

ABSTRAKT

Monitoring is one of the most important methods of overseeing the pursuit of the clinical research. A monitoring person (Clinical research associate) is responsible for verifying correctness of the monitoring process in the trial site and checks that the respect for dignity and rights of individual subjects exposed to the clinical research are being abided by.

The theoretical part of the MA thesis examines the issue of the clinical research of medicinal products and explains the basic terminology pertaining to the performance of the clinical research. The thesis further analyses the position of Clinical research associate and describes the monitoring process. Concurrently, the ethical problems, which Clinical research associate encounters in practice, are traced.

The empirical section studies the outcomes of an investigation conducted via a questionnaire, which focused on how Clinical research associate perceive the ethical problems. As a result, the study identifies the most frequently observed ethical issues. Respondents of the questionnaire view the ethical issues as less significant. Clinical research associates are not united in tagging the most frequent occurrence of ethical problems (in the field of medicine and the catchment area).

In the same section, the MA thesis rebuts a hypothesis according to which Clinical research associate is unable to reveal an investigator's involuntary faults occurred during the clinical research. Outcomes of the questionnaire have vindicated that Clinical research associate is likely to ascribe a bigger importance to the data counterfeiting and to the detriments inflicted upon tested patients than to the ethics, despite the fact that Clinical research associate is often exposed to negative impacts during the monitoring process.

Keywords: monitoring of clinical research, ethics of clinical research, faults in medical research, fraud in medical research, camouflage of faults, investigator's influence on clinical research associate, sanctions for fraud in medical research.