

Ministry of Health of the Russian Federation
Governmental budget-funded educational institution of higher professional education
THE FIRST MOSCOW STATE MEDICAL UNIVERSITY NAMED AFTER I.M. SECHENOV

Seen and approved by
Rector _____ P.V. Glybochko

STEERING DOCUMENT OF THE COURSE
Clinical fundamentals of personalized medicine

(name of the course)

basic professional curriculum of higher education - residency program

31.00.00 Clinical medicine

code and name of the enlarged group of specialties (training areas)

31.08.54 General medical practice (family medicine)

code and name of study area (specialty)

Course credit value: 3 credit units

1. The purpose and objectives of mastering the module of the "**Clinical fundamentals of personalized medicine**" in the framework of study at the clinical internship majoring in 31.08.54 General practice (family medicine).

The *purpose of mastering the module* is development of skills of selection and prescription of medicines and other treatment methods for a particular patient on the basis of pharmacokinetic and pharmacogenomic information.

Module tasks:

As a result of studying the module, a student must:

Know:

the concept of personalization covering the pharmacological agents and individual body responses to them;

principles of molecular diagnostics, in particular determination of a polymorphism by single nucleotides;

fundamentals of clinical integration of diagnostics and treatment of diseases;

essence of the treatment monitoring;

principles of pharmacogenomics, pharmacogenetics and farmacoproteomics.

Be able to:

carry out early detection of diseases and choose the appropriate treatment;

choose medications considered safe and effective based on molecular diagnostics;

integrate the diagnostics and treatment of diseases;

monitor the treatment and formulate the patients' forecast.

Be capable of:

interpreting molecular diagnostics methods;

algorithms of selecting a personalized treatment of diseases.

2. Place of the course in the structure of the University OPOP VO .

2.1. The course refers to the optional part of Unit 1 (O1).

2.2. The study of the course requires the knowledge and skills formed by the previous courses/practices:

Biochemistry

Know: structure and functions of the most important chemical compounds (nucleic acids, natural proteins, water-soluble and fat-soluble vitamins, hormones, etc.).

Be capable of: interpreting the data of enzymological studies of the blood serum.

Master: the skills of establishing a preliminary diagnosis based on results of biochemical studies of human biological fluids.

Histology, embryology, cytology

Know: basic laws of development and functioning of the body, based on the structural organization of cells, tissues and organs; histofunctional peculiarities of the tissue elements and methods of their study.

Be capable of:: giving a histophysiological assessment of a variety of cellular, tissue and organ structures.

Master: medical and anatomical concepts.

Pharmacology

Know: the classification and basic characteristics of drugs, pharmacodynamics, pharmacokinetics, pharmacogenomics and farmacoproteomics, indications and contraindications to the use of drugs, side effects.

Be capable of: analyzing the effect of drugs by the totality of their pharmacological properties, and their potential use for therapy.

Master: the skills of using drugs in the treatment, rehabilitation and prevention of various diseases and pathological conditions.

Pathophysiology

Know: the concepts of etiology, pathogenesis, morphogenesis, pathomorphism illness, nosology, principles of disease classification, the basic concepts of general nosology.

functional systems of the human body, their regulation and self-regulation under the influence of the external environment in health and disease.

Be capable of: interpreting the results of the most common methods of functional diagnostics used to detect the diseases of blood, heart and blood vessels, lungs, kidneys, liver and other organs and systems.

Master: medical and anatomical concepts.

Normal physiology

Know: the structure, topography and development of cells, tissues, organs and systems in cooperation with their function in health and disease, peculiarities of the organism and population levels of life organization.

Be capable of: giving a histophysiological assessment of a variety of cellular, tissue and organ structures.

Master: medical and anatomical concepts.

Microbiology, Virology

Know: the classification, morphology and physiology of microorganisms and viruses, and their impact on human health, the microbiological methods of diagnostics, the use of the basic antibacterial, antiviral and biological drugs.

Be capable of : diagnosing the pathogens of the human parasitic diseases in the sample, slide, photograph. Conduct a microbiological and immunological diagnostics.

Master: medical and anatomical concepts.

Pharmacology

Know: the classification and basic characteristics of drugs, pharmacodynamics, pharmacokinetics, and farmacogenetics, indications and contraindications to the use of drugs, side effects. General principles of prescription issue and preparation of formulations of prescription drugs.

