

Federal State Autonomous Educational Institution of Higher Education
«Peoples' Friendship University of Russia»

Medical Institute

Recommended MCSD

SYLLABUS
(STUDY GUIDE)

Subject

Biostatistics

Recommended for the direction of training / specialty:

31.05.01 General Medicine

Program (profile, specialization)

General Medicine

1. **Goals and objectives of the discipline:** the formation of students' understanding and holistic perception of the basic concept of biostatistics and the concept of evidence in medicine, the clinical and statistical significance of research results, the acquisition of knowledge about modern information technologies, their development trends, to develop skills in building information models, analyzing the results obtained, in pharmacological, medical -biological, experimental and clinical research. Developing skills in presenting data and analyzing the results of one's own research using methods of descriptive and analytical statistics, possession of statistical terminology.

2. **Place of discipline in the structure of high education program:**

The discipline "Biostatistics" refers to the variative part of block 1 of the curriculum.

Table 1 shows the previous and subsequent disciplines aimed at the formation of discipline competencies in accordance with the competence matrix of EP HE.

Table 1

Prior and subsequent disciplines aimed at the formation of competencies

№ п/п	Code and name of competence	Previous disciplines	Subsequent disciplines (groups of disciplines)
Universal Competence Category			
General Professional Competences			
	GPC-10	Mathematics, Medical informatics	Telemedicine; Public health and health care, Clinical Pharmacology; Biostatistics

3. **Requirements for the results of the discipline**

The discipline program is designed to form the following competencies:

Table 2

Formed competencies

Competences	Name of competence	Competence achievement indicators
GPC-10 Information literacy	GPC-10. Being able to understand the operation principles of modern IT and use them to solve professional tasks	GPC-10.1. Being able to use information technology in professional activity. GPC-10.2 Being able to observe the information security rules in professional activity. GPC-10.3. Being able to use information and communication technologies, including applied software for general and special purposes in dealing with professional tasks.

As a result of studying the discipline student should:

To know:

- basic statistical terminology, basic methods of biomedical statistics, types of distribution and their characteristics;
- main characteristics and possibilities of using statistical values; methods of constructing and analyzing variation series;
- types and characteristics of statistical aggregates; data types (qualitative, quantitative variables), their main characteristics and application;
- ways of graphical presentation of data and research results; methods of calculating and applying the confidence interval;
- algorithm for testing statistical hypotheses, type I and II errors, p-level; methods for analyzing relationships (correlation and regression analysis, analysis of qualitative characteristics, analysis of variance); analysis of survival, quality criteria for clinical trials.

Be able to:

- use educational, scientific, popular scientific literature, Internet for professional activities;
- work on a personal computer, use an operating system, carry out text and graphic processing of medical data using standard office applications, develop a database structure;
- search medical data and generate reports using database management systems.

Have skills:

- basic technologies of information transformation: text, table processors,
- basic skills in the use of medical information systems and Internet resources for the implementation of professional tasks.

4. The scope of the discipline and types of educational work

The total workload of the course is **2 credit** units.

Type of educational work	Total hours	Semesters			
		2			
Class hours (total)	34	34			
Including:	-	-	-	-	-
<i>Lectures</i>	34	34			
<i>Practice work (PW)</i>					
<i>Seminars (S)</i>					
<i>Laboratory work (LW)</i>	34	34			
Self study	38	38			
Total workload	hours	72			
	credit units	2			

5. Discipline contents**5.1. Content of the discipline's sections****1. Particular module. BASICS OF BIOMEDICAL RESEARCH****1.1. Modular unit. PLANING of BIOMEDICAL RESEARCH.**

Section contents: Stages of biomedical research: planning and research programs; data collection; processing the collected material; data analysis, conclusions and recommendations. Population and sampling. Requirements for the sample.

