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ФИО: Ястребов Олег Александрович
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**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 trials

course title

Recommended by the Didactic Council for the Education Field of:

31.05.03 Dentistry

field of studies / speciality code and title

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

Dentistry

higher education programme profile/specialisation title

1. COURSE GOAL(s)

The goal of the course “**Clinical trials**” is to equip students with the system of knowledge about the methodology of research, development and launch of drugs on the pharmaceutical market, including knowledge of the main stages and rules for organizing clinical trials.

2. REQUIREMENTS FOR LEARNING OUTCOMES

Mastering the course (module) “Clinical trials” is aimed at the development of the following competences /competences in part: PC-6

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

Competence code	Competence descriptor	Competence formation indicators (within this course)
PC-6	PC-6. Being able to analyze and present in public medical information based on evidence-based medicine, participate in scientific research, introduce new methods and techniques aimed at protecting public health	PC-6.1. Searching for medical information based on evidence-based medicine, interpreting data from scientific publications and/or preparing a presentation to make medical information, the results of scientific research public.
		PC-6.2. Developing algorithms for the examination and treatment of adults and children with dental diseases in accordance with the principles of evidence-based medicine, as well as searching and interpreting medical information based on evidence-based medicine.
		PC-6.3. Conducting public presentation of medical information based on evidence-based medicine/ partial participation in scientific research.

3. COURSE IN HIGHER EDUCATION PROGRAMME STRUCTURE

The course refers to the core/variable/elective* component of (B1) block of the higher education 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*
PC-6	Being able to analyze and present in public medical information based on evidence-based medicine, participate in scientific research, introduce	Pharmacology Immunology, clinical immunology Ophthalmology Prosthetics for	Gnathology and functional diagnostics of the temporal mandibular joint Pediatric

	new methods and techniques aimed at protecting public health	complete absence of teeth Dental prosthetics (complex prosthetics) Dental prosthetics (simple prosthetics) Medical genetics in dentistry	maxillofacial surgery Maxillofacial prosthetics Dentist assistant (general practice), incl. research work Preparing for and passing the state exam State exam (computer testing) State exam (interdisciplinary interview)
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* 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 trials" is equal to 2 credits, 72 academic hours

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

Type of academic activities		Total academic hours	Semesters/training modules	
			9	
Classes (total) ac.h.				
Including:				
Lectures (LC)		-	-	
Lab work (LW)		51	51	
Seminars (workshops/tutorials) (S)				
<i>Self-studies</i>		18	18	
<i>Evaluation and assessment (exam/passing/failing grade)</i>		3	3	
Total course workload	academic hours	72	72	
	credits	2	2	

* To be filled in regarding the higher education programme correspondence training mode.

5. COURSE CONTENTS

Table 5.1. Course contents and academic activities types

Course module title	Course module contents (topics)	Academic activities types
1. Clinical trials (CTs). Types.	1.1 Phase I, II, III, IV clinical trials 1.2 Case-control studies, cohort studies, randomized placebo-controlled clinical trials. 1.3 Retrospective and prospective clinical studies. Main differences, requirements for implementation, significance for clinical practice.	LW
2. Regulations for	2.1 Legislative regulation of the field of	LW

planning and conducting CTs.	CTs. 2.2 Data management within CT (data management), data entry check and validation. 2.3 Data collection and management. Data protection. CT monitoring. 2.4 Completion of CI. Final report and publications. Archiving.	
3. The importance of pharmacokinetics and pharmacodynamics of drugs for CTs.	3.1 Pharmacokinetic studies. Bioequivalence studies. 3.2 Pharmacodynamics. Implications for drug development.	LW
4. Pharmacoepidemiologic trials.	4.1 Basic principles of pharmacoepidemiologic trials.	LW
5. Pharmacoeconomic trials	5.1 Features of conducting pharmacoeconomic studies	LW
6. New molecular targets for pain treatment	6.1 New molecular targets for pain treatment	LW
7. New molecular targets for the treatment of inflammation	7.1 7.1 New molecular targets in the treatment of inflammation of various origins (cytokines and cytokine receptors, chemokines, pathway JAK/STAT)	LW
8. Novel antibacterial agents to treat infectious diseases	8.1 Antimicrobial peptides (AMPs) - candidates for countering multidrug-resistant pathogens. 'Selectively targeted AMPs" (STAMP) 8.2 Oxepanoprolinamides, spiropyrimidinetrions, new bis-benzimidazoles, new fluoroquinolones, glycylcyclines, and lipopeptides. 8.3 Pathogen-specific monoclonal antibodies.	LW

