Federal State Autonomous Educational Institution of Higher Education

PEOPLES' FRIENDSHIP UNIVERSITY OF RUSSIA

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:

31.05.01 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

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) is aimed at the development of the following competences /competences in part: 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)
PC-3	Being able to prescribe treatment and monitor its efficacy and safety	PC-3.1. Being able to develop a treatment plan for a disease or condition taking into account the diagnosis, age and clinical picture in accordance with the current procedures for the provision of medical care, clinical guidelines (treatment protocols) on the provision of medical care taking into account the standards of medical care.
		PC-3.4. Being able to assess the efficacy and safety of the use of drugs, medical devices, medical nutrition and other treatment methods.

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*
PC-3	Being able to prescribe treatment and monitor its efficacy and safety		General surgery Dermatovenereology Neurology, medical genetics, neurosurgery Faculty Surgery Obstetrics and gynecology Otorhinolaryngology Occupational diseases Hospital therapy

			Outpatient therapy Hospital surgery, pediatric surgery Pediatrics Traumatology, orthopedics Endocrinology Clinical pharmacology Oncology, radiation therapy Maxillofacial Surgery Current issues in neonatology Fundamentals of childhood nutrition Outpatient cardiology Surgical practice: assistant surgeon Obstetrics and gynecology practice: assistant gynecologist Therapeutic physician assistant: physician assistant therapist General medical practice: assistant physician in an outpatient clinic Obstetrics and gynecology practice: assistant obstetrician General practice: pediatric assistant Preparing for and passing the state exam State exam (computer testing) State exam (interdisciplinary interview) Basics of therapeutic nutrition Cardiology in quests

* 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 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**	
			5	**6**
Contact academic hours				
including:				
Lectures (LC)				
Lab work (LW)				
Seminars (workshops/tutorials) (S)		34		34
Self-studies		*26*		*26*
Evaluation and assessment (exam/passing/failing grade)		*12*		*12*
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. Regulations for planning and conducting clinical trials (CTs). Types of CTs.	1.1 Legislative regulation of the field of clinical research. 1.2 Ethics committee. Ministry of Health of the Russian Federation. Obtaining permission to conduct a clinical trial. 1.3 Types of clinical trials 1.4 Phases of CTs. 1.5 Main documents in CTs.	S
2. Conducting clinical trials	2.1 Initialization of CT 2.2 Conducting CT 2.3 Completion of CT	S
3. Novel molecular targets in the treatment of cardiovascular diseases	3.1 Novel targets for lipid-lowering drugs. 3.2 Novel targets to affect the renin-angiotensin-aldosterone system (RAAS). 3.3 Novel targets for antiplatelet agents and anticoagulants.	S
4. Novel molecular targets in the treatment of the endocrine system diseases	4.1 Novel molecular targets in the treatment of type 1 diabetes and type 2 diabetes. 4.2 New molecular targets in the treatment of obesity.	S
5. Novel molecular targets in the treatment of respiratory diseases	5.1 Novel molecular targets and new groups of drugs for the treatment of bronchial asthma, COPD, idiopathic pulmonary fibrosis, cystic fibrosis, and other diseases of the respiratory system.	S
6. Novel molecular targets in the treatment of gastrointestinal diseases	6.1 Actual problems of pharmacotherapy of irritable bowel syndrome and potential new targets. 6.2 Novel targets for the treatment of acute pancreatitis	S
7. Novel molecular targets for drugs affecting central nervous system	7.1 Novel targets in the treatment of epilepsy, depressive disorders, neurodegenerative diseases, pain syndrome	S

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.	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)
Seminar	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.
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.
Research and Lab work	Classroom, equipped with a set of specialized furniture;	Wall projection screen, magnetic floor information marker board, Optoma

Type of academic activities	Classroom equipment	Specialised educational / laboratory equipment, software, and materials for course study (if necessary)
	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	HD36 multimedia projector, Lenovo 15.6 laptop, centrifuge 5804, analytical scale AF225DPCT, Vortekx shaker, CryoCubeF101h freezer

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

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. - M. : PFUR, 2019. - 56 с. : ил.

3. Clinical Trials Regulation. European Medicines Agency. Available online: https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/clinical-trials-human-medicines/clinical-trials-regulation

4. Clinical Trials Guidance Documents. FDA. Available online: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents

5. FDA Clinical Trial Requirements, Regulations, Compliance, and GCP Conference. FDA. Available online: https://www.fda.gov/about-fda/office-bioresearch-monitoring-operations-obimo/fda-clinical-trial-requirements-regulations-compliance-and-gcp-conference-06132023

Internet 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!

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

1. The set of lectures on the course "Clinical trials".

2. The laboratory workshop (if any) on the course "Clinical trials".

3. The guidelines for writing a course paper / project (if any) on the course "Clinical trials".

4. ……

* 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 (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:

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HEAD OF EDUCATIONAL DEPARTMENT:

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HEAD

OF HIGHER EDUCATION PROGRAMME:

		Sturov N. V.
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