Abstract

This master thesis is a description of the clinical trial, which is part of medical law under the law aspects. This thesis is split to topic, whose a brief outline is in the introduction. Process of the clinical trial and their institutions are discussed under the law and medical aspects. Resources of this thesis are a professional literature, knowledge of experts from pharmaceutical company and my own experience from part-time job in this type of companies. Aim of the thesis is to bring more resources and information about that topic to experts and other people who are interested in.

This thesis is devided into five chapters. First chapter is speaking about a general institute in the clinical trial. There are listed sources of the law. In the next chapter I deal with the process of the clinical trial from the begining i.e. from the development of a new substance through the clinical trial to the final registration. The chapter about the european law regulation is following. In the fourth chapter I deal with the ethical aspects, which are conected with clinical trial. In that part I emphasised the influence of the international ethical documents. The last chapter is conclusion, where I describe the goal of this master thesis and also I am linking to the opinions of authorities regarding the future of clinical trials.