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

5. 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, equipped with a set of specialized furniture; whiteboard; a set of devices includes portable multimedia projector, laptop, projection screen, stable wireless Internet	Classroom for lectures and lab works, group and individual consultations, current control and intermediate certification. A set of specialized furniture; technical devices: Optoma HD36 multimedia

Type of academic activities	Classroom equipment	Specialised educational / laboratory equipment, software, and materials for course study (if necessary)
	connection. Software: Microsoft Windows, MS Office /Office 365, MS Teams, Chrome (latest stable release), Skype Classrooms 349, 350, 352	projector, Lenovo IdealPad330-5ikb laptop, Internet access. Wall projection screen, floorboard information marker magnetic, interactive complex for testing students.
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. Software: Microsoft Windows, MS Office /Office 365, MS Teams, Chrome (latest stable release), Skype Classroom 349	Classroom for lectures and lab works, group and individual consultations, current control and intermediate certification. A set of specialized furniture; technical devices: Optoma HD36 multimedia projector, HP250G7 laptop, Internet access. Wall projection screen, floorboard information marker magnetic, interactive complex for testing students.
Learning and Research Lab	Classroom, equipped with a set of specialized furniture; whiteboard; a set of devices includes portable multimedia projector, laptop, projection screen, stable wireless Internet connection. Software: Microsoft Windows, MS Office /Office 365, MS Teams, Chrome (latest stable release), Skype Lab No 1 on the base of the city hospital 24	Wall projection screen, magnetic floor information marker board, Optoma HD36 multimedia projector, Lenovo 15.6 laptop, centrifuge 5804, analytical scale AF225DPCT, Vortekx shaker, CryoCubeF101h freezer

7. RESOURCES RECOMMENDED FOR COURSE STUDY

Main readings:

1. Basic and Clinical Pharmacology / B. Katzung, S. Masters. - 16th ed. ; Книга на английском языке. - New York : McGraw-Hill, 2024. - 1368 p. : il. - (Lange Medical Books). - ISBN 978-1260463309

Additional readings

1. Tutorial Guide to Pharmacokinetics: учебное пособие / С.К. Зырянов, О.И. Бутранова, М.Б. Кубаева. – Москва: РУДН, 2022. – 134 с.: ил. ISBN 978-5-209-10837-5

2. Tutorial Guide to Pharmacodynamics [Текст] = Пособие по фармакологии : Учебное пособие / S.K. Zyryanov, O.I. Butranova. - Книга на английском языке. - М. : PFUR, 2019. - 56 с. : ил.

Internet (based) sources

1. Electronic libraries with access for RUDN students:

- Electronic library network of RUDN – ELN RUDN
<http://lib.rudn.ru/MegaPro/Web>
- ELN «University Library online» <http://www.biblioclub.ru>
- ELN Urait <http://www.biblio-online.ru>
- ELN «Student Advisor» www.studentlibrary.ru
- ELN «Lan» <http://e.lanbook.com/>

2. Databases and search engines:

- electronic fund of legal and regulatory and technical documentation
<http://docs.cntd.ru/>
- search system Yandex <https://www.yandex.ru/>
- search system Google <https://www.google.ru/>
- abstract database SCOPUS <http://www.elsevierscience.ru/products/scopus/>

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

1. Additional materials on the discipline "Clinical trials".
2. Guidelines for self-study on the discipline "Clinical trials"
3. Online educational course on the Stepik platform: “Pharmacology of Antibacterial Agents” Free access: <https://stepik.org/course/123136/promo>

* - all educational and methodological materials for independent work of students are placed in accordance with the current procedure on the page of the discipline on RUDN LMS TUIS!

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

Evaluation materials and point-rating system* for assessing the level of competence formation (PC-6) based on the results of mastering the discipline «Clinical trials» are presented in the Appendix to this Work Program of the discipline.

* 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:

Assoc. prof. of the Department of
General and Clinical
Pharmacology

position, department name

signature

Butranova O.I.

initials, last name

HEAD OF THE DEPARTMENT:

of
General and Clinical
Pharmacology

position, department name

signature

Zyryanov S. K.

initials, last name

HEAD OF THE PROGRAMME:

Deputy Director of MI

position, department name

signature

S.N. Razumova

initials, last name