

Abstract

My diploma thesis deals with the Clinical trial in the Czech Republic in the period from 1989 to present and on its impact on management in organizations dealing with clinical trials. The aim of this thesis is to identify key changes that occurred in the clinical trial and to identify how these changes influenced the management of clinical trial organizations. This will be done based on the qualitative research.

The theoretical part provides information about the history of the clinical trial, about international and the Czech legislation, including ethical principles, the submission process including description of institutions that are reviewing the clinical research. The theory also explains the issue of management, its organizational developments and its expected development in the future.

In the research part I described the chosen research method, which extends from the semi-structured interview after the pilot part to the use of the focus group method – in combination with semi-structured interview. Based on these interviews and focus groups have been evaluated 7 parts to describe the evolution of the clinical trial and its impact on the management of clinical trials, including one topic that addresses the expected development of this field in the future.

Key words: clinical trial, clinical trial submission, organization management, development of organization management