Healthcare Project Management Model Approach

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Abstract The aim of this chapter is to present the outline of a model approach for project management in the healthcare sector on the example of clinical trial projects. Special attention was given to non-commercial projects. The authors try to fill the identified gap concerning model approaches and methodologies for managing complex and unique projects in the field of healthcare (particularly R&D projects). The subject of the research is the problem of improving clinical trial project management in the healthcare sector. The undertaken studies include the following objects: research units (including medical schools), pharmaceutical companies, and contract research organizations operating in Poland in the field of R&D. Data used in the research were collected in the form of the results of focused interviews with project managers or persons responsible for their implementation (experts, management staff, researchers), using a questionnaire survey that was prepared for the analysis of applied methods, methodologies, and project management tools for healthcare project management. The results of the presented study are identification of key elements of the model approach to managing healthcare projects, creation of a basis for deepening scientific inquiries regarding the issues of improving the efficiency of their management, formulation of a proposition of clinical trial project management model, and building of foundations for the development of research on critical success factors of healthcare projects.

Keywords Project management · Healthcare projects · Clinical trial projects · R&D · Model approach for project management

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1 Introduction

The term "healthcare" defines the whole of activities undertaken by various entities operating in the state and society, to protect the health of the individual, as well as the entire population. Actions in the field of health protection include conducting clinical trials aimed at broadening medical knowledge related to the treatment, diagnosis, and prevention of diseases (U.S. National Library of Medicine 2018). Noncommercial research is becoming increasingly important in the health sector. Identifying research as noncommercial is important because it is conducted in an objective manner, regardless of the influence of commercial institutions. There are fundamental differences between the commercial and noncommercial research in terms of the applied methods of project management, cost management, the general image of research teams, sometimes the reliability of the results obtained, and the rules for publishing them.

According to medical law in Poland, a noncommercial clinical research project may be defined as a human trial process to discover or confirm clinical, pharmacological, and pharmacodynamic effects of therapeutic products, or to identify adverse effects of investigational medicinal products, or to track the absorption, distribution, excretion, and metabolism of researched medicinal products, bearing in mind their safety and efficacy (Act of 6 September 2001).

Clinical trials management is usually implemented using project management theory and the following project management stages: initiation, planning, execution with monitoring and controlling (McCaskell et al. 2019). Implementing these types of projects is often difficult, with significant challenges regarding methodological approaches that are used. Not only the effectiveness of implemented project activities is of key importance, but the acceptability of applied methods and models of healthcare project management is required. Significant requirements are formulated for them that have not yet been met. In the case of model approaches for project management in the healthcare sector, readability and transparency of the processes used, efficient exchange of information and knowledge (positive, open communication pathways), and acceptance of the environment for the solutions used should be ensured (Arundel and Gellatly 2018).

During planning and implementation of clinical trials project management processes, the most important roles are not played by researchers, investigators, and professors, but key members of trial teams are primarily trial managers using appropriate project management models. The literature emphasizes the limited number of models, methods, and tools supporting decision-making related to management of clinical trial projects (Treweek and Littleford 2018).

The aim of the chapter is to present the outline of a model approach for project management in the healthcare sector on the example of clinical trial projects. As part of the research a questionnaire was prepared for the analysis of applied methods, methodologies, and project management tools for healthcare project management. The following research methods were also used: literature research (approaches, models, and methods of R&D project management) and participating observation

(completed projects, currently implemented and planned). There is fundamental research gap regarding solutions (model approaches and methodologies) for managing complex and unique projects in the field of healthcare (especially R&D projects). The authors try to fill the identified gap concerning useful healthcare project management models.

2 Fast-Growing Healthcare and Clinical Trials Sectors

Clinical research projects of a commercial and noncommercial character are implemented, among others, by universities or other scientific institutions with the authority to award academic degrees, healthcare entities, researchers, patients' organizations, researchers, or other legal persons or organizational units without legal personality, whose business purpose is not to profit from conducting and organizing clinical trials, manufacture, or marketing of medicinal products.

