). *A Guide to Efficient Trial Management. National Institute for Health Science,* NIHR Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton, UK. Retrieved from: https://doi.org/10.3310-/2014-Trial-Managers'-Network-Guide.
13. Farrell, B., Kenyon, S., Shakur, H. (2010). *Managing clinical trials*. *Trials, 11, 78.* Retrieved from: https://doi.org/10.1186/1745-6215-11-78.
14. Finger, R.P., Coch, C., Coenen, M., Mengel, M., Hartmann, G., Holz, F.G. (2011). Grundlagen, Planung und Durchführung nichtkommerzieller klinischer Studien. *Der Ophthalmologe: Zeitschrift der Deutschen Ophthalmologischen Gesellschaft, 108(1), 25-32.* Retrieved from: https://doi.org/10.1007/s00347-010-2310-9.
15. Friedman, L.M., Furberg, C.D., DeMets, D.L., Reboussin, D.M., Granger, C.B. (2015). Introduction to Clinical Trials. In: *Fundamentals of Clinical Trials, 1-23.* Springer International Publishing. Retrieved from: https://doi.org/10.1007/978-3-319-18539-2_1.
16. Goodarzynejad, H., Babamahmoodi, A. (2015). Project Management of Randomized Clinical Trials: A Narrative Review. *Iranian Red Crescent Medical Journal, 24, 17(8), 11602.* Retrieved from: https://doi.org/10.5812%2Fircmj.11602.
17. Gordon, A., Pollack, J. (2018). Managing Healthcare Integration: Adapting Project Management to the Needs of Organizational Change. *Project Management Journal, 49(5), 5-21.* Retrieved from: https://doi.org/10.1177/8756972818785321.
18. Granholm, A., Kaas-Hansen, B.S., Lange, T., Schjørring, O.L., Andersen, L.W., Perner, A., Jensen, A.K.G., Møller, M.H. (2023). An overview of methodological considerations regarding adaptive stopping, arm dropping, and randomization in clinical trials. *Journal of Clinical Epidemiology, 153, 45-54.* Retrieved from: https://doi.org/10.1016/j.jclinepi.-2022.11.002.
19. Griffiths, G., Fitzgerald, R., Jaki, T., Corkhill, A., Marwood, E., Reynolds, H., Stanton, L., Ewings, S., Condie, S., Wrixon, E., Norton A., Radfod, M., Robertson, J., Darby-Dowman, R., Walker, L., Khoo, S. (2020). AGILE-ACCORD: A Randomized, Multicentre, Seamless, Adaptive Phase I/II Platform Study to Determine the Optimal Dose, Safety and Efficacy of Multiple Candidate Agents for the Treatment of Covid-19: A structured summary of a study protocol for a randomised platform trial. *Trials, 21(1).* Retrieved from: https://doi.-org/10.1186/s13063-020-04473-1.
20. Grudzinskas, C., Dyszel, M., Sharma, K., Gombar, C.T. (2022). Portfolio and project planning and management in the drug discovery, evaluation, development, and regulatory review process. *In: Atkinson's Principles of Clinical Pharmacology, 537-562.* Elsevier. Retrieved from: https://doi.org/10.1016/b978-0-12-819869-8.00033-1.

21. Grzeszczyk, T.A., Zawada, M. (2024). *Adaptacyjne planowanie przebiegu projektów niekomercyjnych badań klinicznych.* Warszawa: CeDeWu.
22. Grzeszczyk, T.A., Zawada, M. (2020). Healthcare Project Management Model Approach, In: Bilgin, M.H., Danis, H., Demir, E. (Eds.) *Eurasian Business Perspectives, Eurasian Studies in Business and Economics, 14(2).* Cham: Springer, Springer International Publishing.
23. Hackshaw, A. (2009). *A Concise Guide to Clinical Trials.* Wiley-Blackwell, Hoboken.
24. Harpum, P., Jamieson, A., Fisher, I. (2010). Implementing portfolio, program, and project management best practices in drug development organizations. In: Harpum, P. (Ed.) *Portfolio, program, and project management in the pharmaceutical and biotechnology industries,* 289. New Jersey: Wiley, Hoboken.