Be capable of: analyzing the effect of drugs on the totality of their pharmacological properties, and their potential use for therapeutic treatment; prescribe the drugs, use a variety of dosage forms in the treatment of certain pathological conditions, based on the peculiarities of their pharmacodynamics, pharmacokinetics and pharmacogenetics; apply the basic anti-bacterial, anti-viral, and biological agents; evaluate the possible manifestations of an overdose of drugs and the ways of their elimination.

Master: the skills of using the drugs in the treatment, rehabilitation and prevention of various diseases and pathological conditions.

3. Requirements for the results of mcourse mastering.

The study of the course is aimed at developing the following professional competencies (PC) by the students:

o.	Competence code	Content of the competence (or a part thereof)	As a result of studying the course, the students must:			
			Know	Be capable of	Master	Evaluation tools
1	PC-1	Readiness to implement a set of measures aimed at preservation and	The first instrumental methods of preclinical diagnostics (using	Integrate the diagnostic s and treatment	Interpretation of molecular diagnosti	Tests

		promotion of health and including the formation of a healthy lifestyle, prevention of occurrence and (or) distribution of diseases, their early diagnostics, identification of the causes and conditions of their emergence and development, as well as elimination of the harmful effect of environmental factors on health	the principles of molecular imaging and quantum dots) and learning the latest laboratory technologies of examining the patients at early stages of the disease and/or persons at risk (using the microbiochips)	of diseases	cs methods	
2	PC-5	Readiness to determine the patients' pathological conditions, symptoms, syndromes, diseases, and nosological forms in accordance with the International Statistical Classification of Diseases and Health-Related Issues	The possibilities of genomics, proteomics and metabolomics implemented in various aspects of practical public health problems; the first instrumental methods of preclinical diagnostics (using the principles of molecular imaging and quantum dots) and learning the latest laboratory technologies of examining the patients at early stages of the disease and/or persons at risk (using the microbiochips)	Carry out early detection of diseases and choose the appropriate treatment; integrate the diagnostics and treatment of diseases	Interpretation of molecular diagnostics methods;	tests
3	PC-6	readiness to monitor and treat	A concept of personalization	carry out early	interpretation of	Tests

		the patients in need of medical assistance in the framework of a general practice (family medicine)	extending to the pharmacological agents, and the individual reactions to them; basics of the clinical integration of diagnostics and treatment of diseases	detection of diseases and choose the appropriate treatment	molecular diagnostics methods; algorithms of selecting a personalized treatment of diseases	
	GC-1	Readiness for abstract thinking, analysis, synthesis	Principles of molecular diagnostics, in particular determination of a polymorphism by single nucleotides; the concept of personalization covering the pharmacological agents and individual body responses to them	Integrate the diagnostics and treatment of diseases	Interpretation of molecular diagnostics methods	tests

4. Sections of the course and competences formed during the study of them:

No.	Competence code	Course section name	Section content in didactic units
1.	PC-1, PC-6, PC-5	Clinical fundamentals of personalized medicine	<p>Introduction to PPPM: past experience and the reality of tomorrow. PPPM as a transnational, national and regional practical health care model of the future.</p> <p>Introduction to personalized genomics from the standpoint of clinician and preventive specialist.</p> <p>Introduction to transcriptomics.</p> <p>Modern platforms, toolkit and application of genomic technologies in clinical practice.</p> <p>Fundamentals of pharmacogenomics and genetic resistance phenomenon: ways of overcoming the latter and clinical effect.</p> <p>Biobanks and their network infrastructures: the role and place in scientific research, clinical practice, pharmacologic design and biopharmaceutical manufacturing.</p> <p>Proteomics: modern platforms, toolkit and application of proteomic technologies in clinical practice.</p>

