ABSTRACT OF THE DOCTORAL DISSERTATION

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entitled: "The concept of a project management system in the drug development process"

The doctoral dissertation deals with the subject of improving project management processes in the drug development industry. This industry, due to working on living organisms and the impact on their health and life, is characterized by extremely high complexity and time-consuming processes, the need to constantly generate know-how, the need to meet strict legal regulations, huge costs and the risk of failure. As a result, standard project management methods, such as the classic approaches according to PMI, prove insufficient. They are too rigid, inflexible, and often do not address the needs of the dynamic nature of pharmaceutical projects, which are interdisciplinary, requiring a high level of expertise from the members of the organization working in this area, and at the same time, comprehensive knowledge, laborious, and expensive. Ethical aspects are important in these cases, both related to the conduct of research work and the unpredictable well-being of patients included in the trials and taking a new, already registered therapy. Importantly, the process of conducting design work in drug development is very much influenced by external factors, and they significantly determine the conduct of organizations and project teams. In addition, traditional approaches do not take into account the need for a wide range of preparatory work based on basic research, adaptation to changing regulations on a global scale, which may lead to problems with risk and opportunity management, as well as with adaptation to new legal and ethical requirements. An important factor is the fact that competing organizations are very different, from academic teams and start-ups, through biotechnology organizations, to global pharmaceutical companies. The competition for priority in the advancement of research work, intellectual property protection and drug registration covers significant geographical areas, where for many years the market will be largely influenced by the first registered therapeutic agent – it will set the standard of treatment and influence the type and profile of subsequent therapies in selected medical areas.

The aim of the study was to develop a concept for the management of research projects in drug development to support research organizations in adapting the way they conduct drug development to the changing factors of the organization's external and internal environment. The development of the concept was achieved through the implementation of specific objectives, which include: 1) identification and compilation of existing concepts of research project management in drug development as a result of a systematic literature review, 2)

determination of research project management practices used in drug development on the basis of empirical research conducted – participant indirect observation, interviews and survey, 3) definition of key determinants success of research projects and the relationship between them.

As part of the work carried out, research problems were defined, which were presented in the form of three questions: 1) What is the specificity of research management in drug development? 2) What are the factors determining the success of project management in the area of drug development? 3) How to adapt (configure) project management standards to the specifics (needs) of research activities in the field of drug development?

This paper has been structured in a way to introduce the reader to the specifics of drug development, identify the determinants of work on new therapies, and show the challenges faced by the industry in the context of research organizations, at the local and global level. It consists of five chapters. The first chapter, entitled "The drug development process", provides information about the area of drug development and its characteristics, describes the stages of development of new therapies, and the most important related regulations regarding the conduct of research, registration, and use by patients. The last part of this chapter summarizes success factors in the development of new drugs based on the analysis of the literature. The second chapter entitled "Project management in the area of drug development" is a description of research projects in drug development, taking into account their life cycle, source of origin and standards used in their management. The third chapter, entitled "Research method" introduces the reader to the main and detailed objectives of the work, defines research problems and assumptions. In the further part of the chapter, there is a description of the research model used in the doctoral dissertation, descriptions of selected methods, the research sample and the course of research. As part of the research, a systematic literature review was carried out, which allowed for the identification and compilation of existing concepts for the management of research projects in the area of drug development. Analysis of available models and methods showed both their advantages and limitations in the context of the dynamic and interdisciplinary nature of the drug development industry. Then, through empirical research, i.e. indirect observation for 140 project meetings, in-depth interviews with 14 experts and a global survey with representatives of drug research organisations, practical approaches to project management were identified, taking into account the priorities, various strategies, tools and processes implemented at different stages of the life cycle of a project focused on new medicines. The next step was a case study at two companies that work with drug development project organizations to identify practices and analyze their project management systems. The

fourth chapter entitled "Analysis of the results of empirical research" contains the results of indirect participant observation, in-depth interviews, and a questionnaire. The reader will also find examples of project management systems in organizations participating in the work on new therapies, but not directly conducting research and development work on new therapies. The last part of the chapter provides a summary of the success factors of projects in drug development based on the work carried out. Based on the conducted analyses, the key factors determining the success of research projects were identified, as well as their relationship with the stage of development defined as the level of technological readiness, which allowed for a better understanding of the mechanisms affecting effective project management. The fifth chapter, entitled "The concept of the management system" is the result of many months of research work described in the previous chapters of the work. It is a synthesis of knowledge, as well as an answer to the research questions posed in the work, a reference to the main goal and specific objectives of the work. The concept proposed in the chapter covers the essence of the project management system in drug development, defines its functions, structure, proposed processes and methods, and the proposal of project meetings. The developed system aims to improve the efficiency and effectiveness of research projects in drug development, while increasing control over the demand and use of resources, minimizing the risk of failure, and maximizing the number of new, safer therapies available to patients. The research work carried out allowed to determine the specificity of research management in drug development. Aspects such as ambiguity of research objectives, variability of results, long-term biological impact, high risk of failure and changing priorities in the project, regulations and standards constituting the framework in which research teams operate, unpredictability of research on both models and humans at every clinical stage, high interdisciplinarity and at the same time the need for specialized experts working in an environment with large gaps in knowledge, Safety and ethics, which determine the research approach and the pace of work, significantly affect the definition of project goals and the sense of frustration of those involved in them.

On the basis of the work carried out, it was noted that the success of research projects depends on several factors described in this work as determinants – organizational, management, scientific, infrastructural, financial, economic, technical, technological, intellectual property, legal, ethical, cooperation and brand-related factors. The organization's systematic approach to defining factors specific to the selected project allows for monitoring needs, tasks, resources, progress of work and building a project strategy based on its real needs to increase the project's chances of success, i.e. drug registration and patient assistance. These

are many factors that occur with varying intensity and change as the level of advancement of projects changes. In order to adapt project management standards to the specifics of research activities in the field of drug development, it is necessary to properly define the tasks and acquire the competences necessary to implement them at each level of technological readiness. These issues are individual to each project, as it is the project teams that define the differentiation of a potential drug from the competition and already known therapeutic solutions on the market. However, this approach allows for systematization of work and distribution of resources depending on the requirements of a given stage.

As a result of the work carried out and on the basis of the collected information, a configuration of current project management practices was proposed, taking into account the specifics of the industry and factors determining success, and thus adapted to the needs of the industry focusing on the development of new drugs. The new model integrates the flexibility of agile methods with long-term planning and emphasizes the importance of interdisciplinary collaboration, communication, systematic data and documentation management, and the need to build an organizational culture based on trust, strong relationships and learning. This, in turn, is the basis for organizations to adopt a project management system tailored to their own needs and can contribute to increasing the efficiency and effectiveness of ongoing projects in the area of drug development.

The paper is summarized in a conclusion describing the entire work, its importance for projects focused on new drugs and suggestions for further work to expand knowledge in the field of project management in the drug development industry, increasing the chances of their success and introducing new therapeutic solutions for patients to the market. At the end of the work, there is a bibliography and appendices, where supplementary materials and detailed information on the course of the research procedure are included.