The healthcare sector represented by commercial and noncommercial clinical trial projects is a strategic part of the research and development sector. Approximately in 2010 in many European countries (e.g., in Finland) higher education institutions began to be reformed, which resulted in more effective creation of conditions for conducting various research, also in healthcare and clinical trials sectors (TEM 2014). These reforms contribute to the growth of spending on pharmaceutical as well as healthcare R&D and is confirmed by the historical statistics and forecasts presented in Figs. 1, 2, and 3.

Expenditures on research and development activities in the healthcare sector (in particular, in its pharmaceutical part) are increasing from one year to the next. The number of new clinical trials registered is also growing steadily. Poland is in the top five countries with the largest number of clinical trials. One-third of this market belongs to the USA. Table 1 presents data on the number of researches conducted in

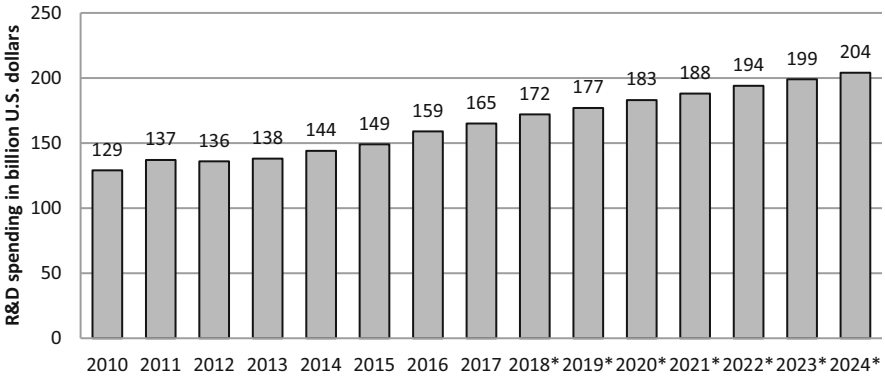

Fig. 1 Total global spending on pharmaceutical R&D from 2010 to 2024 (in billion U.S. dollars). (Source: Statista 2018a)

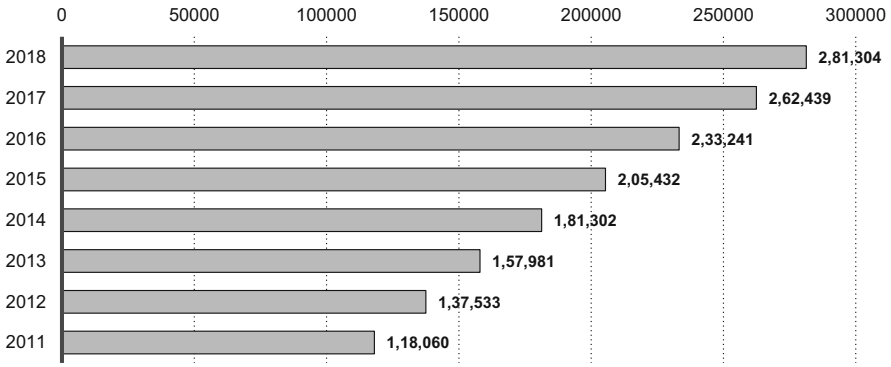

Fig. 2 Total number of registered clinical studies worldwide since 2011. (Source: Statista 2018b)