		<p>Metabolomics: modern platforms, toolkit and application of metabolomic technologies in clinical practice.</p> <p>Interactomics and intercellular communications: modern platforms, toolkit and application of interactomic technologies in clinical practice.</p> <p>Biomarkers: classification, validation principles, methods of screening and identification, as well as the scope of application.</p> <p>Fundamentals of molecular targeting in the practice of a modern clinician.</p> <p>Functional architectonics of the immune system and fundamentals of immune targeting.</p> <p>Principles of managing the computer network structures in clinical and outpatient centers of national, regional and departmental scale.</p> <p>Fundamentals of PPPM economic infrastructure as an updated practical health care model.</p> <p>Bioinformatics in the hands of a pharmacodesigner and clinician.</p> <p>Modern diagnostic platforms in the practice of a clinician.</p> <p>Modern models of the chronic disease of an infectious nature: protocols for diagnostic, monitoring and preventive care and medical rehabilitation measures for the targeted categories.</p> <p>Modern models of chronic autoimmune diseases: protocols for predictive diagnostic, monitoring and preventive care and medical rehabilitation measures for the targeted categories.</p> <p>Protease antibodies as a unique family of biomarkers in pre-clinical and clinical diagnostics and monitoring of demyelination syndrome in patients with multiple sclerosis and those at risk.</p> <p>PIFAS (post-infectious autoimmune syndrome) as a combinatorial biomarker of the new generation in preclinical and clinical diagnostics and monitoring of the dynamics of chronic inflammation and its complications in patients with myocarditis and those at risk.</p> <p>A unique package of diagnostic tools for the predictive diagnostics and monitoring of autoimmune insulinitis and diabetes mellitus of type 1 (DM1) in patients and those at risk.</p> <p>Up-to-date models of carcinogenesis: protocols for predictive diagnostic, monitoring and preventive care and medical rehabilitation measures for targeted categories.</p> <p>Up-to-date models of orphan diseases: protocols for predictive diagnostic, monitoring and preventive care and medical rehabilitation measures for the targeted categories.</p>
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			<p>PPPM as an updated healthcare model: fundamental and clinical aspects in a single package.</p> <p>PPPM as an updated healthcare model: interdisciplinary aspects and their combinatorics.</p> <p>Clinical aspects of predictive and personalized genetics in the practice of a clinician.</p> <p>Clinical aspects of predictive and personalized genetics in the practice of an oncologist.</p> <p>Clinical aspects of predictive and personalized genetics in the practice of a reproduction specialist.</p> <p>Principles and technological toolkit of pharmacogenomics in the practice of an oncologist.</p> <p>Principles and technological toolkit of pharmacogenomics in the practice of a general therapist.</p> <p>Proteomics: modern platforms, toolkit and application of proteomic technologies in the practice of autoimmune diseases.</p> <p>Metabolomics: modern platforms, toolkit and application of metabolomic technologies in clinical practice.</p> <p>Functional architectonics of immune system and fundamentals of immune targeting</p> <p>Endomicrobiom: fundamentals of functional architectonics, methods of evaluation and monitoring, clinical significance and current protocols of pharmacological correction.</p> <p>Principles of managing computer network structures in clinical and outpatient centers of national, regional and departmental scale.</p> <p>Bioinformatics in the hands of a pharmacodesigner and clinician.</p> <p>Biomarkers: classification, validation principles, methods of screening and identification, as well as scope of application.</p> <p>Modern diagnostic platforms in the practice of a clinician.</p> <p>Fundamentals of molecular targeting in the practice of a modern clinician.</p> <p>Current model of cancer pathology: protocols for predictive diagnostic, monitoring and preventive care and medical rehabilitation measures for the targeted categories.</p>
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5. Distribution of the dcourse credit value.

5.1. Distribution of the course credit value and the types of training activities by semesters:

Type of study	Credit value		Credit value by semesters (AH)			
	volume in credit units (CU)	volume in academic hours (AH)	1	2	3	4
Classroom work, including	3	108				
Lectures (L)	6	6	4	2		
Practical training (PT)	36	36				

Seminars (S)	30	30				
Intern's independent work (IW)	36	36				
Interim certification						
test/examination (specify the type)						
TOTAL	3	108	32	34		

5.2. Sections of the course, types of study work and forms of current monitoring:

No.	Semester No.	Course section name	Academic work types (in AH)					Evaluation tools
			L	PW	S	IW	total	
1	1.2	Clinical fundamentals of personalized medicine	6	36	30	36	108	Tests
		TOTAL						

5.3. Lecture distribution by semesters:

No.	Lecture topics	Volume in AH	Semester
1	Introduction to preventive, personalized and prophylactic medicine (PPPM): past experience and the reality of tomorrow.	1	1
2	PPPM as a transnational, national and regional practical health care model of the future	1	1
3	Introduction to personalized genomics from the standpoint of a clinician and preventive specialist	1	1
4	Introduction to transcriptomics	1	1
5	Modern platforms, toolkit and application of genomic technologies in clinical practice	1	2
6	Fundamentals of pharmacogenomics and genetic resistance phenomenon: ways of overcoming the latter and clinical effect	1	2
	TOTAL (total - 6 AH)		

