Federal State Autonomous Educational Institution of Higher Education
PEOPLES' FRIENDSHIP UNIVERSITY OF RUSSIA named after Patrice Lumumba
RUDN University

Institute of Medicine

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

COURSE SYLLABUS

Clinical Pharmacology

course title

Recommended by the Didactic Council for the Education Field of:

31.05.01 General Medicine

field of studies / speciality code and title

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

General Medicine

higher education programme profile/specialisation title

2023-2024

1. COURSE GOAL(s)

The goal of the course "Clinical Pharmacology" is toequip students with theoretical knowledge and practical skills of choosing and prescribing effective, safe and economically reasonable drugs in order to be able to use rational and personalized pharmacotherapy based on the authentic data on pharmacokinetics, pharmacodynamics, drug interactions, adverse drug reactions, pharmacogenetics, pharmacoeconomics, pharmacoepidemiology and principles of evidence-based medicine.

2. REQUIREMENTS FOR LEARNING OUTCOMES

Mastering the course (module) "Clinical Pharmacology" is aimed at the development of the following competences /competences in part: **General Professional Competence (GPC)-7, Professional Competence (PC)-3.**

Table 2.1. List of competences that students acquire through the course study

Competence code	**Competence descriptor**	**Competence formation indicators** (within this course)
GPC-7	Being able to prescribe treatment and monitor its efficacy and safety.	GPC-7.1. Having skills of general clinical examination, assessment of laboratory and instrumental diagnostic test results.
PC-3	Being able to prescribe treatment and monitor its efficacy and safety.	PC-3.1. Developing the treatment plan for a disease or condition with regards to diagnosis, age and clinical picture in compliance with relevant clinical practice guidelines.
		PC-3.2. Prescribing medications, medical devices and nutrition with regards to diagnosis, age and clinical picture in compliance with relevant clinical practice guidelines.

3. COURSE IN HIGHER EDUCATION PROGRAMME STRUCTURE

The course refers to the core/variable/elective* component of (B1) block of the higher educational programme curriculum.

* - Underline whatever applicable.

Within the higher education programme students also master other (modules) and / or internships that contribute to the achievement of the expected learning outcomes as results of the course study.

Table 3.1. The list of the higher education programme components/disciplines that contribute to the achievement of the expected learning outcomes as the course study results

Competence code	**Competence descriptor**	**Previous courses/modules***	**Subsequent courses/modules***

GPC-7	Being able to prescribe treatment and monitor its efficacy and safety.	Pharmacology; Biotechnology; Medical recovery; Dermatovenerology; Neurology, medical genetics, neurosurgery; Professional diseases; Faculty surgery; Endocrinology; Polyclinical therapy; Urology; Obstetrics and gynecology; General surgery; Traumatology, orthopedy; Pediatrics; Evidence-based medicine; Tracheotomy in modern otolaryngology; Out-patient cardiology; Assistant of ward nurse; Assistant of physician; Assistant of physician in out-patient primary care	Anesthesiology, resuscitation, intensive care; Maxillofacial surgery; Endoscopic urology; Reproductive health; Oncology, x-ray therapy; Hospital therapy
PC-3	Being able to prescribe treatment and monitor its efficacy and safety.	Medical recovery; Dermatovenerology; Neurology, medical genetics, neurosurgery; Propedeutics of internal diseases; Imaging diagnostics; Professional diseases; Faculty surgery; General surgery; Faculty surgery; Urology; Ophthalmology; Life safety; Dentistry; Obstetrics and gynecology; Pediatrics; Evidence-based medicine; Actual issues of neonatology; Fundamentals of child threpsology; Out-patient cardiology; Assistant of physician; Assistant of physician in out-patient primary care	Anesthesiology, resuscitation, intensive care; Disaster medicine; Oncology, radiation therapy; Hospital therapy; Hospital surgery; Pediatric surgery

* To be filled in according to the competence matrix of the higher education programme.

4. COURSE WORKLOAD AND ACADEMIC ACTIVITIES

The total workload of the course "Clinical Pharmacology" is 3 credits (108 academic hours).