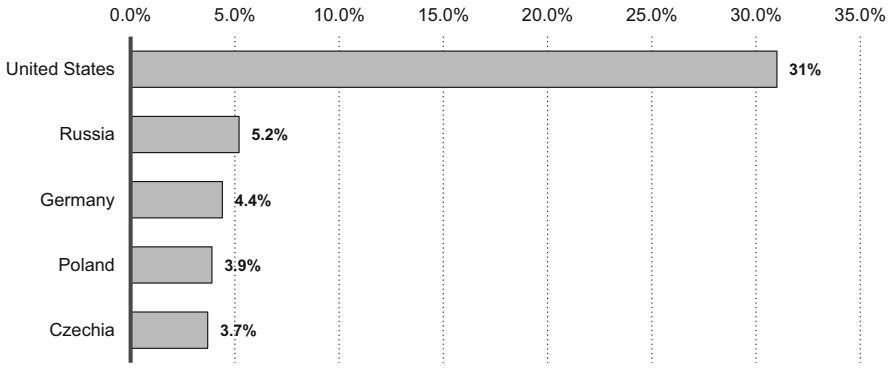

Fig. 3 Top 5 clinical trial participant countries worldwide in 2015–2016, by share of participants (in percentage). (Source: Statista 2018c)

Table 1 Number of registered clinical trials in Poland

Year	No of registered clinical trials	No of registered non-commercial clinical trials	Percent of non-commercial clinical trials
2011	495	3	0.6
2012	449	8	1.8
2013	422	2	0.5
2014	396	6	1.5
2015	441	9	2.0
2016	458	15	3.3
2017	453	15	3.3

Source: Polish Association for Good Clinical Practice 2018

Poland. The total number of applications for registration of a clinical trial is 400–500 a year, of which around 3% is noncommercial. For comparison, according to the Polish Association for Good Clinical Practice, 20–40% of researches in Western

Europe are noncommercial. Despite the significant development of the healthcare market (including clinical trials), there is a shortage of research in this field of project management, in particular, the lack of adequate methods and models supporting the management and evaluation of clinical trial projects.

Clinical trial projects are very complex and multistage undertakings. They are the last stage of drug research, before its launch on the market. These studies are necessary to evaluate the effectiveness and safety of newly developed drugs. Clinical trials typically consist of four phases and are the longest and most expensive stage of drug development.

During the first phase of the research, the safety of the test agent is initially assessed. The goal of the second phase is to determine whether the new drug works in a specific group of patients and is safe. During this part of the work, the relationship between the dose and the effect of the medical product is also established, which allows the final determination of the dose used in the further phase of the study and the necessary assessment of the effectiveness and safety of the medicine. In the third phase of clinical trials, the effectiveness of the test drug is finally confirmed in the case of a specific disease. The aim of this part of research work on the new therapeutic agent is to determine the relationship between its safety and effectiveness during short-term and long-term use. The fourth phase of clinical trials applies to medicines already registered and currently on sale. It aims to determine whether the drug is safe in all indications recommended by the manufacturer and for all groups of patients. Phase four of the research additionally verifies previously obtained results (National Comprehensive Cancer Network 2018; U.S. Department of Health and Human Services 2018).

3 Healthcare Project: Clinical Trial Case

Project management is a dynamically developing field within the discipline of management sciences. Research in this field is conducted by practitioners and the academic community and initiatives common to both trends are undertaken. Problems of knowledge transfer between scientists and practitioners are the subject of research available in the literature (Glodzinski and Marciniak 2018). It is similar in the case of clinical research projects. Research that is carried out responds to the needs of practitioners from medical environments.

The clinical trial design can be defined as a project—it has a specified beginning and end, resources (human, financial) are limited, and research goals are unique. In addition, the following rules are observed (Goodarzynejad and Babamahmoodi 2015):

- Goals are set in advance.
- The necessary resources are identified to achieve these objectives.
- Actions should be planned to achieve the objectives.
- The work should be constantly monitored.

- Performance criteria should be defined.
- The results are to be evaluated.
- The project is closed when the goals have been achieved or if the goals are not reached or cannot be implemented, or when the project need no longer exists.
- The activity follows according to the previously prepared protocol of a clinical trial, and this document is also a tool for monitoring progress.

