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**Federal State Autonomous Educational Institution of Higher Education
PEOPLES' FRIENDSHIP UNIVERSITY OF RUSSIA
NAMED AFTER PATRICE LUMUMBA
RUDN University**

Medical School

educational division (faculty/institute/academy) as higher education programme developer

COURSE SYLLABUS

Discovery and development of anticancer drugs

course title

Recommended by the Didactic Council for the Education Field of:

33.04.01 Industrial pharmacy

field of studies / speciality code and title

The course instruction is implemented within the professional education programme of higher education:

DRUG DISCOVERY AND DEVELOPMENT

higher education programme profile/specialisation title

1. PURPOSE OF LEARNING THE COURSE

The course "Discovery and development of Anticancer Drugs" is part of the Master's programme "Drug Discovery and Development" in the direction 33.04.01 "Industrial Pharmacy" and is studied in the 1st semester of the 2nd year. The discipline is implemented by the Department of Biochemistry named after Academician T.T. Berezov. The discipline consists of 6 sections and 9 topics and is aimed at studying the mechanisms of tumour growth and peculiarities of clinical trials of new antitumour drugs

The purpose of mastering the discipline is to obtain systemic knowledge about molecular mechanisms of tumour cell functioning and carcinogenesis, biochemical features of tumour cell, targets and mechanisms of action of antitumour drugs, models of tumour growth and methods of experimental evaluation of antitumour activity of agents, principles of planning, conducting and evaluation of results of clinical trials of new antitumour drugs.

2. REQUIREMENTS TO THE RESULTS OF LEARNING THE COURSE

Table 2.1. List of competences formed by students in the course of mastering the discipline (results of mastering the discipline)

Code	Competence	Indicators of achievement of the competence (within the discipline)
YK3.2	Is able to manage team work to implement strategy and achieve set goals	Drafting the strategy of drug development and plan relevant studies
ПК2.1	Is able to develop plan of preclinical and clinical trial of new agent	Is able to develop plans and programs of certain elements of pharmaceutical development and discovery based on mechanism of action of agent

3. PLACE OF THE COURSE IN THE STRUCTURE OF THE HIGHER EDUCATION PROGRAMME

Table 3.1. List of the components of the higher education program components, contributing to the achievement of the planned course mastering results

Code	Name of competence	Previous courses/modules, practices*	Subsequent courses /modules, practices*
YK3.2	Drafting the strategy of drug development and plan relevant studies	Clinical epidemiology	
ПК2.1	Is able to develop plans and programs of certain elements of pharmaceutical development and discovery based on	Biochemical fundamentals of pharmacology Fundamentals of Medicinal Chemistry	

	mechanism of action of agent		
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4. COURSE VOLUME AND TYPES OF ACADEMIC WORK

The total labour input of the course "Discovery and development of anticancer drugs" is "2" credit units.

Table 4.1. Types of academic work by periods of mastering the educational programme of higher education for full-time students

Type of academic work	Total, academic hours		Semester (s)
			2
Contact work, academic hours	18		18
Lectures (L)	-		-
Laboratory work (LW)	-		-
Practical/seminars (PS)	18		18
Independent work of students, academic hours	51		51
Control (exam/assessed credit), academic hours	3		3
Total labour intensity of the course)	academic hours	72	72
	credit	2	2

5. COURSE CONTENT

Table 5.1. Course (module) content by types of academic work

Section number	Course section name	Content of the section (topic)		Type of academic work*
Section 1	The main properties of a malignant cell	1.1	Self-sufficiency in proliferative signalling. Insensitivity to growth-inhibitory signals. Infinite replicative potential	PS
		1.2	Avoidance of apoptosis. Tumour angiogenesis. Tissue invasion. Metastasis.	PS
		1.3	Disruption of cell differentiation. Genetic instability. Metabolic atypism	PS
Section 2	Novel targets of anticancer drugs	2.1	Proteins of signalling pathways regulating cell cycle, proliferation and apoptosis. Receptor tyrosine kinases. Intracellular tyrosine kinases	PS
		2.2	Membrane antigens. Cyclin-dependent kinases. Immune checkpoints. Modelling candidate-target binding. Multikinase inhibitors	PS
		2.3	Working with resistant cells. Western blotting. Analysis of gene expression.	PS
Section 3	Models to assess cytotoxic effects <i>in vitro</i>	3.1	Immortalised cell cultures. Spheroids. Multilayer culture models. Primary cultures from patients. NCI-60 panel. Mixed cultures. MTT test. Principle of the method. Study design	PS
		3.2	Basics of culture work. Explanation of the principle of MTT test, determination of live and dead cells in cultures after exposure to cytostatics	PS
Section 4	Models to assess antitumour effects <i>in vivo</i>	4.1	Spontaneous tumours in animals. Inbred animals (pure lines). Transplantable animal tumours. Inducible animal tumours. Human tumour models in immunodeficient mice. Diffusion chambers. Hollow fibre model. Orthotopic transplantation. Primary xenografts of human tumours. Knockout animals	PS
		4.2	Tumour material bank, basic manipulations with laboratory animals: safety procedures, SOPs, tumour cell transplantation, subcutaneous, intraperitoneal, oral, intravenous administration of drugs to mice.	PS
Section 5	Features of preclinical studies	5.1	Dose-limiting types of toxicity. Modes of administration in animals. Dose determination for use in phase I clinical trials in humans. Study design for evaluating antitumour effects. Efficacy criteria for new agents	PS
		5.2	Immunodeficient mice: SCID/NOD, Balb/c nude mice. Peculiarities of maintenance, work with immunodeficient mice	PS