*Table 4.1. Types of academic activities during the periods of higher education programme mastering (**full-time training**)**

Types of academic activities	**TOTAL, academic hours** (ac.h)	**Semesters**
		11
Classroom learning, *ac.h.*	**54**	**54**
Including:		
Lectures (LC)	-	-
Lab work (LW)	-	-
Seminars (workshops/tutorials) (S)	54	54

Types of academic activities		TOTAL, academic hours (ac.h)	Semesters
			11
Self-studies		*54*	*54*
Evaluation and assessment (exam/passing/failing grade)			
Course workload	academic hours_	**108**	**108**
	credits	**3**	**3**

* To be filled in according to the competence matrix of the higher education programme.

5. THE COURSE MODULES AND CONTENTS

Table 5.1. The content of the discipline and types of academic activities

Course module title	Course module contents (topics)	Academic activities types
Module 1 General issues of clinical pharmacology	**Topic 1.1.** Subject and tasks of clinical pharmacology (CP). Clinical research. Principles of evidence-based medicine. Subject and tasks of CP. Pharmacoepidemiology, pharmacoeconomics, their content and significance. Phases of clinical research of novel drugs, modern approaches to drug development. Concepts of controlled clinical trials, principles of evidence-based medicine.	S, S-s
	Topic 1.2. Fundamentals of clinical pharmacodynamics. Clinical pharmacodynamics. Basic concepts. The difference between drugs in pharmacological action. Pharmacological and pharmacodynamic "targets". Pharmacodynamic and clinical efficacy of drugs. Criteria for assessing pharmacodynamic and clinical efficacy.	S, S-s
	Topic 1.3. Fundamentals of clinical pharmacokinetics. Subject and tasks of clinical pharmacokinetics. Pharmacokinetic studies in clinical pharmacology. Pharmacokinetic curve. Types of pharmacokinetic curve. Control over the concentration of drugs in clinical practice (Therapeutic Drug Monitoring), its purpose. The main pharmacokinetic parameters, their role in rational pharmacotherapy. Patient factors influencing bioavailability,	S, S-s

Course module title	Course module contents (topics)	Academic activities types
	distribution, metabolism and excretion of drugs. Principles of dosing drugs.	
	Topic 1.4. Interaction of drugs. The concept of interaction of drugs, types of interaction (pharmacokinetic, pharmacodynamic). Results of drug interaction. Principles of rational combination of drugs.	S, S-s
	Topic 1.5. Drug safety. Adverse drug reactions. Modern concepts and terms in the field of drug safety. Methods of detection, forecasting, prevention and correction of ADRs. Prescription of drugs to pregnant and breast-feeding women, classification of risk. General principles of increasing the safety of pharmacotherapy in elderly patients. Fundamentals of Pharmacovigilance.	S, S-s
	Topic 1.6. Fundamentals of rational pharmacotherapy (P-method). General principles of evaluating the effectiveness and safety of the use of drugs in patients, including the assessment of quality of life. The importance of clinical and laboratory-instrumental methods for assessing the effectiveness and safety of drug use. Methodological bases of rational choice of appropriate drugs. Selection of medicines for compiling an individual list of P(personal)-drugs. The process of rational individualized treatment (P-treatment).	S, S-s
Module 2 Specific issues of clinical pharmacology	**Topic 2.1.** Clinical pharmacology of drugs affecting the main functions of the myocardium. Clinical pharmacology of medications for treatment of stable ischemic heart disease and chronic heart failure. Clinical pharmacology of antiarrhythmic drugs. Principles of clinical and pharmacological approach to the choice of medicines for the treatment of these diseases and relief of emergency conditions in the pathologies of the cardiovascular system.	S, S-s
	Topic 2.2. Clinical pharmacology of drugs affecting vascular tone. Clinical pharmacology of medications for treatment of stable ischemic heart disease and chronic heart failure. Clinical pharmacology of	S, S-s