The determinants of the quality and progress of a clinical trial can be indicated by time constraints, patient–doctor relations, proper selection of patients, lack of proper results, and necessity to obtain trust and consent of the patient (Prescott et al. 1999). Active management of every aspect of the process is the key to the project's success (Farrell and Kenyon 2014). The clinical trial has the same characteristics as other business projects defined in the field of project management (Farrell et al. 2010). However, the planning phase of the clinical trial design is of particular importance (Patel 2018).

The five most-distinguished basic processes during clinical trial management are (Patel 2018; Burke 2018):

- Initiation (defining and formulating clear goals)
- Planning (organizing a team with the required knowledge and skills, setting the schedule and the appropriate methodology, defining resources to achieve project goals, planning and risk management)
- Project implementation
- Monitoring and controlling (operation of the quality control system, monitoring of progress in accordance with the project program)
- Analysis and reporting

In management processes of healthcare projects and clinical trials, traditional approaches and the previously known life cycle stages are not useful. It is necessary to look for new solutions and develop research in this area. For example, in the case of healthcare integration projects, attempts are being made to combine traditional project management methodologies with solutions inspired by change management. There are studies available in the literature, which show that as a result of an improvised and intuitive combination of both methodologies and these solutions, as well as the application of change management in the early stages of the project life cycle, promising results can be achieved (Gordon and Pollack 2018). With the use of different stages of the life cycle and different methodologies, there is a necessity to choose appropriate methods and evaluation approaches, which are based, for example, on the use of mixed systems (Grzeszczyk 2018).

Sometimes when describing the management of clinical trial projects, a limited division into the following three key stages is used (Doganov and Yanev 2006; IMARC Research 2018): first—activities before the start of the research (preparation of the research plan and the clinical trial protocol, risk assessment, as well as resource identification); second—activities during the study (implementation of plans, training of the research team, evaluation and selection of research centers,

Table 2 Typical life cycle phases and activities of clinical trial projects

Phases	Conceptual	Planning	Implementation	Analysis, publication
Activities	Protocol synopsis	Protocol	Enroll subjects	Primary/secondary analysis
	Schedule of activities	Model Informed Consent Form (ICF)	Distribution of drug	Submit abstract
		Sites selected	Answer protocol/ CRF questions	Submit manuscript
		Manual of Procedures (MOP)	Take incident calls	Submit Clinical Technical Report (CTR)
		Case Report Forms (CRF)	Serious Adverse Events (SAE)	Post-hoc analysis
		Institutional Review Board (IRB) approvals	Dosage adjustments	
		Contracts with third party	Premature withdrawals	
		Build database	Drug disclosure	
		Drug packaging/ labeling	Data query process	
			Clean/close database	
			Transfer database to Biostatistics	

Source: Based on Goodarzynejad and Babamahmoodi (2015)

monitoring of the research, and change management); and the third related to the end of the research (activities after the study—final audit, data collection and analysis).

According to the Project Management Institute (PMI) methodology, the following five phases of the life cycle of projects can be distinguished: initiating, defining and planning, executing, performance monitoring, and closing. In the case of healthcare projects, similar stages are also distinguished (Schwalbe and Furlong 2017).

The following four phases (Table 2) are distinguished during the implementation of clinical trial projects (Goodarzynejad and Babamahmoodi 2015):

- Conceptual—preparation of protocol synopsis, i.e., develop assumptions regarding the research scope and prepare a flowchart of activities.
- Planning—preparation of the final version of the protocol and a set of project documents, such as a description of standard procedures, an informed consent form, a clinical observation chart as well as selection of medical research centers for conducting study, obtaining the consent of the Bioethical Commission, preparation of a database
- Implementation—the fundamental research phase—distribution of medicines, management of adverse events, data validation

- Analysis—closing the study, statistical analysis of data obtained during the research, preparation of the final report and sometimes scientific publications.

