

226 PHARMACY, INDUSTRIAL PHARMACY

Educational and professional program of the second (masters) degree

«CLINICAL TRIAL»



The Guarantor of the program — **Zupanets Igor Albertovich**
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The branch of knowledge	22 Health Care
Specialty	226 Pharmacy, Industrial Pharmacy
Program content	90 Credits EKTC
Program duration	1 year and 6 month
The form of education	Distance
Educational qualification	Magister of Pharmacy
Professional qualification	The professional Clinical trials staff

Educational and professional program “Clinical trial” is aimed to training the specialists, who can plan, organize, conduct, and analyze clinical trials of medicines, as well as investigate the bioequivalence of them according to the good clinical practice principles and the international regulatory demands, state regulations and ethical aspects.

The first year: the 1st semester – 30 credits – max 8 disciplines, the 2nd semester – 30 credits – max 8 disciplines. The second year: the 3d semester – 30 credits – practical training (internship at the clinical trials place, contract and research organization, analytic laboratory of bioequivalence study, etc.) and qualification magister thesis conduction

The necessary qualification for application: diploma of specialist, bachelor or magister levels from any university in the field of 22 “Health Care” or 09 “Biology”

The distribution of the disciplines between the departments:

The Clinical Pharmacology and Clinical Pharmacy department – 60%

The Management and Administration department – 40%

The condition of the educational and professional program is based on the use of the effective forms of the achievement and the development of knowledge and skills by students. There are next issues included into educational process:

- Implementation of the modern educational technologies in the studying;
- Practical training in the pharmaceutical companies, contract research organization, clinical trial places, analytic laboratories of the bioequivalence study.

Program components:

№ п/п	The components of the educational program (disciplines, practical trainings, qualification work)
The main subjects	
1.	Methodology and organization of the scientific research
2.	Management (CM1 Management of organizations / CM2 Management of health care establishments)
3.	The management of the changes
4.	The law aspects in the clinical trial field
5.	English (professional)
6	Bioethics in clinical trials
7	Good Clinical Practice
8	Methods of study of bioequivalence of medicines
9	Good laboratory practice
10	Clinical; Pharmacology in clinical trials
The subjects of choice	
1	Modern pharmaceutic technologies
2	Pharmacology
3	Time-management
4	Organization of manager's work
5	Management of quality of clinical trials
6	Clinical medicine
7	Management of dates ion clinical trials
8	Basic of pharmaceutical analysis in clinical trials
9	Clinical epidemiology and statistics methods of results evaluation
10	Statistical methods and analysis of dates in clinical trials
11	Risk-management
12	Anti-crisis management
Practical training	
Practice:	Manufacturing (Clinical Pharmacology and Clinical Pharmacy department, department of Management and Administration)
	Before diploma defend (Clinical Pharmacology and Clinical Pharmacy department, department of Management and Administration)
Alumni attestation	
Preparing of the qualification Master's work	