25. Holm, J.E.J., Ruppert, J.G. and Ramsden, S.D. (2022). Impact of Changing Regulations and the Dynamic Nature of European Risk Management Plans for Human Medicines on the Lifecycle of Safety Concerns. *Pharmaceutical Medicine, 36(1), 33-46.* Retrieved from: https://doi.org/10.1007/s40290-021-00414-8.
26. Jayawardana, A. (2024). *Designing and Conducting Clinical Research: Methodological Approaches.* Uva Clinical Anaesthesia.
27. Jones, C.T., Liu, X., Hornung, C.A., Fritter J. and Neidecker, M.V. (2024). The competency index for clinical research professionals: A potential tool for competency-based clinical research academic program evaluation. *Frontiers in Medicine, 11, 1291667.*
28. Juchniewicz, M. (2018). Projektyzacja – koncepcja, zakres, konsekwencje. *Studia i Prace. Kolegium Zarządzania i Finansów, 159.*
29. Keim-Malpass, J., Heysell, S.K., Thomas, T.A., Lobo, J.M., Mpagama, S.G., Muzoora, C., & Moore, C.C. (2023). Decision Analytic Modeling for Global Clinical Trial Planning: A Case for HIV-Positive Patients at High Risk for Mycobacterium tuberculosis Sepsis in Uganda. *International Journal of Environmental Research and Public Health, 20(6), 5041. Retrieved* from: https://doi.org/10.3390/ijerph20065041.
30. Kerzner, H. (2018). *Project Management Best Practices: Achieving Global Excellence*, 4th Edition. Wiley.
31. Kiani, A.K., Pheby, D., Henehan, G., Brown, R., Sieving, P., Sykora, P., Marks, R., Falsini, B., Capodicasa, N., Miertus, S., Lorusso, L., Dondossola, D., Tartaglia, G.M., Ergoren, M. C., Dundar, M., Michelini, S., Malacarne, D., Bonetti, G., Donato, K., Medori, M.C., Beccari, T., Samaja, M., Connelly, S.T., Martin, D., Morresi, A., Bacu, A., Herbst, K.L., Kapustin, M., Stuppia, L., Lumer, L., Farronato, G., Bertelli, M. (2022). Methodology for clinical research. *Journal of Preventive Medicine and Hygiene, 63(2S3), E267.* Retrieved from: https://doi.org/10.15167/2421-4248/JPMH2022.63.2S3.2769.
32. Kim, E., Yang, J., Park, S., Shin, K. (2023). Factors Affecting Success of New Drug Clinical Trials. *Ther Innov Regul Sci, 57, 737-750.* Retrieved from: https://doi.org/10.1007/s43441-023-00509-1.

33. Kozina, A. (2017). Analiza morfologiczna jako narzędzie planowania negocjacji. *Przegląd Organizacji, 4 (927), 19-23.* Retrieved from: https://doi.org/10.33141/po.2017.04.03.
34. Le Marsney, R., Williams, T., Johnson, George, K.S., Gibbons, K.S. (2022) Research monitoring practices in critical care research: a survey of current state and attitudes. *BMC Medical Research Methodology, 22, 74*. Retrieved from: https://doi.org/10.1186/s12874-022-01551-7.
35. Lunkka, N., Pietiläinen, V., Suhonen, M. (2019). A Discursive Sensemaking Perspective on Project-Based Work in Public Healthcare. *Project Management Journal, 50(6), 657-672.* Retrieved from: https://doi.org/10.1177/8756972819847062.
36. Maroju, M.P., Viswakanth, M., Shaikh, M.A.M.J., Mohammad, S.R.S., Morziul, H., Tanwir, A., Alapati, S.S.G., Kohale, D.A., Anannya, M., Srinivasarao, V. (2024). An overview on clinical data management and role of pharm.d in clinical data management. *World Journal of Pharmaceutical and Medical Research, 10(8), 299-307.*
37. Mitchell, E.J., Goodman, K., Wakefield, N., Cochran, C., Cockayne, S., Connolly, S., Desai, R., Hartley, S., Lawton, S.A., Oatey, K., Savage, J.S., Taylor, J., Youssouf, N.F.J. (2022). Clinical trial management: a profession in crisis? *Trials, 23, 357.* Retrieved from: https://doi.org/10.1186/s13063-022-06315-8.