Course module title	Course module contents (topics)	Academic activities types
	antiarrhythmic drugs. Principles of clinical and pharmacological approach to the choice of medicines for the treatment of these diseases and relief of emergency conditions in the pathologies of the cardiovascular system.	
	Topic 2.3. Clinical pharmacology of lipid-lowering agents and metabolic correctors. Methods of diagnostics and types of dyslipidemias. Selection of optimal drugs depending on the type of hyperlipidemia. Methods for evaluating efficiency and safety. Diagnosis, correction and prevention of adverse reactions. Possible interactions in combination with drugs of other groups.	S, S-s
	Topic 2.4. Clinical pharmacology of drugs affecting hemostasis and hemopoesis. Clinical pharmacology of drugs for the treatment and prevention of arterial and venous thrombosis. Clinical Pharmacology of medications to stop and preventing bleeding. Clinical pharmacology of drugs for the treatment of anemia. Principles of choice of appropriate agents and their dosage regimen depending on the state of coagulation, anticlotting, fibrinolytic systems of the patient. Methods for evaluating the effectiveness and safety of the treatment.	S, S-s
	Topic 2.5. Clinical pharmacology of medications affecting the respiratory system. Clinical pharmacology of anti-asthmatic drugs; medications for the treatment of COPD and pulmonary hypertension. Principles of clinical and pharmacological approach to the choice of drugs for the treatment of these diseases. Control over the effectiveness and safety of the treatment. Rational drug combinations.	S, S-s
	Topic 2.6. Clinical pharmacology of medications affecting the digestive system. Clinical pharmacology of drugs for the treatment of gastric and duodenal ulcer, gastroesophageal reflux disease (GERD). Clinical pharmacology of drugs for the treatment of acute and chronic hepatitis; diseases of the biliary tract; pancreatic	S, S-s

Course module title	Course module contents (topics)	Academic activities types
	diseases; bowel diseases. Principles of clinical and pharmacological approach to the choice of medicines for the treatment of these diseases. Control over the effectiveness and safety of the treatment. Rational drug combinations.	
	Topic 2.7. Clinical pharmacology of medications used in diseases of the kidneys and urinary tract. Clinical pharmacology of medicines used for the treatment of glomerulonephritis, pyelonephritis, renal failure, urinary tract and bladder diseases.	S, S-s
	Topic 2.8. Clinical pharmacology of medicines used in endocrinology. Clinical pharmacology of hypothalamus hormones and their synthetic analogues; pituitary hormones and their synthetic analogues; adrenal cortex hormones and their synthetic analogues; sex hormones and their synthetic analogues. Contraceptives and anti-menopausal agents. Clinical pharmacology of medicines affecting thyroid function and glucose-lowering drugs.	S, S-s
	Topic 2.9. Clinical pharmacology of drugs for the treatment of inflammatory diseases of connective tissue. Clinical pharmacology of NSAIDs; GCSs; monoclonal antibodies.	S, S-s
	Topic 2.10. Clinical pharmacology of medicines used for immune systems pathologies and allergic conditions. Clinical pharmacology of cytostatics, immunomodulators and anti-allergic drugs.	S, S-s
	Topic 2.11. Clinical pharmacology of anti-infectious drugs. Clinical pharmacology of antibacterial drugs; medications for the treatment of antibiotic-associated diarrhea; antiviral drugs; anti-mycotics.	S, S-s
	Topic 2.12. Clinical pharmacology of psychotics. Neuroleptics; Tranquilizers; Antidepressants; Sleeping pills; Nootropic drugs. Clinical and pharmacological approaches to the selection of groups and specific drugs for pharmacotherapy of basic psychopathological syndromes.	S, S-s

* - to be filled in only for **full** -time training: *LC - lectures; LW - lab work; S - seminars.*