1.2. Modular unit. TYPES OF RESEARCH.

Section contents: Cross-sectional and longitudinal, prospective and retrospective studies; case-control study, cohort study, randomized clinical trials, meta-analysis

2. Particular module. DESCRIPTIVE STATISTIC**2.1. Modular unit. GRAPHICAL REPRESENTATION OF DATA**

Section contents: The concept of statistical graphics, the basic elements of graphics, chart types. Histogram. Empirical distribution function and its properties.

2.2. Modular unit. ESTIMATES OF DISTRIBUTION PARAMETERS.

Section contents: Point estimation of distribution parameters, requirements for point estimates: unbiasedness, consistency, efficiency. Interval estimation of distribution

parameters, confidence interval, confidence probability. Interval estimation of the mean, interval estimation of variance.

3. Particular module. STATISTICAL ANALYSIS OF DATA.

3.1. Modular unit. STATISTICAL HYPOTHESIS TESTING.

Section contents: General scheme of testing statistical hypotheses. Types of errors: systematic and random errors, error I and II type. Determination of sample size. Statistical criteria, the critical area, the level of significance, power of the criterion. Pearson, Fisher and Kolmogorov criteria. Testing statistical hypotheses about the equality of the average to the specific numeric value.

3.2. Modular unit. COMPARING THE GROUPS

Section contents: statistical hypotheses about the equality of the average values of the two normally distributed populations. Testing statistical hypotheses about the equality of dispersions of the two research normally distributed general totality with unknown and known average value. Paired and unpaired samples.

3.3. Modular unit. REGRESSION ANALYSIS.

Section contents: Linear regression, regression coefficient, regression equation, estimation of regression parameters using the least square method. Testing the hypothesis on the significance of the regression dependence.

3.4. Modular unit. CORRELATION ANALYSIS.

Section contents: Linear and rank correlation. Pearson's linear correlation coefficient, Spearman's rank correlation coefficient. Testing the hypothesis on the significance of the correlation coefficient.

3.5. Modular unit. ANALYSIS OF THE CONTINGENCY TABLES.

Section contents: Tables of conjugate variables, the contingency coefficients. Testing the hypothesis about the importance of the contingency coefficients.

3.6. Modular unit. ANALYSIS OF VARIANCE.

Section contents: ANOVA table. ANOVA: mathematical model, the formulation of hypotheses, the sequence of hypothesis testing. Two-factor analysis of variance. Cross-model and hierarchical model of two-factor analysis.

3.7. Modular unit. Survival analysis

Section contents: construction of life tables (Kaplan-Meier, Cutler-Ederer method), survival curve. Comparison of two survival curves (Logrank test, Gehan's test).

5.2. Discipline sections and type of activities

№	Discipline sections	Lec..	Pract.	Lab.	Sem.	Self	Total (hours).
1.1	Planning biomedical research			2		4	6
1.2	Types of studies			2		2	4
2.1	Graphical representation of data			2		2	4
2.2	Estimates of distribution parameters			4		4	8
3.1	Statistical hypotheses testing			4		6	10
3.2	Comparison of groups			6		6	12

3.3	Regression analysis			2		2	4
3.4	Correlation analysis			2		2	4
3.5	Analysis of the contingency tables			2		2	4
3.6	ANOVA			4		4	8
3.7	Survival analysis			4		4	8
Total				34		38	72

6. Laboratory workshop

№ п/п	Discipline sections	Topics of lab classes	Hours
1.	1.1	Stages of biomedical research: planning and research programs; data collection; processing the collected material; data analysis, conclusions and recommendations. Population and sampling. Requirements for the sample.	2
2.	1.2	Cross-sectional and longitudinal, prospective and retrospective studies; case-control study, cohort study, randomized clinical trials, meta-analysis	2
3.	2.1	The concept of statistical graphics, the basic elements of graphics, chart types. Histogram. Empirical distribution function and its properties	2
4.	2.2	Point estimation of distribution parameters, requirements for point estimates: unbiasedness, consistency, efficiency. Interval estimation of distribution parameters, confidence interval, confidence probability. Interval estimation of the mean, interval estimation of variance.	4
5.	3.1	General scheme of testing statistical hypotheses. Types of errors: systematic and random errors, error I and II type. Determination of sample size. Statistical criteria, the critical area, the level of significance, power of the criterion. Pearson, Fisher and Kolmogorov criteria. Testing statistical hypotheses about the equality of the average to the specific numeric value.	4
6.	3.2	statistical hypotheses about the equality of the average values of the two normally distributed populations. Testing statistical hypotheses about the equality of dispersions of the two research normally distributed general totality with unknown and known average value. Paired and unpaired samples.	6
7.	3.3	Linear regression, regression coefficient, regression equation, estimation of regression parameters using the least square method. Testing the hypothesis on the significance of the regression dependence	2

