Summary

This doctoral thesis consists of six chapters. The first chapter is the introduction to the discussion of the practical aspects of conducting clinical trials. The main focus is put on the analysis of basic definitions, which were key to understanding the subtle differences in statutory expressions related to the clinical trials. The notions of "clinical trial of a medicinal product" and "veterinary clinical trial" are discussed here. The correlation between the concept of "clinical trial" and "medical experiment" was also examined, which eventually gave an answer to the main question of this subsection, namely, whether a clinical trial can be called a kind of a medical experiment. If so, is it a purely therapeutic or research experiment, or rather a hybrid of the two above. This chapter ends with a concise deliberation on the purpose of conducting clinical trials on medicinal and veterinary products, emphasizing the differences between them.

The second chapter of this dissertation shows the process of historical development of the field of clinical research from the first, often unconsciously conducted, clinical trials. Next, the development of knowledge in the area of proper research design and proper ethical conduct is described. This part of the thesis presents several events from the global medical and pharmaceutical past, which are milestones in the pursuit of recent perceiving of clinical research, including their ethical guidelines. As these events contributed to the progressive development of ethical norms, the paper contains a description of the provisions of the Nuremberg Code, the Helsinki Declaration, Principles of Good Clinical Practice (GCP, ICP GCP), International Ethical Guidelines for biomedical research with people, and the Convention for the Protection of Human Rights and Dignity of Human Beings in the Applications of Biology and Medicine: Convention on Human Rights and Biomedicine, including Additional Protocols. The entities responsible for the creation of the above-mentioned regulations are described, as well as the most important rules that are included in these documents.

The next chapter is entitled "Clinical trials in terms of EU legal regulations and Polish law". It completes the analysis of side issues that outlined the legal background of the clinical trials process. The most important EU acts devoted to clinical trials, in particular the Directive 2001/20 / EC and, repealing and replacing it, Regulation 536/2014 were discussed. The analysis in this respect was mainly devoted to modifications introduced by such a change, especially the fact that it resulted in the change of the essential normative character of legal provisions due to the principle of direct effect of regulations in the EU countries. The

provisions of Regulation 536/2014 were also analyzed in the context of their compliance with the Polish Constitution taking into account the possibility of violating the subsidiarity principle. After presenting the EU legal framework for clinical trials, the focus was put on the Polish legal framework. The changes that occurred in Polish law were discussed in chronological order, starting from the period before the Pharmaceutical Law Act entered in force, by describing its provisions at the moment of entry into force in the original state, ending with the analysis of its development that was a consequence of our country joining the European Union .

The fourth chapter is an introduction to the merits of this dissertation. One of its basic goals is to examine and describe the relationship between original and generic drugs present on the pharmaceutical market in the context of the legal aspects of conducting clinical trials. The entire process of creating innovative medicinal products is presented here: from the stage of preclinical studies, through the description of individual phases of conducting clinical trials, ending with the issue of the authorization of products for marketing and the problems of their functioning on the pharmaceutical market.

In the next part of the thesis, the definition and position of generic drugs on the pharmaceutical market were analyzed. The features that distinguish them from the reference medicinal products are indicated here. Particular attention was paid to discussing the nature of the bioequivalence study. The analysis which attempts to answer the question of whether complete substitutability of reference drugs with generic ones is possible, is considered an extremely important element of this chapter. In this context, opinions of specialists in the fields of medical sciences, pharmacy and law were cited. The above was supplemented by a questionnaire interview conducted among patients - consumers of two pharmacies in the łodzkie voivodship.

The thesis ends with a chapter on patent protection of medicinal products. There were issues such as the evolution of legal regulations regarding the patentability of such products, special rules of their protection, content and scope of patent law and patent limitation in the field of medicinal products discussed. Next, information on data exclusivity was presented. The author emphasized that it is closely related to the need to reduce the amount of research on the same substances or mixtures. Further, the matter of supplementary protection certificates, which may be granted after the period of basic protection, were described. One part of this chapter was devoted to discussion of efforts that are made by the inventors (and other entities entitled to patent), which aim at extending patent protection: patent thickets, second management of the product life cycle ("new generation" products and new

pharmaceutical forms) and strategic withdrawal. The last subsection concerns patent abuse, and in particular instruments aimed at counteracting them, which are available in international and in Polish law. The problem of acceptability of patent restrictions on medicinal products is further discussed. Here information on the applicability of restrictions under international law and those related to the Roche-Bolar clause can be found. Finally, the methods of counteracting strategies for extending the exclusivity period of medicinal products are described. Attention was paid to the need to ensure high quality of patents, the concept of creating uniform patent protection in the EU and the appropriate state policy on generic drugs.

The dissertation ends with briefly presented conclusions. In particular, the focus was put on the verification of the research hypotheses. There are also a few generalized postulates proposed, arising from conducted research and author's own observations as well as from literature studies of the subject matter, carried out for the purposes of this doctoral thesis.