REVIEW OF APPROACHES TO ENSURING PROPER TRAINING OF RESEARCH STAFF IN CLINICAL TRIALS

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Introduction. Good Clinical Practice (GCP) training for staff involved in clinical trials (CT) is usually presented as a "universal" approach and is used both to train new members of the research team and to enhance the training of experienced researchers. It is believed that this provides the minimum level of knowledge required for quality CT.

Aim of the research was to analyze current state of ensuring the proper level of training of the research staff in clinical trials.

Materials and methods. The methods of analysis, synthesis and generalization were used in the work.

Results and discussion. In the United States, in order to promote GCP principles and meet FDA requirements, sponsors, pharmaceutical companies, and some government CT sponsors typically require that all researchers participating in these trials, regardless of previous experience and training, be trained in GCP to participate. in each study. Sometimes such requirements are made to all staff, regardless of the functions they will perform in the CT. For example, the National Institutes of Health and the Department of Veterans Affairs require staff participating in the CT to provide documentation of current training certification (training is recommended to be repeated or updated every 3 years). Therefore, researchers can be trained in GCP several times a year, as well as undergo special training in their specialty in the specialty.

In Ukraine, there are very similar trends in ongoing training in GCP principles. Usually, the specialists involved in the HF on the part of the sponsor and the staff of the clinical sites undergo GCP trainings under the auspices of the State Expert Center of the Ministry of Health of Ukraine. According to the Center, its staff conducts nearly 20 GCP training seminars annually. Regulatory and legal regulation of clinical trials in Ukraine ". The main task of these training seminars is to provide an explanation of the main provisions of regulations in the field of CT both in Ukraine and international regulations, in particular GCP. Such short-term training is provided to researchers, members of local ethics commissions, specialists in clinical research departments of pharmaceutical manufacturers, etc. In addition to enhancing the capabilities of clinical research investigators, extensive professional development and training are necessary for study coordinators, data managers, information technology specialists, regulatory affairs specialists, site managers, project managers at the research sites, contract research organizations, industry, and academic medical centers.

Conclusions. The need to grow, train, and support the clinical research workforce comes at a time of increasing complexity of clinical research protocols, processes, and methods, novel study designs, and globalization of research. Moreover, the setting for clinical research is expanding to community settings, provider practices, and other non-traditional research sites.