8.	3.4	Linear and rank correlation. Pearson's linear correlation coefficient, Spearman's rank correlation coefficient. Testing the hypothesis on the significance of the correlation coefficient.	2
9.	3.5	Tables of conjugate variables, the contingency coefficients. Testing the hypothesis about the importance of the contingency coefficients.	2
10.	3.6	ANOVA table. mathematical model, the formulation of hypotheses, the sequence of hypothesis testing. Two-factor analysis of variance. Cross-model and hierarchical model of two-factor analysis.	4
11.	3.7	Construction of life tables (Kaplan-Meier, Cutler-Ederer method), survival curve. Comparison of two survival curves (Logrank test, Gehan's test).	4

7. *Practical workshop is not provided*

8. Material and technical support of the discipline:

For classes, group and individual consultations, monitoring and intermediate certification, computer classes 426, 428, 429, 434, 448, 451, 452 and 453 are used located at the address: Moscow, st. Miklukho-Maklaya, 10, building 2. and a lecture hall located at the address: Moscow, st. Miklukho-Maclay, 8.

A set of workstations consisting of computer tables, chairs, marker board; technical means: interactive whiteboard, projection screen, multimedia projector, teacher's laptop, monoblocks.

Computing server HP ProLiant ML350 Gen 10, Monoblock Acer Aspire C24-865 - 16 pcs., Monoblock Lenovo V30a-24IML All-In-One 23.8 "- 19 pcs., Monoblock Acer Z3-615 - 12 pcs., Workplace as part of the Dell Optiplex 3010MT system unit and Dell S2240L monitor - 6 pcs., Gladius 210XT0808R-21064 server - 3 pcs.

9. Information support of the discipline

a) software:

- Microsoft Subscription Enrollment for Education Solutions (EES) No. 56278518 dated 04/23/2019 (renewed annually, the program is assigned a new number).
- Operating system Windows 10.0, Office 365, Stat Soft Statistic 6.1

б) databases, reference and search systems:

1. EBS of RUDN University and third-party EBS to which students have access on the basis of concluded agreements:

- RUDN University Library System <http://lib.rudn.ru/MegaPro/Web>
- EBS "University Library Online" <http://www.biblioclub.ru>
- EBS "Yuray" <http://www.biblio-online.ru>
- EBS "Student Consultant" www.studentlibrary.ru
- EBS "Lan" <http://e.lanbook.com/>
- TUIS: <http://esystem.rudn.ru/>
- All-Russian Institute for Scientific and Technical Information of the Russian Academy of Sciences (VINITI RAS) <http://www2.viniti.ru/>