Section 6	Features of clinical trials	6.1	Design features of a phase I clinical trial. Traditional designs. Adjuvant, neoadjuvant and combination use. Primary and secondary endpoints. Life expectancy, overall survival (OS), progression-free survival (PFS). Objective response: complete response (CR), partial response (PR), stabilisation, progression, tumour growth control. Cytogenetic remission. Molecular remission. Surrogate criteria: tumour markers.	PS
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Practical/seminars (PS)

6. MATERIAL AND TECHNICAL SUPPORT FOR THE COURSE

6. CLASSROOM INFRASTRUCTURE AND TECHNOLOGY SUPPORT REQUIREMENTS

Table 6.1. Classroom Infrastructure and Technology Support Requirements

Type of Classroom	Classroom equipment	Technology Support Requirements
Practical/seminars hall	An auditorium for conducting lecture-type classes, equipped with a set of specialized furniture; a blackboard (screen) and technical means of multimedia presentations.	Projector and laptop
Class for Self-studies	Classroom, equipped with a set of specialized furniture; whiteboard; a set of devices includes portable multimedia projector, laptop, projection screen, stable wireless Internet connection. (classroom 203)	An auditorium for students to work independently (can be used for seminars and consultations), equipped with a set of specialized furniture and computers with access to e-system.

7. RECOMMENDED SOURCES FOR COURSE STUDIES

Main readings

1. Baynes J.W., Dominiczac M.H. Medical Biochemistry. - Fifth Edition; - London: Elsevier, 2019. - 682 p.
2. Biochemistry with exercises and tasks : textbook / editors by A. I. Glukhov, V. V. Garin. - Электронные текстовые данные. - Moscow : GEOTAR-Media, 2022. - 296 p. : ill. - Книга на английском языке. - ISBN 978-5-9704-7069-5. https://lib.rudn.ru:443/MegaPro/UserEntry?Action=Link_FindDoc&id=497894&idb=0
3. Berezov T.T. Biochemistry / T.T. Berezov, B.F. Korovkin ; Transl. from the Russian by B.V.Rassadin. - Moscow : Mir, 1992. - 515 p. : il. - ISBN 5-03-001650-3 : 35.00.

Additional readings

1. Netter's Essential Biochemistry / P. Ronner. - Книга на английском языке. - Philadelphia : Elsevier, 2018. - 482 p. : ill. - ISBN 978-1-929007-63-9 : 4833.40.
2. Principles of Medical Biochemistry / G. Meisenberg, W.H. Simmons. - Fourth Edition ; Книга на английском языке. - London : Elsevier, 2017. - 617 p. : il. - ISBN 978-0-323-29616-8 : 5758.50.

3. Clinical Biochemistry: Metabolic and Clinical Aspects / W.J. Marshall, M. Lapsley, A.P. Day, R.M. Ayling. - 3rd Edition ; Книга на английском языке. - London : Elsevier, 2014. - 932 p. : il. - ISBN 978-0-7020-5140-1 : 10283.90.
4. Harper's Illustrated Biochemistry 30th ed./ Victor W. Rodwell, David A. Bender, Kathleen M. Botham, Peter J. Kennelly, P. Anthony Weil / McGraw-Hill Education, 2015.

1. *Internet sources*

Electronic libraries (EL) of RUDN University and other institutions, to which university students have access based on concluded agreements:

RUDN Electronic Library System (RUDN ELS) <http://lib.rudn.ru/MegaPro/Web>

- EL "University Library Online" <http://www.biblioclub.ru>

- EL "Юрайт" <http://www.biblio-online.ru>

- EL "Консультант студента" www.studentlibrary.ru

- EL "Троицкий мост"

2. *Databases and search engines:*

- electronic foundation of legal and normative-technical documentation <http://docs.cntd.ru/>

- Yandex search engine <https://www.yandex.ru/>

- Google search engine <https://www.google.ru/>

- Scopus abstract database <http://www.elsevier.com/locate/scopus/>

3. *Learning toolkits for self-studies during the development of the discipline*

* - All teaching materials for self-studying of students are placed in accordance with the current procedure on the discipline page in the RUDN LMS TUIS.

8. EVALUATION TOOLKIT AND GRADE SYSTEM FOR ASSESSMENT

The assessment toolkits and the grade system to evaluate the level of competences (competences in part) formation as on the results of mastering the discipline "Biochemistry" are presented in the Appendix to this Work Program of the discipline.

* The assessment toolkit and the grade system are formed based on the requirements of the relevant local normative act of RUDN University (regulations / order).

DEVELOPERS:

T.T.Berezov Biochemistry
department, head

Position, department

Signature

V.S. Pokrovsky

Name

HEAD OF THE DEPARTMENT:

T.T.Berezov Biochemistry
department, head

Position, department

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