5.4. Distribution of topics of the practical classes by semesters:

No.	Practical classes topics	Volume in AH	Semester
1	Biobanks and their network infrastructures: the role and place in scientific research, clinical practice, pharmacologic design and biopharmaceutical manufacturing	6	1
2	Proteomics: modern platforms, toolkit and application of proteomic technologies in clinical practice	6	1
3	Metabolomics: modern platforms, toolkit and application of metabolomic technologies in clinical practice	6	1
4	Interactomics and intercellular communications: modern platforms, toolkit and application of interactomic technologies in clinical practice	6	1
5	Biomarkers: classification, validation principles, methods of screening and identification, as well as scope of application	6	2
6	Fundamentals of molecular targeting in the practice of a modern clinician	6	2
	TOTAL (total - 36 AH)		

5.5. Distribution of seminar topics by semesters:

No.	Seminar topics	Volume in AH	Semester
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1	Personalized medicine in modern clinical practice.	3	1
2	Types of personalized biological therapy.	3	1
3	Personalized cancer therapy	2	1
4	Personalized therapy of infectious diseases.	4	2
5	Personalized therapy of neurological diseases.	3	2
6	Personalized therapy of mental disorders.	3	2
7	Personalized therapy of cardiovascular diseases.	3	2
8	Personalized treatment of respiratory system diseases.	3	2
9	Personalized therapy of hereditary diseases	3	2
10	Personalized therapy of autoimmune diseases.	3	2
	TOTAL (total - 30 AH)		

5.6. Distribution of the intern's independent work (IW) by types and semesters:

No.	IW* type	Volume in AH	Semester
1	Personalized cancer therapy	6	1
2	Personalized therapy of infectious diseases.	6	1
3	Personalized therapy of neurological diseases.	6	1
4	Personalized therapy of mental disorders.	6	2
5	Personalized therapy of cardiovascular diseases.	6	2
6	Personalized treatment of respiratory system diseases.	6	2
	TOTAL (total - 36 AH)		

* types of independent work: Working with literature and other sources of information on the section under study, including in interactive form, performance of assignments stipulated by the work program (group and/or individual) in the form of writing case histories, reviews, essays, preparation of reports, presentations; preparation for participation in interactive classes (role and business games, trainings, game design, computer simulation, discussion), work with electronic educational resources placed on the educational portal of the University, preparation of term papers, etc.

6. Evaluation tools to monitor the performance and results of the course mastering.

Examples of evaluation tools:

<p>Tests:</p> <p>IMMUNITY TYPES:</p> <ol style="list-style-type: none"> 1) Hereditary*; 2) Focal; 3) Diffuse; 4) Adaptive*.
<p>Tests:</p> <p>FACTORS OF NONSPECIFIC PROTECTION OF AN ORGANISM:</p> <ol style="list-style-type: none"> 1) Macrophages; 2) Neutrophils; 3) Sweat*; 4) Microglia; 5) Tear fluid*.
<p>THE FUNCTION OF ANTIGEN-PRESENTING CELL MAY BE PERFORMED BY:</p> <ol style="list-style-type: none"> 1) Macrophage*; 2) Dendritic cell (DC)*; 3) Neutrophil; 4) B-lymphocyte*;

5) T-lymphocyte.

Sample of a task:

Patient E. 27 years old, visited antenatal clinic with complaints of a dragging pain in the abdomen and bleeding in the middle of the menstrual cycle. She smokes and attends solarium. Preliminary diagnosis upon examination: cervical dysplasia. Tumor marker SCC - 2.8 ng/ml. After 3 months, the patient's condition worsened, she was hospitalized to the Gynecology Department with uterine bleeding. Tumor marker SCC - 23 ng/ml. Diagnosis after biopsy: cervical dysplasia.

1. What are precancerous conditions? Give examples.
2. Describe the stages of tumor transformation. What is tumor progression? What factors contribute to malignant transformation of cells?
3. What are tumor markers? How exact are the data on the increase in their levels in the body? Specify modern methods of cancer diagnostics.
4. What is pharmaceutical prevention? What are the main goals and concepts of it?
5. What is targeted therapy? Specify types of targeted technologies.

7. Educational, methodical and informational support for the course (printed, electronic publications, the Internet and other network resources).

7.1. Main references*:

No.	Name	Author(s)	Year and place of publication	Number of copies	
				in the library	in the department
1	2	3	4	7	8
1.	Textbook of personalized medicine. 2 nd edition.	KewalK. Jain	Humana Press, 2015		
2.	Genomic and Personalized Medicine, Second Edition: V1-2, 2nd edition	Ginsburg, G. S. (ed.) and Willard, H. F. (ed.)	, Academic Press, (2012).		
3.	Genomic and Precision Medicine, Third Edition: Translation and Implementation, 3rd edition, Academic Press.	Ginsburg, G. S. (ed.) and Willard, H. F. (ed.)	Academic Press, 2016		
4.	Thompson & Thompson Genetics in Medicine, 8th edition,	Nussbaum, R. L., McInnes, R. R. and Willard, H. F.	Elsevier, 2015		
5.	Drug Delivery Systems: Advanced Technologies Potentially Applicable in Personalised Treatment,	Coelho, J. (ed.)	Springer Netherlands, 2013.		
6.	Individualized Medicine,	Fischer, T. (ed.), Langanke, M. (ed.), Marschall, P. (ed.) and Michl, S. (ed.)	Springer International Publishing, 2015.		