6. CLASSROOM EQUIPMENT AND TECHNOLOGY SUPPORT REQUIREMENTS

Table 6.1. Classroom equipment and technology support requirements

Type of academic activities	**Classroom equipment**	**Specialised educational / laboratory equipment, software, and materials for course study** (if necessary)
Lab work	Classroom for lab work, individual and group consultations, ongoing control and interim attestation, self-studies equipped with a set of specialized furniture, whiteboard; interactive system SMART.	technical equipment: interactive board SMART with multimedia projector SMART, laptop HP with stable Internet connection. Software: Microsoft Windows, MS Office 365, MS Teams, Chrome (latest stable release), TUIS system
Self-studies	Classroom for lab work, individual and group consultations, ongoing control and interim attestation, self-studies equipped with a set of specialized furniture, whiteboard	technical equipment: multimedia projector BENQ, laptop HP. Software: Microsoft Windows, MS Office 365, MS Teams, Chrome (latest stable release), TUIS system

* The premises for students' self-studies are subject to **MANDATORY** mention

7. RESOURCES RECOMMENDED FOR COURSE STUDY

Main readings:

1. Clinical Pharmacology / P.N. Bennett, M.J. Brown. - 10th ed.; Книга на английском языке. - Edinburgh: Churchill Livingstone, 2008. - 694 p.: il. - ISBN 978-0-443-10245-5: 2048.65

Additional readings:

1. Basic and Clinical Pharmacology / B. Katzung, S. Masters. - 11th ed.; Книга на английском языке. - New York: McGraw-Hill, 2009. - 1218 p.: il. - (LANGE Basic Science). - ISBN 978-007-127118-9: 4318.03.

2. S.B. Fitilev, I.I. Shkrebneva, A.V. Vozzhaev. The Fundamentals of Rational Pharmacotherapy (Problem-Based Method of Teaching Clinical Pharmacology or How to Create Your Own Guideline) (учебное пособие на английском языке). Москва: РУДН, 2017. – 85 с.

Internet (based) sources

1. Electronic Library System (ELS) of the RUDN University and third-party ELS, to which university students have access on the basis of concluded contracts:
   - Electronic Library System (ELS) of the RUDN http://lib.rudn.ru/MegaPro/Web
   - ELS «Университетская библиотека онлайн» http://www.biblioclub.ru
   - ELS Юрайт http://www.biblio-online.ru
   - ELS «Консультант студента» www.studentlibrary.ru
   - **ScienceDirect** https://www.sciencedirect.com/
   - **Springer** https://www.springer.com/gp
   - **Oxford University Press** http://global.oup.com/?cc=ru

2. Databases and search engines:
   - State register of drugs http://www.drugreg.ru/Bases/WebReestrQuery.asp
   - Source on pharmacogenetics http://www.pharmgkb.org/
   - Source of drug interactions http://medicine.iupui.edu/flockhart/

Learning toolkits for self-studies during the development of the discipline

Methodological guidelines for the implementation and execution of control and independent work on the discipline «Clinical pharmacology».

* - 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.

*Training toolkit for self- studies to master the course *:*

1. The set of lectures on the course “Clinical Pharmacology”

* The training toolkit for self- studies to master the course is placed on the course page in the university telecommunication training and information system under the set procedure.

8. ASSESSMENT TOOLKIT AND GRADING SYSTEM* FOR EVALUATION OF STUDENTS’ COMPETENCES LEVEL UPON COURSE COMPLETION

The assessment toolkit and the grading system* to evaluate the competences formation level (GPC-7,PC-3) upon the course study completion are specified in the Appendix to the course syllabus.

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

DEVELOPERS:

Professor of the Department of General and Clinical Pharmacology		S.B. Fitilev

position, department	signature	name and surname
Associate Professor of the Department of General and Clinical Pharmacology		A.V. Vozzhaev
position, department	signature	name and surname
Associate Professor of the Department of General and Clinical Pharmacology		I.I. Shkrebniova
position, department	signature	name and surname

HEAD OF EDUCATIONAL DEPARTMENT:

of General and Clinical Pharmacology		S.K. Zyryanov
position, department	signature	name and surname

HEAD
OF HIGHER EDUCATION PROGRAMME:

First Deputy Director of MI for Academic Affairs		Iv.V.Radysh
position, department	signature	name and surname