The following are the key challenges associated with running and managing clinical trials (Goodarzynejad and Babamahmoodi 2015):

- Implementing and maintaining effective management systems and techniques in response to the needs of trial projects
- Registering patient groups as quickly and efficiently as possible
- Identification of appropriate research centers and establishing realistic expectations regarding registration
- Gaining ethical acceptance

The challenges related to considerably complex healthcare regulations, the need to record each event minutely, and the significant responsibility and validity of the activities carried out should also be mentioned. This requires relying on extremely committed personnel, often working according to flexible working time.

4 Pilot Study

This part of the chapter is a synthetic description of the pilot study carried out, the subject of which was to identify the elements shaping the project management model in the healthcare sector on the example of clinical trial projects (including noncommercial clinical trials). The results of this research may be helpful in the processes of identifying project management conditions in the healthcare sector, as well as determining factors of success and failure of healthcare projects.

The subjects of the study were people professionally connected with running projects in the healthcare sector—employees of medical universities, contract research organizations, as well as specialists working on behalf of companies from the pharmaceutical sector. The group of researched projects was limited to projects of a clinical (including noncommercial) nature. The applied research methods are literature analysis, participant observation, and interview using a research questionnaire. The research questionnaire was addressed to people who are professionally involved in conducting clinical trials, including noncommercial clinical trials—experts, management staff, and researchers. In total, eight experts took part in the survey.

The survey consists of 13 questions. The respondents were asked to indicate the role they play in clinical trial projects. Subsequently, they were asked about experience—the number of projects due to their value, the research phase, as well as the duration of the project. Three questions related to project management methods and tools. The respondents were asked to specify the methods, methodologies, and tools they know and apply and whether they use them at the project planning stage. In the case of a negative answer, they were asked to indicate reasons for use/non-use. Gantt chart, logic matrix, critical path method (CPM), Program Evaluation and Review

Technique (PERT), Prince2, PMBoK, Scrum, theory of constraints, and work breakdown structure were referred to as the methods and tools.

The remaining questions concerned the following problems:

- Elements that have the greatest impact on the smooth and effective launch of noncommercial clinical trials.
- The most important conditions, the fulfillment of which translates into success, and failure to meet—the failure of noncommercial clinical trials.
- The most important milestones/key stages of noncommercial clinical trials.
- What should be improved at the stage of planning clinical trial projects.
- Which element of the surroundings of projects of noncommercial clinical trials is the most important.
- Which entity plays the most important role in this type of projects.

Respondents were also asked to state their opinion on the anticipated development of the market for noncommercial clinical trials in Poland.

5 Research Results

Below is a summary of the answers obtained during interviews using a research questionnaire. Experts who participated in the study have at least five years of experience working on clinical trial projects, including the following roles: researchers, study coordinators, and clinical trial assistant (Table 3).

In most cases, the indicated methods and tools (Table 4) are not known, nor are they used. Moreover, one of the respondents indicated that he did not know any of the above. The respondents explain this state both by their lack of need to use them and the shortage of knowledge about the topics of these methods. The scarcity of the need to use these methods and tools given by the respondents may result from the lack of knowledge about their capabilities. Among the most well-known methods and tools are Gantt charts, work breakdown structure, and critical path method—used in planning the study in order to arrange the sequence of activities that are necessary to perform.

Among the elements that have the greatest impact on the smooth and effective launch of noncommercial clinical trials (Table 5), the most appropriate selection of

Table 3 Respondents answers

	Eight respondents							
	1	2	3	4	5	6	7	8
Principal investigators	x							
Clinical investigators		x					x	x
Clinical coordinators			x		x			
Clinical trial monitors								
Other persons				x		x		

Source: Own study

Table 4 Methods, methodologies, and tools

	I know	I use	I use at the planning stage
Gantt chart	7	7	7
Logic matrix	2	1	–
Critical path method (CPM)	3	2	2
Program Evaluation and Review Technique (PERT)	1	1	1
Prince2	1	1	1
PMBoK	1	1	1
Scrum	1	–	–
Theory of constraints	2	1	1
Work breakdown structure	5	3	3
Other	–	–	–

