STUDY OF NEEDS IN CLINICAL TRIALS QUALITY MANAGEMENT APPROACHES IMPROVEMENT

Kolodyezna T. Yu., Zupanets K. O., Ratushna K. L.
Scientific supervisor: Doctor of Pharmacy, professor Dobrova V. Ye.
National University of Pharmacy, Kharkiv, Ukraine
ko_t@ukr.net

Background. The organization and conducting of the clinical trial (CT) of any new drug is a complex and responsible process, because the decision on withdrawal of the drug to the market depends on the quality of the data. Compliance with high accuracy of research results and proper execution of all procedures require constant monitoring of their quality. Constant revision and improvement of the quality control ways implementation is needed for the effectiveness of quality control measures. In our previous studies we have highlighted four main types of risks that may affect the CT quality: risks related to CT preparation and organization at clinical site (CS); risk for investigator associated with responsibility for CT conducting; the risk for trial subjects associated with participation in CT; the risk of incorrect assessment of the effectiveness / safety of the studied drugs. The results of experts who participate in CT opinion survey showed that the risks related to CT preparation and organization at CS, the risk for investigator associated with responsibility for CT conducting have an average degree of influence on the quality of the CT of drugs procedures. This means that specialists who participates in CT do not associate these risks with high or maximum impact on the quality of the CT of drugs that can reduce the amount of attention paid to these types of risks control. This in turn may lead to their influence increase on the quality of the CT of drugs.

Thus, **the aim** of this study is to determine the need of CT of drugs quality management practical approaches improvement in Ukraine.

Materials and methods. To achieve this goal, we conducted a survey of 294 specialists with experience of participation in CT of drugs. The proposed to respondents questionnaire consisted of general part and questions to assess the opinion of participants regarding aspects that should be paid attention to the of CT of drugs quality management. The analysis of the results was performed using statistical analysis methods.

The results. Among the CT participants who was surveyed 95% had medical education; 30% of respondents participated in more than 10 CT of drugs, and 27% - in 5-10 trials. Since the majority of respondents had a great experience in CT of drugs, then during their work in this field they performed different functions, namely 71% of the respondents served as the physician-researcher, 21% as the study coordinator and 17% as Principal Investigator.

Since the respondents in their work all the time facing the organization and conducting CT, they were asked to choose from a list of evaluation criteria, which they believe could be used efficiently in practice for the CT of drugs quality control at CS. From the nine proposed criteria, most respondents (68%) selected from seven to nine criteria. Most participants of survey chose the following criteria affecting the quality of CT: "performance of clinical procedures according to the CT protocol " (90%), "the proper maintenance of CT documents according to GCP, their proper archiving and storage" (85%), "trial subjects' protection (filling the informed consent, providing emergency medical care)" (83%). A more detailed analysis of selected by the experts criteria dependence on their experience in CT field showed that more than 85% of specialists with experience in more than 10 CT chose four criteria: "performance of clinical procedures according to the CT protocol", "compliance with all requirements for subjects inclusion in the trial," "the presence of CS staff necessary preparation for participation in CT (certified training on GCP, documents confirming experience in CT and others)", "the proper maintenance of CT documents according to GCP, their proper archiving and storage". Also, more than 80% of respondents with experience of participation in 5-10 CT of drugs chose only three criteria: "performance of clinical procedures according to the CT protocol", "the proper maintenance of CT documents according to GCP, their proper archiving and storage" and "trial subjects' protection (filling the informed consent, providing emergency medical care)". The analysis of selected by the experts criteria dependence on their functions during CT participation showed that more than 80% Principal Investigators chose five criteria, more than 80% of physician-researchers — three criteria, and more than 85% of the study coordinators — six criteria. This means that CT of drugs participants believe that very close attention to this procedures during organizing and conducting of CT of drugs has to be paid.

Conclusions. Summarizing the findings, we can conclude about the need for continuous improvement of quality control approaches during organizing and conducting of CT of drugs by the practical specialists in the field of CT opinion. This requires a constant work on risk assessment, development of methods for their prevention and elimination, as well as continuous improvement of CT of drugs quality management. In future studies it is planned to improve existing ways of CT quality control and develop new approaches to improve them.