7.	An Information Technology Framework for Predictive, Preventive and Personalised Medicine,	Berliner, L. (ed.) and Lemke, H. U. (ed.)	Springer International Publishing, 2015		
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**basic references list must include the books published over the past 10 years (for the humanities, social and economic disciplines over the past 5 years), as well as the textbooks published over the past 5 years.*

7.2. Additional references*:

No.	Name	Author(s)	Year and place of publication	Number of copies	
				in the library	in the department
1	2	3	4	7	8
1.	Healthcare Overview	Costigliola, V. (ed.)	Springer Netherlands, 2012.		
2.	New Strategies to Advance Pre/Diabetes Care: Integrative Approach by PPPM	Mozaffari, M. S. (ed.)	Springer Netherlands, 2013.		
3.	Neurodegenerative Diseases: Integrative PPPM Approach as the Medicine of the Future	Mandel, S. (ed.)	Springer Netherlands, 2013.		
4.	Circulating Nucleic Acids in Early Diagnosis, Prognosis and Treatment Monitoring	Gahan, P. B. (ed.)	Springer Netherlands, 2015.		
5.	Rare Diseases: Integrative PPPM Approach as the Medicine of the Future	Özgüç, M. (ed.)	Springer Netherlands, 2015.		

**additional references contain supplemental material to basic sections of the course curriculum.*

8. Inventory and logistics management of the course

No.	Address of the classrooms*, facilities for holding practical classes, physical fitness and sports facilities	Room No.	Room area (m ²)	Name of the equipped classrooms, facilities for practical classes, physical and sports facilities with a list of basic equipment*
1	Moscow 6 Bolshaya Pirogovskaya Str., Bldg. 1	UCH No. 1, the 5th floor, unit B, Faculty Therapy Department No. 1, classrooms, conference hall.		Multimedia projector, screen, personal computers with Internet access, boards, tables, chairs.

**specially equipped rooms (auditoriums, classrooms, laboratories, etc.) for lectures, seminars, practical and clinical practical training during study of the disciplines, including:*

*dissecting room, anatomical museum, corps storage;
auditoriums equipped with simulation machinery;
offices for working with patients receiving medical care.*

**laboratory, tool equipment (specify which), multimedia system (laptop, projector, screen), TV, video camera slide-scope, VCR, PC, video and DVD players, monitors, sets of slides, tables/multimedia visual materials on various sections of the discipline, video clips, blackboards etc.*

9. Educational technology in an interactive form, used in the process of teaching the discipline*:

1. Online databases of ECG and fluorography

9.1. Examples of online educational technologies:

1. no

9.2. Electronic educational resources used in the course of teaching the discipline:

No.	Names and brief description of electronic educational and information resources (electronic publications and information databases)	Number of copies, access points
<i>1</i>	<i>3</i>	<i>4</i>
1	Blonder, Josip. National Institutes of Health (U.S.). Proteomics Interest Group (2014) Towards Cancer Biomarker Discovery Using Clinical MS-based Proteomics, Available: [https://videocast.nih.gov/launch.asp?18379].	15
2	Wu, Cathy H., National Institutes of Health (U.S.) (2015) Construction of Protein PTM Networks by Data Mining, Text Mining, and Ontology Integration: Application to Multi-Faceted Disease Analysis, Available: [https://videocast.nih.gov/summary.asp?Live=16038&bhcp=1].	15
3	Digital Health Data in a Million-Person Precision Medicine Initiative Cohort (Workshop) Advisory Committee to the Director, National Institutes of Health. Precision Medicine Initiative Working Group, National Institutes of Health (U.S.) (2015) Digital Health Data in a Million-Person Precision Medicine Initiative Cohort (Day 2), Available: [https://videocast.nih.gov/launch.asp?19041].	15
4	http://www.broadinstitute.org/videos/broade-sample-prep-proteomics	15
5	NHLBI (2016) Personalized Medicine and Hispanic Health Workshop – Day 1, Available: [https://videocast.nih.gov/launch.asp?19783].	15