

RESEARCH OF PROFESSIONAL TRAINING AMONG SPECIALISTS INVOLVED IN CLINICAL TRIAL

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Ensuring an appropriate level of professional training is an urgent problem of clinical trials. Lack of ordered training system for professionals in clinical trial (CT) in Ukraine has created a situation in which most of experts working in clinical drug development, have no specialized education - medical or pharmaceutical. To date, there was a need for assessment of CT professionals training and substantiate the importance of ensuring proper qualification of CT specialists by obtaining postgraduate specialized education.

The study aim was to evaluate comprehensively knowledge level regarding principles and standards of proper conducting of clinical research using self-assessments system among CT specialists performed various functions in clinical research. The survey was performed using specific questionnaires in which respondents were required to assess own knowledge level concerning fundamentals aspect of proper clinical study conducting. Statistical methods were used to analyze the respondents' answers.

We found that most of specialists who took part in survey need to extend their knowledge in following CT aspects: GLP; clinical data processing and statistical analysis; CT quality assurance and control; investigational medicinal product handling; responsibilities of auditor company and regulatory bodies. We determined that regardless of functions performed by specialists in CT, knowledge level concerning basic aspects of CT organization and conducting directly depends on basic education. Thus, specialists with pharmaceutical degree who had in their educational programs appropriate courses have the highest knowledge level in CT aspects. At the same time, specialists with medical degree, especially with biological degree, need not only extend their knowledge, but even to learn fundamental ideas and aspect in CT conducting.

All these findings proof the importance of implementing into Ukrainian educational system new specialty "Clinical Trials". This will enables to achieve the specialized education in CT and get sound knowledge and skills that are necessary for successful career. Also it will facilitates the assurance of high level of qualification for specialists involved in CT and proper control of its professional training within national system of higher education quality assurance and will extend the facilities of Ukrainian trial site regarding participation in international research projects.