Source: Own study

Table 5 Elements of efficiency

Elements	Number of responses
The right choice of patients	2
Proper selection of research centers	6
Proper selection of researchers	1
Choosing the principal investigator	1
Choosing the research coordinator	–
Cooperation with the Bioethical Commission	2
Cooperation with Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products	5
Cooperation with the Sponsor	5

Source: Own study

Table 6 Conditions for success and failure

Conditions	Number of responses
Precise definition of the study (including definition of goals)	5
The right plan for recruiting patients	2
The proper plan for monitoring the study	–
Proper risk analysis	1
A proper feasibility study analysis	7
Planning enough time to conduct the study	–
Providing the necessary resources to carry out the research	5
Access to current knowledge and information	1
Efficient communication in the research team	–
Occurrence of adverse events	–
Proper statistical analysis	–

Source: Own study

Table 7 Elements to improve

Elements	Number of responses
Organization of the work of the research team	3
Setting roles in the project	1
Creating a project schedule	3
Communication processes in the project	3
The division of the project into tasks and activities	6
Delegating tasks	3

Source: Own study

Table 8 Elements of the environment

Elements	Number of responses
Legal regulations	8
Development of modern technologies	–
Competition	–
Funding sources	7
Globalization of the economy	–

Source: Own study

research centers, and cooperation with the research sponsor, i.e., a person (often in noncommercial research) or an entity that sets the principles of the research process.

Among the conditions whose fulfillment translates into success and failure to fulfill, the failure of noncommercial clinical trials (Table 6) was most often indicated by the appropriate feasibility study. These studies include assessment of internal and environmental capacity, adaptation of the clinical trial for the study design, dose of the test product, type of comparator, type of patient, local environment, and evaluation of the clinical trial potential (Rajadhyaksha 2010). Other important factors are precisely defining the research and providing the necessary resources.

In the question about the most important milestones (key stages) of projects of noncommercial clinical trials, respondents mentioned a number of important elements. There is a consistent view among the experts that one of the most important stages is the approval of the study protocol—a document that is a procedure for conduct, without which the research process cannot be started. The respondents also mentioned aspects such as research synopsis, finding research funding, registering a study, developing a patient or volunteer recruitment method, first patient visit and last patient visit, ending recruitment, ending treatment phase, statistical analysis of results, report, selection of research centers and signing contracts, obtaining the approval of the Bioethics Committee, defining the purpose of the study, preparing the study documentation, and publication of results.

Collecting the responses of all respondents allows us to conclude that all elements of the clinical trial design planning indicated in the questionnaire should be improved (Table 7). However, most often the division of the project into tasks and activities was indicated, and the roles in projects were rarely determined.

Table 9 Important entities

Institutions	Number of responses
Sponsors	1
CRO companies	–
Participants/patients	1
Research centers (sites)	3
Researchers/doctors	3
Public administration bodies	–
Other financing institutions	3
Bioethics commissions	–

Source: Own study

Table 10 Market development forecast for non-commercial clinical trials in Poland

Forecast	Number of responses
Less than 3%	–
No change (3%)	4
From 3% to 10%	3
From 10% to 15%	1
Over 15%	–

Source: Own study

As the most important elements of the environment of projects of noncommercial clinical trials experts have consistently indicated legal regulations and sources of financing (Table 8).

The researchers (doctors), medical centers, and other financing institutions were indicated as the most important entity that plays the most crucial role in the project of a noncommercial clinical trial (e.g., The National Centre for Research and Development in Poland)—Table 9.

Experts assessing the perspective of the development of the market of noncommercial clinical trials in Poland over the next five years, measured by the share of noncommercial clinical trials in general clinical trials registered in Poland, most often indicated the answer "no change" (3%)—Table 10.

