MAIN FEUTERS OF THE EDUCATIONAL AND PROFESSIONAL PROGRAMME "MANAGEMENT OF CLINICAL SURVEY"

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Annotation. The article provides information on the new educational and professional programme "Management of clinical survey". The relevance of its introduction in specialized educational institutions is substantiated. The purpose of the programme is formulated, its main focus is provided. The contents and competitive advantages of the programme are described. The main programme educational results are determined.

Key words: educational and professional programme, clinical survey, study content, competitive advantages, programme studying results.

Problem. Currently, the pharmaceutical industry in Ukraine is in a leading position. However, international competition continues to attack the national pharmaceutical market. Experts assert that in the domestic market of registered pharmaceuticals about one third is a preparation of Ukrainian production, while the rest is a foreign one. Therefore, strengthening the competitive position of Ukrainian pharmaceutical companies on the market is a very important task. And it is clear that competing in this sector of the economy can only be due to the quality medicines production.

Clinical survey is an integral part of the drug development process, since they can determine the quality of drugs and conduct its further control. Thus, there is a fair thesis that the quality of medicines depends on the substantiality of clinical survey. The latter, in its turn, depends to a large extent on the proper level of planning and organization of clinical survey. An unconditional guarantee of this is the availability of specialists with appropriate managerial education and managerial skills in health care facilities, contract research organizations and pharmaceutical companies. The above is a basis for training of specialists in clinical research management [1-10].

Main material. With regard to the above, starting from the new academic year the National Pharmaceutical University (Kharkiv, Ukraine) establishes on the basis of speciality 073 "Management" (field of knowledge – 07 "Management and Administration" a new educational and professional programme "Management of Clinical Survey", which is the only one and unique in Ukraine, as of today. Students of this programme will be qualified as "Masters in Management" and "Public Health Care Managers". This will enable graduate professionals to hold corresponding primary positions as "Public Health Care Managers", which are characterized by special professional competences in accordance with the generalized object of activity (field of clinical survey).

The main focus of the program is training of specialists for organizational and managerial, as well as analytical activities in the field of clinical survey.

The purpose of the educational and professional programme is to train highly qualified professionals capable of qualitatively performing the functions of planning, organizing, monitoring and adhering to the requirements of the ethical aspects of clinical survey, and effectively managing financial, material and information resources, the project team in health care institutions, contracting research organizations and pharmaceutical companies.

The competitive advantages of the programme are its uniqueness and certain originality of its educational component. The latter, in general, consists of management disciplines (management, change management, time management, managerial work organization, risk management, crisis management, smart logistics and supply chains, supply chain management) and disciplines that provide special, fundamental knowledge with regard to the organization, planning and monitoring

clinical survey (legal aspects in clinical research, data management in clinical survey, proper clinical practice, clinical medicine, pharmacology, clinical pharmacology, quality management in clinical survey, bioethics in clinical survey and pharmacoeconomic analysis in clinical survey).

The practical part of the programme is strengthened by introducing into the curriculum two types of practice – enterprise and pre-graduate. The management of these types of practice will be carried out by two profile departments: the Department of Clinical Pharmacology and Clinical Pharmacy, the Department of Management and Administration.

The final stage of the educational process under this program is the training of masters qualification candidates that will focus on the planning, organization, monitoring of clinical research in health facilities, contract research organizations and pharmaceutical companies.

In order to ensure the high quality of education, the organization of educational process at the university was introduced in such a way that the graduating department has the opportunity to implement an individual approach to each applicant and an easy learning schedule. Applicants will be able to receive full-time or post-graduate education and undergo internships at research sites, contract research organizations, clinical surveys of domestic and foreign pharmaceutical companies. Yet, it should be stressed that competitive advantages of the program mentioned can be created only if the qualified specialists are involved in its implementation. Given the potential of the National Pharmaceutical University, it can be stated that the teaching of curriculum subjects within the program will be carried out by highly qualified instructors, health professionals and business representatives.

One of the important features, forming competitive advantages of the program, is the fact that the pursuit of the programme provides a student with a higher education diploma of a state standard.