2. Database of medical and biological publications:

- Yandex search engine <https://www.yandex.ru/>

- Google search engine <https://www.google.ru/>
- SCOPUS abstract database <http://www.elsevierscience.ru/products/scopus/>
- WHO Documentation Center <http://whodc.mednet.ru/>
- NCBI: <https://p.360pubmed.com/pubmed/>
- RUDN University Bulletin: access mode from the RUDN University territory and remotely <http://journals.rudn.ru/>
- Scientific library Elibrary.ru: access by IP-addresses of RUDN University at: <http://www.elibrary.ru/defaultx.asp>
- ScienceDirect (ESD), "FreedomCollection", "Cell Press" ID "Elsevier". There is remote access to the database, access by IP-addresses of RUDN University (or remotely by individual login and password).
- Google Academy (eng. Google Scholar) - a free search engine for full texts of scientific publications of all formats and disciplines. Indexes full texts of scientific publications. Access mode: <https://scholar.google.ru/>
- Scopus - scientometric database of the publishing house "Elsevier". There is remote access to the database.
Access by IP-addresses of RUDN University and remotely by login and password (Grant of the Ministry of Education and Science). Access mode: <http://www.scopus.com/>
- Web of Science. There is remote access to the database. Access to the platform is carried out by IP-addresses of the RUDN University or remotely. Remote access to WOS is activated without administrator intervention after registering on the platform from RUDN University <http://login.webofknowledge.com/>

10. Methodical support of discipline:

a) Main literature

1. Lukyanova, Shimkevich EM, Lyapunova TV Statistical methods of analysis. M.: RUDN. 2020, 117 p.
2. Lukyanova E.A., Lyapunova T.V., Shimkevich E.M. Biostatistics. Research planning. Description of the data. M.: RUDN. 2020, 32 p.

б) Additional literature

1. A.A. Khalafyan, V.P. Borovikov, G.V. Kalaidin. Probability theory, mathematical statistics and data analysis. Fundamentals of theory and practice on a computer. Statistica. Excel [Text]: more than 150 examples of problem solving: a textbook for bachelors of non-mathematical specialties studying higher mathematics - economic, legal, information technology, technical, natural science, humanitarian / - Moscow: URSS, cop. 2016.-- 317 p. : ill., table; 22 cm; ISBN 978-5-9710-3040-9
2. Rebrova O. "Statistical analysis of medical data. Application of the STATISTICA application package". MediaSphere: Moscow, 2002.
3. M.A. Kamenskaya Information Biology: Textbook of Institutions - M: Publishing Center Academy, 2009.
4. S. Glants Medical and biological statistics. Per. from English - M., Practice, 1998.-459 p.
5. Gmurman V.E. Probability theory and mathematical statistics: Textbook. pos. for universities. Ed. 9th, erased. - M.: Higher school, 2003.-- 480 p.: Ill.

11. Methodical instructions for students on mastering the discipline (module)

In laboratory classes in classrooms, the relevant topics are analyzed using multimedia technology (computer, projector). For each classroom lesson, presentations prepared in Microsoft PowerPoint program are intended, containing from 10 to 30 slides. The main goal of laboratory classes is to form

students' understanding and holistic perception of the basic concept of biostatistics and the concept of evidence in medicine, the clinical and statistical significance of research results., The acquisition of knowledge about modern information technologies, their development trends, to develop skills in building information models, analyzing the results obtained. , in pharmacological, biomedical, experimental and clinical research, developing skills for presenting data and analyzing the results of one's own research using methods of descriptive and analytical statistics, knowledge of statistical terminology

Self-work of students during extracurricular hours can take place in the classrooms of the department and at home.

Extracurricular self-work of a student includes:

1. Studying the material according to the textbook, teaching aids.
2. Self-study of statistical processing programs.
3. Work in an information and educational environment with accessible databases on Biostatistics.

12. Fund of assessment tools for intermediate certification of students in the discipline

Materials for assessing the level of mastering the educational material of the discipline "Biostatistics" (evaluation materials), including a list of competencies with an indication of the stages of their formation, a description of indicators and criteria for evaluating competencies at various stages of their formation, a description of the assessment scales, typical control tasks or other materials necessary for assessing knowledge, skills, skills and (or) experience of activity, characterizing the stages of the formation of competencies in the process of mastering the educational program, methodological materials that determine the procedures for assessing knowledge, skills, skills and (or) experience of activities that characterize the stages of formation of competencies, developed in full and available for students on the discipline page at TUIS RUDN.

Test and control works are grouped in accordance with the main sections of the course and are used in laboratory classes, as well as a part of the intermediate and final assesment of students' knowledge.

The program has been drawn up in accordance with the requirements of the ES HE RUDN.

Developers:

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