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**Federal State Autonomous Educational Institution of Higher Education
PEOPLE'S FRIENDSHIP UNIVERSITY OF RUSSIA
NAMED AFTER PATRICE LUMUMBA
(RUDN)**

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

COURSE SYLLABUS

Clinical Trials

Recommended by the Didactic Council for the Education Field of:

31.05.03 Dentistry

field of studies / specialty code and title

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

Dentistry

higher education programme profile/specialization title

1. THE GOALS OF MASTERING THE DISCIPLINE

The aim 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 to LEARNING OUTCOMES

The mastering of the discipline “Clinical trials” is aimed at the formation of the following competencies of students:

Professional competences (PC)

- PC-6

(in accordance with the Federal State Educational Standard of Higher Education (FSES) 3++ 31.05.01 General Medicine).

Table 2.1. The list of competencies formed by students during the development of the discipline (results of the mastering of the discipline)

Competence code	Competence	Indicators of Competence Formation (within the framework of this discipline)
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	<p>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.</p> <p>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.</p> <p>PC-6.3. Conducting public presentation of medical information based on evidence-based medicine/ partial participation in scientific research.</p>

3. THE COURSE IN THE HIGHER EDUCATION PROGRAMME STRUCTURE

The course “Clinical trials” refers to the elective disciplines of block “ФТД” of the EP HE (ФТД.В.10). Within the framework of the Educational Program, students also master other disciplines and/or practices that contribute to expected learning outcomes of the course “Clinical trials”.

Table 3.1. List of Higher Education Program disciplines that contribute to expected learning outcomes.

Competence Code	The competence	Previous Disciplines	Subsequent disciplines
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	Pharmacology Immunology, clinical immunology Ophthalmology Prosthetics for complete absence of teeth Dental prosthetics (complex prosthetics)	Gnathology and functional diagnostics of the temporal mandibular joint Pediatric maxillofacial surgery Maxillofacial prosthetics Dentist assistant

		Dental prosthetics (simple prosthetics) Medical genetics in dentistry	(general practice), incl. research work Preparing for and passing the state exam State exam (computer testing) State exam (interdisciplinary interview)
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4. THE DISCIPLINE WORKLOAD AND ACADEMIC ACTIVITIES

The total workload of the discipline "Clinical trials" is equal to 2 credits.

Table 4.1. Types of academic activities during the period of the HE programme mastering.

Types of academic activities	TOTAL, academic hours (ac.h)	Semesters	
		9	10
Practical/seminar lessons (PL)	34	34	
Self-studies, ac. h.	20	20	
Evaluation and assessment (exam or pass/fail grading)	18	18	
Total labor content			
hours	72	72	
credits	2	2	

5. THE COURSE MODULES AND CONTENTS

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

Modules and Topics	Content of the topics	Type of academic activities
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.	PL
2. Regulations for and conducting CTs.	2.1 Legislative regulation of the field of 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.	PL
3. The importance of pharmacokinetics and pharmacodynamics of drugs for CTs.	3.1 Pharmacokinetic studies. Bioequivalence studies. 3.2 Pharmacodynamics. Implications for drug development.	PL
4. Pharmacoepidemiologic trials.	4.1 Basic principles of pharmacoepidemiologic trials.	PL

5. Pharmacoeconomic trials	5.1 Features of conducting pharmacoeconomic studies	PL
6. New molecular targets for pain treatment	6.1 New molecular targets for pain treatment	PL
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)	PL
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, glycylicyclines, and lipopeptides. 8.3 Pathogen-specific monoclonal antibodies.	PL

4. CLASSROOM EQUIPMENT AND TECHNOLOGY SUPPORT REQUIREMENT

Table 6.1. Logistical and material provision of the discipline.

Classroom for Academic Activity Type	Classroom Equipment	Specialized educational / laboratory equipment, software and materials for mastering the discipline
Learning 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 Classrooms 349, 350, 352	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, Lenovo IdealPad330-5ikb laptop, Internet access. Wall projection screen, floorboard information marker magnetic, interactive complex for testing students.
Classroom for 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.

Classroom for Academic Activity Type	Classroom Equipment	Specialized educational / laboratory equipment, software and materials for mastering the discipline
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. RECOMMENDED SOURCES FOR COURSE STUDIES.

Main reading

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 reading

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"

* - 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. EVALUATION TOOLKIT AND GRADE SYSTEM FOR ASSESSMENT

Evaluation Toolkit (ET) and a point-rating system (PRS)* for assessment the level of competence formation (part of competencies) based on the results of mastering the discipline "Clinical trials" are presented in the Appendix to this Work Program of the discipline.

** - ET and PRS are formed on the basis of the requirements of the relevant local regulatory act of the RUDN*

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