226 PHARMACY, INDUSTRIAL PHARMACY

Educational and professional program for the second (Master's) level

«CLINICAL TRIALS»

Head of Program — Zupanets Igor Albertovich
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Field of knowledge	22 Health care
Specialty	226 Pharmacy, Industrial Pharmacy
Amount of credits	90 credits of ECTS
Program length	1 years 6 months
Mode of study	low residence
Qualification Educational	Master of Pharmacy
Qualification Professional	Professional of clinical trials

Educational and professional program « Clinical trials» is aimed at the training of specialists capable of planning, organizing, conducting, controlling and analyzing clinical trials of medicinal products and studying the bioequivalence of medicinal products in accordance with the principles of good clinical practice, in accordance with international regulatory requirements, national regulatory documents and ethical principles

First year: 1 semester – 30 credits – max 8 disciplines, 2 semester – 30 credits – max 8 disciplines. Second year: 3 semester – 30 credits – practice (internship at the clinical site, contract research organization, analytical laboratories for bioequivalence research, etc.) and qualification work of the master's degree.

Entry requirements: document on achievement of Specialist, Bachelor (first), Master (second) level degree of highest education in the fields of knowledge: 22 «Health care», 09 «Biology»

Distribution of disciplines between departments:

Department of Clinical Pharmacology and Clinical Pharmacy – 60%

Department of Management and Administration – 40%

The peculiarities of the educational and professional program are the application of effective forms of acquisition and development of skills and competences of higher education graduates, which include:

- introduction of the latest educational technologies into the educational process;
- passing the practice at pharmaceutical companies, contract research organizations, clinical sites, analytical laboratories for bioequivalence research.

Components of the program:

№	Components of the educational program (academic disciplines, practice, qualification work)
Compulsory Courses	
1.	Methodology and organization of scientific research
2.	Management (Module 1 Management of Organizations / Module 2 Management of health care institutions)
3.	Management of changes
4.	Legal Aspects in the Field of Clinical Research
5.	English (for professional purposes)
6	Bioethics in clinical trials
7	Good Clinical Practice
8	Methods of bioequivalence research
9	Good Laboratory Practice
10	Clinical pharmacology in clinical trials
Elective Courses	
1	Modern Pharmaceutical Technologies
2	Pharmacology
3	Time management
4	Organization of manager's work
5	Quality management in clinical trials
6	Clinical Medicine
7	Data management in clinical trials
8	Fundamentals of pharmacoeconomic analysis in clinical trials
9	Clinical epidemiology and statistical methods for the results evaluation
10	Statistical methods and data analysis in clinical trials
11	Risk management
12	Anti-crisis management
Practical training	
Practice:	Industrial (Department of Clinical Pharmacology and Clinical Pharmacy, Department of Management and Administration)
	Pre-diploma (Department of Clinical Pharmacology and Clinical Pharmacy, Department of Management and Administration)
Certification	
Preparation of Master's qualification work	