38. Rahalkar, H., Sheppard, A., Salek, S. (2022). Biosimilar development and review process in the BRICS-TM countries: Proposal for a standardized model to improve regulatory performance. *Expert Review of Clinical Pharmacology. 15(2), 215-236.* Retrieved from: https://doi.org/10.1080/17512433.2022.2034498.
39. Riedel, N., Wieschowski, S., Bruckner, T., Holst, M.R., Kahrass, H., Nury, E., Meerpohl, J.J., Salholz-Hillel, M., Strech, D. (2022). Results dissemination from completed clinical trials conducted at German university medical centers remained delayed and incomplete. The 2014-2017 cohort. *Journal of Clinical Epidemiology, 144, 1–7.* Retrieved from: https://doi.org/10.1016/j.jclinepi.2021.12.012.
40. Schwalbe, K., Furlong, D. (2017). *Healthcare Project Management*. Minneapolis, Minnesota: Schwalbe Publishing.
41. Sonstein, S.A., Kim, L.P., Ichhpurani, N., Padbidri, R., White, S.A., Aldinger, C.E., Bierer, B.E. (2022). Incorporating Competencies Related to Project Management into the Joint Taskforce Core Competency Framework for Clinical Research Professionals. *Therapeutic Innovations & Regulatory Science, 56, 206-211.* Retrieved from: https://doi.org/10.1007/-s43441-021-00369-7.
42. Sonstein, S.A., Silva, H., Jones, C.T., Bierer, B.E. (2024). Education and training of clinical research professionals and the evolution of the Joint Task Force for Clinical Trial Competency. *Frontiers in Pharmacology, 15, 1291675*. Retrieved from: https://doi.org/10.-3389/fphar.2024.1291675.
43. Stabryła, A. (2006). *Zarządzanie projektami ekonomicznymi i organizacyjnymi.* Warszawa: PWN.

44. Stewart-Long, P. (2010). Program management in drug development. In: Harpum, P. (Ed.) *Portfolio, program, and project management in the pharmaceutical and biotechnology industries.* New Jersey: Wiley, Hoboken.
45. Strojny, J., Szmigiel, K. (2015). Analiza porównawcza podejść w zakresie zarządzania projektami. *Modern management review, XX(22), 251-258.*
46. Trocki, M. (2003). Podstawy zarządzania projektami. In: Trocki, M., Grucza, B., Ogonek, K. (Eds.) *Zarządzanie projektami*. Warszawa: PWE.
47. Trocki, M., Wyrozębski, P. (2014). Zastosowanie analizy morfologicznej w naukach o zarządzaniu. *Organizacja i Kierowanie, 2 (162).*
48. Ujwary-Gil, A. (2003). Wykorzystanie analizy morfologicznej w poszukiwaniu nowej formy reklamowania produktu. *Marketing i Rynek, 6.*
49. Wang, Z., Xiao, C., Sun, J. (2023). AutoTrial: Prompting Language Models for Clinical. *Trial Design* (arXiv:2305.11366). arXiv. Retrieved from: https://doi.org/10.48550/arXiv-.2305.11366.
50. Wąsik, D., Kuczur, T. (2016). Badania kliniczne produktów leczniczych i wyrobów medycznych. *Zagadnienia prawne,* Warszawa: Wolters Kluwer.
51. Wright, B. (2017). Clinical Trial Phases. In: *A Comprehensive and Practical Guide to Clinical Trials, 11-15.* Elsevier. Retrieved from: https://doi.org/10.1016/B978-0-12-804-729-3.00002-X.
52. Wysocki, R.K. (2019). *Effective Project Management, 8th Editio*n. John Wiley & Sons, Incorporated.
53. Zwicky, F. (1967). The Morphological Approach to Discovery, Invention, Research and Construction. In: Zwicky, F., Wilson, A.G. (Eds) *New Methods of Thought and Procedure.* Berlin: Springer. Retrieved from: https://doi.org/10.1007/978-3-642-87617-2_14.
54. Zwikael, O., Gilchrist, A. (2021). Planning to Fail: When Is Project Planning Counterproductive? *IEEE Transactions on Engineering Management.* Retrieved from: https://doi.-org/10.1109/TEM.2021.3053585.