Every educational programme claimed to be unique has its own moments. In this case, there is the development of social communications, formation of analytical skills and work with large databases, professionally-oriented training in the field of clinical survey management, systematic exchange of practical experience between educational and healthcare providers, pharmaceutical companies, organizations and, in particular, the faculty members of the National Pharmaceutical University.

The features of the educational and professional programme consist in expanding the spectrum of obtaining and developing skills and abilities of the applicants, which include:

– internship based in research sites, namely, in contract research organizations, clinical research departments, analytical laboratories, pharmaceutical enterprises;

– enterprise practice in modern contract research organizations, analytical laboratories, profile departments of branch educational institutions, pharmaceutical enterprises;

– visiting the leading branch enterprises of Kharkiv with the view to observing specific features of their management systems.

Conclusion. The of the programme and the corresponding organization of the educational process will enable applicants to acquire the main programmatic learning outcomes that will form their skills in:

– applying the concepts, methods and tools of management to effectively manage healthcare institutions, contract research organizations and pharmaceutical companies, analysing their problems, taking management decisions and ensuring the proper conditions for their implementation;

– organizing and communicating with representatives of various professional groups in the international arena;

– applying the legal framework Ukraine on conducting clinical survey, relevant obligations, as well as economic and legal responsibility;

– applying modern methods of managing health care institutions, contract research organizations and pharmaceutical enterprises, carrying out their informational, methodological, material, financial and personnel support, in accordance with international standards and recommendations;

– providing organizing clinical and laboratory research carrying out clinical testing of new drugs, formulating conclusions and interpreting the results of research, as well as implementing such results in practice;

– developing and implementing quality management system at all stages of the clinical survey process, in accordance with the current standards; carrying out quality audits and risk management in order to create the appropriate level of quality of the clinical survey;

– determining the candidates (volunteers) for the medicines testing, advising them on the substance and possible consequences of the test, the properties of the medicines, its expected efficacy, the degree of risk;

– monitoring the effectiveness and safety of the use of medicines by the population according to their clinical and pharmaceutical characteristics.

And, finally, it should be noted that the educational and professional program "Management of clinical survey" takes into account the most advanced concepts of education development, best practices of leading countries in the educational services market, recommendations of potential employers and partners of the University, as well as feedback of higher education graduates in the defined professional orientation.

Reference

1. Yusuf S., Collins R., Peto R. (). Why do we need some large, simple randomized trials? // Statistics in Medicine. – 19843. – (4). – P. 409-422.
2. Farrell B., Kenyon S., H. Shakur. // Managing clinical trials. Trials. – 2010. – 11(1). – P. 78.
3. Campbell M. K., Snowdon C., Francis D., Elbourne D., McDonald A. M, Knight R., Entwistle V., Garcia J., Roberts I., Grant A. Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study // Health Technology Assessment. – 2007. – 11 (48). – P. 105.
4. Francis D., Roberts I., Elbourne D. R., Shakur H., Knight R. C., Garcia J. Marketing and clinical trials: a case study // Trials. – 2007. – 8. – P. 37.
5. Farrell B., Kenyon S. (2018). Effectively managing clinical trials: the Guide to Efficient Trial Management. National Institute for Health Research: Queen's Printer and Controller of HMSO, 62.
6. Lu Z., Su J. Clinical data management: current status, challenges, and future directions from industry perspectives // Open Access Clin Trials. – 20102. – P. 93-105.
7. Bammer G. Enhancing research collaborations: Three key management challenges // Research Policy. – 2008. – 37. – P. 875-887.
8. Edwards P. Questionnaires in clinical trials: Guidelines for optimal design and administration // Trials. – 2010. – 11. – P. 2.
9. Patel M. Effective Clinical Project Management to Streamline Clinical Trial // Current Trends Biomedical Engineering & Bioscience. – 2018. – 16(2). – P. 1-4.
10. Payne J. M., France K. E., Henley N., D'Antoine H. A., Bartu A. E. et al. Researchers' experience with project management in health and medical research: results from a post-project review // BMC Public Health. – 2011. – 11. – P. 424.