6 Clinical Trial Project Management Model

On the basis of the analysis of the literature on the subject and a pilot questionnaire survey carried out with the participation of experts in clinical trial project management, the most important stages of the project are presented graphically in Fig. 4.

In summary, the efficient model of project management in the healthcare sector (based on clinical trials) should be composed of the following stages:

- Defining the research (project)—determining objectives, synthesis of current knowledge, information on the therapeutic substance (medical product and other products), scope of work, budget, and implementation period

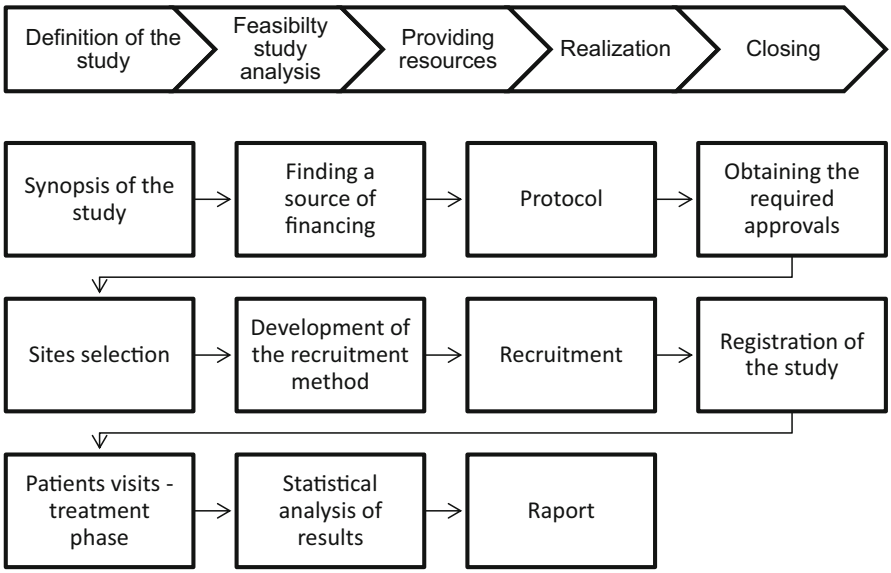

Fig. 4 Clinical trial project management model. (Source: Own study)

- Feasibility studies—research on the feasibility of project implementation, analysis of resources, including researchers, specialist doctors, available medical centers, and estimation of the availability of technical equipment
- Providing resources—employment of the main researcher, recruitment of researchers (medical staff), recruitment of patients and volunteers for the study, recruitment of medical centers, and ordering medicines (including organization of transport)
- Project implementation—basic phase, treatment, ongoing monitoring of progress and compliance with the protocol, as well as security monitoring (adverse events),
- Closing the project—the last visit, carrying out the procedure of organizing all obtained data and information, performing statistical analyzes, preparing the final report, and writing scientific publications.

7 Conclusion

The chapter presents the key elements of the model approach to managing healthcare projects, creation of a basis for deepening scientific inquiries regarding the issues of improving the efficiency of their management, formulation of proposition of clinical trial project management model, as well as building of foundations for the development of research on critical success factors of healthcare projects. It also shows the results of a pilot study, the object of which is to identify the elements shaping the

project management model in the healthcare sector on the example of clinical trial projects (including noncommercial clinical trials). Project management conditions in the healthcare sector have also been identified. To some extent, selected factors of the success and failure of healthcare projects were determined. Participants of the study were people professionally associated with running projects in the healthcare sector, and the group of researched projects was narrowed to projects of clinical (including noncommercial) nature.

The obtained results are promising and can be used to improve the efficiency and effectiveness of project management in the field of health (and medical research), which can bring significant benefits in terms of both management and the results of scientific research carried out in medical projects. Study on the presented clinical trial project management model will be continued. It is anticipated that the scope of the future work will be limited to the project planning stage. This is an important and relatively less researched study area.

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